Clinical Practice Guideline: Sudden Hearing Loss

Talking Points - Executive Summary

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The AAO-HNSF Guideline Development Task Force supported the development of the new clinical practice guideline on Sudden Hearing Loss that will be published as a supplement in the March edition of Otolaryngology—Head and Neck Surgery. This issue, with the supplement, is on its way to you and can be viewed online at www.otojournal.org.

This following summary of "talking points" for physicians is purposely written to oversimplify the guideline’s findings. The intent of this offering is to alert members to the availability of this new multidisciplinary clinical practice guideline so that the complexities of the problem and its treatment can be fully described and understood. The summary gives you an introduction to the topic, the guideline’s purpose, and key action statements with related action statement profiles.

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Sudden hearing loss (SHL) is a frightening symptom that often prompts an urgent or emergent visit to a physician. This guideline focuses on sudden sensorineural hearing loss (SSNHL), one of many causes of SHL, which, if recognized and managed promptly, may improve hearing recovery and patient quality of life (QOL). SSNHL affects 5 to 20 per 100,000 population, with
about 4000 new cases per year in the United States (U.S.).\textsuperscript{1,2} Throughout this guideline the following definitions are used:

- **SHL** is defined as a rapid-onset, occurring over a 72 hour period, of a subjective sensation of hearing impairment in one or both ears.

- **SSNHL** is a subset of SHL that is a) sensorineural in nature and b) meets certain audiometric criteria.
  
  a) Sensorineural hearing loss (SNHL) indicates an abnormality of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing.
  
  b) The most frequently used audiometric criterion is a decrease in hearing of greater than or equal to 30 decibels, affecting at least three consecutive frequencies. Because premorbid audiometry is generally unavailable, hearing loss is defined as related to the opposite ear’s thresholds.

- **Idiopathic sudden sensorineural hearing loss (ISSNHL)** is defined as SSNHL with no identifiable cause despite adequate investigation.

The SSNHL definition used throughout this guideline is based on its consistent use in the literature and National Institute on Deafness and Other Communication Disorders (NIDCD) criteria\textsuperscript{3}; however, the panel recognizes that in clinical practice, expanding the definition to cases with less than 30 decibels of hearing loss may be considered. The panel recognizes that the NIDCD definition is not universally used and, accordingly, published evidence not using this definition was considered.

The distinction between SSNHL and other causes of SHL is one that should be made by the initial treating healthcare provider, so that early diagnosis and management can be instituted. Moreover, non-idiopathic causes of SSNHL must be identified and addressed during the course of management; the most pressing of these are vestibular schwannoma (acoustic neuroma), stroke, and malignancy.\textsuperscript{4} Up to 90% of SSNHL, however, is idiopathic at presentation, and is presumptively attributed to either vascular, viral, or multiple etiologies.\textsuperscript{5}

A maximum of 32% to 65% of cases of SSNHL may recover spontaneously.\textsuperscript{2,6} Clinical experience indicates that even this recovery rate may be an overestimation. Prognosis for
recovery is dependent on a number of factors, including patient age, presence of vertigo at onset, degree of hearing loss, audiometric configuration, and time between onset of hearing loss and treatment. Treatment options are myriad and include systemic and topical steroids, antiviral agents, rheologic agents, diuretics, hyperbaric oxygen treatment, other medications, middle ear surgery for fistula repair, and observation alone. The comparative efficacy of these treatments, however, is not known, considering that the definitive etiology is also commonly not known.

Long term follow-up is recommended as some patients will have an underlying cause identified that may not be evident at initial presentation. Additionally, the patient with partial or no hearing recovery, or persistent tinnitus, will require ongoing management from otolaryngological, audiological, and psychological perspectives.

This guideline is intended for all clinicians who diagnose or manage adult patients (18 and over) who present with SHL. After addressing causes, diagnosis, and treatments of non-SSNHL briefly, this guideline will go on to address SSNHL in detail. Important points to keep in mind include:

- A cause for SSNHL is identified in only 10 to 15% of patients at the time of presentation. Emergency intervention may be needed for rare, life-threatening conditions of which SSNHL is a part. In up to a third of cases, the cause may be identified only after long-term follow-up evaluations.
- In 85% to 90% of cases, in spite of thorough evaluation, the underlying cause is unknown or uncertain at the time of presentation, and treatment decisions are generally made without knowledge of the etiology. It is appropriate, therefore, to approach these idiopathic cases in a common way, understanding that the underlying etiologies may be very dissimilar.
- The primary presenting symptom of SHL is a full or blocked ear. Since this is such a common and non-specific symptom, both patients and physicians are not sufficiently frightened or worried by it. Thus, evaluation and treatment are often delayed. New onset of ear blockage or fullness can be a symptom of potentially serious conditions and warrants prompt evaluation.
- Conversely, the patient with SHL may be very frightened; the nearly-universal accompanying tinnitus seen in SSNHL will frequently contribute intensely to his/her
anxiety and depression. All members of the hearing healthcare team should be cognizant of the psychological response to the sudden loss of a primary sense.

- Familiarity with hearing aids, hearing assistive technology (HAT), tinnitus management, and implantable hearing solutions is required in the ongoing management of these patients.
- A ‘team approach’ to the overall management of these patients is encouraged.

The incidence of this symptom, the debilitating consequences of missed early diagnosis and management, the presentation of the patient to a variety of healthcare providers, the abundance of small series and case reports regarding treatment, and the paucity of randomized controlled trials (RCTs) assessing interventions, create a pressing need for evidence-based guidelines to aid clinicians in managing SSNHL. Moreover, wide variations in evaluation, treatment, counseling, and follow-up of patients with SSNHL exist worldwide. Such variations are usually ascribed to heterogeneity in clinical practice and training rather than to differences in clinical need. The current lack of consensus, both in the U.S. and worldwide, on all aspects of the care of the patient with SSNHL, further supports the need for an evidence-based clinical practice guideline to highlight best practices.

**Purpose**

The purpose of this guideline is to provide clinicians with evidence-based recommendations in evaluating patients with SHL, with particular emphasis on managing SSNHL. The guideline is intended for all clinicians who see adult patients, aged 18 and older. The recommendations outlined in this guideline are not intended to represent the standard of care for patient management, nor are the recommendations intended to limit treatment or care provided to individual patients. The guideline is not intended to replace individualized patient care or clinical judgment.

Although the guideline focuses primarily on managing SSNHL, the panel recognized that patients enter the healthcare system with SHL as a non-specific, primary complaint. Therefore, the initial recommendations of the guideline deal with efficiently distinguishing SSNHL from other causes of SHL at the time of presentation. The purpose of the guideline is not to present an
exhaustive approach to managing SHL, in general, as only a limited number of causes are discussed.

This is the first clinical guideline on SSNHL developed in the US. Use of this guideline may improve the care of patients and result in improved outcomes. Despite numerous published articles on SSNHL, there remains a paucity of high-quality evidence, creating confusion and practice variations in management. This guideline will provide evidence-based recommendations for clinicians based on multidisciplinary consensus and careful consideration of the benefits versus harms of suggested actions. By focusing on opportunities for quality improvement the guideline should improve diagnostic accuracy, facilitate prompt intervention, decrease inappropriate variations in management, reduce unnecessary tests and imaging procedures, and improve hearing and rehabilitative outcomes for impacted patients.

**STATEMENT 1. EXCLUSION OF CONDUCTIVE HEARING LOSS:** Clinicians should distinguish sensorineural hearing loss (SNHL) from conductive hearing loss (CHL) in a patient presenting with sudden hearing loss. *Strong Recommendation based on evidence with a preponderance of benefit over harm.*

**Action Statement Profile for Statement 1:**
- **Aggregate Evidence Quality:** Grade B, based on evidence that a common cause of CHL, cerumen impaction, can be treated effectively to improve hearing. Grade C, for evidence that CHL and SNHL can be distinguished from history, examination, and tuning fork tests.
- **Benefit:** Guide the choice of appropriate diagnostic tests, identify patients with more serious underlying conditions, avoid misdiagnosis, improve diagnostic accuracy, ensure treatment is consistent with diagnosis, guide patient expectations, identify conductive hearing loss that can be treated and resolved.
- **Risk, Harm, Cost:** Adverse effects of cerumen removal, if required; time required for cerumen removal, if required; misdiagnosis.
- **Benefit-Harm Assessment:** Preponderance of Benefit
• Value Judgments: Panel consensus that despite a lack of systematic research evidence supporting this action, distinguishing these types of hearing loss was an essential first step in determining subsequent management.

• Intentional Vagueness: The panel intentionally decided not to specify the time frame to distinguish CHL from SNHL due to inconclusive evidence of the importance of early intervention, but agreed that the distinction should be made as promptly as possible to allow intervention if a diagnosis of SSNHL is confirmed. Ideally the determination should be made at the time of initial presentation.

• Role of Patient Preferences: No role

• Exclusions: None

• Policy level: Strong Recommendation

STATEMENT 2. MODIFYING FACTORS: Clinicians should assess patients with presumptive sudden sensorineural hearing loss for bilateral sudden hearing loss, recurrent episodes of sudden hearing loss, or focal neurologic findings. Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile for Statement 2:
• Aggregate Evidence Quality: Grade C, observational studies and case series’
• Benefit: Identification of patients with a high likelihood of alternative and potentially serious underlying cause, who require specialized assessment and management.
• Risk, Harm, Cost: None
• Benefit-Harm Assessment: Preponderance of Benefit
• Value Judgments: None
• Intentional Vagueness: None
• Role of Patient Preferences: Limited
• Exclusions: None
• Policy level: Recommendation
STATEMENT 3. COMPUTED TOMOGRAPHY: Clinicians should not order computerized tomography of the head/brain in the initial evaluation of a patient with presumptive SSNHL. Strong Recommendation Against based on systematic reviews with a preponderance of benefit over harm for not obtaining CT.

Action Statement Profile for Statement 3:
- Aggregate Evidence Quality: Grade B, systematic reviews and appropriateness criteria from the ACR, plus observational studies clearly documenting the potential harms of radiation and side effects of intravenous contrast.
- Benefit: Avoidance of radiation, cost savings, reduced incidental findings, less inconvenience for the patient, avoiding false sense of security from false negative scan.
- Risk, Harm, Cost: None
- Benefit-Harm Assessment: Preponderance of benefit over harm
- Value Judgments: None
- Intentional Vagueness: The panel recognizes that the terms “initial evaluation” are vague, but the intent is to discourage the routine use of CT scanning of the head/brain when patients initially present with SSNHL.
- Role of Patient Preferences: Very limited
- Exclusions: Patients with focal neurologic findings
- Policy level: Strong recommendation against

STATEMENT 4. AUDIOMETRIC CONFIRMATION OF ISSNHL: Clinicians should diagnose presumptive ISSNHL if audiometry confirms a 30 dB hearing loss at three consecutive frequencies AND an underlying condition cannot be identified by history and physical examination. Recommendation based on randomized controlled trials with a preponderance of benefit over harm.

Action Statement Profile for Statement 4:
• Aggregate Evidence Quality: Grade C, based on criteria used in RCTs assessing the benefits for intervention for SSNHL
• Benefit: Guiding treatment, identifying urgent conditions that require prompt management, ensuring that interventions for ISSNHL are limited to those patients who meet appropriate audiometric criteria for diagnosis
• Risk, Harm, Cost: Potential delay in treatment until audiometry is obtained; direct cost of audiometry
• Benefit-Harm Assessment: Preponderance of benefit over harm
• Value Judgments: While there is limited evidence as to the audiometric cut points for definition of SSNHL, this definition has been used widely
• Intentional Vagueness: None
• Role of Patient Preferences: None
• Exclusions: When audiometry is not available, clinical judgment should be used, based on history, exam, and tuning fork evaluation. Lack of audiometry should not preclude discussion of, and initiation of, treatment.
• Policy level: Recommendation

STATEMENT 5. LABORATORY TESTING: Clinicians should not obtain routine laboratory tests in patients with ISSNHL. *Strong Recommendation against based on large cross sectional studies showing a preponderance of benefit over harm.*

*Action Statement Profile for Statement 5:*

• Aggregate Evidence Quality: Grade B, based on small cross-sectional studies showing no benefit as well as case series
• Benefit: Cost containment, avoidance of stress and anxiety of patient, avoidance of false positives, avoidance of delay of diagnosis, avoidance of delayed treatment
• Risk, Harm, Cost: Missed diagnosis
• Benefit-Harm Assessment: Preponderance of Benefit
• Value Judgments: Minimizing testing and the risks of false positives outweigh the value of finding a potential cause, especially when it has not been shown that early treatment affects prognosis.
Intentional Vagueness: The word “routine” was to discourage a non-targeted approach to use of laboratory assessment. It is recognized that specific lab tests may be useful in assessing these patients based on specific individual patient conditions.

Role of Patient Preferences: Limited

Exclusions: None

Policy level: Strong recommendation against

STATEMENT 6. RETROCOCHLEAR PATHOLOGY: Clinicians should evaluate patients with ISSNHL for retrocochlear pathology by obtaining an MRI, Auditory Brainstem Response (ABR), or audiometric follow-up. Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile for Statement 6:

- Aggregate Evidence Quality: Grade C
- Benefit: Identify brain tumors, identify conditions that might benefit from early treatment, patient peace of mind, supporting idiopathic diagnosis
- Risk, Harm, Cost: Procedure specific risks/costs, anxiety and stress
- Benefit-Harm Assessment: Preponderance of benefit
- Value Judgments: Although the panel agreed that the MRI is the most sensitive means for diagnosing retrocochlear pathology, there was no consensus that identifying this pathology would in all cases influence outcomes. The panel therefore concluded that ABR and follow-up audiometry would be acceptable alternatives for initial follow-up of SSNHL as long as there is appropriate counseling about the limitations of these modalities.
- Intentional Vagueness: None
- Role Of Patient Preferences: Limited in deciding whether or not to assess for retrocochlear pathology, but substantial in making shared decisions with the clinician for using MRI, ABR, or audiology as the diagnostic test
- Exclusions: None
- Policy level: Recommendation
STATEMENT 7. PATIENT EDUCATION: Clinicians should educate patients with ISSNHL about the natural history of the condition, the benefits and risks of medical interventions, and the limitations of existing evidence regarding efficacy. Strong recommendation based on systematic reviews with a preponderance of benefit over harm.

Action Statement Profile for Statement 7:
- Aggregate Evidence Quality: Grade B
- Benefit: Facilitate shared decision-making, increase patient adherence to proposed therapy, empower patients, informed consent, link evidence to clinical decisions
- Risk, Harm, Cost: Time spent, miscommunication, patients get overwhelmed, patient anxiety
- Benefit-Harm Assessment: Preponderance of benefit
- Value Judgments: Shared decision-making is beneficial
- Intentional Vagueness: None
- Role of Patient Preferences: Large
- Exclusions: None
- Policy level: Strong Recommendation

STATEMENT 8. INITIAL CORTICOSTEROIDS: Clinicians may offer corticosteroids as initial therapy to patients with ISSNHL. Option based on systematic reviews of randomized control trials with a balance between benefit and harm.

Action Statement Profile for Statement 8:
- Aggregate Evidence Quality: Grade B, based on systematic reviews of randomized trials with methodological limitations
- Benefit: Hearing improvement
- Risk, Harm, Cost: Oral corticosteroids: Suppression of hypothalamic-pituitary-adrenal axis and Cushing’s like syndrome, minimal with 10-14 day treatment; low cost.
- Intratympanic corticosteroids: minimal systemic effect; local reactions of pain, tympanic membrane perforation, transient dizziness; high cost and multiple office visits.
- Benefit-Harm Assessment: Balance of benefit versus harm.
Value Judgments: Even a small possibility of hearing improvement makes this a reasonable treatment to offer patients, considering the profound impact on QOL a hearing improvement may offer.

Intentional Vagueness: None

Role of Patient Preferences: Large role for shared decision-making with patients

Exclusions: Oral steroids: medical conditions affected by corticosteroids such as insulin-dependent or poorly controlled diabetes, tuberculosis, peptic ulcer disease, among others.

Policy level: Option

**STATEMENT 9. HYPERBARIC OXYGEN THERAPY:** Clinicians may offer hyperbaric oxygen therapy within three months of diagnosis of ISSNHL. *Option based on systematic reviews of randomized control trials with a balance between benefit and harm.*

**Action Statement Profile for Statement 9:**

- Aggregate Evidence Quality: Grade B, based on systematic review of RCTs with methodological limitations
- Benefit: Hearing improvement
- Risk, Harm, Cost: Costs, patient time/effort, patient anxiety and stress, barotraumas, otitis media, oxygen toxicity, worsening of cataracts, fatigue, death
- Benefit-Harm Assessment: Equilibrium
- Value Judgments: Although HBOT is not widely available in the US and is not recognized by many US clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for ISSNHL
- Intentional Vagueness: None
- Role Of Patient Preferences: Large role for shared decision-making
- Exclusions: None
- Policy level: Option
STATEMENT 10. OTHER PHARMACOLOGIC THERAPY: Clinicians should not routinely prescribe antivirals, thrombolytics, vasodilators, vasoactive substances, or antioxidants to patients with ISSNHL. *Recommendation against* based on systematic reviews of RCTs with a preponderance of harm over benefit.

Action Statement Profile for Statement 10:

- Aggregate Evidence Quality: Grade B
- Benefit: Avoidance of unnecessary treatment, avoid adverse events of unnecessary treatment, cost saving
- Risk, Harm, Cost: None as the recommendation is against the use of these therapies
- Benefit-Harm Assessment: Preponderance of benefit
- Value Judgments: None
- Intentional Vagueness: The word “routine” is used to avoid setting a legal standard recognizing that there may be patient specific indications for one or more of these therapies that may be reasonable to try on an individualized basis, with shared decision making.
- Role of Patient Preferences: None
- Exclusions: None
- Policy level: Recommendation against

STATEMENT 11. SALVAGE THERAPY: Clinicians should offer IT steroid perfusion when patients have incomplete recovery from ISSNHL after failure of initial management. *Recommendation based on RCTs with a preponderance of benefit over harm.*

Action Statement Profile for Statement 11:

- Aggregate Evidence Quality: Grade B, based on RCTs with limitations
- Benefit: Hearing recovery
- Risk, Harm, Cost: Perforation, discomfort, cost, patient anxiety
- Benefit-Harm Assessment: Preponderance of benefit over harm
- Value Judgments: None
Intentional Vagueness: Patients qualifying for salvage therapy have failed to respond to initial management or have had an incomplete response. Failure of initial management is not clearly defined as there is limited guidance from the literature as to what level of residual hearing loss qualifies a patient for salvage. The guideline panel recognized that varying degrees of hearing loss will affect patients differently. This may govern the aggressiveness of the decision to pursue further therapy.

Role of Patient Preferences: Significant role for shared decision-making regarding treatment options depending upon various perceived levels of hearing impairment.

Exclusions: None

Policy level: Recommendation

**STATEMENT 12. OUTCOMES ASSESSMENT:** Clinicians should obtain follow-up audiometric evaluation within six months of diagnosis for patients with ISSNHL.

*Recommendation based on observational studies with a preponderance of benefit over harm.*

*Action Statement Profile Statement 12:*

- Aggregate Evidence Quality: Grade C, based on observation studies
- Benefit: Assess outcome of intervention, identify patients who may benefit from audiologic rehabilitation, identify cause of hearing loss, identify progressive hearing loss, improve counseling
- Risk, Harm, Cost: Procedural cost
- Benefit-Harm Assessment: Preponderance of Benefit
- Value Judgments: The patient perception of hearing recovery is not always completely accurate and patients may be unaware of a residual hearing impairment that could be identified through audiometric assessment. Patients who report subjective hearing improvement may still derive additional benefits from objective testing
- Intentional Vagueness: None
- Role of Patient Preferences: Some
- Exclusions: None
- Policy level: Recommendation
STATEMENT 13. REHABILITATION: Clinicians should counsel patients with incomplete recovery of hearing about the possible benefits of amplification and hearing assistive technology (HAT) and other supportive measures. Strong Recommendation based on systematic reviews and observational studies with a preponderance of benefit over harm.

Action Statement Profile for Statement 13:

- Aggregate Evidence Quality: Grade B, based on systematic reviews and observational studies
- Benefit: Improved quality of life, improved functionality, emotional support, improved hearing
- Risk, Harm, Cost: Time and cost of counseling
- Benefit-Harm Assessment: Preponderance of Benefit
- Value Judgments: None
- Intentional Vagueness: None
- Role of Patient Preferences: Patient may decline counseling
- Exclusions: None
- Policy level: Strong Recommendation
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