JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Aural Blast Injury/Acoustic Trauma and Hearing Loss (ID:05)

This CPG will help the reader to quickly identify and treat aural trauma and hearing loss, to prevent morbidity, and to preserve as much function as possible – even while in the combat theater.

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INTRODUCTION

Acoustic trauma has continued to amass veteran disability at a 13-18% annual rate. Of the 2.35 million unique cases of auditory system disability at the end of FY 2013, approximately 870,000 are attributed to the Gulf War era and approximately 551,000 from exposure during operations in Iraq and Afghanistan.¹ Within the Department of Defense (DoD), 2% of the total force develops permanent injury annually, and 11-14% have unique episodes of temporary shifts in hearing. Historically, auditory injuries that are invisible and not life or limb threatening are not brought to the attention of medics, unless they are associated with other sever injuries, or are disabling in severity.²

The goal of this CPG is to elevate the awareness of noise threat, the prevalence of hazardous noise exposure, and the symptoms of acoustic trauma for purpose of facilitating early identification and early intervention of acoustic trauma. Improving outcomes for hearing requires developing a trusted surveillance and early referral and reporting system so that significant symptomatic exposures can be evaluated and diagnosed in a timely manner within therapeutic windows when intervention may mitigate injury progression, rather than current trends that put off consultations that delay care past the point of successful management. Improving the outcomes from acoustic trauma will preserve hearing capabilities in ranges conducive to continued high level function and performance.

INJURY OVERVIEW

For the purposes of this CPG, Service Members exposed to hazardous noise is impact noise or noise greater than (140dB) are at high risk for acoustic trauma and subsequent Hearing Loss (HL). Patients exposed to blasts are at risk for both aural and acoustic trauma.⁽³⁻⁵⁾

Hazardous noise causes injury to the hearing mechanisms in the inner ear. The symptoms of acoustic trauma are: hearing loss, tinnitus (ringing in the ear), aural fullness, recruitment (ear pain with loud noise), difficulty localizing sounds, difficulty hearing in a noisy background, and vertigo. Acoustic trauma may result in sensorineural hearing loss (SNHL) that is either temporary (temporary threshold shift, TTS) or permanent (permanent threshold shift, PTS). A TTS will resolve with time, while the time frame for hearing recovery is unique in every case, any SNHL that persists beyond 8 weeks after injury is most likely permanent and should be considered a PTS. There are no clinical predictors for which patients with a TTS will persist to develop PTS.

The ear, specifically the tympanic membrane (TM), is the most sensitive organ to primary blast injury (PBI). Blasts can perforate the TM. Risk of injury is determined by proximity to the source of the blast, as well as factors related to secondary, tertiary, and quaternary blast effects.⁶ The signs and symptoms of a TM perforation include the signs and symptoms of SNHL as well as pain, bloody ear discharge, and conductive hearing loss (decreased ability to transmit sound through the middle ear to the inner ear,). TM perforations heal spontaneously in 80 to 94% of cases.⁷ The smaller the size of the TM perforation, the greater the likelihood is of spontaneous closure. The majority of TM perforations that close spontaneously do so within the first 8 weeks after injury.^(8,9) For these reasons, perforation rates in mass casualty situations may be under reported when limited resources are utilized for more significant polytraumatic cases. Because the tympanic membrane may be more at risk for damage than other body systems, it may likely be included in the non-immediate injuries deferred for later evaluation during which interval spontaneous healing may occur.¹⁰ The more significant exposures are manifest in the immediate triage and may be the tympanic membrane perforations that are more refractory to spontaneous healing as noticed in the Boston marathon bombing where proximity to blast and significant nonotologic injuries were predictors of perforation.¹¹

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The ossicular chain may be injured as a result of PBI, with fracture of the ossicles or disarticulation of the chain, both of which can result in CHL with or without SNHL. TM perforations and middle ear injuries may heal with scarring that stiffens the ossicular chain also resulting in CHL. Blasts are noise hazards as well as explosive threats. The combination of a CHL with a SNHL is called a mixed hearing loss.

The temporal bone may also be fractured as a result of higher order blast injury, and these often are associated with secondary or tertiary blast effects.¹² Patients with temporal bone fractures may have lacerations in the ear canal or along the TM, resulting in either bloody otorrhea or hemotypanum (blood behind the TM).¹³ They may also have SNHL or CHL, depending on the orientation of the fracture. A small number of these fractures (15%) will have an associated cerebral spinal fluid (CSF) leak.¹⁴ These are termed CSF otorrhea (a leak from the auditory canal) or CSF rhinorrhea (a leak from the nose). The risk of meningitis within the first 7 days post injury ranges from 5-11%, but increases to as high as 88% if left untreated over time; therefore broad spectrum antibiotic prophylaxis and expert consultation are recommended.⁽¹⁴⁺¹⁷⁾ Testing otorhinorrhea to distinguish between patients with bloody drainage containing CSF from those who have bloody drainage without CSF is insensitive unless assay for beta2-transferrin (a protein unique to CSF) is obtained, which is unlikely to be available in the deployed setting. Spontaneous closure of CSF leaks occurs in greater than 90% of cases, and is facilitated by bed rest – head of bed elevation - anti-strain precautions and stool softeners. Failures should be considered for lumbar drainage of CSF. Surgical management of CSF leaks should be considered in CSF otorhinorrhea that does not close with other measures.¹⁸

The facial nerve can be injured in temporal bone fractures.¹⁹ Acute management of intratemporal facial nerve injury is to provide objective documentation of facial movement using the House-Brackmann grading scale.²⁰ Complete immediate paralysis of the face portends more significant injury to the nerve and should be referred for evaluation and possible surgical decompression to improve optimal outcomes for facial function. Significant weakness approaching complete paralysis will often recover completely. Incomplete or complete facial paralyses that preclude eyelid closure should be managed with measures that include eye protection (eye lid taping, ophthalmic tear substitutes and protective ointment). For significant facial pareses/paralyses, early administration of steroids should be provided if not contraindicated, and referral for management by an otolaryngologist is indicated.²¹

Dizziness expressed as unsteadiness or vertigo (spinning sensation) following a blast injury can be a result of traumatic brain injury, but is also often caused by injury to the inner ear, specifically benign paroxysmal positional vertigo (BPPV), damage to sensitive neuroepithelial rests within the inner ear, perilymphatic fistula, and other.²² Other inner ear abnormalities may cause vertigo such as otic capsule violating temporal bone fractures, secondary infections of the inner ear or vestibular nerves, trauma induced endolymphatic hydrops, and activation of subclinical superior semicircular canal dehiscence.

EVALUATION & TREATMENT

All Service Members that develop **symptoms consistent with noise trauma** (acute tinnitus, muffled hearing, fullness in the ear) should be educated and directed to self-report for evaluation and possible treatment as soon as practicable. Patients exposed to hazardous noise occurring from exposure to battle (improvised explosive devices, rockets, and small arms fire) and all patients exposed to a blast should be asked specifically about hearing loss and tinnitus during their initial trauma evaluation, unless other more urgent treatment or mental status conditions do not allow. This should be documented as soon as safe evaluation permits. All patients presenting to concussion care centers should be evaluated for hearing loss and tinnitus. If there is debris in the External Auditory Canal (EAC) or in the middle ear (as seen through a TM perforation), treat the patient with a fluoroquinolone and steroid containing topical antibiotic (e.g., four (4) drops of ciprofloxacin/dexamethasone or ofloxacin in the affected ear three (3) times a day for seven (7) days). Do NOT irrigate the ear as it may provoke pain and vertigo, move debris medially in the canal and middle ear, and promote infection. Also, do not use any

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topical drops containing aminoglycosides (i.e. the neomycin in Cortisporin) since these are ototoxic. Patients should observe strict dry ear precautions and keep ALL water out of the EAC until the TM perforation has healed or is repaired. Removal of debris should only be done by an ENT surgeon in order to avoid further injury to the EAC or the middle ear.

Hearing loss that persists 72 hours after acoustic trauma warrants a hearing test or audiogram. When hearing loss is present, individuals should be restricted from hazardous noise environments and kept on base, if possible. This is important to allow time for healing, and the inner ear is more susceptible to further noise-induced damage while it is under the oxidative stress and glutamate toxicity of an acute injury. A Service Member with hearing loss is less effective during missions and can negatively impact mission performance.

Vestibular trauma to the inner ear may manifest in vertigo. Please refer to the Veteran Affairs/DoD vestibular clinical recommendations for a detailed review of traumatic dizziness

(http://hearing.health.mil/files/vestibclinpractrecs.pdf). All patients with positional vertigo and without other contraindicating injuries should undergo a Dix-Hallpike test, and an Epley or canalith repositioning maneuver if positive. (See <u>Appendix A</u> and <u>Appendix B.</u>)

ABSOLUTE INDICATIONS FOR SCREENING AUDIOGRAM (HEARING TEST)

All patients with subjective hearing loss and tinnitus following blast exposure should have the exposure documented, and should be evaluated by hearing testing as soon as possible. Hearing loss (either subjective or through screening audiograms) that persists for more than 72 hours after an acoustic trauma or blast injury warrants formal comprehensive hearing test or audiogram (including tympanometry, bone conducted thresholds, speech discrimination, and acoustic reflexes not evaluated by screening audiograms). Patients with TTS greater than 25 dB losses in three consecutive frequencies should be considered candidates for high dose oral and/or transtympanic steroid injections when not otherwise contraindicated. An oral steroid regimen of prednisone 60mg daily for 10 days followed by a two week taper, and transtympanic dexamethasone 24mg/ml repeating at 1-2 week intervals for up to three injections are warranted. Hearing response to treatment should be followed by audiometry, and additional injections guided by response to steroid. Patients with threshold shift greater than 60 dB on three consecutive frequencies for ten or more days after noise exposure are not likely to resolve spontaneously and are likely PTS losses. Hearing loss is detrimental to the patient's personal safety and effectiveness and may carry a comorbid vestibular deficit either clinically or sub clinically. Patients should be referred to ENT for evaluation and further testing. If ENT is not available in the specific Area of Operation (AOR), then patients should be evacuated to a higher level of care.

ABSOLUTE INDICATIONS FOR OTOLARYNGOLOGY (ENT) REFERRAL

- Temporal bone fracture with or without ear drainage.
- Persistent HL > 72 hours after acoustic trauma, or inability to perform duties due to perceived HL.
- TM perforation that has not resolved 8 weeks after injury. Referral for simple TM perforations without
 refractory drainage or significant SNHL should be delayed until 8 weeks after injury to allow for healing.
- Vertigo that does not resolve within 7 days after injury, even if episodic.
- Clear ear drainage.
- Persistent discolored ear drainage that does not resolve after 3 days of topical antibiotic steroid combination drop therapy.
- Facial nerve paralysis.
- On screening audiogram:

- Pure tone threshold average across 500, 1000, and 2000 Hz that is greater than 30 dB.
- Or any hearing threshold greater than 35 dB at 500, 1000, and 2000 Hz.
- Or any hearing threshold greater than 45 dB at 3000 Hz or 55dB at 4000 Hz.

Interpretation of the post-traumatic audiogram is facilitated by review of a baseline audiogram, if available.

RELATIVE INDICATIONS FOR OTOLARYNGOLOGY (ENT) REFERRAL

- Debris in the EAC that does not clear with topical ear drops.
- Inability to visualize the TM despite treatment with topical ear drops.
- Persistent dizziness, even if not true vertigo.
- Significant communication problems regardless of the hearing test results.
- Tinnitus that interferes with the patient's duty performance or lifestyle, regardless of hearing test results.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All patients exposed to a blast, and patients who develop symptoms consistent with noise trauma.

INTENT (EXPECTED OUTCOMES)

- 1. All patients with blast injury, with symptoms of acoustic trauma (e.g., tinnitus, vertigo, muffled hearing, and drainage from ear, fullness in the ear, blast injury or documented noise trauma) have documented tympanic membrane examination.
- 2. All patients with blast injury, with symptoms of acoustic trauma (e.g., tinnitus, vertigo, muffled hearing, and drainage from ear, fullness in the ear, blast injury or documented noise trauma) persisting greater than 72h have documented screening hearing test or audiogram.
- 3. All patients in the population of interest with absolute indications for ENT referral (per CPG) have a documented ENT evaluation.

PERFORMANCE/ADHERENCE METRICS

- 1. Number and percentage of patients in the population of interest who have a documented tympanic membrane exam.
- 2. Number and percentage of patients in the population of interest with hearing loss persisting >72h who have a hearing test or audiogram.
- 3. Number and percentage of patients in the population of interest with absolute indications for ENT referral who have a documented ENT examination.

DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the JTS Chief and the JTS PI Branch.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

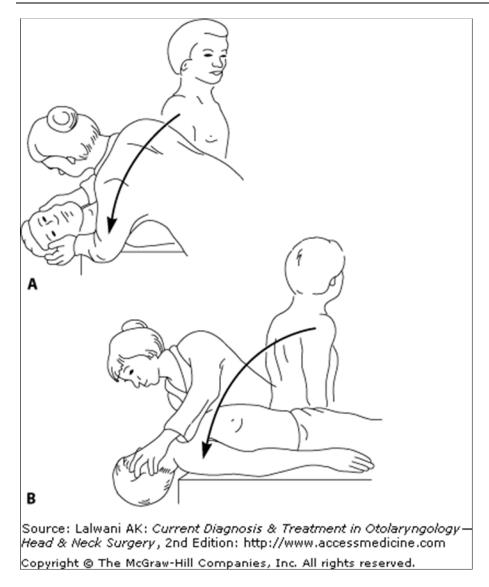
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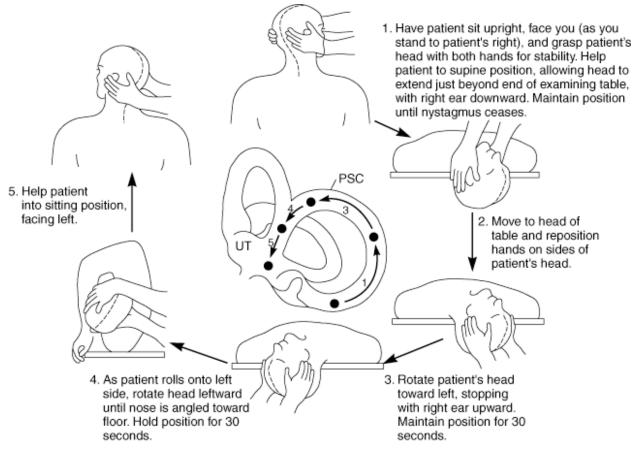
APPENDIX A: DIX-HALLPIKE TEST



DIX-HALLPIKE TEST

- A. For testing the right posterior semicircular canal, the patient sits on the exam table and turns his or her head to the right 45 degrees. This places the posterior semicircular canal in the sagittal plane. The examiner stands facing the patient on the patient's right side or behind the patient.
- B. The patient is then moved by the examiner from the seated to the supine position with the head slightly hanging over the edge of the table. The right ear is down and the chin is pointing slightly up. The eyes are observed for the characteristic nystagmus.

APPENDIX B: EPLEY MANEUVER



Source: Lalwani AK: Current Diagnosis & Treatment in Otolaryngology— Head & Neck Surgery, 2nd Edition: http://www.accessmedicine.com

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EPLEY MANEUVER

The patient is taken through four moves, starting in the sitting position with the head turned at a 45° angle toward the affected side.

- A. The patient is placed into the Dix-Hallpike position (supine with the affected ear down) until the vertigo and nystagmus subside.
- B. The patient's head is then turned to the opposite side, causing the affected ear to be up and the unaffected ear to be down.
- C. The whole body and head are then turned away from the affected side to a lateral decubitus position, with the head in a face-down position.
- D. The last step is to bring the patient back to a sitting position with the head turned toward the unaffected shoulder.

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.