Health Evidence Review Commission's Value-based Benefits Subcommittee

May 19, 2016

8:30 AM - 1:00 PM

Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
May 19, 2016
8:30am - 1:00pm
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
A working lunch will be served at approximately 12:00 PM
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Kevin Olson **8:30 AM**

II. Staff report – Ariel Smits, Cat Livingston, Darren Coffman **8:35 AM**
- **A.** Errata
- **B.** Back line implementation
- **C.** Searchable Prioritized List demo
- **D.** HSD "other" lists searchability—Nathan Roberts

III. Straightforward/Consent agenda – Ariel Smits **8:50 AM**
- **A.** Straightforward table
- **B.** Straightforward guideline changes
- **C.** Back lines straightforward changes
- **D.** Mechanical traction and TENS for back and neck conditions
- **E.** M99 series code placement
- **F.** Fitting for spectacles and contact lenses

IV. 2018 Biennial Review – Ariel Smits **8:55 AM**
- **A.** Tension and migraine headaches
- **B.** Severe insomnia in young children—with the Early Childhood Workgroup

V. New discussion topics – staff **9:30 AM**
- **A.** Pediatric Urology
    - A. Hypospadias
    - B. Retractile testicles
    - C. Congenital urologic conditions
    - D. Pediatric urology guideline
- **B.** Physical therapy modalities
    - A. Physical therapy modality review overview
    - B. Physical therapy modalities with little utilization and little or no evidence of effectiveness
    - C. Paraffin wax therapy
    - D. Vasopneumatic devices
    - E. Whirlpool therapy

C. Implantable cardiac loop recorders
D. Electric tumor treatment fields for initial treatment of glioblastoma
E. Incontinentia pigmenti
F. Sacroiliac joint fusion
G. Low frequency ultrasound for wound healing
H. Posterior tibialis tendinopathy/flatfoot

VI. Guidelines – Ariel Smits, Cat Livingston **11:15 AM**

A. Revisions to GN6 Rehabilitative Services
B. Opioids for back conditions—with Paul Coehlo, MD
C. Tobacco cessation and elective surgery
D. Acupuncture for tobacco cessation
E. Hyperbaric oxygen

VII. Previous discussion topics – Ariel Smits **12:15 PM**

A. Disorders of bilirubin metabolism
B. Pectus excavatum and pectus carnitatum—with Drs. Ruscher and Zeller

VIII. Public comment **12:55 PM**

IX. Adjournment – Kevin Olson **1:00 PM**

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on March 10, 2016

For specific coding recommendations and guideline wording, please see the text of the 3/10/2016 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/16)

- Move several newborn diagnoses to more appropriate covered lines.
- Add diagnosis codes for esophageal hernias with obstruction or gangrene to the covered hernia line with the appropriate treatment codes and delete from the covered GERD/esophagitis line.
- Delete the treatment code for intracranial vascular balloon dilation for atherosclerosis from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Delete the treatment code for intracranial vascular balloon dilation for vasospasm from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Add procedure codes for perioperative pelvic physical therapy and laser hair removal for surgical site preparation to the gender dysphoria line.
- Add various straightforward codes to appropriate lines.

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Several newborn lines with hematologic conditions were considered for merging but not approved.
- Waiving the requirement to live as the desired gender for 1 year prior to breast or chest surgery for gender dysphoria was not approved.

RECOMMENDED GUIDELINE CHANGES (effective 10/1/16 unless)

- Modify the gender dysphoria guideline to remove the requirement for hormone therapy prior to breast or chest surgery, to add laser hair removal for surgical site preparation in the same way as restricted for electrolysis, to clarify when revision surgeries are covered, and to specify that pelvic PT procedures codes are only covered for peri-operative therapy.

BIENNIAL REVIEW CHANGES (effective 1/1/18)

- Merge the two premature baby lines and prioritize to the upper line position. Move the diagnosis codes for intraventricular hemorrhages to another line to pair with required treatments.
- Merge the congenital infections line and congenital syphilis lines and prioritize at their current position.
- Merge three lines containing endocrine conditions of the newborn and prioritize to approximately the mid position of the lines.
- Add diagnosis codes and change the line title for the line containing omphalitis and newborn mastitis codes, reprioritizing to a slightly lower position.

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 10, 2016
8:30 AM – 1:00 PM

Members Present: Susan Williams, MD, Chair Pro Tempore; David Pollack, MD; Irene Croswell, RPh; Holly Jo Hodges, MD; Vern Saboe, DC; Gary Allen, DMD.

Members Absent: Kevin Olson, MD; Mark Gibson.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Daphne Peck (by phone).

Also Attending: Kim Wentz, MD, MPH, and Jim Rickards, MD (Oregon Health Authority); Valerie King, MD, MPH, and Adam Obley, MD, MPH (OHSU Center for Evidence-based Policy); Megan Bird, MD, and Valerie Halpin, MD (Legacy); Amy Penkin (OHSU); Maura Roche and Andrea Zekis (Basic Rights Oregon); Casey Parks (Oregonian); Kimberly Ruscher, MD, and Garret Zallen, MD (via phone) (PeaceHealth); Brenna Legaard; Tobi Rates (Autism Speaks Oregon); Rebekah Brewis (PDX TransPride); Dan Unumb, Esq. (via phone) (Autism Speaks).

- **Roll Call/Minutes Approval/Staff Report**

  The meeting was called to order at 8:45 am and roll was called. Minutes from the January 14, 2016 VbBS meeting were reviewed and approved.

  Staff reviewed errata published since the January meeting. There were no questions about these items.

  Smits introduced the idea of having the October 1 Prioritized List changes only include those without significant fiscal impact. Those changes expected to have significant fiscal impact would be included in January 1 Prioritized List changes to coincide with the next CCO contract period. The subcommittee was generally in favor of this change. Hodges felt that this change would be very helpful for the health plans.

  Vern Saboe, DC was introduced as a new member of VBBS. He comes from the HERC and EGBS and has a long history with the Health Services Commission as well. Dr. Saboe spoke to his background in both policy and clinical expertise.

  Livingston announced that the Obesity Task Force has started to meet and will give recommendations for biennial review changes for coverage of obesity later in the year.

- **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion about the consent agenda items.

Recommended Actions:

1) Add 20924 (Tendon graft, from a distance (eg, palmaris, toe extensor, plantaris)) to line 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
2) Add D62 (Acute posthemorrhagic anemia) to line 152 ACQUIRED HEMOLYTIC ANEMIAS and remove from line 122 NUTRITIONAL DEFICIENCIES
3) Add 96150-96155 (Health and behavior assessment) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
4) Remove 64505, 64508, 64510, 64517, 64520, and 64530 (Injection, anesthetic agent) from line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
5) Add L66.2 (Folliculitis decalvans), L66.8 (Other cicatricial alopecia) and L66.9 (Cicatricial alopecia, unspecified) to line 517 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP
6) Remove L66.2, L66.3 (Perifolliculitis capitis abscedens), L66.8 and L66.9 from line 588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES
7) Remove 92507-92508, 92526, 92607-92609, and 92633 (Speech therapy services) and all CPT codes for inpatient and ICU care from line 501 CALCIUM PYROPHOSPHATE DEPOSITION DISEASE (CPPD) AND HYDROXYAPETITE DEPOSITION DISEASE
8) Add E11.49 (Type 2 diabetes mellitus with other diabetic neurological complication) and E11.59 (Type 2 diabetes mellitus with other circulatory complications) and E11.628 (Type 2 diabetes mellitus with other skin complications) to line 169 PREVENTIVE FOOT CARE IN HIGH RISK PATIENTS
9) Remove 27175-27185 (Treatment of slipped femoral epiphysis) from lines 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY and 508 PERIPHERAL ENTHESOPATHIES
10) Add 96904 (Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma) to lines 234 MALIGNANT MELANOMA OF SKIN, 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
11) Remove 96904 from lines 60, 217, 363, 378, 413, 430, 493, 525, 535, 536, 544 and 548
12) Add roseacea ICD-10 diagnosis codes to line 525 ROSACEA; ACNE and remove from line 507 ERYTHEMATOUS CONDITIONS
    a. L71.1 Rhinophyma
    b. L71.8 Other rosacea
    c. L71.9 Rosacea, unspecified
13) Remove CPT 11450-11471 (Excision of skin and subcutaneous tissue for hidradenitis) from lines 378 ACNE CONGLOBATA (SEVERE CYSTIC ACNE), 525 ROSACEA; ACNE and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES

14) Add E50.0-E50.3 (Vitamin A deficiency with conjunctival or corneal xerosis) to line 122 NUTRITIONAL DEFICIENCIES and remove from line 456 EXOPHTHALMOS AND CYSTS OF THE EYE AND ORBIT
15) Add E50.3 (Vitamin A deficiency with corneal ulceration and xerosis) to line 249 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
16) Remove E50.5 (Vitamin A deficiency with night blindness) from line 455 DISORDERS OF REFRACTION AND ACCOMMODATION

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0.

- **Topic: 2018 Biennial Review—Newborn Line Merging**

Discussion: Smits reviewed the meeting handout with updated staff recommendations for merging various newborn condition lines. The subcommittee generally agreed with all the staff recommendations. The merging of various hematologic conditions was deemed too complicated and liable to have unintended consequences. The changes were accepted as recommended by staff, but the suggested hematologic line changes were not accepted and staff was directed to not pursue this question further.

Recommended Actions:

1) Effective October 1, 2016
    a. Remove P54.0 (Neonatal hematemesis) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 296 ADRENAL OR CUTANEOUS HEMORRHAGE OF FETUS OR NEONATE
    b. Remove P55 (Hemolytic disease of newborn) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
    c. Add the following codes found only on the dysfunction lines to line 2 BIRTH OF INFANT and remove from the dysfunction lines (lines 75, 297, 350 and 382)
        i. P05.01-P05.08, P05.11-P05.2 Newborn light for gestational age
    d. Remove E80.4-E80.8 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and add to line 64 METABOLIC DISORDERS to match similar diagnoses.
        i. E80.4 Gilbert syndrome
        ii. E80.5 Crigler-Najjar syndrome
        iii. E80.6 Other disorders of bilirubin metabolism
        iv. E80.7 Disorders of bilirubin metabolism, unspecified
    e. Remove P54.1-P54.3 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND

FETAL AND NEONATAL JAUNDICE and add to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE

i. P54.1 Neonatal melena
ii. P54.2 Neonatal rectal hemorrhage
iii. P54.3 Other neonatal gastrointestinal hemorrhage
iv. Line 60 contains all endoscopy and other treatment codes as well as NICU codes

2) Make the biennial review changes to lines effective January 1, 2018 as noted in Appendix B.

MOTION: To approve the recommendations in the meeting handout material as amended. CARRIES 6-0.

- **Topic: Diaphragmatic hernia**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

1) Add ICD-10 K44.0 (Diaphragmatic hernia with obstruction, without gangrene) and K44.1 (Diaphragmatic hernia with gangrene) to line 172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE and remove from line 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS
2) Add the CPT codes for repair of complicated diaphragmatic hernia to line 172 and remove from line 385
    a. 39503 Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia
    b. 39540 Repair, diaphragmatic hernia (other than neonatal), traumatic; acute
    c. 39541 Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic
    d. 39560 Resection, diaphragm; with simple repair (eg, primary suture)
    e. 39561 Resection, diaphragm; with complex repair (eg, prosthetic material, local muscle flap)
3) Change the line title for line 385
    a. Condition: ESOPHAGITIS; GERD~~; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS~~

MOTION: To approve the code change recommendations. CARRIES 6-0.

- **Topic: Intracranial stenting and angioplasty for atherosclerosis**

Discussion: Smits reviewed the summary document. There was no substantial discussion.

Recommended Actions:

1) Remove 61630 (Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table
2) Affirm placement of 61635 (Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed) on the Services Recommended for Non-Coverage Table

MOTION: To recommend the code changes as presented. CARRIES 6-0.

- **Topic: Balloon dilation of intracranial vasospasm**

Discussion: Smits reviewed the summary document. There was discussion about the HERC policy for removing a service from the Prioritized List. The current algorithm does not include evidence of harm as a criterion. The subcommittee recommended that harm be taken into account and that HERC staff formulate a new policy for the website. The subcommittee determined that balloon dilation of intracranial vasospasm should be removed from the List due to evidence of harm and placed on the Services Recommended for Non-Coverage Table.

Recommended Actions:

1) Remove CPT 61640-61642 Balloon dilation of intracranial vasospasm, percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table

MOTION: To approve the coding changes listed as "option 1" in the meeting materials. CARRIES 6-0.

- **Topic: Hormone requirements for chest surgery in the gender dysphoria guideline/other gender dysphoria issues**

Discussion: Smits reviewed the summary of the topic in the meeting materials. Testimony was heard from Dr. Megan Bird, MD and Amy Penkin, MSW regarding their support for removing hormone therapy as a prerequisite for breast/chest surgery. Williams raised a question about what would constitute a non-medical contraindication to hormone prior to breast/chest surgery. Bird responded that patients have various reasons not to take hormones such as nausea, emotional problems, exacerbation of mental illness, or identification as gender neutral and therefore not wanting to take hormones at all. The subcommittee later debated the hormone requirement prior to breast or chest surgery. Hodges argued that breast augmentation needs estrogens for optimal outcomes, and stated

she was uncomfortable with the idea of allowing patients to opt out of hormone therapy on the basis of preference without contraindication or intolerance. Wentz was concerned about the equity of requiring trials of drugs prior to procedures for other conditions (such as requiring a trial of OCPs prior to hysterectomy for menorrhagia) but not requiring a trial of a drug prior to a chest/breast procedure for this condition. Bird argued that there was an ethical issue with not allowing patients to access a needed therapy based on refusal of one particular therapy. The final decision was that patients should be allowed to opt out of hormone therapy prior to breast or chest surgery, and additional wording was added to the requirement for estrogen prior to mammoplasty which allowed "intolerance or patient refusal" as allowable indications for not requiring hormones. Smits pointed out that this basically made the estrogen before mammoplasty clause have the only binding effect of disallowing surgery if a patient reaches Tanner stage 5 with estrogens alone; this was felt to be fine as such a patient would have, by definition, adequate adult female breast tissue and any issues with size will then be cosmetic only.

There was minimal discussion about the staff proposal to remove the requirement for living as the desired gender for 1 year prior to chest surgery. The experts advocated for removing this requirement as a safety issue. It was pointed out that there was already a clause that would exempt a patient from this requirement if two providers documented that it was a safety issue. The staff proposed change was not accepted.

Bird testified regarding the use of laser for hair removal. She stated that laser treatment can permanently eliminate dark hair and therefore reduce the need for electrolysis and the amount of time for treatment. A typical treatment regimen is 4-6 months of laser (separate by 4-6 weeks due to hair growth cycles for each area), then followed up with electrolysis for any non-responding hair. Hodges raised concerns that laser hair removal may not be permanent and asked the experts whether electrolysis would be sufficient for the Prioritized List coverage. The experts responded that electrolysis coverage would be enough to allow surgical site preparation, but that laser allows faster treatment and is less painful. The subcommittee asked the experts for guidance regarding what is a standard need for a hair removal regimen, but the experts felt that hair removal was very individualized and could not recommend guidelines. The decision was made to add laser hair removal as an option.

Williams asked if the experts were seeing requests for revisions which were being denied, and the reasons for the denials. Bird replied that standard types of surgical complications such as fistulas have the repair of the fistula covered, but not subsequent reconstruction that might be required (new donor sites not covered, larger procedures not covered). The experts have also seen denials for chronic pain, revisions of older procedures like silicone injections that need removal, etc. Williams asked about what constitutes chronic pain. Bird replied pain can result from scarring, pulling, or other wound/healing issues. The clause regarding revisions to surgeries was accepted, with additional wording that the complication must be directly related to the surgery.

Bird had concerns about requiring tobacco cessation prior to genital surgery. Vaginoplasty has a high rate of failure with smoking, higher than other types of gender conforming surgeries like hysterectomy. The subcommittee debated including a requirement for smoking cessation in the gender dysphoria guideline, or referring to gender dysphoria procedures in the more general tobacco cessation for elective surgery guideline yet to be established. The decision was to have the restrictions in the elective surgery guideline. There was discussion about whether the restriction should be for cessation at 4 weeks, 6 weeks, or 8 weeks prior to surgery. Bird noted that the best outcomes for hysterectomy were with 8 weeks of cessation, but that the abstinent period required for best outcomes was different with different genital surgeries.

The recommended addition of pelvic physical therapy to the gender dysphoria guideline was discussed. There was a discussion about adding the PT included in this guideline to the totals referenced in GN 6 REHABILITATIVE THERAPIES. The subcommittee agreed with this change and wording was added to reference GN6 in the gender dysphoria guideline. It was noted that urinary incontinence has PT in its treatment guideline that is not referenced in GN6, and staff was instructed to propose adding this line/guideline to GN6.

Recommended Actions:

1) Modify GN 127, GENDER DYSPHORIA as shown in Appendix A
2) Add laser hair removal for surgical site preparation (CPT 17110, 17111) to line 317 GENDER DYSPHORIA
    a. 17110: Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
    b. 17111: 15 or more lesions
3) Add pelvic physical therapy to line 317 GENDER DYSPHORIA
    a. 97001 Physical therapy evaluation
    b. 97002 Physical therapy re-evaluation
    c. 97110 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
    d. 97140 Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
    e. 97530 Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
4) Staff to review a tobacco cessation requirement for vaginoplasty as part of the larger tobacco smoking and elective procedures guideline still under discussion

MOTION: To approve the recommendations as amended. CARRIES 6-0.

- **Topic: Acupuncture for tobacco cessation**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Hyperbaric oxygen**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Pectus excavatum and pectus caravatum**

  Discussion: Smits reviewed the summary document and staff recommendations.

  Dr. Ruscher testified that pectus excavatum (PE) results in cardiac impairment and exercise impairment in many children. She requested addition of coverage of treatment of PE for patients meeting certain criteria. She has gotten denials from health plans, which delays surgery to the point where the chest wall is not as elastic and will not respond to surgery as well and results in a more difficult repair. Pectus caravatum (PC) does not have major physiologic effects, but has major physical appearance issues. The treatment of PC is the use of braces, which is not invasive. For bracing, a patient needs a surgery consult, and PT consult and brace fitting. She requested coverage for moderate to severe PC (no accepted scoring system to differentiate severity of the condition exists), and PT coverage including an initial consult and 3 follow-up visits.

  Dr. Zellen testified that PE is the single condition where he hears dramatic thanks from families for the ability of the child to exercise and interact with peers. He noted that brace might need to be altered with breast development in girls, or for breakage, etc for both sexes.

  Wentz asked whether adults with PC have any cardiovascular impacts. Ruscher responded that some adults may have issues if they also have connective tissue disorders. Zellen replied that surgery is very invasive and painful for PE after adolescence, and corrective surgery for PC is a severe surgery not normally done. Therefore the focus is on treatment of adolescents.

  Wentz asked what the efficacy rate is for the use of PC bracing. Ruscher responded that studies show 90% + success rates, which agrees with her clinical experience. Zellen agreed with Ruscher's response.

  Zellen responded to the staff proposed guideline, which required PE to be severe based on the Haller index. This index requires 3D imaging. He and Ruscher do not get this imaging just to confirm clinical findings of severity. This saves money and resources. Both surgeons

recommend allowing expert opinion as an option rather than simply requiring all patients to have an imaging-derived Haller index.

Both Zellen and Ruscher recommended coverage for both PE and PC when there is severe body image disturbance, even with no other cardiac or pulmonary impediments. Pollack felt that severe body disturbance can be a real issue in adolescents.

Williams asked about the harms/complications of PE surgery. Ruscher responded that there has been death reported from bar placed through heart, but that newer surgical techniques elevate the sternum and make other changes to minimize this risk. Other complications include infection (1%), allergic reaction to implant, and bar displaced backwards into the chest. On bar removal, one death has been reported which led to technique change. Recurrence of PE after bar removal is also a risk. Patients might need to limit contact sports while the bar is in place.

The experts recommended not including exercise intolerance as a criteria in the guideline, as many of these kids are not active and cannot get a history and actual testing is expensive (metabolic exercise test) and not a good use of resources.

Williams had issues with including atypical chest pain, exercise limitation, and paradoxical chest movement (without cardiac dysfunction as a result) as criteria for allowing PE surgery.

Coverage for PC was not discussed fully at this meeting; further discussion on coverage of treatment for PC was delayed until the May, 2016 VBBS meeting.

HERC staff was directed to work with the OHP medical directors and Dr. Ruscher and Zellen to rework the proposed guideline for treatment of PE and PC. The VBBS generally felt that PE should be included on a covered line, and also left on an uncovered line, with a guideline to distinguish when it is intended to be covered.

Recommended Actions:

1) Staff will work with experts and CCO Medical Directors to refine guideline wording and bring back for review at the May, 2016 VBBS meeting

- **Topic: Retractile testicles**

This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Remote imaging for screening and management of retinopathy of prematurity**

This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Implantable cardiac loop recorders**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Electric tumor treatment fields for initial treatment of glioblastoma**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Introduction to issues regarding services for autism and dementia**

  Discussion: Smits reviewed the summary document issues, including the possible removal of autism and dementia diagnosis codes from the dysfunction lines and adding certain procedural codes to the autism and dementia specific lines as the Commission deems fit. Coffman reviewed various legal issues around limiting physical therapy (PT) and occupational therapy (OT) and speech services in GN6 REHABILITATIVE SERVICES, including a recent brief on the topic from the Oregon Department of Justice (DOJ).

  Testimony was heard from Brenna Legaard regarding her successful lawsuit against Providence Health Plan for violation of the Mental Health Parity Act in terms of that plan's limitations to PT/OT/speech services for her autistic child. She disagrees with the Department of Justice brief that PT/OT are physical health benefits. She stated that the law determines that a medical service is a mental health benefit based on the nature of the disorder you are treating. Autism is a mental health disorder and therefore PT/OT are mental health treatments and subject to parity. The Oregon Insurance Division has published guidance on this topic that applies to private insurers but not to OHP, which she provided to the subcommittee for review. She feels that OHP cannot cap therapies intended to treat mental health conditions. Furthermore, she said EPSDT requires all medical necessary PT/OT to treat medical and mental health conditions to children.

  Tobi Rates, the Executive Director of the Autism Society of Oregon and parent of 2 children with autism spectrum disorder, provided testimony. She stated that the current limit of PT/OT/speech of 30 visits per year is not sufficient to meet many children's needs. She feels that this is not morally or legally right, and not good long term fiscal policy because of the long-term costs of treating children who are not given adequate services.

  Dan Unumb, an attorney from Autism Speaks, testified that mental health parity does apply to PT/OT services for mental health conditions and requested the removal of limits on these services when treating mental health conditions. He also feels that age limits for ABA violates mental health parity. EPSDT mandates all medically necessary care to ameliorate developmental physical or mental deficits for children under 21. He read the DOJ judgment

as saying that OHP can limit services by not pairing them on the Prioritized List, but once a service is paired to a mental health condition, OHP cannot put a numerical cap on services. He stated that Oregon is the only state that has limits on PT/OT/speech for medically necessary services.

Pollack raised questions about the definition/meaning of mental health parity.

Wentz asked the experts what the amount of unmet need they estimated existed among Medicaid children. The experts could not put a numerical number on the unmet need, but felt that for some children, the numerical cap did create unmet need. Not all children need more than 30 or 60 PT/OT/speech visits in a year.

This topic was informational only and no significant discussion by the subcommittee occurred and no decisions were made.

Recommended Actions:

1) Staff will continue to work with the Department of Justice and with OHA leadership for guidance on this topic and will bring back to the May, 2016 VBBS meeting.

- **Topic: Coverage Guidance— Skin substitutes for chronic skin ulcers**

Discussion: Obley reviewed the evidence summary and public comment. Livingston highlighted the key discussion points at EbGS (quality of evidence, late breaking studies, reimbursement issues, prerequisites for surgery). She addressed the challenges with estimating average costs of the use of skin substitutes. Livingston reviewed the proposed changes to the Prioritized List based on the draft Coverage Guidance box language. The subcommittee decided to include the full table of those skin substitutes that were recommended/not recommended and including information about a maximum number of applications. Pollack asked why the additional skin substitutes available in the US were not reviewed and Obley clarified that these were included based on the AHRQ systematic review. Livingston discussed that Washington has made a different decision about coverage that may have been influenced by the cost, to which Obley clarified that Washington is rereviewing this topic currently. Williams questioned whether the low evidence was sufficient to justify coverage on the Prioritized List. Livingston and Obley clarified that very low evidence lead to noncoverage recommendations, and that even with low quality evidence it is possible to derive a strong recommendation for coverage. Hodges clarified that those skin substitutes that are recommended by EbGS have at least low quality evidence.

Recommended Actions:

1) Approve proposed guideline note language edits. Include within the guideline note the list of included/not included skin substitutes and the maximum application language (for those skin substitutes that will be included on the Prioritized List).

MOTION: To approve the recommended changes to the Prioritized List based on the Draft Skin Substitutes for Chronic Skin Ulcers Coverage Guidance scheduled for review by HERC. CARRIES 6-0.

- **Topic: Coverage Guidance— Metabolic and bariatric surgery**

Discussion: Staff discussed that no decision needed to be made about the draft Coverage Guidance at this meeting; rather, the intent was to understand subcommittee concerns prior to revisiting this topic with the Obesity Task Force. Obley presented the evidence and public comment. Livingston highlighted key discussion points of the HTAS and Obesity Task Force Phase 1 meeting. Specifically the recommended language on reoperations was discussed in detail. Hodges raised the concern about possible decreased success rates in subsequent operations if the first one was a failure. Additionally, concerns were raised about covering reoperations when there are significant capacity concerns for the OHP population. Obley clarified that the evidence is low quality, and most comes from case series.

The subcommittee raised the question about whether to cover gastric banding at all. Dr. Valerie Halpin clarified that it would be very rare to offer gastric banding, and only after a lot of counseling that a bariatric surgeon would recommend it.

Recommended Actions:

1) The Obesity Task Force to continue discussions, but consider the concerns about reoperation and banding in their deliberations.

- **Public Comment:**

Public comment was received from Rebekah Brewis, Executive Director of PDX TransPride. She requested coverage for facial feminization surgery, which is an access barrier and is a safety issue. She testified to her own difficulties in accessing these services. She noted that New York covers these services due to a legal decision that is was discriminatory based on gender and sexual orientation.

- **Issues for next meeting:**
  - Pectus excavatum and pectus carnitatum
  - Rehabilitative services for autism and dementia
  - Tobacco cessation and elective surgery
  - Acupuncture for tobacco cessation
  - Hyperbaric oxygen
  - Ventral hernias
  - Hypospadias
  - Retractile testicles
  - Remote imaging for screening and management of retinopathy of prematurity
  - Implantable cardiac loop recorders
  - Electric tumor treatment fields for initial treatment of glioblastoma

- **Next meeting:**

  May 19, 2016 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 1:25 PM.

Appendix A

Revised Guideline Notes

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 317

Hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development is included on this line for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

1. have persistent, well documented gender dysphoria
2. for genital surgeries, have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3. have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
4. have the capacity to make a fully informed decision and to give consent for treatment
5. have any significant medical or mental health concerns reasonably well controlled
6. for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
7. For genital surgeries, have two referrals from mental health professionals provided in accordance with version 7 of the WPATH Standards of Care.

Electrolysis (CPT 17380) and laser hair removal (CPT 17110, 17111) are ~~is~~ only included on this line ~~for surgical site electrolysis~~ as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. ~~It is~~ These procedures are not included on this line for

facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

Mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, 19357-19380) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any ~~a medical~~ contraindication to, intolerance of or patient refusal of hormonal therapy.

Revisions to surgeries for the treatment of gender dysphoria are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Pelvic physical therapy (CPT 97001, 97001, 97110, 97140, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included on this line and as limited in guideline note 6 REHABILITATIVE THERAPIES.

Appendix B
Biennial List Line Changes

Merge lines 17 VERY LOW BIRTH WEIGHT (UNDER 1500 GRAMS) and 23 LOW BIRTH WEIGHT (1500-2500 GRAMS) as shown below:

- Add P10.2 (Intraventricular hemorrhage due to birth injury), P10.3 (Subarachnoid hemorrhage due to birth injury), P52.00-P52.3 (Intraventricular (nontraumatic) hemorrhage of newborn), P52.5 (Subarachnoid (nontraumatic) hemorrhage of newborn) to line 34 SEVERE BIRTH TRAUMA FOR BABY and do not add to the new merged premature baby line
- Rename line 34 SEVERE BIRTH TRAUMA FOR BABY; INTRAVENTRICULAR HEMORRHAGE

Line: **17**
Condition: LOW BIRTH WEIGHT; PREMATURE NEWBORN (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P07 (Disorders of newborn related to short gestation and low birth weight), P83.0 (Sclerema neonatorum)
CPT: 94772,96154,97802-97804,98966-98969,99051,99060,99070,99078,99184, 99201-99239,99281-99285,99291-99404,99408-99416,99429-99449, 99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are for line 17; line 23 scores in parentheses)
Category: 1 (1)
Healthy life years: 10 (7)
Suffering: 5 (2)
Population effects: 0 (0)
Vulnerable population: 1 (1)
Tertiary prevention:
Effectiveness: 3 (5)
Need for treatment: 1 (0.8)
Net cost: 0 (2)
Score: 4800 (4000)
Line placement: 17 (23)

Appendix B
Biennial List Line Changes

Merge lines 15 CONGENITAL INFECTIOUS DISEASES and 16 CONGENITAL SYPHILIS as shown below

Line: 15
Condition: CONGENITAL INFECTIOUS DISEASES (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: A50 (Congenital syphilis), P35.0-P35.9 (Congenital viral diseases),P37.0-P37.4,P37.8-P37.9 (Other congenital infections and parasitic diseases)
CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 15),98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are for line 15; line 16 scores in parentheses)
Category: 1 (1)
Healthy life years: 9 (8)
Suffering: 3 (3)
Population effects: 0 (1)
Vulnerable population: 0 (1)
Tertiary prevention:
Effectiveness: 4 (4)
Need for treatment: 1 (1)
Net cost: 4 (2)
Score: 4800 (4800)
Line placement: 15 (16)

Merge lines 21 SYNDROME OF "INFANT OF A DIABETIC MOTHER" AND NEONATAL HYPOGLYCEMIA, 35 NEONATAL THYROTOXICOSIS, and 45 HYPOCALCEMIA, HYPOMAGNESEMIA AND OTHER ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN as shown below

- Add P70.2 (Neonatal diabetes mellitus) to the new line and remove from line 36 HEMATOLOGICAL DISORDERS OF FETUS AND NEWBORN
- Add P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified) to the new line and remove from line 13 CONGENITAL HYPOTHYROIDISM

Appendix B
Biennial List Line Changes

Line: ~28
Condition: ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P70 (Transient neonatal disorders of carbohydrate metabolism specific to newborn), P71 (Transitory neonatal disorders of calcium and magnesium metabolism), P72.1 (Transitory neonatal hyperthyroidism), P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified), P72.8 (Other specified transitory neonatal endocrine disorders), P72.9 (Transitory neonatal endocrine disorder, unspecified), P74 (Other transitory neonatal electrolyte and metabolic disturbances)
CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 45),98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are proposed by staff; current line scores shown in parentheses)
Category: 1 (1, 6, 1)
Healthy life years: 6 (6; 8; 5)
Suffering: 1 (1; 3; 1)
Population effects: 0 (0; 0; 0)
Vulnerable population: 0 (1; 0; 0)
Tertiary prevention: NA (NA; 5; NA)
Effectiveness: 5 (5; 5; 5)
Need for treatment: 1 (1; 1; 1)
Net cost: 4 (4; 5; 3)
Score: 3500 (4000; 3300; 3200)
Line placement: approximately 28 (21; 35; 45)

Restructure line 22 OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS

- Add the following codes found only on the dysfunction lines to line 22
  - P39.3 Neonatal urinary tract infection
  - P39.4 Neonatal skin infection
  - P39.8 Other specified infections specific to the perinatal period
- Add P39.9 (Infection specific to the perinatal period, unspecified) to line 22 and remove from the dysfunction lines and line 186 SEPTICEMIA
- Remove all codes found on line 22 from the four dysfunction lines (lines 75, 297, 350 and 382)
  - P38, P39.0, P39.3, P39.4, P39.8. P39.9

Appendix B
Biennial List Line Changes

- Rename line 22 ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~ NEONATAL INFECTIONS OTHER THAN SEPSIS
- Rescore line 22 as shown below

Line: **22 (which will move to ~40)**
Condition: ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~ NEONATAL INFECTIONS OTHER THAN SEPSIS (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P38.1-P38.9 (Omphalitis),P39.0 (Neonatal infective mastitis), P39.3 (Neonatal urinary tract infection), P39.4 (Neonatal skin infection), P39.8 (Other specified infections specific to the perinatal period), P39.9 (Infection specific to the perinatal period, unspecified)
CPT: 98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are staff recommended; current scoring in parentheses)
Category: 1 (1)
Healthy life years: 5 (7)
Suffering: 1 (1)
Population effects: 0 (0)
Vulnerable population: 0 (0)
Tertiary prevention:
Effectiveness: 5 (5)
Need for treatment: 1 (1)
Net cost: 2 (3)
Score: 3000 (4000)
Line placement: 40 (22)

Section 2.0

Staff Report

Prioritized List Errata for May 2016

1) Updated GN36 ADENOTONSILLECTOMY FOR INDICATIONS OTHER THAN OBSTRUCTIVE SLEEP APNEA to include correct line numbers in the text of the guideline
2) Removed 98925 (Osteopathic manipulative treatment (OMT); 1-2 body regions involved) from line 415 MIGRAINE HEADACHES. The other CPT codes in the OMT/CMT code series were removed from that line in 2014.
3) GN126 APPLIED BEHAVIOR ANALYSIS INTERVENTIONS FOR SELF-INJURIOUS BEHAVIOR removed from line 197 AUTISM SPECTRUM DISORDERS and added to line 442 STEREOTYPY/HABIT DISORDER AND SELF-ABUSIVE BEHAVIOR DUE TO NEUROLOGICAL DYSFUNCTION

Section 3.0

Consent Agenda-

Straightforward Items

Straightforward Issues—May, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
H0004	Behavioral health counseling and therapy, per 15 minutes	197 AUTISM SPECTRUM DISORDERS	H0004 appears on the other lines with psychotherapy and other mental health treatments. HSD requested that it be added to the autism line	Add H0004 to line 197
61120	Burr hole(s) for ventricular puncture (including injection of gas, contrast media, dye, or radioactive material)	20 HYDROCEPHALUS AND BENIGN INTRACRANIAL HYPERTENSION	HSD requested that 61120 be paired with G91.9 (Hydrocephalus unspecified). 61120 currently is on lines 51,200,338	Add 61120 to line 20
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	96155 was mistakenly added to line 3 at the March, 2016 VBBS meeting. It should remain Ancillary.	Remove 96155 from line 3
H0038 H2027	Self-help/peer services, per 15 minutes Psychoeducational service, per 15 minutes	125 ABUSE AND NEGLECT	H0038 and H2027 are on most mental health lines, but missing from line 125. A provider requested that they be added. Line 125 has a full set of psychotherapy codes, but does not have psychotherapy in the line treatment description.	Add H0038 and H2027 to line 125 Change the treatment description for line 125 to "MEDICAL/PSYCHOTHERAPY"
Z13.5	Encounter for screening for eye and ear disorders	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	A provider requested Z13.5 be added to line 3 to pair with ophthalmology visit CPT codes. The ICD-9 equivalent (V80.2, screening for eye condition) was on line 3.	Add Z13.5 to line 3 Advise HSD to remove Z13.5 from the Informational File

Straightforward Issues—May, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
78227	Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed		78227 is currently Ancillary; however, it is used for evaluation of diseases of the gallbladder and bile ducts and should be Diagnostic.	Advise HSD to remove 78227 from the Ancillary List and add to the Diagnostic List
12041 12042 13131 13132	Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 2.5 cm or less 2.6 cm to 7.5 cm Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm 2.6 cm to 7.5 cm	1 PREGNANCY	HSD requested that these procedures be added to the pregnancy care line for repair of 3rd degree lacerations after delivery. These codes already appear on a variety of lines.	Add 12041, 12042, 13131, and 13132 to line 1
43653	Laparoscopy, surgical; gastrostomy, without construction of gastric tube (eg, Stamm procedure)		CPT 43653 was placed on the Ancillary List in August, 2013, and then later added mistakenly to line 220 CANCER OF STOMACH. Open gastric tube placement procedures (CPT 43830 and 43832) are Ancillary.	Remove 43653 from line 220 Advise HSD to add 43653 to the Ancillary List.

Straightforward Issues—May, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
50605 50760, 50780-50785 50860	Ureterotomy for insertion of indwelling stent, all types Ureteroureterostomy Ureterostomy	**25** VESICOURETERAL REFLUX **53** CONGENITAL HYDRONEPHROSIS **91** CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM **184** URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER	Dr. David Lashley requested that 50605, 50760, 50780-50785, and 50860 be added to various urology lines to pair with various congenital abnormalities of the ureters.	Add CPT 50605 to lines 25, 91, and 184 Add CPT 50760, 50780-50785 and 50860 to lines 53, 91 and 184
92227 92228	Remote imaging for detection of retinal disease (eg, retinopathy in a patient with diabetes) with analysis and report under physician supervision, unilateral or bilateral Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral	**17** VERY LOW BIRTH WEIGHT (UNDER 1500 GRAMS) **23** LOW BIRTH WEIGHT (1500-2500 GRAMS) **278** RETINOPATHY OF PREMATURITY	Casey Eye Institute requested that 92227 and 92228 be paired with H35.1 (Retinopathy of prematurity) and various prematurity ICD-10 codes. These CPT codes are used for the screening and management of retinopathy of prematurity in premature infants in rural NICUs. 92227 is currently on lines 8, 30, 100, 353, and 365 and 92228 is currently on lines 100, 353, and 365. The American Academy of Pediatrics and the American Academy of Ophthalmology endorse this technology for premature infants.	Add 92227 and 92228 to lines 17, 23, and 278

Straightforward Guideline Note Changes

1) GN33 no longer serves a purpose after GN12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT was extensively modified.
    a. HERC staff recommendation: Delete GN33

~~**GUIDELINE NOTE 33, CANCERS OF ESOPHAGUS, LIVER, PANCREAS, GALLBLADDER AND OTHER BILIARY**~~

~~*Lines 319-321,439*~~

~~Retreatment with chemotherapy after failure from the first full course of chemotherapy places the patient in the category of treatment of cancer with little or no benefit. See Guideline Note 12.~~

Back Lines Straightforward Changes

Issue: As HERC staff prepares the new back conditions lines for inclusion on the Prioritized List, several errors and omissions have been identified.

1) Several guidelines need to be associated with the new back lines.
    a. Add lines 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 366 SCOLIOSIS, 407 CONDITIONS OF THE BACK AND SPINE,532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS to Guideline notes 64 PHARMACIST MEDICATION MANAGEMENT and 65 TELEPHONE AND EMAIL CONSULTATIONS
    b. Add 351, 366, 532 to GL 100 ARTIFICIAL DISC REPLACEMENT and GL 101 ARTIFICIAL DISC REPLACEMENT
    c. Add line 366 to GL 92 ACUPUNCTURE
2) Acupuncture was added to the scoliosis line, but the acupuncture guideline was not modified to reflect this change
3) 62311 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)) was mistakenly not removed from line 407 CONDITIONS OF THE BACK AND SPINE during the discussion of removing epidural steroid injections from the medical back line. The other 2 codes used for ESI were removed. 62311 appears on the dysfunction lines and should remain there for use with antispasmotic medications
4) Changes were made to GN37 in January, 2016. The accepted guideline note did not contain earlier edits made in March 2015.
5) Guideline notes 100 and 101 have not had the appropriate new back conditions lines formally added to them.
6) GN37 needs to be further edited to removed “covered” and replace with “included on this line” to conform with HERC convention

HERC staff recommendations:

EFFECTIVE JULY 1, 2016

1) Remove 62311 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)) from line 407 CONDITIONS OF THE BACK AND SPINE
2) Add lines 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 366 SCOLIOSIS, 407 CONDITIONS OF THE BACK AND SPINE, 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS to Guideline notes 64 PHARMACIST MEDICATION MANAGEMENT and 65 TELEPHONE AND EMAIL CONSULTATIONS
3) Add lines 351, 366, 532 to GL 100 SMOKING AND SPINAL FUSION and add lines 351 and 532 to GL 101 ARTIFICIAL DISC REPLACEMENT
4) Modify GN92 ACUPUNCTURE as shown below
    a. Provides the same restrictions for acupuncture use for scoliosis as for other back conditions
    b. Correct reference to the coverage guidance
5) Modify GN37 SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS as shown, clarify intent and restore previously approved changes.
6) NOTE: there are changes to the medical back conditions guideline (GN57) in the mechanical traction and TENS portion of the physical therapy modalities review

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,208, 366,407,415,467,543

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 366 SCOLIOSIS

Acupuncture is included on line 366 for pairing with visit limitations as in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Line 407 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC coverage guidance. See See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

*Below the current funding line.

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing objective evidence of one or more of the following:

A. Markedly abnormal reflexes
B. Segmental muscle weakness
C. Segmental sensory loss
D. EMG or NCV evidence of nerve root impingement
E. Cauda equina syndrome
F. Neurogenic bowel or bladder
G. Long tract abnormalities

Spondylolisthesis (ICD-10-CM M43.1, Q76.2) is included on Line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on Line 532.

Surgical correction of spinal stenosis (ICD-10-CM M48.0) is only included on Line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is ~~covered~~ included on these lines for spinal stenosis; spinal fusion procedures are not ~~covered~~ included on either line for this diagnosis. ~~Otherwise, these diagnoses are included on Line 532.~~

The following interventions are not ~~covered~~ included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- epidural steroid injections

Mechanical Traction and TENS for Back and Neck Conditions

Question: How best can non-coverage of mechanical traction and transcutaneous electrical nerve stimulation (TENS) for back and neck conditions be clarified on the Prioritized List?

Question source: HERC staff

Issue: Mechanical traction (CPT 97012) is not currently on any of the lines containing neck or back injury or pain diagnoses. However, there is considerable utilization of traction for treating these conditions—about 80% of diagnoses on claims for this service are back and neck conditions. Most utilization of this therapy is by CCOs. The new back condition guidelines which will go into effect soon do not include any reference for the non-coverage of mechanical traction. Traction is on lines for joint and limb injuries, and this treatment is appropriate for some types of these conditions. Therefore, 97012 is not appropriate for the Services Recommended for Non-Coverage list.

TENS (CPT 64550, 97014 and 97032) is on the Services Recommended for Non-Coverage List due to lack of evidence of effectiveness. However, there were approximately 3700 paid claims for 97014 for pack/neck conditions (approximately 80% of all paid claims) in July 2104-June 2015. Approximately 60% of the 620 paid claims for 97032 were for back and neck conditions in the same time period. Nearly all paid claims were by CCOs, who are free to cover more services that mandated by the Prioritized List.

Evidence:

1) **NICE 2015**: Do not offer traction, as a non-pharmacological therapy for low back pain
2) **Graham 2011**, Cochrane review of mechanical traction for treatment of neck conditions
    a. N=7 RCTs (total participants = 958), most with moderate to high risk of bias
    b. Based on one study (N = 100) with a low risk of bias, there is no statistically significant difference (SMD -0.16: 95%CI: -0.59 to 0.27) between continuous traction and placebo traction in reducing pain or improving unction for chronic neck disorders with radicular symptoms. Our review found no evidence from RCTs with a low potential for bias that clearly supports or refutes the use of either continuous or intermittent traction for neck disorders.
    c. **Authors' conclusions** The current literature does not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived effect when compared to placebo traction, tablet or heat or other conservative treatments in patients with chronic neck disorders. Large, well conducted RCTs are needed to first determine the efficacy of traction, then the effectiveness, for individuals with neck disorders with radicular symptoms.
3) **Wegner 2013,** Cochrane review of mechanical traction for treatment of low back pain (study not included due to length) http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003010.pub5/epdf
    a. N=32 RCTs (2762 patients)

b. For people with mixed symptom patterns (acute, subacute and chronic LBP with and without sciatica), there was low- to moderate quality evidence that traction may make little or no difference in pain intensity, functional status, global improvement or return to work when compared to placebo, sham traction or no treatment. Similarly, when comparing the combination of physiotherapy plus traction with physiotherapy alone or when comparing traction with other treatments, there was very-low- to moderate-quality evidence that traction may make little or no difference in pain intensity, functional status or global improvement. For people with LBP with sciatica and acute, subacute or chronic pain, there was low- to moderate-quality evidence that traction probably has no impact on pain intensity, functional status or global improvement. This was true when traction was compared with controls and other treatments, as well as when the combination of traction plus physiotherapy was compared with physiotherapy alone. For chronic LBP without sciatica, there was moderate-quality evidence that traction probably makes little or no difference in pain intensity when compared with sham treatment. No studies reported on the effect of traction on functional status, global improvement or return to work.
c. Adverse effects were reported in seven of the 32 studies. These included increased pain, aggravation of neurological signs and subsequent surgery.
d. **Authors' conclusions:** These findings indicate that traction, either alone or in combination with other treatments, has little or no impact on pain intensity, functional status, global improvement and return to work among people with LBP. There is only limited-quality evidence from studies with small sample sizes and moderate to high risk of bias. The effects shown by these studies are small and are not clinically relevant.
e. **Implications for practice:**To date, the use of traction as treatment for non-specific LBP cannot be motivated by the best available evidence. These conclusions are applicable to both manual and mechanical traction.

<u>HERC staff recommendations:</u>

***Effective July 1, 2016 ***

1) Continue the current non-pairing of mechanical traction (CPT 97012) with back and neck conditions and add language to guideline note as to its non-inclusion.
2) Continue the current placement of TENS (CPT 64550, 97014 and 97032) on the Services Recommended for Non-Coverage list and add language to guideline note as to its non-inclusion.
3) Additional straightforward wording changes to GN57 as shown below to clarify the HERC's intent
    a. Remove "covered"
    b. Change "this line" to "these lines" in several places to reflect the addition of the scoliosis line to this guideline note (from November, 2015).
    c. Replace a comma with a semicolon in the clause about covered medications
    d. Correct the reference to the Coverage Guidance

4) Add HCPCS S9451 (Exercise classes, nonphysician provider, per session) to line 407 CONDITIONS OF THE BACK AND SPINE and limit its use to yoga classes and supervised exercise classes via the changes to GN57 shown below

GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 366, 407

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on ~~this~~ these lines:

- Office evaluation and education,
- Up to 4 total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be considered.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be medium or high risk on the validated assessment tool, the following treatments are included on ~~this~~ these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications~~,~~; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on line 407 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only ~~covered~~ included on ~~this~~ these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
    2) Chiropractic or osteopathic manipulation
    3) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions. Transcutaneous electrical nerve stimulation (TENS; CPT 64550, 97014 and 97032) is not included on the Prioritized List for any condition due to lack of evidence of effectiveness.

~~These coverage recommendations are derived from the State of Oregon Evidence-based Guideline on the Evaluation and Management of Low Back Pain available at~~
The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx.

Evidence Table of Effective Treatments for the Management of Low Back Pain

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

M99 Diagnoses

Issue: The M99 series of diagnosis codes contains many codes that do not belong on the new back lines, but were placed there during the back line reorganization. HERC staff have worked with Vern Saboe, DC to determine the best placement of these codes.

M99.1 represents an unused diagnosis in modern medicine.

HERC staff recommendation:

1) Remove M99.1 (Subluxation complex (vertebral)) from all current lines and advise DMAP to place on the Undefined List
2) Remove any diagnoses from the M99.8 (Other biomechanical lesions) series from line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

ICD-10 Code	Code Description	Current Line	Recommendation
M99.0	Segmental and somatic dysfunction	407 CONDITIONS OF THE BACK AND SPINE	No change
M99.1	Subluxation complex (vertebral)	On various medical lines depending on location	Undefined
M99.2	Subluxation stenosis of neural canal	407 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS	No change
M99.3	Osseous stenosis of neural canal	407, 532	No change
M99.4	Connective tissue stenosis of neural canal	407, 532	No change
M99.5	Intervertebral disc stenosis of neural canal	407, 532	No change
M99.6	Osseous and subluxation stenosis of intervertebral foramina	407, 532	No change
M99.7	Connective tissue and disc stenosis of intervertebral foramina	407, 532	No change
M99.8	Other biomechanical lesions	On various medical lines depending on location Some of these codes also appear on 532	Remove any M99.8 codes from 532
M99.9	Biomechanical lesion, unspecified	663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	No change

Fitting for Spectacles and Contact Lenses

Question: should the procedure codes for fitting of glasses (spectacles) and contact lenses for general vision purposes be limited to the disorders of refraction and accommodation line?

Question source: HERC staff

Issue: Most of the CPT codes for fitting for spectacles and contact lenses (CPT 92310-92371) are on all the 52 ophthalmology lines. Some of these codes are for fitting glasses and/or contact lenses for specific eye conditions and should be limited to just the line or lines containing that condition. Others are for general issues with refraction and accommodation (near-sightedness, far-sightedness, etc.) and should be limited to the line specific for this condition.

Several of the codes in this series specify use for aphakia, which is the absence of the lens of the eye due to surgical removal, injury, disease or congenital anomaly. Aphakia causes a loss of accommodation and far sightedness (hyperopia). The most common cause of aphakia is cataract removal. Currently aphakia is on line 410 APHAKIA AND OTHER DISORDERS OF LENS.

Several of these codes are for scleral or corneoscleral lenses. These types of contact lenses are used for eye conditions such as keratoconus, or for eyes that have undergone a cornea transplant, and for people with severe dry eyes caused by conditions as the Sjorgren's syndrome or graft-vs-host disease. Keratoconus (ICD-10 H18.6) is on line 315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA

Specialized glasses are used for the treatment of esotropia and other abnormal eye positioning in children. These diagnoses are found on lines 375 AMBLYOPIA and 399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN.

A review of paid claims found the vast majority were paired with diagnoses on line 455 DISORDERS OF REFRACTION AND ACCOMMODATION, with some on line 315, 375, 399 and 410. Additionally, some claims were for lenses for cataracts prior to removal, on line 301 CATARACT.

Current ophthalmology lines with contacts and spectacle codes
100 DIABETIC AND OTHER RETINOPATHY
117 CANCER OF EYE AND ORBIT
143 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
159 HERPES ZOSTER; HERPES SIMPLEX AND WITH NEUROLOGICAL AND OPHTHALMOLOGICAL COMPLICATIONS
171 GONOCOCCAL AND CHLAMYDIAL INFECTIONS OF THE EYE; NEONATAL CONJUNCTIVITIS
175 AMEBIASIS
248 PRIMARY ANGLE-CLOSURE GLAUCOMA
249 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
252 RETAINED INTRAOCULAR FOREIGN BODY, MAGNETIC AND NONMAGNETIC
270 ACUTE, SUBACUTE, CHRONIC AND OTHER TYPES OF IRIDOCYCLITIS
274 ADVANCED DEGENERATIVE DISORDERS AND CONDITIONS OF GLOBE

278 RETINOPATHY OF PREMATURITY
284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
301 CATARACT
302 AFTER CATARACT
304 VITREOUS DISORDERS
313 CHRONIC INFLAMMATORY DISORDER OF ORBIT
315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
323 PURULENT ENDOPHTHALMITIS
324 FOREIGN BODY IN CORNEA AND CONJUNCTIVAL SAC
340 SCLERITIS
341 RUBEOSIS AND OTHER DISORDERS OF THE IRIS
342 WOUND OF EYE GLOBE
353 MILD/MODERATE BIRTH TRAUMA FOR BABY
356 STRABISMUS DUE TO NEUROLOGIC DISORDER
359 PENETRATING WOUND OF ORBIT
365 CHORIORETINAL INFLAMMATION
370 HYPHEMA
372 ENTROPION AND TRICHIASIS OF EYELID
375 AMBLYOPIA
379 RETINAL TEAR
388 CENTRAL SEROUS CHORIORETINOPATHY
399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
410 APHAKIA AND OTHER DISORDERS OF LENS
441 RECURRENT EROSION OF THE CORNEA
445 VENOUS TRIBUTARY (BRANCH) OCCLUSION; CENTRAL RETINAL VEIN OCCLUSION
453 DEGENERATION OF MACULA AND POSTERIOR POLE
455 DISORDERS OF REFRACTION AND ACCOMMODATION
456 EXOPHTHALMOS AND CYSTS OF THE EYE AND ORBIT
464 CENTRAL PTERYGIUM AFFECTING VISION
475 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
476 KERATOCONJUNCTIVITIS
488 ENOPHTHALMOS
499 ECTROPION AND BENIGN NEOPLASM OF EYE
505 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
564 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS
567 HORDEOLUM AND OTHER DEEP INFLAMMATION OF EYELID; CHALAZION
572 BLEPHARITIS
597 EPISCLERITIS
630 CONJUNCTIVAL CYST
636 ACUTE VIRAL CONJUNCTIVITIS
644 HYPERTELORISM OF ORBIT

Fitting for Spectacles and Contact Lenses

OAR concerning glasses and contact lenses:

410-140-0050(2)(a) Benefit Coverage for non-pregnant adults (age 21 and older);

A. Visual services and materials to diagnose and correct disorders of refraction and accommodation are covered only when the client has a covered medical diagnosis or following cataract surgery or a corneal lens transplant as described in OAR 410-140-0140.

410-140-0140(4)(d) Visual services for the purpose of prescribing glasses or contact lenses, fitting fees, or glasses or contact lenses:

A. One complete exam and determination of refractive state is limited to once every 24 months for pregnant adult women;
B. Non-pregnant adults are not covered, except when the client:
    i. Has a medical diagnoses of aphakia, psuedoaphakia, congenital aphakia, keratoconus; or
    ii. Lacks the natural lenses of the eye due to surgical removal (e.g. cataract extraction) or congenital absence; or
    iii. Has had a keratoplasty surgical procedure (e.g. corneal transplant) with limitations described in OAR 410-140-0160 (contact lens services and supplies); and
    iv. Is limited to one complete examination and determination of refractive state once every 24 months.

410-140-0160(2)(b)
The contact lenses are covered for eligible adults only when one of the following conditions exists:

A. Refractive error which is 9 diopters or greater in any meridian;
B. Keratoconus;
C. Anisometropia when the difference in power between two eyes is 3 diopters or greater;
D. Irregular astigmatism;
E. Aphakia; or
F. Post keratoplasty (e.g. corneal transplant) when medically necessary and within one year of procedure.

Fitting for Spectacles and Contact Lenses

HERC staff recommendation:

1) Remove CPT 92310-92371 from all lines on the Prioritized List except the lines shown in the "recommended line" column in the table below
    a. Advise DMAP to remove 92314-92317 from the Ancillary List

CPT code	Code Description	Current Lines/List	Recommended line(s)
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia	ophtho lines	**301** CATARACT **315** CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA **375** AMBLYOPIA **399** STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE **455** DISORDERS OF REFRACTION AND ACCOMMODATION
92311	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, 1 eye	ophtho lines	**410** APHAKIA AND OTHER DISORDERS OF LENS
92312	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes	ophtho lines	**410**
92313	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens	ophtho lines	**315**
92314	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens, both eyes except for aphakia	Ancillary	**301, 315, 375, 399, 455**
92315	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and	Ancillary	**410**

	direction of fitting by independent technician; corneal lens for aphakia, 1 eye		
92316	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, both eyes	Ancillary	**410**
92317	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneoscleral lens	Ancillary	**315**
92325	Modification of contact lens (separate procedure), with medical supervision of adaptation	ophtho lines	**301, 315, 375, 399, 455**
92326	Replacement of contact lens	ophtho lines	**301, 315, 375, 399, 455**
92340	Fitting of spectacles, except for aphakia; monofocal	ophtho lines	**301, 315, 375, 399, 455**
92341	Fitting of spectacles, except for aphakia; bifocal	ophtho lines	**301, 315, 375, 399, 455**
92342	Fitting of spectacles, except for aphakia; multifocal, other than bifocal	ophtho lines	**301, 315, 375, 399, 455**
92352	Fitting of spectacle prosthesis for aphakia; monofocal	ophtho lines	**410**
92353	itting of spectacle prosthesis for aphakia; multifocal	ophtho lines	**410**
92354	Fitting of spectacle mounted low vision aid; single element system	SNRC	**SNRC**
92355	Fitting of spectacle mounted low vision aid; telescopic or other compound lens system	SNRC	**SNRC**
92358	Prosthesis service for aphakia, temporary (disposable or loan, including materials)	ophtho lines	**410**
92370	Repair and refitting spectacles; except for aphakia	ophtho lines	**301, 315, 375, 399, 455**
92371	Repair and refitting spectacles; spectacle prosthesis for aphakia	ophtho lines	**410**

Section 4.0

Biennial Review

Biennial Review 2018
Headaches

Question: Should migraine headaches and tension headache lines be combined?

Question source: PK Melethil, LAc

Issue: Mr. Melethil has requested review of placement of tension headaches, and suggested merging the tension and migraine headache lines. He questioned whether there is a clear delineation between these types of headaches and advocated for allowing treatment of both with acupuncture as it is effective for both conditions. He was also concerned that the unfunded position of the tension headache line meant that patients with this condition had access to possibly harmful medications, but not other effective treatments such as acupuncture.

History: There was a Taskforce on the treatment of migraine and non-migraine headaches that met in 1997, and resulted in the merging of these conditions. The Taskforce based this change on the fact that the treatments for these conditions (mainly acupuncture and chiropractic) were equally effective for both conditions. There was some discussion that medications have different effectiveness for the two conditions. It was noted in the Commission discussion of the Taskforce report that the changes were based on weak or unavailable data.

Migraine and tension headaches were later re-split during a reorganization of the Prioritized List due to difference in effectiveness of treatment and on impact on overall health. These differences led to significant differences in the line scoring for these two conditions. The two headache lines were reviewed by the ICD-10 neurology group, but no recommendations made and the review was cursory. The acupuncture review in 2012 found acupuncture effective as a treatment for both migraine and tension headaches. CPT codes for acupuncture were added to both lines.

Evidence

Tension-type headache (TTH)

1) **Banzi 2015**, Cochrane review of SSRI for TTH (not included in packet due to the study's length: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011681/full)
    a. N=8 studies (412 patients)
    b. Evaluation of SSRIs (citalopram, sertraline, fluoxetine, paroxetine, fluvoxamine) and one SNRI (venlafaxine) on the frequency of TTH
    c. At eight weeks of followup, we found no difference when compared to placebo (two studies, N = 127; mean difference (MD) -0.96, 95% confidence interval (CI) -3.95 to 2.03; I2= 0%) or amitriptyline (two studies, N = 152; MD 0.76, 95% CI -2.05 to 3.57; I2= 44%).
    d. When considering secondary outcomes, SSRIs reduce the symptomatic/analgesic medication use for acute headache attacks compared to placebo (two studies, N = 118; MD -1.87, 95% CI -2.09 to -1.65; I2= 0%). However, amitriptyline appeared to reduce the intake of analgesic more

efficiently than SSRIs (MD 4.98, 95% CI 1.12 to 8.84; I2= 0%). The studies supporting these findings were considered to have an unclear risk of bias.

e. We found no differences compared to placebo or other antidepressants in headache duration and intensity.
f. **Authors' conclusions** Since the last version of this review, the new included studies have not added high quality evidence to support the use of SSRIs or venlafaxine (a SNRI) as preventive drugs for tension-type headache. Over two months of treatment, SSRIs or venlafaxine are no more effective than placebo or amitriptyline in reducing headache frequency in patients with chronic tension-type headache. Our conclusion is that the use of SSRIs and venlafaxine for the prevention of chronic tension-type headache is not supported by the evidence.

2) **Derry 2015**, Cochrane review of ibuprofen for TTH
   a. N=12 studies (3094 patients)
   b. For the IHS-preferred outcome of being pain free at 2 hours the NNT for ibuprofen 400 mg (all formulations) compared with placebo was 14 (95% confidence interval (CI), 8.4 to 47) in four studies, with no significant difference from placebo at 1 hour (moderate quality evidence). The NNT was 5.9 (4.2 to 9.5) for the global evaluation of 'very good' or 'excellent' in three studies (moderate quality evidence). The use of rescue medication was lower with ibuprofen 400 mg than with placebo, with the number needed to treat to prevent one event (NNTp) of 8.9 (5.6 to 21) in two studies (low quality evidence).
   c. **Authors' conclusions** Ibuprofen 400 mg provides an important benefit in terms of being pain free at 2 hours for a small number of people with frequent episodic tension-type headache who have an acute headache with moderate or severe initial pain. There is no information about the lesser benefit of no worse than mild pain at 2 hours.
3) **Fernandez de las Penas 2006**, systematic review of manual therapies for TTH
   a. N=6 studies
   b. These trials evaluated different manual therapy modalities: spinal manipulation (three trials), classic massage (one trial), connective tissue manipulation (two trials), soft tissue massage (one trial), Dr. Cyriax's vertebral mobilization (one trial), manual traction (one trial), and CV-4 craniosacral technique (one trial). Methodologic PEDro quality scores ranged from 2 to 8 points out of a theoretical maximum of 10 points (mean=5.8±2.1). Analysis of the quality and the outcomes of all trials did not provide rigorous evidence that manual therapies have a positive effect in reducing pain from TTH: spinal manipulative therapy showed inconclusive evidence of effectiveness (level 4), whereas soft tissue techniques showed limited evidence (level 3).
   c. Conclusions: The authors found no rigorous evidence that manual therapies have a positive effect in the evolution of TTH.
4) **Posadzki 2012**, systematic review of spinal manipulation for TTH

   a. N=5 RCTs, rated as high methodological quality
   b. Four RCTs suggested that spinal manipulations are more effective than drug therapy, spinal manipulation plus placebo, sham spinal manipulation plus amitriptyline or sham spinal manipulation plus placebo, usual care or no intervention. One RCT showed no difference in daily hours of headache, pain intensity, and daily analgesic use compared to soft tissue therapy plus placebo laser.
   c. *Conclusions:* The evidence that spinal manipulation alleviates tension type headaches is encouraging, but inconclusive. The low quantity of the available data prevent firm conclusion.

5) **Verhagen 2009**, Systematic review of behavioral treatments for TTH
   a. N=44 trials (2618 patients)
      i. only 5 studies (11.4%) were considered to have low risk of bias
   b. Behavioral therapies included relaxation, electromyographic [EMG] biofeedback, and cognitive behavioral training.
   c. Most trials lacked adequate power to show statistical significant differences, but frequently, recovery/improvement rates did not reach clinical relevance. In 8 studies, relaxation treatment was compared with waiting list conditions, and in 11 studies, biofeedback was compared with waiting list conditions, both showing inconsistent results.
   d. Conclusions: On the basis of the available literature, we found no indications that relaxation, EMG biofeedback, or cognitive behavioral treatment is better than no treatment, waiting list, or placebo controls.
6) **Jackson 2012**, meta-analysis of botulinum toxin for migraine and TTH
   a. Pooled analyses suggested that botulinum toxin A was associated with fewer headaches per month among patients with chronic daily headaches (1115 patients,−2.06 headaches per month; 95% CI, −3.56 to −0.56; 3 studies) and among patients with chronic migraine headaches (n=1508, −2.30 headaches per month; 95% CI,−3.66 to −0.94; 5 studies). There was no significant association between use of botulinum toxin A and reduction in the number of episodic migraine (n=1838, 0.05 headaches per month; 95% CI, −0.26 to 0.36; 9 studies) or chronic tension-type headaches (n=675, −1.43 headaches per month; 95% CI, −3.13 to 0.27; 7 studies).
   b. **Conclusion** Botulinum toxin A compared with placebo was associated with a small to modest benefit for chronic daily headaches and chronic migraines but was not associated with fewer episodic migraine or chronic tension-type headaches per month.

Migraine headache

1) Previously reviewed and found to be efficacious:
   a. Botulinum toxin injections
   b. Acupuncture

2) **Derry 2014**, Cochrane review of sumatriptan for acute migraine (all routes of administration)
    a. N=52,236 patients
    b. Subcutaneous administration was the most effective, with pain reduced from moderate or severe to none by two hours in almost 6 in 10 people (59%) taking 6 mg sumatriptan, compared with approximately 1 in 7 (15%) taking placebo; the number needed to treat (NNT) was 2.3 (95% confidence interval 2.1 to 2.4) with 2522 participants in the analysis. The most commonly used doses of oral, rectal, and intranasal sumatriptan also provided clinically useful pain relief, with the oral 50 mg dose providing complete relief of pain in almost 3 in 10 people (28%) compared with about 1 in 10 (11%) after placebo (NNT 6.1 (5.5 to 6.9) in 6447 participants).
    c. Authors' conclusions Sumatriptan is an effective abortive treatment for acute migraine attacks, but is associated with increased adverse events relative to placebo.
3) **Linde 2014,** Cochrane review of valproate for migraine prophylaxis (not included in packet due to study's length): http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010611/epdf
    a. N=10 trials
    b. Analysis of data from two trials (63 participants) showed that sodium valproate reduced headache frequency by approximately four headaches per 28 days as compared to placebo (MD-4.31; 95% confidence interval (CI) -8.32 to -0.30). Data from four trials (542 participants) showed that divalproex sodium (a stable combination of sodium valproate and valproic acid in a 1:1 molar ratio) more than doubled the proportion of responders relative to placebo (RR 2.18; 95% CI 1.28 to 3.72; NNT 4; 95% CI 2 to 11). One study of sodium valproate (34 participants) versus placebo supported the latter findings (RR for responders 2.83; 95% CI 1.27 to 6.31; NNT 3; 95% CI 2 to 9). There was no significant difference in the proportion of responders between sodium valproate versus flunarizine (one trial, 41 participants) or between divalproex sodium versus propranolol (one trial, 32 participants). Pooled analysis of post-treatment mean headache frequencies in two trials (88 participants) demonstrates a slight but significant advantage for topiramate 50 mg over valproate 400 mg (MD -0.90; 95% CI -1.58 to -0.22). For placebocontrolled trials of sodium valproate and divalproex sodium, NNHs for clinically important adverse events ranged from 7 to 14.
    c. Authors' conclusions Valproate is effective in reducing headache frequency and is reasonably well tolerated in adult patients with episodic migraine.

Biennial Review 2018
Headaches

HERC Staff summary

Systematic reviews and meta-analyses find little effective treatment for tension type headache, other than a reduction in pain at 1-2 hours with ibuprofen. Cognitive behavioral therapy, spinal manipulation, prophylactic medications, and botulinum injections all appear to be ineffective at reducing the frequency of headaches. Previous review has found acupuncture to be effective for this condition.

Systematic reviews and meta-analyses as well as prior HERC reviews find various treatments to be effective for treatment of migraine headaches, including acupuncture, botulinum injection, and various medications for treatment of acute migraine or for migraine prophylaxis (e.g. triptans, beta blockers, epileptic medications, etc.).

Line scoring:

Line 415 Migraine headaches (Line 543 Tension headaches)
Category 7 (7)
Impact on healthy life: 4 (2)
Pain/Suffering: 3 (1)
Population effects: 0
Vulnerable population: 0
Tertiary Prevention: 0
Effectiveness: 4 (3)
Need for services: 0.7 (0.5)
Cost: 3 (4)
Score: 392 (90)

HERC staff recommendations:

1) Do not merge the migraine and tension headache lines and do not rescore these lines. Tension headache has little effective treatment, compared to the many effective treatments available for migraine headache.
    a. If rescoring is desired, staff recommend increasing pain/suffering for tension headache to 2 and reducing effectiveness to 1 and need for services to 0.3 and cost to 3. This results in a score of 48 and a line position of approximately 560. Staff recommends no change for the scoring for the migraine line.

See 1 citation found using an alternative search:

Pain. 2014 Nov;155(11):2220-8. doi: 10.1016/j.pain.2014.08.009. Epub 2014 Aug 17.

Evidence for efficacy of acute treatment of episodic tension-type headache: methodological critique of randomised trials for oral treatments.

Moore RA[1], Derry S[2], Wiffen PJ[2], Straube S[3], Bendtsen L[4].

Author information

Abstract

The International Headache Society (IHS) provides guidance on the conduct of trials for acute treatment of episodic tension-type headache (TTH), a common disorder with considerable disability. Electronic and other searches identified randomised, double-blind trials of oral drugs treating episodic TTH with moderate or severe pain at baseline, or that tested drugs at first pain onset. The aims were to review methods, quality, and outcomes reported (in particular the IHS-recommended primary efficacy parameter pain-free after 2 hours), and to assess efficacy by meta-analysis. We identified 58 reports: 55 from previous reviews and searches, 2 unpublished reports, and 1 clinical trial report with results. We included 40 reports of 55 randomised trials involving 12,143 patients. Reporting quality was generally good, with potential risk of bias from incomplete outcome reporting and small size; the 23 largest trials involved 82% of patients. Few trials reported IHS outcomes. The number needed to treat values for being pain-free at 2 hours compared with placebo were 8.7 (95% confidence interval [CI] 6.2 to 15) for paracetamol 1000 mg, 8.9 (95% CI 5.9 to 18) for ibuprofen 400mg, and 9.8 (95% CI 5.1 to 146) for ketoprofen 25mg. Lower (better) number needed to treat values were calculated for outcomes of mild or no pain at 2 hours, and patient global assessment. These were similar to values for these drugs in migraine. No other drugs had evaluable results for these patient-centred outcomes. There was no evidence that any one outcome was better than others. The evidence available for treatment efficacy is small in comparison to the size of the clinical problem.

KEYWORDS: Efficacy; IHS outcomes; Systematic review; Tension-type headache

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Are Manual Therapies Effective in Reducing Pain From Tension-Type Headache?

A Systematic Review

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Objectives: A systematic review was performed to establish whether manual therapies have specific efficacy in reducing pain from tension-type headache (TTH).

Methods: Computerized literature searches were performed in MEDLINE, EMBASE, AMED, MANTIS, CINAHL, PEDro, and Cochrane databases. Papers were included if they described clinical (open noncontrolled studies) or randomized controlled trials in which any form of manual therapy was used for TTH, and if they were published after 1994 in the English language. The methodologic quality of the trials was assessed using the PEDro scale. Levels of scientific evidence, based on the quality and the outcomes of the studies, were established for each manual therapy: strong, moderate, limited, and inconclusive evidence.

Results: Only six studies met the inclusion criteria. These trials evaluated different manual therapy modalities: spinal manipulation (three trials), classic massage (one trial), connective tissue manipulation (two trials), soft tissue massage (one trial), Dr. Cyriax's vertebral mobilization (one trial), manual traction (one trial), and CV-4 craniosacral technique (one trial). Methodologic PEDro quality scores ranged from 2 to 8 points out of a theoretical maximum of 10 points (mean = 5.8 ± 2.1). Analysis of the quality and the outcomes of all trials did not provide rigorous evidence that manual therapies have a positive effect in reducing pain from TTH: spinal manipulative therapy showed inconclusive evidence of effectiveness (level 4), whereas soft tissue techniques showed limited evidence (level 3).

Conclusions: The authors found no rigorous evidence that manual therapies have a positive effect in the evolution of TTH. The most urgent need for further research is to establish the efficacy beyond placebo of the different manual therapies currently applied in patients with TTH.

Key Words: tension-type headache, manual therapy, soft tissue techniques, spinal manipulation

(*Clin J Pain* 2006;22:278–285)

Headaches are one of the most common problems seen in medical practice. Among the many types of headache disorders, tension-type headache (TTH) is the most prevalent in adults. Population-based studies suggest 1-year prevalence rates of 38.3% for episodic TTH and 2.2% for chronic TTH.[1] Recently, the second edition of the *Classification of Headache Disorders* of the International Headache Society (IHS) has kept the clinical criteria for the diagnosis of TTH[2,3] but has withdrawn EMG or pressure algometry from the diagnostic features for subdivision, as only tenderness on manual palpation has proved useful to distinguish the different subtypes of TTH.[3] Accordingly, the following subtypes of TTH are now considered: infrequent episodic TTH associated/not associated with pericranial tenderness; frequent episodic TTH associated/not associated with pericranial tenderness; chronic TTH associated/not associated with pericranial tenderness; and probable TTH (infrequent, frequent, or chronic TTH).

Despite its scientific interest, the pathophysiology of TTH is not clearly understood. Bendtsen reported that both peripheral mechanisms (ie, myofascial tenderness of pericranial structures) and central mechanisms (ie, sensitization of supraspinal neurons and decreased antinociceptive activity from supraspinal structures) might explain some of the symptoms of TTH.[4]

There are many therapeutic approaches aimed at treating benign chronic and recurrent headaches such as TTH, including pharmacotherapy, cognitive therapy, relaxation therapy, biofeedback, and physical therapy.[5] Headache sufferers are also frequent users of complementary techniques such as manual therapies and chiropractic care.[6] Vernon and McDermaid reported that upper cervical manipulation, soft tissue therapy, and myofascial trigger point treatment were the techniques

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Abstract

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Complement Ther Med. 2012 Aug;20(4):232-9. doi: 10.1016/j.ctim.2011.12.001. Epub 2011 Dec 29.

Spinal manipulations for tension-type headaches: a systematic review of randomized controlled trials.

Posadzki P[1], Ernst E.

Author information

Abstract

AIMS: The objective of this systematic review was to assess the effectiveness of spinal manipulations as treatment option for tension type headaches.

METHODS: Eight databases were searched from their inception to May 2011. All randomized trials were considered, if they investigated spinal manipulations performed by any type of healthcare professional for treating tension type headaches in human subjects. The selection of studies, data extraction, and validation were performed independently by two reviewers. The Cochrane tool and the Jadad score were used to assess methodological quality of trials.

RESULTS: Five randomized clinical trials (RCTs) met the inclusion criteria. Their methodological quality was mostly high and ranged between 2 and 4 on the Jadad score. Four RCTs suggested that spinal manipulations are more effective than drug therapy, spinal manipulation plus placebo, sham spinal manipulation plus amitriptyline or sham spinal manipulation plus placebo, usual care or no intervention. One RCT showed no difference in daily hours of headache, pain intensity, and daily analgesic use compared to soft tissue therapy plus placebo laser.

CONCLUSIONS: The evidence that spinal manipulation alleviates tension type headaches is encouraging, but inconclusive. The low quantity of the available data prevent firm conclusion.

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REVIEW

CNS Neuroscience & Therapeutics

Behavioral Treatments of Chronic Tension-Type Headache in Adults: Are They Beneficial?

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Keywords
Cognitive behavioral treatment; EMG biofeedback; Randomized clinical trial; Relaxation; Systematic review; Tension-type headache.

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To assess the efficacy of behavioral treatments in patients with tension headache. Medline, Cinahl, EMBASE, and the Cochrane library were searched from inception to October 2007 and reference lists were checked. We selected randomized trials evaluating behavioral treatments (e.g., relaxation, electromyographic [EMG] biofeedback, and cognitive behavioral training) in patients with tension-type headache (TTH). We assessed the risk of bias using the Delphi list and extracted data from the original reports. A qualitative analysis was carried out. We found 44 trials (2618 patients), which were included in this review, of which only 5 studies (11.4%) were considered to have low risk of bias. Most trials lacked adequate power to show statistical significant differences, but frequently, recovery/improvement rates did not reach clinical relevance. In 8 studies, relaxation treatment was compared with waiting list conditions, and in 11 studies, biofeedback was compared with waiting list conditions, both showing inconsistent results. On the basis of the available literature, we found no indications that relaxation, EMG biofeedback, or cognitive behavioral treatment is better than no treatment, waiting list, or placebo controls.

Introduction

Tension-type headache (TTH) or tension headache is the most commonly experienced type of headache. Population-based studies suggest prevalence rates of TTH of 35–40% in adults [1–3]. Chronic TTH has been defined in the classification of the International Headache Society (IHS) as more than 10 lifetime episodes of at least 6 months, with 15 or more headache episodes per month, an average episode duration of 30 min to 7 days, and with at least two quality of pain features (i.e., mild or moderate pain intensity, bilateral, pressing or tightening (non-pulsating) feeling, and no exacerbation by exercise) [4–6]. In addition, one associated symptom of migraine (i.e., nausea, vomiting, or photophobia and phonophobia) is permitted.

Several behavioral treatments such as relaxation, biofeedback, and cognitive behavioral (stress-management) therapy (CBT) are increasingly used in the management of TTH. Relaxation training is the less complicated behavioral strategy and is presumed to enable the headache sufferer to exert control over headache-related physiological responses and, more generally, sympathetic arousal [7]. Biofeedback uses electronic equipment to monitor physiological responses (that normally are unobservable) and reports it to the patients as visual or audio signals. The aim is that the patient learns to bring these normally involuntary processes under conscious control. The most frequently used type of biofeedback employed in the treatment of chronic TTH is electromyographic (EMG) biofeedback; this is feedback of electrical activity from muscles of the scalp, neck, and sometimes the upper body. There are conflicting opinions about the mechanism of biofeedback therapy in TTH, because reduction in the levels of muscle activity may neither be necessary nor be sufficient for the reduction in pain [8]. The use of CBT in headache management comes from the observation that the way individuals cope with everyday stresses can aggravate or maintain headaches and increase the disability and

Botulinum Toxin A for Prophylactic Treatment of Migraine and Tension Headaches in Adults
A Meta-analysis

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Context Botulinum toxin A is US Food and Drug Administration approved for prophylactic treatment for chronic migraines.

Objective To assess botulinum toxin A for the prophylactic treatment of headaches in adults.

Data Sources A search of MEDLINE, EMBASE, bibliographies of published systematic reviews, and the Cochrane trial registries between 1966 and March 15, 2012. Inclusion and exclusion criteria of each study were reviewed. Headaches were categorized as episodic (<15 headaches per month) or chronic (≥15 headaches per month) migraine and episodic or chronic daily or tension headaches.

Study Selection Randomized controlled trials comparing botulinum toxin A with placebo or other interventions for headaches among adults.

Data Extraction Data were abstracted and quality assessed independently by 2 reviewers. Outcomes were pooled using a random-effects model.

Data Synthesis Pooled analyses suggested that botulinum toxin A was associated with fewer headaches per month among patients with chronic daily headaches (1115 patients, –2.06 headaches per month; 95% CI, –3.56 to –0.56; 3 studies) and among patients with chronic migraine headaches (n=1508, –2.30 headaches per month; 95% CI, –3.66 to –0.94; 5 studies). There was no significant association between use of botulinum toxin A and reduction in the number of episodic migraine (n=1838, 0.05 headaches per month; 95% CI, –0.26 to 0.36; 9 studies) or chronic tension-type headaches (n=675, –1.43 headaches per month; 95% CI, –3.13 to 0.27; 7 studies). In single trials, botulinum toxin A was not associated with fewer migraine headaches per month vs valproate (standardized mean difference [SMD], –0.20; 95% CI, –0.91 to 0.31), topiramate (SMD, 0.20; 95% CI, –0.36 to 0.76), or amitriptyline (SMD, 0.29; 95% CI, –0.17 to 0.76). Botulinum toxin A was associated with fewer chronic tension-type headaches per month vs methylprednisolone injections (SMD, –2.5; 95% CI, –3.5 to –1.5). Compared with placebo, botulinum toxin A was associated with a greater frequency of blepharoptosis, skin tightness, paresthesias, neck stiffness, muscle weakness, and neck pain.

Conclusion Botulinum toxin A compared with placebo was associated with a small to modest benefit for chronic daily headaches and chronic migraines but was not associated with fewer episodic migraine or chronic tension-type headaches per month.

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MIGRAINE AND TENSION-type headaches are common. Although up to 42% of adults experience tension-type headaches sometime in their life, most do not seek medical advice. Migraines are less common, with a worldwide prevalence between 8% and 18%,[1-3] but are associated with greater disability.[4,5] Migraine headaches are responsible for $1 billion in medical costs and $16 billion in lost productivity per year[6] in the United States alone.

Headache treatment is either abortive or prophylactic. Abortive treatment manages the acute headache and prophylactic treatment aims to reduce the frequency or severity of the attacks. Common prophylactic medications include anticonvulsants, β-blockers, calcium channel blockers, serotonin reuptake inhibitors, and tricyclic antidepressants.[7] Botulinum toxin A injections were first proposed as headache treatment when it was observed that patients with chronic headaches receiving cosmetic botulinum injections experienced headache improvement, prompting several case series that suggested benefit.[8-10] In October 2010, the US Food and Drug Administration approved botulinum toxin A for prophylactic treatment of chronic migraine headaches at a dose of 155 units divided among 31 injection sites, repeated as needed every 12 weeks, based on 2 clinical trials conducted in Europe and the United States.[11,12] However, the literature on botulinum effectiveness for headaches is mixed. We performed a systematic review to assess the association of botulinum

CME available online at www.jamaarchivescme.com and questions on p 1757.

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Corresponding Author: Jeffrey L. Jackson, MD, MPH, Department of Medicine, Medical College of Wisconsin, 5000 W National Ave, Milwaukee, WI 53295 (jjackson@mcw.edu).

Cochrane Database Syst Rev. 2012 Feb 15;2:CD008615. doi: 10.1002/14651858.CD008615.pub2.

Sumatriptan (oral route of administration) for acute migraine attacks in adults.

Derry CJ[1], Derry S, Moore RA.

Author information

Abstract

BACKGROUND: Migraine is a highly disabling condition for the individual and also has wide-reaching implications for society, healthcare services, and the economy. Sumatriptan is an abortive medication for migraine attacks, belonging to the triptan family.

OBJECTIVES: To determine the efficacy and tolerability of oral sumatriptan compared to placebo and other active interventions in the treatment of acute migraine attacks in adults.

SEARCH METHODS: We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, online databases, and reference lists for studies through 13 October 2011.

SELECTION CRITERIA: We included randomised, double-blind, placebo- and/or active-controlled studies using oral sumatriptan to treat a migraine headache episode, with at least 10 participants per treatment arm.

DATA COLLECTION AND ANALYSIS: Two review authors independently assessed trial quality and extracted data. We used numbers of participants achieving each outcome to calculate relative risk (or 'risk ratio') and numbers needed to treat to benefit (NNT) or harm (NNH) compared to placebo or a different active treatment.

MAIN RESULTS: Sixty-one studies (37,250 participants) compared oral sumatriptan with placebo or an active comparator. Most of the data were for the 50 mg and 100 mg doses. Sumatriptan surpassed placebo for all efficacy outcomes. For sumatriptan 50 mg versus placebo the NNTs were 6.1, 7.5, and 4.0 for pain-free at two hours and headache relief at one and two hours, respectively. NNTs for sustained pain-free and sustained headache relief during the 24 hours postdose were 9.5 and 6.0, respectively. For sumatriptan 100 mg versus placebo the NNTs were 4.7, 6.8, 3.5, 6.5, and 5.2, respectively, for the same outcomes. Results for the 25 mg dose were similar to the 50 mg dose, while sumatriptan 100 mg was significantly better than 50 mg for pain-free and headache relief at two hours, and for sustained pain-free during 24 hours. Treating early, during the mild pain phase, gave significantly better NNTs for pain-free at two hours and sustained pain-free during 24 hours than did treating established attacks with moderate or severe pain intensity.Relief of associated symptoms, including nausea, photophobia, and phonophobia, was greater with sumatriptan than with placebo, and use of rescue medication was lower with sumatriptan than with placebo. For the most part, adverse events were transient and mild and were more common with the sumatriptan than with placebo, with a clear dose response relationship (25 mg to 100 mg).Sumatriptan was compared directly with a number of active treatments, including other triptans, paracetamol (acetaminophen), acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAIDs), and ergotamine combinations.

AUTHORS' CONCLUSIONS: Oral sumatriptan is effective as an abortive treatment for migraine attacks, relieving pain, nausea, photophobia, phonophobia, and functional disability, but is associated with increased adverse events.

Update of

WITHDRAWN: Oral sumatriptan for acute migraine. [Cochrane Database Syst Rev. 2012]

Early Childhood Insomnia

Question: Should treatment of early childhood insomnia be prioritized to a higher position on the Prioritized List?

Question source: Early Childhood Workgroup of the Children's System of Care Committee of the Health Systems Division of OHA

Issue: Insomnia is currently on Line 609 DISORDERS OF SLEEP WITHOUT SLEEP APNEA. Insomnia was placed on a very low line with the creation of the Prioritized list, and this placement has never been formally reviewed.

Insomnia is defined as difficulty initiating sleep (considered in children as the difficulty to fall asleep without a caregiver's intervention); maintaining sleep (frequent awakenings during the night and difficulty returning to sleep without a caregiver's intervention); or waking up earlier than the usual schedule with inability to return to sleep.

From the Early Childhood Workgroup:

> Early childhood sleep problems have been linked to a range of adverse health outcomes, including behavioral problems, inattention/hyperactivity, depression/anxiety and impaired cognitive development. Childhood sleep problems may have a major impact on the family, resulting in mood disturbances of parents, decreased effective parenting practices, and increased risk of child abuse.
>
> Given the negative impact on family functioning of sleep deprivation, if the sleep problem is still not improving by 6 months of age with guidance regarding developmentally appropriate sleep hygiene from their primary care provider, and by addressing any medical causes for the sleep problem, specialized services are indicated. These services should focus on increasing the child's regulation and providing support, and training to the caregiver(s).

Evidence

1) **Meltzer 2014**, meta-analysis of behavioral therapy for pediatric insomnia (not included due to length)
   http://jpepsy.oxfordjournals.org/content/early/2014/06/19/jpepsy.jsu041.full.pdf+html
   a. N=16 controlled clinical trials (N=2133) and 12 within subject studies (N=427)
   b. Included studies had a behavioral intervention for insomnia, with or without pharmacologic intervention
   c. Meta-analysis found significant effects for four specified sleep outcomes: sleep-onset latency, number of night wakings, and duration of night wakings, and sleep efficiency, with small to large effect sizes across the controlled clinical trials involving typical children.
   d. Effects in young children
      i. 12 controlled trials (N=1874)

   ii. Four studies assessed sleep-onset latency, with a significant overall effect and small to medium effect size [Z=4.06, p<.001; standard mean deviation (SMD)=0.33] at posttreatment
   iii. Frequency of night wakings was included in seven studies, resulting in a significant overall effect and small to medium effect size (Z=5.99, p<.001; SMD=0.40).
   iv. night waking duration was included in four studies for a significant overall effect and small to medium effect size (Z=5.50, p<.001; SMD=0.44)
- e. Effects on school aged children and adolescents
   i. N=3 controlled trials (N=214 participants 4-13 yrs)
   ii. All three studies included night waking duration which was significant at posttreatment (Z=2.67, p=.008; SMD=0.39)
   iii. sleep efficiency was included in two studies and was found to have an overall significant effect at posttreatment with a large effect size (Z=8.88, p<.001; SMD=2.24).
- f. Conclusions: Moderate-level evidence supports behavioral interventions for pediatric insomnia in young children. Behavioral interventions are effective at reducing sleep onset latency, night waking frequency, and night waking duration in young children. However, insufficient long term evidence for these changes means limited conclusions can be drawn on the durability of these treatments over time.

2) **Trauer 2015**, meta-analysis of behavioral therapy for adult insomnia
   a. N=20 RCTs (1162 participants)
   b. Approaches to CBT-i incorporated at least 3 of the following: cognitive therapy, stimulus control, sleep restriction, sleep hygiene, and relaxation.
   c. At the posttreatment time point, sleep onset latency improved by 19.03 (95% CI, 14.12 to 23.93) minutes, wake after sleep onset improved by 26.00 (CI, 15.48 to 36.52) minutes, total sleep time improved by 7.61 (CI, -0.51 to 15.74) minutes, and sleep efficiency improved by 9.91% (CI, 8.09% to 11.73%). Changes seemed to be sustained at later time points. No adverse outcomes were reported.
   a. **Conclusion:** CBT-i is an effective treatment for adults with chronic insomnia, with clinically meaningful effect sizes

Reviews

1) **Lahorgue Nunes 2015,** review of insomnia in childhood and adolescence
   a. Prevalence: approximately 15-30% of children meet criteria at some time for insomnia, with the higher rates reported in younger children (3 and under)
   b. Psychiatric (anxiety, depression) or neurodevelopmental disorders (attention deficit disorder, autism, epilepsy) frequently occur in association with or as a comorbidity of insomnia.
   c. The therapeutic approach must include sleep hygiene and behavioral techniques and, in individual cases, pharmacological treatment.
      i. Most behavioral techniques can be taught in the primary care setting
      ii. Cognitive behavioral therapy for the caregiver can be useful

Clinical practice guidelines

1) **Schutte-Rodin 2011**, American Academy of Sleep Medicine practice guidelines for insomnia for adults (study not included due to length) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2576317/pdf/jcsm.4.5.487.pdf
    a. Insomnia symptoms occur in approximately 33% to 50% of the adult population; insomnia symptoms with distress or impairment (i.e., general insomnia disorder) in 10% to 15%; and specific insomnia disorders in 5% to 10%.
    b. Behavioral interventions
        i. Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia. (Standard)
        ii. These treatments should be utilized as an initial intervention when appropriate and when conditions permit. (Consensus)
        iii. Initial approaches to treatment should include at least one behavioral intervention such as *stimulus control therapy or relaxation therapy, or the combination of cognitive therapy, stimulus control therapy, sleep restriction therapy with or without relaxation therapy*—otherwise known as cognitive behavioral therapy for insomnia (CBT-I). (Standard)
        iv. Multicomponent therapy (without cognitive therapy) is effective and recommended therapy in the treatment of chronic insomnia. (Guideline)
        v. Other common therapies include *sleep restriction*, *paradoxical intention*, and *biofeedback therapy*. (Guideline)
        vi. Although all patients with chronic insomnia should adhere to rules of good *sleep hygiene*, there is insufficient evidence to indicate that sleep hygiene alone is effective in the treatment of chronic insomnia. It should be used in combination with other therapies. (Consensus)
        vii. When an initial psychological/ behavioral treatment has been ineffective, other psychological/ behavioral therapies, combination CBT-I therapies, combined treatments (see below), or occult comorbid disorders may next be considered. (Consensus)

HERC staff summary:

Insomnia is a very common condition in children and adults. Treatment with cognitive behavioral therapy or other behavioral therapies has moderate evidence of effectiveness. Insomnia in young children may be comorbid with or causal for depression, anxiety, ADHD, and other psychiatric conditions.

Early Childhood Insomnia

HERC staff recommendations:

1) Consider creation of a new line for treatment of early childhood insomnia
    a. May also consider addition of older children, adolescents and adults
    b. If new line is created, adopt a new guideline as shown below

Line: XXX
Condition: EARLY CHILDHOOD INSOMNIA (See Guideline Notes 64,65,XXX)
Treatment: MEDICAL/PSYCHOTHERAPY
ICD-10: F51.01 (Primary insomnia), F51.09 (Other insomnia not due to a substance or known physiological condition), G47.00 (Insomnia, unspecified), G47.09 (Other insomnia)
CPT: 90785,90832-90840,90846-90853 (psychotherapy) 96150-96154 (health and behavior assessment codes), 98966-98969,99051,99060,99184,99201-99216, 99341-99350,99366,99408,99409,99415,99416,99441-99449,99487-99498,99605-99607
HCPCS: G0406-G0408,G0410,G0411,G0425-G0427,G0459,G0463,G0466,G0467,G0469, G0470, H0004

Line scoring:
Line XXX EARLY CHILDHOOD INSOMNIA (Line 609 DISORDERS OF SLEEP WITHOUT SLEEP APNEA)
Category 7 (9)
Impact on healthy life: 3 (0) Note: advocates suggested 5
Pain/Suffering: 3 (2) Note: advocates suggested 4
Population effects: 0 (0)
Vulnerable population: 1 (0) Note: advocates suggested 5
Tertiary Prevention: NA
Effectiveness: 3 (3)
Need for services: 0.3 (0.3)
Cost: 4 (4)
Score: 126 (2.7)
Line 516 (609)

GUIDELINE NOTE XXX, EARLY CHILDHOOD INSOMNIA
Lines XXX, 609
Insomnia (ICD-10 F51.01, F51.09, G47.00, G47.09) is only included on line XXX when all of the following criteria are met:

1) The child is 6 months of age or older, but younger than age 4
2) The sleep pattern or disturbance is significantly out of the range of typical developmental expectations
    a. For age 6-11 months, <10 hours of total sleep and <5 hours for longest duration of sleep
    b. For ages 1-2 years, <9 hours of total sleep and <7 hours for longest duration of sleep

   c. For age 3 years, <8 hours of total sleep and <8 hours for longest duration of sleep
3) Coexisting medical, developmental, or mental disorders do not adequately explain the predominate complaint of insomnia
4) Symptoms have persisted for at least 4 weeks with 4 episodes per week

Otherwise, these conditions are included on line 609.

Appropriate interventions for this problem include: parent training such as infant massage training, behavioral training, dyadic family therapy such as attachment and bio-behavioral catch-up, and family peer support services.

HEALTH SYSTEMS DIVISION

Kate Brown, Governor

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May 1, 2016

Dear members of the Health Evidence Review Commission,

The members of the Early Childhood Workgroup of the Children's System of Care Committee (CSAC-EC Workgroup), in conjunction with the OHA Health Systems Division recommend that the diagnosis G47.0 (Insomnia) be added to line 419 of the prioritized list. The membership of the CSAC-EC workgroup is comprised of stakeholders, parents, early childhood service providers, early learning, and OHA public health staff.

Oregon needs coordinated, effective and consistent services to promote healthy social emotional development in children across systems in all communities. Healthy social and emotional development refers to a child's developing capacity to express and manage emotions, build close, satisfying relationships with other children and adults, learn, and actively explore their environment; and it is more commonly called early childhood mental health, or infant mental health. The focus of the CSAC early childhood workgroup is on children aged birth to three years. However, many of the same concerns are common to all children under 6 years old.

Development in all domains (physical, social, emotional, adaptive, linguistic, and cognitive) begins prenatally and continues throughout life. The experiences of the first three years of life create the neurological pathways and connections which form procedural memories and responses (positive or negative lifelong expectations, physiological stress responses, emotion regulation, and style of relating to others). Both external (light, temperature, social interactions) and internal conditions contribute to the ability to regulate sleep and awake states. Due to a newborns immature nervous system infants are initially dependent on their caregiver to assist them with state regulation, however over time a healthy child learns to develop the ability to self-regulate (Barnard and Thomas 2014).

Sleep is a basic component of developing self-regulation. "Control of sleep requires integrated function of multiple areas of the brain and varying levels of neurochemicals," K. Barnard. Early childhood sleep problems have been linked to a range of adverse health outcomes, including behavioral problems, inattention/hyperactivity, depression/anxiety and impaired cognitive development. Childhood sleep problems may have a major impact on the family, resulting in mood disturbances of parents, decreased effective parenting practices, and increased risk of child abuse.

By 3 months of age, a baby is typically developing a normal sleep-wake cycle and is more engaged when awake. This promotes regulation in the presence of an emotionally available caregiver who is regulated. If this co-regulation is not happening by then, there may be concern that the baby's social emotional development is falling off track and the dyadic relationship is stressed (dwindling parental confidence, parental fatigue).
The opportunity for building emotional connections that are healthy and regulated is in jeopardy.
Given the negative impact on family functioning of sleep deprivation, if the sleep problem is still not improving by 6 months of age with guidance regarding developmentally appropriate sleep hygiene from their primary care provider, and by addressing any medical causes for the sleep problem, specialized services are indicated. These services should focus on increasing the child's regulation and providing support, and training to the caregiver(s).
Adding G47.0 Early Childhood Insomnia to the Anxiety Disorder line is recommended as the most appropriate placement on the prioritized list. High cortisol levels are associated with Anxiety and Depression. The currently available effective interventions for Early Childhood insomnia without sleep apnea appear to lower cortisol levels while improving sleep and other regulatory functions.

Some of the research used to make this recommendation are cited below:

Reut Gruber, Normand Carrey, Shelly Weiss, Jean Yves Frappier, Leslie Rourke, Robert Brouillette, Merrill S. Wise Position Statement on Pediatric Sleep for Psychiatrists, *J Can Acad Child Adolesc Psychiatry*, 23:3, Fall 2014, http://www.cacap-acpea.org/en/cacap/Volume_23_Number_3_September_2014_s5.html?ID=1322

Victoria C. Smith , Katherine A. Leppert, Candice A. Alfano ,Lea R. Dougherty; Construct validity of the Parent–Child Sleep Interactions Scale (PSIS): associations with parenting, family stress, and maternal and child psychopathology DOI: http://dx.doi.org/10.1016/j.sleep.2014.04.002

Ferber SG, Laudon M, Kuint J, Weller A, Zisapel N. Massage therapy and sleep-wake rhythms in the neonate. *Journal of Developmental and Behavioral Pediatrics 2002; 23(6):410-415.*

Field, T., & Hernandez-Reif, M., (2001). Sleep problems in infants decrease following massage therapy. *Early Child Development and Care, 168, 95-104*

Rebecca Giallo, Melissa Dunning, Amanda Cooklin, Monique Seymour, Helen Graessar, Nikki Zerman & Renzo Vittorino; Acceptability of Wide Awake Parenting: A psycho-educational intervention to manage parental fatigue ,*Journal of Reproductive and Infant Psychology ,Volume 30, Issue 5, 2012 DOI: 10.1080/02646838.2012.742999*

Aideen Naughton and Alan Heath, Developing an early intervention programme to prevent child maltreatment Child Abuse Review Volume 10, Issue 2, pages 85–96, March/April 2001 DOI: 10.1002/car.667

Mercer RT (1985). The Process of Maternal Role Attainment Over the First Year, *Nursing Research* 34, 198-204

Kathryn E. Barnard and Karen A. Thomas, Beginning Rhythms, The Emerging Process of Sleep Wake Behaviors and Self-Regulation. 2nd Edition. 2014. *NCAST Programs, University of Washington. Seattle, WA*

Thank you for your consideration on this very important topic.
Sincerely,

The Children's System of Care Advisory Council (CSAC) and the Oregon Health Systems Division Youth and Family Behavioral Health Unit

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Annals of Internal Medicine REVIEW

Cognitive Behavioral Therapy for Chronic Insomnia

A Systematic Review and Meta-analysis

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Background: Because psychological approaches are likely to produce sustained benefits without the risk for tolerance or adverse effects associated with pharmacologic approaches, cognitive behavioral therapy for insomnia (CBT-i) is now commonly recommended as first-line treatment for chronic insomnia.

Purpose: To determine the efficacy of CBT-i on diary measures of overnight sleep in adults with chronic insomnia.

Data Sources: Searches of MEDLINE, EMBASE, PsycINFO, CINAHL, the Cochrane Library, and PubMed Clinical Queries from inception to 31 March 2015, supplemented with manual screening.

Study Selection: Randomized, controlled trials assessing the efficacy of face-to-face, multimodal CBT-i compared with inactive comparators on overnight sleep in adults with chronic insomnia. Studies of insomnia comorbid with medical, sleep, or psychiatric disorders were excluded.

Data Extraction: Study characteristics, quality, and data were assessed independently by 2 reviewers. Main outcome measures were sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE%).

Data Synthesis: Among 292 citations and 91 full-text articles reviewed, 20 studies (1162 participants [64% female; mean age, 56 years]) were included. Approaches to CBT-i incorporated at least 3 of the following: cognitive therapy, stimulus control, sleep restriction, sleep hygiene, and relaxation. At the posttreatment time point, SOL improved by 19.03 (95% CI, 14.12 to 23.93) minutes, WASO improved by 26.00 (CI, 15.48 to 36.52) minutes, TST improved by 7.61 (CI, −0.51 to 15.74) minutes, and SE% improved by 9.91% (CI, 8.09% to 11.73%). Changes seemed to be sustained at later time points. No adverse outcomes were reported.

Limitation: Narrow inclusion criteria limited applicability to patients with comorbid insomnia and other sleep problems, and accuracy of estimates at later time points was less clear.

Conclusion: CBT-i is an effective treatment for adults with chronic insomnia, with clinically meaningful effect sizes.

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Insomnia is a prevalent condition, with 5% to 15% of adults meeting formal diagnostic criteria for chronic insomnia (1–5) (now termed insomnia disorder [6]) and one third reporting dissatisfaction with sleep. Insomnia is associated with both medical and psychiatric comorbidity, being linked to anxiety; depression (7); chronic health problems, such as hypertension (8, 9) and type 2 diabetes (10); health care use; non–motor vehicle accidents; pain (11); and use of medication and alcohol (12–15). Symptoms of insomnia have functional consequences even in the absence of a formal diagnosis (16), with the high economic burden of the condition largely mediated through the productivity cost of work absenteeism (17).

Hypnotics, such as benzodiazepines and related drugs, are the most commonly used treatment for insomnia, with around 6% to 10% of U.S. adults using hypnotics in 2010 (18) and 27 daily doses of such drugs being taken per 1000 U.S. persons (19). In Australia, around 90% of primary care encounters for insomnia result in hypnotic prescription (20). Furthermore, despite a lack of evidence, use of second-generation antipsychotics (such as quetiapine) is also increasing, possibly due to patient and physician dissatisfaction with available treatments and a perceived lack of alternatives (21, 22). In this context, considering nonpharmacologic treatment options for insomnia disorder is important.

Cognitive behavioral therapy for insomnia (CBT-i) is an effective nonpharmacologic treatment that improves sleep outcomes with minimal adverse effects (23) and is preferred by patients to drug therapy (24). The approach to CBT-i has been refined in recent years, and it is now most commonly studied as a combined cognitive and behavioral treatment incorporating some or all of 5 components. The components are described in Table 1, and although the precise efficacy of each has not been determined, the package of care is more effective than separate delivery of the cognitive or behavioral components (25). Although previous meta-analyses have been performed (26–29), no recent meta-analysis has assessed the efficacy of this now-established package of care. We present a meta-analysis of the efficacy of CBT-i on sleep diary outcomes, compared with control, for the treatment of adults with chronic insomnia.

See also:

Editorial comment 236

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REVIEW ARTICLE

Insomnia in childhood and adolescence: clinical aspects, diagnosis, and therapeutic approach☆

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KEYWORDS
Insomnia;
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Abstract
Objectives: To review the clinical characteristics, comorbidities, and management of insomnia in childhood and adolescence.
Sources: This was a non-systematic literature review carried out in the PubMed database, from where articles published in the last five years were selected, using the key word ''insomnia'' and the pediatric age group filter. Additionally, the study also included articles and classic textbooks of the literature on the subject.
Data synthesis: During childhood, there is a predominance of behavioral insomnia as a form of sleep-onset association disorder (SOAD) and/or limit-setting sleep disorder. Adolescent insomnia is more associated with sleep hygiene problems and delayed sleep phase. Psychiatric (anxiety, depression) or neurodevelopmental disorders (attention deficit disorder, autism, epilepsy) frequently occur in association with or as a comorbidity of insomnia.
Conclusions: Insomnia complaints in children and adolescents should be taken into account and appropriately investigated by the pediatrician, considering the association with several comorbidities, which must also be diagnosed. The main causes of insomnia and triggering factors vary according to age and development level. The therapeutic approach must include sleep hygiene and behavioral techniques and, in individual cases, pharmacological treatment.

PALAVRAS-CHAVE
Insônia;
Distúrbios do sono;
Infância;
Adolescência

Insônia na infância e adolescência: aspectos clínicos, diagnóstico e abordagem terapêutica

Resumo
Objetivos: Revisar as características clinicas, as comorbidades e o manejo da insônia na infância e adolescência.

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Fonte dos dados: Revisão não sistemática da literatura realizada na base dados PubMed,onde foram selecionados artigos publicados nos últimos 5 anos, selecionados com o uso da palavra chave insônia e o filtro faixa etária pediátrica. Adicionalmente foram também incluídos artigos e livros texto clássicos da literatura sobre o tema.
Síntese dos dados: Na infância existe predomínio da insônia comportamental na forma de distúrbio de início do sono por associações inadequadas e/ou distúrbio pela falta de estabelecimento de limites. Na adolescência a insônia está mais associada a problemas de higiene do sono e atraso de fase. Transtornos psiquiátricos (ansiedade, depressão) ou do neurodesenvolvimento (Transtorno do déficit de atenção, autismo, epilepsias) ocorrem com frequência em associação ou como comorbidade do quadro de insônia.
Conclusões: A queixa de insônia nas crianças e adolescentes deve ser valorizada e adequadamente investigada pelo Pediatra, levando em consideração a associação com diversas comorbidades, que também devem ser diagnosticas. As causas principais de insônia e fatores desencadeantes variam de acordo com a idade e nível de desenvolvimento. A abordagem terapêutica deve incluir medidas de higiene do sono e técnicas comportamentais, e em casos individualizados tratamento farmacológico.

Introduction

Sleep disorders (SD) are a frequent complaint in routine medical appointments and increasingly, the pediatrician must be able to adequately establish their diagnosis and management, thus avoiding referral to specialist consultations, as well as unnecessary and excessive examinations/interventions.

SD mostly present as the primary entity, but may also be associated with several organic diseases (e.g., asthma, obesity, neuromuscular diseases, gastroesophageal reflux disease, epilepsy, attention disorder, autism spectrum disorder) or psychiatric comorbidities (anxiety, depression, bullying).

Clinical presentation is variable and multiple. During the first years of life, the most frequent complaints are difficulty falling asleep and/or frequent nocturnal awakenings, followed by parasomnias (confusional arousals) and sleep-disordered breathing (obstructive apnea-hypopnea syndrome). From preschool age onwards, disorders related to inadequate sleep hygiene occur and, in adolescence, the disorders are related to circadian issues (delayed sleep phase) or excessive movement during sleep (restless leg syndrome [RLS]).

This review will assess a frequent SD, i.e., insomnia, which may present in different clinical forms during childhood, with varied management. The clinical features, diagnosis, comorbidities, and treatments will be assessed, aiming to give the pediatrician an overview of the problem and to provide tools for its diagnosis and management.

Sleep characteristics and classification of SD

Recommendations about sleep duration in children and adolescents vary according to the source used. Recently, the National Sleep Foundation published a consensus based on an expert panel, stating the ideal number of sleeping hours for every age group and a variability range that contains the acceptable number of sleeping hours (Table 1).[1]

Nocturnal awakenings occur frequently in childhood and its distribution varies with age. In the first six months of life, they are concentrated in one to two evening peaks; after the sixth month, they follow a distribution that accompanies the sleep cycle (which lasts 90–120 min) and occur more commonly in the REM stage. In these cases, it is common that the child goes back to sleep spontaneously.[2]

The classification of SD is proposed by the American Academy of Sleep Medicine and the Chronic Insomnia Definition-ICSD-3, which is the updated version of ICSD-2, was published in 2005. This classification review maintained the basic principles of the previous one, identifying seven major SD categories: insomnia, sleep-disordered breathing, central hypersomnia, circadian rhythm disorders, movement disorders during sleep, parasomnias, and others.[2] There was a standardization of diagnostic criteria for adults and children, maintaining the recognition of specific age-dependent situations. Table 2 shows the prevalence of different SD in childhood, according to the American Academy of Sleep Medicine.[3]

Insomnia definition

Insomnia can be defined as difficulty initiating sleep (considered in children as the difficulty to fall asleep without a caregiver's intervention); maintaining sleep (frequent awakenings during the night and difficulty returning to sleep without a caregiver's intervention); or waking up earlier than the usual schedule with inability to return to sleep. Insomnia can cause distress and social, professional, educational-academic, or behavioral impairment.[2]

Insomnia prevalence

SD that manifest with difficulty falling asleep and/or difficulty maintaining sleep (due to nocturnal awakenings) affect

Table 1 Sleep duration.[a]

Age range	Ideal hours of sleep	Acceptable hours of sleep (maximum and minimum)
Newborns (0–3 months)	14–17	18–19 and 11–13
Infants (4–12 months)	12–15	16–18 and 10–11
Toddlers (1–2 years)	11–14	15–16 and 9–10
Preschoolers (3–5 years)	10–13	14 and 8–9
School-aged children (6–13 years)	9–11	12 and 7–8
Adolescents (14–17 years)	8–10	11 and 7
Young adults (18–25 years)	7–9	10–11 and 6
Adults (26–64 years)	7–9	10 and 6
Elderly (>65 years)	7–8	9 and 5–6

[a] Recommendations of the National Sleep Foundation in 2015, based on an expert panel.

Table 2 Prevalence of sleep disorders in childhood according to ICSD-3.

Disorder	Prevalence
Insomnia	20–30%
Sleep-disordered breathing	2–3%
Hypersomnia	0.01–0.20%
Circadian rhythm disorders	7%
Parasomnias	25%
Sleep-related movement disorders	1–2%

approximately 30% of children. The increase in prevalence, which has been observed in recent years, is closely related to social habits in the family, as there is often a difference between the child's natural sleep-alertness rhythm and social requirements. This disorder, when chronic, can result in deleterious effects on cognitive development, mood regulation, attention, behavior and quality of life, not only of the child but the entire family, resulting in parents' sleep deprivation, with consequences for their work activities.[4,5]

Data on the prevalence of insomnia vary with age. In the first two years, the rates are high, around 30%, and after the third year of life the prevalence remains stable at around 15%. It is worth mentioning that, as insomnia definition and diagnosis vary widely among the available studies, this fact directly influences the data on prevalence.[4,5]

In a population-based study conducted in Pennsylvania, it was demonstrated that one out of five children or pre-adolescents have insomnia symptoms; the highest prevalence (approximately 30%) is observed in girls aged 11–12 years, which appears to be more related to hormonal changes than to anxiety/depression.[6]

Another large population-based study was carried out in China, using two data collection stages, with a five-year interval between them. An increase in insomnia prevalence from 4.2% to 6.6% and incidence from 6.2% to 14.9% was demonstrated. The initial cases were associated with health issues (laryngopharyngitis) and lifestyle (caffeine intake, smoking), whereas the new cases were associated with parents' low educational level, alcohol intake, and mental illness.[7]

A population-based study conducted in Norway with adolescents showed that, on weekdays, the average number of sleep hours was 6 h 25 m, leading to a deficit of approximately 2 h; most subjects (65%) showed long latency to sleep onset (>30 min). The prevalence of insomnia in this population was 23.8% according to the DSM-IV criteria, 18.5% using the DSM-V, and 13.6% when quantitative criteria were used.[8]

Types of insomnia according to age range

In children, insomnia has clearly defined behavioral characteristics and can be defined as two main types, sleep-onset association disorder (SOAD) and limit-setting SD.[9]

1) SOAD

   In this condition, the infant learns to sleep under a specific condition (object, circumstance), which usually requires intervention/presence of parents. After a nocturnal physiological awakening, he/she needs the same intervention to resume sleeping. Although the number of awakenings is normal for their age group, the problem occurs due to the inability to return to sleep alone, which prolongs the alertness period. Diagnosis is based on the history of long latency to sleep onset, requiring specific and pre-determined conditions, as well as the need for caregiver intervention during the nocturnal awakenings. By definition, two or three awakenings/night, lasting between 5 and 10 min or longer, occur five times a week.

   This type of insomnia tends to disappear at approximately 3–4 years of age. Polysomnography is normal if the associations are present to facilitate sleep onset. The differential diagnosis with other types of insomnia is made through the rapid sleep onset in the presence of the initial conditions. The therapeutic approach is through the gradual extinction of the association stimulus.[2,5]

2) Limit-setting SD

   It is typical in preschool and school-age children, characterized by the parents' difficulty in setting limits and rules for bedtime or having them followed. As a result, the child refuses to sleep or stay asleep all night. Excuses for not going to sleep are a common occurrence (hunger, thirst, ''one more story...''), with parents usually giving in. Total sleep time may be reduced by 1–2 h, with approximately three to five awakenings that result in the child leaving the bed or calling the parents.

Polysomnography is normal, as once the child sleeps, sleep architecture is adequate. For the differential diagnosis, it is important to analyze the parents' relationship and attitude with the child.

Management essentially involves parents, who should establish the limits/rules and maintain them firmly, and utilize behavioral techniques. It is acceptable to use sleep-inducing antihistamines or benzodiazepines for a limited period of time, while behavioral techniques are consolidated.[2,5]

Some children may experience a combination of the two types of behavioral insomnia.[5]

Studies have shown that sleep plays a crucial role in the healthy development of adolescents. However, changes in sleep patterns are very common in adolescence, due to biological and environmental factors such as late bedtime, inadequate sleep hygiene, and sleep restriction and fragmentation. Insomnia in this age group is associated with a poor prognosis in terms of mental health, school performance, and risk behavior.[2]

In adolescence, insomnia may be related to inadequate sleep hygiene and delayed sleep phase, or it can have a psychophysiological origin.

1) Insomnia due to inadequate sleep hygiene:

   During adolescence, insomnia has characteristics related to changes in social habits (tendency to sleep later) and sleep hygiene problems. The following habits are considered to be inadequate sleep hygiene: sleeping after 11 pm and waking up after 8 am; irregular sleep schedule between weekdays and the weekend; use of stimulating substances or drugs (licit and illicit); excess caffeine in the late afternoon or at night; and/or use of electronic devices in the bedroom before going to bed (TV, computer, mobile). Social and family pressures, hormonal changes, and the need for belonging to a group also influence sleep quality.[10]

   Insomnia due to poor sleep hygiene leads to an increase in sleep latency and reduction in total sleep time. As a consequence, it results in excessive daytime sleepiness and/or hyperactivity, academic and relationship problems, and sleep-wake cycle inversion.[11,12] It is important to make the differential diagnosis with psychiatric disorders such as depression and schizophrenia, noting that insomnia may be the initial symptom of these morbidities. Therapeutic management consists in following an adequate sleep hygiene routine, behavioral therapy and, in selected cases, the use of melatonin.[5]

2) Delayed sleep phase insomnia:

   It is defined as the delay in the sleep schedule that leads to a late awakening. This is a circadian rhythm disorder that occurs in adolescents due to hormonal changes, with a shift in the nocturnal sleep time as a function of the endogenous pacemaker. It is a common cause of insomnia and can occur at other ages, in addition to adolescence.

   Conflicts occur because the bedtime does not match the sleep schedule; the adolescent refuses to go to sleep and has trouble waking up in the following morning. It results in symptoms of sleep deprivation, hyperactivity, aggression, and even learning disabilities, due to excessive daytime sleepiness. After they manage to fall sleep, sleep is tranquil, with adequate structure and duration (if they do not have to be awakened in the morning). The attempt to compensate for sleepiness with naps during the day or unlimited sleep time on weekends leads to more nocturnal delayed sleep phase.

   Optimal management consists in readjusting sleep onset time. The use of low-dose melatonin (1 mg) in the late afternoon was shown to be effective in correcting delayed sleep phase in a double-blinded study conducted with an adolescent population.[13] The association between delayed sleep phase as a cause of insomnia in adolescents has been extensively assessed in the literature. In population-based study, carried out in Norway, including 10,220 adolescents aged 16–18 years, delayed sleep phase was observed in 3.3% of the population; over half of these adolescents (54% girls and 57% boys) also met the criteria for insomnia. Additionally, the delayed sleep phase diagnosis resulted in a three-fold increased risk for school absenteeism in males and 1.8-fold in females.[14]

3) Psychophysiological insomnia:

   Characterized by a combination of previously experienced associations and hypervigilance. The complaint consists of an exaggerated preoccupation with sleep, getting to sleep, and the adverse effects of ''not sleeping'' on the following day. This type of situation occurs through a combination of risk factors (genetic vulnerability, psychiatric comorbidities), triggering factors (stress), and other factors (poor sleep hygiene, caffeine intake, etc.).[5]

Clinical characteristics

Among the factors that predispose to insomnia are: birth order (more prevalent in the first-born and/or only child), genetic factors (positive family history); temperament (mood variability); presence of maternal psychopathology or depression; caregivers' behavior during the nocturnal awakenings (the tendency to make the child fall asleep while holding him/her on one's lap or pick up the infant in one's arms immediately after the nocturnal awakening tends to make insomnia a chronic condition); night feeding (nocturnal awakenings are more common in infants who are breastfed between 6 and 12 months and persist longer in children who continue to be breastfed after 12 months); and co-sleeping (frequently associated with insomnia).[2]

Different causes of insomnia or its precipitating factors are directly related to the child's neuropsychological development stage and/or typical characteristics of adolescence, as detailed in Table 3. The division by age group is an instructive presentation; however, overlaps between different age groups can occur. It should be noted that an irregular and erratic sleep routine can also lead to insomnia at all ages, as well as acute and/or chronic systemic diseases. Although scarcely discussed in childhood, the genetically determined characteristic of short sleep duration (an individual who sleeps well, but has a total duration of sleep below the average expected for age and level of development) can occur, and these cases have normal sleep quality (organization).[15]

Table 3 Causes and/or triggering factors of insomnia according to the age group.

Age range	Causes
Infants	Sleep-onset association disorder (SOAD) Food allergies Gastroesophageal reflux Colic in infants Excessive nighttime fluid intake Acute otitis media or other infectious diseases Chronic diseases
2–3 years	SOAD Fear Parental separation anxiety Prolonged naps or at inappropriate times Acute infectious diseases Chronic diseases
Preschoolers and school-aged children	Limit-setting sleep disorder Fear Nightmares Acute infectious diseases Chronic diseases
Adolescents	Sleep hygiene problems Delayed sleep phase Psychiatric comorbidities (anxiety, depression, attention deficit hyperactivity disorder) Family, school pressure Sleep-disordered breathing Movement disorders Acute infectious diseases Chronic diseases

Clinical investigation

Clinical history is extremely important for the diagnosis of insomnia, in which the falling asleep routine, as well as sleep and wake characteristics should be investigated. The impact of sleep disturbance on the child's life and family structure should be evaluated. The physical examination also helps to exclude possible causes of secondary insomnia.[2,5,16]

Early detection of SD is essential for the proper management to be established and for prognosis to be favorable. During the routine pediatric consultation, a tool that can assist in the screening is the Bedtime routines, Excessive daytime sleepiness, Awakenings during night, Regularity and duration of sleep, Sleep-disordered breathing; (BEARS) algorithm, consisting of five easy-to-apply questions that have good power to detect sleep alterations.[17] Table 4 shows the trigger questions for adequate sleep assessment.

Another option that can help assess the dimension of insomnia is the use of sleep journals. These allow for the assessment of the circadian rhythm and time (amount of sleep). Some questions may be directed to assess sleep habits and routine. The journal should cover the 24-h period, and contain information related to a mean period of two weeks.

Additionally, validated questionnaires that assess sleep quality are also quite useful and should be used in association with interviews and the sleep journal.

For children aged between 0 and 3 years, the Brief Infant Sleep Questionnaire, created by Sadeh et al. and validated in Brazilian Portuguese should be used.[18,19] For children older than 3 years, the Sleep Disturbance Scale for Children, proposed by Bruni et al. and also validated in Brazilian Portuguese, should be used.[20,21] The Brazilian Portuguese version of this scale is available in the digital version of this article (Appendix 1).

Actigraphy is also a simple way to evaluate the sleep-wake rhythm. This device is shaped like a wristwatch and monitors body movements. The obtained signals can be analyzed through software and correlated with the child's condition, and can be used at any age.[22]

Polysomnography (PSG) is the gold standard exam for sleep evaluation. It consists in recording the electroencephalogram (EEG) with other physiological variables (eye movements, submental electromyogram, respiratory channels, ECG, oxygen saturation, leg movements, position sensor, snore sensor). It allows for a complete analysis of sleep architecture, respiratory events, and body movements. It assists in the assessment of sleep organization, time asleep, sleep latency, and in the differential diagnosis between epileptic and non-epileptic motor events.[23]

Comorbidities

1) Depression

   Psychiatric disorders are usually associated with sleep problems such as hypersomnia, fatigue, irregular sleep-wake pattern, and nightmares, among others. Children with major depression have a high prevalence of insomnia (around 75%), and 30% have severe insomnia. The use of psychotropic medications can also negatively affect sleep. Conversely, there is new evidence suggesting that childhood insomnia itself is a risk factor for the development of psychiatric disorders in adolescence and adulthood.[5]

   A population-based study conducted with Norwegian adolescents showed that depression leads to significant sleep time reduction, as well as longer latency to sleep onset and more episodes of nocturnal awakenings in both genders. Adolescents with insomnia had a four to five times higher risk of depression than those who sleep well. Sleep deprivation (sleeping fewer than 6 h/night) results in an eight-fold higher risk of depression.[24]

2) Attention-deficit disorder/hyperactivity disorder (ADHD)

   It is estimated that around 25–50% of children with ADHD have sleep disorders. Miano et al. suggest different patterns, including hyperarousal, latency delay, association with respiratory disorders, RLS, and epilepsy.[25] Children with the combined subtype of ADHD tend to have more sleep problems. Strategies related to better sleep hygiene and positive sleep routines are effective in these children. In selected cases, it may be necessary to use drugs to treat the insomnia, such as alpha

Table 4 BEARS algorithm.[a]

BEARS	2–5 years	6–12 years	13–18 years
Bedtime/sleep problems	Does your child have any problems going to bed? Falling asleep?	Does your child have any problems at bedtime? Do you have any problems going to bed?	Do you have any problems falling asleep at bedtime?
Excessive daytime sleepiness	Does your child seem overly tired or sleepy a lot during the day? Does he/she still take naps?	Does your child have difficulty waking in the morning, seem sleepy during the day, or take naps? Do you feel tired a lot?	Do you feel sleepy a lot during the day? At school? While driving?
Awakenings during the night	Does your child wake up a lot at night?	Does your child seem to wake up a lot at night? Any sleepwalking or nightmares? Do you wake up a lot at night? Do you have trouble getting back to sleep?	Do you wake up a lot at night? Have trouble getting back to sleep?
Regularity and duration of sleep	Does your child have a regular bedtime and wake up time? What are they?	What time does your child go to bed and get up on school days? On weekends? Do you think he/she is getting enough sleep?	What time do you usually go to bed on school nights? Weekends? How much sleep do you usually get?
Sleep-disordered breathing	Does your child snore a lot or have breathing difficulties at night?	Does your child snore a lot or have any breathing difficulties at night?	Does your child snore?

Source: Modified from Mindell & Owens.[17]
BEARS, Bedtime routines, Excessive daytime sleepiness, Awakenings during night, Regularity and duration of sleep, Sleep-disordered breathing.
[a] Questions in the age group 2–5 years are addressed to parents/caregivers; between 6 and 12 years, they are addressed to parents/caregivers and to the child him/herself; between 13 and 18 years, they are addressed to the adolescents, while the last (snoring) is also answered by the partner.

agonists (clonidine), non-benzodiazepine sleep-inducers (zolpidem), or melatonin.[26]

3) Autism spectrum disorder (ASD)
   ASD consists of neurodevelopmental disturbances (pervasive diseases, Asperger's) characterized by significant social interaction and communication (language) impairment. SDs are common in this population and have severe effects on the affected child's and family's quality of life. Sleep restriction has been associated with increased frequency of stereotypies and worse severity scores. The complaint of insomnia characterized by long latency to sleep onset, resistance to sleep, reduced sleep efficiency, and nocturnal awakenings are of great concern to parents. In younger children, there is also increased prevalence of behavioral insomnia (SOAD and limit-setting SD).[27]
4) Epilepsy
   Patients with epilepsy have several changes in macro and micro sleep architecture, such as increased latency to sleep onset, reduced sleep efficiency, reduced REM sleep, and sleep fragmentation (especially those who have nocturnal seizures or refractory epilepsy). Complaints of excessive daytime sleepiness and poor sleep quality are also frequent.[28–30]
5) Tourette syndrome
   Patients with Tourette syndrome frequently have sleep and attention disorders. Insomnia is the most frequent SD and is usually associated with behavioral disorder during sleep.[31]

Therapeutic approach

The treatment of insomnia starts with a detailed assessment of its causes and triggers. Parents should be educated about sleep hygiene and adequate sleep routines by the pediatrician during routine visits. Some of these recommendations are listed in Table 5.

Strategies for the treatment of primary insomnia involve sleep hygiene routines, behavioral techniques, and/or pharmacological treatment.

1) Sleep hygiene routines
   Parents' education regarding what is adequate sleep hygiene is the start of the treatment, noting that these procedures start during the day. Diet is an important factor, and high intake of caffeine (chocolate, teas, soft drinks) should be avoided during the day and especially at night. Another daytime aspect is physical activity, which, when moderate, has a beneficial effect on sleep. At least 3 h before the child's established bedtime, he/she should be involved in relaxing activities; overstimulation should be avoided. Activities involving electronic media (TV, computer, tablet, and mobile phone) should also be restricted and avoided at least 1 h before bedtime. The bedroom environment is also a sleep hygiene factor. It should be well ventilated, quiet and dark, at an adequate temperature, and have a comfortable bed. It is advisable not to use the bedroom for punishments (''time-outs'')

Table 5 Sleep routine recommendations.

Overall recommendations
Place the baby/child in the crib/bed still awake
Encourage the practice of sleeping alone without intervention from parents/caregivers
Avoid making the child sleep while being held, in the stroller, or other place rather than his/her room/bed
Use a transitional object to help baby/child fall asleep
Avoid bottle-feeding the baby/child to sleep
Have regular hours for daytime and nighttime activities
Establish consistent sleep preparation routines that exclude activities with the potential to excite the child
Differentiate daytime from nighttime activities
Establish bedtime and wake up times that are appropriate to the age range and personal characteristics of the child and his/her daytime activities, as well as the nighttime routine of the family
Teach relaxation techniques that the child can follow on his/her own
Offer positive reinforcement with awards when the child reaches goals of not waking up at night
Do not encourage inappropriate behaviors or the bargaining of bedtime hours
Avoid foods/drinks with caffeine at night

applied during the day to prevent negative associations with the place of sleep.[26]

Positive routines can also help the child learn appropriate sleep behaviors and reduce stress. In addition to defining bedtime, consistent routines (activities that help prepare for sleep) should be established and repeated every night. As an example, let the child know that is almost time to go to bed, brush the teeth, perform other hygiene routines, put on pajamas, read a story or spend some time with the parents, turn off the lights. It is important to make sure that the time set for these routines is sufficient, so that they can be conducted calmly, without harming (reducing) total sleep time.[26]

In brief, adequate sleep hygiene consists of (1) regular/consistent bedtime that is appropriate for the age group; (2) avoiding high caffeine consumption; (3) welcoming nocturnal atmosphere; (4) bedtime routines; and 5) consistent and regular wake-up time, regardless of what occurred during the night (to maintain internal clock synchronization).[17]

2) Behavioral therapy

The main objective of the behavioral approach is to eliminate the negative associations that lead to insomnia. It is possible to start this type of therapy after six months of life. Several studies have demonstrated the effectiveness of this approach in most cases, with clear benefits to the child's daytime routine, as well as to that of the family.[32,33]

There are several behavioral techniques that have been developed or adapted for the management of children with behavioral insomnia. These techniques have proven efficacy and safety and are widely used, especially in Anglo-Saxon countries. The technique should be decided by the pediatrician together with the parents, so that they can define the most appropriate one according to the child's age and the parents' circumstances regarding treatment adherence.[34]

The following briefly describes the most often used techniques.[2,16,17,34]

Extinction: consists in putting the child to sleep safely and ignoring the nocturnal behavior (crying, tantrums, calling the parents) until the following morning. This procedure can also be performed with a parent in the bedroom, who will not interact until the predetermined time.

Gradual extinction: consists in putting the child to sleep safely and ignore the nocturnal behavior (crying, tantrums, calling the parents) for periods of time that increase during the night (starting with 5 min and gradually increasing the waiting time by 5 min each time). The purpose of this technique is to encourage the child to learn to self-comfort and return to sleep alone.

Positive routines: consists of developing a series of activities/calm routines that the child enjoys to prepare for bedtime, trying to disconnect the act of going to bed from a stressful routine. It is also possible to establish rewards to be given on the next day for those who manage to stay in bed until the next morning without going to the parents' room or calling them.

Planned bedtime: consists of removing the child from bed if he/she cannot fall asleep within the pre-established time interval (15–30 min) and letting him/her perform some calming activity to get sleepy; the parents should delay bedtime, so that the child goes to bed when feeling sleepy. After establishing the time when the child goes to sleep spontaneously, put the child to bed 15–30 min earlier every day, until the appropriate time is achieved.

Programmed awakening: consists of waking up the child at night, between 15 and 30 min before the usual time of spontaneous awakening, and after that, increasing the interval between episodes.

Cognitive restructuring: consists of using cognitive-behavioral techniques, in which the patient is taught to control his/her negative thoughts about sleep and bedtime. For instance, instead of thinking ''I won't sleep tonight'', the child should think ''tonight I will relax and rest in my bed.''

Relaxation techniques: consists of meditation, muscle relaxation, taking deep breaths, visualizing positive images.

Sleep restriction: consists of restricting the time in bed, so that the child will only lie in bed when he/she is almost asleep; it helps to disconnect the idea of staying in bed without feeling sleepy and helps to consolidate the connection between bed and sleep.

Stimulus control: consists of avoiding performing activities that are not sleep-inducing when the child/adolescent is already in bed (TV, social media, worries, etc.).

Gradual extinction and extinction techniques, which have been used for several decades, still generate discussion and debate, and parents have difficulty adhering to them, especially in Latin culture countries. Controlled studies have shown that the use of behavioral interventions in children with insomnia not only improves their

Table 6 Pharmacotherapy of insomnia according to the type of nocturnal symptoms.

Symptom	Medications
Difficulty in initiating sleep without nocturnal awakenings	Melatonin, antihistaminic
Difficulty in initiating sleep with multiple nocturnal awakenings	Antihistaminic, melatonin
Multiple nocturnal awakenings but no difficulty in initiating sleep	5-Hydroxytryptophan, antihistaminic
Awakens in the middle of the night with difficulty returning to sleep	5-Hydroxytryptophanantihistaminic in the middle of the night
Partial awakening with continuous crying	5-Hydroxytryptophan
Awakening with intense motor activity (restless leg syndrome)	Iron, gabapentin
Delayed sleep phase and insomnia in adolescents	Melatonin, zolpidem

Source: Modified from Bruni & Angriman.[2]

daily functions (sense of well-being and less crying), but also the mood, sleep, and parental marital satisfaction.[34]

More recent studies support and confirm these findings, demonstrating that, at school age, children with insomnia who received behavioral intervention had better performance at social skills when compared to children who did not receive it.[35] Additionally, another study also reported improvements in maternal sleep and mood.[36]

During the literature review for the preparation of this article, the authors did not retrieve any studies that associated the use of behavioral interventions in children with insomnia to deleterious effects on mental health or on the emotional connection with parents. On the contrary, several studies that consistently demonstrated the benefits of this intervention were retrieved.[37,38] It is also important to mention two studies in which children who received early behavioral interventions for insomnia were reassessed at the follow-up and the authors did not detect any changes in emotional function or internalizing and externalizing behaviors.[37,39]

3) Pharmacological therapy

Pharmacological therapy indication in childhood insomnia should occur when the parents cannot adapt to behavioral therapies due to objective difficulties or when the therapy does not show adequate results. The indication must be made before the problem becomes chronic, and must be conducted in association with behavioral therapy and for a limited period of time. It is important to emphasize that there are no drugs for insomnia approved for use in children with such an indication, which already limits this strategy.[2,17] Indications are empirical, based more on clinical experience than on evidence. In most children, sleep problems can be solved using a sleep hygiene approach and behavioral techniques; however, if there is drug indication, it is recommended to follow these guidelines when choosing it:

a) The medication should act on the target symptom (pain, anxiety);
b) Primary SDs (e.g., apnea, RLS) should be treated before insomnia medication is indicated;
c) The choice of medication must be appropriate for the age and neurodevelopmental level, always weighing the benefits against the side effects.

3.1) Antihistaminic agents:

They are the most frequently prescribed drugs for insomnia therapy at the level of primary care (e.g., hydroxyzine, diphenhydramine, promethazine). They assist in the acute phase, leading to a decrease in latency and awakenings, and must be used in combination with a behavioral intervention program. Daytime sedation, dizziness, or paradoxical hyperactivity can occur as side effects.[40]

3.2) Alpha-agonists (clonidine)

They are used for the treatment of insomnia in children due to their sedative effect. Their duration of action is 3– h and the half-life is 12–6 h. They should be administered at bedtime, orally. Hypotension and weight loss have been described as side effects. Rapid withdrawal can lead to unwanted symptoms, such as shortness of breath, high blood pressure, and tachycardia.[26]

3.3) Melatonin

It is a hormone (N-acetyl-5-methoxytryptamine) synthesized by the pineal gland, whose secretion is controlled by the suprachiasmatic nucleus of the hypothalamus, with a peak between 2 and 4 am. It reduces latency to sleep onset and number of awakenings, as well as improving mood and daytime behavior. Its efficacy in children with ADHD and ASD has been reported in several studies. The recommended dose is 0.5–3 mg in children and 3–5 mg in adolescents. At the usual doses, the side effects are irrelevant. The medication does not interfere with antiepileptic drug action, endogenous melatonin production, or pubertal development, and does not cause addiction.[41]

3.4) L5-hydroxytryptophan

It is a serotonin precursor. It has shown to be effective in episodes of certain types of parasomnia, such as night terrors, at a dose of 1–2 mg/kg/day at bedtime. It appears to have a sleep stabilizing function, being effective in some patients. It can be used as an alternative treatment, as it has practically no side effects.[40]

3.5) Iron

The association between reduced iron levels and motor activity during sleep has been widely discussed in recent years. Iron deficiency in the substantia nigra can reduce dopaminergic function, as this element has a modulatory function. Iron-deficiency anemia may be associated with nocturnal motor hyperactivity, with reduced sleep time and

increase in the number of awakenings. As this hyperactivity can be a precursor of RLS, oral iron replacement is indicated when ferritin levels are low.[42]

3.6) Benzodiazepines

These are the most often prescribed psychotropic drugs for children with neurological and/or psychiatric problems. They reduce the latency to sleep onset and improve sleep efficiency. Side effects may occur and vary from daytime sedation, changes in behavior, paradoxical hyperactivity, and memory deficits. They are contraindicated in suspected sleep-disordered breathing.[41]

3.7) Tricyclic antidepressants

Imipramine at a dose of 0.5 mg/kg/day at bedtime appears to have some efficacy in insomnia; however, it is not widely used due to the risk of severe side effects.[41]

3.8) Non-benzodiazepine sleep inducers (imidazopyridine)

Their use in children younger than 12 years is contraindicated. Zolpidem and zaleplon are the most often used; as they have few side effects, they can be administered in children aged 12 years and older at a dose of 5–0 mg at bedtime.[41]

Table 6 summarizes drug indications for insomnia according to the nocturnal complaint.

In conclusion, insomnia complaints in children and adolescents should be taken into account and properly investigated by the pediatrician, considering its association with several comorbidities, which must also be diagnosed. The main causes of insomnia and its triggers vary according to the age and level of development. The therapeutic approach should include sleep hygiene measures, behavioral techniques, and, in individual cases, pharmacological treatment.

Conflicts of interest

The authors declare no conflicts of interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jped.2015.08.006.

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Section 5.0

New Discussion Items

Hypospadia

Question: Where should various types of hypospadias be prioritized?

Question source: Dr. David Lashley, pediatric urologist

Issue: ICD-9 had a single diagnosis code for hypospadias, while ICD-10 has 7 codes differentiating by location of the abnormal urethral opening. Hypospadias is a congenital condition where the urethra exits the phallus in an abnormal location. This defect can result in abnormal urinary streams and sexual dysfunction. Hypospadias is frequently associated with abnormal foreskin development and chordee, an abnormal bending or curving of the penis.

During the ICD-10 review, the all-adult urology review group suggested that 2 of the 7 hypospadias diagnoses should be placed on a lower, uncovered line; however, the final result of the review was to place these two diagnoses on both a covered and an uncovered line with no guideline or other differentiation about when the diagnoses where intended to be covered. Dr. Lashley contacted HERC staff to report that he is having difficulty getting some visits and procedures done for boys with various hypospadias diagnoses since the ICD-10 conversion.

ICD-10 Code	Code Description	Code Placement
Q54.0	Hypospadias, balanic	438 HYPOSPADIAS AND EPISPADIAS 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Q54.1	Hypospadias, penile	438
Q54.2	Hypospadias, penoscrotal	438
Q54.3	Hypospadias, perineal	438
Q54.4	Congenital chordee	438, 662 with guideline
Q54.8	Other hypospadias	438
Q54.9	Hypospadias, unspecified	438, 662

Dr. Lashley provided information and feedback about Q54.0 and Q54.9. He felt that Q54.9 (hypospadias, unspecified) was not required for coverage as urologists should specify the type of hypospadias. He did note that PCPs might use this code as they might be unsure how to classify the type of hypospadias, but use of Q54.9 would still allow one specialist visit after which the specific diagnosis would be determined.

Dr. Lashley felt that Q54.0 (Balanic hypospadias) was a diagnosis that may or may not require treatment. This diagnosis specifically requires treatment in cases of meatal stenosis, significant chordee, abnormal urinary stream or dorsal hood foreskin. However, he felt this diagnosis was rare enough that a guideline would not be required.

Evidence:

1) There was scant literature on this topic. A few papers were identified which compared the outcomes of various surgical techniques for repair of balanic hypospadias

Hypospadia

HERC staff recommendations:

1) Remove ICD-10 Q54.9 (Hypospadias, unspecified) from line 438 HYPOSPADIAS AND EPISPADIAS and leave on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2) Make no change to placement of ICD-10 Q54.0 (Hypospadias, balanic) on both lines 438 and 662
    a. See separate document with new pediatric urology guideline which will specify placement on line 438 for children and on line 662 for adults

Retractile Testicles

Question: Should the diagnosis code for retractile testicles (Q55.22) be returned to a covered line?

Question source: David Lashley, MD, pediatric urologist

Issue: During the ICD-10 urology review, ICD-9 752.52 and ICD-10 Q55.22 (retractile testicles) were moved from line 98 UNDESCENDED TESTICLE to line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY, as there is no effective treatment for this condition.

Dr. Lashley has raised concerns that this condition needs continued monitoring by the patient's PCP, and in many cases, by a pediatric urologist. The initial consultation for this condition is covered, but not any follow up visits for monitoring. While he agrees that there is no treatment for this condition, he feels that it should be on a covered line to allow monitoring.

Retractile testis is considered as a testis that is located at the upper scrotum or lower inguinal canal and that can be made to descend completely into the scrotum without resistance by manual reduction but returns to its original position. Retractile testis has traditionally been considered as a variant of normal testis because it usually descends into the scrotum during adolescence and shows no difference in testicular volume or childbearing capacity compared with the normal testis. However, retractile testicles have been reported to have a significant rate of testicular ascent out of the scrotum, becoming undescended and requiring surgical correction. The American Urologist Association (AUA 2014) guideline reports that "Studies have reported an extremely broad range of incidence of testicular ascent out of the scrotum (between 2-45%) in boys with retractile testes."

The AUA 2014 guidelines on the diagnosis and management of undescended testes recommends

1) In boys with retractile testes, providers should assess the position of the testes at least annually to monitor for secondary ascent. (Standard; Evidence Strength: Grade B).
2) Providers should not perform ultrasound (US) or other imaging modalities in the evaluation of boys with cryptorchidism prior to referral, as these studies rarely assist in decision making. (Standard; Evidence Strength: Grade B)

From Dr. Lashley:

> PCP's send us a lot of kids with a concern about undescended testicle..?25% or more of the time the testicles are retractile and do not require surgery. No problem…they are new patient visits so they get covered regardless of the diagnosis. I tell the family:
>
> Retractile testicles: The family and I talked about treatment options for retractile testicles. Etiologies of retractile testicles were discussed with the family including the

benign nature of this condition, the lack of association with the future development of testicular cancer, and the tendency for the testicles to drop permanently into the scrotum normally between now and puberty. The family and I talked about the fact that surgery in general is not indicated as a treatment of retractile testicles. Alternative treatment options were discussed with the patient in detail. All questions were answered. The family gave fully informed consent to proceed with conservative therapy for their retractile testicles at this time.

On occasion (7-12%) these retractile testicles may "ascend" with the child's linear growth and subsequently require surgical repair. For this reason I recommend that annual genital examinations at his well-child visits continue to document the ability to bring the testicles into the dependant scrotum. I would be happy to see him back if there are ongoing questions or concerns. The patient/family was given instructions to call for incomplete descent of the testicles over time, scrotal/groin/abdominal pain, especially if associated with nausea, vomiting, swelling redness, etc.

so when the pcp checks the next year and can not get the testicle(s) into the scrotum they send them back for re eval. if the testicle is ascended..I am covered as the dx is now above the line. if the testicle is still retractile then i am not covered. it is a total hassle because pcp's will send the kids back to us with undescended testicle diagnosis and thus will not have the follow up visit authorized. i did not realize the retractile code is now BTL so i have a few claims which will not pay. The pcp's want to serve their patients so they often refer BTL diagnosis with ATL codes..which gets them in my door..but then i am often stuck trying to get paid for a BTL visit.

Utilization: For the period 1/1/14-9/30/15, more than >10,000 billings (in any diagnosis position), with 4,402 are in the primary diagnosis position on the billing

HERC staff recommendation:

1) Add ICD-10 Q55.22 (retractile testicle) to line 98 UNDESCENDED TESTICLE and keep on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Will allow specialty consultation and monitoring visits
    b. See proposed pediatric urology guideline in separate document which limits inclusion on line 98 to children; this condition in adults in included on line 662

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Pediatric Urology

Long-Term Outcomes of Retractile Testis

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Purpose: Retractile testis is considered to be a variant of normal testis in prepubertal boys. There is no agreed-upon management of retractile testis. The aim of this study was to provide data on the long-term outcomes of patients with retractile testis.

Materials and Methods: This study retrospectively reviewed the medical record of 43 boys who were referred for suspected undescended or retractile testis and were finally diagnosed with retractile testis between January 2001 and December 2008. All boys were biannually examined by a pediatric urologist to evaluate the presence of retractile, descended, or undescended testis and testicular volume.

Results: Of 43 boys, there were 22 boys with unilateral retractile testis (51.1%) and 21 boys with bilateral retractile testis (48.9%). Their mean age was 3.0±2.7 years and the follow-up duration was 4.4±1.7 years. Of 64 retractile testes, 29 (45.3%) succeeded in descending, 26 (40.6%) remained retractile, and 9 (14.1%) became undescended testis or of a decreased size requiring orchiopexy. The mean initial diagnostic age of the patients who underwent orchiopexy was 1.3±0.9 years; meanwhile, the mean initial diagnostic age of those who went on to have normal testis was 4.3±3.3 years (p=0.009). The mean follow-up duration was 3.6±1.5 years in the orchiopexy group, 4.0±1.4 years in the descended testis group, and 5.1±1.8 years in group with remaining retractile testis.

Conclusions: Retractile testis has a risk of requiring orchiopexy. The risk is higher in the population diagnosed at a younger age. Boys with retractile testis should be observed periodically until the testis is descended in the normal position.

Key Words: *Cryptorchidism; Orchiopexy; Testis*

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INTRODUCTION

Boys with retractile testis are often transferred from primary health clinics because of suspected cryptorchidism [1]. In many studies, retractile testis is considered as a testis that is located at the upper scrotum or lower inguinal canal and that can be made to descend completely into the scrotum without resistance by manual reduction but returns to its original position by the cremasteric reflex [2-4]. Retractile testis has traditionally been considered as a variant of normal testis because it usually descends into the scrotum during adolescence and shows no difference in testicular volume or childbearing capacity compared with the normal testis [5]. In general, patients with retractile testis are periodically reviewed until the end of adolescence or until the testis has completely descended into the scrotum. However, surgical correction is necessary if testicular maturation appears to be poor or if the testis fails to descend into the scrotum and cryptorchidism develops secondarily.

Some previous studies conducted with boys with retractile testis reported that 18 to 32% of patients required surgical correction owing to the development of undescended testis or decreases in testicular volumes [6,7]. One study reported tissue degeneration among patients with retractile testis that was similar to that of undescended testis [8]. Another study suggested a possible relation between retractile testis and sterility owing to the fact that adults with retractile testis who receive follow-up care show abnormalities in semen analysis compared with normal adults [9]. Treatments of retractile testis remain

controversial, but domestic research on the clinical follow-up of boys with retractile testis is insufficient. This study followed up and observed boys diagnosed with retractile testis to investigate the natural course of retractile testis and to analyze the need and the appropriate time of surgical treatments.

MATERIALS AND METHODS

Eighty-eight boys were transferred from primary health clinics to the department of urology in the hospital for suspected retractile testis or undescended testis between January 2001 and December 2008. Among them, 43 boys were included in this study who attended follow-up for longer than 1 year. Their medical records were retrospectively analyzed. Boys who underwent hormonal therapy were excluded.

Retractile testis was defined as a testis that was located in the upper scrotum or lower inguinal canal but that could be made to descend completely into the scrotum by manual reduction and then returned to the original position by the cremasteric reflex. Undescended testis was defined as a testis located in the upper scrotum or inguinal canal that could not be made to descend into the scrotum by manual reduction or that showed any resistance to reduction or returning immediately to its original position.

All patients were examined by a pediatric urologist. Their testicular location, mobility, and volume were compared with the results of their previous examination at the outpatient department every 6 months after the first diagnosis. According to testicular location, mobility, and volume, the patients were classified into the retractile testis, normal, and orchiopexy groups. Follow-up was terminated once the testis had descended into the scrotum or if any of the boys were diagnosed with undescended testis. Otherwise, the boys having retractile testis were subjected to further follow-ups. If testicular volume was smaller than the previously observed volume or smaller than that of the opposite testis, follow-up was also terminated owing to the judgment that testicular maturation had become poor. Testicular volume was measured with an orchidometer. Orchiopexy was performed for the boys whose testis had become undescended testis or whose testicular volume had decreased. We analyzed their long-term outcomes according to patients' age at the time of the diagnosis, testicular positions, and the status of the contralateral testis and changes in testicular volume.

One-way analysis of variance was used to compare the mean values of the normal, retractile, and orchiopexy groups and chi-square and linear-to-linear association tests were performed to analyze the categorical data. Results were considered to be significant if the p-value was less than 0.05.

RESULTS

There were 22 boys (51.1%) with unilateral retractile testis and 21 boys (48.9%) with bilateral retractile testis among a total of 64 retractile testes. Of these 64 retractile testes, 29 cases (45.3%) succeeded in descending into the normal scrotum. By contrast, 9 cases (14.1%) underwent orchiopexy owing to decreased testicular volume (5 cases) or persistent undescended testis (4 cases). Twenty-six cases (40.6%) remained retractile testis until the end of adolescence. The mean follow-up period of the 43 boys was 4.4±1.7 years, and the mean follow-up period of the boys with persistent retractile testis until the last follow-up was 5.1±1.8 years. The mean diagnostic age was 3.0±2.7 years. The mean age of the patients whose testis succeeded in descending into the scrotum was 4.3±3.3 years, showing that it had taken an average of 4.0±1.4 years until their testis came to descend in the normal scrotum. By contrast, the mean age of the boys who underwent orchiopexy was 1.3±0.9 years, showing that it had taken an average of 3.6±1.5 years. The mean diagnostic age of the boys who underwent orchiopexy was significantly younger than that of the boys whose testis came to descend in the scrotum without surgical correction (p=0.009). There were no statistical differences according to position or bilaterality (p=0.284, 0.292) (Table 1).

TABLE 1. Comparison of the patients' characteristics according to the final outcomes of retractile testis

	Final outcome				
	Normal	Retractile	Orchiopexy	Total	p-value
No. of patients (%)	20 (41.9)	16 (41.9)	7 (16.3)	43	
No. of testis (%)	29 (45.3)	26 (40.6)	9 (14.1)	64	
Age, diagnosis (yr)	4.3±3.3	2.3±1.7	1.3±0.9		0.009
Follow-up duration (yr)	4.0±1.4	5.1±1.8	3.6±1.5		0.069
Testis location					
Upper scrotum	1 (20.0)	3 (60.0)	1 (20.0)	5	
Inguinal canal	29 (49.2)	22 (37.3)	8 (13.6)	59	0.284
Testis bilaterality					0.292
Unilateral	11 (55.0)	6 (37.5)	5 (71.4)	22	
Bilateral	9 (45.0)	10 (62.5)	2 (28.6)	21	

Values are presented as number (%) or mean±SD.

TABLE 2. Change in testicular volume

Testicular volume		No. of patients
Initial	Final	
Normal	Normal	57
Normal	Small[a]	4[b]
Small	Normal	2
Small	Small	1[b]

[a]:Smaller than the contralateral testis, [b]:Orchiopexy was performed.

TABLE 3. Final outcomes according to the state of the contralateral testis

Contralateral testis	Final outcome			p-value
	Normal	Retractile	Orchiopexy	
Normal	6	7	4	0.328
Retractile	9	10	2	0.328
Undescended	3	1	1	0.328

Among the total 64 cases, 61 cases showed normal volume and 3 cases had smaller volumes at the first diagnosis compared with the contralateral testis. According to the follow-up results, 4 cases among those 61 cases with normal volume showed a decrease in volume and underwent orchiopexy, whereas 57 cases maintained a normal volume. Among those 3 cases with smaller volumes, 2 cases recovered to a normal volume when the testis succeeded in descending into the normal scrotum, whereas 1 case showed a decrease in volume and underwent orchiopexy (Table 2).

The authors subdivided the subjects into 3 groups according to the status of the contralateral testis. Among the total 43 boys, 17 boys had a unilateral retractile testis and normal opposite testis, 21 boys had bilateral retractile testis, and 5 boys had a unilateral retractile testis and undescended opposite testis that previously underwent surgical correction. Of the 17 boys with unilateral retractile testis and normal opposite testis, 4 boys (23.5%) underwent orchiopexy, 8 boys (47.1%) came to have descended testis, and the other 5 boys (29.4%) continued to have retractile testis. Of the 5 boys with unilateral retractile testis and undescended opposite testis, 1 patient (20%) underwent orchiopexy, 3 patients (60%) came to have descended testis, and 1 patient (20%) continued to have a retractile testis. Of the 21 boys with bilateral retractile testis, 2 patients (9.5%) underwent orchiopexy for bilaterally persistent undescended testis, 9 patients (42.9%) came to have both testes in the scrotum, and 10 patients (47.6%) continued to have bilateral retractile testis. There was no statistically significant difference between the 3 groups (p=0.611) (Table 3).

DISCUSSION

Management methods for retractile testis remain controversial, whereas treatment methods for undescended testis have been well established through many studies [10-12]. It has been reported that retractile testis is accompanied by histological changes; abnormality on semen analysis was found during follow-up when patients with retractile testis became adults [8,9]. In addition, La Scala and Ein [7] reported that boys with retractile testis need periodic follow-up.

Testicular maturation requires a 2°C to 4°C lower temperature than the normal core body temperature of 36.5°C, and a normal scrotum can meet such a requirement by protrusion. However, a retractile testis goes up and down between the inside of the normal scrotum and the inguinal canal, and the temperature of the inguinal canal exerts an adverse effect on testicular maturation because it is close to the core body temperature. It is difficult, however, to accurately assess how long the testis stays inside the normal scrotum or in the upper scrotum. Therefore, it is essential to examine testicular volume and any changes affecting testicular maturation during the follow-up of patients with retractile testis. If there is any decrease in testicular volumes, immediate surgical correction will be required. It has been reported that a shrunken testis can recover to the normal level of testicular volume after surgical correction [13,14]. This result implies that the appropriate decrease in the temperature around the testis after surgical correction allows for testicular maturation. In this study, 4 of 9 patients underwent surgical correction after showing shrinkage of the ipsilateral testis compared with the contralateral testis or compared with the results of the previous physical examination before surgery. All 4 of these cases showed testicular growth after surgical correction, resulting in testicular volumes similar to those of the contralateral testis. Surgical correction is also required if the following abnormalities are detected during the physical examination. First, an undescended testis that fails to descend into the normal scrotum is developed; second, the development of a sliding testis secondary to increased spermatic cord tension in which the testis can descend into the normal scrotum but immediately returns to the original position; and finally, the development of pain during the descent of the testis, although the testis can descend into the normal scrotum [3]. In this study, 4 boys showed failure of complete descent and subsequently developed undescended testis during the follow-up period; therefore, they underwent orchiopexy.

There are contradictory results concerning histological changes in a retractile testis. Some previous studies reported that the retractile testis had the histological structure of the normal testis [4,15], whereas recent studies showed conflicting results. Recent studies have suggested that surgical correction is necessary to prevent histological changes if patients with retractile testis develop undescended testis [8,16,17]. However, according to research that investigated the testicular volumes and childbearing

capacity of adults who had a medical history of retractile testis in both testes but did not undergo surgical correction, these variables were similar to those of a control group [18].

This study showed that a large number of boys with retractile testis diagnosed at a younger age tended to develop undescended testis, whereas none of the subjects diagnosed at the age of 6.5 years or older underwent surgical correction. Agarwal et al. [6] reported a similar result, claiming that the risk of development of undescended testis was higher in boys younger than 7 years old. However, this study included only 8 boys whose age was 6.5 or older at the time of the diagnosis. Therefore, further research with larger samples will be required in the future.

Previous studies showed that between 6.9% and 32% of boys with retractile testis require orchiopexy; in particular, 50.8 to 56% of boys with any resistance of the spermatic cord require orchiopexy [6,7,19]. The ratio of the boys who underwent orchiopexy in this study was 16.3%. A testis with any resistance against manual reduction was considered an undescended testis in this study. In previous studies, undescended testis was often misdiagnosed as retractile testis, which was subject to follow-up. This suggests that it is highly possible that the total sum of surgical candidates among patients with retractile testis may be much larger than the actual number. This result implies that care should be taken during the examination of patients with retractile testis to make a differential diagnosis with undescended testis. Much research has shown that a retractile testis may become an undescended testis during follow-up and annual or biannual follow-up for boys with retractile testis has been recommended [3,6,20]. In this study, the ratio of boys requiring orchiopexy for any reason was 16.3%. Therefore, we also agree with this recommendation that patients with retractile testis be examined closely concerning testicular location or volume until the testis has completely descended into the scrotum.

In addition, this study also analyzed outcomes according to the status of the contralateral testis. Agarwal et al. [6] reported that boys with 1 descended and 1 retractile testis had a higher probability for the retractile testis to be descended and boys with 1 undescended and 1 retractile testis had a higher probability for the retractile testis to be remained undescended. However, in this study, there was no significant difference in descent according to the status of the contralateral testis. All bilateral retractile testes had similar outcomes.

Hormonal therapy with human chorionic gonadotropin or gonadotrophin-releasing hormone is the most common treatment for undescended testis [21,22]. The action of hormones is similar to that of luteinizing hormones leading to a stimulation of the testis; the testis may then descend as it grows [23,24]. However, proof of the efficacy of hormonal therapy for undescended testis is limited as yet. There was a report that the practice of hormone therapy for less than 1 week was almost not effective for boys with unilateral undescended testis although it was found to be effective in about 56% of boys with bilateral undescended testis [25]. A number of studies have been conducted regarding hormone therapy among patients with retractile testis, and testicular descent was achieved by short-term hormone therapy. However, although short-term hormone therapy was effective, the therapy failed to prevent the return to retractile testis during follow-up [26]. Miller et al. [27] reported a response rate to hormonal therapy of 58% in a study conducted with 26 retractile testes among 16 patients and a response rate of 40% among patients with a retractile testis located in the inguinal canal. Boys who underwent hormonal therapy were excluded from the present study, because the aim of this study was to investigate the natural course of retractile testis. The rate of natural descent of the retractile testes located in the inguinal canal was 49.2% in this study.

This study demonstrated that boys who were diagnosed with retractile testis at a younger age were more likely to undergo orchiopexy. The status of the contralateral testis and testicular positions had no correlation to orchiopexy. Therefore, we suggest that boys with retractile testes, especially those diagnosed at a younger age, need closer observation and more frequent follow-up (annually or semiannually).

The limitations of this study include the error of selecting boys through retrospective investigations; the lack of a random design; judgements based only on physical examination without testicular biopsy; and the lack of complete follow-up until the end of adolescence in some boys. Other limitations are that the number of boys involved in the research was not large enough and that the results do not reflect the progress of patients who failed to attend the follow-up. Future research can address such limitations by involving a larger number of patients in a multi-center study that would allow the investigation of more details concerning the natural course of retractile testis.

CONCLUSIONS

About 16.3% of the boys diagnosed with retractile testis required surgical correction during long-term follow-up. The risk of orchiopexy was higher in the population diagnosed at a younger age. Judging from the results of this study, retractile testis might be considered as a variant of normal testis. Yet, close observation regarding testicular position, mobility, and volume through periodic follow-up is necessary until the testis has successfully descended into the scrotum or until the end of adolescence.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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Congenital Urologic Conditions

Question: Should various ICD-10 codes for congenital anomalies of the genitourinary tract be returned to covered lines?

Question source: Dr. David Lashley, pediatric urologist

Issue: During the ICD-10 Urology review, various congenital urinary tract anomaly diagnoses were moved to line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY, due to the reviewers' belief that these conditions do not require any monitoring or treatment. All urologists involved with this review were adult urologists. Previously, all these conditions (or the less specific ICD-9 code from which they were derived) were on covered lines. Dr. Lashley feels that these conditions do require monitoring in infants and children, generally with ultrasounds or with follow up urology visits. He is requesting that these conditions be moved back to their previous covered positions.

Dr. Lashley reports that he may be required to bill for one of these conditions in several situations:

1) Prenatal consultation: Dr. Lashley sees pregnant women with fetuses with moderate to severe genitourinary issues as a prenatal urologic consultation to discuss prognosis and implication of the condition and to set up a post natal treatment plan.
2) Follow up ultrasound at 2 months of age—minimum follow up for any infant with a GU anomaly seen on prenatal ultrasound
3) Serial ultrasound and often nuclear medicine renal scans for most moderate to severe anomalies, to ensure that there is no associated problem such as UPJ or UVJ obstruction or reflux. Once pediatric urology has determined that there is no associated condition requiring surgery, the child is transferred to pediatric nephrology, who normally does annual urine and lab studies to follow the health of the single kidney (in the case of unilateral agenesis) or abnormal kidney. These children also need to have their blood pressure followed closely. Most of these conditions require ultrasounds on varying schedules as well to ensure that the kidneys are growing normally and have no infections (reflux) and to ensure that hydronephrosis is not developing or progressing.
4) Surgeries (procedures may be required depending on the condition/associated condition present). Many of these conditions are billed with covered conditions such as ureteral reflux; however, some require the congenital anomaly diagnosis to be billed as well to allow coverage of more extensive surgeries.
    a. pyeloplasty (repair of UPJ obstruction)
    b. ureter implantation (for reflux or UVJ obstruction)
    c. common sheath reimplantation (for reflux or UVJ obstruction when there is ureteral duplication)
    d. tapered reimplantation (for severe reflux or UVJ obstruction)
    e. uretero-ureterostomy (for reflux or UVJ obstruction when there is ureteral duplication)
    f. cutaneous ureterostomy (for severe uvj obstruction in infants)

g. excision of ureterocele
h. nephrectomy (reflux or obstruction and minimal or no function)
i. nephroureterectomy (reflux or obstruction and minimal or no function)

5) Most of these conditions do not need any follow up after a child is done growing and renal function presumably becomes stable. Unilateral kidney patients may require periodic follow up in nephrology in adulthood.

Previously covered conditions now found only on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

ICD-10 code	**Code description**	**ICD-9 code equivalent and placement**	**Comments**
Q60.3	Renal hypoplasia, unilateral	753.0 (Renal agenesis and dysgenesis) was on lines 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM and 104 ESRD	Q60.4 (bilateral) and Q60.5 (unspecified) are on line 104
Q62.4	Agenesis of ureter	753.4 (Other specified anomalies of ureter) was on line 91	Q62.63 (Anomalous implantation of ureter) and Q62.9 (Anomalous implantation of ureter) are on line 91
Q62.5	Duplication of ureter	753.4	
Q62.60	Malposition of ureter, unspecified	753.4	
Q62.61	Deviation of ureter	753.4	
Q62.62	Displacement of ureter	753.4	
Q63.0	Accessory kidney	753.3 Other specified anomalies of kidney was on line 91	
Q63.1	Lobulated, fused and horseshoe kidney	753.3	
Q63.2	Ectopic kidney	753.3	
Q63.3	Hyperplastic and giant kidney	753.3	
Q63.8	Other specified congenital malformations of kidney	753.3	
Q63.9	Congenital malformation of kidney, unspecified	753.3	

Evidence:

1) **Rodriguez 2014**, review of congenital urologic anomalies

   a. The majority of cases [of duplicated ureter] are asymptomatic in adults; however, in children the risk of renal infection is increased 20-fold… A duplex system can be associatedwith other renal complications such as obstruction, reflux, and infection. If the obstruction is maintained for some time, the kidney can become hydronephrotic. When the infection becomes persistent, it can also lead to a severe chronic pyelonephritis,which ultimately produces chronic renal disease
   b. Horseshoe or fused kidneys: Sometimes the horseshoe kidneys are associated with UPJ obstruction and children can present with urinary tract infections, abdominal mass, and hematuria.
   c. Renal dysplasia: approximately 60% of kidneys affected by renal dysplasia have an obstructive component.

2) **Kerecuk 2008**, review of renal track malformations
   a. Data from the UK Renal Registry62 show that unobstructed and obstructed dysplastic or hypoplastic kidneys together account for about 40% of all children on dialysis
   b. In registries of adults receiving renal replacement therapy, dysplastic or hypoplastic kidneys account for only a small proportion of primary diagnoses; for example, these conditions have a prevalence of 0.6% in the US Renal Data System
   c. there are reports of selected individuals born with solitary functioning kidneys who developed hypertension, proteinuria and renal failure as adults
   d. We lack comprehensive, long-term followup studies in large cohorts of individuals born with different types of renal tract malformations. In addition, the contribution of renal tract malformations to chronic kidney disease and ESRD in adults could be more clearly defined.
   e. Whether prenatal decompression of obstructed renal tracts or initiation of postnatal therapies, such as prophylactic antibiotics or angiotensin blockade, in childhood improve long-term renal outcomes of patients with renal tract malformations is unclear.

3) **Ingraham 2011**, review of congenital urologic malformations
   a. unilateral upper urinary tract obstructive disease rarely results in proteinuria or azotemia, so conservative management of these patients is usually recommended. However, some authors have raised concern about the possibility of increased long-term risk for hypertension as a result of ureteral obstruction. Bilateral upper urinary tract obstruction or obstruction of a solitary functional kidney is far more ominous and often requires prompt surgical intervention and careful medical management to minimize and monitor renal injury.
   b. Unilateral and bilateral hypodysplasia of the kidney, horseshoe kidney, and solitary kidney all have a considerable rate of progression to ESRD requiring dialysis over the first 30 years of life

Congenital Urologic Conditions

HERC staff recommendation:

1) Add Q60.3 (Renal hypoplasia, unilateral), Q62.4 (Agenesis of ureter), Q62.5 (Duplication of ureter), Q62.60 (Accessory kidney), Q62.61 (Deviation of ureter), Q62.62 (Displacement of ureter), and Q63 (Other congenital malformations of kidney) to line 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM and keep on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Would allow periodic specialty visits, labs and imaging. Would also pair with a variety of surgical treatment codes
    b. See proposed pediatric urology guideline in separate document which limits inclusion on the covered line to children

Pediatric Urology Guideline

Question: Should a new guideline be adopted limiting evaluation and treatment of various congenital urologic conditions to children?

Question source: HERC staff

Issue: During the ICD-10 Urology review, the all adult urologist specialty group recommended moving various congenital urologic conditions to uncovered lines, as they felt these conditions did not require treatment. Since that review, Dr. David Lashley, a pediatric urologist, has requested that most of these conditions be returned to covered lines as they need periodic monitoring and possibly imaging, laboratory tests, and in some cases, repair in children. Once a child reaches puberty, most of these conditions stabilize and no longer require monitoring or treatment.

HERC staff recommendation:

1) Adopt the following new guideline to apply to lines 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 98 UNDESCENDED TESTICLE, 438 HYPOSPADIAS AND EPISPADIAS and 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

GUIDEINE NOTE XXX CONGENTIAL UROLOGIC CONDITIONS

Lines 91, 98, 438, 662

The following conditions are included on these lines 91, 98, or 438 only for children aged 18 and younger. For adults, these conditions are included on line 662.

1) ICD-10 Q54.0 (Hypospadias, balanic)
2) ICD-10 Q55.22 (Retractile testicle)
3) ICD-10 Q60.3 (Renal hypoplasia, unilateral)
4) ICD-10 Q62.4 (Agenesis of ureter)
5) ICD-10 Q62.5 (Duplication of ureter)
6) ICD-10 Q62.60 (Accessory kidney)
7) ICD-10 Q62.61 (Deviation of ureter)
8) ICD-10 Q62.62 (Displacement of ureter)
9) ICD-10 Q63 (Other congenital malformations of kidney)

Physical Therapy Modalities

Question: Should various physical therapy modalities be removed from the Prioritized List or other list locations, or have other restrictions placed on them?

Question source: HERC staff

Issue: Physical therapy mainly consists of therapeutic exercises. However, there are other, generally passive modalities which are used as part of PT therapy. These other modalities may or may not have evidence to support their use.

Several of these therapies are already not covered or in below the funding line areas of the Prioritized List. There is high utilization of some of these modalities, but nearly all by the CCOs, who are free to cover additional services not paired on the Prioritized List.

Those modalities which underwent evidence review have recommendations in separate documents. The summary of staff recommendations are shown in the table below. CPT code

	Code description	**Line(s)/Lists**	**Paid claims**	**HERC staff recommendation**
97010	Hot or cold packs	**663** MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE…	2268	Not reviewed. No changes.
97012	Mechanical Traction	All PT lines EXCEPT back and neck condition lines	1626	No evidence of effectiveness for back/neck conditions. Modify back guidelines to clarify non-coverage. Review of other indications not justified due to low utilization
97014	Electric Stimulation Therapy	SNRC	10820	Not reviewed. Modify back guidelines to clarify non-coverage
97016	Vasopneumatic Device Therapy	Ancillary	112	Place on lines on PL or make SNRC
97018	Paraffin Bath Therapy	Ancillary	79	Place on lines on PL
97022	Whirlpool Therapy	All PT lines, deep open wound lines, burn lines	847	Remove from wound, burn and back conditions lines
97024	Diathermy	**471** BRACHIAL PLEXUS LESIONS **512** PERIPHERAL NERVE DISORDERS	35	Straightforward remove from PL
97026	Infrared Therapy	Ancillary	753	Evidence found for use in back and neck conditions. Also used for many other conditions. Utilization does not justify extensive review. Continue Ancillary
97028	Ultraviolet Therapy	Ancillary	1	Straightforward remove from PL

Physical Therapy Modalities

97032	Electrical Stimulation	SNRC	1070	Not reviewed. Modify back guidelines to clarify non-coverage
97033	Iontophoresis	Ancillary	137	Used as adjunctive therapy to assist in delivery of topical medications. Remain Ancillary
97034	Contrast Bath Therapy	Ancillary	0	Straightforward add to SNRC
97035	Ultrasound Therapy	SNRC	2510	Not reviewed. No changes.
97036	Hubbard Tank	**212** DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT **384** CHRONIC ULCER OF SKIN **428** COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	1	Straightforward remove from PL

Physical Therapy Modalities with Little Utilization and Little or No Evidence of Effectiveness

Question: Should various little-used PT modalities with little or no evidence of effectiveness be removed from the Prioritized List?

Question source: OHP Medical Directors, HERC staff

Issue: Several PT services have very little utilization and little evidence to support use. They have been suggested for removal from the Prioritized List.

1) **Diathermy/microwave**
    a. CPT 97024 Application of a modality to 1 or more areas; diathermy (eg, microwave)
    b. Technique by which microwaves are used to deliver heat to areas deep in the body
    c. Currently appears on lines 471 BRACHIAL PLEXUS LESIONS and 512 PERIPHERAL NERVE DISORDERS.
        i. Pairs only with ICD-10 G54.0 (Brachial plexus disorders) above the current funding line
    d. Utilization: 35 paid claims 7/14-6/15 (all payers)
    e. Evidence: literature search on MEDLINE limited to use of diathermy for peripheral nerve injuries and brachial plexus disorders
        i. No literature found
2) **Ultraviolet therapy**
    a. CPT 97028 Application of a modality to 1 or more areas; ultraviolet
    b. Technique in which light waves are used for treatment of a physical condition. There is another type of light therapy used to treat skin conditions such as psoriasis
    c. Currently on the Ancillary List
    d. Utilization: 1 paid claim 7/14-6/15 (all payers)
    e. Evidence:
        i. One article found
        ii. **Chen 2014**, Cochrane review of phototherapy for the treatment of pressure ulcers (study not included due to size) http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009224.pub2/epdf
            1. N=7 RCTs (403 patients), comparing phototherapy to standard care or sham phototherapy
            2. Overall, there was insufficient evidence to determine the relative effects of phototherapy for healing pressure ulcers.
            3. Among five studies reporting the rate of change in ulcer area, three studies found no statistically significant difference between the two groups.

4. **Authors' conclusions:** We are very uncertain as to the effects of phototherapy in treating pressure ulcers. The quality of evidence is very low due to the unclear risk of bias and small number of trials available for analysis. The possibility of benefit or harm of this treatment cannot be ruled out. Further research is recommended.

3) Hubbard Tank

a. CPT 97036 Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes
b. A form of hydrotherapy in which the patient is immersed in a full body tank
    i. Does not include aquatic exercise therapy (CPT 97113)
c. Currently appears on lines 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT, 384 CHRONIC ULCER OF SKIN,428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
d. Utilization: 1 paid claim 7/14-6/15 (all payers)
e. Evidence
    i. **White 2015**, PT association recommendations for Choosing Wisely (study not included due to length: http://ptjournal.apta.org/content/ptjournal/95/1/9.full.pdf
        1. Don't use whirlpool for wound management.
        2. The concern with whirlpool and other large open tanks of water is increased risk of infection for open wounds. Other wound care strategies have been found to be more effective for wound care, such as directed wound irrigation or a pulsed lavage with suction.

4) Contrast baths

a. CPT 97034 Application of a modality to 1 or more areas; contrast baths, each 15 minutes
b. A form of hydrotherapy in which a body part (normally a limb) is placed in alternately hot and cold baths
c. Currently is on the Ancillary List
d. Utilization: 0 paid claims 7/14-6/15 (all payers)
e. Evidence
    i. **Bregor Stanton 2009**, systematic review and meta-analysis of use of contrast baths
        1. N=28 studies (1938 onward)
        2. Subjects had diagnosis of rheumatoid arthritis, diabetes, or foot/ankle injuries.
        3. The diversity of conditions, protocols, and outcomes limited the ability to make definitive conclusions on efficacy.
        4. Conclusions: The contrast bath procedure may increase superficial blood flow and skin temperature, though the evidence on the impact on edema is conflicting. No relationship between

physiologic effects and functional outcomes has been established. Level of Evidence: 2A

ii. NCOR 2012

1. Found evidence for improved exercise performance, mainly in high level athletes
2. Contraindications include open wounds, poorly controlled epilepsy, infection wounds, hypertension, diabetes, and fear of water

HERC staff recommendations:

1) Remove CPT 97024 (Application of a modality to 1 or more areas; diathermy (eg, microwave)) from lines 471 BRACHIAL PLEXUS LESIONS and 512 PERIPHERAL NERVE DISORDERS
    a. Add 97024 to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
2) Add CPT 97028 (Application of a modality to 1 or more areas; ultraviolet) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
    a. Advise HSD to remove 97028 from the Ancillary List
3) Add CPT 97034 (Application of a modality to 1 or more areas; contrast baths, each 15 minutes) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
    a. Advise HSD to remove 97034 from the Ancillary List
4) Remove CPT 97036 Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes from lines 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT, 384 CHRONIC ULCER OF SKIN, 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
    a. Add 97036 to the Services Recommended for Non-Coverage Table due to evidence of harm

Paraffin Wax Therapy

Question: Should paraffin wax therapy coverage be clarified?

Question source: HERC staff

Issue: Paraffin wax therapy (CPT 97018) is currently Ancillary. This therapy involves the submersion of an extremity, normally a hand, into a bath of hot wax to improve circulation, increase flexibility, and reduce pain. The majority of use of this modality is for hand conditions, with some treatment of foot conditions.

Utilization: 79 paid claims 7/1/14-6/30/15. All 8 diagnoses paired with 97018 were hand conditions (osteoarthritis, carpal tunnel syndrome, contractures, fractures).

Evidence:

1) **Chang 2014**, RCT of paraffin therapy vs ultrasound for carpal tunnel syndrome
    a. N=47
    b. Statistical analysis revealed significant improvements in symptom severity scores in both groups. After adjusting for age, gender and baseline data, the analysis of covariance revealed a significant difference in the functional status score between two groups.
    c. Conclusions: The combination of ultrasound therapy with a wrist orthosis may be more effective than paraffin therapy with a wrist orthosis.
2) **Dilec 2013**, RCT of paraffin therapy for hand osteoarthritis
    a. N=57 (29 paraffin, 27 control)
    b. After treatment, the paraffin group exhibited significant improvement in pain at rest and during ADL, ROM of the right hand, and pain and stiffness dimensions of the AUSCAN ($P<.05$). There was no significant improvement in functional dimension of the AUSCAN and the DFI ($P>.05$). The control group showed a significant deterioration in right hand grip and bilateral lateral pinch and right chuck pinch strength ($P<.05$). When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of painful and tender joints at 12 weeks significantly decreased in the paraffin group ($P<.05$). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks ($P<.05$).
    c. Conclusions: Paraffin bath therapy seemed to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. It may be regarded as a beneficial short-term therapy option, which is effective for a 12-week period.

Paraffin Wax Therapy

Summary: There are few studies on the effectiveness of paraffin wax therapy. Based on limited evidence, paraffin wax therapy is likely effective for treatment of hand arthritis and carpal tunnel syndrome.

HERC staff recommendation:

1) Advise HSD to remove paraffin wax therapy (CPT 97018) from the Ancillary List
2) Add paraffin wax therapy (CPT 97018) to the following lines, which contain hand arthritis, contracture, and fracture diagnoses
    a. 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    b. 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
    c. 359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
    d. 362 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
    e. 420 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS
    f. 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Vasopneumatic devices

Question: Should vasopneumatic device coverage be clarified?

Question source: HERC staff

Issue: Vasopneumatic device therapy (CPT 97016) is currently Ancillary. This therapy involves the use of device to apply pressure to a part of the body. This device is used for reducing swelling (edema) after acute injury and for the treatment of lymphedema.

Utilization: 112 paid claims 7/1/14-6/30/15. The top 10 diagnoses paired with 97016 were injuries to the joints of the lower leg. It was also paired with diagnoses of neck and back conditions.

Evidence:
No articles were found

Summary: There is minimal evidence concerning the effectiveness of vasopneumatic device therapy.

HERC staff recommendation:

1) Advise HSD to remove vasopneumatic device therapy (CPT 97016) from the Ancillary List
2) Option 1:
    a. Add vasopneumatic device therapy (CPT 97016) to the following lines, which contain limb arthritis, sprain, and other injury diagnoses as well as lymphedema. This allows use for conditions generally considered treatable by this therapy and not other conditions, such as back and neck pain.
        i. 359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
        ii. 380 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
        iii. 435 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
        iv. 468 OSTEOARTHRITIS AND ALLIED DISORDERS
        v. 579 LYMPHEDEMA
        vi. 616 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR
3) Option 2:
    a. Add vasopneumatic device therapy (CPT 97016) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness

Whirlpool Therapy

Question: Should whirlpool therapy be removed from wound and burn care lines?

Question source: HERC staff

Issue: Whirlpool therapy (CPT 97022 (Application of a modality to 1 or more areas; whirlpool) is an adjunctive PT therapy in which a part of the body is placed into a whirlpool bath. This reportedly increases circulation, decreases pain and swelling, and increasing mobility. It is also used for found care, as a method of debriding wounds through the shearing action of the water. CPT 97022 appears on many lines on the Prioritized List, including lines 61 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE, 76 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE, 200 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE, and 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT.

CPT 97022 is also found on all 4 new back lines which are planned for implementation shortly.

Utilization: 847 paid claims (7/1/14-6/30/15). The top 10 diagnoses associated with 97022 were injuries of the extremities and low back pain. There were no wound or burn diagnoses in the top 10 diagnoses submitted for this procedure. There were 161 claims for CPT 97022 coded with lumbago as the diagnosis.

Evidence—wound care

1) **White 2015**, PT association recommendations for Choosing Wisely (not included in the packet due to study's length)
   http://ptjournal.apta.org/content/ptjournal/95/1/9.full.pdf
   a. Don't use whirlpool for wound management.
   b. Whirlpools are a nonselective form of mechanical debridement. Utilizing whirlpool to treat wounds predisposes the patient to risks of bacterial cross-contamination, damage to fragile tissue from high turbine forces, and complications in extremity edema when arms and legs are treated in a dependent position in warm water. Other, more selective forms of hydrotherapy should be utilized, such as directed wound irrigation or a pulsed lavage with suction.

Evidence—back conditions

No articles were identified in MedLine using whirlpool, hydrotherapy, or related terms for the treatment of low back pain. There is a robust literature on the use of aquatic therapy (pool exercises) for the treatment of back pain.

Whirlpool Therapy

HERC staff recommendations:

1) Effective October 1, 2016: Remove CPT 97022 (Application of a modality to 1 or more areas; whirlpool) from the following lines due to evidence of harm:
    a. 61 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE
    b. 76 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE
    c. 200 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE
    d. 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
2) Effective July 1, 2016: Remove CPT 97022 (Application of a modality to 1 or more areas; whirlpool) from all of the new back conditions lines due to lack of evidence of efficacy
    a. 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    b. 366 SCOLIOSIS
    c. 407 CONDITIONS OF THE BACK AND SPINE
    d. 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

JHT Read for Credit article #116.

A Systematic Review of the Effectiveness of Contrast Baths

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ABSTRACT: Study Design: Systematic review.
Introduction: Contrast baths are used as an intervention in hand therapy, yet it is unclear which patients, if any, benefit from this intervention.
Purpose of the Study: To examine the nature and quality of the evidence regarding the use of contrast baths using a systematic review process.
Methods: Of a total of 28 clinical research articles on contrast baths, from 1938 forward, ten met the inclusion criteria set by the authors.
Results: These studies addressed the physiological changes of hot and cold on blood flow, intramuscular temperature, subcutaneous temperature, and the influence of room temperature and age. The subjects included normal/healthy volunteers and patients with a diagnosis of rheumatoid arthritis, diabetes, or foot/ankle injuries. The diversity of conditions, protocols, and outcomes limited the ability to make definitive conclusions on efficacy.
Conclusions: The contrast bath procedure may increase superficial blood flow and skin temperature, though the evidence on the impact on edema is conflicting. No relationship between physiologic effects and functional outcomes has been established.
Level of Evidence: 2A
J HAND THER. 2009;22:57–70.

Contrast baths constitute a thermal modality whereby the hand is alternately immersed in hot and cold water for a specified temperature, time, and duration to therapeutically decrease edema, stiffness, and pain.[1] This procedure is commonly described in textbooks[2–13] and continues to be used in practice[14] although the evidence to support this practice has not been convincing.[5,9–11,13] To ascertain the frequency and patterns of contrast baths, a survey was developed and sent to a randomized sample of 100 therapists, members of the American Society of Hand Therapists. Seventy percent of the respondents reported use of contrast baths as a treatment intervention; however, they reported variability in timing, duration, and temperature of the baths. Of the 30% respondents who reported they do not use contrast baths, a majority (69%) of this group stated that they do not use the modality because there was no evidence to support their use.[1]

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A review of multiple texts and publications that describe the contrast bath procedures and protocols used clinically was performed before beginning the systematic review of the related clinical research. This informal review was sufficient to establish that there is no clear standardized methodology. Contrast bath protocols vary by temperature range, timing, and overall duration of contrast bath procedure (see protocols in Table 1). Cold water temperatures ranged from 45 to 71.6°F (7.22–22°C) and from 80 to 113°F (26.67–45°C) for warm/hot water immersion. The more frequently cited timing regimen is immersion for 10 minutes in hot water, alternated with 1-minute immersion in cold water, followed by alternate immersion of 4 minutes in hot and 1 minute in cold for another three or four repetitions for a total duration of 30 minutes.[2,3,5–7,11,15–17] Another method described does not include the initial 10 minutes of warm water immersion and the ratio suggested alternate immersion in either 4- or 3-minute warm water and 1-minute cold water immersion (ratio of 4:1 or 3:1) with variation depending upon the protocol used.[4,8,10,18–24]

The inconsistency found in the literature, yet continued clinical use suggests that a thorough and systematic review of the literature is needed.

National Council for Osteopathic Research

Contrast bathing – a snapshot summary report (Nov 2012)

Key messages

- It has been suggested that contrast therapy causes a "pumping effect" due to a cycle of vasoconstriction and vasodilation, therefore facilitating the removal of oedema. However, controversy exists around this theory.
- Current theory is that constriction of the vessel walls increases intraluminal pressure in the blood vessel; this causes fluid to move with the valves, preventing back flow of fluid and subsequent oedema accumulation.
- Effects of CWI shown in the studies so far include:
- *Reduced lactate post-exercise*
- *Improved maintenance of exercise performance.*
- *Possible effect on cardiovascular function.*
- There is not yet any evidence showing a dose-response from the duration of contrast water immersion.
- Contra-indications include open wounds, poorly controlled epilepsy, infected wounds, hypertension, fear of water and diabetes. If shared facilities are used then those with MRSA should not use them.

Historical background

The therapeutic use of water has a long history dating back to ancient cultures. Water therapies were classified in traditional medicine as:

Hydrotherapy – techniques involving therapeutic bathing and using water;

Balneotherapy – therapeutic bathing in medicinal and thermal springs; and

Thalassotherapy – therapeutic bathing in the sea and using marine products[1].

Hydrotherapy has become the most popular of the water therapies. Hahn, Oertel, Priessnitz, Rausse and Kneipp developed the use of water cures in Europe in the eighteenth and nineteenth century[2]. Hydrotherapy has been advocated using a number of variations including, Kniepp baths, Schlenz baths, Sitz baths and Stanger baths. A variety of disorders were recorded as being treated and aided by such bathing including fibromyalgia[3], osteoarthritis[4], insomnia[5] and rheumatoid arthritis[6,7].

A later development was the galvanic bath, which was introduced by Sere and further developed by Stanger[2]. Galvanic baths were constructed with electrodes and a low voltage direct current (DC) circuit. The electromagnetic field produced was claimed to contribute to improved circulation in the periphery of the body and promoting "detoxification"[8].

Physical therapies continue to recommend a derivation of water cures, most commonly in the form of "contrast bathing", using repeated application of, or immersion in, hot/warm water and cold water. Scientific literature now describes this as "contrast water immersion" or "contrast therapy". In clinical practice, contrast therapy/immersion is recommended to treat symptoms associated with local inflammation and the response to tissue trauma. A more recent use for contrast therapy has been to aid the signs and symptoms of delayed muscle soreness, particularly in athletes[9].

Physiological mechanism

It has been suggested for some time that contrast therapy produces a cycle of local vasoconstriction and vasodilation resulting in a "pumping effect" to facilitate the removal of oedema by venous and lymphatic removal. Controversy still exists regarding this theory[10,11]; concern that adequate deep tissue vasoconstriction fails to occur has led to an amendment to the ratio of heat and cold application or immersion used to produce a therapeutic benefit[11].

Current theories suggest that oedema is removed because the constriction increases the intraluminal pressure in the blood vessel, causing the fluid to move with the valves in the veins, thereby preventing backflow of the fluid[12]. This would produce a beneficial effect of minimising the influence of oedema accumulation while the healing process takes place.

The majority of research in this area has focused on the isolated use of heat or cold and the vascular pumping theory has had little specific investigation and is currently not well supported by evidence. Denegar[13] suggests that the limited duration of heat and cold application (three minutes and one minute) would be insufficient to effect deep blood flow and to produce a pumping action. Lymph capillaries do not have muscular

walls and would be unable to effect a pumping mechanism, and the intrinsic contraction in blood vessel walls contributes in a limited way to lymphatic flow[13].

Contrast therapy does, however, produce some therapeutic benefits: Coffey *et al*[14] investigated the use of contrast water immersion (CWI) after exercise and showed that post-exercise lactate was lowered and the subjective perception of recovery improved. Morton[15], in turn, demonstrated that CWI significantly increased the hastening of plasma lactate decrease during recovery after intense anaerobic exercise.

Physiological effects

A growing body of research has been built looking at the physiological effects of contrast therapy. Changes in arterial blood flow in response to contrast therapy have been measured by a number of researchers using a variety of techniques. Fiscus *et al*[16] used strain gauge plethysmography to measure blood flow in the lower limb. This study used four minutes warm water immersion to one minute cold water immersion, over a period of 20 minutes, and produced a significant fluctuation of lower leg blood flow. Decrease in blood flow occurred during the change from warm to cold; increase in blood flow occurred during the change from cold to warm; this effect reduced during successive immersions. A growing number of studies have taken place in the past decade; the variables measured and the physiological effects produced in a small number of recent studies are summarised in the table below.

Study author(s)	Number of participants in study	Physiological process measured	Intervention time ratio (heat to cold)	Total duration of intervention	Effect produced
Myrer *et al.* (1997)[17]	9 men, 7 women	Subcutaneous and intramuscular muscle temperatures.	1:1 (5 minutes heat and cold repeated twice)	20 minutes	Cutaneous circulation only affected.
Coffey *et al.* (2004)[14]	14 men	Blood lactate concentration and blood pH.	2:1	15 minutes	Lowers post-exercise lactate.

Fiscus *et al.* (2005)[16]	24 men	Arterial blood flow in the lower leg.	4:1	20 minutes	Unclear
Morton. (2006)[15]	6 men, 5 women	Blood lactate concentration.	4:1	30 minutes	Hastens reduction of plasma lactate after exercise.
Hamlin MJ. (2007)[18]	20 men	Blood lactate concentration and repeated sprint performance.	3:1	12 minutes	Decreases blood lactate concentration; little effect on subsequent repetitive sprint performance (1 hour later).
Vaile JM et al. (2007)[19]	Athletes: 4 male, 9 female	Creatine kinase concentration, perceived pain, thigh volume, isometric squat strength and weighted jump squat performance.	2:1	15 minutes	Smaller reduction and faster restoration of strength and power measured by isometric force and jump squat performance. Thigh volume was significantly less. No significant difference was found in perceived pain and creatine kinase levels.
French et al. (2008)[20]	26 men	Limb girth (mid-thigh and mid-calf), range of motion, lower body power, speed and agility, whole body strength, soreness (using a visual analogue scale) and serum creatine kinase and myoglobin levels	3:1	Not disclosed	Creatine kinase and myoglobin levels were elevated; soreness fell transiently and mid-thigh girth increased - no other significant recovery effects noted.

Crampton *et al.* (2011)[21]	16 men split into Wingate cycling group (n=8) And Repeated intermittent sprint cycling group (n=8)	Blood lactate, heart rate and repeated exercise performance.	1:1 (2.5mins) 4:1 (4mins:1 min)	30 mins	Improved maintenance of exercise performance. Likely to be due to the effect on cardiovascular function as a result of alternating hot and cold water immersion.
Stanley *et al*. (2012)[22]	18 male cyclists	Performance time-trial, heart rate variability measurements, perceptions of recovery.	2:1	10 mins (ending on cold water)	Increased perceptions of recovery. After cold water immersion and contrast water immersion cardiac parasympathetic activity remained above pre-exercise values compared with passive rest for at least 90 mins. No significant effect on subsequent exercise performance.
Higgins et al (2012)[23]	24 men: Cold water immersion n=8 Contrast bath therapy n=8 Passive recovery n=8	Performance tests, perceived exertion, flexibility, thigh circumference, delayed onset muscle soreness (DOMS) using a visual analogue scale and a pressure algometer.	1:1 (1 min)	10 mins	No positive effects of contrast therapy recorded.

Dose-response

Versey et al[24] specifically looked at dose-response in contrast water therapy (CWT). They compared CWT for 6 minutes, 12 minutes and 18 minutes with a seated rest control. They found no dose-response effect from CWT duration on the recovery from high-intensity cycling.

Contraindications and adverse events

Adverse events recorded with this treatment intervention have been notably lacking in the literature. Common exclusion criteria for participants in clinical trials involving CWI include open wounds, poorly controlled epilepsy, infected wounds, hypertension, fear of water and diabetes[6,25]. In situations where CWI is undertaken using shared facilities known carriers of methicillin resistant *Staphylococcus aureus* (MRSA) are also excluded from participation[6].

CWI has demonstrated physiological and beneficial therapeutic effects. The mechanism of action requires further research, and the "dose" required in terms of application or immersion time, as with so many other physical therapy interventions, also requires further investigation.

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BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

Comparative effectiveness of ultrasound and paraffin therapy in patients with carpal tunnel syndrome: a randomized trial

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Abstract

Background: Conclusive evidence indicating an effective treatment for carpal tunnel syndrome (CTS), a common entrapment neuropathy, is lacking. Ultrasound therapy (US therapy) has long been used as one of the combination treatments for CTS. In addition, paraffin bath therapy has been applied widely as a physical modality in treating patients with hand conditions. The purpose of this randomized trial was to compare the efficacy of combining a wrist orthosis with either US therapy or paraffin bath therapy in treating CTS patients.

Methods: Patients with CTS were randomized into two groups. All patients received a wrist orthosis. Twice per week, one group underwent paraffin therapy, and the other group underwent ultrasound therapy. Each patient received a questionnaire, physical examination and nerve conduction study of the upper extremities before and after treatment for eight weeks.

Results: Sixty patients were recruited, and 47 completed the study. Statistical analysis revealed significant improvements in symptom severity scores in both groups. After adjusting for age, gender and baseline data, the analysis of covariance revealed a significant difference in the functional status score between two groups.

Conclusions: The combination of ultrasound therapy with a wrist orthosis may be more effective than paraffin therapy with a wrist orthosis.

Trial registration: Clinicaltrial.gov: NCT02278289 Oct 28, 2014

Keywords: Carpal tunnel syndrome, Paraffin therapy, Ultrasound therapy

Background

Carpal tunnel syndrome (CTS) is a common entrapment neuropathy that causes symptoms of pain, numbness and paresthesia in the distribution of the median nerve and may even cause atrophy of the thenar muscle [1,2]. For patients with mild to moderate symptoms, nonsurgical treatments, such as local steroid injection, oral medication, wrist orthoses, therapeutic exercise, ultrasound therapy (US therapy), low-level laser and paraffin bath have been implemented clinically [1,3,4]. However, conclusive evidence on the best treatment for patients with CTS is lacking.

For years, US therapy has been used as one of the combination treatments for CTS [1-3,5]. The mechanism of US therapy includes thermal and nonthermal effects. The thermal effect occurs when acoustic waves penetrate the tissue and produce molecular vibration, which results in heat production and facilitates pain relief. [6] The nonthermal effect of US therapy includes cavitation, media motion and standing waves, which might elicit anti-inflammatory and tissue-stimulating effects [7,8]. Several clinical trials have revealed US therapy has a positive effect on patients with CTS [5,9]. However, Cochrane's 2013 review concluded that there is still insufficient evidence to support that US therapy is more effective than placebo or other nonsurgical interventions for CTS [10]. Additional research is still needed to compare the effectiveness of US therapy with other modalities for patients with CTS, particularly in the long term.

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Paraffin therapy has been widely used as a physical modality in treating patients with hand conditions, such as rheumatoid arthritis, osteoarthritis and CTS [4,11,12]. Paraffin therapy provides superficial heat to the hands, which can both relieve pain and improve local circulation [6,13]. Previous studies have revealed that paraffin therapy could improve pain and finger joint range of motion in patients with hand arthritis [11,12]. Symptom improvements were also observed in patients with CTS after receiving combination treatments with paraffin therapy and a wrist orthosis [4]. However, to the best of our knowledge, no previous clinical trial has compared the effectiveness of paraffin bath with US therapy for CTS patients.

Purpose

The purpose of this exploratory study is to compare the combination of a wrist orthosis with either US therapy or paraffin bath therapy in the treatment of CTS patients. We hypothesized that US therapy might be more effective than paraffin therapy because it provides both thermal and nonthermal effects.

Methods

Patients and controls

The Institutional Review Board of our hospital (Taipei Tzuchi Hospital Institutional Review Board Committee) approved this study, and patients provided informed consent prior to the study. Sixty individuals diagnosed with CTS were recruited from the Department of Physical Medicine and Rehabilitation in one community hospital during 2010 and 2011. Study inclusion criteria required patients to have subjective symptoms (such as pain and/or numbness in the median nerve distribution of the digits or nocturnal pain). Furthermore, patients were required to have either a positive Phalen's sign or a positive Tinel's sign along with electrophysiological evidence of CTS. We excluded patients with (1) age younger than 18 years old; (2) underlying medical disorders, such as diabetes mellitus, renal failure, autoimmune disease or hypothyroidism; and (3) pregnancy, previous wrist trauma or surgery.

All eligible patients were invited, and the participants were randomly assigned to two groups. A total of 60 lots were prepared with 30 lots for each group, and each lot was sealed in a non-transparent envelope with the same appearance. All envelopes were randomly mixed together numerous times. Finally, the envelopes were marked from 1 to 60 by an assistant who was not involved in the mixing process, and the study nurse simply picked up the lot sequentially. The allocations were concealed with the use of packages of prescription orders, which were given by the nurse to the physical therapists, and the therapy programs were administered by physical therapists who did not participate in evaluating the study outcome.

The participants were randomly allocated into two groups. One group received paraffin therapy and a wrist orthosis, and the other group received US therapy and a wrist orthosis. Custom-made neutral wrist orthoses were given to all the patients, who were instructed to wear the wrist orthoses while sleeping for at least eight weeks. A CONSORT flowchart describing the process of participant randomization and intervention is depicted in Figure 1.

A series of physical examinations and nerve conduction studies (NCSs) were performed on each patient. Physical examination included the palmar pinch power test, the Semmes-Weinstein Monofilament sensory test, Tinel's test and Phalen's test. Participants completed a set of questionnaires, including the Boston CTS questionnaire and several questions involving basic demographic information. Numbness and pain were assessed using a 10-cm visual analog scale (VAS).

After receiving the designated 8-week therapy, all patients were re-evaluated using the same clinical examinations, questionnaires and NCSs. The outcomes of the physical examination and the NCSs were assessed by physiatrists who were not aware of the group assignments.

Paraffin therapy

Patients in the paraffin therapy group were treated with the dip-and-wrap method of paraffin bath therapy in the hospital twice per week for 8 weeks. The temperature of the paraffin bath was maintained at approximately 55°C (Parabath, Hygenic Corporation, Akron, OH, USA). The whole procedure is described as follows. Patients dipped their affected hands into the paraffin wax. Next, they waited for the paraffin wax to harden and then dipped their hands again into the paraffin wax. This step was repeated 5 times. When the last paraffin layer hardened, it was covered with plastic wrap and a towel. After 20 minutes of heating, the paraffin was removed [12].

Ultrasound therapy

Patients in the ultrasound group were treated with US therapy for 5 minutes each session, twice per week for 8 weeks. The US machine was set at a frequency of 1 MHz, an intensity of 1.0 W/cm^2, in pulsed mode (1:4) with a transducer 5 cm^2 in size (Therasound 3.5, RichMar Corporation, Inola, OK, USA), and with aquasonic gel as couplant [3]. The transducer was placed over the wrist carpal tunnel area, ranging from wrist crease to palmar region. A stroking method was used with a sonation area of approximately 5 × 5 cm^2. The machine was calibrated, and the output was adjusted regularly with a simple underwater balance.

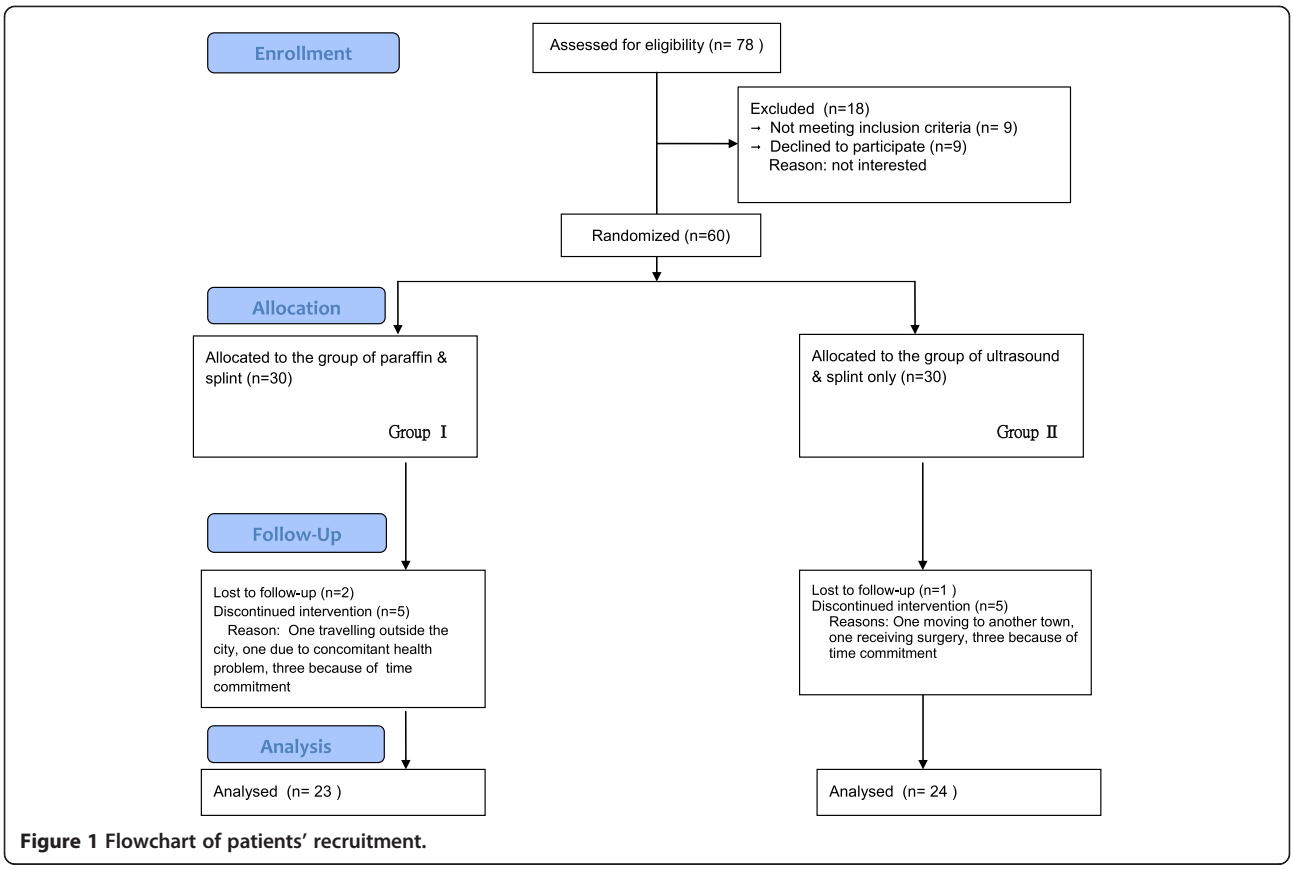

Figure 1 Flowchart of patients' recruitment.

Outcome measurements

The patients were evaluated with the Boston CTS questionnaire, a pain scale, physical examinations and NCSs before and after treatment for eight weeks.

Primary outcome

The primary outcome was the functional status scale of the Boston CTS questionnaire. The Boston CTS questionnaire is a self-administered outcome measurement for CTS patients, consisting of two parts: a symptom severity scale (11 questions) and a functional status scale (8 questions). All of the answers were scored from 1 to 5 according to the patient's clinical condition, such that 1 indicated no symptoms, and 5 indicated the most severe symptoms. The questionnaire's reproducibility, internal consistency and responsiveness were validated in the previous paper [14]. The functional status scale of the Boston CTS questionnaire was chosen as the primary outcome because it is closely correlated with the patient's ability to perform daily activities. The goal of rehabilitation is to improve the functional status of patients, rather than only symptom relief.

Secondary outcomes

The secondary outcomes were the symptom severity scale of the Boston CTS questionnaire, the pain scale, changes in the monofilament sensory test, palmar pinch power and the distal sensory and motor latencies of the median nerve.

Physical examinations

Phalen's test was performed by asking the patients to fully flex their wrist for 60 seconds. A positive test occurred when patients experienced symptoms of numbness and tingling in the median nerve distribution [15]. Tinel's sign was elicited by gently tapping the median nerve at wrist level. This test was considered positive when patients reported signs of a tingling sensation or shooting pain along the median nerve distribution of the hand [16]. Palmar pinch strength was measured by pressing the thumb and the index finger tip against a standard dynamometer. This procedure was repeated 3 times, and a mean score was obtained [17].

The Semmes-Weinstein monofilament sensory test was measured by applying force-calibrated nylon filament to the fingertips with the wrist in a neutral supine position. Each type of filament was pressed perpendicularly against the fingertips until the filament bent into a C shape. This examination was considered positive if the patient was able to correctly identify which digit the monofilament was touching with his/her eyes closed. A weighted score from 1 to 5 was acquired according to each filament's calculated force [14]. We recorded the

scores from seven sample areas in each hand and summed the scores to analyze as a continuous variable.

Nerve conduction study

Median and ulnar nerve sensorimotor NCSs were conducted on all patients utilizing Neuropack M1 MEB-9200 J/K electrodiagnostic equipment (Nihon Kohden Corporation, Tokyo, Japan) in a quiet, air-conditioned room (26°C). The patients were prepared in the supine position with their skin temperature measured on the palms and maintained above 32°C. Standard techniques of supramaximal percutaneous stimulation with a constant current stimulator and surface recording were used for the NCS. Median motor nerve conduction and distal motor latency were measured by placing a stimulating electrode at the wrist and a recording electrode on the abductor pollicis brevis muscle 8 cm from the stimulus electrode. A standard distance (14 cm) was maintained between the stimulator and recording electrodes for the sensory nerve conduction studies [18]. The ring finger difference was calculated as the median nerve peak latency minus the ulnar nerve peak latency [19]. The diagnosis of CTS was established if at least one of three criteria was achieved: (1) distal motor latency >4.4 milliseconds, (2) distal sensory latency >3.4 milliseconds [20] or (3) median-ulnar distal sensory latency difference (ring difference) >0.4 milliseconds [19].

Sample size

For sample size estimation, previous randomized, controlled trial studies, conducted in CTS patients receiving carpal tunnel injection, suggested that 26 subjects per group would provide 90% statistical power and a 5% significance level by two-sided tests to detect a significant decrease in the Boston CTS questionnaire score from 1.6 to 2.0 [21,22]. To compensate for a 15 to 20% drop-out rates, we recruited 30 subjects per group.

Statistical analysis

The following data were analyzed: (1) descriptive statistics to summarize the participants' basic demographics; (2) the baseline and follow-up scores for patient-reported outcomes (PROs; including the symptom severity scale, the functional status scale and pain intensity), using paired t-tests for each patient; (3) the differences in changes in the PROs after treatment between the groups by analysis of covariance (ANCOVA), with adjustments for age, sex and the baseline data for each item before treatment to accommodate individual differences; (4) the baseline and follow-up physical examinations and NCS data for each affected hand, using the generalized estimate equation (GEE) method, which is a quasi-likelihood approach for correlated data that does not fully specify the distribution of responses in each cluster, while considering that these examinations were performed on both hands for those patients who had bilateral CTS; this GEE method was applied with the subjects as clusters, and in this model, the two hands of each individual were treated as correlated [23]; and (5) the differences in changes in the physical examination and NCS data between the two studied groups using the GEE model, with age, sex and baseline values as covariates. In addition, we calculated the effect size (ES; mean changes in scores divided by baseline standard deviation) for PROs. All of the statistical analyses were performed using the SAS statistical software package, version 9.2. (SAS Institute Inc., Cary, NC, USA).

Results

Patient characteristics and patient-reported outcomes

Seventy-eight patients were enrolled in this study, and 18 patients were excluded after being assessed for eligibility. Among the excluded patients, nine did not meet the inclusion criteria and nine declined to participate. A total of 60 patients with CTS were recruited and randomized into the two study groups. Forty-seven patients completed the study. Seven and six patients were unable to complete the study in the paraffin and US therapy groups, respectively (Figure 1). Table 1 summarizes the demographic

Table 1 Frequency distributions (percentages) of demographic characteristics in patients with CTS who completed the study

Characteristics	Treatment group	
	Paraffin therapy	US therapy
	n = 23, n (%)	n = 24, n (%)
Personal characteristics		
Age, mean±SD, yrs	51.9±8.8	48.8±11.2
Body mass index, mean±SD	25.7±4.5	25.0±3.7
Male	3 (13.0)	2 (8.3)
Married	17 (77.3)	17 (70.8)
Employed	10 (40.5)	14 (58.3)
Smoking habit	0 (0.0)	1 (4.2)
Right-hand dominant	21 (95.5)	23 (100.0)
Bilateral hands involved	20 (87.0)	17 (70.8)
Educational level		
College/University	7 (30.4)	9 (37.5)
Senior High	8 (34.8)	11 (45.8)
Junior High or below	8 (34.8)	4 (16.7)
Household monthly income (US$)		
<1200	8 (34.8)	3 (12.5)
1200-3500	10 (43.5)	16 (66.7)
>3500	5 (21.7)	5 (20.8)

characteristics and basic participant information. As shown in Table 1, the mean ages of the patients in the paraffin and US therapy groups were 51.9 ± 8.8 and 48.8 ± 11.2 years, respectively. More than half of the patients were female and had bilateral CTS.

After treatment, significant improvements in symptom severity scores were seen in both groups (Table 2). The effect size (ES) of the symptom severity scores was 0.63 for both groups. However, significant improvements in functional status scores (ES 0.38) and pain scales (ES 0.74) were only seen in the US therapy group. An effect size of 0.3 to 0.8 is considered a "moderate" effect [24]. After adjusting for age, gender and baseline data, the ANCOVA analysis revealed significant differences in the functional status scores between the two study groups.

Physical findings and NCSs

A significant improvement in the monofilament sensory test was observed in the paraffin group, and a significant improvement in the palmar pinch power test was observed in the US therapy group as well (Table 3). However, NCSs did not detect significant changes in the distal motor or sensory latencies of the median nerve in either group. Despite adjusting for baseline data, age and sex, there were no significant differences between the two study groups in any of the outcomes of the physical examinations or NCSs (Table 3).

Table 2 Comparison of the CTS Questionnaire and the pain scale in CTS patients

	Treatment group		P value[b]
	Paraffin therapy (n = 23)	US therapy (n = 24)	
Functional status score			0.04
BT	1.7±0.6	1.8±0.8	
AT	1.8±0.9	1.6±0.7	
Difference (AT-BT)	0.1±0.9	-0.3±0.4	
Effect size	0.17	0.38	
P value[a]	0.88	0.0017	
Symptom severity score			0.51
BT	2.5±0.8	2.6±0.8	
AT	1.9±0.7	2.1±0.8	
Difference (AT-BT)	-0.5±0.7	-0.5±0.7	
Effect size	0.63	0.63	
P value[a]	<0.0001	0.0046	
Pain scale			0.81
BT	56.3±20.9	68.3±19.3	
AT	50.7±22.7	54.2±22.6	
Difference (AT-BT)	-5.7±24.1	-14.2±27.3	
Effect size	0.27	0.74	
P value[a]	0.29	0.01	

Abbreviations: CTS carpal tunnel syndrome; US ultrasound; BT before treatment; AT after treatment.
[a]Paired t test.
[b]ANCOVA comparison of differences in changes after treatment between groups after adjusting for age, gender and baseline values.

Table 3 Comparison of the results of physical examinations and NCSs in CTS patients

	Treatment group		P value[b]
	Paraffin therapy (n = 43)	US therapy (n = 37)	
Monofilament test			0.95
BT	29.5±3.7	30.1±4.1	
AT	30.7±3.0	30.9±2.7	
Difference (AT-BT)	1.2±3.5	1.2±3.3	
P value[a]	0.03	0.05	
Palmar pinch power (kg)			0.34
BT	3.2±1.8	3.2±1.2	
AT	3.6±1.5	3.6±1.1	
Difference (AT-BT)	0.4±1.8	0.5±1.4	
P value[a]	0.44	0.01	
Distal motor latency of the median nerve (ms)			0.06
BT	5.10±1.27	5.11±1.34	
AT	4.98±1.51	5.08±1.30	
Difference (AT-BT)	-0.3±0.6	-0.03±0.6	
P value[a]	0.77	0.91	
Distal sensory latency of the median nerve (ms)			
BT	3.7±0.9	3.6±0.8	0.83
AT	3.4±0.8	3.6±1.4	
Difference (AT-BT)	-0.2±0.9	0.03±1.1	
P value[a]	0.11	0.91	

Abbreviations: CTS carpal tunnel syndrome; NCS nerve conduction study; US ultrasound; BT before treatment; AT after treatment.
[a]Paired t test (generalized estimating equation).
[b]Comparison of differences in changes after treatment between groups after adjusting for age, gender and baseline values (generalized estimating equation).

Discussion

In this study, we found that US therapy tends to be more effective than paraffin therapy in treating CTS patients. Patients who underwent US therapy and a wrist orthosis not only experienced improvements in their functional status scores compared to those receiving paraffin therapy and a wrist orthosis but also showed statistically significant improvements in their symptom severity scores and palmar pinch power. In contrast, patients who underwent paraffin therapy and a wrist orthosis only experienced significant improvements in their symptom severity scores.

Different modes, frequencies and intensities have been used in US therapy for CTS patients [1,3,5,9,25,26]. Generally, in US therapy, continuous mode is chosen when the thermal effect is desired, while pulsed mode is applied when the nonthermal effect is preferred [13]. Although the study conducted by Dincer et al. revealed symptom improvements after continuous mode US therapy in CTS patients [9], Oztas et al. reported a prolonged distal motor latency and a decrease in motor nerve conduction velocity after treatment with continuous mode US therapy [26]. These findings implied that though continuous mode US therapy was able to improve the symptoms in CTS patients, selective heating of the median nerve might lead to temporal conduction block [26]. On the contrary, pulsed mode US therapy effectively enhanced peripheral nerve regeneration in an animal study, possibly through the mechanisms of local blood vessel dilatation, nerve sprouting stimulation, Schwann cell activation and chemotactic stimulator release [27].

This study utilized pulsed mode US therapy on CTS patients and observed improvements in subjective symptoms and palmar pinch power, similar to previous studies [1,3]. However, we did not note significant improvements in distal motor and sensory latencies of the median nerve after eight weeks of treatment. These findings corroborate studies conducted by Yildiz et al. and Baysal et al., who were also unable to find significant improvement in distal latencies of the median nerve in CTS patients after applying pulsed mode US therapy and followed up for eight weeks [3,25]. This negative result might be because A fibers in the peripheral nerve system are measured mostly in clinical NCSs, but C fibers, which transmit somatic pain signals, are more sensitive to US effects than A fibers [6,28,29]. This difference might explain the fact that, despite significant symptom improvements in our study, NCSs did not detect significant improvements in distal motor and sensory latencies of the median nerve. Moreover, delayed recovery of nervous tissue could contribute to the lack of improvement seen in NCSs. As shown in Harris et al.'s study, CTS patients who underwent surgical decompression experienced delayed electrophysiological recovery of up to six months [30]. Inadequate follow-up time may underestimate the electrophysiological improvement; thus, further study with a longer follow-up time is recommended.

Paraffin therapy is a superficial heat physical agent that uses conduction to transfer heat. Its therapeutic effects include increasing blood flow, producing analgesic effects, decreasing chronic inflammation, improving connective tissue elasticity and stimulating general muscle relaxation [6,31]. In this study, patients receiving a combination treatment of paraffin therapy and a wrist orthosis exhibited improvements in symptom severity scores and in the monofilament sensory test, consistent with a previous study [4]. These findings could be regarded as a validation of the baseline measurements of this trial. In the US therapy group, a significant improvement in pinch power was noted, in addition to symptom improvements, which further improved patients' functional status. This result might be partially contributed by the nonthermal effect of pulsed US therapy.

Though it requires more manpower to implement US therapy than paraffin therapy, combination treatment with US therapy and a wrist orthosis is recommended because of its superior effect on functional status and possibly on nerve regeneration. Further study to compare the effectiveness of pulsed vs. continuous US therapy in CTS patients is suggested.

This study has several limitations. First, because this study was performed in the Department of Physical Medicine and Rehabilitation, the patients usually suffered from mild to moderate symptoms. Therefore, we should remain cautious in our attempts to generalize our findings to patients with more severe symptoms. Second, this study used a combination treatment of a wrist orthosis with either US or paraffin therapy because it would have been unethical to withhold wrist orthoses when they have been reported to be effective [9]. Therefore, the treatment effects might partially originate from the wrist orthoses. Third, because approximately 20% of the participants did not complete this study, we could not perform the intention-to-treat analyses. To examine the potential bias caused by loss of follow-up, we compared the demographic and baseline symptoms severity scales, functional status scores and pain scales between the patients who completed the study and those who did not. The results revealed no significant differences between the follow-up and non-follow-up groups. Thus, we believe the potential bias may be minimal because all patients were instructed in the same manner and were randomized into two different groups. Fourth, because this study compared the two studied groups regarding their functions, symptoms, pain and results on four clinical tests, we were concerned about multiplicity issues. Of the 7 outcomes evaluated, only the primary outcome (functional status score) exhibited a significant difference between the two studied groups. Thus, further randomized, controlled trials with long-term follow-ups could be needed to validate these results.

Conclusions

To improve the functional status of CTS patients, a combination of ultrasound therapy and a wrist orthosis may be more effective than a combination of paraffin therapy and a wrist orthosis. Since this is an exploratory trial, further confirmatory testing is suggested to justify the efficacy of these two treatments.

Abbreviations
CTS: Carpal tunnel syndrome; US therapy: Ultrasound therapy; NCSs: Nerve conduction studies; VAS: Visual analog scale; PRO: Patient-reported outcomes; ANCOVA: Analysis of covariance; GEE: Generalized estimate equation.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
YWC participated in study design/data analysis and drafted the manuscript, and acted as first author. SFH carried out nerve conduction studies. Yu-SH helped in performing clinical examinations of the subjects. HLC helped in implementing therapy programs. KCL participated in data collection and interpretation. Yi-SH assisted to obtain the funding, supervised the study design and data analysis, revised the manuscript and acted as the corresponding author. All authors read and approved the final manuscript.

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ORIGINAL ARTICLE

Efficacy of Paraffin Bath Therapy in Hand Osteoarthritis: A Single-Blinded Randomized Controlled Trial

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Abstract

Objective: To evaluate the efficacy of paraffin bath therapy on pain, function, and muscle strength in patients with hand osteoarthritis.

Design: Prospective single-blinded randomized controlled trial.

Setting: Department of physical medicine and rehabilitation in a university hospital.

Participants: Patients with bilateral hand osteoarthritis (N=56).

Interventions: Patients were randomized into 2 groups with a random number table by using block randomization with 4 patients in a block. Group 1 (n=29) had paraffin bath therapy (5 times per week, for 3-week duration) for both hands. Group 2 (n=27) was the control group. All patients were informed about joint-protection techniques, and paracetamol intake was recorded.

Main Outcome Measures: The primary outcome measures were pain (at last 48h) at rest and during activities of daily living (ADL), assessed with a visual analog scale (0−10cm) at 12 weeks. The secondary outcome measures were the Australian Canadian Osteoarthritis Hand Index (AUSCAN) and the Dreiser Functional Index (DFI), used for subjective functional evaluation, loss of range of motion (ROM), grip and pinch strength, painful and tender joint counts, and paracetamol intake. A researcher blind to group allocation recorded the measures for both hands at baseline, 3 weeks, and 12 weeks at the hospital setting.

Results: At baseline, there were no significant differences between groups in any of the parameters ($P>.05$). After treatment, the paraffin group exhibited significant improvement in pain at rest and during ADL, ROM of the right hand, and pain and stiffness dimensions of the AUSCAN ($P<.05$). There was no significant improvement in functional dimension of the AUSCAN and the DFI ($P>.05$). The control group showed a significant deterioration in right hand grip and bilateral lateral pinch and right chuck pinch strength ($P<.05$), but there was no significant change in the other outcome measures. When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of painful and tender joints at 12 weeks significantly decreased in the paraffin group ($P<.05$). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks ($P<.05$).

Conclusions: Paraffin bath therapy seemed to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. It may be regarded as a beneficial short-term therapy option, which is effective for a 12-week period.

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Hand osteoarthritis is the most common cause of pain in hand joints and can lead to loss of function, as well as pain, swelling, stiffness, and deformity in the affected joints. Hand osteoarthritis especially affects older adults and postmenopausal women, with population-based studies reporting that this prevalence is 30% to 52%.[1] Clinically, hand osteoarthritis can be classified as nodular, thumb-based, generalized, or erosive.[2] Major factors influencing the development of hand osteoarthritis are age, joint location, genetic predisposition, joint deformity, joint hypermobility, obesity, trauma, and sex.[2,3] Treatment guidelines recommended by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) include a range of conservative (pharmacologic and nonpharmacologic) and surgical treatments for hand osteoarthritis, as well as a general approach for osteoarthritis treatment.[4,5] Local application of heat, such as paraffin baths, hot packs, and ultrasound are recommended for the

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treatment of hand osteoarthritis by EULAR.[4] But because research evidence for the benefit of the local application of heat or ultrasound for hand osteoarthritis is lacking, this recommendation is currently based solely on expert opinion. EULAR suggests that the future agenda for research on hand osteoarthritis should include a thorough evaluation of physical treatments, such as ultrasound, laser, transcutaneous electrical nerve stimulation, and local application of heat.[4] Although evidence of the benefit of paraffin is lacking in the literature, in vivo studies have shown that paraffin bath therapy causes temperature increases of 7.5°C in the joint capsule and 4.5°C in muscle.[6] Paraffin bath therapies have a local effect of relaxing the smooth muscle fibers in arterioles, which in turn results in the vasodilatation of the peripheral blood vessels. This produces hyperemia, increased transduction of tissue fluid, increased lymph flow, and the absorption of exudates.[7,8] To our knowledge, despite the common use of paraffin baths in clinical practice, no randomized controlled trial (RCT) of the efficacy of paraffin bath therapy in the treatment of hand osteoarthritis has been previously reported in the literature.

The aim of this study was to evaluate the efficacy of paraffin bath therapy on pain, functional status, and muscle strength in patients with hand osteoarthritis.

Methods

Participants

Patients with bilateral hand osteoarthritis were recruited consecutively from the outpatient clinic of the Department of Physical Medicine and Rehabilitation at the Dokuz Eylül University Hospital in Izmir, Turkey. The study was planned and conducted over a 30-month period. There was no suitable comparable study in the literature to use in the calculation of the sample size. We decided to use a medium effect size to determine the decrease in pain, both at rest and during activities of daily living (ADL). When the sample size was calculated according to the medium effect size ($d = .50$, $\alpha = .05$, with a power of 80%), the result was 64 patients in each group. The study was conducted from September 2008 to March 2011. The study protocol was approved by the ethics committee at the same institution. During the study, the inclusion criteria were provided to the outpatient physicians in order to assess eligible patients. Patients who met the inclusion criteria during their routine outpatient physical and radiologic examinations were reassessed by the researchers (B.D., M.B.) to determine eligibility and to then obtain written informed consent. After reviewing inclusion and exclusion criteria, patients who submitted written informed consent were included in the trial. The inclusion criterion was the fulfillment of the ACR criteria for bilateral hand osteoarthritis. Exclusion criteria included: acute inflammation, trauma or open wounds, steroid or nonsteroidal anti-inflammatory drugs intake, glucosamine drug intake, sensory deficits (polyneuropathy and diabetic neuropathy), muscle weakness (cervical disk hernia, nerve damage), malignancy, Raynaud disease and phenomenon, atrophic skin, palmar tenosynovitis, trigger finger, Dupuytren contracture, or collagen diseases, inflammatory arthritic diseases (rheumatoid arthritis, psoriatic arthritis, lupus, gout, etc), high acute phase reactants, steroid or hyaluronan injection to joints, history of physical therapy, and coagulation disorders.

List of abbreviations:

ACR	**American College of Rheumatology**
ADL	**activities of daily living**
AUSCAN	**Australian Canadian Osteoarthritis Hand Index**
DFI	**Dreiser Functional Index**
EULAR	**European League Against Rheumatism**
RCT	**randomized controlled trial**
ROM	**range of motion**

Research design

The study was designed as a prospective, single-blinded RCT. For this RCT, an independent researcher (G.E.) provided a randomization scheme from a random number table by using block randomization with 4 patients in a block, prior to the start of the study. The eligible patients who had submitted a written informed consent were then referred to another researcher (Ö.E.) who was not involved in the selection and consent process. This researcher used the randomization scheme to assign patients into intervention or control groups. This process thus ensured allocation concealment.

Setting and intervention

Demographic data including age, sex, education, occupation, body mass index, dominant extremity, symptom duration, systemic diseases, Heberden and Bouchard nodules, and drug use were recorded for both groups by a researcher (M.G.) blind to group allocation at the outpatient clinic of the Department of Physical Medicine and Rehabilitation. Another researcher (E.S.) provided written and verbal information about the disease and joint protection techniques to both groups. Group 1 (n = 29) was treated with dip-wrap paraffin bath therapy. The temperature of the paraffin bath was 50°C. Patients dipped both hands into the paraffin, removed them, and waited for the layer of paraffin to harden and become opaque. Then they redipped both hands. These steps were repeated 10 times. When the last layer hardened, their hands were wrapped within a plastic bag and covered with a towel. They then waited for 15 minutes until the paraffin cooled. A physiotherapist in the Department of Physical Medicine and Rehabilitation in the university hospital conducted these treatments 5 days per week for a period of 3 weeks. Group 2 (n = 27) was the control group. Only paracetamol intake was permitted during the study, and the patients were asked to keep a drug diary.

Outcome

The primary outcome measures were pain (during last 48h) at rest and pain during ADL, assessed with a 0 to 10cm visual analog scale at 12 weeks.

The secondary outcome measures were the Australian Canadian Osteoarthritis Hand Index (AUSCAN) and the Dreiser Functional Index (DFI), which were used for subjective functional evaluation, loss of range of motion (ROM), grip and pinch strength, painful and tender joint counts, and paracetamol intake both at 3 and 12 weeks. Loss of ROM was assessed by measuring the distance between fingertips and the distal palmar crease of the hand. The validity and reliability of this procedure was reported in healthy joints and in patients with systemic sclerosis.[9,10] The standard finger-to-palm measurement was obtained for both hands by using a ruler to measure the distance (in centimeters) between the tip of the pulp of the 4 fingers and the distal palmar crease, while the patient attempted to clench his/her fist (maximal finger flexion at all

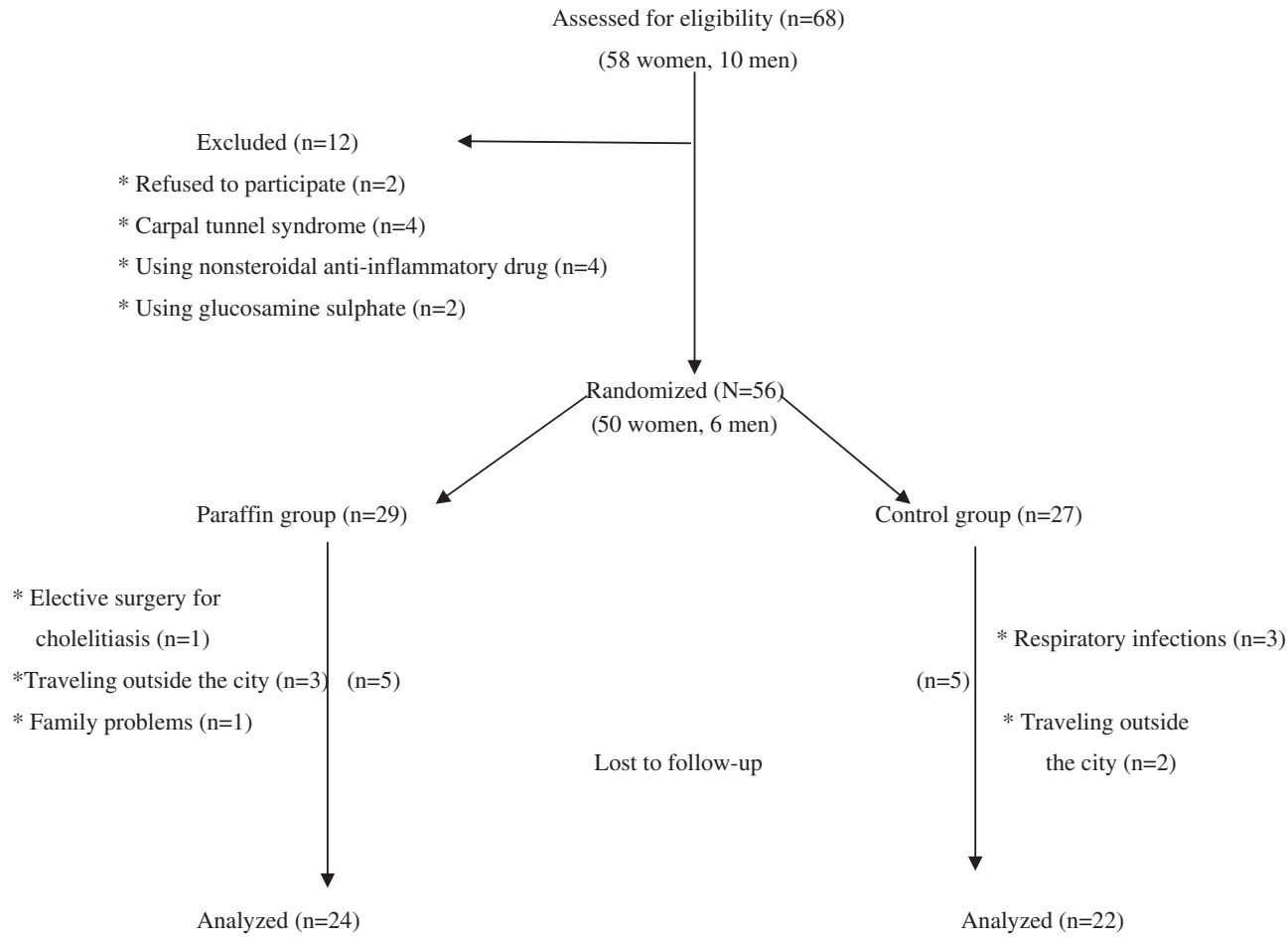

Fig 1 Flowchart of patients.

3 finger joints: metacarpophalangeal, proximal interphalangeal, and distal interphalangeal). The sums of finger-to-palm measurements of the fingers of both hands were recorded separately. Handgrip strength was measured with a JAMAR dynamometer,[a] and a pinchmeter[b] was used to determine the pinch strength of fingers in 3 different positions (lateral, chuck, and pulp-to-pulp pinch) of each hand. For grip and pinch strength measurements, 3 trials were conducted, and the average value was calculated. Patients were given a 1-minute rest period between each test. Both hands were assessed for painful and tender joints. A total number of painful and tender joint counts were recorded. Translated forms of the DFI and the AUSCAN were used for functional evaluation.[11-13] At weeks 3 and 12, total paracetamol intake (in grams) was calculated according to the patients' drug diaries.

All measures were recorded for both groups at baseline, 3 weeks, and 12 weeks by a researcher (M.G.) blind to group allocation.

Statistical analysis

Statistical evaluation was performed using SPSS 15.0.[c] Data were analyzed using Shapiro-Wilk tests to establish whether there was a normative distribution. Normally distributed data were expressed as means and SDs. For data that were not normally distributed, the median was used as the measure of central tendency, with variability expressed as the interquartile range. Analysis of variance in repeated measures and the Bonferroni test for pair-wise comparisons were used for normally distributed parameters (function and pain dimensions of the AUSCAN). The Friedman test was used for nonnormally distributed parameters (pain at rest and during ADL, distance between tip of fingers and the distal palmar crease of hand, pinch and grip-strength measurements, stiffness dimension of the AUSCAN, and DFI scores). Groups were compared for differences using the Mann-Whitney *U* test, and within-group differences were analyzed using the Wilcoxon signed-rank test for differences between baseline, 3 weeks, and 12 weeks. Comparisons of the measures were assessed with the Bonferroni correction in the Wilcoxon signed-rank test, and the significance level was set at $P<.016$ for these measures. For all other measures, the significance level was accepted as $P<.05$. All analyses were carried out by intention-to-treat analysis and per protocol. Both results are provided separately in the Results section. Per protocol analysis was conducted to demonstrate the effects of the intervention on those who adhered to the treatment. In the intention-to-treat analysis, the last observation carried forward method was used, in which the last observation obtained from a patient was substituted for all subsequent observations that were either missing or obtained after the patient was no longer considered to be evaluable.

A retrospective power analysis was also implemented. In the post hoc power analysis, performed using sample sizes, means, and SD values for the significance level (alpha) of .05, the power was calculated by statistical software, PASS.[d]

Table 1 Demographics of the groups

Demographics	Paraffin (n=24)	Control (n=22)	*P*
Age	58.87±9.47	59.95±8.71	.50
Body mass index (kg/m^2)	26.70±3.59	26.92±3.96	.84
Sex (female/male)	20/4	20/2	.44
Education level	11/13*	15/7*	.12
Symptom duration (mo)	64.42±57.19	67.60±55.85	.54
Heberden nodules (no.)	4.50±2.51	4.00±2.55	.41
Bouchard nodules (no.)	0.00±1.25	0.00±2.16	.19

NOTE. Values are mean ± SD or as otherwise indicated.
* Primary school and preprimary school/postprimary school.

Results

Sixty-eight patients met the inclusion criteria during their routine outpatient physical and radiologic examinations for hand osteoarthritis. After reviewing inclusion and exclusion criteria, 56 patients (50 women, 6 men) with bilateral hand osteoarthritis, and who had submitted written informed consent, were included in the trial. These patients were randomly allocated into intervention (n=29) or control (n=27) groups. Five patients in each group were lost at follow-up. Therefore, 46 patients completed the study (fig 1). During treatment, no complications were observed in the study groups.

Per protocol

The mean age ± SD was 58.9±9.4 years in the paraffin group and 59.9±8.7 years in the control group. Demographic characteristics of the groups are presented in table 1. There were no significant differences between groups in terms of age, body mass index, sex, symptom duration, education level, or Heberden and Bouchard nodules (see table 1). There were also no significant between-group differences at baseline in terms of pain at rest and during ADL, number of painful and tender joints, loss of ROM, grip and pinch strength, stiffness, function, and pain dimensions of the AUSCAN (tables 2–7) and the DFI ($P=1.00$). There were no significant differences between groups in terms of drug intake at 3 weeks ($P=.73$) and 12 weeks ($P=.42$). The dominant hand of all patients was right; therefore, dominant and nondominant hand differences were not compared.

Within-group differences in the paraffin group were significant in terms of the primary outcomes, pain at rest and pain during ADL ($P<.001$ and $P<.001$, respectively) (see table 2) at 12 weeks. However, within-group differences in the control group were not significant in terms of the primary outcomes, pain at rest and pain during ADL ($P=.74$ and $P=.06$, respectively) (see table 2). As for secondary outcomes, there was a significant decrease in terms of the pain ($P<.001$) and stiffness ($P=.002$) dimensions of the AUSCAN and loss of ROM of the right hand ($P=.03$) in the paraffin group (see tables 3–4). There were no significant differences in terms of the DFI ($P=.84$) and the functional dimension of the AUSCAN ($P=.13$). In addition, there were no significant differences in terms of hand-grip (see table 5) and pinch strength (see table 6) in the paraffin group. Within-group differences in the control group were only significant at 12-weeks follow-up when there was deterioration in right hand grip (see table 5), bilateral lateral pinch, and right chuck pinch strength (see table 6).

When the 2 groups were compared, pain at rest at 3 and 12 weeks significantly improved in the paraffin group ($P=.01$ and $P=.003$, respectively), while there was no difference in pain during ADL ($P=.07$ and $P=.09$, respectively) (see table 2). In addition, when compared with the control group, the numbers of painful and tender joints at 12 weeks decreased significantly in the paraffin group ($P=.01$ and $P=.02$, respectively) (see table 7). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks (see tables 5–6). Differences between the paraffin and control groups in other parameters, such as the dimensions of the AUSCAN, loss of ROM (see tables 3–4), and the DFI ($P=.29$ and $P=.05$, respectively), were not significant. Although there were no statistically significant differences between the 2 groups as regards hand function, pain during ADL, and loss of ROM measurements, there was a tendency toward improvement in the paraffin group.

Intention to treat

In the intention-to-treat analysis, the significance of the results did not differ from the per protocol analysis for the primary outcomes. The *P* values are provided in tables 2 through 7.

Table 2 Pain scores of groups

Pain (VAS)	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa* Int
At rest					
Beginning	5.00 (4.00–5.00)	*Pd*<.001†	4.00 (3.00–8.00)	*Pd*=.74	.703/.740
3wk	2.00 (0.00–4.00) *Pb**, *Pb*-int*	*Pd*-int<.001†	4.00 (3.00–5.00)	*Pd*-int=.98	.010‡/.010‡
12wk	0.00 (0.00–3.00) *Pc**, *Pc*-int*		5.00 (1.00–6.00)		.003‡/<.001‡
During ADL					
Beginning	7.00 (7.00–9.00)	*Pd*<.001†	8.00 (6.00–8.00)	*Pd*=.06	.880/.840
3wk	5.00 (3.00–6.00) *Pb**, *Pb*-int*	*Pd*-int<.001†	7.00 (5.00–8.00)	*Pd*-int=.07	.070/.030‡
12wk	5.00 (3.00–6.50) *Pc**, *Pc*-int*		7.00 (5.00–8.00)		.090/.050

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pb*, within-group difference between baseline and 3 weeks; *Pc*, within-group difference between baseline and 12 weeks; *Pd*, the differences of measurements within groups.
* In the *Pb* and *Pc* groups, Wilcoxon signed rank test, $P<.016$, significant value.
† In the *Pd* group, Friedman test, $P<.05$, significant value.
‡ In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value.

Table 3 AUSCAN scores in groups

Dimensions of AUSCAN	Paraffin Group (n=24)		Control Group (n=22)		*Pa*/*Pa*-Int
Stiffness	Median (25%–75%)		Median (25%–75%)		
Beginning	2.00 (1.00–2.00)	*Pd*=.002†	2.00 (0.00–3.00)	*Pd*=.58	.82/.95
3wk	1.00 (1.00–2.00) *Pb**, *Pb*-int*	*Pd*-int=.001†	1.00 (0.00–2.00)	*Pd*-int=.28	.78/.58
12wk	1.00 (0.00–2.00) *Pc**, *Pc*-int*		1.00 (0.00–2.00)		.50/.34
Pain	Mean ± SD		Mean ± SD		
Beginning	10.65±3.25	*Pe*<.001†	9.78±5.69	*Pe*=.64	.42/.47
3wk	7.73±4.66 *Pb**, *Pb*-int*	*Pe*-int<.001†	8.89±5.11	*Pe*-int=.57	.53/.57
12wk	6.47±3.98 *Pc**, *Pc*-int*		9.52±4.97		.05/.07
Function					*Pf*/*Pf*-int
Beginning	16.17±6.69		17.10±9.21	*Pe*=.13	.37/.50
3wk	14.52±7.05		15.44±7.99	*Pe*-int=.07	
12wk	13.82±7.04		17.84±8.44		

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups (Mann-Whitney *U* test); *Pb*, within-group difference between baseline and 3 weeks; *Pc*, within-group difference between baseline and 12 weeks; *Pd*, differences of measurements within groups; *Pe*, differences of measurements within groups; *Pf*, difference between groups (analysis of variance).

* In the *Pb* and *Pc* groups, Wilcoxon signed rank test, $P<.016$, significant value.

† In the *Pd* group, Friedman test, $P<.05$, significant value. In the *Pe* group, analysis of variance, $P<.05$, significant value.

In the post hoc power analysis, performed using sample sizes, means, and SD values for the significance level (alpha) .05, the power was found to be 89.7% for pain at rest. However, the power was below 50% for the functional dimension of the AUSCAN, the DFI, and pain during ADL.

Discussion

In this study, paraffin bath therapy reduced pain and tenderness and alleviated the pain and stiffness dimensions based on the AUSCAN in patients with hand osteoarthritis at 12 weeks, but it had no statistically significant effect on function. Local heat applications are frequently used in therapy for hand osteoarthritis and are often combined with other treatments.[4] This study is the first, to the best of our knowledge, single-blinded RCT evaluating the efficacy of paraffin bath therapy in hand osteoarthritis.

Most available therapeutic heating modalities demonstrate their effectiveness by producing analgesia, hyperemia, changes in local or systemic temperature, and reduced muscle tone. The therapeutic effects derived from these physiological responses are relief of pain, reduction of muscle spasm, and increased metabolism.[7,8,14] A pilot study[15] of the use of paraffin bath therapy in patients with systemic sclerosis showed that hand exercises in combination with paraffin baths seemed to improve mobility, perceived stiffness, and skin elasticity. In addition, even though the symptoms of hand osteoarthritis are not as severe as in systemic sclerosis, on the completion of the paraffin bath therapy in our study, we observed significant improvement regarding the regaining of motion, reduction of pain, and tenderness of hand joints. The loss of ROM in left hands in both groups was less than in right hands. This may be attributed to hand dominancy. In general, right hands are used more than left, and this may therefore cause more pain and loss of ROM in the right hand. Similarly, Dellhag et al[16] reported that a combination of paraffin bath therapy and exercise was more effective than exercise alone for treating rheumatoid arthritis. They found better improvement of grip function and ROM in the group undergoing paraffin bath therapy followed by active hand exercise, but paraffin wax alone had no significant effect. The loss of function and loss of strength in rheumatoid arthritis are more prominent than in osteoarthritis.[2,17,18] Despite the fact that we observed improvements in the reduction of pain and the regaining of motion, we did not notice any statistically significant improvement of function in the paraffin group. This result could be attributed to the power of the study. Our study was not powerful enough to detect the differences in functional dimension of the AUSCAN and the DFI. Nevertheless, there was an obvious tendency toward improvement of hand function in the paraffin group. Further studies with

Table 4 Loss of ROM in groups*

Loss of ROM	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa*-Int
Right hand					
Beginning	60.00 (37.50–90.00)	*Pd*=.03†	45.00 (22.50–96.25)	*Pd*=.51	0.75/0.53
3wk	27.50 (12.50–38.75)	*Pd*-int=.01†	30.00 (7.50–87.50)	*Pd*-int=.36	0.53/0.45
12wk	25.00 (2.50–55.00)		20.00 (0.00–80.00)		1.00/0.44
Left hand					
Beginning	15.00 (2.50–35.00)	*Pd*=.20	20.00 (0.00–82.50)	*Pd*=.75	0.75/0.58
3wk	0.00 (0.00–7.50)	*Pd*-int=.09	10.00 (0.00–90.00)	*Pd*-int=.95	0.20/0.10
12wk	5.00 (0.00–40.00)		17.50 (0.00–50.00)		0.91/0.24

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pd*, differences of measurements within groups.

* Measured by the distance between tip of fingers and distal palmar crease (mm).

† In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value. In the *Pd* group, Friedman test, $P<.05$, significant value.

Table 5 Hand-grip strength of groups (kg)

Grip Strength (kg)	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		Pa/Pa-Int
Right hand					
Beginning	18.00 (14.66–24.66)	Pd=.34	16.66 (11.33–22.66)	Pd=.009†	.270/.380
3wk	18.00 (15.33–22.66)	Pd-int=.43	16.00 (12.60–20.66)	Pd-int=.004†	.070/.110
12wk	20.00 (14.66–23.33)		13.33 (10.00–18.66) Pc-int*		.010‡/.004‡
Left hand					
Beginning	18.00 (14.00–21.33)	Pd=.11	15.33 (12.66–21.00)	Pd=.050	.360/.460
3wk	17.33 (15.00–22.00)	Pd-int=.18	16.66 (12.00–20.66)	Pd-int=.080	.130/.190
12wk	18.00 (14.66–22.00)		12.00 (9.33–18.00)		.010‡/.010‡

Abbreviations: int, intention-to-treat analysis; Pa, difference between groups; Pc, within-group difference between baseline and 12 weeks; Pd, differences of measurements within groups.

* In the Pc group, Wilcoxon signed rank test, $P<.016$, significant value.

† In the Pd group, Friedman test, $P<.05$, significant value.

‡ In the Pa group, Mann Whitney U test, $P<.05$, significant value.

a larger sample size are needed to analyze the effect of paraffin bath therapy on function.

The severity of functional impairment in hand osteoarthritis reported in the literature is equivocal. One controlled study pinpointed only minor global impairment of ADL in patients with erosive osteoarthritis compared with patients with nodular osteoarthritis.[19] In another study of 522 subjects, hand osteoarthritis accounted for only 5% to 7% of the variation in function, grip strength, and pain, and the association with function and grip strength seemed to be mediated by pain.[20] In the present study, we found significant deterioration in terms of right hand grip, bilateral lateral pinch, and right chuck pinch strength in our control group, whereas these strengths were maintained in the paraffin group. Both groups were provided information not only concerning the disease, but also about joint protection techniques to be used during daily activities. They were also asked to avoid forceful gripping activities that caused pain. The strength decrease in the control group may be related to limited use of

Table 6 Pinch strength of groups (kg)

Pinch Strength (kg)		Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		Pa/Pa-Int
Right hand	Pulp-to-pulp pinch					
	Beginning	3.33 (2.33–4.00)	Pd= .23	3.50 (3.16–4.66)	Pd=.160	.32/.36
	3wk	3.66 (2.66–4.50)	Pd-int=.15	3.66 (2.33–4.33)	Pd-int=.120	.20/.23
	12wk	3.33 (2.83–4.50)		3.33 (2.33–4.16)		.82/.43
	Chuck pinch					
	Beginning	4.33 (3.50–5.50)	Pd=.62	5.16 (3.83–6.33)	Pd=.003†	.54/.68
	3wk	4.50 (3.66–6.00)	Pd-int=.48	4.33 (3.00–5.83) Pb-int*	Pd-int=.003†	.20/.23
	12wk	5.33 (3.33–6.33)		3.66 (2.66–5.33) Pc-int*		.10/.03‡
	Lateral pinch					
	Beginning	5.00 (4.50–6.16)	Pd=.76	6.00 (5.16–6.83)	Pd=.010†	.44/.48
	3wk	5.66 (4.83–7.00)	Pd-int=.63	5.33 (3.83–7.00)	Pd-int=.003†	.09/.10
	12wk	6.00 (4.66–7.00)		4.33 (3.83–6.16) Pc-int*		.07/.01‡
Left hand	Pulp-to-pulp pinch					
	Beginning	3.50 (2.66–4.00)	Pd=.09	3.66 (2.66–4.33)	Pd=.230	.99/.99
	3wk	3.16 (2.66–4.16)	Pd-int=.09	3.16 (2.33–4.33)	Pd-int=.090	.34/.40
	12wk	3.66 (2.66–4.50)		3.00 (2.50–3.66)		.11/.08
	Chuck pinch					
	Beginning	4.66 (3.33–6.00)	Pd=.61	4.83 (3.50–5.16)	Pd=.120	.69/.63
	3wk	4.33 (3.83–5.50)	Pd-int=.47	4.50 (3.00–5.66)	Pd-int=.030†	.24/.20
	12wk	4.83 (3.50–6.16)		3.66 (2.60–5.00) Pc-int*		.03‡/.01‡
	Lateral pinch					
	Beginning	5.00 (4.66–5.83)	Pd=.59	5.66 (4.50–6.33)	Pd=.020†	.75/.42
	3wk	5.33 (4.50–7.16)	Pd-int=.46	5.50 (3.83–6.33)	Pd-int=.010†	.27/.56
	12wk	5.16 (4.83–6.33)		4.33 (3.50–5.66) Pc-int*		.02‡/.05

Abbreviations: int, intention-to-treat analysis; Pa, difference between groups; Pb, within-group difference between baseline and 3 weeks; Pc, within-group difference between baseline and 12 weeks; Pd, differences of measurements within groups.

* In the Pb and Pc groups, Wilcoxon signed rank test, $P<.016$, significant value.

† In the Pd group, Friedman test, $P<.05$, significant value.

‡ In the Pa group, Mann Whitney U test, $P<.05$, significant value.

Table 7 Number of painful and tender joints in groups

Joint Counts	Paraffin Group (n=24) Median (25%–75%)		Control Group (n=22) Median (25%–75%)		*Pa*/*Pa*-Int
Painful joint					
Beginning	8.00 (6.00–12.00)	*Pd*=.07	8.00 (8.00–16.00)	*Pd*=.36	.32/.88
3wk	4.00 (3.00–9.00) *Pb*-int*	*Pd*-int=.04†	8.00 (4.00–12.00)	*Pd*-int=.35	.05/.28
12wk	3.00 (2.00–9.00)		10.00 (6.00–16.00)		.01‡/.04‡
Tender joint					
Beginning	8.00 (4.00–13.00)	*Pd*=.49	7.00 (5.00–14.00)	*Pd*=.94	.62/.85
3wk	8.00 (3.00–10.00)	*Pd*-int=.65	8.00 (6.00–18.00)	*Pd*-int=.54	.12/.15
12wk	6.00 (4.00–9.00)		8.00 (6.00–14.00)		.02‡/.20

Abbreviations: int, intention-to-treat analysis; *Pa*, difference between groups; *Pb*, within-group difference between baseline and 3 weeks; *Pd*, differences of measurements within groups.

* In the *Pb* group, Wilcoxon signed rank test, $P<.016$, significant value.

† In the *Pd* group, Friedman test, $P<.05$, significant value.

‡ In the *Pa* group, Mann Whitney *U* test, $P<.05$, significant value.

their hands because of pain. The fact that patients tended to protect their hands by decreasing muscle activity or avoiding forceful activities might have caused the strength loss in dynamometric assessment.

Recently, in a randomized study, Myrer et al[7] compared treatment with paraffin bath and paraffin bath combined with topical analgesic for patients with symptomatic hand osteoarthritis. Results indicated that both treatments produced immediate posttreatment relief of pain, albeit not to a great extent. After 12 treatments, the researchers concluded that the addition of topical analgesic to the paraffin bath produced significantly greater pain relief at rest and during movement and greater improved function than paraffin baths alone[7]; however, their study did not include a control group. In our RCT, we found that paraffin bath therapy, without the addition of topical analgesic, did reduce pain, but had no statistically significant effect on hand function when compared with the control group. We had anticipated a medium-sized effect, but we observed that the improvement was not as significant as we had initially expected.

Paraffin bath therapy is usually applied by an immersion or dipping method, with the latter being easier and more common.[14] In our study, we used dipping: both hands were slowly dipped 10 times into a 50°C wax bath, and were later wrapped in a plastic bag and then a towel, in which they were kept for 15 minutes. There are no existing data about the optimal number of treatment sessions or the application frequency of paraffin bath therapy. Paraffin applications may be applied 3 or 5 times a week.[8,15,16] In our daily practice, we applied this treatment 5 times a week; meanwhile, our patients attended outpatient physical therapy sessions and did their exercises diligently after applying superficial heat modalities, according to the recommendations of EULAR.[4]

Therefore, during the study, we conducted paraffin bath applications 5 times a week, just like we do in our normative daily practice. Other than the patients who we lost contact with at follow-up, all of the patients were compliant with the therapy sessions. Although this adherence to therapy is a definite strength of our study, such a high level of adherence may be unusual in the daily clinical practice of physical therapy. Future research may also establish the optimal number of treatment sessions for paraffin bath therapy.

There were not many patients lost at follow-up during the study period. Also, there was no remarkable difference between intention-to-treat and per protocol analyses, which suggests that those lost at follow-up were random in each group.

Study limitations

One of the major limitations of our study was the sample size. Although we calculated the sample size at the beginning of the study, we could not attain the estimated sample size within the time frame of the study because of changes in the Turkish health care system. As a result of the changes, fewer patients were referred to our hospital, and therefore the estimated sample size could not be attained. Another major limitation was the power of the study. Although our study seemed to be sufficiently powerful to detect the differences in our primary outcome, which was pain, it was not powerful enough to detect the differences in functional dimension of the AUSCAN and the DFI. The lack of a placebo or sham control group was another limitation. It is obvious that evaluating the efficacy of paraffin bath therapy is problematic in a double-blinded controlled design. In addition, the disproportional distribution of sex limited the generalization of the results. However, the fact that this was a single-blinded, randomized, controlled study with a low lost to follow-up rate enables this work to provide an ideal platform on which to build a larger scale trial. This study also provides some evidence for paraffin bath treatments, which are a routine procedure in many rehabilitation clinics.

Conclusions

Paraffin bath therapy seems to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. This method may be regarded as a beneficial short-term therapy option, which is effective for a 12-week duration. Further randomized studies with larger sample sizes are warranted to confirm the results and to evaluate the effects of paraffin bath therapy on function in hand osteoarthritis.

Suppliers

a. Sammons Preston, 1000 Remington Blvd, Bolingbrook, IL 60440.

b. Baseline, Trent Building, South Buckout St, Irvington, NY 10533.
c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.
d. NCSS LLC, 329 North 1000 East, Kaysville, UT 84037.

Keywords

Hand; Osteoarthritis; Pain; Rehabilitation

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[Intervention Review]

Mechanical traction for neck pain with or without radiculopathy

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ABSTRACT

Background

Neck pain is a frequently reported complaint of the musculoskeletal system which can be disabling and costly to society. Mechanical traction is often used as an adjunct therapy in outpatient rehabilitation.

Objectives

To assess the effects of mechanical traction for neck disorders.

Search strategy

A research librarian searched computerized bibliographic databases without language restrictions up to March 2008 for randomized controlled trials (RCTs) from the medical, chiropractic, and allied health literature.

Selection criteria

The RCTs we selected examined adults with neck disorders who received mechanical traction alone or in combination with other treatments compared to a placebo or another treatment. Our outcomes of interest were pain, function, disability, global perceived effect, patient satisfaction, and quality of life measures.

Data collection and analysis

Two review authors with different backgrounds in medicine, physiotherapy, massage therapy and chiropractics independently conducted study selection, risk of bias assessment and data abstraction using pre-piloted forms. We resolved disagreement through consensus.

Main results

Of the seven selected RCTs (total participants = 958), only one (N = 100) had a low risk of bias. It found no statistically significant difference (SMD -0.16: 95%CI: -0.59 to 0.27) between continuous traction and placebo traction in reducing pain or improving function for chronic neck disorders with radicular symptoms. Our review found no evidence from RCTs with a low potential for bias that clearly supports or refutes the use of either continuous or intermittent traction for neck disorders.

Authors' conclusions

The current literature does not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived effect when compared to placebo traction, tablet or heat or other conservative treatments in patients with chronic neck disorders. Large, well conducted RCTs are needed to first determine the efficacy of traction, then the effectiveness, for individuals with neck disorders with radicular symptoms.

PLAIN LANGUAGE SUMMARY

Mechanical traction for neck pain with or without symptoms that radiate to the neck or arm

Twenty-six to 71% of the adult population can recall experiencing an episode of neck pain or stiffness in their lifetime. Neck pain is more common in females than in males, with rates reported as high as 77.8%. The natural history is unclear. Neck pain has a costly impact on society because of visits to healthcare providers, sick leave, disability and loss of productivity. There are a number of treatments available for neck pain, one of which is mechanical traction.

Mechanical traction 'stretches' the neck. With the patient lying on their back, a head halter is placed under the back of the head and possibly the jaw and attached to a machine. The machine is set for a certain time period and specific weight for the pulling action to occur. The traction can remain on steadily for the specified time (referred to as continuous or static) or intermittently (on/off cycle) during the treatment session. Experts think that traction expands the space between the vertebrae, increases the movement of the joints and stretches the muscles and ligaments around the vertebrae. Side effects are generally few, but can include headache, nausea, fainting and injury to tissue.

We included seven randomized controlled trials (RCT), with a total of 958 participants, that looked at the effects of continuous or intermittent mechanical traction for individuals with chronic neck pain (lasting for more than three months). Some had symptoms that radiated into the arms and head (radicular symptoms), others did not.

Only one RCT (100 participants) had a low risk of bias, which means we can have confidence in the findings. This trial found that on average, there was no statistically significant difference between continuous and placebo traction in reducing pain or improving function for individuals with chronic neck disorder with radicular symptoms.

In summary, our review found no evidence from RCTs with a low potential for bias that clearly supports or refutes the use of either continuous or intermittent traction for individuals with chronic neck disorders.

BACKGROUND

Neck pain is a frequently reported complaint of the musculoskeletal system which can be disabling and costly to society. The natural history of neck pain is unclear. Twenty-six to 71% of the adult population can recall experiencing an episode of neck pain or stiffness in their lifetime (Cote 1998; Makela 1991). Prevalence of neck pain is higher in females than in males with rates as high as 77.8% (Chiu 2006; Fejer 2006; Guez 2006). A U.S. study from the National Ambulatory Medical Care Survey reported an average of 10.2 million visits to healthcare facilities for neck pain (Riddle 2007). Neck pain has a large impact on health care expenditure, attributed to visits to health care providers, sick leave, disability and the related loss of productivity (Borghouts 1999; Hoving 2001).

Mechanical traction for the cervical spine involves a pulling force

Implantable Cardiac Event Monitors

Question: Should implantable cardiac event monitors be a covered service?

Question source: Tracy Muday, MD, OHP Medical Director

Issue: Implantable cardiac event monitors (CPT 33282 and HCPCS C1764) are currently Excluded. Dr. Muday received a request for placement of this device for evaluation of cryptogenic stroke. The HSC reviewed this device in 2000 and placed it on the Excluded List; the rationale and documentation for this decision is not available. The minutes note that this decision was made with the input of specialty groups familiar with the procedure. This device has not been reviewed since 2000.

An insertable cardiac monitor, also referred to as an implantable loop recorder (ILR), is a small insertable device that continuously monitors heart rhythms and records them either automatically or when a hand-held patient assistant is used. Unlike Holter monitors (monitor for 1-7 days) or external cardiac loop recorders (monitor for 3-4 weeks), the ILR's record for about 3 years. They are most commonly used to evaluate fainting spells/transient loss of consciousness that remain unexplained after initial evaluation. ILRs are also used for evaluation of seizures, recurrent palpitations, lightheadedness and dizziness.

Cryptogenic ischemic stroke, one in which the origin of the emboli cannot be determined after full evaluation (e.g. ECG, 24 hours of telemetry, echocardiogram, carotid ultrasound), make up nearly a quarter of all ischemic strokes. There is growing interest in the use of ICLRs to identify occult paroxysmal atrial fibrillation in patients with cryptogenic stroke (MED 2015).

Code	Code description	Placement
33282	Implantation of patient-activated cardiac event recorder	Services recommended for non-coverage table
33284	Removal of an implantable, patient-activated cardiac event recorder	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
C1764	Event recorder, cardiac (implantable)	Ancillary

Evidence

1) **MED 2015**, Implantable Loop Recorders for the Evaluation of Cryptogenic Stroke
    a. There is no high-quality comparative evidence on the use of implantable cardiac loop records or other ambulatory monitoring modalities on the initiation of oral anticoagulation or stroke recurrence in patients diagnosed with occult atrial fibrillation.
    b. In the past two years, four systematic reviews found increased detection of occult atrial fibrillation by ILCRs compared to other ambulatory monitoring efforts. However, these reviews do not report on change in management nor impact on stroke recurrence (Afzal et al., 2015; Dussault et al., 2015; Kishore et

al., 2014; Sposato et al., 2015). None of the systematic reviews identified head-to-head comparative trials of different ICLR devices or extended monitoring devices. The limited data available for inclusion in the reviews were based on observational trials with short follow up periods.

c. In a small, poor-quality cohort study of 61 patients receiving ICLRs, all received weeklong serial ECGs as well. The authors reported that within the first week of use, ILCR compared to serial ECG detected cases of intermittent atrial fibrillation at a 3:1 ratio. The authors did not discuss the potential clinical significance of this finding. This study did not observe any recurrent stroke or TIAs in their short follow-up period.
d. In a fair-quality, industry funded, RCT of 441 patients, higher rates of stroke and lower use of oral anticoagulation were observed in those randomized to conventional monitoring compared to ICLRs (i.e. baseline and serial ECGs every 6 months, thus not meeting strict inclusion criteria). At 6-and 12-months follow-up, the ICM group compared to controls had statistically significantly higher percentages of participants that received anticoagulation (6 months: 10.1% vs. 4.6%, P=0.04 and 12 months: 14.7% vs. 6.0%, P=0.007).
e. Among the included studies, adverse events were rare and included site infection, pocket erosion, pain, and irritation. A single patient experienced device failure from sub-optimal placement preventing rhythm detection.
f. Summary: Patients with ischemic stroke found to have atrial fibrillation on initial evaluation experience decreased risk of recurrent stroke with the use of oral anticoagulation therapy. In patients with cryptogenic stroke, despite an extensive initial evaluation without detection of atrial fibrillation, the use of prolonged monitoring demonstrates increased detection of paroxysmal or occult atrial fibrillation. The current literature is limited on the impact of the detection of occult atrial fibrillation through prolonged monitoring and subsequent initiation of anticoagulation on stroke recurrence. Clinicians and researchers are advocating for more comparative research to be conducted on ICLRs and their use in cryptogenic stroke, as well as the clinical impact of detecting occult atrial fibrillation in those with cryptogenic stroke.

2) **Parry 2010**, review of ILR for evaluation of unexplained syncope
   a. Conclusion: The ILR has entered routine clinical practice over the last 15 years with surprisingly few rigorous data. In this era of evidence-based practice, this requires to be addressed with a focus on high quality trials of up-to-the minute technology. In the interim, the ILR offers a useful adjunct in the investigation of unexplained syncope, particularly where an arrhythmic cause is suspected. Further controlled data are required to inform clinical practice with attention focused on empowering ILR-guided diagnosis, establishing the optimal timing of ILR use in syncope and embracing new technological advancements

<u>Expert groups</u>

1) **European Society of Cardiology 2009**, (http://europace.oxfordjournals.org/content/11/5/671 study not included in packet due to length) ILR position statement
    a. For management of transient loss of consciousness (TLoC)
        i. Class I. ILR is indicated:
            1. In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:
                a. absence of high-risk criteria that require immediate hospitalization or intensive evaluation and
                b. a likely recurrence within battery longevity of the device (Level of evidence A)
            2. In high-risk patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to specific treatment (Level of evidence B)
        ii. Class II A. ILR may be indicated:
            1. To assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes (Level of evidence B)
        iii. Class II B. ILR may be indicated:
            1. In patients with T-LOC of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism (Level of evidence C)
    b. For diagnosis of undocumented palpitations
        i. Class IIA: ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause (Level of evidence B). The outcome of asymptomatic arrhythmias remains uncertain.
    c. For diagnosis of atrial fibrillation
        i. Continuous monitoring by implantable devices further increases the detection of AF, but it is hampered by misdetections and artefacts.
        ii. Technological improvements are required for significant reduction of maldetection. Manual analysis can improve diagnostic yield if stored electrograms are provided. The results of some on-going studies with new generation devices are awaited
        iii. The clinical relevance of Loop Recorders to guide medical and device therapy has yet to be demonstrated
    d. For risk stratification after MI
        i. The clinical usefulness of ILR to guide medical and device therapy in patients surviving myocardial infarction has yet to be demonstrated
        ii. ILRs have a potential role in identifying the correlation between symptoms and suspected ventricular tachyarrhythmia in selected high-risk patients affected by Brugada ECG pattern, long or short QT, hypertrophic cardiomyopathy, and arrhythmogenic right ventricular dysplasia.

Other policies

1) **NICE 2010** http://guidance.nice.org.uk/cg109 (Study not included in packet due to length)
    - **a.** For evaluation of transient loss of consciousness (TLoC) in adults: For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC. For people who have TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder.
2) **Aetna 2015 (not included due to length**
   http://www.aetna.com/cpb/medical/data/1_99/0073.html
    a. Aetna considers an implantable loop recorder (e.g., Reveal Insertable Loop Recorder by Medtronic, Inc.) medically necessary for evaluation of recurrent unexplained episodes of pre-syncope, syncope, "seizures", palpitations, or dizziness when both of the following criteria are met:
        i. A cardiac arrhythmia is suspected as the cause of the symptoms; *and*
        ii. Either of the following criteria is met:
            1. For persons with heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), noninvasive ambulatory monitoring, consisting of 30-day presymptom external loop recordings or MCT, fails to establish a definitive diagnosis; *or*
            2. For persons without heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), symptoms occur so infrequently and unpredictably (less frequently than once per month) that noninvasive ambulatory monitoring (MCT or external loop recorders) are unlikely to capture a diagnostic ECG.
    b. Aetna considers implantable loop recorders experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.
3) **Cigna 2015 (not included due to length)**
   http://s-rm3.cigna.com/assets/docs/health-care-professionals/coverage_positions/mm_0085_coveragepositioncriteria_cardiac_event_monitors.pdf
    a. Cigna covers the use of an implantable loop recorder (CPT codes 33282, 33284, 93285, 93291, 93297, 93298, 93299, C1764, E0616) as medically necessary for the evaluation of recurrent unexplained episodes of fainting when ALL of the following criteria are met:
        i. cardiac arrhythmia is suspected to be the cause of fainting
        ii. noninvasive ambulatory monitoring failed to establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the length of the monitoring period may have been inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder

iii. tilt-table testing is negative or nondiagnostic

HERC staff summary:
The use of implantable loop recorders (ILRs) appears to have evidence to support and expert recommendations for use for evaluation of recurrent transient loss of consciousness in patients in whom a comprehensive evaluation including noninvasive ambulatory monitoring did not demonstrate a cause of the TLoC or lead to specific treatment, and in whom a cardiac cause is suspected, and in whom an event is expected to recur within the battery life of the ILR.

The use of ILRs for evaluation for possible atrial fibrillation as the cause of cryptogenic stroke appears to be an area of active research and controversy.

HERC staff recommendations:

1) Add coverage for the use of implantable loop recorders (ILRs) for the evaluation of recurrent transient loss of consciousness in selected patients. Do not add coverage for other indications due to their experimental nature
    a. Advise HSD to add CPT 33282 (Implantation of patient-activated cardiac event recorder) to the Diagnostic Procedures File and remove from the Services Recommended for Non-Coverage Table
    b. Advise HSD to add HCPCS C1764 (Event recorder, cardiac (implantable)) to the Diagnostic Procedures File and remove from the Ancillary List
    c. Adopt the following Diagnostic Guideline Note

DIAGNOSTIC GUIDELINE DX, IMPLANTABLE LOOP RECORDERS
Use of an implantable cardiac loop recorder (ILR) is a covered service only when the patient meets all of the following criteria:

1) The evaluation is for recurrent transient loss of consciousness (TLoC); and
2) A comprehensive evaluation including noninvasive ambulatory cardiac monitoring did not demonstrate a cause of the TLoC; and
3) A cardiac arrhythmia is suspected to be the cause of the TLoC; and
4) There is a likely recurrence of the TLoC within the battery longevity of the device.

ILRs are not a covered service for evaluation of cryptogenic stroke or any other indication.

Implantable loop recorders in the investigation of unexplained syncope: a state of the art review

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ABSTRACT

Since its introduction 15 years ago, the implantable loop recorder (ILR) has become the investigative tool of choice in recurrent unexplained syncope following negative initial investigations. This is based on very few randomised controlled clinical trials and modestly sized observational studies. Further controlled data are required to inform clinical practice with attention focused on empowering ILR-guided diagnosis, establishing the optimal timing of ILR use in syncope and embracing new technological advancements.

INTRODUCTION

Syncope accounts for 1–6% of emergency attendances and 0.6–1.0% of hospital admissions.[1] The 10-year cumulative incidence of syncope in the Framingham study was 6% with increasing burden in tandem with advancing years.[2] The majority of cases are neurally-mediated in origin, but syncope is a common presentation of cardiac rhythm disturbance. The sporadic nature of presentation makes syncope a logical target for prolonged cardiac rhythm monitoring.

The implantable loop recorder (ILR) is a device implanted in the subcutaneous tissue of the left hemithorax under local anaesthetic. The ILR records a high fidelity bipolar ECG signal stored as a loop, frozen at the time of symptoms using a handheld activator. Newer devices have programmable automatic recognition (typically >160 beats/min, <30 beats/min or pauses >3 s).

The majority of clinical studies involving the ILR have focused on the investigation of recurrent unexplained syncope or neurally-mediated syncope. We reviewed the English language scientific literature by searching MEDLINE from 1966 through January 2009 using the PubMed interface under the terms syncope [MeSH] OR neurally mediated syncope [MeSH] AND ILR. The reference lists from articles identified by this search were also reviewed for relevant publications. A total of 139 articles were identified, with those representing the strongest evidence included in our review which confines itself to the adult population and the key evidence concerning ILR use in these contexts. Gaps in the evidence base will be highlighted and suggestions for future research proposed.

RECURRENT SYNCOPE

The initial clinical experience with the ILR was in a population of highly symptomatic patients with recurrent unexplained syncope.[3] Sixteen patients with a mean of 8.4±4.4 episodes of previous syncope, all with negative ambulatory monitoring, tilt table testing and electrophysiological (EP) study, underwent device implantation. Fifteen of the 16 patients (94%) had recurrent syncope during follow-up (13±8.4 months). A diagnosis was obtained in all 15 patients with symptom-rhythm correlation possible in 9 of them (60%). Treatment was instituted in all 15 with no recurrence of syncope by study termination.

This initial success paved the way for further work[4–31] in using the ILR as part of the diagnostic strategy in recurrent unexplained syncope (table 1). The considerable majority of these studies are observational, small and/or retrospective. While conclusions drawn from them individually are tempered by the inherent flaws of this study design, collectively they form a limited but persuasive evidence base to justify the clinical use of the ILR in recurrent unexplained syncope.

Randomised controlled trials

Clinical effectiveness

Only two randomised trials studies involving ILRs have been undertaken, both of which compared the role of the ILR with a conventional testing strategy. The Randomised Assessment of Syncope Trial (RAST)[6] involved 60 consecutive patients attending a specialist syncope service with recurrent unexplained syncope or a single episode of syncope with injury warranting cardiovascular investigation. At baseline all 60 patients had a negative initial evaluation similar to that recommended by the European Society of Cardiology guidelines on the management of syncope,[32] in common with the remainder of the ILR studies. An ILR was implanted in 30 patients; the remainder underwent prolonged external monitoring, tilt table testing and EP study. If the allocated strategy did not provide a diagnosis, patients were offered crossover to the alternative arm. A diagnosis was established in 14 patients in the ILR arm compared with 6 patients in the conventional arm (52% vs 20%, p=0.012). Six patients in the ILR group and 21 in the conventional testing group crossed over. Overall, when combining the primary strategy with crossover, a diagnosis was established in 55% with a prolonged monitoring strategy compared with 19% with conventional testing (p=0.0014).

The other randomised study is the Eastbourne Syncope Assessment Study (EaSyAS).[27] Two hundred and one unselected patients presenting to a single institution with recurrent syncope without a definite diagnosis following initial clinical investigation were randomly assigned to ILR implantation (n=103) or conventional investigation and management (n=98). There were further syncopal events in 43 (43%) of the ILR group compared with

Electric Tumor Treatment Fields for Glioblastoma

Question: Should electric tumor treatment field therapy be covered for initial treatment of glioblastoma?

Question source: Andy Luther, MD, OHP medical director

Issue: Electric tumor treatment field therapy (ETTF) involves a portable device which delivers low-intensity, intermediate frequency electric fields via non-invasive, transducer arrays. It is thought to physically interfere with tumor cell division. Glioblastoma is a very difficult to treat cancer of the brain with a typical life expectancy with current therapy of 1-2 years. Standard treatment involves surgical resection, radiation therapy, and chemotherapy.

ETTF therapy was reviewed for treatment of recurrent glioblastoma in May, 2014. At that time, little evidence was found to support its effectiveness and it was found to be less cost effective than conventional therapy for recurrent glioblastoma. The HCPCS codes for this therapy (HCPCS A4555 and E0766) were placed on the Services Recommended for Non-Coverage Table.

ETTF recently received FDA approval for initial treatment of glioblastoma. This approval was based on the results of a single trial of 695 participants.

A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

From Dr. Luther:

> … had a request for the Optune "tumor treating fields" system for treatment of glioblastoma in conjunction with temozolomide. It was FDA approved in October for certain patients, but Up-To-Date is fairly cautious about it's use given data available so far. We have an unfortunate patient that it might be appropriate for, and of course it is very expensive, OHP coverage not clear. There is now (as of October) an indication for treatment for newly diagnosed glioblastoma, after rad/chemo, in conjunction with ongoing temozolomide. I think the ancillary GL only addresses recurrent glioblastoma, so this may deserve another look, as it seems likely to keep coming up.

Originally approved entry in the Services Recommended for Non-Coverage Table
ELECTRONIC TUMOR TREATMENT FIELDS
Most recent review date: May, 2014
Electronic tumor treatment field therapy (ETTF; HCPCS A4555 and E0766) has been found to have significantly lower cost effectiveness compared to conventional chemotherapy for treatment of recurrent glioblastoma. See VBBS/HERC minutes from 5/8/14 for details [link].

Current entry in the Services Recommended for Non-Coverage Table

HCPCS A4555, E0766	Electronic tumor treatment field (ETTF) therapy	June, 2014	Found to have comparable effectiveness to conventional treatments, but significantly higher cost[3]

Evidence

Stupp 2015 (http://www.ncbi.nlm.nih.gov/pubmed/?term=26670971 Study not included due to length)

1) Randomized, non-controlled trial, open label trial of temozolomide chemotherapy alone vs temozolomide chemotherapy followed by TTF therapy for initial treatment of glioblastoma
2) N=695 patients (466 TTF+chemo, 229 chemo alone)
    a. Trial stopped after analysis of 315 patients (280 actually included in analysis after exclusions)
    b. Excluded patients who progressed rapidly after initial diagnosis and thus had the poorest prognoses
3) Intention to treat trial, endpoint was progression free survival
4) Median follow up 38 months (range, 18-60 months).
5) Median progression-free survival in the intent-to-treat population was 7.1 months (95%CI, 5.9-8.2 months) in the TTFields plus temozolomide group and 4.0 months (95%CI, 3.3-5.2 months) in the temozolomide alone group (hazard ratio [HR], 0.62 [98.7%CI, 0.43-0.89]; *P* = .001). Median overall survival in the per-protocol population was 20.5 months (95%CI, 16.7-25.0 months) in the TTFields plus temozolomide group (n = 196) and 15.6 months (95%CI, 13.3-19.1 months) in the temozolomide alone group (n = 84) (HR, 0.64 [99.4%CI, 0.42-0.98]; *P* = .004).
6) Further data analysis and follow up will be done; however, control patients were allowed to cross over to the ETTF group after official study termination and therefore future study results will be difficult to interpret
7) Significant differences in chemotherapy received by the TFF and control groups
    a. Number of cycles of temozolomide in the TTF group until disease progression=6 vs 4 cycles in the control group
    b. Second line chemotherapy received in 67% of the TTF group vs 57% of the temozolomide alone group
    c. Unclear if due to benefit of TTF (longer healthy life) or whether the additional chemotherapy explains some or all of the observed TTF benefit
    d. Question about whether the open-label use of TTF impacted provider or patient decision making regarding additional therapies (see **Sampson 2015** critique)
8) No increase in adverse events seen in the TTF group compared to the temozolomide alone group
9) CONCLUSIONS AND RELEVANCE In this interim analysis of 315 patients with glioblastoma who had completed standard chemoradiation therapy, adding TTFields to maintenance temozolomide chemotherapy significantly prolonged progression-free and overall survival.
10) Industry sponsored trial

Major guidelines:

NCCN 2015 (study not included due to length)

1) ETTF mentioned as a possible therapy option for treating recurrent glioblastoma
    a. "Consider alternating electric field therapy for glioblastoma (category 2B)"
    b. No change from recommendation reviewed by HERC in 2014
2) No mention of ETTF as possible therapy for treatment of initial treatment of glioblastoma

European Society for Medical Oncology 2014

(http://annonc.oxfordjournals.org/content/early/2014/04/29/annonc.mdu050 Guideline not included due to length)

1) Reviewed ETTF as treatment for recurrent glioblastoma and did not find evidence to support its use
2) Use for initial treatment of glioblastoma was not reviewed

HERC staff summary:

The current evidence to support the use of electric tumor treatment fields in the initial treatment of glioblastoma is based on a single trial, which had questions regarding the trial methodology. No major specialty group is currently including ETTF as a recommended treatment for initial glioblastoma treatment. However, this does appear to be a rapidly evolving field and a promising treatment.

HERC staff recommendations:

1) Do not add ETTF (HCPCS A4555 and E0766) as an initial treatment for glioblastoma
2) Amend the entry to the Services Recommended for Non-Coverage as shown below

HCPCS A4555, E0766	Electronic tumor treatment field (ETTF) therapy	June, 2014 (Affirmed March 2016) March, 2016	For recurrent glioblastoma: Found to have comparable effectiveness to conventional treatments, but significantly higher cost[3] For initial treatment of glioblastoma: Experimental[2]

Footnotes 2 and 3 refer to OARs

Incontinentia Pigmenti

Question: Should incontinentia pigmenti (ICD-10 Q82.3) be moved to a higher priority line and paired with ophthalmologic treatment codes?

Question source: Casey Eye Institute

Issue: Dr. Pete Campbell, an ophthalmologist at OHSU, has requested review of incontenentia pigmenti. He feels that this condition should be paired with several ophthalmology treatment CPT codes.

The ICD-10 code Q82.3 (Incontinentia pigmenti) is on line 660 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. The equivalent ICD-9 code was generic [ICD-9 757.33 (Congenital pigmentary anomalies of skin)] and was also this line.

From Dr. Campbell:

> Incontientia pigmenti (Q82.3) is a genetic disorder that can cause problems in many different body parts and organ systems including hair, skin, bones, brain, and the eye. Approximately 30% of patients with IP will develop ocular complications and 20% will develop vision threatening disease. As a result, the standard of care is to perform examinations under anesthesia, ocular imaging including fluorescein angiography, and laser panretinal photocoagulation to reduce the risk of blindness.

Dr. Campbell is requesting the Q82.3 be moved to a covered line on the Prioritized List and pair with CPT codes 92002-92014, 99201-99215, 92018, 92235, 92250, 92134, and 67228.

O'Doherty et al (2010) reviewed incontinentia pigmenti ophthalmologic manifestations and treatment. This is a very rare disorder, so few children were included in the case review (N=11). Reported ocular complications include nystagmus, strabismus, microphthalmos, ptosis, blue sclera, pigmentation of the conjunctiva, corneal changes, cataract, optic atrophy, vitreous hemorrhage and myopia. However, the most typical abnormality is fibroblastic retinal detachment secondary to an ischemic vasculopathy not dissimilar in appearance to retinopathy of prematurity. Expert recommendation is for examination under anesthesia, with laser photocoagulation if needed. Fluorescein angiography has been found to be useful to identify neovascularization and allow earlier treatment and reduce the risk of retinal detachment.

This condition can also result in seizures, structural brain abnormalities, developmental delay, and dental issues.

Dr. Campbell reports that Casey Eye Institute has seen 38 cases of incontinentia pigmenti in the past 4 years, most of which required only office visits.

Incontinentia Pigmenti

HERC staff recommendation:

1) Add Q82.3 (Incontinentia pigmenti) to line 278 RETINOPATHY OF PREMATURITY Treatment: CRYOSURGERY and remove from line 660 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Allows pairing with CPT 92002-92014, 99201-99215, 92018, 92235, 92250, 92134, and 67228 (Ophthalmologic visits and treatments)
    b. Expert literature describes presentation, treatment, etc. as similar to retinopathy of prematurity
    c. Neurologic and developmental delay complications can be treated by using the specific dysfunction diagnosis, which would likely be found on one of the dysfunction lines
    d. Seizures can be treated by using a seizure diagnosis code

OREGON HEALTH & SCIENCE UNIVERSITY

02/23/2016

Casey Eye Institute

Marquam Hill - Portland

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3375 SW Terwilliger Blvd.
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tel 503 494-3000
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Vancouver

16701 SE McGillivray Blvd., Ste. 170
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fax 360 260-5523

Darren D. Coffman
Director, Health Services Commission
1225 Ferry Street NE
Salem, OR 97301

RE: Prioritized List Addition Request

Dear Mr. Coffman:

Or email: HERC.Info@state.or.us

We occasionally notice that the condition and treatment pairs list is either missing ocular diagnoses or their corresponding treatments. We concluded that there may be a lack of understanding of ocular disease processes or their therapy, including surgical repair. We also feel that many conditions/treatments missing, or below-the-line, meet medical necessity criteria and are considered standard of care, not experimental.

Please consider the following for inclusion on the Prioritized List:

Incontinentia pigmenti (Q82.3) is a genetic disorder that can cause problems in many different body parts and organ systems including hair, skin, bones, brain, and the eye. Approximately 30% of patients with IP will develop ocular complications and 20% will develop vision threatening disease.[1,2] As a result, the standard of care is to perform examinations under anesthesia, ocular imaging including fluorescein angiography, and laser panretinal photocoagulation to reduce the risk of blindness.

The impacted CPT are:

Exams: 92002-92014, 99201-99215, 92018
Imaging: 92235, 92250, 92134
Laser: 67228

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Casey Eye Institute

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tel 360 260-7132 - Pediatric Ophthalmology
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Thank you for your consideration of adding this condition/treatment to the Prioritized List. Do not hesitate to contact me if further clarification is needed.

Sincerely,

Pete Campbell, MD
Retina Service
OHSU - Department of Ophthalmology

1. Zafeiriou DI, Vargiami E, Hatzidimitriou V, Kyriazi M. Incontinentia pigmenti: a skin, brain, and eye matter. *J Pediatr*. 2013;163(5):1520. doi:10.1016/j.jpeds.2013.06.029.

2. Goldberg MF, Custis PH. Retinal and other manifestations of incontinentia pigmenti (Bloch-Sulzberger syndrome). *OPHTHA*. 1993;100(11):1645-1654.

Incontinentia pigmenti—ophthalmological observation of a series of cases and review of the literature

M O'Doherty,[1] K Mc Creery,[1] A J Green,[1,2] I Tuwir,[1] D Brosnahan[1]

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ABSTRACT

Aim The aims of this study were to make an inventory of the disease in Ireland, to acquire better knowledge of the relationship between genetic makeup and phenotypic ocular presentation and, finally, through literature review and personal experience, to establish clear guidelines on best practice in the management of children with this rare condition both in terms of screening and follow-up.

Methods All patients who attended the dermatology and genetic clinic in Our Lady's Hospital for Sick Children, Crumlin, with incontinentia pigmenti (IP) were contacted and invited to attend the eye clinic for ocular assessment. Children who were already attending the ophthalmic services before commencement of the study had their charts reviewed for assessment.

Results 11 of 19 patients agreed to attend the clinic for ocular assessment. Of these patients, nine had genetic testing. The mean age of the patients at the examination was 8 years (3 months to 29 years). In 10 patients, IP was the result of a spontaneous mutation, whereas the condition was inherited from an affected mother in one patient. Of the 11 patients with IP, 5 have visually significant ocular findings (47%). We describe the case history of four of these children briefly to outline the severity of this condition.

Conclusion Our patients had a significant percentage of ocular abnormalities (47%). We have outlined an examination schedule for patients with and without retinal pathology and recommend fluorescein angiography in patients with retinal pathology to fully determine the extent of ischaemia. Like other studies, early treatment with peripheral retinal photocoagulation to reduce the risk of retinal detachment is recommended in this study.

Incontinentia pigmenti (IP), or Bloch–Sulzberger syndrome, is a rare X-linked dominant genodermatosis that affects mostly female patients and is usually lethal for males in utero. It is a multisystem disorder, primarily affecting the skin at or after birth, accompanied by dental, ocular and central nervous system disorders such as seizures, spastic paralysis, microcephaly and mental retardation.[1]

Although the anomaly of skin pigmentation can be quite dramatic, the most significant medical problems in patients with IP are blindness and neurological disturbances.[1 2] Although virtually every patient with IP exhibits the skin abnormality to some degree, the blindness and the central nervous system anomalies are less frequent, occurring in about 40% and 30% of patients, respectively.[2–4] Visual problems develop in patients with IP when retinal ischaemia occurs at and after birth and subsequently manifest reactive neovascularisation and fibrovascular scarring, vaguely similar to retinopathy of prematurity.[4 5] If left untreated, this condition progresses to retinal detachment and consequent blindness. The central nervous system manifestations in IP also appear to arise from compromised vascularisation or from vaso-obliteration in the developing brain. This results in ischaemia and generalised atrophy, yielding defects in neural migration and field evolution, and thus sequelae ranging from seizures and paralysis to mental retardation. In addition to dermal, visual and brain defects, patients with IP exhibit some uncommon, less medically significant problems, including hair loss (alopecia); conical, peg-shaped or absent teeth (anodontia); and nail dystrophy.

The gene responsible for this condition, NEMO, has been identified and a common recurrent deletion in the gene has been reported in approximately 80% of those affected by the condition.[6] The Nemo gene is on Xq28 on the long arm of the X chromosome. NEMO is essential for nuclear factor κB (NF-κB) activation. Because activated NF-κB normally protects against tumour necrosis factor-α (TNFα)-induced apoptosis, IP cells are highly sensitive to proapoptotic signals.[7 8]

The aims of the present study were to make an inventory of the disease in Ireland, to acquire better knowledge of the relationship between genetic makeup and phenotypic ocular presentation and, finally, through literature review and personal experience, to establish clear guidelines on best practice in the management of children with this rare condition both in terms of screening and follow-up.

METHODS

All patients who attended the dermatology and genetic clinic in Our Lady's Children's Hospital, Crumlin, with IP were contacted and invited to attend the eye clinic for ocular assessment. The criteria described by Landy and Donnai[1] were used to confirm the diagnosis of IP. Ocular assessment involved visual acuity assessment, orthoptic assessment, anterior segment examination, dilated retinal examination and retinoscopy.

Children who were already attending the ophthalmic services before commencement of the study had their charts reviewed for assessment.

We performed a literature search of all ocular cases of IP. We ascertained (where possible) the age at which the retina detached and the long-term

Sacroiliac Joint Fusion for Sacroiliitis

Question: Should sacroiliac joint fusion be added as a treatment for sacroiliitis?

Question source: Andy Kranenburg, MD and Adam Cabala, MD, surgeons

Issue: Drs. Kranenburg and Cabala have requested that the HERC consider pairing sacroiliac joint fusion (CPT 27279) with sacroiliitis (ICD-10 M46.1). They report that this procedure can reduce pain and increase function and quality of life. Please see their letter for full details.

Currently, sacroiliac joint fusion (CPT 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) is on line 187 FRACTURE OF PELVIS, OPEN AND CLOSED. M46.1 (Sacroiliitis, not elsewhere classified) which includes sacroiliitis and sacroiliac arthritis is currently on line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (LINE 545 FROM THE OCT. 1, 2015 PRIORITIZED LIST†) and will be only included on the medical back line when the back line revisions are implemented.

Evidence

Note: none of the articles in the surgeon-provided bibliography were available in MEDLINE.

1) **Ahmad Al-khayer 2008**
    a. Case series N=9, percutaneous SIJ arthrodesis technique for patients with intractable SIJ pain. Preoperative
    b. 2 year follow up
    c. Results: The mean Oswestry Disability Index value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively (Pr0.005). The mean Visual Analog Scale value dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively (Pr0.002). The mean patients' satisfaction was 6.8 (range: 5 to 8).
    d. Conclusions: This new technique may offer a safe and effective treatment for intractable SIJ pain.
2) **Rashbaum 2016**, review of treatments for sacroiliac joint dysfunction
    a. There have been multiple reports from various countries reporting good outcomes of minimally invasive SIJ fusion.
    b. Reported on two studies that were not locatable in MEDLINE:
        i. Whang et al (2015): There is level I evidence available from a recent prospective, randomized study comparing SIJ fusion to nonoperative care. The follow-up for the study period reported was 6 months. Patient selection criteria for the study included SIJ localized pain, positive findings on at least 3 of 5 established manual examinations, and at least 50% improvement in SIJ pain 30–60 minutes after image-guided anesthetic injection into the joint. The SIJ fusion group had a significantly higher success rate (based on improvement in SIJ pain scores and lack of device-related complications, revision surgery, or neurological

complications) as well as a statistically significantly greater improvement in Oswestry Disability Index scores, and quality of life assessment.

ii. Rudolf et al (2014): Five-year follow-up was available for a small series of patients. Five-year follow-up was available for 17 of 21 patients (80.9%) who underwent SIJ fusion 5 years before the analysis. Plain radiographs and CT scans were performed on 15 of these patients. Imaging showed increased bone density adjacent to all implants with intraarticular osseous bridging in 87% of patients and no evidence of implant loosening or migration.

iii. Both articles were reported to have at least 1 author who was an employee of a manufacturer and one or more of the other authors had a potential conflict most often as a consultant or stockholder

Other policies:

1) Aetna 2015 does not cover sacroiliac joint fusion

HERC staff recommendation:

1) Do not add sacroiliac joint fusion (CPT 27279) to 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT or the new surgical back line
    a. No evidence of effectiveness
    b. Appears experimental

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Ariel Smits, MD, MPH
Oregon Health Policy and Research
421 SW Oak Street, 8th Floor
Portland, OR 97204

Re: Requesting Coverage for Minimally Invasive (MIS) Sacroiliac (SI) Joint Fusion, CPT Code 27279

Dear Dr. Smits:

We would like to appeal for reconsideration of the current Oregon Health Plan for Sacroiliac Joint Fusion. Specifically, we are writing to request a face-to-face meeting to share the clinical evidence that supports MIS SI joint fusion and respectfully request the removal from the "Experimental & Investigational" list, and allow coverage for CPT code 27279 as medically necessary for patients who have been properly diagnosed with sacroiliac (SI) joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis.

Why access to SI joint fusion is important to our practice

The SI joint is a well-recognized source of pain in many patients who present with chronic lower back pain (LBP). Quality of life is markedly impaired in patients with SI joint pain compared with age- and gender-matched cohorts, and the impairment is similar or worse than many common disabling medical conditions such as hip, knee, and spine conditions treated surgically [Cher 2014].

Similarly, patients with SI joint dysfunction considering surgery have decrements in quality of life as or more severe compared to patients with degenerative spondylolisthesis, spinal stenosis, and intervertebral disc herniation [Cher 2015]. We reserve surgery as a last resort; we'll first seek to provide pain relief through conservative treatments such as physical therapy and pain management. In fact, thanks to our skilled physical therapists, physicians, and other specialists, only 10 percent of our patients ever undergo surgery.

To date, we have performed approximately 50 minimally invasive SI joint fusion procedures with the iFuse Implant System®. The majority of patients have had excellent results as demonstrated in multiple randomized, controlled clinical trials. SI joint fusion is considered only in carefully selected patients. We employ a diagnostic algorithm designed to determine the specific pain generator by conducting a thorough evaluation of the lumbar spine, hip, and SI joint. Our diagnostic algorithm is consistent with the patient selection guidelines published by the North American Spine Society ("NASS") and the International Society for the Advancement of Spine Surgery ("ISASS").

Patient Selection Guidelines

Proper diagnosis of the SI joint is of paramount importance to obtain good health outcomes and can be achieved by following a diagnostic algorithm. Appropriate diagnosis begins with a complete patient history, followed by a comprehensive physical examination of the lumbar spine-SIJ-hip complex. A series of SI joint provocative maneuvers that stress the joint has been shown to be helpful in diagnosing SI joint pathology.[1,2]

The diagnosis is confirmed with a radiographically confirmed intraarticular SI joint diagnostic injection. Multiple pain management and spine surgery specialty societies recommend and support this diagnostic algorithm (IASP, AAPM&R, APS, ASIPP, ASA, ASRA, SIS, IPM, ISASS). Several of these professional medical societies have published guidelines that describe a similar diagnostic algorithm.[3–12]

Patient selection guidelines for MIS SI joint fusion have been published by both NASS [13] and ISASS. [14] Both societies acknowledge that MIS SI joint fusion is the standard of care for appropriately selected patients and recommend coverage for patients who have failed appropriate non-surgical treatment. The guidelines can be accessed via the links below.

• NASS:
http://sibone.com/uploads/documents/PercutaneousSacroiliacJointFusion.pdf

• ISASS: http://www.isass.org/public_policy/2015-03-19-coverage-criteria-for-minimally-invasive-si-joint-fusion-2015.html

Number of Procedures Performed Worldwide

The iFuse Implant System has been commercially available since 2009 and is well accepted by the medical community. As of January 2016, more than 20,000 iFuse Implant System procedures (>60,000 implants) have been performed worldwide by over 1,100 surgeons, with the majority being performed in the United States (18,000+ procedures, 850+ surgeons).

FDA Indication Statement

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function and quality of life at 12-months post-implantation.

Clinical Evidence

The evidence supporting MIS fusion of the sacroiliac (SI) joint has continued to grow in volume and in quality. More than 25 peer-reviewed publications demonstrate the safety, effectiveness and durability of MIS SI joint fusion performed with the iFuse Implant System. Demonstrated outcomes include:

- **Pain Relief** – clinically important rapid (6 weeks) and sustained (12, 24, 40, and 60 month) decrease in VAS pain (70-80% reduction)[15–25]

- **Patient Function Improvement** – clinically important reduction in disability as measured by ODI (Oswestry Disability Index) at 6, 10, and 12 months (mean 30 point reduction)[15,16,18,20,21,23,26,27]

- **Quality of Life (QOL) Improvement** – measured by SF-36, EuroQol-5D (EQ-5D), and Roland Morris Disability [15,16,18,21]

- **High Patient Satisfaction** (< 90%)[15–19,21–23,25]

- **Favorable complication and revision rates** [15,16,28,29]

Additional published articles address the safety, health state utility, and the biomechanics of the iFuse Implant System.

- One-year results from SI-BONE's prospective, multicenter, randomized controlled trial (INSITE): This randomized controlled trial included 148 subjects, randomized 2:1, MIS SI joint fusion surgery versus non-surgical management. This level 1 study showed that MIS SI joint fusion using triangular titanium implants was more effective than non-surgical management in relieving pain, improving patient function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruptions. Pain, disability and quality of life also improved after crossover from non-surgical to surgical treatment.[15]

- One-year results of a prospective multicenter trial (SIFI): Results from the one-year prospective study are extremely positive. Mean SI joint pain improved from 79.8 at baseline to 30.0 and 30.4 at 6 and 12 months, respectively (mean improvements of 49.9 and 49.1 points, $p < 0.0001$ each). Mean ODI improved from 55.2 at baseline to 32.5 and 31.4 at 6 and 12 months, respectively (improvements of 22.7 and 23.9 points, $p < 0.0001$ each). SF-36 physical component summary improved from 31.7 at baseline to 40.2 and 40.3 at 6 and 12 months respectively ($p < 0.0001$). At 6 and 12 months, 93% and 87% of subjects, respectively, were somewhat or very satisfied and 92% and 91%, respectively, would have the procedure again. The study concluded that MIS SI joint fusion resulted in improvement of pain, disability, and quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis and SI joint disruption.[16]

- Five Year Outcomes (17 patients followed up out to five years): Rudolf et al reported that long-term clinical and radiographic outcomes after MIS SI joint fusion are favorable. Clinical improvements observed at twelve months postoperatively were maintained at five years. There was no evidence of long-term complications, implant loosening or migration. Pain on VAS scale improved from 8.3 at baseline to 2.4 at five years.[22]

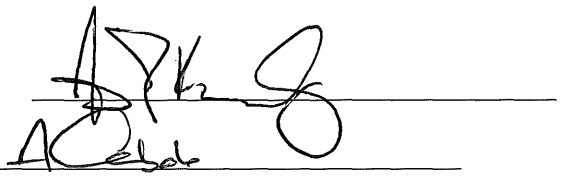
Additionally, please note that effective January 1, 2016 Medicaid reimburses for CPT 27279 in the following 35 states:

> AK, AL, AZ, CA, CT, FL, GA, HI, ID, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MT, NE, NV, NH, NY, NC, ND, OH, SC, SD, UT, VA WV, WY, WI, and the District of Columbia.

Thank you for considering our request for a face-to-face meeting to present and discuss with you and your team the MIS technique for SI joint fusion, the clinical evidence, and relevant case studies. We will follow-up next week to confirm a date and time that will work for you.

Sincerely,

Andy Kranenburg, MD



Adam Cabalo, MD

The below Oregon spine surgeons have asked to be included as supporters of this request for coverage.

Bret Ball, MD
Mark Belza, MD
Greg Ha, MD
Chris Noonan, MD
Scott Kitchel, MD
George Oji, MD
Tim Keenen, MD
Jeffery Flemming, MD
Michael Sandquist, MD
Wael Musleh, MD

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Percutaneous Sacroiliac Joint Arthrodesis
A Novel Technique

Ahmad Al-khayer, MRCS, Jim Hegarty,† David Hahn, FRCS (Tr&Orth),† and Michael Paul Grevitt, FRCS (Tr&Orth)†*

Study Design: Consecutive case series.

Objective: To report a new percutaneous sacroiliac joint (SIJ) arthrodesis technique utilizing a Hollow Modular Anchorage screw.

Summary of Background Data: A variety of SIJ arthrodesis techniques have been reported in the established academia to treat intractable SIJ pain. None combines minimal surgical exposure, instrumented fixation, and bone grating.

Methods: We describe a new percutaneous SIJ arthrodesis technique for patients with intractable SIJ pain. Preoperative and postoperative Oswestry Disability Index (ODI), Visual Analog Scale (VAS) for pain, and postoperative subjective patients' satisfaction were assessed for all patients. Minimum 2 years follow-up is documented.

Results: Nine patients underwent SIJ arthrodesis with the new technique. The mean ODI value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively ($P \leq 0.005$). The mean VAS value dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively ($P \leq 0.002$). The mean patients' satisfaction was 6.8 (range: 5 to 8).

Conclusions: The new technique may offer a safe and effective treatment for intractable SIJ pain.

Key Words: sacroiliac joint pain, arthrodesis, technique

(*J Spinal Disord Tech* 2008;21:359–363)

Sacroiliac joint (SIJ) pain is an important cause of low back pain. Treatment is initially conservative. However, various SIJ arthrodesis techniques have been described in the literature for patients that fail conservative treatment. None has been accepted universally as the standard.

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In this paper, we report our experience with a new percutaneous technique utilizing a Hollow Modular Anchorage (HMA) screw (Aesculap, Sheffield, UK).

MATERIALS AND METHODS

Patients' Selection

The authors reviewed the records of a single university hospital from August 2000 to August 2006 to identify patients with SIJ disorders who were treated surgically with the new technique and who had a minimum of 24 months follow-up. Nine patients (all female) were identified and recruited for the study. The arthrodesis was bilateral in 3 patients. The demographic information for the 9 patients is summarized in Table 1.

All patients suffered from chronic SIJ pain, and presented with pain and tenderness over the sacral sulcus and the posterior SIJ. The pain was localized solely over the joint in 2 cases, and radiated to the ipsilateral lower limb or the groin in the remaining. Patrick (Faber) test was positive in 8 out of 9 patients.

The average age was 42.4 years (range: 35 to 56 y). Mean duration of symptoms before surgery was 30 months (range: 12 to 84 mo). Plain radiographs of the pelvis and the lumbosacral region were obtained as part of the initial assessment of all patients. Other radiologic investigations were occasionally contemplated to exclude other pain sources (lumbar disc prolapse, degenerative spinal disease). Temporary pain relief with SIJ block confirmed the diagnosis. All patients failed rigorous conservative treatment.

Outcome Assessment

Plain anteroposterior radiograph of the pelvis and lateral radiograph of the sacrum were performed for all patients preoperatively, and at 12 weeks and 1 year following the procedure.

Validated outcomes measures in the form of Oswestry Disability Index (ODI), and Visual Analog Scale (VAS) for pain (ranging from 0 for no pain to 10 for very severe pain) were assessed preoperatively (once surgery was decided) and at the time of the latest follow up via a standardized questionnaire in a prospective manner.

A change of 10% on ODI and 2 on VAS was considered to be the minimal clinically important

Sacroiliac Joint Pain and Its Treatment

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Abstract: The sacroiliac joint (SIJ) as a source of symptoms has been controversial; however, as knowledge about the joint increased, its role as a pain generator in patients complaining of symptoms that are often attributed to spinal pathology has become better appreciated. The literature reports that the SIJ is the pain origin in as many as 30% of patients presenting with low back pain. Clinically, the SIJ can be challenging to evaluate; however, assessing pain location, patient posture/movement, and provocative manual testing are useful in making the presumptive diagnosis of SIJ disruption. The most definitive evaluation is image-guided injection of anesthetic solutions into the joint which is diagnostic if there is at least 75% symptom relief acutely. Treatment begins with nonoperative intervention including physical therapy and/or chiropractic care. If these fail, the next option is generally radiofrequency denervation (rhizotomy) of the joint. If this does not provide adequate relief, surgical intervention, in the form of minimally invasive SIJ fusion may be considered. The literature increasingly supports favorable results of SIJ fusion in appropriately selected patients. The purpose of this review is to provide an overview of the current literature on the SIJ, with focus on its surgical treatment.

Key Words: sacroiliac joint, review, diagnosis, treatment, fusion

(*Clin Spine Surg* 2016;29:42–48)

The sacroiliac joints (SIJs) are responsible for the transfer of load from the trunk of the body to the lower extremities. Although it is accepted that it is a true joint, there is disagreement regarding its mobility, role as a pain generator, the diagnosis of SIJ-specific pain, and treatment. In recent years there has been increasing interest in the role of the SIJ as a pain generator and its treatment. Using data from the National Health Measurement Study, the health impact of SIJ pain has been put in the context of other medical problems.[1] On the basis of SF-36 and EQ5-D scores, the disease burden in patients being considered for SIJ fusion was higher than that of individuals with health problems such as c*hronic obstructive pulmonary disease*, angina, and coronary heart disease. The SIJ pain burden was similar to that of patients undergoing surgery for hip and knee osteoarthritis, and lumbar spondylolisthesis. The disease burden was slightly less than that of populations with liver cirrhosis or severe Parkinson disease. These findings indicate that SIJ pain can have a significant impact on the well-being of patients. The purpose of the present review is to provide an overview of the current literature on the SIJ. This review will focus on SIJ pain that is not related to major trauma (ie, pelvic fracture), tumor, or infection, with a particular emphasis on indications and outcomes of surgical treatment.

EPIDEMIOLOGY AND ETIOLOGY

No literature was identified reporting on the incidence of SIJ pain outside the context of low back pain. Among back pain patients, 15%–30% were found to have pain arising from the SIJ.[2–5] Symptoms may arise from degenerative changes, sacroilitis and/or arthritis, or joint disruption following trauma or during pregnancy. Among patients who have previously undergone fusion in the lower lumbar spine, pain may be related to degeneration as a form of adjacent segment degeneration or may have been present before the fusion but was somewhat masked by more severe pain from the lumbar spine. Ha et al[6] reported that 5 years after lumbar posterior fusion 75% of patients had degenerative SIJ changes visualized on radiographic images. This was significantly more than the 38% seen in the control group. However, the authors did not report on the percentage of these patients who had SIJ symptoms. In a study evaluating patients with pain after a lumbar fusion, it was found that 40% had symptoms arising from the SIJ.[7] This is consistent with the rate of 43% reported in another study of postfusion patients with pain.[8]

ANATOMY, BIOMECHANICS, AND MOTION

The SIJ is a large, irregularly shaped diarthroidal joint (Fig. 1) with cartilage surfaces. It contains synovial fluid and is itself contained in a fibrous capsule. The joint is stabilized by a thick posterior ligamentous complex that limits motion. A recent study provided a detailed analysis of the innervation of the SIJ. Roberts et al[9] indicated that the posterior section of the joint is innervated by a nerve plexus formed by lateral branches of the posterior rami of L5–S4. This work, as well as earlier studies,[10] confirm

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Non-Contact, Low-Intensity Ultrasound for Chronic Wound Healing

Question: Is non-contact, low-intensity ultrasound for chronic wound healing effective either as sole or adjuvant therapy compared to other modalities?

Question source: Alliqua Biomedical, company which produces MIST Therapy® (a non-contact, low-frequency ultrasound technology)

Issue: Non-contact, low-frequency ultrasound is not currently covered for wound healing treatment. Suspected deep tissue injury (SDTI) was excluded.

Low frequency ultrasound (CPT 97610) was reviewed in October, 2013 when the new CPT code for this procedure was released. At that time, it was placed on the Services Recommended for Non-Coverage table due to being experimental.

The manufacturer of MIST therapy has requested that the HERC re-review this procedure, as "there is significant data demonstrating a reduction in healing times and increase in complete healing rates compared to standard of care treatment."

Evidence:
Systematic Reviews:

1) **NICE 2011,** Medical Technology Guidance of MIST Therapy system for the promotion of wound healing (not included due to length) https://www.nice.org.uk/guidance/mtg5/resources/the-mist-therapy-system-for-the-promotion-of-wound-healing-1788114109381
    a. N=10 studies
        i. N=2 RCTs (203 patients total).
            1. Kavros et al. 2007: 70 patients with non-healing wounds and chronic critical limb ischemia comparing standard wound care (daily dressing changes and weekly debridement) with standard wound care + MIST Therapy system 3x/week for 12 weeks. 63% of wounds healed (defined as >50% reduction in volume) in intervention compared with 29% in control group ($p<0.01$).
            2. Ennis et al. 2005: 133 patients with diabetic foot ulcers comparing MIST Therapy system with sham device 3x/week for 10 weeks. Standard wound care for both groups as well. Intention to treat analysis: 26% of wounds healed in intervention group compared to 22% in control group (not statistically significant.)
        ii. N=8 observational studies: "Overall the Committee recognised that the quality of evidence in the area of wound care is generally low and heterogeneity of chronic wounds poses a challenge...[but] evidence supporting the clinical effectiveness of the MIST Therapy system was equal to or better than evidence for many other wound care interventions in current use in the NHS."

b. **Authors' conclusions:** "Evidence suggested real potential for the MIST Therapy system to enhance the healing of chronic wounds, but that overall the quality of the evidence was limited by small patient numbers and lack of appropriate comparison groups."
c. **Technology coverage conclusions:** The amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient, at the time of writing, to support the case for routine adoption of the MIST Therapy system in the NHS.

2) Cullum 2011: Cochrane Systematic Review on Therapeutic Ultrasound for venous leg ulcers

a. N=8 RCTs (6 high frequency ultrasound, 2 low frequency ultrasound)
    i. Low frequency RCTs: Peschen 1997, Weichenthal 1997
        1. Peschen 1997 N=24 people with one venous ulcer each, larger than 2 cm x 2 cm of > three months' duration. Everyone received standard treatment of hydrocolloid dressing + compression bandage. Intervention arm also received low-freq ultrasound 3x/wk for 12 weeks while the control group received sham ultrasound. Outcome: RR for ulcer healing at 12 weeks is 5.00, 95% CI 0.27-94.34.
        2. Weichenthal 1997 N=37 people with a venous ulcer > three months' duration and no e/o arterial dz or diabetes. Everyone received conventional treatment (fibrinolytics, antibiotics, antiseptics, and occlusive dressings) but 19 also received low-frequency ultrasound in a footbath (not saline mist.) Unknown frequency or duration of ultrasound treatments. One person from intervention group excluded at the end for having evidence of arterial vascular disease. Outcomes: At eight weeks one ulcer healed completely in ultrasound group and none in control. RR 2.85, 95% CI 0.12 - 65.74. Not statistically significant. German study.
    ii. Pooled both studies using fixed effect model: RR 3.91, 95% CI 0.47 - 32.85, not statistically significant difference in healing.
    iii. Limitations: Both RCTs are underpowered.
    iv. **Authors' conclusions**: "There is no evidence to support the routine use of therapeutic ultrasound (US) as a treatment for venous leg ulcers. The evidence that exists is of low quality and volume, and a beneficial effect cannot be ruled out."

3) Akbari 2009: Cochrane Systematic Review Therapeutic Ultrasound for Pressure Ulcers

a. N=3 RCTs (146 people.)
    i. McDiarmid 1985: N=40. Compared low-frequency ultrasound 3x/wk for unclear duration with sham treatment for patients with pressure ulcers. 48% pressure ulcers healed in intervention group compared with 42% in sham group. RR 1.13, 95% CI 0.57 to 2.26.

ii. ter Riet 1995: 88 nursing home patients with pressure ulcers > stage I, randomized to receive low-frequency ultrasound 5x/wk for 12 weeks. 40% wounds healed in intervention group compared with 44% in sham group. RR 0.91, 95% CI 0.55 to 1.48.
iii. Nussbaum 1994: Compared a combination of ultrasound and laser treatment with standard wound care, so this study is not relevant to this inquiry.
iv. ter Riet + McDiarmid pooled using fixed effects model: RR 0.97, 95% CI 0.65 to 1.45.

c. **Authors' conclusions**: Pooled analysis from 2 available RCTs "found no evidence of a benefit of ultrasound on the healing rates of pressure ulcers."

Meta-analysis:

1) **Driver 2011**: meta-analysis of low frequency ultrasound for treatment of chronic wounds
    a. N=8 studies (1 RCT—not blinded, 5 retrospective of which only 1 had a control group receiving standard care, and 2 prospective nonrandomized)
        i. Patients=444.
    b. Results:
        i. 4/8 studies (N=278) had data on reduction in wound volume. Ultrasound was associated with 79.7% reduction over approx 12 wks, no significant evidence of heterogeneity or study bias.
        ii. 7/8 studies (N=429) had data on proportion of wounds healed by end of study period. Average time to healing was 8.2 wks, median 6.8 wks all with ultrasound.
        iii. 4/8 studies (N=188) reported on wound area change from baseline, with ultrasound intervention arms suggesting a pooled estimate of 85.2% reduction with 95% CI of 64.7%-97.6% over the study period (undefined.)
    c. Limitations:
        i. The meta-analysis looked at studies with historical controls in order to compare to standard of care, rather than directly compare ultrasound to standard wound care. This meta analysis noted that the 62% wound area reduction in the historical controls was lower than the lower limit of the CI in this pooled analysis (CI 65%-98%). There was concern from the reviewer that the meta analysis misreports some data from these historical studies
        ii. Standard of care varied across studies.
        iii. Wound etiology varied across studies.
        iv. All but one of the eight studies were observational, non-randomized, non-blinded studies.

        v. This meta-analysis does not describe funding sources or any conflicts of interest, but a subsequent RCT (Olyaie 2013) refers to it as an "industry-sponsored meta-analysis."
    d. Authors' Conclusions: "Remarkable consistency of reductions in wound area, wound volume, and wound pain were observed...Future research on this noncontact, low-frequency ultrasound therapy should focus on larger, randomized clinical trials."
2) **Voight 2011**: Meta-analysis of low frequency ultrasound as adjunctive therapy for wound healing
    a. N=5 RCTs (1 included in Cullum 2011)
        i. only two pairings of 2 studies were able to be pooled for outcomes.
    b. Two studies dealing specifically with venous ulcers (Peschen 1997 and Weichenthal 1997) pooled for % wound size reduction. N=61. Mean difference 25.97%, CI 11.09%-40.86%, P=0.0006.
    c. Two studies were pooled for outcome of nonhealed wounds at 3 months comparing ultrasound vs sham events (Ennis 2005 and Peschen 1997.) N=60. Pooled Risk Ratio 0.74 [0.58, 0.95]
    d. Limitations: Significant differences between the five studies meant that the authors could only pool two studies for two different outcomes. One study was industry funded, issues in the protocol of another was criticized.
    e. Authors' conclusions: "Although it appears...that [low-frequency, low intensity, noncontact ultrasound] is more effective at complete healing than standard of care, the quality of the evidence as it relates to biases was poor...Although the quality of the evidence is in general of lower quality for both types of ultrasound, the evidence does demonstrate a short-term clinically beneficially effect of [low-frequency, low intensity, noncontact ultrasound]...used as an adjunctive therapy on the clinical end points of complete healing and reduction in wound area size for patients presenting with venous stasis and diabetic foot ulcers."

Guidelines**:** none identified

Other coverage policies: Aetna and Anthem BCBS do not cover due to investigational nature of the therapy

HERC staff summary

Systematic reviews from trusted sources (NICE and Cochrane) and well-conducted meta-analyses failed to find evidence to support significant improvement in wound healing with low frequency ultrasound compared to usual wound care. The one meta-analysis submitted by the manufacturer (Driver 2011) supporting this technology had significant methodological flaws.

HERC staff recommendations:

1) Do not add overage for low frequency ultrasound for any type of chronic wound. Keep CPT 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) on the Services Recommended for Non-Coverage table

[Intervention Review]

Therapeutic ultrasound for venous leg ulcers

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ABSTRACT

Background

Venous leg ulcers pose a significant burden for patients and healthcare systems. Ultrasound (US) may be a useful treatment for these ulcers.

Objectives

To determine whether US increases the healing of venous leg ulcers.

Search methods

We searched the Cochrane Wounds Group Specialised Register (searched 24 February 2010); The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 1, 2010); Ovid MEDLINE (1950 to February Week 2 2010); In-Process & Other Non-Indexed Citations (searched 24 February 2010); Ovid EMBASE 1980 to 2010 Week 07; EBSCO CINAHL 1982 to 24 February 2010.

Selection criteria

Randomised controlled trials (RCTs) comparing US with no US.

Data collection and analysis

Two authors independently assessed the search results and selected eligible studies. Details from included studies were summarised using a data extraction sheet, and double-checked. We tried to contact trial authors for missing data.

Main results

Eight trials were included; all had unclear, or high, risks of bias, with differences in duration of follow-up, and US regimens. Six trials evaluated high frequency US and five of these reported healing at 7 - 8 weeks. Significantly more patients healed with US than without it at 7 - 8 weeks (pooled RR 1.4, 95% CI 1.0 to 1.96), but later assessments at 12 weeks showed the increased risk of healing with US was no longer statistically significant (pooled RR 1.47, 95% CI 0.99 to 2.20). One poor-quality study of high-frequency US found no evidence of an effect on healing after three weeks' treatment.

Two trials evaluated low frequency US and reported healing at different time points. Both trials reported no evidence of a difference in the proportion of ulcers healed with US compared with no US: both were significantly underpowered.

Authors' conclusions

The trials evaluating US for venous leg ulcers are small, poor-quality and heterogeneous. There is no reliable evidence that US hastens healing of venous ulcers. There is a small amount of weak evidence of increased healing with US, but this requires confirmation in larger, high-quality RCTs. There is no evidence of a benefit associated with low frequency US.

PLAIN LANGUAGE SUMMARY

Ultrasound therapy used for healing venous (varicose) leg ulcers and to improve symptoms

Venous leg ulcers are common, especially in the elderly. They are caused by damage or blockages in the veins of the legs, which in turn lead to pooling of blood and increased pressure in these veins. Eventually, these changes can damage the skin and lead to ulcer formation.

Compression with stockings or bandages is the most widely used, and acceptable, treatment for venous leg ulcers. Ultrasound has been used as an additional intervention, especially for difficult, long-standing ulcers. The mechanisms by which ultrasound waves interact with healing tissues are not fully understood. We conducted a review to establish whether ultrasound speeds the healing and improve symptoms of venous leg ulcers, and examined all the available evidence from medical trials. This showed that there is no strong evidence that ultrasound hastens ulcer healing. There is, however, some weak evidence from poor-quality research that high-frequency ultrasound may increase the healing of venous leg ulcers. This finding, however, requires confirmation in larger and rigorously conducted medical trials before we can be certain that it is true and can be trusted. There is no evidence that low frequency ultrasound improves the healing of venous leg ulcers.

[Intervention Review]

Therapeutic ultrasound for pressure ulcers

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ABSTRACT

Background

Pressure ulcers have been recorded as occurring in 5 to 32% of patients admitted to a UK District General Hospital (the precise rate depends on case-mix) and 4 to 7% in the community. They represent a major burden of sickness and reduced quality of life for patients and their carers, and are costly to health service providers.

Pressure ulcers are treated by using wound dressings, relieving pressure on the wound, by treating concurrent conditions which may delay healing, and by the use of physical therapies such as electrical stimulation, laser therapy and ultrasound.

Objectives

To assess the effect of therapeutic ultrasound on the healing of pressure ulcers.

Search strategy

For this update we searched the Cochrane Wounds Group Specialised Register (April 2008) , The Cochrane Central Register of Controlled Trials (CENTRAL) - The Cochrane Library Issue 2, 2008, Ovid MEDLINE (1950 to April Week 3 2008), Ovid EMBASE (1980 to 2008 Week 16) and Ovid CINAHL (1982 to April Week 3 2008).

Selection criteria

Randomised controlled trials (RCTs) comparing therapeutic ultrasound with sham ultrasound or standard treatment.

Data collection and analysis

Two authors independently checked the result of the search to identify relevant RCTs. Details of eligible studies were extracted and summarised using a data extraction sheet. Attempts were made to obtain missing information by contacting authors. Data extraction was checked by a second author. Meta-analysis was used to combine the results of trials where the interventions and outcome measures were sufficiently similar.

Main results

Three trials involving 146 people were included. Two RCTs compared ultrasound therapy with sham ultrasound and the third compared a combination of ultrasound and ultraviolet light with laser and with standard treatment.

Neither of the two RCTs comparing ultrasound with sham found a significant difference in healing rates. The trials were pooled, in the absence of significant heterogeneity. There was no evidence of benefit associated with the use of ultrasound in the treatment of pressure ulcers.

In the three-arm comparison there was no statistically significant difference in ulcers healed.

Authors' conclusions

There is no evidence of benefit of ultrasound therapy in the treatment of pressure ulcers. However, the possibility of beneficial or harmful effect cannot be ruled out due to the small number of trials, some with methodological limitations and small numbers of participants. Further research is needed.

PLAIN LANGUAGE SUMMARY

The effect of therapeutic ultrasound on pressure ulcers.

Pressure ulcers (also called pressure sores, bed sores or decubitus ulcers) are sores on the body caused by pressure or rubbing. They usually happen to immobile people, on bony parts of their bodies, such as hips, heels and elbows.

Low levels of ultrasound (not enough to generate heat) are sometimes used to treat pressure ulcers. It is not clear how ultrasound might affect healing, and ultrasound waves may have a positive or negative impact on the blood flow around the sore. The review with three trials involving 146 people found that there is very little evidence from trials on the effects of ultrasound on pressure ulcers.

BACKGROUND

Pressure ulcers (also known as bed sores, pressure sores and decubitus ulcers) are areas of localised damage to the skin and underlying tissue caused by pressure, shear or friction. They usually occur over bony prominences such as the sacrum, heels, hips and elbows, most often in immobile elderly people (for example elderly orthopaedic patients), patients with severe acute illnesses (such as in people in Intensive Care Units) and in people with neurological problems (for example in people with spinal cord injuries).

Pressure ulcers have been recorded as occurring in 5 to 32% of patients admitted to a UK District General Hospital (the precise rate depends on case-mix) and 4 to 7% in the community (Kaltenthaler 2001). They represent a major burden of sickness and reduced quality of life for patients and their carers, and are costly to health service providers.

Pressure ulcers present on a continuum of tissue damage from persistently reddened, unbroken skin (non-blanching erythema) through to destruction of the muscle and bone.

The treatment of pressure ulcers consists of four main strategies:

1. local treatment of the wound using wound dressings and other topical applications;

2. pressure relief using beds, mattresses or cushions, or by repositioning the patient;

3. treating concurrent conditions which may delay healing, e.g. poor nutrition, infection;

4. use of physical therapies such as electrical stimulation, electromagnetic, ultrasound, laser therapy.

The mechanisms by which ultrasound may affect wound healing have been reviewed by Dyson 1982. Briefly, the cellular effects of ultrasound can be divided in thermal and non-thermal (Dyson 1982); the lower intensities used therapeutically mean that

Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: A meta-analysis

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ABSTRACT

Our objective was to summarize and quantify the effects of a noncontact low-frequency ultrasound (NLFU) therapy on healing of chronic wounds. We performed a meta-analysis of eight published studies reporting effects of NLFU on wound size and healing rate of chronic wounds in 444 NLFU-treated patients. A search of the PubMed database was conducted in January 2010 and updated in October 2010. We used random-effects linear regression models to estimate the proportional reductions in wound area and volume and the proportion of wounds healed from baseline to last follow-up. In four studies (N=188) reporting change in wound area from baseline, NLFU was associated with 85.2% area reduction (95% CI 64.7%–97.6%) over a mean 7 weeks. In four studies (N=278) reporting reduction in wound volume, NLFU was associated with 79.7% volume reduction (95% CI 46.1%–98.8%) over a mean 12 weeks. In seven studies (N=429) reporting proportion of wounds healing by study end (mean time to healing 8.2 weeks; median 6.8 weeks), meta-analyzed healing rates over time suggest 32.7% of wounds healed on average by 6 weeks (95% CI 23.3%–42.1%) and 41.7% by 12 weeks. NLFU for treatment of chronic wounds was associated with consistent and substantial wound size reductions, as well as favorable rates of healing.

The importance of expeditious wound closure for avoiding infections, medical complications, and costly hospital admissions is well established. In contemporary wound care, a plethora of topical treatments are available aimed at accelerating the healing of chronic wounds.[1] In fact, clinical studies of dressings, agents and devices are often relatively small, unblinded, and uncontrolled, which leaves wound care clinicians without a solid evidence based on which to make treatment decisions.

Meta-analysis is a well-understood approach to arrive at an estimate of overall treatment effect for a given therapy across multiple smaller studies. This form of systematic review and analysis involves developing a specific statistical strategy for extracting and combining the results of several studies on a given therapy to generate a single estimate of treatment effect.[2]

The clinical effectiveness of a particular therapy can also be evaluated in a systematic review and analysis, in which the authors attempt to synthesize the results and conclusions of multiple studies but do not necessarily pool the extracted study data and perform statistical analyses. For instance, a systematic review by the Cochrane Collaboration of topical agents (gauze, foam, bead, alginate, and hydrocolloid dressing) for postoperative wounds healing by secondary intention reported that there were no statistically significant differences in wound healing for various dressing comparisons in 11 of the 13 trials they reviewed.[1] A systematic review of clinical studies of negative pressure wound therapy (NPWT) compared with conventional therapy identified significant differences in favor of NPWT for time to wound closure or incidence of wound closure in approximately half of the studies reviewed.[3] As part of their analysis, those authors also performed a meta-analysis of change in wound size with data extracted from four randomized controlled trials (RCTs) and two non-RCTs, in which a greater reduction in wound size was observed for NPWT in the RCTs.

Beyond simply estimating treatment effect, the process of performing meta-analyses and systematic analyses allows for examination of factors such as effect size across studies, heterogeneity of study populations, and consistency of treatment effect across studies. These analyses often highlight for clinicians either an abundance or dearth of high-quality studies and, more specifically, guide future research by elucidating the types of studies and study populations that are needed going forward. Such efforts to better understand the clinical effectiveness of the vast array of modern wound therapies are essential for the practice of evidence-based medicine and, ultimately, for avoiding healing delays and associated medical complications. Furthermore, there is increased urgency to control health care costs and ensure reimbursement for wound care therapies as reimbursement becomes more closely tied to evidence of efficacy. It has been shown that early, expeditious, advanced wound care can be cost effective and even allow for a cost savings by decreasing the cost of failure due to hospitalizations and procedures.[4–7]

Like most wound therapies, noncontact low-frequency ultrasound (NLFU) therapy (MIST Therapy System, Celleration Inc., Eden Prairie, MN) has been studied in smaller, pragmatic, and often uncontrolled, studies. This ultrasound therapy delivers low-frequency (40 kHz),

Low-Frequency Ultrasound (20-40 kHz) as an Adjunctive Therapy for Chronic Wound Healing: A Systematic Review of the Literature and Meta-Analysis of Eight Randomized Controlled Trials

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Low-Frequency Ultrasound (20-40 kHz) as an Adjunctive Therapy for Chronic Wound Healing: A Systematic Review of the Literature and Meta-Analysis of Eight Randomized Controlled Trials

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Abstract

Ultrasound as a therapeutic agent in chronic wound healing has been studied extensively. This systematic review and meta-analysis specifically examines low-frequency (20-30 kHz) ultrasound delivered at either low or high intensity. The objective of this review was to determine whether low-frequency ultrasound used as an adjunctive therapy improves the outcomes of complete healing and reduction of size of chronic lower limb wounds. PubMed, Cochrane/CENTRAL, technical assessment, relevant wound-related journals, and clinical guidelines were searched along with contacting manufacturers and authors of relevant randomized controlled trials were completed. Searches focused on the use of low-frequency ultrasound in randomized controlled trials. Data were collected via a data collection form and was adjudicated independently via coauthors. Meta-analyses and heterogeneity checks were performed using Mantel–Haenszel and inverse variance (fixed and random effects) statistical methods on studies with similar outcomes (complete healing and percent wound area reduction) over similar time periods. Single study results were reported via the statistical methods used in the study. Eight randomized controlled trials were identified. Results demonstrated that early healing (at ≤5 months) in patients with venous stasis and diabetic foot ulcers was favorably influenced by both high- and low-intensity ultrasound delivered at a low frequency—either via contact or noncontact techniques. However, the quality of the data may be suspect, especially for low-frequency low-intensity noncontact ultrasound because of significant biases. In patients presenting with either venous stasis or diabetic foot ulcers (Wagner classification 1-3), early healing appears to be facilitated by either low-frequency low-intensity noncontact ultrasound or low-frequency high-intensity contact ultrasound.

Keywords

Low frequency ultrasound, chronic wound healing, wound debridement

Chronic recalcitrant lower extremity wounds (pressure ulcers, arterial insufficiency ulcers, venous leg ulcers, diabetic foot ulcers, burns) are wounds that have failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity, or proceeded through the repair process without establishing a sustained anatomic and functional result.[1] There are numerous recommended treatment modalities for the healing of these types of wounds, including debridement (eg, with scalpel, autolytic, enzymatic, mechanical [wet to dry technique], laser, maggot therapy, high-pressure water jet), dressings, compression therapy, and drug therapy to improve the blood flow in patients with circulatory problems.[2-10] Ultrasound as a primary therapy has been studied and evaluated in Cochrane Reviews[11] and has been shown not to have an effect on healing when compared with sham or to the combination of ultrasound along with ultraviolet light. However, it was noted that the possibility of a beneficial or harmful effect could not be ruled out because of the small number of trials (4) and the small numbers of participants

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MIST®

Ultrasound Healing Therapy

CLINICAL SUMMARY

Celleration®

Clinical Evidence

Many of the wound care products available today have limited clinical evidence to support their use. Celleration made the decision early on to invest in high quality clinical evidence that supports the appropriate use of MIST Therapy to assist medical professionals in their wound care treatment decisions.

CLINICAL EVIDENCE LEVEL I-III SUMMARY

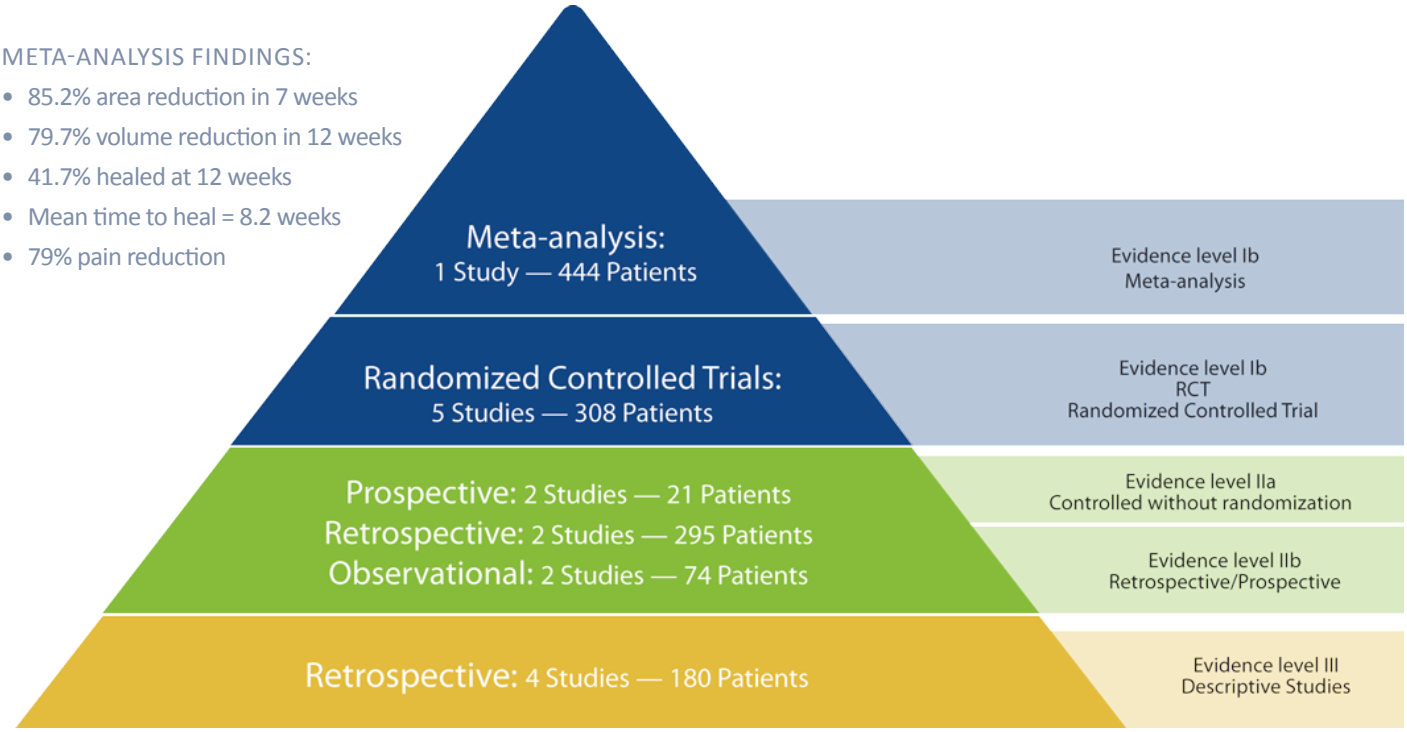
MIST Therapy was introduced into the market in late 2004 and has been investigated in a variety of Level I-III Clinical Studies including one (1) meta-analysis, five (5) randomized controlled trials, two (2) prospective, six (6) retrospective, and two (2) observational studies.

Few wound care technologies have the clinical evidence to support a meta-analysis. In the meta-analysis using only MIST Therapy ultrasound clinical data, eight (8) peer-reviewed studies with consistent designs for treatment and control wound groups were pooled to review the effects of MIST Therapy on healing time, wound size, volume, and pain. The authors concluded that "MIST Therapy demonstrates remarkable consistency of reduction in wound area, volume, pain and healing times across a wide range of wounds."

SUMMARY OF MIST THERAPY LEVEL I-III CLINICAL DATA

META-ANALYSIS FINDINGS:

- 85.2% area reduction in 7 weeks
- 79.7% volume reduction in 12 weeks
- 41.7% healed at 12 weeks
- Mean time to heal = 8.2 weeks
- 79% pain reduction



The results of these Level I-III studies demonstrate accelerated wound healing in patients with multiple comorbidities. When compared to standard of care results, MIST Therapy provides nearly twice the healing in the same period of time as traditional Standard of Care (SOC). ***See tables on following pages for more details.***

TABLE OF CLINICAL EVIDENCE **LEVEL I STUDY DETAILS**

LEVEL OF EVIDENCE	PUBLICATION AUTHOR JOURNAL	WOUND POPULATION	MEASUREMENT	MIST RESULT	SOC RESULT	TREATMENT DURATION	STATISTICS
I b	Noncontact Low-Frequency Ultrasound Therapy in the Treatment of Chronic Wounds: A Meta-Analysis Driver VR, Yao M, Miller CJ Wound Regeneration and Repair 2011	N* = 444 (463 wounds)	Wound Closure (N=429)	41.7%	*24%	12 weeks	95% CI (Confidence Interval)
			Wound Area Reduction (N=188)	85.2% reduction	Not reported	Mean 7 weeks	95% CI
		Diabetic Foot, Ischemic, Neuropathic, Venous, Multifactorial Etiology, Pressure, Surgical, Traumatic	Wound Volume Reduction (N=278)	79.7% reduction	Not reported	Mean 12 weeks	95% CI
			Pain Reduction (N=139)	79% reduction	Not reported	From Baseline	Not reported
I b NEW	A Prospective, Randomized, Controlled Trial Comparing the Effects of Noncontact, Low-Frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers Gibbons GW, Orgill DP, Serena TE, Novoung A, O'Connell JB, Li WW, Driver VR Ostomy and Wound Management 2015	N = 81	Mean % Wound Area Reduction	61.6% reduction	45% reduction	4 weeks	p=0.02
		Venous Leg Ulcers	Pain VAS Measurement	80% reduction	20% reduction		p=0.01
I b	High-Frequency and Noncontact Low-Frequency Ultrasound Therapy for Venous Leg Ulcer Treatment: A Randomized, Controlled Study Olyaie M, Rad FS, Elahifar MA,Garkaz A, Mahsa G Ostomy and Wound Management 2013	N = 90	Wound Area Reduction	72.8% at 4 months	55.4% at 4 months	12 weeks followed by SOC	p=0.04
		Venous Leg Ulcers	Mean time to healing in months	6.65	8.5		p<0.05
			Pain Reduction	47.1% reduction at 4 months	17.7% reduction at 4 months		p=0.001
I b	A Pilot Study Evaluating Noncontact Low Frequency Ultrasound on Diabetic Foot Ulcers and Underlying Molecular Mechanisms Yao M, Hasturk H, Kantarci A, Gu G, Garcia-Lavin S, Fabbi M, Park N, Hayashi, H, Attala K, French M, Driver V International Wound Care Journal 2012	N = 12	Wound Area Reduction	86% reduction	39% reduction	4 weeks	p<0.05
		Diabetic Foot Ulcers					
I b	Treatment of Ischemic Wounds with Noncontact, Low-Frequency Ultrasound: The Mayo Clinic Experience, 2004-2006 Kavros SJ, Miller JL, Hanna SW Advances in Skin & Wound Care 2007	N = 70	>50% Wound Area Reduction	63% achieved >50% reduction	29% achieved >50% reduction	12 weeks	p<0.001
		Ischemic, Neuropathic, Venous, Multifactorial					
I b	Ultrasound Therapy for Recalcitrant Diabetic Foot Ulcers: Results of a Randomized, Double-Blind, Controlled Multicenter Study Ennis WJ, Formann P, Mozen N, Massey J, Conner-Kerr T, Meneses P Ostomy & Wound Management 2005	N = 55	Wound Closure	40.7%	14.3%	12 weeks	p<0.0366
		Diabetic Foot Ulcers					

*Total patient population from 8 studies = 519 (444 treated with MIST), 538 wounds (463 treated with MIST)
**Margolis meta-analysis of standard of care treatments for DFU's was discussed in the article and used for comparison to MIST results.

TABLE OF CLINICAL EVIDENCE LEVEL II STUDY DETAILS

LEVEL OF EVIDENCE	PUBLICATION / AUTHOR / JOURNAL	WOUND POPULATION	MEASUREMENT		MIST RESULT	SOC RESULT	TREATMENT DURATION	STATISTICS
II a	A Prospective Pilot Study of Ultrasound Therapy Effectiveness in Refractory Venous Leg Ulcers Escandon J, Vivas AC, Perez R, Kirsner R, Davis S International Wound Journal 2012	N = 10 Venous Leg Ulcers	Wound Area Reduction		45% reduction	Failure to improve in previous 30 days	4 weeks	p<0.0039
II a	The Impact of Noncontact, Nonthermal, Low-Frequency Ultrasound on Bacterial Counts in Experimental and Chronic Wounds Serena T, Lee SK, Lam K, Attar P, Meneses P, Ennis W Ostomy Wound Management 2009	N = 11	Wound Volume Reduction		20% reduction	NA	2 weeks	Not reported
		Pressure Ulcers (Stage III)	Wound Area Reduction		26% reduction			
II b	Effects of Noncontact Low-Frequency Ultrasound on Healing of Suspected Deep Tissue Injury: A Retrospective Analysis Honaker JS, Forston MR, Davis EA, Wiesner MW, Morgan JA International Wound Care Journal 2012	N = 85 (127 DTIs)	Wound Evolution/Resolution at hospital discharge	Resolved	18%	2%	10 MIST Treatments over 21 days	Not reported
				Stage II	62%	20%		
				DTI	5%	30%		
				Stage III, IV unstageable	15%	48%		
		Deep Tissue Injuries (Pressure Ulcers)	Severity Scale Assessment		1.45 reduction	1.06 reduction		p<0.000
					2.51 difference			
II b	Expedited Wound Healing with Noncontact, Low-Frequency Ultrasound Therapy in Chronic Wounds: A Retrospective Analysis Kavros SJ, Liedl DA, Boon, AJ, Miller JL, Hobbs JA, Andrews KL Advances in Skin and Wound Care 2008	N = 210 Ischemic, Venous, Neuropathic, Multifactoral	Wound Closure		53% in mean of 147 days	32% in mean of 134 days	SOC followed by 12 weeks MIST treatment then SOC	p = 0.0009
II b	Use of Noncontact Low-Frequency Ultrasound in the Treatment of Chronic Foot and Leg Ulcerations Kavros SJ, Schenck EC J of American Podiatric Medical Assn 2007	N = 51	Wound Closure		51%	0% patients were treated with SOC prior to starting MIST	MIST mean 5.5±2.8 weeks SOC mean 9.8±5.5 weeks	p<0.05
		Chronic Lower Leg and Foot Ulcers, Multifactorial, Arterial, Diabetic	Wound Volume Reduction		94.9± 9.8% reduction	37.3± 18.6% reduction		p<0.0001
II b	Evaluation of Clinical Effectiveness of MIST Ultrasound Therapy for the Healing of Chronic Wounds Ennis WJ, Valdes W, Gainer M, Meneses P. Advances in Skin and Wound Care 2006	N = 23 (29 wounds)	Wound Closure		MIST only 69%	<15% area reduction in 2 week prior to MIST	6.82 weeks	Not reported
		Diabetic, Ischemic, Venous, Pressure, Post-operative, Inflammatory			MIST assisted* 73.3%		10.47 weeks	Not reported

*addition of Apligraf

TABLE OF CLINICAL EVIDENCE LEVEL III STUDY DETAILS

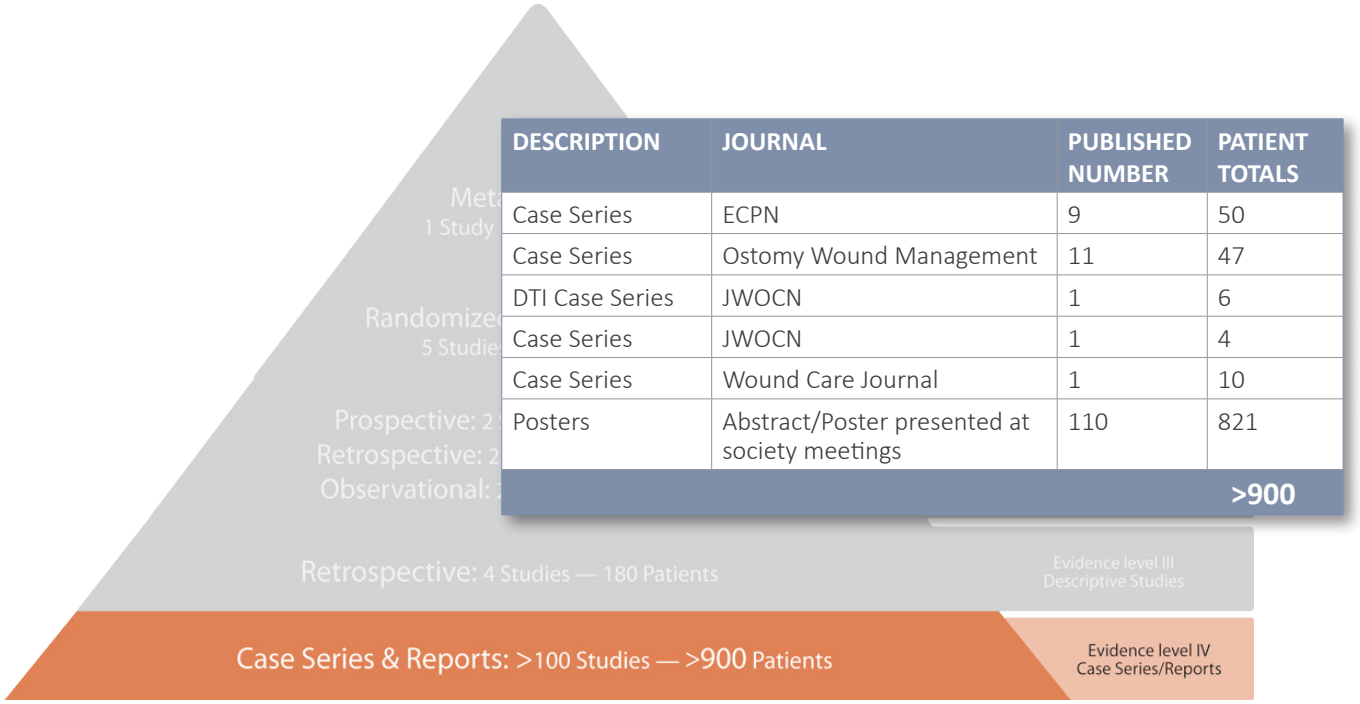
LEVEL OF EVIDENCE	PUBLICATION AUTHOR JOURNAL	WOUND POPULATION	MEASUREMENT	MIST RESULT	SOC RESULT	TREATMENT DURATION	STATISTICS
III	Adjuvant Use of Acoustic Pressure Wound Therapy* for Treatment of Chronic Wounds Cole PS, Quisberg J, Melin MM J Wound Ostomy Continence Nursing 2009	N = 41 (52 wounds)	Wound Closure	38%	<15% wound area reduction in 2 weeks prior to MIST	Mean 6.8 weeks	Not reported
			Wound Area Reduction	88% reduction		Mean 7.6 weeks	p<0.0001
		Pressure, Venous, Arterial, Surgical, Traumatic, other	Wound Volume Reduction	100% reduction			p<0.0001
			Pain VAS Measurement	2.9 reduction	NA		p<0.0001
III	A Retrospective Analysis of Acoustic Pressure Wound Therapy: Effects on the Healing Progression of Chronic Wounds Haan J, Lucich S J American College of Certified Wound Specialists 2009	N = 48 (50 wounds)	Wound Closure	24%	<15% wound area reduction in 2 weeks prior to MIST	Mean 4.2 weeks	Not reported
		Pressure, Venous, Arterial, Surgical, Traumatic, Neuropathic, other	Wound Area Reduction	92% reduction		Mean 5.5 weeks	p<0.0001
			Pain VAS Measurement	1.8 reduction	NA		p<0.0001
III	Noncontact Ultrasound Therapy for Adjunctive Treatment of Nonhealing Wounds: Retrospective Analysis Bell AL, Cavorsi J PT Journal 2008	N = 76	Wound Closure	18%	<15% reduction in 2 weeks prior to MIST	Median 3.6 weeks	Not reported
			Wound Area Reduction	79% reduction		Median 4.3 weeks	p<0.0001
		Pressure, Venous (28), Arterial, Surgical/Traumatic (25), other	Pain VAS Measurement	1.8 reduction	NA		p=0.001
III	The Effect of Noncontact, Low-Intensity, Low-Frequency Therapeutic Ultrasound on Lower-Extremity Chronic Wound Pain: A Retrospective Chart Review Gehling ML, Samies JH Ostomy Wound Management 2007	N = 15	Pain VAS Measurement	80% reduction (8.07±1.91 to 1.67±1.76) VAS	Baseline	2-4 weeks	p = 0.0003
		Venous, Ischemia, Sickle cell					

*Acoustic Pressure Wound Therapy = Noncontact Low Frequency Ultrasound = MIST Therapy

VAS Measurement = Visual Analog Scale used to assess pain- 10 point scale

CLINICAL EVIDENCE LEVEL IV SUMMARY - PUBLISHED CASE SERIES AND REPORTS

Over 900 patients have been studied in peer reviewed case series/reports showing successful outcomes with MIST Therapy across all care settings.



DESCRIPTION	JOURNAL	PUBLISHED NUMBER	PATIENT TOTALS
Case Series	ECPN	9	50
Case Series	Ostomy Wound Management	11	47
DTI Case Series	JWOCN	1	6
Case Series	JWOCN	1	4
Case Series	Wound Care Journal	1	10
Posters	Abstract/Poster presented at society meetings	110	821
			>900

These cases include patients with a wide variety of wound types including:

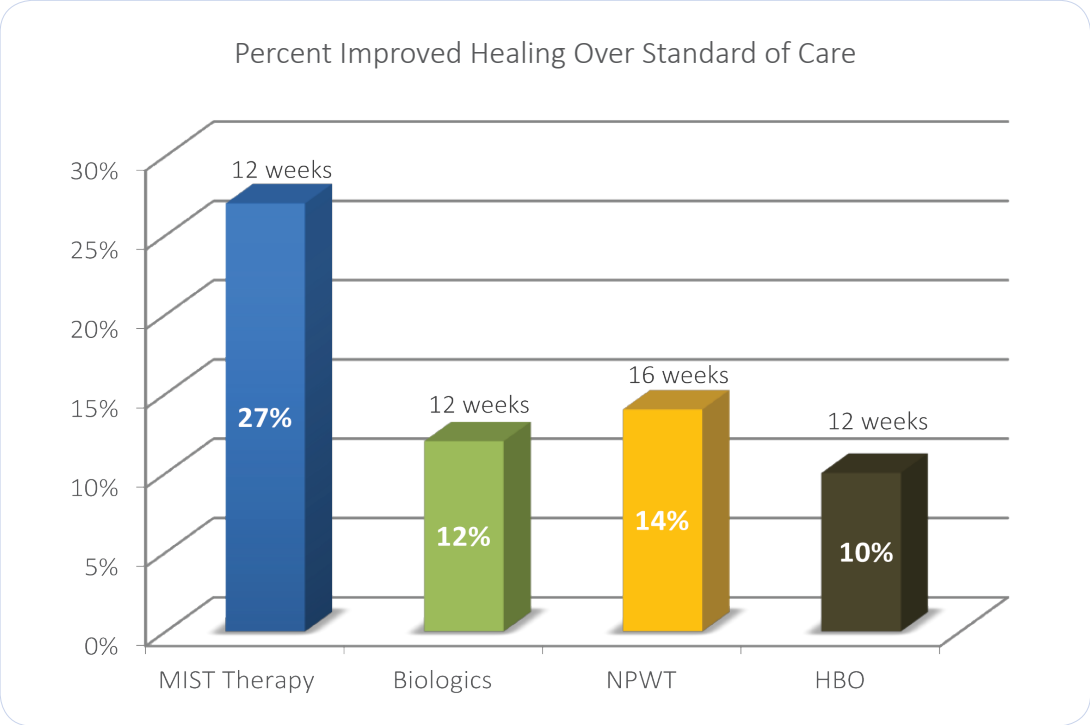
- Amputation Incisions
- Arterial Ulcers
- Burns
- Calciphylaxis
- Graft Preparation
- Deep Tissue Injuries
- Dehisced Wounds
- Diabetic Ulcers
- Donor Sites
- Exposed Tendons
- Fungal
- IV Infiltrates
- Medical Device Induced Wounds
- Necrotizing Fasciitis
- Perirectal Abscess
- Pilonidal Cysts
- Pressure Ulcers
- Pyoderma Gangrenosum
- Sickle Cell
- Surgical Wounds
- Traumatic Wounds
- Undermining/Tunnels
- Vascular Ulcers
- Wound Matrix Product

As wound care specialists have gained a better understanding MIST Therapy's mechanism of action, the versatility of the system has allowed them to apply this technology to a number of challenging wound types.

MIST THERAPY COMPARED TO OTHER ADVANCED WOUND CARE TREATMENTS

It can be difficult to compare one advanced wound care treatment to another as very little comparative data exists today. In addition, many of the studies that exist have been completed in different patient populations with different wound types.

To evaluate how MIST Therapy compared to other advanced wound care treatments, we looked at randomized control trials in a single wound type- diabetic foot ulcers (all studies compared treatment arm to standard of care). To control for differences in patient populations, we evaluated the difference in healing rates between the treatment group and the control group.



	Weeks Treated	Treatment Group % healed	Control Group % healed	Difference	Study
MIST Therapy	**12**	**41.7%**	**14.3%**	**27.4%**	Ennis 2005, Celleration MIST Therapy (n=55)
Biologics	12	30%	18%	12%	Marston 2003, Smith and Nephew- Dermagraft (n=314)
NPWT	16	43%	29%	14%	Blume 2008, KCI- VAC (n=342)
HBO	12	12%	2%	10%	Londahl 2010, Independent Study (n=94)

All of the advanced wound care treatments demonstrated faster healing rates in the same period of time when compared to the standard of care arm. However, MIST Therapy provided twice the benefit when compared to the other advanced wound care treatments.

Posterior Tibialis Tendinopathy

Question: Should surgical correction of flat foot (posterior tibialis tendinopathy) be reprioritized higher on the Prioritized List?

Question source: Dr. Richard Owens, orthopedic surgery

Issue: Flatfoot diagnoses are generally on uncovered lines, and the diagnoses on the Prioritized List used for this condition generally do not pair with the most used repair codes. Dr. Owens has requested that the HERC consider coverage for flat foot due to posterior tibialis tendonopathy. Dr. Owens feels that lack of coverage for the early forms of this disorder results in patients developing more severe stages and finally getting coverage for an ankle fusion surgery for the late states, when earlier care might have prevented the need for such extensive surgery.

Flatfoot (hyperpronation and flattening-out of the longitudinal arch) (also known as pes planus or pes planovalgus) is a common deformity among children and adults. It may be congenital, or be acquired due to various conditions including posterior tibial tendon dysfunction. Lack of a functional arch affects the biomechanics of the lower leg and can result in pain. Flat feet are very common in children, and may resolve as the child grows. Flat feet can also develop as an adult ("adult acquired flatfoot") due to injury, illness, unusual or prolonged stress to the foot, faulty biomechanics, or as part of the normal aging process.

If a youth or adult appears flatfooted while standing in a full weight bearing position, but an arch appears when the person plantar flexes, or pulls the toes back with the rest of the foot flat on the floor, this condition is called flexible flatfoot. Most flexible flat feet are asymptomatic, and do not cause pain. In these cases, there is usually no cause for concern. In some patients, lower leg pain results from the flat foot, which can be treated with the use of shoes with properly fitting, arch-supporting orthotics.

Rigid flatfoot, a condition where the sole of the foot is rigidly flat even when a person is not standing, often indicates a significant problem in the bones of the affected feet, and can cause pain in about a quarter of those affected. Other flatfoot-related conditions, such as various forms of tarsal coalition (two or more bones in the midfoot or hindfoot abnormally joined) or an accessory navicular (extra bone on the inner side of the foot) should be treated promptly, usually by the very early teen years, before a child's bone structure firms up permanently as a young adult. Both tarsal coalition and an accessory navicular can be confirmed by X-ray. Rheumatoid arthritis can destroy tendons in the foot (or both feet) which can cause this condition, and untreated can result in deformity and early onset of osteoarthritis of the joint. Such a condition can cause severe pain and considerably reduced ability to walk, even with orthoses. Ankle fusion is usually recommended.

There are 4 stages of acquired flat foot deformity. Stage I is an inflammation of the tendon and normally is treated conservatively with braces. Stage II has the foot remaining flexible, with arch collapse and mild sinus tarsi pain. Stage III is a rigid fore and hindfoot, with severe sinus

tarsi pain and subtalar arthritis. Stage IV involves ankle pain, deltoid ligament compromise, and subtalar arthritis and talar tilt in ankle mortise are seen on xray. Acquired flat foot deformity is typically seen in middle aged patients with conditions such as diabetes.

Treatment of asymptomatic flat feet is not required. Foot or leg pain due to flat feet is treated with orthotics for arch support, NSAIDs, and/or foot exercises. Surgery may be done for more severe stages of flat foot or when conservative therapy fails.

From Dr. Rich Owen

> I am sending a review article from our orthopedic review journal. It discusses the four stages of adult acquired flatfoot deformity. Patients predictably progress from Stage 1 to at least Stage 3 and sometimes Stage 4 without treatment. Currently, OHP doesn't cover surgical or nonsurgical options. The condition is severely debilitating, and gets worse with time. Many times nonsurgical treatment does not work.

Dr. Owens recommended the following coverage for acquired flatfoot:

1) Stage 1: braces or orthotics to prevent progression.
2) Stage 2: braces or orthotics. Repair for patients less than 70 years of age (CPT 20902, 27687, 27690, 28090, 28300, 28306, 28307, 28715)
3) Stage 3: surgical repair (CPT 27605, 27687, 28715)
4) Stage 4: surgery-total ankle replacement (CPT 27702)

Posterior Tibialis Tendinopathy

Current Prioritized List status

ICD-10 Code	Code description	Current Line(s)
M19.07	Primary osteoarthritis, ankle and foot	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE **467** OSTEOARTHRITIS AND ALLIED DISORDERS
M21.4	Flat foot [pes planus] (acquired))	**580** CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
M21.6	Other acquired deformities of foot	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*M21.961	Unspecified acquired deformity of right lower leg	**382** **545** DEFORMITIES OF FOOT
*M66.9	Spontaneous rupture of unspecified tendon	**506** OTHER DISORDERS OF SYNOVIUM, TENDON AND BURSA, COSTOCHONDRITIS, AND CHONDRODYSTROPHY
M76.82	Posterior tibial tendinitis	**490 and 508** ERIPHERAL ENTHESOPATHIES
Q66.5	Congenital pes planus	**545**
Q66.9	Congenital deformity of feet, unspecified	**545**

*identified by Dr. Owens as appropriate diagnosis code

CPT code	Code Description	Current Line(s)
*20902	Bone graft, any donor area; major or large	**164** TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION **447** MALUNION AND NONUNION OF FRACTURE **488** ENOPHTHALMOS **587** ATROPHY OF EDENTULOUS ALVEOLAR RIDGE
*27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **364** DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS

		392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
*27687	Gastrocnemius recession (eg, Strayer procedure)	**297**, **364**, **392** **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (eg, anterior tibial extensors into midfoot)	**297,364,392,530** **545** DEFORMITIES OF FOOT
27700-27703	Arthroplasty, ankle	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
*28090	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (eg, cyst or ganglion); foot	**361,364,392, 545** **596** GANGLION
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (eg, Kidner type procedure)	**364, 392, 545**
*28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation	**297,364,392,530,545**
*28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	**545**
*28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)	**297,364,392,545**
*28715	Arthrodesis; triple	**290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT **297,361,364,392,545**
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)	**364,392,545**

29907	Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **361,364,392** **447** MALUNION AND NONUNION OF FRACTURE **545**
HCPCS Code		
S2117	Arthroereisis, subtalar	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

*identified by Dr. Owens as appropriate procedure code
Other codes identified through literature and other insurer policy statements
Note: S2117 is a controversial procedure

Evidence

1) **Rome 2012**, Cochrane review of non-surgical treatments for pediatric flatfoot (study not included due to length)
   http://www.bcu.ac.uk/cmsproxyimage?path=/_media/docs/cd006311.pdf
   a. N=3 trials (305 children)
   b. Data from one trial (40 children with juvenile arthritis and foot pain) indicated that use of custom-made orthoses compared with supportive shoes alone resulted in significantly greater reduction in pain intensity (mean difference (MD) -1.5 points on a 10-point visual analogue scale (VAS), 95% CI -2.8 to -0.2; number need to treat to benefit (NNTB) 3, 95% CI 2 to 23), and reduction in disability (measured using the disability subscale of the Foot Function Index on a 100mm scale (MD -18.65mm, 95% CI -34.42 to -2.68mm).
   c. The second trial of seven to 11 year old children with bilateral flat feet (n = 178) found no difference in the number of participants with foot pain between custom-made orthoses, prefabricated orthoses and the control group who received no treatment.
   d. A third trial of one to five year olds with bilateral flat feet (n=129) did not report pain at baseline but reported the subjective impression of pain reduction after wearing shoes. No adverse effects were reported in the three trials.
   e. **Authors' conclusions** The evidence from randomised controlled trials is currently too limited to draw definitive conclusions about the use of non-surgical interventions for paediatric pes planus. Future high quality trials are warranted in this field. Only limited interventions commonly used in practice have been studied and there is much debate over the treatment of symptomatic and asymptomatic pes planus
2) **MacKenzie 2012**, review of treatment of pediatric flatfoot
   a. N=13 studies, generally poor quality
   b. Conclusions: evidence for efficacy of nonsurgical interventions for flexible pediatric flat feet is very limited. Future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up.
3) **Bouchard 2014**, review of flatfoot in children and adolescents
   a. Most flexible flatfoot deformities are asymptomatic, will not lead to future pain or disability, and do not require treatment.
   b. Scant convincing evidence exists to support the use of inserts or shoe modifications for effective relief of symptoms, and there is no evidence that those devices change the shape of the foot.
   c. Surgery is rarely indicated, and in nearly all cases, an associated contracture of the heel cord is present
   d. Indications for flatfoot surgery are strict: failure of prolonged nonsurgical attempts to relieve pain that interferes with normal activities and occurs under the medial midfoot and/or in the sinus tarsi.

   e. Osteotomies with supplemental soft-tissue procedures are the best proven approach for management of rigid flatfoot.

4) **Stegeman 2015**, review of outcomes after tarsal joint fusion
   a. Only one study was considered to have best evidence for flatfoot treatment by subtalar fusion
      i. An increase in the AOFAS score from 46 preoperatively to 70 points postoperatively was observed without concomitant use of low-intensity ultrasound (US) bone growth stimulation, and this score had increased from 50 to 84 when low-intensity US stimulation was used.
   b. Flatfoot treated using triple arthrodesis was described in 2 of the studies (12.5%); however, no best evidence could be deduced from those reports, and no study was found with flatfoot treated using talonavicular arthrodesis.
   c. van der Krans et al described 20 patients with posterior tibial tendon disease and calcaneocuboid distraction arthrodesis and noted improvement in the AOFAS score from a mean of 46 preoperative to a mean of 79 postoperatively, along with structural improvement in the alignment of the foot as measured radiographically, with the talar–first metatarsal angle decreasing from 15 deg preoperatively to 4.1 deg postoperatively.

<u>Submitted literature</u>

1) **Deland 2008**, acquired flatfoot deformity in adults
   a. Stage 1 should be treated conservatively with NSAIDs, orthotics, or immobilization with a cast or brace
      i. No study has been done to document whether these devices slow or prevent the progression of deformity
   b. Reviewed various surgical options for treating various stages of flatfoot deformity

Posterior Tibialis Tendinopathy

HERC staff recommendations:

1) Add ICD-10 M21.6 (Other acquired deformities of foot) to line 545 DEFORMITIES OF FOOT and remove from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    a. More appropriate placement
2) Add ICD-10 Q66.5 (Congenital pes planus) to line 580 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES and remove from line 545
    a. More appropriate placement
3) Add CPT codes for surgical treatment of flatfoot to line 580
    a. Will allow pairing and limited coverage through the exceptions process
    b. Add CPT 28735 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)) to line 580 and remove from lines 364, 392, 545
    c. Add the following CPT codes to line 580
        i. 20902, 27605, 27687, 27690, 27700-27703, 28090, 28238, 28300, 28306, 28307, 28715, 29907
        ii. See table above for procedure descriptions
4) Do not change current prioritization/placement of flatfoot; maintain on line 580.
    a. Generally does not require treatment. If progresses to ankle arthritis, can have surgical and non-surgical treatment of that condition. Severe flat foot deformity treatment can be pursued through the exceptions process
    b. No evidence identified on rate of progression of early stages to later stages or on the ability of orthotics or braces to prevent such progression
    c. If coverage is considered, only acquired flat foot should be considered (not congenital) with guideline

The Efficacy of Nonsurgical Interventions for Pediatric Flexible Flat Foot: A Critical Review

Angela Jane MacKenzie, BSc, Keith Rome, PhD,* and Angela Margaret Evans, PhD*†*

Background: The pediatric flat foot frequently presents as a common parental concern in the health care setting. Foot orthoses are often used, yet benefits are uncertain and disputed, having been variably investigated. A recent Cochrane review cites limited evidence for nonsurgical interventions. This critical and structured review evaluates the effect of pediatric foot orthoses from assessment of the current literature.

Methods: A systematic search of the following electronic databases: Medline, CINAHL, AMED, and SPORTDiscus, using an array of search terms. A further search was also performed on relevant reference listings. Inclusion criteria were peer-reviewed journal articles, publication date from 1970 onwards, in the English language. Exclusion criteria were surgery interventions, adult subjects, rigid flat foot, articles based on opinion. A structured Quality Index was used to evaluate the research quality of articles. Three reviewers independently assessed the studies with disputes resolved by majority consensus. Studies were then grouped according to the outcome measures used.

Results: Thirteen articles, from an initial 429, met the criteria for quality evaluation. The mean Quality Index score was 35% (range: 13% to 81%), indicative of generally poor and varying methodological quality.

Conclusions: The low quality of the studies negates definitive conclusions. Only 3/13 quality evaluations scored > 50%; hence, evidence for efficacy of nonsurgical interventions for flexible pediatric flat feet is very limited. Future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up.

Clinical Relevance: There is very limited evidence for the efficacy of nonsurgical interventions for children with flexible flat feet. Clinicians need to consider the lack of good-quality evidence in their decision-making for the management of pediatric flat foot.

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K.R. and A.M.E. are authors of a Cochrane Library systematic review for nonsurgical interventions for pediatric flexible flat foot. The other author declares no conflict of interest.

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Key Words: flat foot, pediatric, orthoses, quality, evidence

(*J Pediatr Orthop* 2012;32:830–834)

Pediatric flat foot continues to be a frequent presentation to a range of health professionals, as it remains a common concern to parents.[1,2] A recent Cochrane review, and a subsequent wider topic review, has highlighted the limited evidence relating to the use of foot orthoses, which are commonly used by clinicians for treating pediatric flat foot.[3,4] Cochrane reviews are central to evidence-based medicine. However, by focusing exclusively on randomized controlled trials (RCTs) a large swath of the published literature is excluded from general purview. Our experience, conducting 2 published reviews that examined interventions for pediatric flat feet, has brought particular methodological issues to light,[3,4] which in turn, contribute to the benefits of treatment being disputed, and the conclusions about studies addressing intervention effects, becoming polarized.[5–11]

The aim of this literature review was to evaluate the effect of foot orthoses on the flexible pediatric flat foot, and using a structured critical framework, to assess the methodological quality of the reported studies.

METHODS

Data Sources

A systematic search of electronic databases included Medline, CINAHL, AMED, and SPORTDiscus. The following search terms were used: flatfoot; flatfeet; flat foot; flat feet; pes planus; planovalgus; pronat* foot; pronat* feet; hyperpronat* feet; hyperpronat* foot; child*; pediatric*; infant*; adolescen*; teenag*; juvenile*; study; studies; trial; research; conservative; treat*; manage*; intervention; insole; insert; orthoses; orthotic*; footwear; shoe*; therapy; and rehabilitati*. The last electronic search was run on March 30, 2011. In addition, a secondary search was performed on the reference sections of the relevant articles.

Study Selection

The inclusion criteria were: peer-reviewed journal articles, publication date from 1970 to April 2011, participant sample size of > 1, and published in the English language. Articles based on expert opinion and clinical practice guidelines, despite their valued contribution, were

Review Article

Flatfoot Deformity in Children and Adolescents: Surgical Indications and Management

Maryse Bouchard, MD, MSc
Vincent S. Mosca, MD

Abstract

Most children with flatfeet are asymptomatic and will never require treatment. In general, flatfoot deformity is flexible and will not cause pain or disability; it is a normal variant of foot shape. Thus, it is essential to reassure and educate patients and parents. A flatfoot with a contracture of the Achilles tendon may be painful. In these cases, a stretching program may help relieve pain. Scant convincing evidence exists to support the use of inserts or shoe modifications for effective relief of symptoms, and there is no evidence that those devices change the shape of the foot. The surgeon must be vigilant to identify the rare rigid flatfoot. Indications for flatfoot surgery are strict: failure of prolonged nonsurgical attempts to relieve pain that interferes with normal activities and occurs under the medial midfoot and/or in the sinus tarsi. In nearly all cases, an associated contracture of the heel cord is present. Osteotomies with supplemental soft-tissue procedures are the best proven approach for management of rigid flatfoot.

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Neither of the following authors nor any immediate family member has received anything of value from or has stock or stock options held in a commercial company or institution related directly or indirectly to the subject of this article: Dr. Bouchard and Dr. Mosca.

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Although flatfoot deformity is a common reason for a child to present for evaluation by a healthcare provider, understanding of the deformity and consensus regarding its management is poor, particularly among healthcare providers in different medical specialties. This is due to several factors, including the poor methodology of published reports, the lack of controlled research studies, and conflicting evidence in the literature. Studying the natural history of the flatfoot is difficult because most affected patients are asymptomatic and do not seek medical attention. Moreover, because no established clinical or radiographic criteria exist to define the flatfoot, the true prevalence of the deformity is unknown. Traditionally, flatfoot was described as a low or absent medial longitudinal arch, with the hindfoot in excessive valgus alignment.[1]

The present consensus is that flexible flatfoot is present from birth and exhibits good joint mobility and normal muscle function.[1] Despite the lack of high-quality research, it is clear that most flatfoot deformities in children are flexible, painless, and functional and do not require treatment. Children with a painless flatfoot who visit an orthopaedist are generally brought in because their parents are concerned that the foot deformity will cause pain and/or disability in adulthood. The role of the orthopaedist is to reassure patients and parents of children with flexible flatfeet that no treatment is necessary and to identify and treat the rare flatfoot deformities that may become disabling.

In their 1947 study of foot pathology in 3,600 Canadian soldiers, Harris and Beath[2] reported that flatfeet were seen in approximately 23% of the recruits. Sixty-four percent of flatfeet were

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Outcome After Operative Fusion of the Tarsal Joints: A Systematic Review

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outcome scores

ABSTRACT

Arthrodesis of 1 or more joints of the hindfoot is performed to treat severe functional impairment due to pain, deformity, and/or instability. Evaluation of the results of hindfoot arthrodesis from the published data has been difficult owing to the great variety of pathologic entities and surgical techniques reported in the studies. A comprehensive search for relevant reports, reference lists, and citation tracking of the included studies was conducted using the PubMed®, Embase®, and CINAHL® databases. The studies had to have been prospective, included patients with hindfoot problems, evaluated arthrodesis of 1 or more tarsal joints, and had at least 1 of the following primary clinical outcome parameters: pain, function, or complications. Two of us independently selected the relevant studies using predefined criteria and graded the quality of evidence using a 0 to 9 star scale according to the Newcastle-Ottawa Scale. A total of 16 prospective case series were included; 5 studies scored 6 stars, 8 scored 5 stars, 2 scored 4 stars, and 1 scored 3 stars. A best evidence synthesis was performed, and improvement in function and pain was found for 3 combinations: talonavicular arthrodesis for rheumatoid arthritis, triple arthrodesis for rheumatoid arthritis, and subtalar arthrodesis for post-traumatic arthritis showed good results for pain and function, the last especially when performed arthroscopically. The best evidence syntheses revealed good results for pain and function for these disease-operative technique combinations.

Functional impairment of the hindfoot due to pain, deformity, and/or instability is common in adults. When conservative treatments, such as the use of orthotics and custom made shoe wear, adaptation of one's activities of daily living, and medications, have failed to resolve the pain and improve function, surgery can be considered. Surgical fusion has long been regarded as a salvage operation for relief of the symptomatic hindfoot because of movement limitations and relatively high complication rates. Triple arthrodesis (fusion of the talocalcaneal, talonavicular, and calcaneocuboid joints) has long been the preferred technique and has been extensively documented by various investigators (1–3). A number of retrospective studies, and a few prospective studies, have documented good functional results and high patient satisfaction rates after hindfoot arthrodesis. In recent years, emphasis has been increasing on single arthrodesis of the tarsal joints, including isolated fusion of the talonavicular (4,5), calcaneocuboid (6), and subtalar joint (7–15) to preserve the adjacent unaffected joints. Also, the technique of arthroscopic arthrodesis of hindfoot joints has been described, with promising results (16–18).

An important question to answer is which specific tarsal fusion technique will be most effective with regard to which pathologic entity. Because of the heterogeneity of pathologic entities and patient groups, the variety of surgical techniques, and the lack of disease-specific and surgery-specific scoring systems, it has been difficult to evaluate the results of hindfoot arthrodesis. The first step in answering this question is to examine the published data regarding outcome studies that were prospective in design and focused only on tarsal (talocalcaneal, calcaneocuboid, and/or talonavicular joint) fusion. The aim of the present systematic review was to evaluate which specific tarsal fusion (isolated or combined) was the most effective for the treatment of specific hindfoot pathologic features.

Materials and Methods

Search Methods

In January, 2013, a comprehensive published data search for relevant studies was conducted using PubMed® (Medline® PubMed®, U.S. National Institutes of Health,

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Adult-acquired Flatfoot Deformity

Jonathan T. Deland, MD

Abstract

Originally known as posterior tibial tendon dysfunction or insufficiency, adult-acquired flatfoot deformity encompasses a wide range of deformities. These deformities vary in location, severity, and rate of progression. Establishing a diagnosis as early as possible is one of the most important factors in treatment. Prompt early, aggressive nonsurgical management is important. A patient in whom such treatment fails should strongly consider surgical correction to avoid worsening of the deformity. In all four stages of deformity, the goal of surgery is to achieve proper alignment and maintain as much flexibility as possible in the foot and ankle complex. However, controversy remains as to how to manage flexible deformities, especially those that are severe.

Adult-acquired flatfoot deformity (AAFD) encompasses a wide range of deformities.[1] Originally known as posterior tibial tendon dysfunction or insufficiency, AAFD was first described as tendon failure.[2,3] However, failure of the ligaments that support the arch also occurs, often resulting in progressive deformity of the foot.[1,4-6] Deformities vary in severity, rate of progression, and location along the arch. Treatment has been effective in relieving pain. However, achieving maximum function remains a challenge. When the deformities become more severe and fixed, the results of treatment are more limited. Controversies persist regarding how to treat AAFD, especially the more severe flexible deformities.

The presenting symptoms of AAFD vary according to the stage of disease. Early on, a patient presents with pain and swelling medially over the posterior tibial tendon. The tendon failure is a degenerative process. Even though the tendon may not rupture, it often becomes dysfunctional. Tendon failure occurs most often just distal to and at the level of the medial malleolus. The etiology of the condition is multifactorial. Preexisting flatfoot is common, and obesity is often present. Relative hypovascularity in this area of the tendon is another possible factor.[7] AAFD is more common in females, with peak incidence at age 55 years.

With time, medial foot pain caused by tendon failure may dissipate, although swelling may persist. Ligament failure commonly occurs along with the tendon dysfunction. However, it may take place after or, less commonly, before tendon failure. The spring ligament complex that supports the talonavicular joint often is involved, resulting in increasing deformity at this joint. Along with subluxation at the talonavicular joint comes involvement of the interosseous ligament and subluxation at the subtalar joint.[6] A combination of plantar and medial migration of the talar head occurs, resulting in flattening of the arch as the foot displaces from un-

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Table 1

The Four Stages of Adult-acquired Flatfoot Deformity

Stage	Deformity	Surgical Treatment
I	No deformity from AAFD (may have preexisting flatfoot)	Tenosynovectomy, possible tendon transfer, and/or medial slide osteotomy
IIa	Mild/moderate flexible deformity (minimal abduction through talonavicular joint, <30% talonavicular uncoverage)	Tendon transfer, medial slide osteotomy, possible Cotton procedure
IIb	Severe flexible deformity (abduction deformity through talonavicular joint, >30% talonavicular uncoverage)	Tendon transfer, medial slide osteotomy, and possible lateral column lengthening or hindfoot fusion (subtalar or talonavicular and calcaneocuboid fusion) Cotton procedure or metatarsal-tarsal fusion performed as needed for elevation of the first ray
III	Fixed deformity (involving the triple-joint complex)	Hindfoot fusion, most commonly triple arthrodesis. Correction requires fusion of all three joints.
IV	Foot deformity and ankle deformity (lateral talar tilt)	Complete correction of foot deformity, possible deltoid reconstruction. For severe arthritis, perform ankle fusion or total ankle arthroplasty, including correction of foot deformity.
IVa	Flexible foot deformity	Foot deformity corrected as with stage IIb
IVb	Fixed foot deformity	Foot deformity corrected as with stage III

AAFD = adult-acquired flatfoot deformity

derneath the talus. The ligaments supporting the naviculocuneiform and tarsometatarsal joints also may degenerate, resulting in deformities at these joints. Thus, deformities can occur along the entire medial longitudinal arch. With progression of hindfoot deformity, a patient can develop lateral pain from bony impingement at the lateral subtalar joint and distal tip of the fibula. There may be a significant period of time between resolution of medial pain and the development of lateral pain, when the symptoms may consist more of a weakness in the foot than pain. However, pain eventually returns when the deformity progresses.

Diagnosis

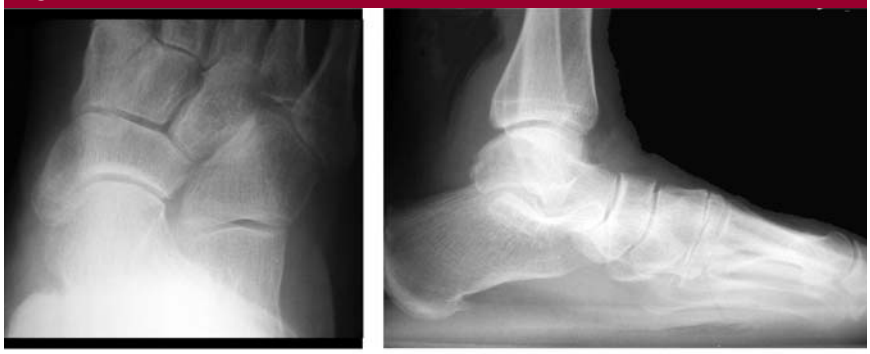
The diagnosis of AAFD is based on patient history, physical examination, and standing radiographs of the foot and ankle. Magnetic resonance imaging may confirm the tendon pathology; however, it is not required. An important clinical sign is the inability to perform a single heel rise normally. For a normal heel rise, the patient must be able, with the opposite foot off the ground, to raise the heel off the ground; the physician should see normal inversion of the heel occur during heel rise. To properly perform the test, a second person is needed to balance the patient. Alternatively, the patient may place his or her hands against the wall for balance. The examiner kneels behind the patient and asks the patient to stand on one foot. While the knee of the affected leg is held straight, the patient is asked to lift the heel off the ground and go up onto the toes. This may be impossible on the affected side. Some patients can lift the heel off the ground or maintain the heel in valgus without the normal shift into the varus or inverted position. The test is considered positive when the patient is unable to lift the heel off the ground or normal heel inversion does not occur. Other conditions, such as Achilles rupture, arthritis, and fusion involving the talonavicular or subtalar joints, may give a false-positive result. However, this test is usually a good indicator of posterior tibial tendon dysfunction.

Stages of Adult-acquired Flatfoot Deformity

Staging of AAFD is based on the deformity; four stages have been described (Table 1). The first three stages were originally described by Johnson and Strom.[4] The patient with stage I AAFD presents with flatfoot that has been present throughout adulthood but without deformity. Tenosynovitis and/or tendinosus may be present. A subgroup of patients in stage I present with spondyloarthropathy.[1]

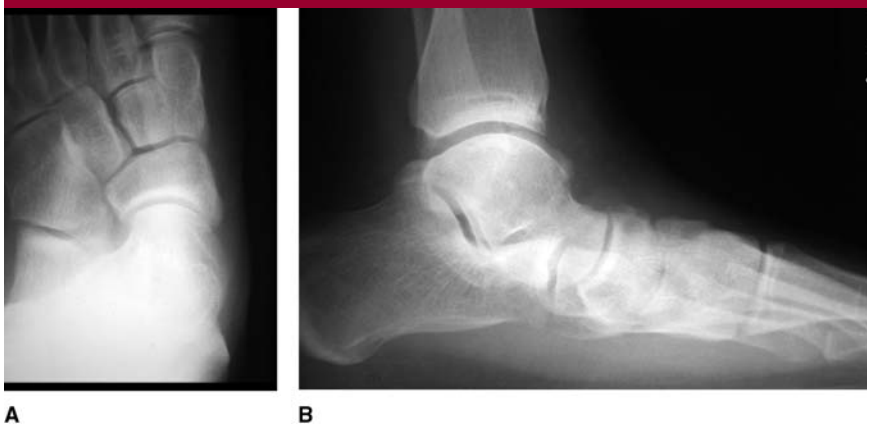
In stage II, AAFD causes a change in alignment of the foot (ie, developed deformity). The distinguishing characteristic of stage II is passively correctible deformity. The talonavicular joint can be placed into an inverted position and the heel alignment passively corrected. Stage II has been further divided into stages IIa and IIb.[8,9] Stage IIa AAFD involves deformity with minimal abduction through the midfoot (ie, <30% talar head uncoverage on the standing anteroposterior [AP] radiograph [Figure 1]). In Stage IIb, patients generally ex-

Figure 1



Anteroposterior (AP) **(A)** and lateral **(B)** standing radiographs of a patient with stage IIa adult-acquired flatfoot deformity. Note the talonavicular sag on the lateral view, with minimal (<30%) talonavicular uncoverage on the AP view.

Figure 2

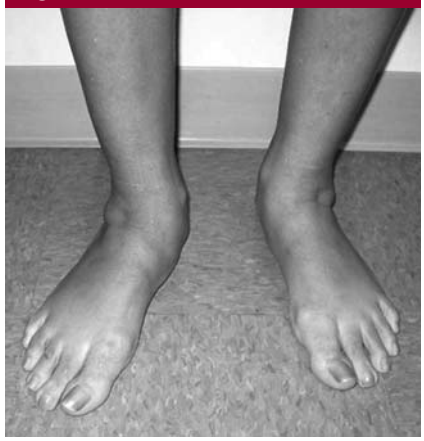


AP **(A)** and lateral **(B)** standing radiographs of a patient with stage IIb adult-acquired flatfoot deformity. Note the uncoverage of the medial talar head on the AP view.

hibit more deformity clinically, with >30% talar head uncoverage on standing AP radiographs. As the deformity through the talonavicular joint becomes more severe, greater foot abduction occurs at that joint. This can be seen when the standing AP alignment of the foot is inspected clinically and on radiographs that demonstrate uncoverage of the medial talar head (Figure 2). The lateral talonavicular joint can be inspected for incongruency on an AP radiograph. The lateral margins of the talonavicular joint demonstrate lateral rotation/displacement of the navicular with respect to the talar head. The standing AP radiograph may underestimate the extent of abduction if the patient holds up the arch while the radiograph is being made or if positioning does not allow full weight bearing with the lower leg directly over the foot. Thus, it is important to evaluate the patient's standing clinical alignment as well (Figure 3).

Stage III AAFD involves fixed deformity, meaning that passive inversion of the triple-joint complex (ie, talonavicular, subtalar, calcaneocuboid joints) beyond the neutral plantigrade position of the foot is not possible (Figure 4). Most commonly, there is fixed hindfoot valgus and abduction through the midfoot.

Figure 3



Clinical photograph of a patient with stage IIb adult-acquired flatfoot deformity demonstrating abduction through the midfoot.

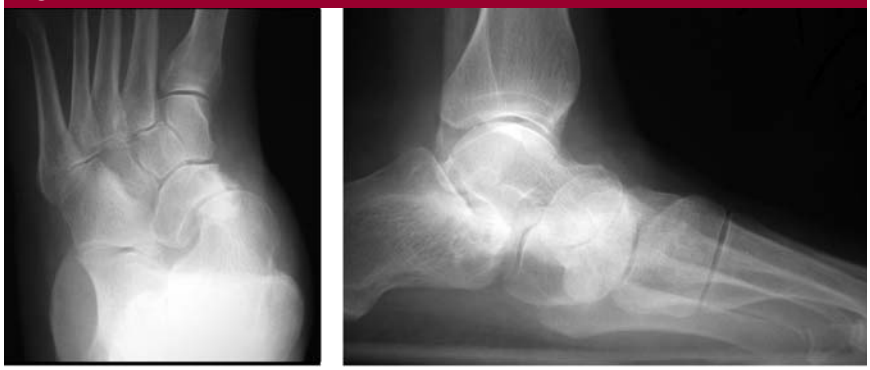
In stage IV AAFD, as defined by Myerson,[1] the patient has deformity in the ankle joint in addition to the foot. An AP radiograph of the ankle shows a lateral talar tilt, indicating failure of the deltoid ligament (Figure 5). In stage IV, the foot deformity may be either flexible or fixed. It is more common for the deformity to be fixed but it can be flexible. This stage can be subclassified into IVa (ie, flexible foot deformity) and IVb (ie, fixed foot deformity) to differentiate these different types (Table 1).

Treatment

Nonsurgical

Nonsurgical treatment is recommended first because it may be helpful in alleviating symptoms.[10-12] A removable boot or cast is most often helpful as initial treatment in the patient who is highly symptomatic. Although nonsteroidal anti-inflammatory medications may be helpful, immobilization followed by support is the most effective means of nonsurgical management. Depending on the results of immobilization, as well

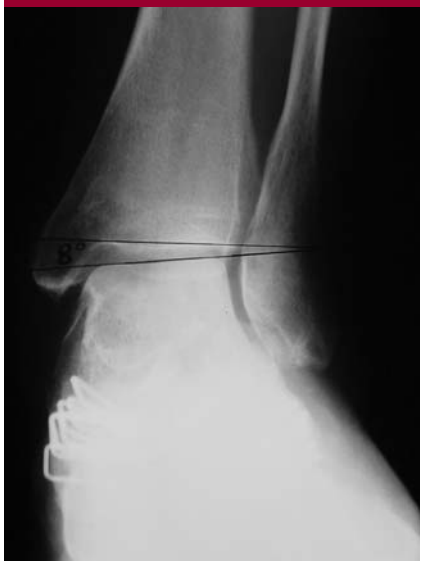
Figure 4



A B

AP **(A)** and lateral **(B)** radiographs of a patient with stage III adult-acquired flatfoot deformity.

Figure 5



Standing AP radiograph of the ankle of a patient with stage IV adult-acquired flatfoot deformity. Note the lateral tilt of the talus in the ankle mortise.

as the level of deformity and duration of symptoms, support may be achieved with a customized brace. A short articulated ankle-foot orthosis allows ankle motion and provides support via the tibia and the medial longitudinal arch.[10,11] The Arizona brace (Arizona, Inc, Mesa, AZ) provides excellent support with its firm leather lace-up design, but it limits ankle motion.[12] These braces are most often used longer than 2 months in patients with considerable pronation in the foot (ie, moderate to severe increased heel valgus and abduction through the midfoot, resulting in lowering of the medial longitudinal arch). They can be used long-term if necessary or, if the deformity is not severe, for several months, then followed by a foot orthosis. A foot orthosis (ie, an orthotic with a medial longitudinal arch support and medial heel wedge) is less cumbersome than a brace, but it provides less support. A foot orthosis is most suitable once the initial symptoms have improved. Orthoses do not provide adequate support for more severe deformities.

No study has been done to document whether these devices slow or prevent the progression of deformity. A short-term study on patients with stage I and II deformity demonstrated an 89% satisfaction rate with a program that included orthotic support (eg, short articulated ankle-foot orthosis, foot orthosis [when the pain subsided]) and adequate physical therapy.[10] This study had 1-year follow-up. Long-term results of nonsurgical treatment have not been reported.

Although nonsurgical treatment is an appropriate option, patients should be watched for increasing deformity. A patient may progress slowly, quickly, or not at all. Each patient should be made aware of the advantages and disadvantages of waiting. The patient should be advised that if deformity increases considerably, surgical treatment may not be as successful. The author prefers to immobilize a patient in a removable boot for 3 to 6 weeks, often with a foot orthosis to correct heel valgus. If this is successful and the deformity is mild to moderate, the patient can be progressed out of the boot, and the foot orthosis is used in a lace-up shoe or sneaker.[10] For more severe deformities, a short articulated ankle-foot orthosis or an Arizona brace is used instead. Device selection is made based on deformity and patient preference.[10-12] Physical therapy can be helpful after the initial inflammation has dissipated. A program of Achilles tendon stretching, inversion, and toe flexor strengthening along with proprioception exercises is used. When immobilization followed by orthotic or brace support fails to alleviate symptoms or when the amount of deformity is increasing, surgery is strongly advised.

Surgical

Stage I

Surgical treatment of stage I AAFD classically includes tenosynovectomy, tendon repair, or tendon transfer, depending on the condition of the tendon. Surgery is performed only after the failure of 3 months of nonsurgical care. In the author's experience, surgical treatment with débridement or repair has a significant long-term failure rate when the patient has a flatfoot, even when the patient and physician believe there has been no increase in the flatfoot.[13] The patient who presents with symptoms lasting >3 months is a candidate for surgical treatment. Although controversial in stage I, a calcaneal medial slide osteotomy may be added to the tendon procedure for the patient with a flatfoot.[14]

Stage IIa

Surgical treatment selection for stage IIa deformity is based on the type and amount of deformity. With a flexible mild deformity and a compromised tendon, tendon transfer (usually of the flexor digitorum longus) is performed along with bony procedures. A medial calcaneal heel slide has been shown to correct deformity and provide satisfactory results in patients with stage IIa AAFD.[14] The medial heel slide corrects heel valgus and takes strain off the medial ligaments and posterior tibial tendon, resulting in minimal stiffness.[15] There are differences of opinion regarding the severity of deformity that can be adequately treated with a medial heel slide in contrast with when other procedures in the hindfoot are required.[8,16,17] Some surgeons have attempted an arthroereisis implant without a calcaneal osteotomy. Preliminary results on these procedures have shown patient satisfaction.[17] The procedure does not require osteotomy or fusion, but sinus tarsi pain from the implant can occur; long-term follow-up data are not available. Procedures to treat deformity at the metatarsal-tarsal joints and the naviculocuneiform joints may include first metatarsal-tarsal fusion, Cotton or opening wedge medial cuneiform osteotomy, and naviculocuneiform fusion.[18] Surgeons should weigh the symptomatic benefit of these procedures against the morbidity. A stable first ray, one that is not in dorsiflexion in comparison with the second metatarsal, is important to the alignment of the arch. Metatarsal-tarsal fusion can be used to bring the first ray down. However, when the first ray is stable, plantar flexion of the first ray may be gained with an opening wedge cuneiform osteotomy rather than a metatarsal-tarsal fusion. Naviculocuneiform fusion can stabilize instability at that joint, but correction must be weighed against the difficulty of achieving fusion in these joints. Some remaining deformity at the naviculocuneiform joint is often well tolerated.

Postoperative care following tendon transfer and medial slide osteotomy requires non–weight bearing or touch-down weight bearing in a cast or removable cast/brace for 6 weeks. This is followed by progression to full weight bearing by 8 weeks after surgery. From 6 to 12 weeks, the patient is kept in a removable boot. Range-of-motion exercises are begun at 6 weeks, and progressive strengthening exercises are begun 12 weeks postoperatively when the tendon transfer has healed. These exercises are done with a physical therapist or by the patient alone, using gentle strengthening at first. A foot orthosis is recommended when the patient progresses to lace-up shoes (12 to 14 weeks postoperatively). The patient should be informed that improvement is not expected until 4 to 6 months after surgery.

Stage IIb

Treatment of the more severe stage IIb AAFD is controversial compared with treatment of other stages of the disease. Some surgeons commonly use lateral column lengthening,[19-21] while others use it rarely, if at all.[16] Lateral column lengthening provides correction to the abducted talonavicular joint and raises the arch.[22] However, it also decreases eversion and increases the pressure along the plantar lateral border of the foot.[23] Lateral column lengthening may be performed through the anterior calcaneus or the calcaneocuboid joint.[24,25] Either autograft or allograft may be used for the lengthening; a high union rate has been shown for both when the graft is used through an osteotomy in the anterior calcaneus.[26] Calcaneocuboid distraction arthrodesis has a high incidence of nonunion and, even with healing, the procedure results in more residual discomfort in the foot.[8,25] Precisely when lateral column lengthening is needed has not been defined. Because it is very powerful in the correction of abduction and because overcorrection occurs easily, it should be done only in the presence of abduction deformity (ie, >30% to 40% talar head uncoverage or incongruency at the lateral talonavicular joint on a standing AP radiograph). Lengthening may result in lateral foot overload, fifth metatarsal stress fracture, and significant stiffness.[25] However, a patient with moderate to severe abduction deformity at the talonavicular joint may not achieve sufficient correction with a medial slide osteotomy.

Because of the potential problems related to lateral column lengthening, some surgeons opt to accept limited correction with a medial slide osteotomy or to proceed to a hindfoot fusion, such as a subtalar fusion.[25,27,28] For the more severe deformities, the surgeon may elect to proceed to a fusion that includes the talonavicular joint. A comparison study of patients treated for stage IIa with a medial slide osteotomy versus patients with stage IIb treated with medial slide osteotomy and lateral column lengthening did show a higher incidence of lateral discomfort and stiffness in the group that underwent medial slide osteotomy and lateral column lengthening.[8] Forty-five percent of patients in the group treated with medial slide osteotomy and lateral column lengthening had some degree of lateral discomfort, whereas 55% did not.[8] Admittedly, medial slide osteotomy plus lateral column lengthening was done on patients with a greater level of deformity. Interestingly, those patients who had lateral discomfort after a medial slide osteotomy and lateral column lengthening also had a statistically significant ($P < 0.05$) greater incidence of perceived stiffness. Thus, minimizing stiffness while providing only the amount of correction necessary is likely to be helpful in minimizing lateral discomfort when a lateral column lengthening is performed. Because overcorrection is easy to do, it is important to carefully choose the

amount of correction in this powerful procedure. Correction should be done judiciously to avoid excessive stiffness on the lateral side of the foot. The goal is not to obtain a high arch or stiff foot; rather, it is to achieve acceptable alignment (ie, no valgus or abduction deformity), with no excessive stiffness on the lateral side. Normal but not excessive eversion motion should remain in the foot. Further work needs to be done on how to avoid stiffness and minimize residual symptoms after lateral column lengthening.

Postoperative care after tendon transfer and medial slide osteotomy with lateral column lengthening is somewhat longer than after tendon transfer and medial slide osteotomy. The patient is kept non–weight bearing or touch-down weight-bearing in a cast or removable boot for 8 weeks, with progression to full weight bearing between weeks 8 and 10. Range-of-motion exercise is begun at 8 weeks and strengthening, by 10 weeks.

Spring ligament repair or reconstruction has a place in the treatment of stage IIa and IIb AAFD, although its role has not been precisely defined. Because the spring ligament is often degenerated, repair alone should not be counted on to provide correction of bony alignment. Repair is most commonly done for a gross tear in the ligament. There are no data to prove its efficacy, given that it is done in conjunction with concomitant procedures such as calcaneal osteotomy. However, repair of tears, whether acute or chronic, is recommended. In some instances, flexible deformity that cannot be corrected with a medial slide osteotomy and lateral column lengthening may be successfully managed with the addition of spring ligament reconstruction using tendon graft. This has provided further correction of alignment in the operating room that has lasted in clinical follow-up. No clinical series of these procedures has been published, but the author's experience to date is that such procedures can add small amounts of correction of alignment to bony procedures.

Stage III

Stage III AAFD is not passively correctable even under anesthesia. Arthrodesis is required to correct deformity and stabilize the foot. Most often, correction requires fusion of at least the talonavicular joint because much of the deformity occurs through that joint. The author prefers triple arthrodesis because adequate correction commonly requires fusion of all three joints. Major bone graft is not required, but small amounts of graft are commonly used, which are obtained from the tibia, either medially above the ankle or laterally just below the knee or using a bone graft substitute. It is important to carefully check the alignment set at the time of hindfoot fusion. In situ fusions should be avoided. Adequate correction of deformity without overcorrection into varus offers the best result. The heel should be in ≤5° of valgus with the forefoot in neutral (ie, no forefoot supination or elevation of the first ray and no forefoot pronation). When excessive heel valgus remains even after realignment of the forefoot and triple-joint complex, then a medial slide osteotomy is added. A metatarsal-tarsal fusion for an unstable first ray or a Cotton osteotomy is used to correct an elevated first metatarsal. A plantigrade foot with the heel properly aligned (ie, no increased heel valgus but no heel varus) and the forefoot out of supination are important goals.

The functional result after a triple arthrodesis has limitations.[8,29] Walking on uneven ground and walking for exercise are often hindered. In one study, the function of patients with stage II AAFD treated with either medial slide osteotomy or medial slide osteotomy and lateral column lengthening was compared with that of patients with stage IIb or III AAFD who were treated with hindfoot arthrodesis.[8] Greater limitation of function was evident in the arthrodesis group. This supports the hypothesis that with progressive deformity, it is best to correct the foot early, before more advanced fusion procedures are required.

Stage IV

Little has been published on the surgical results of the treatment of stage IV AAFD. Different techniques for reconstruction of the deltoid have been published.[30,31] One small clinical series on reconstruction of the deltoid ligament using tendon graft and simultaneous correction of foot deformity showed correction of the talar tilt at the ankle.[30] The patient with the most severe deformity at the ankle was the only patient of five in this study who did not gain correction of the talar tilt. Drill holes in the tibia and talus were used to approximate the insertions of the deep deltoid ligament. Correction of foot deformity, including full correction of heel valgus, elevation of the first ray, and abduction through the midfoot, is felt to be critical to the success of the procedure. This correction can be done without a triple arthrodesis in a flexible foot (stage IVa). Instead, the patient can be treated with medial slide osteotomy, lateral column lengthening, and possibly a metatarsal-tarsal fusion or Cotton osteotomy. With fixed deformity (stage IVb), a triple arthrodesis is used. When >5° of heel valgus is still present, a medial slide osteotomy is added at the time of the triple arthrodesis. It is not known how much reconstruction of the deltoid contributes to the success of the procedure. Without full correction of the foot deformity, reconstruction of the ankle deformity is expected to fail.

In the patient with stage IV AAFD who has severe arthritis in the ankle (ie, bone-on-bone contact with correction of the talar tilt), ankle arthrodesis or total ankle arthroplasty is required. Because of the stiffness and limitation of ambula-

tion with a pantalar fusion, the use of tibiocalcaneal arthrodesis or total ankle arthroplasty with reconstruction of the foot should be considered. When deformity can be adequately corrected without fusing the talonavicular joint, it is important to maintain motion of the transverse tarsal joint.

In all stages, the Achilles tendon or the gastrocnemius-soleus complex can be contracted. Contraction is more common in the more severe deformities in stage IIa and IIb as well as in stages III and IV. Surgeon preference varies regarding the frequency of lengthening the Achilles tendon. Tightness of the Achilles should be examined with the knee extended and in 90° of flexion. When the hindfoot and ankle cannot be brought into any dorsiflexion with the knee extended and the foot in the corrected position, consideration should be given to gastrocnemius recession. With the foot in the corrected position and the knee flexed, dorsiflexion should be present to confirm that just a gastrocnemius recession will provide adequate relief of the contracture. Triple-cut lengthening of the Achilles tendon is performed when the gastrocnemius and soleus are both contracted (ie, no dorsiflexion of the ankle with the knee in 90°of flexion). The surgeon should be careful to avoid overlengthening with the triple-cut procedure. Postoperative care of the reconstruction consists of non–weight bearing or touchdown weight bearing in a cast for 10 to 12 weeks, followed by increasing weight-bearing in a removable boot for 2 to 4 weeks.

Summary

There is considerable surgeon-to-surgeon variability in the treatment of AAFD, particularly in stage II disease. A patient with stage I AAFD often can be treated nonsurgically, which should be considered in the initial treatment in all stages of AAFD. In stage IIa deformity, surgical treatment with a medial slide osteotomy and tendon transfer has been shown to provide consistently good results. Lateral column lengthening provides more correction; thus, it should be considered for the patient with more severe deformity (ie, stage IIb). However, there is a risk of lateral overload with this procedure, and care should be taken to avoid overcorrection and excessive stiffness. When multiple osteotomies are being performed, temporary fixation is recommended so that the final position and flexibility of the foot can be assessed before definitive fixation is placed. The patient with stage III AAFD requires hindfoot fusion, most commonly involving the talonavicular joint. Positioning is important in achieving optimal functional result. Care should again be taken to avoid over- and undercorrection. More progress is needed in the management of stage IV disease. An initial study has shown that correction of deformity in both the foot and ankle is possible.[30]

The end result of surgical treatment of the patient with AAFD has much to do with the management of the associated deformity. The principle of correcting the deformity while avoiding overcorrection and excessive stiffness is important in determining the outcome of the surgical treatment in these patients. In all stages, there are benefits to achieving proper alignment and maintaining as much flexibility as possible. Working on the maximum achievement of these two goals is likely to continue to optimize the results for patients with AAFD.

References

Evidence-based Medicine: There is one level I prospective, randomized study (reference 6). There are no level II studies. Most of the references are level III/IV (case-control or cohort reports) or level V (expert opinion).

Citation numbers printed in **bold type** indicate references published within the past 5 years.

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Section 6.0

Guidelines

Guideline note 6 revisions

Question: How should GN6 REHABILITATIVE SERVICES be modified to comply with federal rules on EPSDT, habilitative services and mental health parity?

Question sources: HERC staff, OHA, HSD, medical directors

Issues: The federal government has issued new rules regarding parity for mental health conditions and habilitative services. These limits are also affected by existing EPSDT requirements. Based on these rules, HERC staff have identified several issues with the current coverage of PT and OT in GN6.

Under Parity law, coverage for services to treat mental health conditions can only be as restrictive as restrictions on the majority of physical health services in the same category. The Oregon Department of Justice has drafted an internal memo outlining the impact of these regulations on Guideline note 6. As physical health office visits are not limited, it would be challenging to justify the existing limits in guideline note 6, when applied to mental health conditions.

In addition (and separately) OHP needs to comply with provisions of the Affordable Care Act requiring that habilitative services be limited no more than rehabilitative services, effective immediately. Revisions to guideline note 6 are required in order to make clear OHP will comply with this requirement. (By January 1, 2017, limits for habilitative and rehabilitative services will also need to be separated, but we will address that in a future revision.)

Early and Periodic Screening, Diagnosis and Treatment (EPSDT) benefits are defined by CMS. A wide variety of treatments are included in EPSDT benefits. These benefits can be limited as medically appropriate but cannot have hard numerical limits:

> While the treating health care provider has a responsibility for determining or recommending that a particular covered service is needed to correct or ameliorate the child's condition, both the state and a child's treating provider play a role in determining whether a service is medically necessary. If there is a disagreement between the treating provider and the state's expert as to whether a service is medically necessary for a particular child, the state is responsible for making a decision, for the individual child, based on the evidence. That decision may be appealed by the child (or the child's family) under the state's Medicaid fair hearing procedures, as described in Section VII. (From CMS EPSDT guide.)

Additional concerns about GN6 in general have been raised by various CCO medical directors and by HERC staff. HERC staff would like to discuss possible revisions to GN6 as it applies to non-behavioral health conditions. Some specific concerns include:

1) General concerns among the CCOs about the language and desire to eliminate the clause about 30 additional visits per year being authorized for “exceptional circumstances.” This clause is considered difficult to interpret.
2) Cardiac rehabilitation involves more than just PT, and the cardiac lines are not even mentioned in the guideline note. Cardiac rehabilitation should considered for removal from the guideline note.

HERC staff recommendations:

1) Effective October 1, 2016: Revise GN6 Rehabilitative Therapies with the following changes
    a. Add the word "habilitative" to the guideline to comply with federal requirements around habilitative services
    b. Remove cardiac and vascular rehabilitation as these are not the same type of services as PT and OT for other conditions
2) Effective January 1, 2017: Revise GN6 Rehabilitative Therapies as shown below
    a. Add a clause to exclude mental health conditions from any numerical limits in anticipation of the mental health parity law requirements. This clause would apply to autism, dementia, developmental delay and similar conditions
    b. Clarify what is intended by "exceptional circumstances" allowing an additional 30 visits
    c. Remove children under age 21 from the hard limits in this guideline to comply with EPSDT requirements

GUIDELINE NOTE 6, REHABILITATIVE AND HABILITATIVE THERAPIES

Lines 34,50,61,72,75,76,78,85,95,96,135,136,140,154,157,164,182,187,188,200,201,205, 206,212,259,261,276,290,292,297,305,306,314,322,346,350,351,353,360,361,364,366,381, 382,392,406,413,421,423,427,428,436,447,459,467,470,471,482,490,501,512,532,558,561, 574,592,611,666

The quantitative limits in this guideline note do not apply to mental health or substance abuse conditions.

A total of 30 visits per year of rehabilitative or habilitative therapy (physical, occupational and speech therapy~~, and cardiac and vascular rehabilitation~~) are included on these lines when medically appropriate. Additional visits, not to exceed 30 visits per year, may be authorized in ~~exceptional circumstances, such as in~~ cases of ~~rapid growth/development~~ a new acute injury, surgery, or other significant change in functional status. Children under age 21 may have additional visits authorized beyond these limits if medically appropriate.

Physical, occupational and speech therapy~~, and cardiac and vascular rehabilitation~~ are only included on these lines when the following criteria are met:

1. therapy is provided by a licensed physical therapist, occupational therapist, speech language pathologist, physician, or other practitioner licensed to provide the therapy,
2. there is objective, measurable documentation of clinically significant progress toward the therapy plan of care goals and objectives,
3. the therapy plan of care requires the skills of a medical provider, and
4. the client and/or caregiver cannot be taught to carry out the therapy regimen independently.

No limits apply while in a skilled nursing facility for the primary purpose of rehabilitation, an inpatient hospital or an inpatient rehabilitation unit.

Spinal cord injuries, traumatic brain injuries, or cerebral vascular accidents are not subject to the visit limitations during the first year after an acute injury.

Opioid Guideline Taper Deadline

Question: Should the opioid guideline for back conditions be modified to allow more time for the taper off of chronic opioids for those patients already on long term opioid therapy?

Question source: HERC staff, OHP Medical Directors/CCOs, HSD

Issue: The implementation of the back line changes was delayed from its planned implementation on January 1, 2016. The new implementation date is July 1, 2016. However, the deadline for tapering patients off chronic opioid therapy remains the end of 2016. There needs to be clarification about whether this date should be changed given the changed implementation date.

The initial Taskforce recommendation was for a 1 year timeframe for taper, due to patients and providers needing to be educated, other systems to be brought into place to allow for other care such as comprehensive pain clinic care.

The CCOs generally feel that 12 months will be required to get systems in place to ensure that all chronic patients are tapered off. At the May QHOC meeting of the CCOs, there was a suggestion to change the wording to allow a continued slow taper if such a taper was successfully progressing, without having a hard time limit. Proposed wording from this group was "By the end of 2016, all patients currently treated with long term opioid therapy for diagnoses on these lines must be ~~tapered off of long term opioids~~ on an opioid taper plan, with the taper reassessed every 3 months and coverage continued only if tapering is successfully proceeding ~~for diagnoses on these lines~~.

The Oregon Pain Management Commission met on April 28, 2016 and discussed a preference for beginning to offer and implement the non-pharmacologic modalities for treatment of back pain prior to starting a taper on opioid medications. The Pain Commission members were concerned that the recommended 10% per week taper was abrupt and difficult, and would result in increased fear and anxiety, concern about "taper failures" and illegal narcotic use. The proposed wording for this section from the Pain Commission was "By the end of 2016, all patients currently treated with long term opioid therapy must be ~~tapered off of long term opioids~~ re-evaluated including psychosocial factors and plan of care to include multidisciplinary treatment options for diagnoses on these lines." The Pain Commission also noted that criteria #3 in the guideline was unrealistic to allow only an additional 7 days when there was also a 38 day exception allowed.

Additionally, QHOC members requested that the guideline be modified to clarify what validated tools should be used to document improvement in function.

HERC staff recommendations:

1) Add in specific information about the "validated tools" required for documentation of improvement in function
    a. Proposed wording matches the medical back pain guideline
2) Discuss possible changes to the opioid guideline to push back the date for ending chronic opioid therapy for those patients already on such therapy. Several possible options have been identified:
    a. Keep the opioid deadline at the end of 2016 (6 month tapers at most), OR
    b. Push back the opioid deadline from end of 2016 to July 2017 (conforms with the original intent of 1 year taper time and CCO preferred), OR
    c. Consider alternative wording removing a hard time limit
        i. QHOC proposed wording: "By the end of 2016, all patients currently treated with long term opioid therapy for diagnoses on these lines must be ~~tapered off of long term opioids~~ on an opioid taper plan, with the taper reassessed every 3 months and coverage continued only if tapering is successfully proceeding ~~for diagnoses on these lines.~~"
            1. Consider adding wording clarifying that the intent is to eventually taper off completely. Possible additional wording: "The goal of this taper must be a complete taper off opioids."
        ii. Pain Commission proposed wording: "By the end of 2016, all patients currently treated with long term opioid therapy must be ~~tapered off of long term opioids~~ re-evaluated including psychosocial factors and plan of care to include multidisciplinary treatment options for diagnoses on these lines."
3) Discuss the HERC's intent that moving back conditions to a covered line was not intended to cover medications previously denied by a CCO, but rather to provide a wider range of services for these conditions

GUIDELINE NOTE 60, OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE

Lines 351, 366, 407, 532

The following restrictions on opioid treatment apply to all diagnoses included on these lines.

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks after the acute injury, flare or surgery, opioid treatment is included on these lines ONLY
    a. When each prescription is limited to 7 days of treatment, AND
    b. For short acting opioids only, AND
    c. When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
    d. When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND

   e. There is documented lack of current or prior opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days, requires the following
   a. Documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b. Must be prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c. Verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i. Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii. Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii. Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d. Each prescription must be limited to 7 days of treatment and for short acting opioids only
3) Further opioid treatment after 90 days may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be covered, subject to the criteria in #2 above.

For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long term opioids for diagnoses on these lines. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on line 4 SUBSTANCE USE DISORDER.

Tobacco smoking and surgical procedures

Question: Tobacco smoking and elective surgeries

Question source: Medical Directors from CCOs

Issue: At the November 2015 and January 2016 VbBS meetings, a new guideline on tobacco cessation and elective surgeries was proposed. Members debated a guideline that would require intensive smoking cessation counseling prior to elective surgery versus a guideline requiring tobacco cessation prior to elective surgery. CCO and FFS medical directors were consulted. In general, implementation of the behavioral intervention was thought to be quite challenging and several members preferred requiring cessation. Concerns about equity and addiction were also raised. Additionally, there were concerns raised about the acceptability of other nicotine replacement strategies, what the definition of elective entails, presence of severe psychiatric comorbidity interfering with cessation, and which specific surgeries might be included or excluded. Members asked HERC staff to return with further details that would assist with implementation.

The following questions thus need to be addressed:

1) Should the guideline note require intensive smoking cessation interventions or require smoking cessation to occur prior to elective surgeries?
2) How should elective versus urgent/emergent surgical procedures be defined?
3) Which types of surgeries should be included? Should they be by general body system and/or specialty or specifically defined by code?
4) What other procedures should be excluded from the guideline note?
5) Are there certain underlying health conditions such as people with severe and persistent mental illness who should be excluded from the guideline?
6) Should there continue to be a discrepancy between these elective surgeries requiring 1 month of cessation (if this is chosen) versus other surgeries such as bariatric and spinal fusion surgery which have 6 month abstinence requirements?

Evidence on specific surgeries

MED, 2015 report

1. Key findings:
    a. Smoking is associated with greater morbidity across a wide range of surgeries
    b. Smoking cessation initiated at least four weeks before surgery was associated with reduced complications for certain types of surgeries
    c. The longer the abstinence the greater the benefit
2. General elective surgeries

a. Moderate strength of evidence that smokers have an increased risk of general morbidity, wound complications, general infections, pulmonary complications, neurological complications, and admission to the intensive care unit (ICU) after undergoing various types of elective surgery.

3. Specific surgeries
    a. Dental
        i. Moderate strength of evidence that smokers experience greater dental implant failure rates
        ii. Low strength of evidence that smokers have a higher risk of developing postoperative complications for:
            1. Subepithelial connective tissue grafts
            2. Guided tissue regeneration
            3. Periodontal flap surgery.
    b. Orthopedic
        i. Rotator cuff repair – more postoperative complications (moderate SOE). smokers experience worse functional outcomes, greater pain, and lower quality of life scores up to two years following surgery.
        ii. Glenoid labrum surgery – higher failure rates (very low SOE)
        iii. Total hip arthoplasty – greater general postoperative complications
        iv. Total knee arthroplasty – higher risk of general postoperative complications; but conflicting results in current and former smokers for function, need for revision, cardiac and pulmonary complications, prosthetic loosening, and infection.
    c. Cardiovascular - moderate strength of evidence that smokers have significantly worse postoperative outcomes following cardiac and arterial surgery
        i. Coronary artery bypass graft: smokers experience higher rates of general pulmonary complications and worse functional outcomes.
        ii. Non-specific elective cardiac surgery: smokers experience greater rates of general pulmonary complications, ICU hours and readmission, infection rates, and mean mechanical ventilations hours.
        iii. Heart transplant: smokers have lower survival outcomes.
        iv. Lower extremity bypass graft: smokers are more likely to have graft failure; smokers were more likely to have graft failure (odds ratio [OR] =2.35 [95% CI 1.98 to 2.78], P<0.00001, 21 trials, 2,792 participants). Difference in graft patency in former smokers compared with current smokers was significantly better (P=0.003) and graft patency rates in former smokers were comparable with the never smokers group (specific rates not reported). There were

no differences noted between studies with a follow-up period of less or greater than two years.

Additional types of surgeries

1. Sinus surgery (review upon request of QHOC medical director)
    a. *Reh, 2012* (study not included due to length http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3443524/pdf/nihms372192.pdf)
        i. Literature review of impact of active smoking and second hand smoke on chronic rhinosinusitis
        ii. 31 papers on exposure to smoke and sinusitis
        iii. 29 papers to evaluate impact of smoking on sinus surgery
        iv. Smoke exposure increases risk of asthma, otitis media
        v. Retrospective studies in the 1990s found association with poorer, symptom scores, worse patient reported outcomes, and possibly higher revision rates. More recent prospective studies have found equivalence in endoscopy scores, health related quality of life, although higher rates of revision. One larger prospective study 784 patients found worse endoscopic scores, but similar QOL outcomes. A small study in children showed poorer ciliary regrowth when exposed to second hand smoke and less symptom improvement.
        vi. Authors Conclusion: There is clear evidence in the literature that cigarette smoke, either through active smoking or passive exposure to SHS, contributes to CRS. Recent prospective studies suggest that active smoking is not a contraindication to ESS while the impact of smoking volume and longterm smoking after ESS has not been sufficiently evaluated.
    b. *Rudmik, 2011* (study not included due to length: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124774/pdf/nihms-258797.pdf)
        i. Prospective cohort study of patients with rhinosinusitis electing endoscopy sinus surgery
        ii. N= 784
        iii. Tertiary academic medical center
        iv. RESULTS: Smokers (heavy or light) and nonsmokers experienced similar improvement in health related quality of life following surgery. While overall changes in endoscopy scores did not differ between smokers and nonsmokers, there was a significant difference in the prevalence of worsening postoperative endoscopy scores between heavy smokers, light smokers, and nonsmokers (100%, 33%, and 20%, respectively; p = 0.002).
        v. Patient oriented outcomes appear similar, but markedly worse postoperative endoscopy scores vary by smoking intensity

2. Vaginoplasty and phalloplasty
    a. At the last VbBS meeting there was expert testimony that vaginoplasty is associated with poorer outcomes, and the one surgeon who does this in Portland requires a 6 week cessation prior to surgery.
    b. Chesson, 1996
        i. Expert review and case series, 20 phalloplasty procedures after instituting a new technique
        ii. In female-to-male reassignment, smoking and other addictions carry an unacceptable complication rate and are relative contraindications to hormonal and surgical reassignment. Microsurgical vascular techniques necessary for this procedure are not successful in heavy smokers, and therefore smoking is an absolute contraindication to phalloplasty.
        iii. Smoking associated with severe vascular problems
    c. WPATH is silent
    d. University of Michigan http://www.med.umich.edu/1libr/Surgery/PlasticSurgery/GenderReassignment/SRS-PenileInversion-Preop.pdf
        i. requires 6 weeks smoking cessation prior to penile inversion vaginoplasty
    e. Gender surgery Amsterdam http://www.gendersurgeryamsterdam.com/operation-female-male/phalloplasty/smoking-weight/
        i. requires smoking cessation 12 weeks prior to phalloplasty
    f. Vancouver Health Guideline Care of the Patient undergoing sex reassignment surgery http://www.amsa.org/wp-content/uploads/2015/04/CareOfThePatientUndergoingSRS.pdf
        i. MTF patients are strongly encouraged to stop smoking. This is an absolute requirement if a free flap phalloplasty will be performed in the future.

<u>Evidence on timing of smoking cessation</u>

Thomsen, 2014

1. Cochrane systematic review of RCTs looking at interventiosn for preoperative smoking cessation
2. 13 trials including 2010 participants
3. Smoking cessation at least 4 weeks prior to surgery results in improved morbidity
4. Smoking cessation counseling
    a. Brief interventions ineffective for either complication reduction or long term smoking cessation
    b. Intensive interventions, defined as weekly face to face for 4-8 weeks with telephonic support, and with pharmacotherapy (NRT) are effective

5. Optimal period unclear
6. Conclusion: There is evidence that preoperative smoking interventions providing behavioural support and offering NRT increase short-termsmoking cessation and may reduce postoperative morbidity. Based on indirect comparisons and evidence from two small trials, interventions that begin four to eight weeks before surgery, include weekly counselling and use NRT are more likely to have an impact on complications and on long-term smoking cessation.

<u>Evidence on nicotine replacement and elective surgery</u>

Sorenson, 2012

1. Systematic review of nicotine and nicotine replacement therapy (NRT) on pathophysiology of wound healing
    a. Nicotine used to be considered responsible for effects of smoking on wound healing
    b. Nicotine infusion increased tissue oxygen tension, but smoking decreases
    c. Animal and cell studies show transient mixed effects
    d. "In summary, the effect of nicotine on wound healing processes is complex and as of yet not fully understood. Nicotine appears to attenuate inflammatory wound healing mechanisms, compared to proliferative wound healing mechanisms including angiogenesis and collagen synthesis. Clinically, there is no evidence to suggest that nicotine administered as nicotine replacement drugs to abstinent smokers has a detrimental or beneficial effect on postoperative outcome of wound or tissue healing."
2. *Thomsen, 2014* Cochrane systematic review
    a. Of the 10 RCTs examining behavioral support for cessation, nicotine replacement therapy (NRT) offered or recommended to some or all patients in 8 trials.
    b. 1 trial – varenicline given 1 week preoperatively, continued 11 weeks postoperatively
        i. No increase in smoking cessation
        ii. No surgical morbidity benefit
    c. 1 trial – nicotine lozenges from night before surgery + brief counseling
        i. No increase in smoking cessation

<u>Definition of elective surgical procedures:</u>

1. MedicineNet.com - Surgery that is subject to choice (election). The choice may be made by the patient or doctor. For example, the time when a surgical procedure is performed may be elective. The procedure is beneficial to the patient but does not need be done at a particular time. As opposed to urgent or emergency surgery.
2. http://www.surgeryencyclopedia.com/Ce-Fi/Elective-Surgery.html

   a. An elective surgery is a planned, non-emergency surgical procedure. It may be either medically required (e.g., cataract surgery), or optional (e.g., breast augmentation or implant) surgery.
3. http://www.health.wa.gov.au/electivesurgery/docs/Elective_Surgery_Patient_Information_ENGLISH.pdf
   a. Elective surgery is a term used for non-emergency surgery which is medically necessary, but which can be delayed for at least 24 hours. Patients requiring emergency surgery will not be placed on the elective surgery list.
4. http://medical-dictionary.thefreedictionary.com/elective+surgery
   a. Elective surgery
      i. Any operation that can be performed with advanced planning–eg, cholecystectomy, hernia repair, colonic resection, coronary artery bypass
      ii. Surgery a patient chooses to undergo although its need is neither vital nor urgent.
      iii. Non-emergency surgery, taking place at a predetermined date
   b. Urgent surgery
      i. Surgery required within < 48 hrs Examples Kidney stone, stomach obstruction or ulcer, bleeding hemorrhoids, ectopic pregnancy
5. Merriam Webster
   a. Urgent = calling for immediate attention
6. Oxford http://www.oxforddictionaries.com/us/definition/american_english/urgent
   a. (Of a state or situation) requiring immediate action or attention
   b. (Of action or an event) done or arranged in response to a pressing or critical situation

<u>Information on cotinine testing in nicotine replacement therapy</u>

1. *Thomsen 2012,* Cochrane review
   a. Most RCTs used exhaled carbon monoxide (CO) testing
      i. Self reported smoking cessation (Andrews, 2006; Lindstrom, 2008; Wolfenden, 2005)
      ii. Exhaled CO (≤ 10 ppm) (Lee, 2013; Moller, 2002, Ratner, 2004; Shi, 2013; Thomsen, 2010; Warner, 2012)
      iii. Urine cotinine (Ratner, 2004)
      iv. Expired CO and Sputum cotinine (Sorenson, 2007, Ostroff, 2013)
      v. Exhaled CO and urinary cotinine (Sorenson, 2003a; Wong 2012)

2. *Jacob, 2002*
   a. Validation study of Anabasine and anatabine in users of nicotine replacement therapy compared to smokers
   b. 99 cigarette smokers and 205 smokeless tobacco users

   c. Objective: to evaluate the use of urine concentrations of the minor tobacco alkaloids anabasine and anatabine as outcome measures for persons undergoing NRT.
   d. Results: Subjects abstaining from smokeless tobacco and using nicotine gum did not excrete measurable amounts of anabasine or anatabine.
3. Mayo Clinic laboratories http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/82510
   a. In addition to nicotine and metabolites, tobacco products also contain other alkaloids that can serve as unique markers of tobacco use. Two such markers are anabasine and nornicotine. Anabasine is present in tobacco products, but not nicotine replacement therapies. Nornicotine is present as an alkaloid in tobacco products and as a metabolite of nicotine. The presence of anabasine >10 ng/mL or nornicotine >30 ng/mL in urine indicates current tobacco use, irrespective of whether the subject is on nicotine replacement therapy. The presence of nornicotine without anabasine is consistent with use of nicotine replacement products. Heavy tobacco users who abstain from tobacco for 2 weeks exhibit urine nicotine values <30 ng/mL, cotinine <50 ng/mL, anabasine <2 ng/mL, and nornicotine <2 ng/mL.
   b. Passive exposure to tobacco smoke can cause accumulation of nicotine metabolites in nontobacco users. Urine cotinine has been observed to accumulate up to 20 ng/mL from passive exposure. Neither anabasine nor nornicotine accumulates from passive exposure.
4. NV Public Employee Benefits Program, "through consultation with their lab"
   a. Heavy smoker, cotinine will be positive for 7-10 days
   b. Average pack a day smoker, cotinine will be positive for 4-5 days
   c. Second hand smoke exposure would not result in a clinically significant positive cotinine

<u>Relevant codes for specific procedures</u>

   a. Orthopedic
      i. Rotator cuff

Code	Code Description	Line
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic	423
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)	423
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	423

      ii. Glenoid labrum

29807	Arthroscopy, shoulder, surgical; repair of SLAP lesion	364,392,423

      iii. Total hip

27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	85,204,205,290, 360,361,447
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	85,290,361,428
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	290,428
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	290,428
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	290,364,392,428

iv. Total knee

27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	361,364,392

b. Dental

Dental implants

Code	Code Description	Prioritized List Status
D6010	SURGICAL PLACEMENT OF IMPLANT BODY: ENDOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6011	Second stage implant surgery	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6012	SURGICAL PLACEMENT OF INTERIM IMPLANT BODY FOR TRANSITIONAL PROSTHESIS: ENDOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6013	Surgical placement of mini implant	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6040	SURGICAL PLACEMENT: EPOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6050	SURGICAL PLACEMENT: TRANSOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6051	Interim abutment - includes placement and removal. A healing cap is not an interim abutment	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6052	Semi-precision attachment abutment-includes placement of keeper assembly	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6055	CONNECTING BAR - IMPLANT SUPPORTED OR ABUTMENT SUPPORTED	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Code	Code Description	Prioritized List Status
D6056	Prefabricated abutment - includes modification and placement. Modification of a prefabricated abutment may be necessary	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6057	Custom fabricated abutment - includes placement – Created by a laboratory process specific for an individual application	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6058	ABUTMENT SUPPORTED PORCELAIN/CERAMIC CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6059	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6060	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6061	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6062	ABUTMENT SUPPORTED CAST METAL CROWN (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6063	ABUTMENT SUPPORTED CAST METAL CROWN (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6064	ABUTMENT SUPPORTED CAST METAL CROWN (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6065	IMPLANT SUPPORTED PORCELAIN/CERAMIC CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6066	IMPLANT SUPPORTED PORCELAIN FUSED TO METAL CROWN (TITANIUM, TITANIUM ALLOY, HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6067	IMPLANT SUPPORTED METAL CROWN (TITANIUM, TITANIUM ALLOY, HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6068	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN/CERAMIC FPD	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6069	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6070	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Code	Code Description	Prioritized List Status
D6071	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6072	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6073	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6074	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6075	IMPLANT SUPPORTED RETAINER FOR CERAMIC FPD	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6076	IMPLANT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (TITANIUM, TITANIUM ALLOY, OR HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6077	IMPLANT SUPPORTED RETAINER FOR CAST METAL FPD (TITANIUM, TITANIUM ALLOY, OR HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6080	IMPLANT MAINTENANCE PROCEDURES WHEN PROSTHESES ARE REMOVED AND REINSERTED, INCLUDING CLEANSING OF PROSTHESES AND ABUTMENTS	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6090	REPAIR IMPLANT SUPPORTED PROSTHESIS BY REPORT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6091	REPLACEMENT OF SEMI-PRECISION OR PRECISION ATTACHMENT (MALE OR FEMALE COMPONENT) OF IMPLANT/ABUTMENT SUPPORTED PROSTHESIS, PER ATTACHMENT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6092	RE-CEMENT OR RE-BOND IMPLANT/ABUTMENT SUPPORTED CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6093	RE-CEMENT OR RE-BOND IMPLANT/ABUTMENT SUPPORTED FIXED PARTIAL DENTURE	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6094	ABUTMENT SUPPORTED CROWN - (TITANIUM)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6095	REPAIR IMPLANT ABUTMENT, BY REPORT	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Subepithelial connective tissue grafts

Code	Code Description	Prioritized List Line number
D4270	PEDICLE SOFT TISSUE GRAFT PROCEDURE	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4273	SUBEPITHELIAL CONNECTIVE TISSUE GRAFT PROCEDURES, PER TOOTH	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4274	DISTAL OR PROXIMAL WEDGE PROCEDURE (WHEN NOT PERFORMED IN CONJUCTION WITH SURGICAL PROCEDURES IN THE SAME ANATOMICAL AREA)	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4275	SOFT TISSUE ALLOGRAFT	Services recommended for non-coverage table,496
D4276	COMBINED CONNECTIVE TISSUE AND DOUBLE PEDICLE GRAFT, PER TOOTH	Services recommended for non-coverage table,496
D4277	Free soft tissue graft procedure (including donor site surgery) - first tooth or edentulous tooth site in graft	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4278	Free soft tissue graft procedure (including donor site surgery) -each additional contiguous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4283	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4285	Non-autogenous connective tissue graft procedure (including recipient surgical site and donor material) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)

Guided tissue regeneration

Code	Code Description	Prioritized List Status
D4266	Guided tissue regeneration -- resorbable barrier, per site This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic materials to aid in osseous reg	Services recommended for non-coverage table
D4267	Guided tissue regeneration -- non-resorbable barrier, per site (includes membrane removal) This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic	Services recommended for non-coverage table

Periodontal flap surgery

Code	Code Description	Prioritized List Status
D4240	GINGIVAL FLAP PROCEDURE, INCLUDING ROOT PLANING - FOUR OR MORE CONTIGUOUS TEETH OR TOOTH BOUNDED SPACES PER QUADRANT	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4241	GINGIVAL FLAP PROCEDURE, INCLUDING ROOT PLANING - ONE TO THREE CONTIGUOUS TEETH OR TOOTH BOUNDED SPACES PER QUADRANT	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4245	APICALLY POSITIONED FLAP	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)

c. Cardiovascular

CABG (33510-33536)

Code	Code Description	Current Prioritized List Status
33510	Coronary artery bypass, vein only; single coronary venous graft	49,73,103,193,290
33511	Coronary artery bypass, vein only; 2 coronary venous grafts	73,103,193,290
33512	Coronary artery bypass, vein only; 3 coronary venous grafts	73,103,193,290
33513	Coronary artery bypass, vein only; 4 coronary venous grafts	73,103,193,290
33514	Coronary artery bypass, vein only; 5 coronary venous grafts	73,103,193,290
33516	Coronary artery bypass, vein only; 6 or more coronary venous grafts	73,103,193,290
33517	Coronary artery bypass, using venous graft(s) and arterial graft(s); single vein graft (List separately in addition to code for primary procedure)	73,103,193,290
33518	Coronary artery bypass, using venous graft(s) and arterial graft(s); 2 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33519	Coronary artery bypass, using venous graft(s) and arterial graft(s); 3 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33521	Coronary artery bypass, using venous graft(s) and arterial graft(s); 4 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290

Code	Code Description	Current Prioritized List Status
33522	Coronary artery bypass, using venous graft(s) and arterial graft(s); 5 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33523	Coronary artery bypass, using venous graft(s) and arterial graft(s); 6 or more venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33530	Reoperation, coronary artery bypass procedure or valve procedure, more than 1 month after original operation (List separately in addition to code for primary procedure)	49,73,74,86,90,103,110,115 and 7 other lines.
33533	Coronary artery bypass, using arterial graft(s); single arterial graft	73,193,290
33534	Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts	73,193,290
33535	Coronary artery bypass, using arterial graft(s); 3 coronary arterial grafts	73,193,290
33536	Coronary artery bypass, using arterial graft(s); 4 or more coronary arterial grafts	73,193,290

Lower extremity bypass graft

Code	Code Description	Prioritized List Status
35533	Bypass graft, with vein; axillary-femoral-femoral	240,290,354
35537	Bypass graft, with vein; aortoiliac	240,258,289,290,310,330,452
35538	Bypass graft, with vein; aortobi-iliac	240,258,289,290,310,330,452
35539	Bypass graft, with vein; aortofemoral	240,258,289,290,310,330,354,452
35540	Bypass graft, with vein; aortobifemoral	240,258,289,290,310,330,354,452
35556	Bypass graft, with vein; femoral-popliteal	240,290,354
35558	Bypass graft, with vein; femoral-femoral	240,290,354
35563	Bypass graft, with vein; ilioiliac	240,289,290,310,330,452
35565	Bypass graft, with vein; iliofemoral	240,290,354
35566	Bypass graft, with vein; femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels	240,290,354
35570	Bypass graft, with vein; tibial-tibial, peroneal-tibial, or tibial/peroneal trunk-tibial	240,290,354
35571	Bypass graft, with vein; popliteal-tibial, -peroneal artery or other distal vessels	240,290,354

Code	Code Description	Prioritized List Status
35583	In-situ vein bypass; femoral-popliteal	240,290,354
35585	In-situ vein bypass; femoral-anterior tibial, posterior tibial, or peroneal artery	240,290,354
35587	In-situ vein bypass; popliteal-tibial, peroneal	240,290,354
35621	Bypass graft, with other than vein; axillary-femoral	240,290,330,354
35623	Bypass graft, with other than vein; axillary-popliteal or -tibial	240,258,290,330,354
35637	Bypass graft, with other than vein; aortoiliac	240,258,289,290,310,330,452
35638	Bypass graft, with other than vein; aortobi-iliac	240,258,289,290,310,330,452
35646	Bypass graft, with other than vein; aortobifemoral	240,258,289,290,310,330,354,452
35647	Bypass graft, with other than vein; aortofemoral	240,258,289,290,330,354,452
35654	Bypass graft, with other than vein; axillary-femoral-femoral	240,258,290,330,354,452
35656	Bypass graft, with other than vein; femoral-popliteal	240,290,330,354
35661	Bypass graft, with other than vein; femoral-femoral	240,290,330,354
35663	Bypass graft, with other than vein; ilioiliac	240,289,290,310,330,452
35665	Bypass graft, with other than vein; iliofemoral	240,290,330,354
35666	Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery	240,290,330,354
35671	Bypass graft, with other than vein; popliteal-tibial or -peroneal artery	240,290,330,354

HERC staff summary

Smoking cessation at least 4 weeks prior to surgery results in morbidity improvements for a wide range of elective surgeries. Intensive smoking cessation interventions that often included NRT showed improvements in postoperative morbidity. NRT is therefore an acceptable practice as part of intensive smoking cessation interventions to reduce perioperative morbidity when the surgery is planned in the following 4-8 weeks.

With regard to the following questions

1) *Should the guideline note require intensive smoking cessation interventions or* require smoking cessation to occur prior to elective surgeries?
    a. The group seemed to lean toward requiring cessation to occur. QHOC medical directors definitely preferred requiring cessation to make this an implementable requirement.
2) *How should elective versus urgent/emergent surgical procedures be defined?*

   a. General literature suggests a high acuity definition (e.g. within 48 hours) however, there are many surgeries, including those for cancer, subacute cardiovascular disease, etc, that may easily be pushed off for a few days to a week or two due to access issues, but postponing them until cessation occurs (or doesn't) may not be clinically appropriate nor ethically acceptable. Having the same definition of the time period of cessation as the need for surgery makes some sense. Recommend 1 month as the time period.

3) *Which types of surgeries should be included? Should they be by general body system and/or specialty or specifically defined by code?*
   a. Including all "elective" surgeries may be fraught with issues. Recommend listing specific surgeries for which we know that smoking worsens outcomes. The challenge with this is that some other related surgeries, for example, shoulder replacement surgery may not have identified studies but outcomes may fair equally poorly among active smokers.
4) *What other procedures should be excluded from the guideline note?*
   a. At least, cancer-related, diagnostic, and reproductive services. But by listing specific types of surgeries and including specific codes, these (and many others) would naturally be excluded.
   b. The codes for those specific surgeries for which there is information about worse perioperative morbidity fall on many lines on the Prioritized List. Consider not applying the guideline to the following lines:
      i. Orthopedic - *lines 85* (hip fracture), *204* (cancer of soft tissue), *205* (cancer of bones), *290* (complications of a procedure always requiring treatment), *360* (closed fracture of extremities), *447* (malunion and nonunion of fracture)
      ii. Cardiovascular - *Line 73* (acute and subacute ischemic heart disease); *Line 103* (cardiomyopathy); exclude life and limb threatening lines
5) *Are there certain underlying health conditions such as people with severe and persistent mental illness who should be excluded from the guideline?*
   a. Proposed language included
6) *Should there continue to be a discrepancy between these elective surgeries requiring 1 month of cessation (if this is chosen) versus other surgeries such as bariatric and spinal fusion surgery which have 6 month abstinence requirements?*
   a. It is reasonable to have different requirements given the invasiveness, potentially for delayed healing and complications associated with specific surgeries (e.g. fusion, bariatric).
   b. However, those with a requirement for shorter term smoking cessation (i.e 1 month) use of NRT would be considered acceptable, whereas those surgeries using a 6 month requirement would entail complete cessation, including of NRT products.
   c. Different objective testing would need to be used in elective surgeries for which NRT is acceptable compared to when it is not.

HERC STAFF RECOMMENDATIONS

1. Discussion adoption of a new guideline note:

GUIDELINE NOTE XXX, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Lines 193, 317, 354, 361, 364, 392, 423, 469, 496, 622

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required at least 1 month prior to the procedure and requires objective evidence of abstinence from smoking.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine level may be positive in nicotine replacement therapy (NRT) users (which is not a contraindication to elective surgery coverage). In patients using NRT the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing (well studied)
- Anabasine or anatabine testing

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month.

The specific surgical procedures that fall under this guideline include elective:

- Orthopedic - rotator cuff *(Line 423),* glenoid labrum (*Lines 364, 392, 423*), total hip (*Line 361*) and total knee arthroplasty *(Line 361*)
- Cardiovascular
  - CABG (*Line 193* = chronic ischemic heart disease)
  - Lower extremity bypass graft – *Line 354* (NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE)
- Invasive dental procedures – implants, subepithelial connective tissue grafts, ~~guided tissue regeneration,~~ periodontal flap surgery (*Lines 496, 622*)
- Vaginoplasty and phalloplasty (*Line 317*)
- Chronic sinusitis surgery (*Line 469*)

For patients with severe and persistent mental illness (e.g. schizophrenia) smoking cessation for any duration may be an insurmountable barrier, and adherence to this guideline may be waived.

Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, and 112.

Additional issues:

Modify guideline notes 8, 100, and 112:

A) to be consistent in requiring cotinine level testing, and

B) consider adding language about the frequency of testing.

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 51,154,204,258,374,412,484,533,588

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking for 6 months prior to the planned procedure, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery). Patients should be given access to appropriate smoking cessation therapy.

GUIDELINE NOTE 8, BARIATRIC SURGERY

Lines 30,594

…Excerpt

Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the surgery to confirm abstinence from ~~nicotine and~~ illicit drugs. Tobacco abstinence to be confirmed in active smokers by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 288

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 288 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (diagnosis code ICD-10-CM J43.9/ICD-9-CM 492.0, 492.8) and all of the following:

1. BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
2. Stable with ≤20 mg prednisone (or equivalent) dose a day
3. Pulmonary function testing showing
   a. Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   b. Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   c. Residual volume (RV) ≥ 150% predicted post-bronchodilator
4. PCO 2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)

5. PO 2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)
6. Post-rehabilitation 6-min walk of ≥ 140 m
7. Non-smoking for 6 months prior to surgery, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

2) Add a new guideline about surgical treatment of erectile dysfunction based on the November VbBS discussion.

GUIDELINE NOTE XXX SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION

Line 526

Surgical treatment of erectile dysfunction is only included on this line when patients are non-smoking for 6 months prior to surgery, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

Interventions for preoperative smoking cessation (Review)

Thomsen T, Villebro N, Møller AM

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[Intervention Review]

Interventions for preoperative smoking cessation

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ABSTRACT

Background

Smokers have a substantially increased risk of postoperative complications. Preoperative smoking intervention may be effective in decreasing this incidence, and surgery may constitute a unique opportunity for smoking cessation interventions.

Objectives

The objectives of this review are to assess the effect of preoperative smoking intervention on smoking cessation at the time of surgery and 12 months postoperatively, and on the incidence of postoperative complications.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialized Register in January 2014.

Selection criteria

Randomized controlled trials that recruited people who smoked prior to surgery, offered a smoking cessation intervention, and measured preoperative and long-term abstinence from smoking or the incidence of postoperative complications or both outcomes.

Data collection and analysis

The review authors independently assessed studies to determine eligibility, and discussed the results between them.

Main results

Thirteen trials enrolling 2010 participants met the inclusion criteria. One trial did not report cessation as an outcome. Seven reported some measure of postoperative morbidity. Most studies were judged to be at low risk of bias but the overall quality of evidence was moderate due to the small number of studies contributing to each comparison.

Ten trials evaluated the effect of behavioural support on cessation at the time of surgery; nicotine replacement therapy (NRT) was offered or recommended to some or all participants in eight of these. Two trials initiated multisession face-to-face counselling at least four weeks before surgery and were classified as intensive interventions, whilst seven used a brief intervention. One further study provided an intensive intervention to both groups, with the intervention group additionally receiving a computer-based scheduled reduced smoking intervention. One placebo-controlled trial examined the effect of varenicline administered one week preoperatively

Wound Healing and Infection in Surgery: The Pathophysiological Impact of Smoking, Smoking Cessation, and Nicotine Replacement Therapy

A Systematic Review

Lars Tue Sørensen, MD

Objective: The aim was to clarify how smoking and nicotine affects wound healing processes and to establish if smoking cessation and nicotine replacement therapy reverse the mechanisms involved.

Background: Smoking is a recognized risk factor for healing complications after surgery, but the pathophysiological mechanisms remain largely unknown.

Methods: Pathophysiological studies addressing smoking and wound healing were identified through electronic databases (PubMed, EMBASE) and by hand-search of articles' bibliography. Of the 1460 citations identified, 325 articles were retained following title and abstract reviews. In total, 177 articles were included and systematically reviewed.

Results: Smoking decreases tissue oxygenation and aerobe metabolism temporarily. The inflammatory healing response is attenuated by a reduced inflammatory cell chemotactic responsiveness, migratory function, and oxidative bactericidal mechanisms. In addition, the release of proteolytic enzymes and inhibitors is imbalanced. The proliferative response is impaired by a reduced fibroblast migration and proliferation in addition to a downregulated collagen synthesis and deposition. Smoking cessation restores tissue oxygenation and metabolism rapidly. Inflammatory cell response is reversed in part within 4 weeks, whereas the proliferative response remains impaired. Nicotine does not affect tissue microenvironment, but appears to impair inflammation and stimulate proliferation.

Conclusions: Smoking has a transient effect on the tissue microenvironment and a prolonged effect on inflammatory and reparative cell functions leading to delayed healing and complications. Smoking cessation restores the tissue microenvironment rapidly and the inflammatory cellular functions within 4 weeks, but the proliferative response remain impaired. Nicotine and nicotine replacement drugs seem to attenuate inflammation and enhance proliferation but the effect appears to be marginal.

(*Ann Surg* 2012;255:1069–1079)

For a number of decades, there has been a growing amount of literature demonstrating that smoking has a negative impact on both wound healing and tissue repair. This has been demonstrated across all surgical specialties and highlights a significantly higher risk of adverse healing events after surgery including tissue flap necrosis, wound and sutured tissue dehiscence, and surgical site infections. Smoking has also been associated with longer-term complications such as fistulas, a lack of bone fusion, and incisional hernia.[1–6]

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Wound and tissue healing may be defined as the reaction of the organism to restore the continuity and function of the damaged tissue or organ. The variety of healing complications associated with smoking suggest that it may be impacting at a number of different pathophysiological levels. Smoking affects many biologic processes and is contributory to cancer, atherosclerosis, chronic obstructive pulmonary disease, and degenerative disorders. There is reason to believe that many of the molecular and cellular mechanisms associated with the healing process are affected by smoking. However, the pathophysiological impact of smoking on impaired wound healing remains unclear. Equally, there is uncertainty whether any of the important mechanisms associated with defective wound healing induced by smoking are reversible by smoking cessation.

This review aims to clarify the effect of smoking and smoking cessation on wound healing by systematically reviewing the impact and reversibility of smoking on the mechanisms involved in healing processes following surgery. In addition, the impact of nicotine and nicotine replacement therapy in abstinent smokers on healing mechanisms will be reviewed.

MATERIAL AND METHODS

A formal computerized search in the databases MEDLINE (1963–2010) and EMBASE (1985–2010) was performed to identify relevant studies according to the search strategies listed in Table 1 and Figure 1. In addition, a manual cross-reference search of all potentially eligible papers retrieved for full-text evaluation was undertaken. From the electronic search 1460 citations were identified. After title and abstract review, 325 articles were retained as eligible. A full-text evaluation resulted in 177 studies to be included for systematic review (Fig. 1).

RESULTS

The Impact of Smoking on Wound Hemostasis and Inflammation

Immediately after wounding, the coagulation cascade and platelets are activated to form a thrombus in the wound cavity. The formation of this hemostatic clot, the composition of which is predominantly polymerized fibrin cross-linked with fibronectin,[7] is enhanced by smoking as a result of platelet activation and blood fibrinogen release.[8–10] In smokers' blood and probably also in the wound clot, there is a higher concentration of fibronectin, probably due to the effect of oxidative injury on vascular endothelial cells.[11,12] The clot composition with respect to cytokines, chemoattractants, and growth factors appears to be altered by smoking. For example, there is a reduction in platelet-derived growth factor and transforming growth factor-β1 (TGF-β1) suggestive of a decrease in inflammatory stimulatory wound components.[13]

Shortly after hemostasis, the inflammatory phase of healing is initiated as inflammatory cells and fibroblasts migrate into the wound from capillaries in the wound periphery using the matrix components

Anabasine and Anatabine as Biomarkers for Tobacco Use during Nicotine Replacement Therapy[1]

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Abstract

In this study we determined urine concentration of the tobacco alkaloids anabasine and anatabine, nicotine and its metabolites cotinine, and nornicotine in 99 cigarette smokers and 205 smokeless tobacco users. We also investigated the possibility that anabasine and anatabine can be used as biomarkers for tobacco use during nicotine replacement therapy.

Urine samples and data on self-reported tobacco use were obtained from subjects enrolled in tobacco cessation programs. Urine concentrations of tobacco alkaloids and metabolites were measured and correlated with self-reported tobacco use. Concentrations of anabasine and anatabine were used to validate abstinence in smokeless tobacco users who used nicotine gum as part of the therapy.

Correlations of alkaloid concentration with self-reported tobacco use before treatment ranged from fair to poor. In subjects abstaining from smokeless tobacco but using nicotine gum, anabasine and anatabine levels were below the cut-point of 2 ng/ml despite high concentrations of nicotine and cotinine resulting from nicotine gum use.

Anabasine and anatabine concentrations in urine can be used to validate abstinence or measure the extent of tobacco use in persons undergoing nicotine replacement therapy.

Introduction

More than 4000 compounds have been identified in tobacco smoke, and at least 50 of these have been found to be carcinogenic (1, 2). Epidemiological studies in smokers indicate a dose-response relationship between the number of cigarettes smoked per day and the risk of developing certain smoking-related diseases (3). The alkaloid nicotine is the major pharmacologically active substance in tobacco (4). There is good evidence that most smokers are dependent on nicotine and that the severity of tobacco dependence may be related to the level of nicotine intake. Consequently, determining exposure to specific substances in tobacco and tobacco smoke is useful in epidemiological studies exploring relationships between exposure to particular toxic substances and development of disease, in assessing the outcome of tobacco dependence treatment programs, and in assessing the risks of potentially less harmful or nonaddictive tobacco products.

A major methodological issue is measuring exposure. Self-report measures, such as the number of cigarettes smoked per day, do not take into account individual differences in smoking behavior or consumption of tobacco products that may differ in their delivery of toxic substances. To validate self-reports of subjects in tobacco-dependence treatment studies, it is desirable to have a biochemical measure of tobacco use for determining treatment outcome (5–10). The most widely used biochemical measure of tobacco use is cotinine, the proximate metabolite of nicotine, which can be measured in blood, saliva, or urine (5, 6, 8, 10). Cotinine is quite specific for use of tobacco or for use of nicotine-containing medications. Small amounts of nicotine are found in some foods, but nicotine derived from dietary sources is insignificant compared with the amounts derived from tobacco use. Cotinine also has the advantage that it has a long half-life compared with nicotine (11). Cotinine concentrations do not fluctuate greatly during the day, and levels in blood are much higher than those of nicotine, thus facilitating its measurement. Thiocyanate (a metabolite of hydrogen cyanide) in serum, carboxyhemoglobin in blood, or expired carbon monoxide have been used to detect smoking, but these biomarkers have significant dietary and environmental sources, and are less specific and less sensitive for detecting smoking than nicotine or its metabolites (5, 6, 8, 10).

Although an excellent biomarker for tobacco use, cotinine is not a valid marker in persons undergoing treatment with nicotine medications such as gum, transdermal patches, nasal sprays, or inhalers. Carbon monoxide (expired CO or carboxyhemoglobin) and thiocyanate may be used to detect heavy

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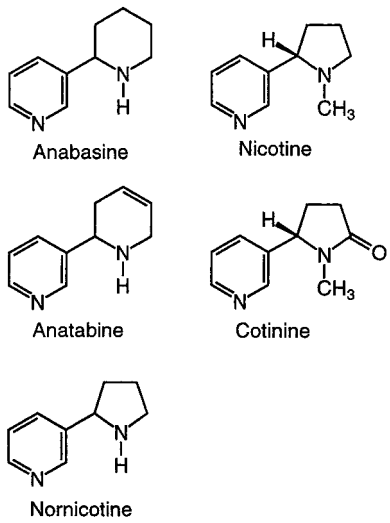

Fig. 1. Structures of anabasine, anatabine, nornicotine, nicotine, and cotinine. Nicotine and cotinine are shown as the *S*-enantiomers, because nicotine in tobacco (12) and metabolically produced in cotinine (13) are nearly enantiomerically pure. Anabasine, anatabine, and nornicotine in tobacco exist as mixtures of enantiomers (14), hence the isomeric form is not specified.

smoking but, being products of combustion, are not applicable for detecting smokeless tobacco use. Substances that are present in tobacco, measurable in biological fluids, but not derived metabolically from nicotine would be valuable for validating tobacco abstinence in persons undergoing NRT.[3]

Tobacco contains alkaloids, structurally related to nicotine (Fig. 1), that are not likely to be present in foods or to have other sources of exposure, and are not present in nicotine-containing medications. Nicotine in tobacco (12) and its metabolite cotinine (13) are nearly optically pure *S*-isomers, whereas tobacco contains substantial (4–45%) amounts of the *R*-isomers of the minor alkaloids nornicotine, anabasine, and anatabine (14). In this paper, we report concentrations of the tobacco alkaloids anabasine and anatabine in the urine of cigarette smokers and smokeless tobacco users, and describe the application of these measures to validate abstinence in smokeless tobacco users undergoing therapy with nicotine gum. Concentrations of nicotine and its metabolites nornicotine and cotinine, as well as anabasine and anatabine, in urine of a large population of cigarette smokers and smokeless tobacco users are also reported.

Materials and Methods

Subjects and Clinical Protocols. Subjects were persons enrolled in clinical trials for cessation of tobacco use. Study 1 (Pacific Research Institute) and study 2 (University of Minnesota) were programs for cessation of smokeless tobacco use that used nicotine gum as part of the therapy. Study 3 (University of California San Francisco) was a smoking cessation program using behavioral therapy and nicotine gum. Informed consent was obtained from all of the subjects. The studies involving human subjects were approved by the respective Institutional Review Boards.

Urine samples were obtained before treatment and, for studies 1 and 2, urine specimens were also obtained at follow-up. Urine samples were acidified with sodium bisulfate and stored frozen until analysis. Determination of anabasine and anatabine concentrations in urine was used as an outcome measure in studies 1 and 2.

In study 1 (15), 100 smokeless tobacco users were recruited to a four-session cessation program. All of the subjects were medically screened and randomly assigned to receive either 2 mg of nicotine gum (Nicorette) or a placebo gum, as an adjunct to the behavioral group treatment program. Both subjects and group leaders were blind as to the condition of the subject. Ninety-seven males and 3 females entered the program, and 76% completed the 6-week treatment program and attended the four group counseling sessions. Concentrations of anabasine and anatabine were determined in urine of all of the subjects before treatment, and in urine of 76 subjects completing the study.

Study 2 examined the effects of nicotine gum *versus* placebo by group behavioral treatment *versus* minimal contact treatment (16). Smokeless tobacco users (210) who were willing to quit were randomly assigned to one of the following: (*a*) behavioral treatment plus 2 mg of nicotine gum ($n = 55$); (*b*) behavioral treatment and placebo gum ($n = 50$); (*c*) minimal treatment contact and 2 mg of nicotine gum ($n = 51$); or (*d*) minimal contact and placebo gum ($n = 54$). Participants were asked to chew either active nicotine or placebo gum for a period of 8 weeks. At the end of this treatment period, subjects were given the option to receive another box of free gum. Participants assigned to the group behavioral treatment participated in eight sessions over the course of 10 weeks. Those individuals assigned to the minimal contact condition met four times for individual sessions with the nurse over the 10-week period. Nonuse of tobacco was determined by self-report. Concentrations of anabasine and anatabine were determined in the urines of the 105 subjects who were assigned to nicotine gum treatment before treatment and in urine of 103 of these subjects on follow-up, having completed the study. Urine samples from 118 subjects using nicotine gum in another study with a similar protocol (16) were analyzed to verify that nicotine gum does not contain significant amounts of anabasine or anatabine.

Study 3 urine samples (99 persons) were obtained from cigarette smokers before beginning smoking cessation programs. Of these, 52 were from a study of early *versus* late quitting (17). The subjects were 59% female and 91% Caucasian, who smoked >10 cigarettes per day. Subjects were between 21 and 60 years of age. The remaining 47 subjects were from a study of cognitive behavioral therapy *versus* psychoeducational therapy. All of the participants received NRT. Subjects were 52% women and 88% Caucasian who smoked >20 cigarettes per day.

Urine samples from 35 nonsmokers were obtained to determine the specificity of anabasine and anatabine for tobacco use. The subjects were persons who provided a urine specimen before beginning a study of the effects of a low dose of nicotine in smokers or were laboratory personnel. Nonsmoking status was determined either by plasma cotinine being <15 ng/ml (10) or by being obtained from laboratory personnel known to be nonsmokers. Of these, 49% were female and 49% were Caucasian.

Analysis of Urine Samples. Concentrations of nicotine and cotinine in urine were determined (limit of quantitation, 10 ng/ml) using gas chromatography with nitrogen-phosphorus detection by a modification of a method published previously (18). The structural analogs of nicotine and cotinine, 5-meth-

[3] The abbreviations used are: NRT, nicotine replacement therapy.

Table 1 Mean concentrations of tobacco alkaloids in urine of smokers and smokeless tobacco users[a]

	n		Anabasine	Anatabine	Nornicotine	Nicotine	Cotinine
Smokeless tobacco study 1	100	ng/ml (SD)	24 (31)	41 (51)[b]	107 (107)	1310 (1170)[c]	2420 (1730)[b]
		Range	0–201	0–246	6.2–616	0–4780	264–9470
		ng/mg Creatinine (SD)	19 (20)	34 (41)[c]	87 (78)	1590 (2700)[c]	2700 (3200)
		Range	0–106	0–239	5.4–440	0–19,800	187–22,100
Smokeless tobacco study 2	105	ng/ml	23 (30)	45 (61)[b]	127 (105)	1550 (1650)[c]	2310 (1300)[b]
		Range	0–208	0–456	0–543	10–8320	254–5920
		ng/mg Creatinine (SD)	16 (16)	32 (33)[c]	102 (93)	1110 (1150)[b]	2040 (1750)
		Range	0–86	0–164	0–400	6.6–6090	89–8940
Cigarette smokers study 3	99	ng/ml (SD)	22 (23)	22 (24)[b]	113 (103)	1960 (1770)[c]	1790 (1030)[b]
		Range	0–120	0–118	3.4–513	9.2–7940	187–4980
		ng/mg Creatinine (SD)	19 (14)	20 (17)[c]	101 (64)	2050 (1980)[b]	1980 (1300)
		Range	0–84	0–83	3.3–302	6.1–11,100	170–6660

[a] Urine concentrations before beginning tobacco cessation programs.
[b] $P < 0.005$ comparing smokeless tobacco *versus* cigarettes.
[c] $P < 0.05$ comparing smokeless tobacco *versus* cigarettes.

ylnicotine and 1-methyl-5-(2-pyridyl)-pyrrolidinone (orthocotinine), were used as internal standards. A procedure for simultaneous extraction of nicotine and cotinine was used (19).

Concentrations of anabasine, anatabine, and nornicotine (limit of quantitation, 1 ng/ml) were determined by gas chromatography-mass spectrometry (20).

Data Analysis. The ratio of nicotine:cotinine was determined for each individual subject, and the mean values for smokers and smokeless tobacco users were computed from these ratios. Analyses of differences in means comparing smokeless tobacco users and cigarette smokers were performed by *t* tests.

The criterion for tobacco use was set at a concentration of >2 ng/ml in urine for both anabasine and anatabine. The basis for this criterion was inspection of urine concentration data from a group of people who were known not to use tobacco.

Sensitivity and specificity of anabasine and anatabine concentrations for detecting tobacco use were determined as described by Browner *et al.* (21). Sensitivity was determined in 179 persons enrolled in smokeless tobacco cessation programs (studies 1 and 2).

Sensitivity (expressed as percent) is defined as $100 \times a/(a + c)$, where a is the number of subjects who continued to use tobacco (true positives), and c is the number of tobacco users with concentrations of anabasine and anatabine below the cutoff of 2 ng/ml (false negatives). Self-reported tobacco use was considered to be accurate, because there would be no incentive to falsely report continued tobacco use.

Specificity was determined in 35 persons who did not use any form of tobacco. Specificity (expressed as percent) is defined as $100 \times d/(b + d)$, where d is the number of nontobacco users with urine concentrations of anabasine and anatabine below the cutoff of 2 ng/ml (true negatives), and b is the number of nontobacco users with anabasine and anatabine concentrations >2 ng/ml (false positives).

Results

Concentrations of nicotine, cotinine, and the minor alkaloids anabasine, anatabine, and nornicotine in urine of smokers and smokeless tobacco users before beginning tobacco cessation programs are given in Table 1. Mean nicotine concentrations ranged from 1310 to 1960 ng/ml, and were significantly lower in smokeless tobacco users than in cigarette smokers. Mean cotinine concentrations ranged from 1790 to 2420 ng/ml, and were significantly higher in smokeless tobacco users than in cigarette smokers. The ratio of nicotine:cotinine in urine of smokeless tobacco users (subjects from studies 1 and 2 combined) and cigarette smokers averaged 0.67 and 1.24, respectively. The difference between the two groups was significant, $P < 0.005$. Because some investigators (22) have reported cotinine concentrations normalized to creatinine concentrations, levels expressed as ng/mg creatinine are also reported in Table 1.

Mean nornicotine concentrations in urine of all of the tobacco users were similar (range = 107–127 ng/ml), as were anabasine concentrations (range = 22–24 ng/ml). Mean anatabine concentrations in urine of cigarette smokers (22 ng/ml) were about half those found in urine of smokeless tobacco users (41–45 ng/ml).

To test the specificity of the alkaloids for tobacco use, we measured concentrations of nornicotine, anabasine, and anatabine in the urine of 35 nonsmokers (confirmed by cotinine analysis), who reported that they did not use other forms of tobacco and did not use nicotine-containing medications. Concentrations of nornicotine, anabasine, and anatabine were below the limit of quantitation (1 ng/ml) in all but 3 of the subjects. Of these 3, the urine of one subject contained 3.4 ng/ml anabasine, with anatabine and nornicotine below the limit of quantitation. Another of the 3 contained 4.4 ng/ml nornicotine and 1.7 ng/ml anabasine, with anatabine below the limit of quantitation. The urine of the third subject contained 12.2 ng/ml nornicotine, 2.42 ng/ml anabasine, and 1.84 ng/ml anatabine. Whether these results were because of a low level of tobacco use or exposure, or whether because of small amounts of substances interfering with the assay is unknown, although the subject whose urine contained measurable amounts of all three alkaloids might indicate some prior tobacco use. However, using the criterion of both anabasine and anatabine concentrations being >2 ng/ml to classify a person as using tobacco, none of the 3 persons would have been classified as having used tobacco, and the specificity for detecting tobacco use is 100% (21).

Concentrations of anabasine and anatabine were used to validate cessation of smokeless tobacco use in studies 1 and 2. Subjects were considered to have relapsed if concentrations of both anabasine and anatabine were >2 ng/ml. The results are presented in Table 2. In study 1, concordance between self-reported abstinence and urinary concentrations of both anabasine and anatabine <2 ng/ml was 100%. In study 2, the concordance was 79%. The absence of measurable amounts of either anabasine or anatabine in the urine of many subjects (n =

Table 2 Urine anabasine and anatabine concentrations as outcome measures in smokeless tobacco cessation studies employing nicotine gum[a]

	Study 1	Study 2
Number of subjects completing study	76	103
Number claiming abstinence	45	89
Validated abstinence	45 (100%)	70 (79%)
Number of deceivers[b]	0 (0%)	19 (21%)
Number reporting relapse	31	14
Number of false negatives[c]	7 (23%)	5 (36%)

[a] Subjects were considered to be using tobacco if concentrations of both anabasine and anatabine in urine were >2 ng/ml.
[b] Deceivers are defined as those who claim abstinence but are judged to be using tobacco based on urine anabasine and anatabine levels.
[c] False negatives defined as those who report relapse to tobacco use, but whose urine anabasine and anatabine levels are below those set to define tobacco use.

118, study 2) using nicotine gum verifies that anabasine and anatabine are not present in nicotine gum, and validates their use as biomarkers during NRT.

Concordance between self-reported relapse, and of anabasine and anatabine levels >2 ng/ml was 77% (23% false negatives) and 64% (36% false negatives) for studies 1 and 2, respectively (Table 2). Overall, this corresponds to a sensitivity of 79% (21). The absence of measurable levels in some subjects reporting relapse is presumably because of infrequent tobacco use and/or sufficient time between the last tobacco use and obtaining a urine specimen for concentrations to fall below the limit of quantitation of the assay. The half-lives of anabasine and anatabine, based on urinary excretion data, were found to be 16 h and 10 h, respectively (23).

Correlations of anabasine, anatabine, and cotinine in urine of subjects before beginning tobacco cessation programs were correlated with their self-reported tobacco use (Table 3). Correlations ranged from fair to poor.

Discussion

Urine concentrations of anabasine, anatabine, nornicotine, nicotine, and cotinine were determined in 99 cigarette smokers (study 3), and were compared with concentrations of these alkaloids in 205 smokeless tobacco users (studies 1 and 2) before initiating treatment (Table 1). The sums of concentrations of nicotine and its metabolite cotinine in the urines of cigarette smokers and smokeless tobacco users were similar, suggesting similar levels of nicotine absorption. The lower ratio of nicotine:cotinine in smokeless tobacco users (0.67) compared with cigarette smokers (1.24) is most likely a result of more nicotine being swallowed by smokeless tobacco users, which then undergoes presystemic metabolism to cotinine in the liver (24). Concentrations of anabasine and anatabine in urine of all tobacco users were much less than concentrations of nicotine, as expected, because of much lower levels in tobacco (23). Cotinine levels were high because it is a major nicotine metabolite. Nornicotine, both a minor alkaloid found in tobacco and a minor metabolite of nicotine, was present at levels higher than those of anabasine and anatabine, but much lower than nicotine and cotinine.

Interestingly, concentrations of anatabine were on average 2-fold higher in urine of the smokeless tobacco users as compared with cigarette smokers, despite similar nicotine and cotinine levels, and although smokeless tobacco products contain considerably lower levels of anatabine than cigarette tobacco, 0.084 mg/gram *versus* 0.27 mg/gram (23). A likely explanation is that anatabine is decomposed to a much greater extent than is nicotine in burning tobacco, resulting in lesser absorption by cigarette smokers than by smokeless tobacco users. It should also be pointed out that anabasine, anatabine, and nornicotine, being secondary amines, are capable of being converted to nitrosamines by reaction with nitrogen oxides or nitrite *in vivo* (25). *N′*-nitrosoanabasine and *N′*-nitrosonornicotine are carcinogenic in animal models (26). For this reason, urine nornicotine concentrations, which have not been reported previously for a large population of tobacco users, are included in Table 1.

Objective outcome measures to validate self-reports of abstinence in tobacco cessation programs are needed (5–10). In addition, methods for quantitating tobacco consumption are needed in studies for evaluating potential harm reduction. The nicotine metabolite cotinine, measured in blood, saliva, or urine, is the most widely used biomarker for tobacco use (5). However, cotinine or other nicotine metabolites are not applicable for assessing tobacco use in persons undergoing NRT. The objective of our studies was to evaluate the use of urine concentrations of the minor tobacco alkaloids anabasine and anatabine as outcome measures for persons undergoing NRT. These alkaloids should not be present in nicotine-containing medications, and, indeed, we found that subjects abstaining from smokeless tobacco and using nicotine gum did not excrete measurable amounts of anabasine or anatabine.

Urine levels of anabasine and anatabine were evaluated as outcome measures for smokeless tobacco cessation in two studies that used nicotine gum as part of the treatment. There was generally good concordance between self-reported tobacco abstinence, and urine concentrations of anabasine and anatabine being below the cutoff (2 ng/ml; Table 2). In study 1, concordance was 100% of the 45 subjects reporting abstinence, and in study 2 it was 79% of the 89 subjects who reported abstinence.

Concordance with self-reported relapse and urine measures of anabasine and anatabine was also evaluated (Table 2). In study 1, there were 7 false negatives, with 23% of the 31 subjects reporting relapse, and in study 2 there were 5 false negatives, which was 36% of the 14 subjects who reported relapse. The finding of false negatives is presumably because of infrequent or low-level tobacco use, with enough time elapsed between relapse and obtaining a sample for concentrations to drop below the limit of quantitation of the assay. The half-lives of anabasine and anatabine, based on urinary excretion data, were found to be 16 h and 10 h, respectively (23). Our laboratory has developed a much more sensitive assay using liquid chromatography-tandem mass spectrometry methodology (limit of quantitation, 0.2 ng/ml) that should make it possible to detect much less frequent tobacco use in future studies. Also, it is possible that a metabolite of anabasine or anatabine exists that has a longer half-life than the parent alkaloids, which might make it possible to detect infrequent tobacco use. This possibility is suggested by the fact that the nicotine metabolite cotinine has a much longer half-life than nicotine (11). However, to our knowledge, studies of the metabolic disposition of anabasine and anatabine *in vivo* have not been reported.

In the present study, we proposed the use of the alkaloids anabasine and anatabine as biomarkers for tobacco use in persons undergoing NRT, and have applied these measures to treatment trials for cessation of smokeless tobacco use using nicotine gum. It would also be of interest to use these measures to estimate tobacco consumption. Self-reported tobacco consumption, such as number of cigarettes smoked per day, generally does not correlate well with nicotine intake (27). In the present study, correlations between self-reported tobacco use and urine concentrations of anabasine, anatabine, and cotinine ranged from fair to poor (Fig. 2; Table 3). Correlations were

Table 3 Correlations of alkaloid concentrations in urine with self-reported tobacco use and with nicotine intake from tobacco determined by pharmacokinetic techniques

	n	Self-report mean (SD)	Nicotine intake mg/day mean (SD)	Anabasine r	Anatabine r	Cotinine r
Smokeless tobacco study 1	93	11.4 (5.3)[a]		0.13	0.13	0.09
Smokeless tobacco study 2	98	3.6 (1.6)[b]		0.05	0.10	0.23
Cigarette smokers study 3	97	26 (13)[c]		0.40[d]	0.35[d]	0.60[d]
Smokeless tobacco[e]	9		20.3 (14.4)	0.52[f]	0.59[f]	0.80[g]
Cigarette smokers[e]	12		32.5 (16.3)	0.70[f]	0.62[f]	0.80[g]

[a] Dips/day.
[b] Tins/week.
[c] Cigarettes/day.
[d] $P < 0.001$.
[e] Data from Jacob *et al.* (23).
[f] $P < 0.05$.
[g] $P < 0.01$.

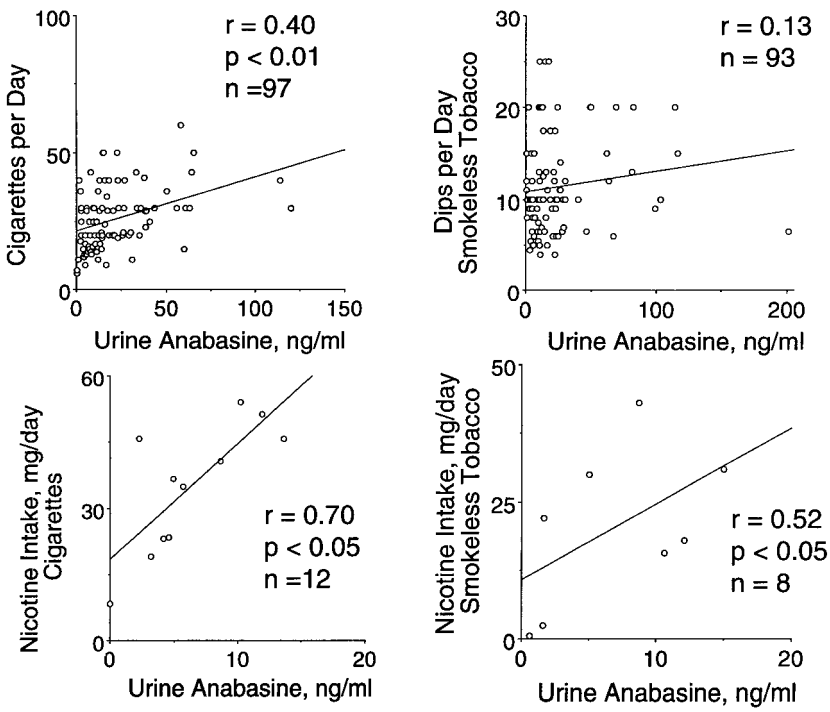

Fig. 2. Correlations of anabasine levels in urine with self-reported tobacco use (*top panel*) and nicotine intake from tobacco (*bottom panel*). *Top panel* data from studies 1 and 3; *bottom panel* data from Jacob *et al.* (23).

better with cigarette consumption than they were for smokeless tobacco consumption. Presumably, this is because of less variability in the systemically absorbed dose of nicotine from a cigarette than from a dip or tin of tobacco. This could be because the dips are of different sizes, there are different concentrations of nicotine in different smokeless tobacco products, the products are used differently by different people (*i.e.*, used for different duration of time or held in the mouth differently), and/or because of differences in saliva pH, which affect nicotine absorption. However, for smokeless tobacco, it has been reported that frequency and duration of tobacco use, rather than amount, appear to be better indicators of nicotine/cotinine exposure (28). Consequently, if frequency and duration measures had been obtained in the present study, correlations may have been better.

In a previous study, we found generally good correlations between nicotine intake from tobacco (determined from blood nicotine concentrations and nicotine clearance data; Ref. 29) and urine concentrations of nicotine, cotinine, anabasine, and anatabine. Data from that study are also shown in Table 3 and in Fig. 2 (23). Consequently, the measurement of tobacco alkaloids or their metabolites as biomarkers is advantageous for estimating the amount of tobacco consumed (11, 23). In tobacco cessation studies, it may be useful to have a quantitative estimate of tobacco consumption; for example, to assess potential harm reduction in persons who cut down on tobacco use but cannot quit. Our studies have demonstrated that urine levels of anabasine and anatabine can be used to assess tobacco consumption during NRT.

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Anabasine and Anatabine as Biomarkers for Tobacco Use during Nicotine Replacement Therapy

Peyton Jacob III, Dorothy Hatsukami, Herbert Severson, et al.

Cancer Epidemiol Biomarkers Prev 2002;11:1668-1673.

Acupuncture for Tobacco Cessation

Question: Should limits be placed on the use of acupuncture for tobacco cessation?

Question source: HERC staff

Issue: Acupuncture (CPT 97810-97814) is included on line 5 TOBACCO DEPENDENCE but currently has no mention/limits in the acupuncture guideline. The ACA does not require coverage for acupuncture treatment for smoking cessation.

Line: 5
Condition: TOBACCO DEPENDENCE (See Guideline Notes 4,64,65)
Treatment: MEDICAL THERAPY/BEHAVIORAL COUNSELING
ICD-10: F17.200-F17.228,F17.290-F17.299,Z71.6
CPT: 96150-96154,97810-97814,98966-98969,99078,99201-99215,99224,99324-99350, 99366,99406,99407,99415,99416,99441-99449,99487-99498,99605-99607
HCPCS: D1320,G0425-G0427,G0436,G0437,G0459,G0463,G0466,G0467,G0469,G0470, G9016,H0038,S9453

Current guideline

GUIDELINE NOTE 92, ACUPUNCTURE (ADAPTED FROM THE OCT. 1, 2015 PRIORITIZED LIST†)

Lines 1,208,351,415,467,532,543 (Lines 351 and 532 represent lines 374 and 545 from the Oct. 1, 2015 Prioritized List†)

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:
Line 1 PREGNANCY
Acupuncture pairs on Line 1 for the following conditions.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 351 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT (Line 374 from the Oct. 1, 2015 Prioritized List†)

Acupuncture is included on Line 351 (Line 374 from the Oct. 1, 2015 Prioritized List†) only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by ICD-10-CM G83.4, M47.2, M50.0, M50.1, M51.0, M51.1, M54.1), for up to 12 sessions.

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (Line 545 from the Oct. 1, 2015 Prioritized List†)

Acupuncture pairs on Line 532 (Line 545 from the Oct. 1, 2015 Prioritized List†) with the low back diagnoses appearing on this line (ICD-10-CM M51.36, M51.86, M54.5, M99.03, S33.5, S33.9, S39.092, S39.82, S39.92). Acupuncture pairs with chronic (>90 days) neck pain diagnoses on this line (ICD-10-CM M53.82, M54.2, S13.4, S13.8), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC evidence-based guideline. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

Acupuncture for Tobacco Cessation

Evidence:

1) **White 2014**[i]**,** Cochrane review of acupuncture for smoking cessation
    a. N=38 studies
        i. N=3 studies (393 patients) comparing acupuncture to waiting list control
        ii. N=19 studies (1,588 patients) comparing active acupuncture to sham acupuncture
    a. Based on three studies, acupuncture was not shown to be more effective than a waiting list control for long-term abstinence, with wide confidence intervals and evidence of heterogeneity (n = 393, risk ratio [RR] 1.79, 95% confidence interval [CI] 0.98 to 3.28, I^2 = 57%). Compared with sham acupuncture, the RR for the short-term effect of acupuncture was 1.22 (95% CI 1.08 to 1.38), and for the long-term effect was 1.10 (95% CI 0.86 to 1.40). Acupuncture was less effective than nicotine replacement therapy (NRT). There was no evidence that acupuncture is superior to psychological interventions in the short- or long-term.
    b. Moderate quality of evidence of no long term benefit for acupuncture on smoking cessation, although evidence of short term effect
    c. Wide variety of acupuncture protocols. Details of included studies' intervention frequency/duration as well as adjunct therapy, if any (studies only listed here if full articles were available):
    i. Bier 2002: 20 sessions over 4 wks. Three arms: true acupuncture, true acupuncture + intensive ed program, sham acupuncture + intensive ed program
    ii. Clavel 1985: single session. *Adjunct therapy: 3 one-hour sessions of group therapy in first month
    iii. Clavel 1992: 3 sessions over one month
    iv. Cottraux 1983: 3 weekly sessions
    v. Fritz 2013: 5 weekly 20 min sessions of b/l auriculotherapy
    vi. He 1997: Both groups received combination of body electroacupuncture, ear acupuncture and ear acupressure (genuine vs sham points), 6 treatments over 3 wks + 6 plant seeds taped to "correct" or "incorrect" points on the ear and subjects instructed to press on each seed 100x on 4 occasions daily
    vii. Lagrue 1980: facial acupuncture vs sham acupuncture, day 0 and day 7. *Adjunct therapy: "standardised advice"
    viii. Waite 1998: lung point in ear vs control patella point. *Both groups received one 20-minute session of acupuncture w electrical stimulation followed by placement of seed on needle site. Instructed to press seed with desire to smoke.ix. White 1998: acupuncture with electrical stim to lung points in both ears vs sham acupuncture to mastoid bone. Days 1,3, 7. *Adjunct therapy: counseling by a nurse
    x. Wu 2007: indwelling auricular needles in active vs sham points, 4 points retained for one week, then replaced. 8 wk tx period. *Adjunct therapy: counseling from nurse
    d. **Authors' conclusions** Although pooled estimates suggest possible short-term effects there is no consistent, bias-free evidence that acupuncture, acupressure, or laser therapy have a sustained benefit on smoking cessation for six months or

more. However, lack of evidence and methodological problems mean that no firm conclusions can be drawn.

2) **Patnode 2015[ii]: USPSTF Review of Reviews.** (article not included in meeting materials due to length)
   a. Includes all types of behavioral and pharmacotherapy interventions. In total, reviewed 638 abstracts and 114 full-text reviews for possible inclusion, narrowing down to 54 systematic reviews which met eligibility criteria. Identifies 2 reviews on acupuncture (White 2014 and Di 2014) and classifies them both as "good." Additionally, it evaluates Cheng 2012's review of acupoint stimulation as "fair." No other reviews regarding acupuncture or acupressure identified.
   b. Authors' conclusions: Concluded that "evidence on the use of...complementary and alternative therapies was limited and not definitive."

3) **McRobbie 2007[iii]: NICE Rapid Review of Non NHS Treatments for Smoking Cessation** (Study not included in meeting materials due to length)
   a. 19 reviews narrowed to 9 reviews after further exclusion based on poor quality, no systematic method, or review of reviews. Included White's Cochrane review from 2006. Additionally, 21 studies were narrowed to 14 studies after exclusion for not being an RCT. Further, of those 14 studies, 13 were included in the Cochrane Review. Only one new RCT (Docherty 2003) was included, but it was examining laser therapy and thus is not relevant to this lit review.
   b. Since this NICE Review relied heavily on an old Cochrane review, this is less relevant to HERC's current lit review.
   c. **Authors' conclusion**: Marginal effect compared to placebo in short-term but no evidence of efficacy in long-term abstinence rates. Level 1+ evidence "well-conducted meta-analyses, systematic reviews of RCTs, or RCTs (including cluster RCTs) with a low risk of bias."

4) **Cheng 2012[iv]** Systematic Review and Meta-Analysis in American Journal of Chinese Medicine.
   a. n = 20 studies total
      n = 9 studies evaluating smoking cessation rate at 3,6 months
      n = 3 studies evaluating daily cigarette consumption
   b. Includes 13 of same acupuncture studies as White 2014 Cochrane.
   c. Combined all types of acupoint stimulation (acupuncture, acupressure, laser therapy) and all types of controls into single analysis. White 2014 comments that this likely explains the differences in the reviews.
   d. Smoking cessation RR 1.24 (95% CI 1.07,1.43) immediately after tx, 1.70 (1.17,2.46) at 3 months, 1.79 (1.13,2.82) at 6 months compared to control or sham interventions.
   d. Authors' conclusions: "Acupoint stimulation increases smoking cessation rate and reduces daily cigarette consumption. Multi-modality treatment,

especially acupuncture combined with smoking cessation education..., can help."

5) **Di 2014**[v] (Drug and Alcohol Dependence Journal) "A Meta-Analysis of Ear-Acupuncture, Ear-Acupressure and Auriculotherapy for Cigarette Smoking Cessation"

a. Did not take body acupuncture or laser therapy into account.
b. n = 25 RCTs, two pools: 1) comparing to inactive control and 2) comparing to other smoking cessation specific treatment.
c. Pool 1) immediate RR = 1.77 (1.39, 2.25), 3 months RR = 1.54 (1.14, 2.08), 6 months RR = 2.01 (1.23, 3.28), insufficient data for 12 months. Pool 2) "no superiority or inferiority...[immediately] or at 3 and 6 month follow-ups." Small trials.
d. Authors' conclusions: Ear acupuncture, ear acupressure and auriculotherapy is superior to inactive controls for smoking cessation immediately and at 3 months and 6 months.

6) **Tahiri 2012**[vi] Meta-analysis in American Journal of Medicine (not included due to size) http://bscw.rediris.es/pub/bscw.cgi/d5001225/Tahiri-Alternative_smoking_cessation_aids.pdf

a. n = 6 acupuncture trials (823 patients). All 6 were included in Di 2014 meta-analysis and 5 of them included in White 2014. The sixth RCT (Kerr 2008) was classified as laser therapy and excluded from White 2014.
b. OR = 3.53 (1.03,12.07)
c. Very wide confidence interval.
d. Authors' conclusions: "acupuncture...may help smokers quit."

Expert input:
From Laura Ocker, Lac

February 18 2016

I think 12 acupuncture treatments is a good starting point for pain / chronic pain conditions. For smoking cessation, more treatment would be warranted (assuming the patient is truly making progress). For smoking cessation, my recommendation to patients is 2-3 visits per week the first two or three weeks and then 1-2 times per week for several weeks following. Then I am available for a few follow-up appointments throughout the year when stressors trigger the urge to start smoking again. **So, I'd say 18 treatments would be better.** For the person who is truly making progress. If I treat them 3-5 times and they show no signs of cutting down or quitting, I suggest they pursue other options or come back when they feel more ready.

Would be great to combine acupuncture with CBT or other therapies, but I wouldn't necessarily make it a requirement. If someone is doing really well with acupuncture alone, they may not need the additional support. Or vice versa. Also, there are times when medications are not appropriate, such as pregnancy or for patients who are medication-adverse, and this is another good area for acupuncture.

I'd say 18 treatments is a good number for private practice. Although in community health center / community acupuncture settings where a patient can come in more easily and more often for a drop-in treatment (and where you're more likely to be seeing Medicaid patients and people with multiple chronic health conditions and other significant life stressors) up to 24-30 treatments (IF MAKING PROGRESS) would be completely reasonable.

I would recommend 18. I would expect my colleagues to be ethical enough to not treat past the first couple of weeks if the patient has not quit or substantially reduced the number of cigarettes per day.

March 2015

I think that smoking cessation may be one of those conditions, like so many others, for which we see a high degree of efficacy in clinical practice, but for which there may not adequate evidence to support the use of acupuncture as a treatment option from a coverage standpoint. My colleagues and I find that acupuncture and Oriental medicine is a helpful therapy for smoking cessation - in that it reduces cravings and withdrawal symptoms and reduces associated symptoms such as anxiety, rage, nervousness, frustration, etc. Acupuncture alone, or often combined with other therapies, such as CBT or use of nicotine products gradually weaned under a physician's guidance, is very helpful to people who would like to quit smoking. I would like to see acupuncture remain an option for smoking cessation.

HERC staff summary

Four meta-analyses (White 2014, Di 2014, Cheng 2012, and Tahiri 2012) came to varying conclusions, either finding superiority of acupuncture over control/sham at 0-6 months or inconclusive. The differences between the meta-analyses was most attributable to differing methods of pooling. In general, the widely varying acupuncture techniques and protocols used in RCTs let to the inability to draw firm conclusions on effectiveness.

The general staff conclusion is that acupuncture may be helpful for smoking cessation, and is definitely not harmful. The number of visits used in study protocols ranged from 3-20, but were generally fewer than recommended by experts. There is insufficient evidence about the need to pair acupuncture with other therapies for smoking cessation.

HERC staff recommendation:

1) Modify GN92 Acupuncture as shown below
    a. 18 visits maximum
    b. Wording in purple includes wording proposed in the Straightforward Back Line Changes document

GUIDELINE NOTE 92, ACUPUNCTURE (ADAPTED FROM THE OCT. 1, 2015 PRIORITIZED LIST†)

Lines 1,208,351,415,467,532,543 (Lines 351 and 532 represent lines 374 and 545 from the Oct. 1, 2015 Prioritized List†)

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 18 sessions.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 351 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT (Line 374 from the Oct. 1, 2015 Prioritized List†)

Acupuncture is included on Line 351 (Line 374 from the Oct. 1, 2015 Prioritized List†) only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by ICD-10-CM G83.4, M47.2, M50.0, M50.1, M51.0, M51.1, M54.1), for up to 12 sessions.

Line 366 SCOLIOSIS

Acupuncture is included on line 366 for pairing with visit limitations as in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (Line 545 from the Oct. 1, 2015 Prioritized List†)

Acupuncture pairs on Line 532 (Line 545 from the Oct. 1, 2015 Prioritized List†) with the low back diagnoses appearing on this line (ICD-10-CM M51.36, M51.86, M54.5, M99.03, S33.5, S33.9, S39.092, S39.82, S39.92). Acupuncture pairs with chronic (>90 days) neck pain diagnoses on this line (ICD-10-CM M53.82, M54.2, S13.4, S13.8), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC evidence-based guideline. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

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[i] White, Adrian R., et al. "Acupuncture and related interventions for smoking cessation." *Cochrane Database Syst Rev* 1 (2014).

[ii] Patnode, Carrie D., et al. "Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Review of Reviews for the US Preventive Services Task Force." *Annals of internal medicine* 163.8 (2015): 608-621.

[iii] McRobbie, Hayden, et al. "Rapid Review of Non NHS Treatments for Smoking Cessation." NICE (2007).

[iv] Cheng, Hsiao-Min, et al. "Systematic review and meta-analysis of the effects of acupoint stimulation on smoking cessation." *The American journal of Chinese medicine* 40.03 (2012): 429-442.

[v] Di, Yuan Ming, et al. "A meta-analysis of ear-acupuncture, ear-acupressure and auriculotherapy for cigarette smoking cessation." *Drug and alcohol dependence* 142 (2014): 14-23.

[vi] Tahiri, Mehdi, et al. "Alternative smoking cessation aids: a meta-analysis of randomized controlled trials." *The American journal of medicine* 125.6 (2012): 576-584.

Acupuncture and related interventions for smoking cessation (Review)

White AR, Rampes H, Liu JP, Stead LF, Campbell J

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WILEY

[Intervention Review]

Acupuncture and related interventions for smoking cessation

Adrian R White[1], Hagen Rampes[2], Jian Ping Liu[3], Lindsay F Stead[4], John Campbell[5]

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ABSTRACT

Background

Acupuncture and related techniques are promoted as a treatment for smoking cessation in the belief that they may reduce nicotine withdrawal symptoms.

Objectives

The objectives of this review are to determine the effectiveness of acupuncture and the related interventions of acupressure, laser therapy and electrostimulation in smoking cessation, in comparison with no intervention, sham treatment, or other interventions.

Search methods

We searched the Cochrane Tobacco Addiction Group Specialized Register (which includes trials of smoking cessation interventions identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, and PsycINFO) and AMED in October 2013. We also searched four Chinese databases in September 2013: Sino-Med, China National Knowledge Infrastructure, Wanfang Data and VIP.

Selection criteria

Randomized trials comparing a form of acupuncture, acupressure, laser therapy or electrostimulation with either no intervention, sham treatment or another intervention for smoking cessation.

Data collection and analysis

We extracted data in duplicate on the type of smokers recruited, the nature of the intervention and control procedures, the outcome measures, method of randomization, and completeness of follow-up.

We assessed abstinence from smoking at the earliest time-point (before six weeks) and at the last measurement point between six months and one year. We used the most rigorous definition of abstinence for each trial, and biochemically validated rates if available. Those lost to follow-up were counted as continuing smokers. Where appropriate, we performed meta-analysis pooling risk ratios using a fixed-effect model.

Main results

We included 38 studies. Based on three studies, acupuncture was not shown to be more effective than a waiting list control for long-term abstinence, with wide confidence intervals and evidence of heterogeneity (n = 393, risk ratio [RR] 1.79, 95% confidence interval [CI] 0.98 to 3.28, I^2 = 57%). Compared with sham acupuncture, the RR for the short-term effect of acupuncture was 1.22 (95% CI 1.08 to 1.38), and for the long-term effect was 1.10 (95% CI 0.86 to 1.40). The studies were not judged to be free from bias, and there was evidence of funnel plot asymmetry with larger studies showing smaller effects. The heterogeneity between studies was not explained by the technique used. Acupuncture was less effective than nicotine replacement therapy (NRT). There was no evidence that acupuncture is superior to psychological interventions in the short- or long-term. There is limited evidence that acupressure is superior to sham acupressure for short-term outcomes (3 trials, n = 325, RR 2.54, 95% CI 1.27 to 5.08), but no trials reported long-term effects, The pooled estimate for studies testing an intervention that included continuous auricular stimulation suggested a short-term benefit compared to sham stimulation (14 trials, n = 1155, RR 1.69, 95% CI 1.32 to 2.16); subgroup analysis showed an effect for continuous acupressure (7 studies, n = 496, RR 2.73, 95% CI 1.78 to 4.18) but not acupuncture with indwelling needles (6 studies, n = 659, RR 1.24, 95% CI 0.91 to 1.69). At longer follow-up the CIs did not exclude no effect (5 trials, n = 570, RR 1.47, 95% CI 0.79 to 2.74). The evidence from two trials using laser stimulation was inconsistent and could not be combined. The combined evidence on electrostimulation suggests it is not superior to sham electrostimulation (short-term abstinence: 6 trials, n = 634, RR 1.13, 95% CI 0.87 to 1.46; long-term abstinence: 2 trials, n = 405, RR 0.87, 95% CI 0.61 to 1.23).

Authors' conclusions

Although pooled estimates suggest possible short-term effects there is no consistent, bias-free evidence that acupuncture, acupressure, or laser therapy have a sustained benefit on smoking cessation for six months or more. However, lack of evidence and methodological problems mean that no firm conclusions can be drawn. Electrostimulation is not effective for smoking cessation. Well-designed research into acupuncture, acupressure and laser stimulation is justified since these are popular interventions and safe when correctly applied, though these interventions alone are likely to be less effective than evidence-based interventions.

PLAIN LANGUAGE SUMMARY

Do acupuncture and related therapies help smokers who are trying to quit

We reviewed the evidence that acupuncture, acupressure, laser therapy or electrical stimulation help people who are trying to stop smoking.

Background

Acupuncture is a traditional Chinese therapy, generally using fine needles inserted through the skin at specific points in the body. Needles may be stimulated by hand or using an electric current (electroacupuncture). Related therapies, in which points are stimulated without the use of needles, include acupressure, laser therapy and electrical stimulation. Needles and acupressure may be used just during treatment sessions, or continuous stimulation may be provided by using indwelling needles or beads or seeds taped to to acupressure points. The aim of these therapies is to reduce the withdrawal symptoms that people experience when they try to quit smoking. The review looked at trials comparing active treatments with sham treatments or other control conditions including advice alone, or an effective treatment such as nicotine replacement therapy (NRT) or counselling. Sham treatment involves inserting needles or applying pressure to other points of the body not believed to have an active effect, or using dummy needles that do not go through the skin, or inactive laser or electrical stimulation devices. Using this type of control means that the patients should not know whether they are receiving active treatment or not.

To assess whether there was a sustained benefit in helping people to stop smoking we looked at the proportion of people who were abstinent at least six months after quit date. We also looked at short term outcomes, up to six weeks after quit date. Evidence of benefit after six months is regarded as necessary to show that a treatment could help people stop smoking permanently.

Study characteristics

We included 38 randomised studies published up to October 2013. Trials tested a variety of different interventions and controls. The specific points used, the number of sessions and whether there was continuous stimulation varied. Three studies (393 people) compared acupuncture to a waiting list control. Nineteen studies (1,588 people) compared active acupuncture to sham acupuncture, but only 11 of these studies included long-term follow-up of six months or more. Three studies (253 people) compared acupressure to sham

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Systematic Review and Meta-Analysis of the Effects of Acupoint Stimulation on Smoking Cessation

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Abstract: Smoking represents a serious worldwide public health problem because of its close association with the development of chronic disease and cancer. Acupoint stimulation has been used as treatment mode for smoking cessation but its efficacy remains controversial. This systematic review and meta-analysis aimed to determine the effects of acupoint stimulation on smoking cessation rate and daily cigarette consumption. Electronic literature searches in eight electronic databases up to March 2011 were performed to identify acupoint stimulation for smoking cessation. The outcomes assessed were smoking cessation rate and cigarette consumption. We assessed abstinence from smoking at the earliest and last measured time points, and at the 3- and 6-month follow-ups. Meta-analysis was performed using CMA software. A total of 20 RCTs were included in the meta-analysis. A significant effect of acupoint stimulation was found in smoking cessation rates and cigarette consumption at immediate, 3- and 6-month follow-ups, with effect sizes 1.24 (95%CI = $1.07 \sim 1.43$, $p = 0.003$), -2.49 (95%CI = $-4.65 \sim -0.34$, $p = 0.02$), 1.70 (95%CI = $1.17 \sim 2.46$, $p = 0.01$), and 1.79 (95%CI = $1.13 \sim 2.82$, $p = 0.01$), respectively. Multi-modality treatments, especially acupuncture combined with smoking cessation education or other interventions, can help smokers to eschew smoking during treatment, and to avoid relapse after treatment.

Keywords: Acupoint Stimulation; Smoking Cessation; Meta-Analysis; Acupuncture; Acupressure; Electroacupuncture.

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Review

A meta-analysis of ear-acupuncture, ear-acupressure and auriculotherapy for cigarette smoking cessation

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ABSTRACT

Background: This systematic review evaluated the effects of ear acupuncture, ear acupressure and auriculotherapy for cigarette smoking cessation (SC) at end-of-treatment (EoT), three, six and 12 months follow-up.
Methods: Searches of six English and Chinese databases located 25 randomized controlled trials (3735 participants). Methodological quality was assessed using Cochrane Risk of Bias. Meta-analyses were conducted in two pools: 1. SC-specific ear acupuncture/acupressure or auriculotherapy (EAP/R) vs. non-specific/inactive control; and 2. SC-specific EAP/R vs. other SC-specific treatment. Sensitivity analyses were conducted based on the validity of interventions as SC-specific treatments or non-specific/inactive interventions; and the use of biochemical SC confirmation.
Results: Pool 1: the 12 valid SC-specific EAP/R interventions were superior to inactive EAP/R controls at EoT (RR = 1.77 [1.39, 2.25]), three months follow-up (RR = 1.54 [1.14, 2.08]), and six months follow-up (RR = 2.01, [1.23, 3.28]) but data were insufficient at 12 months. In Pool 2: there was no superiority or inferiority for EAP/R at EoT or at 3 and 6 month follow-ups compared to SC-specific behavioural therapy or SC-specific body acupuncture.
Conclusions: Pool 1 data appeared most consistent for studies of ear acupressure (EAPR) vs. non-specific EAPR controls, with confirmed SC rates at 3 months post-treatment of 20.0% for test groups vs. 7.5% for controls. In Pool 2 the EAP/R interventions appeared neither inferior nor superior to the behavioural interventions at 3 and 6 month follow-ups. However, meta-analysis results derived from relatively small-sized trials with no biochemical validation of SC in Pool 2. Larger, well-controlled studies using biochemical confirmation of SC are needed.

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0376-8716/

Hyperbaric Oxygen Guideline

Question: Should the hyperbaric oxygen guideline be clarified/simplified?

Question source: HERC staff; CCO medical directors; Dr. Alejandro Perez, Providence hyperbaric oxygen medical director

Issue: The current hyperbaric oxygen guideline is confusing to many readers. HERC staff has worked to clarify language for this guideline.

Dr. Carl Stevens, a medical director with CareOregon, has suggested modifications to the guideline to clarify language. One specific request was to apply the requirement for re-evaluation of the wound healing to all conditions listed in the guideline, as all may or may not respond to hyperbaric oxygen therapy.

Review of the CMS National Coverage Determination wording found that it was unclear whether CMS intended that the 30 day re-evaluation requirement be applied to diabetic wounds, or to all wounds. Dr. Alejandro Perez, the Providence Hyperbaric Oxygen program medical director, has recommended to HERC staff that the wording only apply to diabetic wounds and ulcers. Specifically, many of the post-radiation wounds or osteoradionecrosis conditions need specific numbers of treatments which do not correspond well to a 30 day limit. Other conditions need specialized follow up evaluations such as cystoscopy or colonoscopy, which might not be appropriate to do every 30 days.

From Dr. Perez

> For jaw osteoradionecrosis and for soft tissue radiation injuries, however, this is not appropriate. For jaw osteoradionecrosis, for most protocols used, one would do some treatments (20) before surgery and 10 after. This would not fit into a 30 day cycle because of the break needed for surgery and because most hyperbaric centers only are active 5 days per week. Assessment and completion of treatment is appropriate after 30 treatments, not 30 days. For radiation injuries like radiation cystitis, radiation colitis, radiation related ulcerations the process for healing and to see impact is often measured clinically and not by some objective measure. One would not do a cystoscopy or colonoscopy every 30 days for example. Additionally the treatment can take >60 treatments before clinical effect seen. 30 day evaluation would only prove that 30 days is insufficient to see improvement in many patient, but yet by this measure a patient may never get to therapeutic benefit (a self fulfilling prophecy).

On review of the guideline, staff identified that the current guideline note is confusing regarding whether other ICD-10 codes included on the line are actually covered when they are not specifically mentioned in the guideline. Clarification is needed, as there are many conditions included in this line (such as carbon monoxide poisoning, air embolism, etc.) which

are not included in the guideline as the guideline is just a list of limitations for certain ICD-10 codes or restrictions on certain conditions.

Staff identified that the code for osteoradionecrosis of the jaw was possibly incorrect. However, Dr. Perez recommended continuing to use M27.8 (Other specified diseases of jaws) is included on this line, as this is the CMS recommended code for this condition. Additionally, Dr. Perez identified that L59.9 (Disorder of the skin and subcutaneous tissue related to radiation, unspecified) was missing from this line and should be added. The coverage guidance for hyperbaric oxygen therapy recommended coverage of radiation injury. Currently L59.9 appears only on line 536 CONTACT DERMATITIS AND OTHER ECZEMA.

Guideline history

1) 2011, reviewed osteomyelitis and determined no evidence to support coverage
2) 2013, modified guideline wording to improve readibility
3) 2014, coverage guidance on hyperbaric oxygen was adopted and a modified guideline was adopted to reflect the coverage guidance recommendations. The diabetic wound portions of the guideline note were adopted with exact wording from the coverage guidance, except the addition of the requirement for re-evaluation every 30 days. This requirement was added to address medical director concerns and was based on the CMS coverage determination.

Current guideline note:

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

Hyperbaric oxygen is a covered service only under the following circumstances:

- when paired with ICD-10-CM codes E11.5x and E11.621, E11.622 and E11.623 for diabetic wounds with gangrene OR diabetic wounds of the lower extremities in patients who meet the all of the following criteria:
    - Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, AND
    - Patient has a wound classified as Wagner grade III or higher, AND
    - Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days, AND
    - Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
- when paired with ICD-10-CM codes M27.8 for osteoradionecrosis of the jaw only
- when paired with ICD-10-CM codes O08.0, M60.000-M60.09 only if the infection is a necrotizing soft-tissue infection
- when paired with ICD-10 CM codes S07.xxx,S17.xxx,S38.xxx,S47.1xxA-S47.1xxD,S47.2xxA-S47.2xxD,S47.9xxA-S47.9xxD, S57.xxx,S67.xxx,

S77.xxx,S87.xxx,S97.xxx, T79.Axx only for posttraumatic crush injury of Gustilo type III B and C

- when paired with ICD-10--CM codes T66.xxxA only for osteoradionecrosis and soft tissue radiation injury
- when paired with ICD-10-CM codes T86.820-T86.829,T82.898A/T82.898D, T82.9xxA/T82.9xxD, T83.89xA/T83.89xD, T83.9xxA/T83.9xxD, T84.89xA/T84.89xD, T84.9xxA/T84.9xxD, T85.89xA/T85.89xD, T859xxA/T859xxD only for compromised myocutaneous flaps

HERC staff recommendations:

1) Add L59.9 (Disorder of the skin and subcutaneous tissue related to radiation, unspecified) to line 337
2) Modify GN107 as shown below

[easier to read format]

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

Hyperbaric oxygen therapy is included on this line, subject to the following limitations:

1. Codes appearing on this line from ICD-10-CM E08-E13 are included only when they are diabetic wound ulcers of the lower extremities which are Wagner grade 3 or higher (that is, involving bone or gangrenous) and show no measurable signs of healing after 30 days of adequate standard wound therapies including arterial assessment. Courses of treatment for wounds or ulcers are limited to 30 days after the initial treatment; additional 30 day treatment courses are only covered for patients with incomplete wound/infection resolution AND measurable signs of healing
2. ICD-10-CM M27.8 is included on this line for osteoradionecrosis of the jaw only
3. ICD-10-CM O08.0 and M60.0 are included on this line only if the infection is a necrotizing soft-tissue infection
4. ICD-10-CM S07, S17, S38, S47.1, S47.2, S47.9, S57, S67, S77, S87, S97, T79.A are included on this line only for posttraumatic crush injury of Gustilo type III B and C
5. ICD-10-CM T66.XXXA-T66.XXXD are included on this line only for osteoradionecrosis and soft tissue radiation injury
6. ICD-10-CM T86.82, T82.898, T82.9, T83.89, T83.9, T84.89, T84.9, T85.89, T85.9 are included on this line only for compromised myocutaneous flaps

[edited guideline format]

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

A course of ~~H~~hyperbaric oxygen treatment is included on this line ~~a covered service~~ subject to the following limitations: ~~only under the following circumstances~~:

~~when paired with ICD-10-CM codes E11.5x and E11.621, E11.622 and E11.623 for diabetic wounds with gangrene OR diabetic wounds of the lower extremities in patients who meet the all of the following criteria:~~

~~a. Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, AND~~

~~b. Patient has a wound classified as Wagner grade III or higher, AND~~

~~c. Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days, AND~~

~~d. Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen~~

~~therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.~~

2) Codes appearing on this line from ICD-10-CM E08-E13 are included only when they are diabetic wound ulcers of the lower extremities which are Wagner grade 3 or higher (that is, involving bone or gangrenous) and show no measurable signs of healing after 30 days of adequate standard wound therapies including arterial assessment. Courses of treatment for wounds or ulcers are limited to 30 days after the initial treatment; additional 30 day treatment courses are only covered for patients with incomplete wound/infection resolution AND measurable signs of healing

1) ~~when paired with~~ ICD-10-CM M27.8 is included on this line for osteoradionecrosis of the jaw only
2) ~~when paired with~~ ICD-10-CM O08.0 and M60.0 are included on this line only if the infection is a necrotizing soft-tissue infection
3) ~~when paired with diagnosis codes included on this line from~~ ICD-10-CM S07, S17, S38, S47.1, S47.2, S47.9, S57, S67, S77, S87, S97, T79.A are included on this line only for posttraumatic crush injury of Gustilo type III B and C
4) ~~when paired with~~ ICD-10-CM T66.XXXA-T66.XXXD are included on this line only for osteoradionecrosis and soft tissue radiation injury
5) ~~when paired with~~ ICD-10-CM T86.82, T82.898, T82.9, T83.89, T83.9, T84.89, T84.9, T85.89, T85.9 are included on this line only for compromised myocutaneous flaps

Tracking Information

Publication Number

100-3 Manual Section Number

20.29 Manual Section Title

Hyperbaric Oxygen Therapy

Version Number

3 Effective Date of this Version

6/19/2006 Implementation Date

6/19/2006

Description Information

Benefit Category

Incident to a physician's professional Service
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

CIM 35-10
For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

Indications and Limitations of Coverage

A. Covered Conditions
Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

- Acute carbon monoxide intoxication,
- Decompression illness,
- Gas embolism,
- Gas gangrene,
- Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive

treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
Progressive necrotizing infections (necrotizing fasciitis),
Acute peripheral arterial insufficiency,
Preparation and preservation of compromised skin grafts (not for primary management of wounds),
Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
Osteoradionecrosis as an adjunct to conventional treatment,
Soft tissue radionecrosis as an adjunct to conventional treatment,
Cyanide poisoning,
Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
Diabetic wounds of the lower extremities in patients who meet the following three criteria:
Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
Patient has a wound classified as Wagner grade III or higher; and
Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 –days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Noncovered Conditions
All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A).
No program payment may be made for HBO in the treatment of the following conditions:
Cutaneous, decubitus, and stasis ulcers.
Chronic peripheral vascular insufficiency.
Anaerobic septicemia and infection other than clostridial.
Skin burns (thermal).
Senility.

Myocardial infarction.
Cardiogenic shock.
Sickle cell anemia.
Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
Acute or chronic cerebral vascular insufficiency.
Hepatic necrosis.
Aerobic septicemia.
Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
Tetanus.
Systemic aerobic infection.
Organ transplantation.
Organ storage.
Pulmonary emphysema.
Exceptional blood loss anemia.
Multiple Sclerosis.
Arthritic Diseases.
Acute cerebral edema.

C. Topical Application of Oxygen
This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established.
Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

Cross Reference
§270.5 of this manual.

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Transmittal Information
Transmittal Number

48
Coverage Transmittal Link

http://www.cms.gov/transmittals/downloads/R48NCD.pdf
Revision History

07/01/1997 - Clarified coverage limited to conditions listed under §35-10.A. Effective date 08/11/1997. (TN 102)
04/01/1999 - Clarified covered conditions and physician supervision requirement. Effective date 05/01/1999. (TN 112)
10/19/2000 - Manualized program memorandum AB-00-15 (dated 4/1/2000) and clarified that "preparation and preservation of compromised skin graft" in section 35-10A.9 is not for primary management of wounds. Effective date NA. (TN 129) (CR 1138)
12/27/2002 - Expanded coverage for treatment of diabetic wounds of the lower

extremities in patients that meet three criteria. Effective date 04/01/2003. (TN 164) (CR 2388)
03/2006 - Technical corrections to the NCD Manual. Effective date 06/19/2006. (TN48) (CR4278)
01/2013 - CMS translated the information for this policy from ICD-9-CM/PCS to ICD-10-CM/PCS according to HIPAA standard medical data code set requirements and updated any necessary and related coding infrastructure. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 04/01/2013 Effective date: 10/1/2015. (TN 1165) (CR 8109)
05/2014 - CMS translated the information for this policy from ICD-9-CM/PCS to ICD-10-CM/PCS according to HIPAA standard medical data code set requirements and updated any necessary and related coding infrastructure. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 10/06/2014 Effective date: 10/1/2015. (TN 1388) (TN 1388) (CR 8691)

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National Coverage Analyses (NCAs)
National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.
Original consideration for Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities (CAG-00060N) opens in new window
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Additional Information
Other Versions

Hyperbaric Oxygen Therapy - Version 2, Effective between 4/1/2003 - 6/19/2006

Hyperbaric Oxygen Therapy - Version 1, Effective between 10/19/2000 - 4/1/2003

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Section 7.0

Previously Discussed Items

Disorders of Bilirubin Metabolism

Issue: at the March, 2016 meeting, the VBBS approved moving 4 diagnoses from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and added to line 64 METABOLIC DISORDERS, as the conditions are not neonatal conditions. However, on further examination, all but one of these conditions are all benign and do not require treatment. Criglar-Najjar syndrome is actually a neonatal condition and should be returned to a neonatal line. These conditions all had a single ICD-9 code (277.4 Disorders of bilirubin metabolism) which was on line 106.

E80.4 is Gilbert syndrome, a hereditary disorder in bilirubin metabolism. Gilbert syndrome results in mild anemia and mild elevations in bilirubin levels but has no clinical significance.

E80.5 is Criglar-Najjar syndrome, a rare inherited disorder affecting the metabolism of bilirubin. The disorder results in a form of nonhemolytic jaundice, which results in high levels of unconjugated bilirubin and often leads to brain damage in infants. Treatment is phototherapy, medications, and exchange transfusion in infancy, with liver transplant as the definitive therapy. Type II Criglar-Najjar is a less serious form of the condition that can normally be managed with medications. The 2014 American Association for the Study of Liver Diseases, the American Society of Transplantation and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition practice guideline for pediatric liver transplant (**Squires 2014**) (study not included due to length https://www.aasld.org/sites/default/files/guideline_documents/EvaluationPediatricLT2014.pdf) recommends all infants with Criglar-Najjar syndrome type 1 be evaluated as soon as possible, before irreversible brain damage occurs, for liver transplantation. Liver transplant is noted to be the only effective treatment for this disease.

E80.6 (Other disorders of bilirubin metabolism) has a few subdiagnoses including Dubin-Johnson syndrome, which is an autosomal recessive disorder that causes an increase of conjugated bilirubin in the serum without elevation of liver enzymes (ALT, AST). This condition is associated with a defect in the ability of hepatocytes to secrete conjugated bilirubin into the bile, and is similar to Rotor syndrome. It is usually asymptomatic. E80.6 is also used for Rotor's syndrome, which is an inherited autosomal recessive disorder characterized by the presence of mild jaundice due to abnormalities in the bilirubin transportation from the liver parenchyma to the biliary system. It is rare and considered benign.

E80.7 is Disorders of bilirubin metabolism, unspecified.

Disorders of Bilirubin Metabolism

HERC staff recommendations:

1) Remove E80.4-E80.8 from line 64 METABOLIC DISORDERS
2) Add E80.4 (Gilbert syndrome), E80.6 (Other disorders of bilirubin metabolism), and E80.7 (Disorders of bilirubin metabolism, unspecified) to line 656 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
3) Add E80.5 (Crigler-Najjar syndrome) to line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and to line 246 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (EG. MAPLE SYRUP URINE DISEASE, TYROSINEMIA) Treatment: LIVER TRANSPLANT

Pectus Excavatum and Pectus Carinatum
May 2016

Question: Should pectus excavatum and pectus carinatum be moved to a higher priority line on the Prioritized List?

Question source: Kimberly Ruscher, MD, pediatric surgeon; Garret Zallen, MD surgeon from PeaceHealth

Issue: Currently, pectus excavatum (ICD-10 Q67.6) and pectus carinatum (Q67.7) are on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. There are no surgical repair codes on line 665.

A large body of literature was reviewed at the March, 2016 VBBS meeting. The staff summary of this literature review is below:

> *Pectus excavatum*: The literature is conflicting regarding whether surgical repair of pectus excavatum improves cardiac or pulmonary function or exercise tolerance, based on large case series and case-control studies. At best, there is a modest improvement in cardiopulmonary function long term, with short term decreases in pulmonary function after surgery. The vast majority of the literature reports on intermediate outcomes such as cardiac ejection fraction or forced expiratory volume, rather than patient oriented outcomes such as exercise tolerance. Cases with severe deformities causing measurable cardiac or pulmonary impairment or patients with certain co-morbidities may benefit more from surgical intervention than less impacted individuals.
>
> *Pectus carinatum*: There is no evidence that surgical correction or bracing of this condition improves cardiac or pulmonary outcomes or improves other health outcomes. Correction of this condition appears to be solely cosmetic.

Drs. Ruscher and Zollen testified about the resulting cardiac impairment and exercise intolerance caused by pectus excavatum (PE). They requested coverage of treatment for PE for more severely affected patients. The group who respond best from treatment are adolescents. Significant harms including death can result from the surgical treatment of this condition.

The surgeons testified that pectus caravatum (PC) has major physical appearance issues, and treatment involves bracing, which requires a surgery consult, and PT consult and brace fitting. Bracing at a 90+% success rate.

Coverage of PE with a guideline was discussed. The surgical experts argued against using the Haller index to determine severity, as this requires 3D imaging and allowing expert opinion is more cost effective. The staff guideline required cardiac or pulmonary impediments; the surgical experts recommended coverage for severe body image disturbance as well. The experts proposed an alternate guideline, which included atypical chest pain and paradoxical chest pain as possible criteria for coverage.

Pectus Excavatum and Pectus Carinatum
May 2016

HERC staff was directed to work with the OHP medical directors and Dr. Ruscher and Zellen to rework the proposed guideline for treatment of PE and PC. The VBBS generally felt that PE should be included on a covered line, and also left on an uncovered line, with a guideline to distinguish when it is intended to be covered. Staff was directed to review other insurance coverage policies.

Current Prioritized List status

Q67.6 (pectus excavatum) is on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Q67.7 (pectus carinatum) is on line 665
Q76.6-Q76.9 (congential malformation of ribs/sternum/bony thorax) are on line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS

21740 Reconstructive repair of pectus excavatum or carinatum; open
21742 minimally invasive approach (Nuss procedure), without thoracoscopy
21743 minimally invasive approach (Nuss procedure), with thoracoscopy
All appear on line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS

Other policies (all documents appeared in the March, 2016 VBBS meeting packet)

1) **NICE 2009**
    a. Current evidence on the safety and efficacy of placement of pectus bar for pectus excavatum (also known as MIRPE [minimally invasive repair of pectus excavatum] or the Nuss procedure) is adequate to support its use
    b. Key efficacy outcomes in the review were cosmetic appearance and patient satisfaction
        i. Outcomes listed in review were improved quality of life, self-esteem and cosmetic appearance scores
2) **Cigna 2009**
    a. Under many benefit plans, surgery for chest wall deformities is not covered when performed solely for the purpose of improving or altering appearance or self-esteem or to treat psychological symptomatology or psychosocial complaints related to one's appearance.
    b. If coverage for surgical repair of chest wall deformities is available, the following conditions of coverage apply.
        i. CIGNA covers surgical repair of severe pectus excavatum as medically necessary when imaging studies (e.g., computerized tomography [CT] scans, radiographs) confirm a pectus index (i.e., Haller index) greater than 3.25 and EITHER of the following criteria is met:
            1. Pulmonary function studies demonstrate at least a moderately severe restrictive lung defect.
            2. Cardiac imaging (e.g., echocardiography, stress echocardiography, magnetic resonance imaging [MRI]) demonstrates findings consistent with external compression.
    c. CIGNA covers surgical repair of pectus carinatum as medically necessary when there is documented evidence of significant physical functional impairment (e.g., cardiac or respiratory insufficiency), and the procedure is expected to correct the impairment
    d. CIGNA covers the surgical repair of a chest deformity associated with Poland syndrome as medically necessary when rib formation is absent.
3) **Aetna 2015** Aetna considers surgical repair of severe pectus excavatum deformities that cause functional deficit medically necessary when done for medical reasons in members who meet all of the following criteria:
    a. Well-documented evidence of complications arising from the sternal deformity. Complications include but may not be limited to:
        i. Asthma
        ii. Atypical chest pain
        iii. Cardiopulmonary impairment documented by respiratory and/or cardiac function tests
        iv. Exercise limitation
        v. Frequent lower respiratory tract infections; *and*

b. An electrocardiogram or echocardiogram has been done if a heart murmur or known heart disease is present to define the relationship of the cardiac problem to the sternal deformity; a*nd*
c. A CT scan of the chest demonstrates a pectus index, derived from dividing the transverse diameter of the chest by the anterior-posterior diameter, greater than 3.25.
d. Aetna considers surgical repair of pectus excavatum cosmetic when criteria are not met.
e. Aetna considers the following interventions for the treatment of pectus excavatum experimental and investigational because their effectiveness has not been established;
    i. The magnetic mini-mover procedure
    ii. The vacuum bell
    iii. Dynamic Compression System
f. Aetna considers surgical reconstruction of musculo-skeletal chest wall deformities associated with Poland's syndrome that cause functional deficit medically necessary
g. Aetna considers bracing and surgical procedures to correct pectus carinatum cosmetic because this deformity does not cause physiologic disturbances from compression of the heart or lungs.

4) **<u>United Indications for Coverage</u>**
    a. Surgical repair of pectus excavatum is considered reconstructive and medically necessary when the following criteria has been met:
        i. Pectus Excavatum
            1. Imaging studies confirm Haller index greater than 3.25; and
            2. The functional impairment is defined by one or more of the following:
                a. For restrictive lung capacity the total lung capacity is documented in the physician current office notes as <80% of the predicted value; or
                b. There is cardiac compromise as demonstrated by decreased cardiac output on the echocardiogram; or
                c. There is objective evidence of exercise intolerance as documented by:
                    i. Cardiopulmonary exercise testing that is below the predicted values; or
                    ii. Exercise pulmonary function tests that are below the predicted values and show restrictive lung disease
        ii. Pectus Carinatum
            1. It is extremely uncommon that pectus carinatum will cause a functional/physiological deficit. Pectus carinatum is not a congenital anomaly; it is a developmental condition of the

cartilage that generally occurs during an adolescents growth spurt. (Goretsky, 2004) Requests for coverage of repair of pectus carinatum will be reviewed by a UHC Medical Director on a case by case basis.

5) **<u>HealthPartners Indications for Coverage</u>**
   a. Pectus Excavatum:
      i. All of the following criteria must be met for coverage of repair of pectus excavatum:
         1. A Pectus/ Haller Index greater than 3.25 (calculated by using chest measurements from a CT scan of the area of the chest with the greatest depression.)
         2. Exercise limitation with symptoms OR chest pain related to pectus excavatum present for more than six months and unresponsive to more conservative treatment. Documentation of either of these is required.
         3. Diminished cardiopulmonary function during exercise, documented by lung/cardiac function tests (i.e. 20% depression of cardiopulmonary function.); and
         4. Cardiologist/pulmonologist concurs with need for surgical correction.
      ii. Pectus Carinatum repair is not covered unless there is documentation in the medical record of related functional problems.
      iii. Repairs for cosmetic reasons are not covered.

HERC staff recommendations:

1) Keep Q67.7 (pectus carinatum) on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Treatment is cosmetic
    b. Severe cases can be reviewed through the exceptions process
2) Move pectus excavatum to a covered line for severe cases
    a. Remove Q67.6 (pectus excavatum) from line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and add to lines 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    b. Add CPT codes for the Nuss procedure and other repair procedures (CPT 21740-21743) to line 406. These codes are already present on line 530.
    b. Add Q79.8 (Other congenital malformations of musculoskeletal system) to line 406 and keep on line 530.
    c. Add a new guideline note to lines 406 and 530 as shown below
        i. Require a Haller index, as all private insurance plans require this measurement
        ii. Do not include atypical chest pain or paradoxical chest wall movement as these are difficult to relate directly to the PE
        iii. Do not include significant body image disturbance as other conditions on the PL are not covered when only body image disturbance is present
        iv. Do not include exercise limitation as a criteria because this is difficult and expensive to objectively determine

GUIDELINE NOTE XXX PECTUS EXCAVATUM

Lines 406, 530

Pectus excavatum (ICD-10 Q67.6) is included on line 406 only for patients with all of the following:

1) severe deformity (Haller index >3.25) AND
2) documented pulmonary or cardiac dysfunction demonstrated by either
    a. Cardiac effects to include cardiac compression or displacement, bundle branch block or other cardiac pathology secondary to compression of the heart, OR
    b. Pulmonary function studies demonstrating at least a moderately severe restrictive lung defect, AND
3) cardiologist/pulmonologist concurs with need for surgical correction AND
4) these conditions are reasonably expected to be relieved with surgery.

Otherwise, this condition is included on line 530.

ICD-10 Q79.8 is included on line 406 only for Poland syndrome. Other diagnoses using this code are on line 530. Surgical reconstruction of musculo-skeletal chest wall deformities associated with Poland's syndrome are only included on line 406 when causing functional deficits.