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Clinical Practice Guideline: Tinnitus

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Abstract

Objective. Tinnitus is the perception of sound without an external source. More than 50 million people in the United States have reported experiencing tinnitus, resulting in an estimated prevalence of 10% to 15% in adults. Despite the high prevalence of tinnitus and its potential significant effect on quality of life, there are no evidence-based, multidisciplinary clinical practice guidelines to assist clinicians with management. The focus of this guideline is on tinnitus that is both bothersome and persistent (lasting 6 months or longer), which often negatively affects the patient's quality of life. The target audience for the guideline is any clinician, including nonphysicians, involved in managing patients with tinnitus. The target patient population is limited to adults (18 years and older) with primary tinnitus that is persistent and bothersome.

Purpose. The purpose of this guideline is to provide evidence-based recommendations for clinicians managing patients with tinnitus. This guideline provides clinicians with a logical framework to improve patient care and mitigate the personal and social effects of persistent, bothersome tinnitus. It will discuss the evaluation of patients with tinnitus, including selection and timing of diagnostic testing and specialty referral to identify potential underlying treatable pathology. It will then focus on the evaluation and treatment of patients with persistent primary tinnitus, with recommendations to guide the evaluation and measurement of the effect of tinnitus and to determine the most appropriate interventions to improve symptoms and quality of life for tinnitus sufferers.

Action Statements. The development group made a *strong recommendation* that clinicians distinguish patients with bothersome tinnitus from patients with nonbothersome tinnitus. The development group made a *strong recommendation against* obtaining imaging studies of the head and neck in patients with tinnitus, specifically to evaluate tinnitus that does not localize to 1 ear, is nonpulsatile, and is not associated with focal neurologic abnormalities or an asymmetric hearing loss. The panel made the following *recommendations*: Clinicians should (a) perform a targeted history and physical examination at the initial evaluation of a patient with presumed primary tinnitus to identify conditions that if promptly identified and managed may relieve tinnitus; (b) obtain a prompt, comprehensive audiologic examination in patients with tinnitus that is unilateral, persistent (≥ 6 months), or associated with hearing difficulties; (c) distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussions about natural history and follow-up care; (d) educate patients with persistent, bothersome tinnitus about management strategies; (e) recommend a hearing aid evaluation for patients who have persistent, bothersome tinnitus associated with documented hearing loss; and (f) recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus. The panel *recommended against* (a) antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for the routine treatment of patients with persistent, bothersome tinnitus; (b) Ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients with persistent, bothersome tinnitus; and (c) transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus. The development group provided the following *options*: Clinicians may (a) obtain an initial comprehensive audiologic examination in patients who present with tinnitus (regardless of laterality, duration, or perceived hearing status);

and (b) recommend sound therapy to patients with persistent, bothersome tinnitus. The development group provided *no recommendation* regarding the effect of acupuncture in patients with persistent, bothersome tinnitus.

Keywords

amplification, hearing aids, hearing loss, quality of life, sound therapy, tinnitus

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Introduction

Tinnitus is the perception of sound without an external source. More than 50 million people in the United States have reported experiencing tinnitus, resulting in an estimated prevalence of 10% to 15% in adults.[1,2] About 20% of adults who experience tinnitus will require clinical intervention.[3] Not a disease in and of itself, tinnitus is actually a symptom that can be associated with multiple causes and aggravating co-factors. Tinnitus is relatively common, but in rare cases it can be a symptom of serious disease such as vascular tumor or vestibular schwannoma (VS).

Tinnitus can be persistent, bothersome, and costly. The prevalence of tinnitus was estimated in the National Health Interview Survey conducted in the United States in 1994 by asking whether individuals experienced "ringing, roaring, or buzzing in the ears that lasted for at least 3 months." Such tinnitus was present in 1.6% of adults ages 18 to 44 years, 4.6% of adults ages 45 to 64 years, and 9.0% of adults 60 years and older.[4] In the Beaver Dam offspring study of more than 3000 adults between the ages of 21 and 84 years studied between 2005 and 2008, 10.6% reported tinnitus of at least moderate severity or causing difficulty falling asleep.[5] Tinnitus can also have a large economic effect. For example, tinnitus was the most prevalent service-connected disability for U.S. military veterans receiving compensation at the end of fiscal year 2012, resulting in nearly 1 million veterans receiving disability awards.[6]

Tinnitus can occur on 1 or both sides of the head and can be perceived as coming from within or outside the head. Tinnitus most often occurs in the setting of concomitant sensorineural hearing loss (SNHL), particularly among patients with bothersome tinnitus and no obvious ear pathology. The quality of tinnitus can also vary, with ringing, buzzing, clicking, pulsations, and other noises described by tinnitus patients. In addition, the effects of tinnitus on health-related quality of life (QOL) vary widely, with most patients less severely affected but some experiencing anxiety, depression, and extreme life changes. Patients who have tinnitus accompanied by severe anxiety or depression require prompt identification and intervention, as suicide has been reported in tinnitus patients[7] who have coexisting psychiatric illness. Most tinnitus is subjective, perceived only by the patient. In contrast, objective tinnitus can be perceived by others, is rare, and is not the focus of this guideline.

The focus of this guideline is tinnitus that is bothersome and persistent (lasting 6 months or longer), often with a negative effect on the patient's QOL. The guideline development group (GDG) chose 6 months as the criterion to define persistent tinnitus, since this duration is used most often as an entry threshold in published research studies on tinnitus. Some studies have used tinnitus of 3 months' duration for eligibility; it is possible that the recommendations of this clinical practice guideline (CPG) may be applicable to patients with tinnitus of shorter duration as well.

As noted in **Table 1**, tinnitus should be classified as either primary or secondary. In this guideline, the following definitions are used:

- *Primary tinnitus* is used to describe tinnitus that is idiopathic and may or may not be associated with SNHL. Although there is currently no cure for primary tinnitus, a wide range of therapies has been used and studied in attempts to provide symptomatic relief. These therapies include education and counseling, auditory therapies that include hearing aids and specific forms of sound therapy, cognitive behavioral

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Table 1. Abbreviations and Definitions of Common Terms.

Term	Definition
Tinnitus	The perception of sound when there is no external source of the sound
Primary tinnitus	Tinnitus that is idiopathic[a] and may or may not be associated with sensorineural hearing loss
Secondary tinnitus	Tinnitus that is associated with a specific underlying cause (other than sensorineural hearing loss) or an identifiable organic condition
Recent onset tinnitus	Less than 6 months in duration (as reported by the patient)
Persistent tinnitus	6 months or longer in duration
Bothersome tinnitus	Distressed patient, affected quality of life[b] and/or functional health status; patient is seeking active therapy and management strategies to alleviate tinnitus
Nonbothersome tinnitus	Tinnitus that does not have a significant effect on a patient's quality of life but may result in curiosity of the cause or concern about the natural history and how it might progress or change

[a]The word *idiopathic* is used here to indicate that a cause other than sensorineural hearing loss is not identifiable.
[b]*Quality of life* is the degree to which persons perceive themselves as able to function physically, emotionally, mentally, and/or socially.

therapy (CBT), medications, dietary changes and supplements, acupuncture, and transcranial magnetic stimulation (TMS).

- *Secondary tinnitus* is tinnitus that is associated with a specific underlying cause (other than SNHL) or an identifiable organic condition. It is a symptom of a range of auditory and nonauditory system disorders that include simple cerumen impaction of the external auditory canal, middle ear diseases such as otosclerosis or Eustachian tube dysfunction, cochlear abnormalities such as Ménière's disease, and auditory nerve pathology such as VS. Nonauditory system disorders that can cause tinnitus include vascular anomalies, myoclonus, and intracranial hypertension. Management of secondary tinnitus is targeted toward identification and treatment of the specific underlying condition and is not the focus of this guideline.

Despite the high prevalence of tinnitus and its potential significant effect on QOL, there are no evidence-based, multidisciplinary CPGs to assist clinicians with management. This guideline attempts to fill this void through actionable recommendations to improve the quality of care that tinnitus patients receive, based on current best research evidence and multidisciplinary consensus. The guideline recommendations will assist clinicians in managing patients with primary tinnitus, emphasizing interventions and therapies deemed beneficial and avoiding those that are time-consuming, costly, and ineffective.

Guideline Purpose

The purpose of this guideline is to provide evidence-based recommendations for clinicians managing patients with tinnitus. The target audience is any clinician, including nonphysicians, involved in managing these patients. Patients with tinnitus will often be evaluated by a variety of health care providers, including primary care clinicians, specialty physicians, and nonphysician providers such as audiologists and mental health professionals. The target patient population is limited to adults (18 years and older) with primary tinnitus that is persistent and bothersome.

Tinnitus is often a bothersome, potentially significant complaint of patients with identified causes of hearing loss such as Ménière's disease, sudden SNHL, otosclerosis, and VS. Patients with these identifiable and other causative diagnoses of secondary tinnitus are excluded from this guideline, as they are often excluded from nearly all randomized controlled trials (RCTs) of tinnitus management, making it impossible to generalize trial results. However, the GDG placed emphasis on the need for thorough clinical evaluation to identify these potentially treatable and sometimes serious disorders. Clinicians should decide whether to apply these recommendations to patients with these conditions on an individualized basis. The guideline also excludes patients with pulsatile tinnitus, or tinnitus related to complex auditory hallucinations or hallucinations related to psychosis or epilepsy.

This is the first evidence-based clinical guideline developed for the evaluation and treatment of chronic tinnitus. This guideline provides clinicians with a logical framework to improve patient care and mitigate the personal and social effects of persistent, bothersome tinnitus. It will discuss the evaluation of patients with tinnitus, including selection and timing of diagnostic testing and specialty referral to identify potential underlying treatable pathology. It will then focus on the evaluation and treatment of patients with persistent primary tinnitus, with recommendations to evaluate and measure its effect as well as to determine the most appropriate interventions to improve symptoms and QOL for tinnitus sufferers.

In formulating this guideline, a broad range of topics was identified as quality improvement opportunities by the GDG. These topics fall into the 3 broad domains of assessment, intervention/management, and education (**Table 2**). The group further prioritized these topics to determine the focus of the guideline.

Health Care Burden

Prevalence

Tinnitus is a common auditory complaint in the United States and globally. The estimated prevalence in the United States of experiencing tinnitus at any time is 25.3% and experiencing frequent (almost always or at least once a day) tinnitus is 7.9%.[8]

Table 2. Topics and Issues Considered in Tinnitus Guideline Development.[a]

Topic	Issue
Assessment	• How should patients who first present with tinnitus be evaluated?
	• What is the initial evaluation of patients with recent onset tinnitus?
	• What is the initial evaluation of patients with persistent tinnitus?
	• Should all patients with tinnitus have an audiologic evaluation?
	• What is the relationship of hearing loss to tinnitus?
	• Can the level and type of hearing loss associated with tinnitus be identified?
	• Which patients with tinnitus require diagnostic tests and evaluation?
	• How should clinicians distinguish bothersome tinnitus from nonbothersome tinnitus?
	• What are the best methods/instruments for evaluating the severity of tinnitus and the effects of treatment?
	• How should patients be triaged according to tinnitus severity?
	• When should a patient with tinnitus be referred for specialty evaluation (mental health, audiology, emergency care, or otolaryngology)?
	• What is the natural history of recent onset tinnitus? What should patients expect?
	• How should clinicians distinguish primary tinnitus (tinnitus that is idiopathic or associated with sensorineural hearing loss) from secondary tinnitus (tinnitus that is associated with a specific underlying cause or condition, other than sensorineural hearing loss)?
	• Are certain patients with 1 or more chronic conditions (eg, depression) at increased risk for tinnitus? How might this affect management?
	• Can modulating factors (eg, sleep apnea, allergies, medication use) be identified that exacerbate or alleviate tinnitus?
Intervention/management	• What is the role of medical therapy in managing persistent, bothersome tinnitus?
	• What is the effectiveness of cognitive behavioral therapy for persistent, bothersome tinnitus?
	• What is the role of hearing aids and other forms of sound therapy (maskers, modulated music) in the treatment of tinnitus with and without associated hearing loss?
	• What is the role of complementary and alternative medicine in managing tinnitus?
	• What is the role of over-the-counter therapies in managing tinnitus?
	• What is the effectiveness of Ginkgo biloba for persistent, bothersome tinnitus?
	• What is the effectiveness of acupuncture for persistent, bothersome tinnitus?
	• What is the effectiveness of transcranial magnetic stimulation for persistent, bothersome tinnitus?
	• Are there particular therapies that patients should avoid because they promote false hope?
	• Are some treatments for tinnitus harmful?
	• What can patients do for relief of bothersome, recent onset tinnitus, recognizing that most therapies have been studied only for persistent tinnitus?
	• What is the best way for specialists to communicate with primary care clinicians in managing patients with tinnitus?
	• How should clinicians manage patients with tinnitus and modify conditions such as hyperlipidemia, high cholesterol, migraine, depression, etc?
	• What is the association of tinnitus with other medical conditions such as anxiety, depression, hyperlipidemia, hypercholesterolemia, migraine, etc?
Education	• How should clinicians be educated that tinnitus can be managed and avoid attitudes and statements such as "you just have to live with it."
	• How can patients be counseled about expectations of therapy and avoiding unproven therapies with potential harm or cost?
	• What education and counseling should clinicians provide to patients with recent onset tinnitus?
	• What education and counseling should clinicians provide to patients with persistent tinnitus?

[a]This list was created by the guideline development group to refine content and prioritize action statements; not all items listed were ultimately included or discussed in the guideline.

This may be an underestimate, as only 10% to 15% of individuals with persistent tinnitus will present for medical evaluation.[9] In the United States, the prevalence of experiencing any tinnitus in a given year increases with age, peaking at 31.4% in the 60 to 69 year age group.[8] The prevalence of tinnitus is higher among males, non-Hispanic whites, individuals with a body mass index (BMI) of ≥ 30 kg/m^2, or those with a diagnosis of hypertension, diabetes mellitus, dyslipidemia, or anxiety disorder.[8] Any association between tobacco use and tinnitus is not well defined in the literature.[8,10] In addition, individuals with a history of loud noise exposure from firearm usage or occupational or leisure activities have a higher prevalence of tinnitus.[8]

The economic burden to the United States due to tinnitus and its management is likely quite large. Tinnitus is the most

frequent service-connected disability in U.S. veterans, and the number of veterans receiving disability payments for tinnitus, which exceeded 970,000 individuals as of fiscal year 2012, has increased by at least 16.5% annually since 2000.[11] The economic burden of tinnitus outside the realm of military service is not known.

Effect of Tinnitus on Health-Related QOL

A survey by Tyler and Baker[12] in 1983 first identified the wide range of effects of tinnitus on QOL. Some of the more common complaints were insomnia, impaired understanding of speech, depression, impaired concentration, and problems with both work and family life. Numerous other studies, with similar results, have documented the wide range of difficulties faced by those with bothersome tinnitus.[1,10,13-15]

A World Health Organization committee[16] reviewed the effects of tinnitus on an individual's well-being. Tinnitus can cause insomnia, and that tinnitus-related disability should be considered distinct from any disability associated with hearing loss. The World Health Organization schema was used to categorize the functions impaired by tinnitus into 4 broad groups: (1) thoughts and emotions, (2) hearing, (3) sleep, and (4) concentration.[17] When these primary functions are affected by tinnitus, numerous secondary activities can be affected and this can broadly impair QOL.

The persistence of tinnitus coupled with the difficulty in identifying a defined cause of primary tinnitus can contribute to substantial patient distress and significant adverse effects on QOL.[10,14] Sleep deprivation, which may be reported in more than half of tinnitus patients, can reduce the ability to concentrate and can lead to anger, frustration, and other emotional disturbances.[1,13] General health-related and tinnitus-related QOL is worsened further in tinnitus patients with comorbid conditions such as hypertension, diabetes mellitus, and arteriosclerosis.[10]

Psychiatric conditions are common in tinnitus patients. The association of major depression and tinnitus has been studied, with depression reported in 48% to 60% of tinnitus sufferers.[18,19] The severity of depression and anxiety has been related to the severity of tinnitus.[20] The precise relationship between depression and tinnitus is poorly understood, as depression may affect the severity or tolerance of tinnitus, tinnitus may predispose individuals to depression, or tinnitus may be an independent comorbidity in depressed patients.[21] Other common psychiatric comorbidities seen in tinnitus patients include social and specific phobias and adjustment disorders.[20,22] Four of 6 major health-related QOL instruments currently used to evaluate tinnitus outcomes incorporate cognitive or emotional domains, although their ability to measure effectiveness of interventions is not established.[23]

Prognosis and Natural History

The incidence of tinnitus has been reported in 2 large cohort studies. In 1 study of 3753 adults, there was an 8.2% baseline prevalence of tinnitus, with a new incidence of 5.7% after 5 years, rising to a 12.7% cumulative incidence at the 10-year follow-up.[24] Another study of 1292 adults found that the incidence of new tinnitus after 5 years was 18.0%.[25] Risk factors were not consistent among studies but included male sex, history of arthritis or head injury, preexisting hearing loss, and any history of tobacco use.

Tinnitus may improve spontaneously. In 1 cohort study, nearly 50% of patients with significant tinnitus (moderate severity, sleep problems, or both) improved after 5 years, with 43% of those improved reporting complete resolution and the remaining 57% reporting only mild symptoms.[26] In another study,[27] 82% of patients who reported tinnitus at baseline had persistent tinnitus after 5 years, suggesting close to a 20% rate of spontaneous improvement. Similarly, subjects assigned to the "wait-list" control groups of some clinical trials show small, but significant, improvements in tinnitus distress.[28] The largest spontaneous improvement is seen with short duration tinnitus, younger age, and longer intervals between pre- and post-assessment. For example, in 1 study,[29] 28% of subjects with acute tinnitus (lasting < 6 months) improved spontaneously in a control group that received only educational information.

The severity of tinnitus can fluctuate. Hallam et al[30] reviewed the psychological aspects of tinnitus and described a natural habituation process that improves tinnitus tolerance. An observational study of 528 patients seen in otolaryngology clinics found that, regardless of symptom duration, tinnitus severity declined over time in 3% to 7% of patients.[15,31] Another large cohort study found that 55% of patients with severe tinnitus reported only moderate, or mildly bothersome, symptoms 5 years later.[27] Conversely, 45% of tinnitus patients in the same cohort progressed from mildly annoying symptoms at baseline to moderate or severely annoying symptoms after 5 years. Those with persistent tinnitus, defined in the study as having had symptoms at baseline and at 5 years, were significantly more likely to report moderately or extremely bothersome symptoms compared to their counterparts with newly reported tinnitus.

Tinnitus Cost and Economic Burden

Because the management of tinnitus is not standardized, inefficiencies and variations in care can contribute to increased health care costs.[32] By 2016, more than 1.5 million U.S. veterans are expected to receive disability compensation for tinnitus-related claims, at an annual cost estimated to exceed $2.75 billion.[11] In the workplace, tinnitus may reduce employee productivity by adversely affecting concentration and limiting participation in occupational activities.[1,33,34] Tinnitus accompanied by hearing loss may induce physical disability and, in severe cases, end a person's occupation.[1]

Methods

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the third edition of *Clinical Practice Guideline Development Manual: A Quality-Driven Approach for Translating Evidence into Action*.[35] Members of the GDG include pediatric and adult otolaryngologists, otologists/neurotologists, a geriatrician, a behavioral neuroscientist, a

neurologist, an audiologist, a family physician, a radiologist, a psychiatrist, an internist, a psychoacoustician, an advanced nurse practitioner, a resident physician, and consumer advocates.

Literature Search

An information specialist conducted 2 literature searches using a validated filter strategy. The search terms used were tinnitus [MeSH], tinnit*, ear and (ring* or buzz* or roar* or click* or puls*). These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The initial literature search identified clinical practice guidelines, systematic reviews, and meta-analyses related to tinnitus in adults published up to March 12, 2013. The search was performed in multiple databases including Medline, Embase, the National Guidelines Clearinghouse (www.guideline.gov), The Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database, Agency for Healthcare Research and Quality (AHRQ), PubMed, Guidelines International Network, Health Services/Technology Assessment Tools, CMA InfoBase, NHS Evidence, National Institute of Clinical Excellence, Scottish Intercollegiate Guidelines Network, New Zealand Guidelines Group, Australian National Health and Medical Research Council, and the TRIP database.

The initial search yielded 271 potential guidelines and 621 potential systematic reviews or meta-analyses. After removing duplicates, articles not related to tinnitus, those not indicating or explicitly stating a systematic review methodology, and non-English language articles, 8 guidelines and 71 systematic reviews or meta-analyses remained. After review by authors and GDG leadership, 29 systematic reviews were ultimately used in the final publication.

A second literature search identified RCTs published up to April 1, 2013. The following databases were used: Medline, Embase, CINAHL, and CENTRAL. The search identified 2046 potential RCTs. After removing duplicates, non-English language articles, animal model studies, and nonrandomized trials, 232 RCTs remained.

Final results of both literature searches were distributed to panel members. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through August 2013.

Toward the end of the CPG development process, an AHRQ comparative effectiveness review (CER) on the evaluation and treatment of tinnitus was published in August 2013.[36] The evidence reviews in this document were studied by the GDG, analyzed, and integrated into the recommendations of this CPG where appropriate and relevant.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in November 2013, the group met twice, with in-person meetings following the format previously described,[35] using electronic decision-support (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut, USA) software to facilitate creating actionable recommendations and evidence profiles.[37] Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting CPGs.[38]

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.[39] Guideline panel members received summary appraisals in November 2013 and modified an advanced draft of the guideline.

The final guideline draft underwent extensive external peer review, including a period for open public comment. All comments received were compiled and reviewed by the panel's chair, and a modified version of the guideline was distributed and approved by the guideline development panel. The recommendations contained in the guideline are based on the best available data published through April 2013. Where data were lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur at 5 years from publication, or sooner if new compelling evidence warrants earlier consideration.

Classification of Evidence-Based Statements

Guidelines are intended to produce optimal health outcomes for patients, to minimize harms, and to reduce inappropriate variations in clinical care. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in **Table 3** and **Table 4**.[40] As much of the guideline dealt with evidence relating to diagnostic tests, **Table 4** was adapted to include current recommendations from the Oxford Centre for Evidence-Based Medicine.[41]

Guidelines are not intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability.[40] Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be

Table 3. Guideline Definitions for Evidence-Based Statements.

Statement	Definition	Implication
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or that the harms, including monetary costs, clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternate approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means either that the quality of evidence that exists is suspect (grade D)[a] or that well-done studies (grade A, B, or C)[a] show little clear advantage to 1 approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation	No recommendation means that there is both a lack of pertinent evidence (grade D)[a] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

[a]See **Table 4** for definition of evidence grades.

Table 4. Evidence Quality for Grades of Evidence.[a]

Grade	Evidence Quality for Diagnosis	Evidence Quality for Treatment and Harm
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

[a]American Academy of Pediatrics[40] classification scheme updated for consistency with current level of evidence definitions.[41]

transparent and explicit about how values were applied and to document the process.

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,[42] the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.[43]

Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: an evidence-based key action statement in bold, followed by the strength of the recommendation in italics. Each key

Table 5. Summary of Guideline Action Statements.

Statement	Action	Strength
1. History and physical exam	Clinicians should perform a targeted history and physical examination at the initial evaluation of a patient with presumed primary tinnitus to identify conditions that if promptly identified and managed may relieve tinnitus.	Recommendation
2A. Prompt audiologic examination	Clinicians should obtain a prompt, comprehensive audiologic examination in patients with tinnitus that is unilateral, persistent (≥ 6 months), or associated with hearing difficulties.	Recommendation
2B. Routine audiologic examination	Clinicians may obtain an initial comprehensive audiologic examination in patients who present with tinnitus (regardless of laterality, duration, or perceived hearing status).	Option
3. Imaging studies	Clinicians should not obtain imaging studies of the head and neck in patients with tinnitus, specifically to evaluate the tinnitus, unless they have 1 or more of the following: tinnitus that localizes to 1 ear, pulsatile tinnitus, focal neurological abnormalities, or asymmetric hearing loss.	Strong recommendation against
4. Bothersome tinnitus	Clinicians must distinguish patients with bothersome tinnitus from patients with nonbothersome tinnitus.	Strong recommendation
5. Persistent tinnitus	Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussions about natural history and follow-up care.	Recommendation
6. Education and counseling	Clinicians should educate patients with persistent, bothersome tinnitus about management strategies.	Recommendation
7. Hearing aid evaluation	Clinicians should recommend a hearing aid evaluation for patients with hearing loss and persistent, bothersome tinnitus.	Recommendation
8. Sound therapy	Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus.	Option
9. Cognitive behavioral therapy	Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus.	Recommendation
10. Medical therapy	Clinicians should not routinely[a] recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus.	Recommendation against
11. Dietary supplements	Clinicians should not recommend Ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients with persistent, bothersome tinnitus.	Recommendation against
12. Acupuncture	No recommendation can be made regarding the effect of acupuncture in patients with persistent bothersome tinnitus.	No recommendation
13. Transcranial magnetic stimulation	Clinicians should not recommend transcranial magnetic stimulation for the routine[a] treatment of patients with persistent, bothersome tinnitus.	Recommendation against

[a]The words *routine* and *routinely* are used to avoid setting a legal precedent and to acknowledge that there may be individual circumstances for which clinicians and patients may wish to deviate from the prescribed action in the statement.

action statement is followed by an "action statement profile" of quality improvement opportunities, aggregate evidence quality, benefit-harm assessment, and statement of costs. In addition, there is an explicit statement of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of the evidence-based statements in the guideline is shown in **Table 5** and an algorithm for use of these statements is seen in **Figure 1**.

STATEMENT 1. PATIENT HISTORY AND PHYSICAL EXAMINATION: Clinicians should perform a targeted history and physical examination at the initial evaluation of a patient with presumed primary tinnitus to identify conditions that if promptly identified and managed may relieve tinnitus. *Recommendation based on observational studies, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To promote a consistent and systematic approach to the initial evaluation of the patient with tinnitus
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: Moderate, as few if any studies specifically investigate the diagnostic yield or effect of history and examination on tinnitus patients

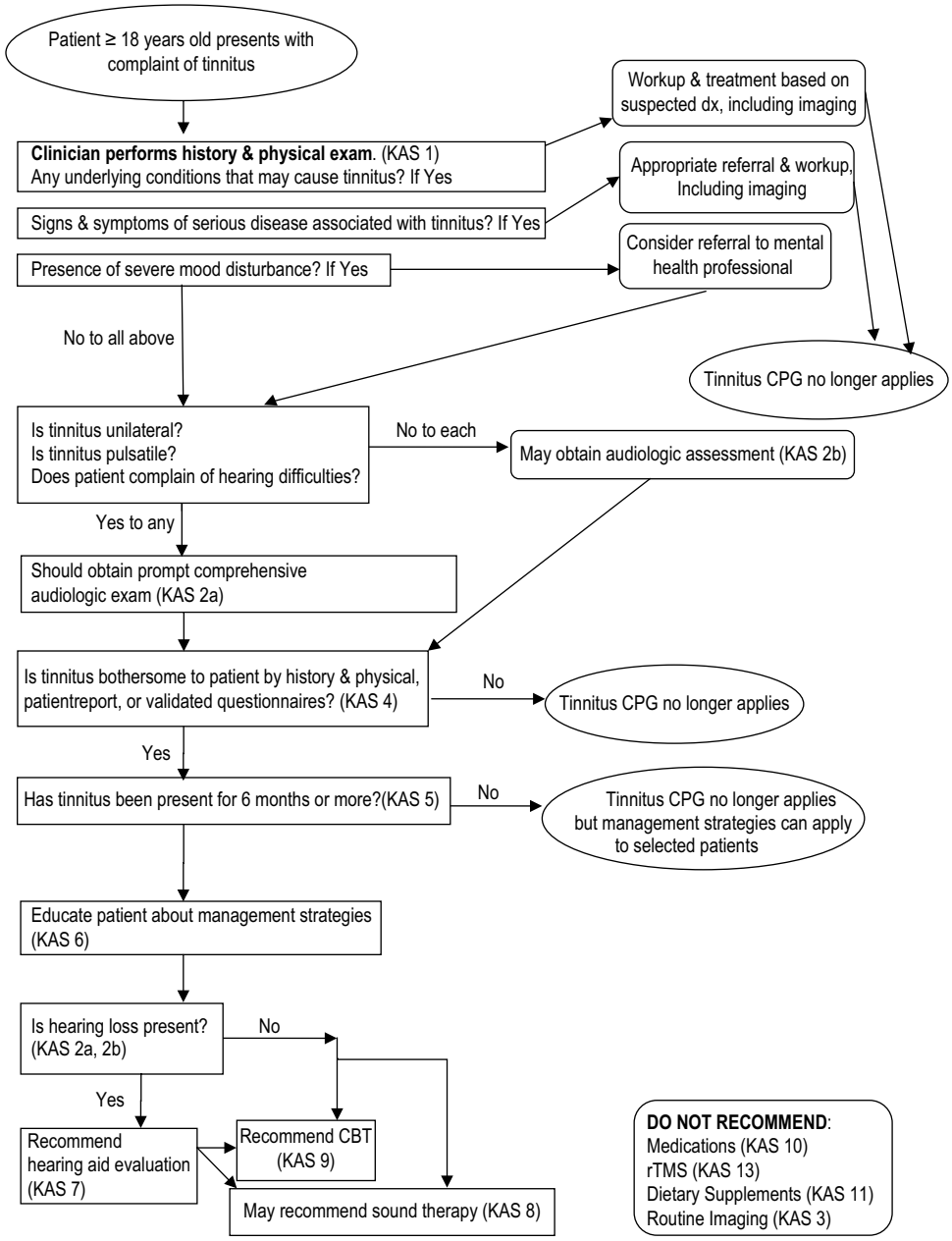

Figure 1. Algorithm of guideline key action statements.

- Benefits: Identify organic, and potentially treatable, underlying causes (eg, secondary tinnitus); minimize cost and administrative burden through a targeted approach to history and physical examination; streamline care/increase efficiency; improve patient satisfaction; identify patients with primary tinnitus who may benefit from further management (as outlined in this guideline)
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception by the GDG that tinnitus sufferers may not receive thorough evaluations from clinicians; further perception that many clinicians are unaware of the optimal targeted history and physical examination to evaluate a patient with tinnitus
- Intentional vagueness: The definition of a "targeted" history and physical examination is elaborated upon in the supporting text.
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to emphasize the importance of history and physical examination to identify potentially treat-

Table 6. Key Details of Medical History in the Tinnitus Patient.[a]

Key Issue	Significance	Implication
Unilateral tinnitus	Concern for focal auditory lesions, some serious, such as VS or vascular tumor	Referral for comprehensive audiologic assessment and an otologic evaluation; additional testing such as imaging where indicated
Pulsatile tinnitus	Concern for vascular lesion, systemic cardiovascular illness	Consider cardiovascular and general physical examination (hypertension, heart murmurs, carotid bruits, venous hums); examination of the head and neck for signs of vascular tumors or other lesions; comprehensive audiology; imaging and other testing where indicated
Hearing loss	Tinnitus is frequently associated with hearing loss, particularly SNHL; differentiate between conductive and SNHL, unilateral and bilateral; establish severity of hearing loss	Referral for comprehensive audiology; otologic evaluation to look for the wide range of pathologies that could cause hearing loss associated with tinnitus; consider hearing aid evaluation when indicated
Sudden onset of hearing loss with tinnitus	Sudden hearing loss requires prompt treatment to stabilize or improve hearing.	See sudden SNHL guideline[44]
New onset tinnitus	Tinnitus perception may diminish or disappear, and/or tinnitus reactions may be reduced.	Evaluation and treatment is based on severity, and presence and absence of other symptoms
Noise exposure	Tinnitus may be associated with prolonged noise exposure from occupational or recreational activities.	Counseling and education related to potential damaging effect of noise, acoustic trauma, and pertinent environmental exposures; referral for comprehensive audiologic assessment
Medications and potential ototoxic exposures	Some medications such as salicylates are associated with tinnitus; ototoxins can cause hearing loss and tinnitus. Interactions between medications have unknown effects and can exacerbate tinnitus symptoms.	Counseling regarding medication use, etiology of tinnitus is facilitated; patients can be provided list of known ototoxic medications as part of counseling; comprehensive audiologic assessment
Unilateral or asymmetric hearing loss	Possible presentation of serious lesion such as VS	Audiologic and otologic assessment; imaging where indicated
Vertigo or other balance malfunction	Possible cochlear, retrocochlear, or other central nervous system disorder (Ménière's disease, superior canal dehiscence, VS, other)	Audiologic, otologic, vestibular assessment; imaging and referral where indicated
Symptoms of depression and/or anxiety	Tinnitus is often accompanied by symptoms of depression and anxiety. The presence and severity of such symptoms will dictate the pace of evaluation and treatment as well as the need for referral to treat these issues.	Referral to mental health professionals for assessment and treatment of depression and/or anxiety; urgent referral for suicidal patients
Apparent cognitive impairments	Elderly patients at risk for tinnitus are also at risk for cognitive decline from dementia.	The presence of dementia will affect the results of tinnitus and audiologic assessments.

Abbreviations: SNHL, sensorineural hearing loss; VS, vestibular schwannoma.
[a]A definition of *comprehensive audiologic assessment* can be found in **Table 8**.

able causes of tinnitus as well as to identify serious conditions that may cause tinnitus or accompany tinnitus. An appropriate clinical evaluation should occur early to direct the need for and the type of additional testing and treatment. Although these causes of secondary tinnitus should be evaluated and managed, exclusion of these disorders is necessary to identify the patients with primary tinnitus that are the focus of this CPG. In addition, the patient encounter should identify any severe coexisting mental illness, such as depression or dementia, as these patients may need expedited referral and management.

Clinicians who evaluate patients with tinnitus should document the presence or absence of symptoms and conditions that dictate the need for referral to otolaryngology, audiology, and related specialties. These key signs and symptoms are listed in **Table 6** and **Table 7**.

The history should include the details of onset of tinnitus, the duration of symptoms, and the effects of the tinnitus on patient QOL. The characteristics of the tinnitus should be detailed, including laterality and pulsatile nature. Auditory phenomena such as hallucinations should be excluded. Symptoms of hearing loss,[44] disequilibrium, or other neurologic deficits should be documented. Ototoxic agents, including common over-the-counter medications such as aspirin (in high doses), can cause tinnitus.[45] Potential exposure to such ototoxic agents or suspect medications should be discussed. A history of excessive alcohol, caffeine, or tobacco use should be elicited.

Although most tinnitus patients will have few relevant positive physical findings, the examination should be directed to identify secondary tinnitus, with potentially treatable or explainable causes, as well as to find signs of serious disease

Table 7. Key Details of Physical Examination in the Tinnitus Patient.

Key Issue	Significance	Implication
Objective tinnitus	Rarely, tinnitus can be heard by the clinician as well as the patient.	Objective tinnitus may be caused by identifiable diseases, such as vascular abnormalities and myoclonus.
Heart murmurs, carotid bruits, or vascular sounds	Cardiovascular disease and vascular lesions may cause tinnitus.	Treatment of the underlying disease may help tinnitus symptoms. Cardiovascular disease (carotid stenosis, heart murmurs, hypertension) can have morbidities more substantial than tinnitus and requires appropriate evaluation and treatment.
Focal neurologic signs	Tinnitus patients should undergo neurologic assessment. Any focal neurologic deficits will dictate additional evaluation and treatment.	Referral to appropriate specialists (neurologists, otologists/neurotologists, head and neck surgeons, etc) and for appropriate workup, which may include imaging of the central nervous system
Otorrhea	Sign of middle ear infection or otitis externa	Treatment of otitis media/externa may improve tinnitus as well as associated hearing difficulties.
Signs of other external or middle ear disease on examination and/or otoscopy	Simple problems such as cerumen impaction or otitis media can be detected. Cholesteatoma, glomus tumors, and other uncommon middle ear disorders can be detected by otoscopy.	Appropriate referral can be made for diagnosis and treatment of external auditory canal issues such as cerumen, and middle ear disease such as otitis media or middle ear masses. Imaging can be performed when indicated.
Head and neck masses	A head and neck mass associated with ipsilateral tinnitus requires prompt investigation.	Referral to appropriate specialists; imaging when indicated

associated with tinnitus. A routine examination of the head and neck, including careful otoscopy, is the focus of such an examination. A focused neurologic examination should exclude motor and/or sensory deficits as well as cranial nerve issues that may accompany central nervous system lesions. When pulsatile tinnitus is reported, the examination should focus on identification of cardiovascular disease and vascular lesions. A full head and neck examination, a general cardiovascular examination, and auscultation/palpation of the head and neck, the skull and mastoid prominences, and orbits should be part of this evaluation.

The examination may find treatable otologic conditions that cause tinnitus. Cerumen impaction or other ear canal obstructions are diagnosed with otoscopy.[46] Tinnitus can occur in patients with middle ear disease, with or without resultant conductive hearing loss, such as that caused by Eustachian tube dysfunction, otitis media, or otosclerosis.[47,48] Disorders of the cochlea or vestibular apparatus, such as Ménière's disease (endolymphatic hydrops)[49] and superior canal dehiscence,[50] can cause tinnitus. Vestibular schwannoma can cause tinnitus as well, as discussed in Key Action Statement (KAS) 2A.[51]

Tinnitus can occur with medical conditions not directly associated with the ear. Vascular tumors and other vascular anomalies can cause tinnitus, as can palatal/middle ear myoclonus.[52] Intracranial hypertension and even temporomandibular joint dysfunction have also been associated with tinnitus.[53-55]

Pulsatile tinnitus can be caused by intracranial hypertension, neoplasms, and vascular disorders and deserves special attention during the directed history and examination. Paragangliomas, also known as glomus tumors, can cause tinnitus. Although most of these tumors are in the abdomen, 3% of nonadrenal paragangliomas are in the head and neck.[56] Glomus tumors are rare, but they are the most common tumor of the middle ear.[56,57] Patients with glomus tumors commonly present with pulsatile tinnitus (80%), whereas some present with hearing loss (60%).[58,59] Tinnitus from these lesions is usually unilateral.[56] Arteriovenous malformations (AVMs) and fistulae can cause tinnitus, and serious consequences, including intracerebral hemorrhage, may occur without treatment.[60,61] Although the significance of vascular loop compression of the eighth cranial nerve is debated, 1 systematic review showed that such loops were 80 times more common in patients with pulsatile tinnitus than those with nonpulsatile tinnitus.[62]

Pulsatile tinnitus can be caused by less serious phenomena such as venous hums, aberrant carotid arteries, and carotid transmissions, many of which are unilateral. Venous hums are caused by turbulent blood flow through the jugular bulb, which is adjacent to the mastoid and middle ear, and can be associated with sigmoid sinus diverticulum or dehiscence. Tinnitus can occur from transmission of sound from the carotid artery to the cochlea. This can be caused by stenosis of the carotid artery and can also occur with transmitted sounds of heart murmurs.[63] In light of these issues, the patient with pulsatile tinnitus should have a thorough medical evaluation to rule out systemic cardiovascular or neurologic disease. Examples of such disease include hypertension, hyperthyroidism, vascular stenoses and aneurysms, and coronary artery disease.

Emotional distress and/or disturbance of sleep are often associated with severe tinnitus. The assessment of these issues associated with tinnitus is discussed in KAS 4. The initial history and physical examination should also include assessment of possible associated emotional disturbance or psychiatric illness, which is crucial for patients who may be severely depressed. Patients may not recognize or report anxiety and/or depressive symptoms associated with tinnitus. Such

assessment will expedite appropriate referrals and interventions and can also direct the most appropriate therapies as discussed in the other key action statements.

When evaluations are performed in adults older than age 70, cognitive disorders represent comorbidities that could potentially alter management strategies and may impair the accuracy of the instruments used to assess the effect of tinnitus. For example, the incidence of Alzheimer's disease worldwide is 1% in those ages 60 to 70 years and up to 6% to 8% in those 85 years or older.

A complete evaluation for cognitive disorders is beyond the scope of this guideline; screening guidelines for Alzheimer's disease and mild cognitive impairment have been previously published.[64,65] However, a rapid screening test may facilitate the workup of tinnitus and guide appropriate referrals. One such brief assessment of cognitive function, *the clock drawing test*, can be performed in such patients at the time of an evaluation for tinnitus. The following is a widely accepted method for the clock drawing test:

> The patient is given a piece of paper and a pen. The examiner says, "I want you to draw a clock. Put the numbers on the face of the clock. Put the hands of the clock at 10 minutes after 11." The examiner should not cue or assist the patient in the task but encourage the patient to do his or her best.

Studies of the clock drawing test have shown a mean sensitivity (85%) and specificity (85%) for the diagnosis of dementia.[64] Multiple scoring guidelines have been used to judge the clock as either "normal" or "abnormal" and thus determine whether the patient passes this screen for dementia.[65-67] For screening purposes, the clock should be judged as either correct (the numbers and the hands are placed appropriately) or incorrect (presence of any errors). Patients who produce an incorrect clock may be referred to an appropriate clinician for evaluation of cognition.

STATEMENT 2A. PROMPT AUDIOLOGIC EXAMINATION: Clinicians should obtain a comprehensive audiologic examination in patients with tinnitus that is unilateral, associated with hearing difficulties, or persistent (≥ 6 months). *Recommendation based on observational studies, with a preponderance of benefit over risk.*

Action Statement Profile

- Quality improvement opportunity: To address potential underutilization of audiologic testing in patients with tinnitus who are likely to have underlying hearing loss and to avoid delay in such diagnosis
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: Moderate, as literature about the effect of prompt audiologic assessment on tinnitus management is scant
- Benefits: Prioritize the need for otolaryngologic evaluation (if not already completed) using audiologic criteria; identify hearing loss, which is frequently associated with tinnitus; characterize the nature of hearing loss (conductive, sensorineural, or mixed; unilateral or bilateral); detect hearing loss that may be unsuspected; initiate workup for serious disease that causes unilateral tinnitus and hearing loss (ie, VS)
- Risks, harms, costs: Direct cost of examination; access to testing; time
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The term *prompt* is used to emphasize the importance of ordering a timely test and ensuring that it is done within 4 weeks of assessment, preferably.
- Role of patient preferences: Small; patients may participate in decisions regarding timing of audiogram
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this recommendation is to advise the clinician on situations that warrant prompt audiology evaluation. Although evidence on the ideal timing of audiologic evaluation for tinnitus is scant and publication quality is modest, based on observational cohort studies, case series, or systematic reviews and meta-analyses of these studies, the GDG felt that priority for hearing evaluation is needed for those with perceived hearing difficulties and those with persistent or unilateral tinnitus.

Audiologic examination is ideally obtained within 4 weeks of initial patient presentation, as more urgent audiologic evaluation is rarely needed for tinnitus patients and may not be readily available. Even though some medical conditions that cause tinnitus are serious, nearly all are indolent, slow-growing, or chronic lesions that rarely require urgent diagnosis or therapy. Sudden SNHL may occur along with tinnitus, and this condition warrants audiologic testing preferably at the time of presentation, or otherwise no later than 2 weeks after presentation.[68]

Unilateral tinnitus, as compared to bilateral tinnitus, is more likely to be a symptom of a vascular lesion or VS, barring a clear history of trauma or surgery on the affected ear. Prompt audiologic evaluation is warranted in these cases as an initial diagnostic measure. Patients with tinnitus associated with hearing difficulties merit timely audiologic evaluation, as diagnosis and treatment of hearing loss may prove beneficial for communication as well as affording tinnitus relief (see KAS 7).

Vestibular schwannoma classically presents with unilateral SNHL with or without tinnitus.[69] Vestibular schwannoma has an annual incidence of about 1 case per 100,000 in the United States,[70] representing 5% to 10% of intracranial tumors in adults.[71] In patients with VS, tinnitus is unilateral in 95% of cases.[72] However, although unilateral tinnitus and hearing loss are common with VS, only 2% of patients with asymmetric or unilateral SNHL and tinnitus will actually have VS.[71] A

Table 8. Components of Comprehensive Audiologic Examination.

Key Component	Pertinent Details
Thorough case history	See Key Action Statement 1
Otoscopy with removal of excessive or obstructive cerumen	See cerumen management guideline[46]
Current American National Standards Institute (ANSI) standards should be met regarding maximum allowable ambient noise levels in the test environment; calibration of the audiometer; audiogram documentation, including use of the proper aspect ratio; and symbols.	Ear-specific masked air and bone conduction thresholds, speech recognition threshold (SRT), and word recognition scores (WRS) should be obtained. Reliability and validity of test results should be documented. Air conduction (AC) thresholds should be measured at 250 to 8000 Hz. Additional mid-octave frequencies that may be helpful include 750, 1500, 3000, and 6000 Hz and should be measured if differences in thresholds at 500 and 1000 or 1000 and 2000 Hz are ≥ 20 dB hearing level (HL). Bone conduction (BC) thresholds should be measured at 250 to 4000 Hz.
Ear-specific SRT in dB HL should be measured using standardized spondee word lists (eg, CID W-1), preferably recorded, but monitored-live voice (MLV) is acceptable.	Agreement between pure tone average (PTA) and SRT is helpful in assessing accuracy of hearing assessment and reliability of responses.
Ear-specific masked WRS (in %) should be measured at a presentation level of a 30- to 40-dB sensation level in reference to SRT using recorded versions of monosyllabic word lists (ie, NU-6, W-22, etc) and different word lists for each ear.	The clinician managing the patient with tinnitus will of necessity rely on the results of serial audiometric evaluations. As such, there is a need for proper audiologic documentation, not only of AC and BC thresholds as well as SRT and WRS, but also of masking levels, reliability, validity, word lists used, method of presentation (MLV or recorded), and type of transducer, in order for ongoing comparisons to be useful.
Ear-specific immittance measurements may be completed on each ear using equipment calibrated to current ANSI standards.	Immittance measures may include ear-specific tympanograms, ear-specific contralateral acoustic reflex thresholds (dB HL) at 500 to 4000 Hz, ear-specific ipsilateral acoustic reflex thresholds (dB HL) at 500 to 4000 Hz, and/or ear-specific acoustic reflex decay (dB HL) at 500 and 1000 Hz.

systematic review of natural history studies found that in approximately 46% of cases, VS will demonstrate growth, with a mean annual growth rate of 1.2 mm/year.[73] Although rare, the possibility of disease progression of VS, with consequences from brainstem or cerebellar mass effect, advances the need for early diagnosis with audiologic testing and, where warranted, neuro-otologic workup and imaging.

Since tinnitus symptoms of 6 months or longer are less likely to improve spontaneously, audiologic testing is indicated to identify coexisting hearing loss, to detect hearing loss that may have been unsuspected or unnoticed by the patient, and to identify unilateral or asymmetric hearing loss that may indicate a more serious underlying problem. Audiology results can also assist in planning treatment interventions, as described later in this guideline. Last, documenting the baseline hearing status in a patient with persistent tinnitus allows future comparisons to detect progressive or fluctuating hearing loss and can also be useful for patient education.

The Role and Performance of Audiologic Testing

Audiologic testing is used to document the type, laterality, and severity of hearing loss, to determine whether additional audiologic or radiographic studies should be considered, and to determine if intervention is required for managing tinnitus and/or hearing loss. A comprehensive audiologic examination should adhere to the *Preferred Practice Patterns*[74] standards established by the American Speech-Language-Hearing Association, as detailed in **Table 8**.

STATEMENT 2B. ROUTINE AUDIOLOGIC EXAMINATION: Clinicians may obtain an initial comprehensive audiologic examination in patients who present with tinnitus (regardless of laterality, duration, or perceived hearing status). *Option based on observational studies, with a balance of benefit and harm.*

Action Statement Profile

- Quality improvement opportunities: To promote awareness of hearing loss associated with tinnitus, even in patients who do not have unilateral tinnitus or hearing difficulties, and to emphasize that clinicians do not have to wait 6 months before obtaining an audiogram if deemed appropriate
- Aggregate evidence quality: Grade C, based on observational studies and prevalence of hearing loss in RCTs of tinnitus therapy
- Level of confidence in the evidence: High
- Benefits: Detect a hearing loss not perceived by the patient—SNHL, which is a treatable condition commonly associated with tinnitus; identify patients who may be candidates for sound therapy; identify opportunities for patient counseling/education
- Risks, harms, costs: Direct costs of audiologic testing; detection of minor audiologic abnormalities leading to potentially unnecessary further testing or referral; inconsistent access to testing
- Benefit-harm assessment: Equilibrium

- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making to proceed with audiologic examination
- Exclusions: None
- Policy level: Option
- Differences of opinion: None

Supporting Text

The purpose of this recommendation is to emphasize that audiologic evaluation is an appropriate option at any time for any patient with tinnitus, even if the tinnitus is of recent onset, bilateral, or not accompanied by perceived hearing difficulties. Tinnitus is usually associated with some degree of hearing loss.[75-79] Although the majority of patients who complain of tinnitus also complain of hearing problems,[80] some hearing loss may be unappreciated in tinnitus patients. The audiologic evaluation should define the degree and nature of any hearing loss and assess the potential need for audiologic management of hearing loss and tinnitus.

In addition to the audiology testing, a brief assessment should be performed to determine if intervention specific to tinnitus is warranted. This assessment should involve the use of appropriate tinnitus questionnaires.[81] Patients with tinnitus commonly attribute hearing problems to tinnitus.[75,76,82] In these cases, it is particularly important to evaluate hearing levels to determine how much of the patient's complaint is due to a hearing deficit and how much is due specifically to the tinnitus. Such assessments of tinnitus are detailed in KAS 4.

Assessment of Auditory Function

A comprehensive audiologic examination should adhere to the *Preferred Practice Patterns*[74] standards established by the American Speech-Language-Hearing Association, as detailed in **Table 8**.

A standard audiologic evaluation is routine practice for audiologists, but some of the procedures warrant special considerations when patients present with tinnitus.[83]

Otoscopy is performed routinely prior to placing earphones for audiometric testing. Even a small amount of cerumen on the tympanic membrane can create a mass effect resulting in high frequency conductive hearing loss and tinnitus.[84] It is therefore important to consider this possibility when performing otoscopy.

It is acceptable to use pulsed, warbled, or continuous tones for threshold testing, although the use of pulsed tones may assist some patients in distinguishing between the tones and the tinnitus, especially when the tinnitus pitch is close to the test frequency.[85-87]

Some patients with tinnitus have trouble tolerating louder sounds, and some report that certain sounds make their tinnitus louder. It is important to use caution when conducting suprathreshold audiologic testing. The following recommendations can be helpful:

- Use the softest effective masking sounds during traditional audiometry (the need for masking can be reduced by using insert earphones that increase interaural attenuation).
- Use comfortable levels of sound during word recognition testing.
- Approach reflex threshold and decay testing with particular caution as some patients have trouble tolerating the sounds used in these tests. In no instance should pure tones be delivered above 105 dB HL. Speech stimuli should not be delivered above 100 dB HL.

It should be noted that psychoacoustic testing of tinnitus is not routinely recommended, as these results are not helpful for diagnostic purposes, for guiding intervention, or for assessing outcomes of intervention. These measures typically include tinnitus loudness and pitch matching, minimum masking levels, and residual inhibition testing.[88]

STATEMENT 3. IMAGING STUDIES: Clinicians should not obtain imaging studies of the head and neck in patients with tinnitus, specifically to evaluate the tinnitus, unless they have 1 or more of the following: tinnitus that localizes to 1 ear, pulsatile tinnitus, focal neurological abnormalities, or asymmetric hearing loss. *Strong recommendation (against) based on observational studies, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Avoid overuse of imaging in patients with a low likelihood of any significant benefit from the imaging.
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: High
- Benefits: Avoid testing with low yield; avoid harms of unnecessary tests (radiation, contrast, cost); avoid test anxiety; avoid detecting subclinical, incidental findings
- Risks, harms, costs: Slight chance of missed diagnosis; relatively high costs and limited access to certain types of imaging studies
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The GDG made this a strong recommendation against, instead of a recommendation against, based on consensus regarding the importance of avoiding low-yield, expensive tests with potential adverse events in patients with tinnitus
- Intentional vagueness: Specific imaging studies are specified in the supporting text, including computerized tomography (CT), computerized tomographic angiography (CTA), magnetic resonance imaging (MRI), and magnetic resonance angiography (MRA)
- Role of patient preferences: None
- Exclusions: None
- Policy level: Strong recommendation (against)
- Differences of opinion: None

Supporting Text

The purpose of this statement is to avoid inappropriate use of imaging studies in the evaluation of patients presenting with primary tinnitus. It is of the utmost importance to determine a number of historical and specific features of tinnitus early in the evaluation of these patients (see KAS 1) to determine whether or not to pursue imaging.

Common choices of imaging studies for patients with primary tinnitus include computerized tomography or computerized tomographic angiography of the brain or temporal bone, or magnetic resonance imaging/angiography of the brain or internal auditory canals. The utility of imaging procedures in primary tinnitus is undocumented; no articles were found regarding the diagnostic yield of imaging studies with primary tinnitus, although there is considerable literature support for imaging patients who have tinnitus in association with hearing loss or other cranial neuropathies. Even in the setting of tinnitus and hearing loss, the yield of imaging studies is low and the yield is improved by correlative abnormal examinations.[89,90]

Computerized tomography studies use ionizing radiation, with a typical exposure level for a head CT with and without contrast media of 4 mSv.[91] Four mSv is equivalent to approximately 40 chest radiographs or 10 mammograms; home exposure to background radiation from radon gas is estimated at 2 mSv annually.[91] The potential exists for radiation-induced cancers appearing after a 10- to 20-year latency period, which is of particular concern in younger patients. Although the risk is small, it is real, and it requires a careful review of the risk-benefit ratio for the study.[91] Iodinated contrast is commonly used in evaluations of the brain and is a relatively safe product, but it introduces the potential risk of allergic reactions including anaphylaxis and can be a nephrotoxic agent. The risk of severe or very severe reactions to iodinated contrast media ranges from 0.22% to 0.04%, depending on the agent used.[92,93] Using iodinated contrast media also adds additional cost to the CT examination.

Magnetic resonance is more expensive and often less accessible than CT. Magnetic resonance has its own unique set of potential contraindications and warnings. Some patients cannot tolerate the confinement of the MR equipment and long protocol durations. Some implantable medical devices, such as pacemakers, implanted neurostimulators, and so on, may be contraindicated in the MR environment. Gadolinium, used as an MR contrast agent, can be toxic in the setting of renal failure and is responsible for the syndrome termed *nephrogenic systemic fibrosis*.[94] Such contrast agents also add to the cost of the MR procedure. If MR is performed, the high amount of noise generated by the procedure may be bothersome[95]; this may even exacerbate preexisting tinnitus. Magnetic resonance procedures are loud, even with noise protection using earplugs.

The cost for imaging studies varies widely, in part due to the wide range of studies that may be ordered, physician preference, whether the studies were performed in a hospital or outpatient setting, regional practice variances, and negotiated insurance plan adjustments. Example costs (Medicare 2013 data downloaded from physician fee schedules on www.cms.gov) for typical studies are $392 to $668 for a head CT angiographic study, or $529 to $871 for a head MRI with and without contrast; facility fees for CT and MRI may be even higher.

Ultimately, the low yield[96-98] of these imaging studies and their potential downsides including costs, expensive incidental findings, and risks reduce their utility in the routine evaluation of a patient with isolated or primary tinnitus. Imaging of a patient with tinnitus should instead be directed by presence or absence of associated symptoms (eg, unilateral or asymmetric hearing loss, cranial neuropathy).

STATEMENT 4. BOTHERSOME TINNITUS: Clinicians must distinguish patients with bothersome tinnitus from patients with nonbothersome tinnitus. *Strong recommendation based on inclusion criteria for RCTs on tinnitus treatment, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To identify those patients in need of clinical management and limit unnecessary testing and treatment for others
- Aggregate evidence quality: Grade B, based on inclusion criteria for RCTs on tinnitus treatment
- Level of confidence in evidence: High
- Benefits: Identify patients for further counseling and/or intervention/management; determine effect of tinnitus on health-related QOL; identify patients with bothersome tinnitus who may benefit from additional assessment for anxiety and depression; encourage an explicit and systematic assessment of patients to avoid underestimating or trivializing the effect of tinnitus; avoid unnecessary interventions/management of patients with nonbothersome tinnitus
- Risks, harms, costs: Time involved in assessment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: Method of distinguishing bothersome from nonbothersome is not specifically stated. One or more of the validated questionnaires described in the supporting text may be helpful.
- Role of patient preferences: None
- Exclusions: None
- Policy level: Strong recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to assist clinicians in distinguishing bothersome from nonbothersome tinnitus. Identification of those with bothersome tinnitus will enable appropriate intervention/management for patients with bothersome tinnitus and avoid unnecessary intervention/management for those who neither need nor want it. This guideline defines bothersome tinnitus as that which distresses the patients and affects their QOL and/or functional health status. These patients desire management strategies to alleviate their tinnitus. Nonbothersome tinnitus does not have a significant effect on QOL but may result in curiosity or

Table 9. Comparison of Self-report Tinnitus Questionnaires.[a]

Questionnaire (Author, Year)	Content	Interpretation
Tinnitus Questionnaire and Tinnitus Effects Questionnaire (Hallam et al, 1988)[105]	52 items • sleep disturbance • emotional distress • auditory perceptual difficulties • inappropriate or lack of coping skills	3 level category scale • true • partly true • not true
Tinnitus Handicap Questionnaire (Kuk et al, 1990)[101]	27 items • physical, emotional, social consequence (factor 1) • effects on hearing (factor 2)	0 (strongly disagrees) to 100 (strongly agrees)
Tinnitus Reaction Questionnaire (Wilson et al, 1991)[100]	26 items: distress consequences including: • anger • confusion • annoyance • helplessness • activity avoidance • panic	5-point scale (0 = not at all; 4 = almost all of the time)
Tinnitus Handicap Inventory (Newman et al, 1996)[99]	25 items • role limitations in mental, social/occupational, physical functioning • anger, frustration • irritability • depression • catastrophic subscale: desperation, loss of control, inability to cope and escape, fear of grave disease	3 level category scale • yes • sometimes • no
Tinnitus Functional Index (Meikle et al, 2012)[102]	30 items with 8 subscales (subscales not validated) • intrusive • feeling • thinking • hearing • relaxing • sleeping • managing • quality of life	11-point scale (0 to 10)

[a]Adapted from Newman and Sandridge.[106]

concern about the cause, the natural history of the condition, and treatment options.

Tinnitus, as currently understood, has 2 components: perception and reaction. Whereas a patient may complain of the *perception* (sound) of tinnitus, the clinician must also appreciate the significance of the patient's negative *reaction* (eg, anxiety and depression) to tinnitus. Clinicians should recognize and attempt to manage both components.

A clinician may distinguish bothersome from nonbothersome tinnitus by

1. Asking the patient if the tinnitus is bothersome, and if so, whether it is bothersome enough that the patient would like to pursue further intervention(s).
2. Asking the patient if the tinnitus interferes with communication, concentration, sleep, or enjoyment of life.
3. Asking the patient how much time and effort the patient has put into seeking treatments for the tinnitus.
4. Administering 1 of several validated questionnaires/surveys (**Table 9**).

Distinguishing bothersome from nonbothersome tinnitus will ensure that those patients who are offered therapy are similar to those enrolled in clinical trials, thereby making it possible to apply the recommendations from those trials. It is important that within the category of patients with bothersome tinnitus is a subset of individuals who may be depressed or even suicidal. These patients warrant immediate psychiatric evaluation and treatment. For the patients with bothersome tinnitus, administration of 1 of several validated questionnaires will help characterize the type of tinnitus-related disability, as well as quantify the severity of such disability. These instruments will also obtain a baseline assessment to assess the effect of interventions. In addition, the clinician should determine who needs urgent or emergent psychiatric referral. In patients who appear severely anxious or depressed, it can be helpful to ask them if they have seen, or have considered seeing, a mental health professional.

Questionnaires can provide an important tool for understanding the problems faced by the patient. A simple clinical approach is to ask patients to make a list of the problems they attribute to their tinnitus.[12] A number of tinnitus questionnaires have been developed to determine the level and types of handicaps faced by tinnitus patients, including the Tinnitus Handicap Inventory (THI),[99] Tinnitus Reaction Questionnaire (TRQ),[100] Tinnitus Handicap Questionnaire (THQ),[101] and Tinnitus Functional Index (TFI).[102] These questionnaires have also been used in clinical trials to assess treatment effects.

Commonly used instruments are summarized in **Table 9**. These tinnitus questionnaires have been used to document problems resulting from tinnitus as well as to measure changes in tinnitus with treatment. The questionnaires differ primarily in the measurement scales they use and the primary functions and secondary activities affected by tinnitus.[103,104] Because tinnitus is often associated with complex psychological issues, most of the questionnaires focus on emotions and the challenging thoughts experienced by these patients. Each of these instruments includes questions about sleep.

STATEMENT 5. PERSISTENT TINNITUS: Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussions about natural history and follow-up care. *Recommendation based on inclusion criteria in RCTs, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To identify patients with a duration of tinnitus similar to that studied in RCTs of tinnitus treatment; to identify those who may need and benefit from intervention; and to avoid inappropriate interventions for patients with shorter duration tinnitus
- Aggregate evidence quality: Grade B, based on inclusion criteria in RCTs
- Level of confidence in the evidence: Moderate, based on varying tinnitus duration in RCTs, with some including patients with tinnitus of less than 3 months' duration
- Benefits: Identify patients who have a duration of tinnitus similar to the patients included in RCTs, and identify those patients who are most likely to benefit from intervention
- Risks, harms, costs: Defer treatment that may benefit some tinnitus patients who do not have persistent symptoms
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Despite some variation in inclusion criteria for duration of tinnitus used in clinical trials, the GDG felt that 6 months was a reasonable time to conclude that the tinnitus would likely persist.
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to emphasize the importance of identifying patients with tinnitus that is bothersome and persistent for longer than 6 months. These patients are less likely to have spontaneous improvement and are the ones who have been included in most studies of interventions for tinnitus. The majority of RCTs of tinnitus therapies enroll subjects with moderate severity tinnitus of at least 6 months' duration. A review of 89 RCTs yielded only 1 trial with enrollment limited to new onset tinnitus (less than 3 months' duration)[107] and 1 trial of tinnitus less than 6 months' duration.[29]

Another reason for distinguishing those with recent onset tinnitus from those with persistent tinnitus is the potential for resolution of tinnitus within 6 months of onset, with avoidance of expensive or time-consuming evaluations and treatments. Clinical trials that use either wait list control groups or minimal interventions report significant spontaneous improvement in tinnitus distress over study periods of several months in subjects with short duration tinnitus and young age.[28,29] Surveys of tinnitus self-help groups also report a decreased range and intensity of tinnitus-related problems as a function of time since onset.[12]

Patients with new onset tinnitus can be reassured that, for many, the natural course of tinnitus is to improve over time and become less problematic and intrusive. The data discussed in the CPG previously provide some benchmarks regarding the natural progression (and regression) of bothersome tinnitus over time. There is a moderate degree of spontaneous improvement over time, and there appears to be habituation in a sizeable percentage of patients over a prolonged period. These improvements pertain to reactions to tinnitus and do not indicate that the tinnitus perception is decreased over time.

STATEMENT 6. EDUCATION AND COUNSELING: Clinicians should educate patients with persistent, bothersome tinnitus about management strategies. *Recommendation based on studies of the value of education and counseling, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To address potential underutilization of education and counseling by clinicians who manage patients with persistent, bothersome tinnitus. To bring awareness of available management strategies to the patient.
- Aggregate evidence quality: Grade B, based on studies of the value of education and counseling in general, and grade C based on such studies in tinnitus in particular
- Level of confidence in the evidence: High
- Benefits: Improved QOL; increased ability to cope with tinnitus; improved outcomes and patient satisfaction; less health care utilization

- Risks, harms, costs: Direct cost and time
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to make sure clinicians and patients understand that management strategies for persistent, bothersome tinnitus do exist. Clinicians should engage the patient or the patient's proxy in decision making with awareness of the natural history, the prognosis, and management options. Although many patients seek help for their tinnitus, they are often told that little or nothing can be done to help them. Most patients, and many clinicians, do not know the options available for management of tinnitus. They face tempting advertisements and claims of treatments and cures. Some patients are desperate, and some not well-informed; often, such patients will seek any kind of treatment offer that has the appearance of legitimacy. Despite a lack of cure for primary tinnitus, there are many approaches to treatment that can improve symptoms and relieve distress.

Tinnitus is a complex, multifactorial problem with many potential options that can help the patient cope with the condition. Clinicians should point out that there is no established cure for tinnitus, but they should also avoid making statements that may exacerbate a patient's negative reaction to tinnitus. Members of the GDG recalled statements such as, "There is nothing that can be done for tinnitus," "You'll just have to learn to live with it," or "This can be caused by a brain tumor." Patient education should instead emphasize that tinnitus itself is a symptom and not a dangerous disease, and a comprehensive assessment can exclude any associated medical conditions that require prompt treatment.

Patient counseling should include information on the association between tinnitus and hearing loss and should also discuss lifestyle factors that can have positive and negative effects on tinnitus management. Counseling should include information on hearing protection from noise, noting the association between noise-induced hearing loss and tinnitus. Patients should be encouraged to return for follow-up and reassessment if their tinnitus persists and remains bothersome or if it worsens over time.

The evidence for counseling and sound therapy for management of tinnitus is discussed in KAS 6 through 9. These studies demonstrate that patients can benefit from counseling and sound therapy. There are also studies showing that self-help brochures and books provide benefit.

The clinician can inform and educate tinnitus patients (**Table 10**) by

- Providing brochures.
- Suggesting self-help books.
- Describing counseling and sound therapy options.
- Discussing the availability, but also the lack of proven benefits, of pharmacologic and other medical therapies, as well as other options such as complementary and alternative medicine (CAM).
- Referral to other professionals.
- Referral to support organizations and member health professionals (**Table 11**).

Provide Brochure

Many brochures are available from professional organizations and some have been published (eg, http://www.ata.org/resources, www.entnet.org, www.washingtondc.va.gov/departments/audiology.asp, http://www.asha.org/).[108]

Suggest Self-Help Book

Self-help books are available that focus on different approaches. For example, Henry and Wilson[109] focused on a cognitive behavior modification approach, providing structured and systematic exercises. Preliminary results of a controlled study showing the benefits have been reported.[110] Tyler[111] addressed a variety of topics, including sleep, medications, hyperacusis, "Your Life and Tinnitus," and "Changing Reactions." A number of books in the lay press may help patients and clinicians understand the mechanisms of tinnitus as well as some treatments that have been studied.[112] Patient workbooks such as the "step-by-step guide" by Henry et al[113] may be helpful. The work by Davis[114] contains review chapters on hearing, causes, and "Changing Your Thinking." One controlled study showed that self-help books help patients with tinnitus.[115] A meta-analysis of self-help interventions found greater reduction of tinnitus distress and depressiveness when compared to a passive control (information only/discussion forums), and no difference when compared to face-to-face group treatment control.[29]

Describe Counseling and Sound Therapy Options

The clinician should emphasize to patients that although there is no "cure" at present, there are many things that they can do to make tinnitus less of a problem and thereby to improve their QOL. There is a wide variety of tinnitus counseling options available (see KAS 8 and 9).[116] These options range from providing basic information to focused activities in the areas primarily affected by tinnitus (thoughts and emotions, hearing, sleep, and concentration). A wide variety of nonwearable and wearable sound therapy devices is also available. These range from broadband noise to background music, and on most devices, the sound quality and level can be modified. Although not for everyone, these devices can be very helpful for many. Many everyday devices, such as CD and MP3 players, smartphones, and radios, can actually be helpful for sound therapy. Patients should be educated about the potential benefits of sound therapy and can use these everyday devices to determine their benefit prior to considering the purchase of sound therapy devices. These options are discussed in this guideline in KAS 8.

Table 10. Patient Education Discussion Points for Bothersome Tinnitus.

1. Definition of tinnitus	Tinnitus is sound that is created in the ears or in the head. It is a symptom and not a disease. People with chronic tinnitus usually hear it all or most of the time. For some people, tinnitus is intermittent.
2. Distinguishing tinnitus from transient ear noise (brief spontaneous tinnitus)	Transient ear noise is a sudden whistling sound accompanied by the perception of hearing loss. The event is unilateral and seems to occur completely at random without anything precipitating the sudden onset of symptoms. Often, the ear feels blocked during the episode. The symptoms generally dissipate within a period of about a minute. Transient ear noise, sometimes also called brief spontaneous tinnitus, is normal.
3. Assessment of tinnitus and associated hearing loss	Patients with tinnitus commonly attribute hearing problems to tinnitus. The clinician should determine how much of a patient's complaint is due to a hearing problem and how much is due specifically to the tinnitus. Such assessment may require an audiologic examination and appropriate questionnaires.
4. Tinnitus can be temporary	Exposure to loud noise can cause temporary threshold shift as well as temporary tinnitus. Tinnitus induced in this fashion will likely resolve within a few days following the insult. Repeated episodes of noise exposure increase the likelihood that the tinnitus will become permanent.
5. Drugs and tinnitus	Tinnitus can be induced by a number of medications and drug interactions. Such tinnitus is usually temporary (typically lasting 1 to 2 weeks postexposure) but can be permanent—especially with the use of aminoglycoside antibiotics or the cancer chemotherapeutic drug cisplatin. Aspirin is well known to cause temporary tinnitus, although the dosage generally has to be rather high to induce tinnitus. Other medications that can cause temporary tinnitus include nonsteroidal anti-inflammatory drugs, loop diuretics, and quinine. Drugs used to treat mental health and sleep conditions also may trigger or exacerbate tinnitus.
6. No cure for primary tinnitus	A cure for primary tinnitus does not yet exist, and despite claims to the contrary, no method has been proven to provide long-term suppression of tinnitus. We can help patients by relieving the functional effects of tinnitus, such as sleep disturbance, difficulty concentrating, problems with hearing, and difficulty relaxing. Patients need to be informed that although tinnitus cannot be cured, they can learn to manage their reactions to it, thereby improving their QOL. Health care professionals should be compassionate regarding patients' concerns and fears about tinnitus. A brief overview of the evidence-based interventions discussed later in this guideline can be presented.
7. Current theory on the pathophysiology of tinnitus	Research suggests that tinnitus results from the compensatory adaptation of the central auditory system to hearing loss. Clinical observations establish the near universal association of tinnitus with hearing loss. Hearing loss associated with tinnitus can range in severity from minimal to profound, and most people with hearing loss do not experience tinnitus. Changes in inhibitory and excitatory neurotransmitters occur throughout the auditory pathway in association with tinnitus.

Refer to Other Professionals

Patients with persistent, bothersome tinnitus can be referred to health care professionals, particularly those who offer evidence-based approaches to tinnitus management. These would include audiologists, otolaryngologists/otologists, psychiatrists, and psychologists.

STATEMENT 7. HEARING AID EVALUATION: Clinicians should recommend a hearing aid evaluation for patients with hearing loss and persistent, bothersome tinnitus. *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunities: To promote awareness of the beneficial effect of hearing aids on tinnitus and encourage utilization of this first-line audiologic intervention for patients with tinnitus, even those who might otherwise be marginal hearing aid candidates
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: High
- Benefits: Raise awareness of potential beneficial effects of hearing aids on tinnitus; ensure that patient receives proper guidance regarding benefits and costs of hearing aids; provide patients who have hearing loss with access to information and interventions that may alleviate hearing loss and improve function/QOL
- Risks, harms, costs: Direct cost related to dispensing of a hearing aid
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perceived lack of awareness regarding the ability of hearing aids to improve QOL for patients with tinnitus
- Intentional vagueness: The level of hearing loss is not specified because hearing loss-associated tinnitus may benefit from hearing aids even if the hearing loss is only of a mild degree, or even if there is a more severe unilateral SNHL associated with the tinnitus.
- Role of patient preferences: Patient may accept or decline the recommendation to pursue a hearing aid evaluation

Table 11. Professional Organizations and Patient Support Groups for Tinnitus.

Organization	Contact Information (Website)	Description	Publication
American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS)	www.entnet.org	• Largest professional organization of otolaryngologists	• AAO-HNS *Bulletin* • *Otolaryngology–Head and Neck Surgery*
American Tinnitus Association (ATA)	www.ata.org	• Largest tinnitus patient membership and advocacy organization	• *Tinnitus Today*
American Speech-Language-Hearing Association (ASHA)	www.asha.org	• Professional association of > 166,000 audiologists, speech-language pathologists, and hearing scientists	• *American Journal of Audiology* • *ASHA Leader*
American Academy of Audiology (AAA)	www.audiology.org	• Largest professional organization of audiologists	• *Audiology Today* • *Journal of the American Academy of Audiology*
Hearing Health Foundation (HHF)	www.hearinghealthfoundation.org	• Largest private funder of hearing research	• *Hearing Health Magazine*
Tinnitus Research Initiative Foundation (TRI)	http://www.tinnitusresearch.org/	• Research foundation based in Germany • Hosts worldwide collaborations of tinnitus investigators with workshops and conferences	• *TRI* Newsletter • Proceedings of the conferences and workshops
National Institute on Deafness and Other Communication Disorders (NIDCD)	www.nidcd.nih.gov	• National Institutes of Health institute that supports and conducts research on hearing health care issues, including tinnitus	• NIDCD News Updates • *Inside* Newsletter
British Tinnitus Association	www.tinnitus.org.uk	• British organization that provides support and education about tinnitus • Hosts annual conferences • Funds research	• *Quiet* quarterly magazine
Hyperacusis Network	www.hyperacusis.net	• Support/education for those suffering from sound sensitivity and pain	

- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Supporting Text

The purpose of this statement is to recommend a hearing aid evaluation for possible hearing amplification in patients with bothersome tinnitus and hearing loss. Hearing aids can potentially improve QOL for patients and are most likely underutilized because the level of hearing loss and severity of tinnitus may not be directly correlated. Hearing aids, in general, are underutilized, as 3 of 4 people with hearing loss and 6 of 10 with moderate to severe hearing loss do not use hearing aids.[117]

Hearing aid or amplification refers to ear-level devices, which are custom fit by an audiologist or hearing aid dispenser. Sound therapy devices, including ear-level sound generators used for masking or habituation, are discussed in KAS 8.

The recommendation of hearing aids for tinnitus is mostly based on empiric evidence. As many tinnitus patients suffer from hearing loss and benefit from the use of sound to mitigate effects of tinnitus, a natural first step is to offer them hearing aids.[24] Survey and case control studies have shown that some tinnitus patients who use their aids consistently have reduced symptoms.[118,119] The prospective studies of hearing aids for relief of tinnitus are generally of low quality. These studies are limited by methodologic issues that include selection bias, small sample size, short treatment duration, and use of confounding additional treatments such as sound therapy and/or counseling.[120-124]

Hearing amplification can improve a patient's QOL by both treating hearing loss and making the tinnitus less noticeable. Based on long-term retrospective studies, patients suffering from hearing loss and tinnitus receive at least modest benefit from amplification in coping with their tinnitus.[118,125,126] The conclusions and generalizability of these studies are limited by selection bias, issues with control groups, and use of counseling for tinnitus in controls and active treatment (hearing aid) groups.

It is unfortunate that the expense of hearing aids is usually not fully covered by medical insurance plans. Medicare does not provide coverage for hearing aids. Compliance with hearing aids is low even for those with documented hearing loss. Chien and Lin[127] analyzed National Health and Nutritional Examination Surveys data from 1999 to 2006 and noted that hearing aids were used by only 14.2% of individuals ≥ age 50 years with hearing loss as defined by a pure tone average > 25 dB HL. These authors

Table 12. Examples of Sound Therapy Device Options.

Device	Example
Environmental enrichment devices	• Tabletop sound machines generate different types of nature and/or environmental sounds (eg, rain, wind, waterfall) • CD recordings or personal audio players generate music, nature sounds, and/or environmental sounds through speakers • Tabletop water fountains • Fans, TV, radio • Smartphones or tablets with apps specifically created to produce a variety of sounds that aid in tinnitus relief
Hearing aids (see KAS 7)	• Digital signal processing devices allow for flexibility in manipulating the acoustic signal based on the patient's hearing loss severity and audiometric configuration • Open-fit hearing aids permit normal entry of environmental sounds into the ear canal, promoting a masking/partial masking effect
Sound generators	• Ear-level sound generators that produce broadband noise(s) (eg, white noise, pink noise) are a choice for patients with normal or near-normal audiometric thresholds • Available in in-the-ear or behind-the-ear styles
Combination tinnitus instruments	• Contain hearing aid circuit and noise-producing circuit in the same device • Allow patients who have both hearing loss and tinnitus to use a single device • Hearing technology is now available that incorporates wireless, portable, audio-streaming devices that can be connected, via a mini-jack plug or Bluetooth, to a variety of audio sources (eg, MP3 player, smartphone, tablet)

estimated that almost 23 million older Americans with documented hearing loss did not use hearing aids. A recent review of studies of hearing aid nonuse identified key issues with hearing aid value, amount of perceived benefit, and fit and comfort of the devices.[128] Although minor problems associated with hearing aid use include skin hypersensitivity, cerumen impaction, or recurrent otitis externa, these issues usually can be managed with appropriate fitting and follow-up.

Despite the lack of high-quality evidence supporting hearing aids as a treatment for tinnitus, the GDG felt that recommending a hearing aid evaluation would enable tinnitus patients to make better decisions about whether to proceed with a hearing aid trial. Although Shekhawat et al[129] acknowledged the general low quality of evidence in a review of the use of hearing aids for tinnitus, they did report that 17 of 18 reviewed trials showed benefit with hearing aid use. Given the improvement in communication functions and health-related QOL following the provision of amplification[130] coupled with the potential benefits of tinnitus relief with minimal risks, evaluation for hearing aid use is a reasonable recommendation for patients with tinnitus and documented hearing loss.

STATEMENT 8. SOUND THERAPY: Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus. *Option based on RCTs with methodological concerns, with a balance between benefit and harm.*

Action Statement Profile

- Quality improvement opportunity: To promote awareness and utilization of sound therapy as a reasonable management option in patients with persistent, bothersome tinnitus
- Aggregate evidence quality: Grade B, based on RCTs with methodological concerns
- Level of confidence in the evidence: Medium, as strength of evidence is low
- Benefits: Access to technology/devices that may relieve tinnitus; improve QOL, sleep, and concentration
- Risks, harms, costs: Consequences of recommending an intervention of uncertain efficacy; promoting false hope; costs associated with sound therapy
- Benefit-harm assessment: Equilibrium
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Significant role in deciding whether to pursue sound therapy and to choose among the available options
- Exclusions: None
- Policy level: Option
- Difference of opinion: One GDG member expressed a difference of opinion about mechanisms of sound therapy, in particular with the concepts of partial and total masking.

Supporting Text

The purpose of this statement is to inform clinicians about the role of sound therapy as an option for treatment of persistent, bothersome tinnitus. Sound therapy is used to induce a sense of relief from the stress of tinnitus, reduce the contrast between the environment and the patient's perception of the tinnitus, and distract attention from the tinnitus, using a variety of acoustic device options (**Table 12**).

Proposed Mechanism of the Benefits of Sound Therapy for Tinnitus

Sound therapy for tinnitus is defined as any use of sound intended to alter the tinnitus perception and/or reactions to tinnitus for clinical benefit. Hearing aid use for tinnitus relief has been discussed in KAS 7. Numerous methods of sound therapy have been used since tinnitus masking was introduced in the 1970s.[131,132] Two general types of sound therapy approaches have been investigated for tinnitus management: partial masking and total masking. Both employ broadband noise sound generators, hearing aids, or combination devices (sound generator and hearing aid circuitry housed in the same unit) in the management process. The clinical application of sound therapies has generally focused on managing *reactions* to tinnitus and suppressing *perception* of tinnitus. Evidence is currently lacking that the tinnitus can be suppressed using acoustic stimulation.[133]

Sound therapy is thought to provide relief from tinnitus[134] and reduce the emotional consequences of tinnitus. Some individuals experience residual inhibition following total or partial masking (ie, tinnitus suppression or temporary disappearance of the tinnitus sensation after exposure to an external sound). Sound therapy may promote habituation to the tinnitus by reducing the contrast between the tinnitus and environmental sound,[131,132,135] provide sounds that are soothing to induce a sense of relief from stress or tension caused by tinnitus,[136] or provide sounds that are interesting with the goal of distracting the patient's attention away from the tinnitus (active attention diversion).[136] The specific parameters of sound therapy that optimally provide tinnitus benefit are not yet established.

Evidence to support most tinnitus treatment strategies used in current practice is either lacking or of poor quality,[137] including the use of sound therapy.[138] Hobson et al[120] performed a systematic review of sound therapy for tinnitus and concluded that studies of sound therapy for tinnitus have generally been of low quality, and analysis of these studies did not show that sound therapy on its own provides significant benefit. These authors noted that this "absence of conclusive evidence should not be interpreted as evidence of lack of effectiveness," and they stated that "optimal management may involve multiple strategies."

A recent AHRQ CER[36] evaluated 4 RCTs assessing 5 different sound technology interventions in head-to-head comparisons. Two of the studies evaluated whether benefits are enhanced when sound generators are combined with other management options such as CBT, informational counseling, or relaxation therapy. Although half of the studies reported benefit from sound therapy, none showed any significant differences between treatments. This AHRQ review considered tinnitus retraining therapy (TRT) to be a "psychological and behavioral intervention." All studies included in the review demonstrated insufficient strength of evidence due to high risk of bias and imprecise estimates due to small sample sizes. Yet, results of RCTs may be somewhat misleading when patients with tinnitus are treated as a homogeneous group. That is, sound therapy treatment effects for individual patients may be washed out due to reported mean data, lax inclusion/exclusion criteria, and existence of subtypes of tinnitus that respond differently to treatments.[108,139,140]

Some Examples of Sound Therapy for Tinnitus

The primary objective of tinnitus masking therapy (TMT) is to use sound, primarily broadband noise, to induce tinnitus relief and promote habituation.[141] The aforementioned review of TMT in the management of adults with tinnitus[120] did not find strong evidence of benefit. Only 6 trials met inclusion criteria, and these trials varied in design, type of sound therapy device used, and outcome measures employed to evaluate treatment effect.

Tinnitus habituation is defined as an adaptation process of the auditory system that reduces the perceived signal intensity of the tinnitus as well as an individual's reaction to the tinnitus.[30] Tinnitus retraining therapy, a modification of habituation therapy,[142,143] is composed of 2 major components: (1) maskers set at the "mixing point" (ie, where the masking noise and tinnitus blend together) or slightly below the patient's perceived tinnitus (ie, partial masking); and (2) "directive" counseling, which is primarily educational in content. Recently, it has been shown that total masking can also promote habituation.[144]

Phillips and McFerran[145] performed a systematic review of the literature to assess the efficacy of TRT and included trials that compared TRT with either no treatment or other forms of tinnitus therapy. Only 1 trial[146,147] met inclusion criteria. Most studies were excluded because they used modified versions of the TRT protocol. The single included study found benefit for TRT in the treatment of tinnitus based on validated outcome measures (THI, THQ, and Tinnitus Severity Index); however, the study had methodological flaws that included problems in subject allocation, lack of blinding, and perhaps inability to generalize to the entire tinnitus population, as most subjects were male veterans with a history of noise exposure.

Criticism of the original description of TRT includes acknowledgment that there may be a need for additional psychological intervention (beyond directive counseling) such as CBT/cognitive restructuring techniques.[148,149] Furthermore, several roadblocks to the habituation process posed by patients undergoing sound therapy have been suggested, including an elevated arousal state, avoidance of exposure to external noise and/or tinnitus, and negative beliefs about tinnitus.[150]

Because music therapy may have health and wellness-related benefits,[151] it has been used as an alternate sound therapy for tinnitus. For example, neuromonics tinnitus treatment (NTT) was developed using an acoustic desensitization protocol combining music and ongoing counseling.[152] The NTT body-worn device generates spectrally modified music (compensating for the patient's hearing loss) delivered to the ears using noise that is embedded within the music stimuli. In a second phase of NTT, the noise is removed. Neuromonics tinnitus treatment has been the subject of several peer- and non-peer-reviewed clinical studies conducted by developers of this intervention protocol[153-157]; however, the reported merits of

NTT have been questioned, based on the lack of "methodological transparency" of published papers, limited independent investigations demonstrating long-term benefit in a large sample of patients, and a dearth of studies comparing this approach to other sound therapy options.[158]

Harm versus Benefit of Sound Therapy

Despite the paucity of systematic reviews and RCTs demonstrating clear-cut evidence for sound therapy in alleviating bothersome tinnitus, there is an extensive body of literature describing the underlying rationale, clinical methodologies, and success rates for different sound therapy approaches.[159-163] No side effects or morbidity have been reported from the use of any sound therapy intervention or placebo therapy.[36] Sound therapy has the disadvantages of cost, inconvenience, and dissatisfaction. Therefore, patients seeking sound therapy must be provided realistic expectations regarding potential outcomes as well as costs (both emotional as well as financial) associated with the various forms of sound therapy. Sound therapy may be a reasonable management option to offer patients when appropriate counseling is provided by the clinician.

STATEMENT 9. COGNITIVE BEHAVIORAL THERAPY: Clinicians should recommend CBT to patients with persistent, bothersome tinnitus. *Recommendation based on RCTs, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To promote awareness and utilization of CBT as an effective management option in patients with persistent, bothersome tinnitus
- Aggregate evidence quality: Grade A, based on multiple systematic reviews of RCTs
- Level of confidence in the evidence: Moderate, based on concerns about methodology and sample size of trials
- Benefits: Treatment of depression and anxiety; improved QOL, tinnitus coping skills, and adherence to other tinnitus treatments
- Risks, harms, costs: Direct cost; time involved (multiple sessions, 1-2 hours each); availability to services may be limited
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences in opinion: None

Supporting Text

The purpose of this statement is to support the use of CBT for persistent, bothersome tinnitus. Cognitive behavioral therapy, originally developed for treatment of depression and anxiety, has been shown to be effective in the treatment of tinnitus-related distress (**Figure 2**).

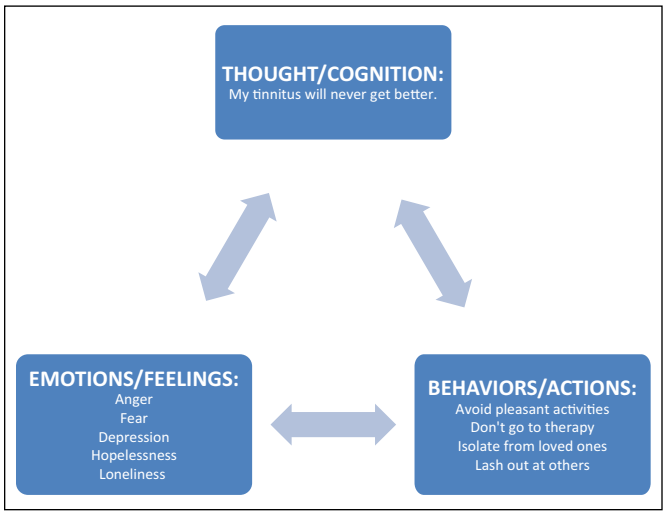

Figure 2. Cognitive behavioral therapy for tinnitus-related distress.

Cognitive behavioral therapy teaches skills to identify negative thoughts that result in distress and restructure them so the thoughts are more accurate or helpful (**Table 13**). For example, a tinnitus patient may have the thought, *I won't enjoy dinner because I won't be able to hear over my tinnitus*, which leads to the behavior, *Do not go to dinner*, and the feeling, *Sad because my wife went to dinner without me*. With CBT, the alternate thought could be, *I might not be able to hear over my tinnitus but I might still enjoy the food and atmosphere*, with the resulting alternate behavior, *Go to dinner and see if you enjoy yourself*, and an alternate outcome/feeling, *Enjoying the food and feeling content*. The treatment also includes behavioral interventions such as learning relaxation techniques, exposure to feared stimuli, instruction on sleep hygiene, and auditory enrichment. An example of an 8-week tinnitus treatment program using CBT is detailed in **Table 14**.

A beneficial effect of CBT for patients with tinnitus is suggested by several systematic reviews, although conclusions must be tempered by the modest sample sizes and combinability of the included studies. Andersson and Lyttkens[164] analyzed 18 studies of psychological treatments for tinnitus and concluded that CBT was more effective than behavioral treatments alone. A Cochrane review by Martinez-Devesa and colleagues[165] later found CBT to offer a significant improvement in the depression associated with tinnitus and QOL (decrease of global tinnitus severity) in 8 trials but did not find any effect on subjective tinnitus loudness in 6 trials. Hesser et al[166] reviewed 15 studies and found sustained benefits of CBT on tinnitus-specific outcome measures and smaller benefits for mood outcomes. Hoare et al[138] reviewed strategies for tinnitus management identified in a guideline from the United Kingdom, of which only CBT had adequate data for statistical pooling that showed moderate efficacy to be reasonably established. In contrast to the reviews just discussed, the evidence report from AHRQ found low strength of evidence to support CBT, but their review included studies of interventions that did not include a cognitive component.[36]

Table 13. Example Thoughts and Alternate Thoughts about Tinnitus.

Baseline Thought	Alternate Thought	Technique
I have tinnitus; life is rotten.	I have tinnitus and parts of life are rotten and parts of life are good.	Identifying thought distortion—*discounting the positive*
I'll never get better.	I might get better; I might not.	Identifying thought distortion—*predicting the future*
Tinnitus never goes away; I can't shut it off.	Sometimes the tinnitus is not as loud.	Identifying thought distortion—*all or none thinking*
No one can be happy if they have tinnitus.	Some people have learned to be happy and still have tinnitus.	Identifying thought distortion—*focusing on negative*
Tinnitus makes my life miserable.	I have tinnitus and sometimes I am miserable, but not every minute of the day.	Identifying thought distortion—*all or none thinking*
I cannot stand this another minute.	I would prefer not to have this another minute, but I have been standing it and can continue to do so. I can also listen to some relaxing music or go fishing, and distract myself or enjoy myself a bit.	Identifying thought distortion—*predicting the future*
I can't cope with this; there is nothing I can do about it.	I have been coping with it, perhaps not so well; maybe I can learn some coping techniques if I go to therapy.	Identifying thought distortion—*predicting the future*
I can't escape from this; there is nothing I can do about this.	My tinnitus is present all the time but the volume fluctuates and sometimes it is not as noticeable, like when I am at the beach.	Identifying thought distortion—*all or none thinking*
This will drive me crazy; I will kill myself.	Right now, I feel like I am at my wits' end, but it has been intense for a while and I haven't killed myself yet. Perhaps therapy will help. I won't know if it will help if I don't try.	Identifying thought distortion—*catastrophizing*
I can't sleep; I won't be able to function tomorrow, and then I can't make a living.	I have had a rough night of sleep; however, I have been able to work many times in the past with little sleep. I am not as efficient with work when I have slept poorly, but it is unlikely I will get fired. If they keep X around, I feel confident I won't get fired. Even on my worst day, my work is better than that of X.	Identifying thought distortion—*catastrophizing*

Most studies of CBT for tinnitus involve 8 to 24 weekly sessions, each lasting 60 to 120 minutes. Benefits persist for 12 months and longer. Cognitive behavioral therapy has been used to treat tinnitus for 3 decades, and 1 study with 15-year follow-up showed stability of improvement after the end of such therapy.[167] Cognitive behavioral therapy can be delivered to individuals or to a group. Most studies of CBT and tinnitus have investigated group therapy for people with persistent tinnitus. Cognitive behavioral therapy can also be performed remotely using online resources.

Cognitive behavioral therapy is usually provided by a mental health professional (MHP). Audiologists or other health professionals trained in cognitive behavioral intervention can also provide this treatment. Studies of CBT for tinnitus have included CBT performed by therapists with varying degrees of training and expertise. In clinical practice, most MHPs have CBT training, specifically for mental health conditions. Many professionals would be able to generalize their skills to treat physical conditions, but treatment of physical conditions with psychotherapy is considered a unique subspecialization for MHPs. A recent Cochrane review of CBT for tinnitus included 8 trials with a total of 468 participants.[165] Although CBT did not reduce tinnitus loudness as assessed by subjective reports, it did improve the well-being of tinnitus patients based on validated questionnaires, such as the THQ and TRQ.

Internet-delivered CBT has become popular and is compelling because of the potential for improved access to such treatment. Patients with persistent tinnitus were randomized to either Internet-based CBT or a wait-list control group; significantly more patients after active treatment had a 50% reduction in their TRQ score.[168] One-third of the patients who completed treatment (23% in the intent to treat analysis) maintained this level of improvement at 1 year follow-up. Internet-delivered CBT and group CBT provided similar improvements in tinnitus immediately posttreatment and at 1 year follow-up.[115] Internet-based treatment was less costly and time intensive for therapists. Although Internet-based CBT appears to be a viable treatment delivery method for tinnitus management, these protocols are not yet available to the general public.

A comparison of treatment using either Internet-based CBT, Internet-based acceptance and commitment therapy (ACT), or a control Internet-based discussion forum showed

Table 14. A Representative 8-Week Cognitive Behavioral Therapy Program for Tinnitus.

Week	Program Intervention
1	• Discuss cognitive behavioral therapy model • Assign homework
2	• Review homework • Discuss recognizing emotions vs thoughts • Assign homework
3	• Review homework • Discuss identifying thought distortions and helpful vs unhelpful thoughts • Assign homework
4	• Review homework • Discuss establishing alternate thoughts • Assign homework
5	• Review homework • Discuss relaxation techniques • Assign homework
6	• Review homework • Discuss improving your sleep • Assign homework
7	• Review homework • Discuss increasing pleasant activities and activity tracking • Assign homework
8	• Review homework • Discuss goal setting • Review what skills have been helpful

that both CBT and ACT outperformed the control condition immediately posttreatment and at 1 year follow-up.[28] Acceptance and commitment therapy focuses on acceptance of one's condition and commitment to living one's life. The benefit of ACT for tinnitus was greater than that of TRT for problems with sleep and tinnitus effect.[169]

Although potential risks of CBT include possible patient anxiety during discussion of thoughts and behaviors in a group or individual treatment, no adverse events were reported in the trials of CBT for tinnitus. Cognitive behavioral therapy is covered by Medicare and other insurance plans, but many mental health professionals do not accept insurance for these services, increasing direct costs to the patient.

STATEMENT 10. MEDICAL THERAPY: Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus. *Recommendation (against) based on systematic reviews and RCTs with methodological concerns, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To decrease the use of medications that may have no benefit and have significant potential side effects, in the management of patients with tinnitus
- Aggregate evidence quality: Grade B, based on RCTs with methodological concerns and systematic reviews demonstrating a low strength of evidence
- Level of confidence in the evidence: Medium regarding the lack of efficacy of medical therapy as a primary treatment for persistent bothersome tinnitus, as several studies with methodological flaws, bias, and lack of power did show some benefit in certain tinnitus outcome measures
- Benefits: Avoid unproven therapy, side effects/adverse events (including tinnitus), and false hope; reduce expense. Avoid use of medications that are not approved for use in geriatric population.
- Risks, harms, costs: Denying some patients benefit
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Although these therapies appear to be beneficial in some studies, the evidence from systematic reviews and RCTs is insufficient to justify routine use in managing tinnitus patients, especially given the known harms, cost of therapy, and potential for some medications (eg, antidepressants) to worsen tinnitus.
- Intentional vagueness: The term *routine* is used to acknowledge that there may be individual circumstances for which clinicians and patients may wish to pursue therapy.
- Role of patient preferences: Limited; a trial of medication may be administered based on individual circumstances
- Exclusions: Patients with depression, anxiety, or seizure disorders that constitute an indication for pharmacologic therapy independent of tinnitus
- Policy level: Recommendation (against)
- Differences in opinion: None

Supporting Text

The purpose of this statement is to avoid the routine use of medications for tinnitus, as medications have not been shown to alleviate tinnitus and may have adverse effects. At this time, there are no medications approved by the US Food and Drug Administration (FDA) for treatment of tinnitus. No medications have been shown to reliably eliminate or reduce tinnitus perception. Benefits of the recommendation against use of medications in routine treatment of tinnitus include avoiding unproven therapy, avoiding side effects (including production or worsening of tinnitus), avoiding false hope, avoiding the use of medications that may be harmful in certain patient populations (such as the elderly), avoiding the potential for substance use disorder, and avoiding unnecessary medication costs. This key action statement does not apply to those patients with comorbid disorders, such as anxiety, seizure disorder, or depression, where treatment with these agents could be indicated and useful.

The AHRQ CER analyzed 13 studies regarding the use of antidepressants, neuromodulators, and other drugs such as intratympanic steroid injections in relation to tinnitus-specific QOL

and subjective loudness outcomes.[36] Whereas the review identified 6 studies that favored treatment over control for tinnitus-specific QOL outcomes[169-174] and 5 studies that favored treatment over control for subjective tinnitus loudness outcomes,[169,173-176] selection and other bias, small sample sizes, and imprecise effect estimates led to an assessment of low or insufficient strength of evidence for these outcomes.

Antidepressants

Antidepressants are not recommended for treating tinnitus based on results from 7 RCTs and 1 Cochrane review that failed to demonstrate a preponderance of benefit over harm. Antidepressants have been investigated as a treatment for tinnitus, as the auditory cortex is rich in serotonin receptors, and there is a strong correlation between annoyance from tinnitus and the presence of depression and/or anxiety disorders.[177-179]

Although 4 of 7 trials of antidepressants for tinnitus showed significant improvement of tinnitus measures, these trials had significant methodological limitations, heterogeneity of inclusion and outcome measures, and lack of generalizability to patients without depression. The most recent Cochrane review included 4 trials of tricyclic antidepressants, 1 trial of trazodone, and 1 trial of a selective serotonin reuptake inhibitor (paroxetine).[170,171,180-184] Of these trials, 4 are double blind, 1 is single blind, and 1 does not clearly state blinding. Three of the tricyclic antidepressant trials showed modest improvement of tinnitus, but the treatment effects may have been related to modulation of depression and anxiety rather than any change in character or intensity of tinnitus.[171,182,183] Methodological concerns in these trials included dosing issues, failure to use validated tinnitus questionnaires, and small numbers of subjects.[169-171,181-184]

Commonly reported side effects of antidepressants include sexual dysfunction, drowsiness, and dry mouth; more subjects dropped out of the treatment groups than the placebo control groups of trials. It is also concerning that tinnitus is listed as a rare side effect of all available antidepressants.

Anticonvulsants

Anticonvulsants are not recommended for treating tinnitus based on results from 8 RCTs and a Cochrane review that failed to demonstrate a preponderance of benefit over harm. Anticonvulsants potentially suppress central auditory hyperactivity that may be related to tinnitus. Anticonvulsants are believed to reduce tinnitus by augmenting the action or levels of neurotransmitters (gamma-aminobutyric acid [GABA], glutamate) or via the inhibition of cell depolarization by blocking voltage gated sodium channels.[185] None of the RCTs of anticonvulsants for tinnitus have shown a clear benefit. A recent Cochrane review of 7 placebo-controlled trials of anticonvulsants for chronic tinnitus found no improvement of tinnitus or health-related QOL.[185-192] A small, favorable effect of anticonvulsants was seen in this meta-analysis when measuring "any improvement" in self-assessment of tinnitus, but no effect was seen on near or total eradication of tinnitus annoyance.[185]

A randomized placebo-controlled trial of an 8-week treatment with gabapentin in an escalating dosing scale,[193] published subsequent to the Cochrane review, showed no differences between gabapentin and control groups when assessing the tinnitus severity index or loudness scores. A small subgroup of patients with hypertension, diabetes, or dyslipidemia showed a significantly better response to gabapentin than those without these comorbidities. Of note, side effects of anticonvulsants reported during these RCTs were significant, most commonly nausea, dizziness, and headaches.[185,194]

Anxiolytics

Anxiolytics, such as benzodiazepines, should not be used to treat tinnitus, because clinical trials do not consistently show benefit. These medications can have adverse effects, particularly in the elderly, unless dosing is carefully monitored and tailored with drug holidays. A double-blind, placebo-controlled study of alprazolam showed decreased tinnitus loudness based on tinnitus matching as well as with a visual analogue scale.[176] However, another trial of alprazolam with a triple-blind randomized crossover design, using an active control, chlorpheniramine, to simulate the effect of drowsiness, did not find a significant difference in THI or tinnitus loudness but did find a significant improvement in a visual analog scale for tinnitus severity.[195] A single-blind randomized study of 66 patients treated with diazepam, flurazepam, oxazepam, clonazepam, and carbamazepine demonstrated improvement on a tinnitus visual analogue scale with oxazepam and clonazepam.[196] However, this study did not assess tinnitus loudness or use validated questionnaires, and subjects received more than 1 medication during the trial.

Other Agents

Acamprosate, a medication that is used to treat alcohol dependence, regulates GABA- and glutamate-mediated neurotransmission. Two RCTs of this medication for treatment of tinnitus did show favorable results but had methodologic issues, and the evidence is insufficient to recommend such treatment.[172,175]

Intratympanic Medications

Intratympanic steroid injections are not recommended for treating tinnitus based on results from 3 prospective RCTs.[174,197-199] Intratympanic dexamethasone injections[197] and intratympanic methylprednisolone[174] produced no benefits over placebo saline injections when measuring subjective tinnitus severity scores. A third study randomized patients to intratympanic prednisone injection, intratympanic dexamethasone, and oral carbamazepine. Although no benefit for intratympanic steroids was seen over carbamazepine, absence of a placebo group prohibited further conclusions regarding treatment effect.[198] Side effects reported in these studies were minimal, most commonly vertigo, otalgia, and aggravation of tinnitus.

Intratympanic lidocaine injection is not recommended for treating tinnitus. No RCTs exist that support this treatment. Substantial side effects of this treatment were seen in 2 studies performed without controls, including severe vertigo, nausea, and vomiting.[182,200]

STATEMENT 11. DIETARY SUPPLEMENTS: Clinicians should not recommend Ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients with persistent, bothersome tinnitus. *Recommendation (against) based on RCTs and systematic reviews with methodological concerns, with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: To avoid use of commonly available supplements that have no proven efficacy and pose potential harm, in the management of patients with tinnitus
- Aggregate evidence quality: Grade C, RCTs and systematic reviews with extreme heterogeneity; most of the RCTs raise significant concerns regarding methodology and subject selection
- Level of confidence in the evidence: High confidence regarding potential harm and adverse effects related to these agents, particularly in the elderly population; low confidence in benefits due to methodological concerns and study quality and ability to generalize results to patients with persistent, primary tinnitus
- Benefits: Avoid unproven therapy, side effects/adverse events (including tinnitus), and false hope; reduce expense
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: There is concern regarding the actual content and dosage of proposed active agents in these preparations, as they are currently packaged over-the-counter. Many of these supplements, not under the regulation of the FDA, have varying amounts of the active agent. The GDG was concerned over the widespread availability for easy purchase of these agents without considering potential drug interactions and adverse events.
- Intentional vagueness: The term *dietary supplements* is used to generalize nutritional and herbal supplements promoted as remedies for tinnitus.
- Role of patient preferences: Limited role
- Exclusions: None
- Policy level: Recommendation (against)
- Differences in opinion: The majority of the GDG felt that there was a clear predominance of harm over benefit; a minority felt that there was equilibrium. None of the group perceived a preponderance of benefit over harm.

Supporting Text

The purpose of this statement is to highlight the lack of proven efficacy regarding use of Ginkgo biloba, melatonin, or dietary supplements for the treatment of patients with primary tinnitus. The panel recognizes that a significant number of patients use dietary supplements and other CAM therapies for the treatment of tinnitus, especially when persistent and bothersome. Of all the dietary supplements studied for the management of tinnitus, the aggregate data are mostly for Ginkgo biloba, melatonin, and zinc; therefore, this guideline will comment primarily on these supplements. The potential side effects of these agents are significant and well documented, and the studies have methodological flaws and are conflicting regarding benefit for persistent, bothersome tinnitus.

Ginkgo Biloba

Ginkgo biloba is the most commonly used herbal supplement for tinnitus. The 2 most important active ingredients, flavonoids and terpenoids, are associated with antiplatelet, antioxidant, antihypoxic, free-radical scavenging, and antiedema properties.[201] Such mechanisms of action may purportedly help reduce tinnitus through decreasing free-radical damage to the cochlea or increasing blood flow and the health of the inner ear.[202] The clinical trials used varying amounts of active ingredients, flavonoids, and terpenoids in their formulations.

The 2 latest systematic reviews included 3 RCTs on Ginkgo biloba for tinnitus as a primary complaint.[203,204] A Cochrane review, first published in 2004 and most recently updated in 2013, concluded that Ginkgo biloba was not effective,[203] whereas another systematic review determined that the Ginkgo biloba extract, EGb 761, consistently demonstrated superiority over placebo.[204]

A third systematic review included 5 RCTs and used the Jadad scale to rate the quality of each, with most trials having a low methodological rigor.[205,206] The results were favorable toward Ginkgo, but the authors stated that a firm conclusion about efficacy was not possible.[205] A meta-analysis pooled data from 6 RCTs and concluded that there was no benefit of Ginkgo over placebo.[207]

Table 15 summarizes the RCTs on Ginkgo biloba for tinnitus. Given the variation in conclusions, methodological limitations, and heterogeneity in study protocols among these RCTs, along with the conflicting comments generated from systematic reviews and meta-analyses to date, the panel recommended against using Ginkgo biloba for treating primary tinnitus. The AHRQ CER[36] on the evaluation and treatment of tinnitus included 2 studies on Ginkgo biloba, and the strength of evidence was rated as insufficient to make recommendations when evaluating tinnitus-specific QOL, subjective tinnitus loudness, global QOL, and depression.

The most frequent side effects for Ginkgo biloba include gastrointestinal symptoms, headache, nausea, and vomiting, although these are usually mild, transient, and reversible.[201] The most comprehensive review of the drug interactions involving Ginkgo looked at almost 100 clinical reports.[209] The most significant adverse effects involve the platelet inhibitory actions of the herb, particularly when taken along with other medications that impair coagulation. This has resulted in reports of hemorrhage, hematoma, apraxia, permanent neurologic deficit, and death. Because of the widespread use of anticoagulants and analgesics in older adults, it may be wise to avoid this herb in older adults as well as those with bleeding disorders or those taking medications that inhibit clotting. Other significant herb-drug interactions may occur with thiazide diuretics, resulting in increased blood pressure, and with

Table 15. Summary of Randomized Controlled Trials on Ginkgo Biloba for Tinnitus as Primary Complaint.

First Author (Year)	Design	Methodological Concern
Han (2012)	Open-label, crossover (clonazepam vs Ginkgo)	No placebo control, lack of blinding[203]
Rejali (2004)	Double-blind, placebo-controlled	High attrition rate, information lacking regarding Ginkgo's preparation, composition, or standardization[207]
Morgenstern (2002)	Double-blind, placebo-controlled	Patients pretreated with 10-day infusion of Ginkgo extract; allocation concealment unclear; very high attrition[203]
Drew (2001)	Double-blind, placebo-controlled; entire study conducted through mail and phone	Exact diagnoses uncertain; no physician-patient contact; existence and identity of patients unverifiable; no medical examination; no audiogram; questionable quality and reliability of data; difficult assessment of adverse events[207,208]
Juretzek (1998)	(A) Open study; (B) double-blind, placebo-controlled	Not evaluated, study reported as an extended summary only[206]
Morgenstern (1997)	Double-blind, placebo-controlled	None
Holgers (1994)	(A) Open study; (B) double-blind, placebo-controlled, crossover	Patients pretreated with 2-week course of Ginkgo extract[203]
Meyer (1986a)	Multicenter, double-blind, placebo-controlled	Allocation concealment unclear; attrition rate unclear; marked intergroup difference in severity of tinnitus; no drop-out data given[203]
Meyer (1986b)	Multicenter, 3-armed	Outcome measure was a specialist's evaluation[206]; no placebo control[203]

trazodone, leading to increased sedation.[210] Ginkgo may also inhibit hepatic cytochrome P450 and thereby affect metabolism of its substrates.[202]

Melatonin

Melatonin is a hormone secreted by the pineal gland that is involved with regulation of the sleep-wake cycle. Mechanisms of action that may explain its potential therapeutic effects on tinnitus include antioxidant, free-radical scavenging, and vasoregulatory properties.[211,212] It has been postulated that melatonin may modulate the central nervous system, improve hemodynamics with enhanced labyrinthine perfusion, and reduce muscular tone affecting tensor tympani contractions.[213]

Three RCTs, with a total of 193 participants, have studied melatonin to treat tinnitus, and each demonstrated benefit with the greatest improvement in those patients with severe tinnitus and insomnia. However, these results should be interpreted cautiously given the small number of overall patients studied and the methodological limitations, including lack of a placebo group in the largest trial. Although another study demonstrated potential benefit for patients with concomitant sleep disturbance due to tinnitus, this study lacked randomization, blinding, or placebo control.[214] Only 1 study reported possible adverse effects of melatonin, which included bad dreams and fatigue.[215]

Zinc

Zinc is an essential trace element found in minute quantities in living cells and fluids throughout the body. Its purported mechanisms of action affecting tinnitus involve (1) wide distribution in the central nervous system, including the auditory pathway in synapses of the eighth cranial nerve and in the cochlea, (2) an essential role with protection against reactive oxygen species through copper-zinc superoxide dismutase, and (3) a plausible effect on depression.[216-218] Prevalence rates of zinc deficiency in individuals with tinnitus range from 2% to 69%, with elderly persons affected more frequently.[218]

Three RCTs of zinc as a treatment for tinnitus, with a total of 205 participants, showed inconsistent benefit. There was some suggestion that benefit could be associated with underlying pretreatment zinc deficiency. The recent AHRQ CER[36] on the evaluation and treatment of tinnitus included 1 study of zinc treatment and concluded that this treatment, along with most other interventions, had insufficient strength of evidence to support use. Although potential adverse effects of zinc include gastrointestinal symptoms, such as diarrhea, headache, and anemia, zinc products are generally recognized as safe by the FDA (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm084104.htm). Myelopathy has been reported when zinc is given at high doses to patients with low copper levels.[219,220]

Other Dietary Supplements

Several other dietary supplements have been used for tinnitus, including lipoflavonoids, garlic, homeopathy, traditional Chinese/Korean herbal medicine, honeybee larvae, and other various vitamins and minerals. Evidence for efficacy of these therapies for tinnitus does not exist.

As compared to regulation of foods and conventional medications, the FDA regulates these dietary supplements under a different set of regulations, the Dietary Supplement Health and Education Act of 1994. These supplements may contain

Table 16. Patient Information on Dietary Supplements for Tinnitus.

- No dietary supplement or herb has been approved for the treatment of tinnitus, and none has been shown to cure tinnitus.
- Such supplements are readily available and, at present, do not need US Food and Drug Administration approval.
- Dietary supplements can cause side effects, especially when taken along with conventional medications or other supplements.
- Ginkgo biloba can interact with other blood thinners to cause serious bleeding and can worsen bleeding risk in patients with underlying clotting disorders.
- Patients with tinnitus should discuss use of dietary supplements with their physician or other health care practitioner to minimize the risk of side effects.

varying amounts of the active agent. Additional information can be found at http://www.fda.gov/food/dietarysupplements.

Clinicians should counsel tinnitus patients about the use of supplements. Representative content to frame such counseling is presented in **Table 16**.

STATEMENT 12. ACUPUNCTURE: No recommendation can be made regarding the effect of acupuncture in patients with persistent bothersome tinnitus. *No recommendation based on poor quality trials, no benefit, and minimal harm.*

Action Statement Profile

- Quality improvement opportunity: Limited, to educate patients and providers about the controversies regarding the use of acupuncture for tinnitus
- Aggregate evidence quality: Grade C, based on inconclusive RCTs and the presence of costs and potential harm with no established benefit with the use of acupuncture for tinnitus
- Level of confidence in the evidence: Low regarding benefit because of heterogeneity and methodological flaws in the RCTs; high regarding harm or cost, with the understanding that serious harm from acupuncture is rare.
- Benefits: No direct benefits of no recommendation
- Risks, harms, costs: Cost of acupuncture therapy, time required for therapy, and potential delay in instituting sound therapy or hearing aids
- Benefit-harm assessment: Unknown
- Value judgments: The poor quality of the data and the limited potential for harm from acupuncture kept the GDG from making a recommendation about acupuncture.
- Intentional vagueness: None
- Role of patient preferences: Significant role for shared decision making; patients may wish to try acupuncture based on circumstances
- Exclusions: None
- Policy level: No recommendation
- Differences in opinion: Minor: The GDG was divided between making no recommendation and making a recommendation against the use of acupuncture.

Supporting Text

The purpose of this statement is to highlight uncertainty about the efficacy of acupuncture in the treatment of patients with primary tinnitus. The panel recognizes that a significant number of patients with persistent and bothersome tinnitus are consumers of CAM therapies, including acupuncture. However, given the methodological limitations as well as considerable heterogeneity of study design and results among various trials, the panel was unable to make a recommendation regarding the use of acupuncture for tinnitus.

Acupuncture, a therapeutic modality that involves insertion and manipulation of thin needles in the body, has been described specifically as a treatment for tinnitus as early as the 5th century BCE.[221] Possible mechanisms of action involved in reducing tinnitus include modulation of 1 or several of the following: neurophysiology of the olivocochlear nucleus,[222,223] nonclassical ascending auditory pathway with its subcortical connections to limbic structures and the amygdala,[224,225] neural plasticity,[226,227] somatosensory system,[228] or pain pathways akin to physiology involved in phantom limb pain.[229,230]

A systematic review in 2012 on acupuncture for the treatment of tinnitus included 9 RCTs, with a total of 431 participants.[222] Five of the RCTs used manual acupuncture (MA),[231-235] 1 used electroacupuncture (EA),[236] 1 used both MA and EA,[237] and the other 2 used scalp acupuncture.[238,239] Five RCTs compared effectiveness of manual or electroacupuncture with sham acupuncture and showed no statistically significant improvement. Two RCTs compared scalp acupuncture with sham acupuncture and demonstrated significant positive effects. Two RCTs compared acupuncture with conventional drug therapy, with 1 showing a statistically significant difference.

However, this systematic review highlighted the heterogeneity among study designs as well as their methodological limitations using the Cochrane tool for assessing risk of bias.[222] Variations in study design included types of acupuncture intervention, number of treatment sessions, duration of acupuncture sessions, frequency of acupuncture treatment, intensity of acupuncture stimulation, choice of acupoints, types of sham controls, selection of other control groups, variability with blinding, and selection of outcome measures, many of which were not validated. The authors concluded that the small number of RCTs of acupuncture for the treatment of tinnitus, with small sample size and methodologic issues, were insufficient to make conclusions about effectiveness.

A systematic review done in 2000 included 6 RCTs, of which 4 used MA and 2 used EA, with a total of 185 participants, and assessed methodological quality of these trials using the Jadad scale. Only 3 RCTs received a Jadad score of 3 points or more.[223] Four of the 6 studies used a crossover des-ign,[235,236,240,241] and 4

RCTs had a sham acupuncture control.[234-236,241] Two unblinded studies showed a positive result, whereas 4 blinded studies demonstrated no significant effect of acupuncture.

A CER on the evaluation and treatment of tinnitus was also conducted by AHRQ, which included 1 RCT on acupuncture, and concluded that the strength of evidence was insufficient to draw any conclusions when evaluating tinnitus-specific QOL and subjective tinnitus loudness.[36]

There is general consensus that acupuncture is a relatively safe treatment when administered by well-trained and experienced practitioners.[242-247] Based on prospective observational studies conducted in Europe, the incidence of mild adverse events was found to be from 4% to 10.7%, with serious adverse events ranging from 0.024% to 2.2%. The most common adverse events described were bleeding/hematoma, needling pain, fatigue, headache, fainting, and local skin irritation. Although transmission of infectious diseases such as hepatitis and human immunodeficiency virus have been reported, these occurrences are now very rare since the advent and common use of sterile, disposable needles. Caution should be exercised among patients who have a bleeding diathesis or are on anticoagulants as well as those who are pregnant, since some acupuncture points can induce labor.

STATEMENT 13. TRANSCRANIAL MAGNETIC STIMULATION: Clinicians should not recommend TMS for the treatment of patients with persistent, bothersome tinnitus. *Recommendation (against) based on inconclusive RCTs.*

Action Statement Profile

- Quality improvement opportunity: To avoid use of a therapy that has inconclusive efficacy and poses potential financial and physical harm, in the management of patients with tinnitus
- Aggregate evidence quality: Grade B, based on inconclusive RCTs and systematic reviews that show low strength of evidence
- Level of confidence in the evidence: High regarding the absence of a long-term (> 6 months) benefit of TMS; moderate regarding the absence of a short-term benefit, since a minority of trials demonstrated transient beneficial outcomes, and strength of this evidence is low
- Benefits: Avoid unproven therapy, side effects/adverse events, and false hope; reduce expense
- Risks, harms, costs: Denying some patients benefit
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exclusions: Patients with depression or other neurological conditions for which TMS is indicated
- Policy level: Recommendation (against)
- Differences in opinion: None

Supporting Text

The purpose of this statement is to avoid the routine use of TMS for treatment of tinnitus. Transcranial magnetic stimulation is a technique where specific areas of the brain are stimulated through an intact scalp. Cortical neurons are depolarized based on electromagnetic induction. Transcranial magnetic stimulation was first used in humans in 1985 to stimulate the primary motor cortex.[248] Repetitive TMS (rTMS) has been shown to induce long-term potentiation or depression of cortical excitability. Repetitive transcranial magnetic stimulation has been investigated for the treatment of chronic tinnitus as well as for depression, schizophrenia, seizures, movement disorders, and stroke. With this action statement, rTMS should not be recommended for routine treatment of tinnitus, as the best available evidence from clinical trials shows inadequate and conflicting data without proven long-term benefit.[249]

Transcranial magnetic stimulation is applied using coils that contact the patient's scalp and deliver intermittent magnetic fields of about 1 Tesla.[250] Repetitive transcranial magnetic stimulation appears to reduce neural activity in directly stimulated areas of the brain as well as structurally connected remote areas. The perception of tinnitus has been associated with abnormal activity in central auditory pathways, or *dysfunctional neuroplastic processes*, as demonstrated by functional imaging.[251] Thus, rTMS has been used to treat tinnitus.

Although some studies have shown improvements in tinnitus severity and longer durations of tinnitus suppression after rTMS, methodological issues with these studies included small sample size, inadequate placebo conditions, variations in patient entry criteria, and differences in outcome measures.[252-254] Randomized controlled trials and systematic reviews of available evidence have not demonstrated lasting reduction of tinnitus or improvements in patient QOL with rTMS.

Piccirillo et al[255,256] performed 2 trials of rTMS and found no differences in improvement in tinnitus severity between active rTMS and sham stimulation over 2 weeks or 4 weeks, as measured by changes in the THI. Anders et al[257] conducted an RCT of 42 tinnitus patients and found a very small improvement in tinnitus severity as measured by the THI or the Tinnitus Questionnaire after active rTMS as compared to a placebo condition, but no improvement was seen when tinnitus severity or perceived disruption of daily activities was assessed with visual analog scales. Plewnia et al[258] performed an RCT of a type of rTMS called theta burst stimulation in 48 patients with chronic tinnitus, randomized to temporal cortex stimulation, temporoparietal cortex stimulation, and sham stimulation over the mastoid. Although tinnitus severity was slightly reduced in all 3 groups, there were no significant differences between the sham group and the temporal or temporoparietal stimulation groups.

A recent Cochrane review identified 5 RCTs of rTMS for tinnitus, totaling 233 patients who met inclusion criteria.[259] These trials compared active rTMS with placebo rTMS, and crossover trials were not included. The included trials used a variety of placebo conditions, and the primary outcomes in

these trials were measured using validated instruments such as the THI, the Tinnitus Questionnaire, and others. Only 1 study showed statistically significant improvement in THI at 4 months' follow-up after low-frequency rTMS therapy, but 2 other studies of similar rTMS treatment showed no statistically significant improvement. These authors pooled the results from 2 studies and found significant reduction in tinnitus loudness after rTMS, but the sample size was small and the confidence interval wide. Meng et al[259] concluded that there was limited support for the use of rTMS to treat tinnitus but also noted that 5 additional trials were ongoing at the time of their review.

Peng et al[260] performed a systematic review of RCTs of rTMS that included 5 trials, 3 of which were included in the aforementioned Cochrane review and 2 were not. Meta-analysis was not performed because of design variations and differences in tinnitus assessment among the trials. In 2 of the studies that used THI as the primary outcome measure, initial reduction in THI was seen at the first short-term assessment after active rTMS. These 2 trials showed reduction in THI lasting for 6 months. Similar transient improvement was seen in a study that used a visual analog scale as a tinnitus measure. Variation in patient population, stimulation parameters, and study design makes comparison of trials difficult. Long-term benefits of rTMS for treatment of tinnitus were not demonstrated.

The recently released AHRQ CER on the evaluation and treatment of tinnitus contained an analysis of 6 studies of rTMS or electromagnetic stimulation for tinnitus. Evidence was rated as insufficient, due to small sample sizes, high risk of bias, and effect estimates with wide confidence intervals.[36] The rTMS trials included in this review had low strength of evidence for evaluation of changes in tinnitus-related QOL measures, and none of the trials evaluated subjective tinnitus loudness.

The principal risk of rTMS is provocation of seizures, with the greatest risk in patients who have a history of epilepsy or brain lesions and in those taking medications that lower seizure threshold (ie, antidepressants).[261] Low-frequency rTMS in healthy patients, with appropriate stimulus intensity that approximates the resting motor threshold, is unlikely to produce seizures. Although the frequency of severe adverse effects of rTMS appears to be low in the reviewed trials, the AHRQ report on tinnitus noted that such events were in general poorly evaluated and reported.[36] In addition, long-term complications of rTMS cannot be appreciated in trials with generally short follow-up periods. Exclusion criteria for rTMS research subjects or patients have included focal brain lesions, neurodegenerative diseases, pacemakers or other electronic implants (cochlear implant), seizure history, or medications that lower seizure threshold.[250] In addition, rTMS can cause local pain and discomfort during the procedure and transient headaches afterward.

Implementation Considerations

This clinical practice guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. A full-text version of the guideline will be accessible, free of charge, at http://www.entnet.org. In addition, all AAO-HNSF guidelines are now available via the *Otolaryngology–Head and Neck Surgery* app for smart phones and tablets. The guideline will be presented to AAO-HNS members as a mini-seminar at the 2014 AAO-HNSF Annual Meeting & OTO EXPO. Existing website content, brochures, and publications by the AAO-HNSF will be updated to reflect the guideline's recommendations. Podcasts will be developed to introduce the recommendations of this guideline to target clinicians. A plain language summary will be developed to help lay persons navigate the recommendations of this guideline, with emphasis on avoiding unproven and potentially harmful tinnitus treatments. In addition, we have developed a flow chart for clinicians (**Figure 1**) to help clinicians understand the key decisions for evaluation and management of tinnitus as well as to demonstrate the appropriate target patients for the recommendations of this CPG.

The GDG agreed that the action statements likely to generate the most discussion among clinicians are those recommending against the use of conventional medical therapies and CAM (including dietary supplements). The group recognized the wide use of a variety of medications for tinnitus, as well as a number of available CAM treatments for tinnitus. The quality of available evidence did not support the use of such medications. Suggestions for future study of these agents for tinnitus, with strict methodology, are detailed in the next section.

The GDG also discussed the cost and availability of recommended interventions, such as hearing aid evaluation, sound therapy devices, and cognitive behavioral therapies. These treatments are often excluded from traditional medical insurance coverage, and specialists who can evaluate and recommend these treatments for tinnitus may not be available to the large number of persons with persistent, bothersome tinnitus.

Research Needs

The large number of interventions for tinnitus, the limitations of the existing studies, and the difficulties with assessing effect of tinnitus help us identify areas that would benefit from further study and clinical research. In general, clinical trials of interventions for tinnitus need (1) well-defined entry criteria with regard to duration and severity of tinnitus, presence of comorbid medical and psychiatric conditions, and the prior use of therapies; (2) use of a validated instrument to assess effect of tinnitus on QOL and daily functions as well as a reliable assessment of perceived tinnitus loudness (these instruments and assessments should also reliably assess changes afforded by the treatment intervention); (3) careful selection of the placebo as well as randomization/blinding; (4) short- and long-term assessments; (5) adequate sample size; and (6) study of a population of tinnitus patients who are representative of most patients who suffer from this symptom, to allow generalizability of results. Recommendations for future research have been made in the recent AHRQ CER[36] and several authors have made suggestions for improvement of tinnitus trials.[262,263]

The GDG has also suggested the following:

- Future clinical trials should be registered into databases such as ClinicalTrials.gov or the International Clinical Trials Registry Platform and adhere to the Consolidated Standards of Reporting Trials (CONSORT) statement to facilitate synthesis of evidence. Adequate power should be achieved during study recruitment to detect meaningful differences in outcomes.
- Future studies of tinnitus should be methodologically enhanced in terms of reducing wide variations in patient characteristics, better defining the nature of tinnitus on entry (eg, auditory, emotional, and attentional features), and improving uniformity in the selection of validated outcome measures in order to assess clinically relevant changes in tinnitus severity and effect. Future studies of tinnitus should use both audiologic testing and validated questionnaires for reliable and reproducible results and incorporate patient-reported outcomes with validated psychometric properties.
- Assess the validity and responsiveness of each of the various instruments used in tinnitus trials.
- Tinnitus trials should include a broader, more representative population of adults in terms of age, sex, and race/ethnicity in future clinical trials of tinnitus therapy.
- Future studies of tinnitus treatments should control for the use of confounding medications and other therapies that could affect the severity and perception of tinnitus.
- Include global QOL measures into clinical trials to assess how patients with tinnitus value the risk-benefit trade-off between benefits and harms of therapy.
- Determine which validated tinnitus questionnaire is most effective in assessing the severity of tinnitus effects in patients. Determine which questionnaire is most useful for assessing relevant treatment effects.
- Surveys or cohort studies are needed to determine which clinicians are approached first by patients with tinnitus (eg, otolaryngologists, audiologists, primary care physicians, psychiatrists) (where do tinnitus patients go for initial evaluation?). Are there differences in the characteristics of tinnitus patients who see primary care providers compared to those treated by tinnitus specialists?
- Epidemiological studies are needed to establish duration/natural history of recent onset tinnitus and determine the time to spontaneous resolution of tinnitus when this occurs.
- Document the most common medical and/or psychiatric comorbidities in patients with tinnitus.
- Identify subsets of patients who respond especially well to specific treatments such as pharmacotherapy, sound therapy, and so on in open-label trials, and incorporate these specific patient subsets into subsequent RCTs.
- Conduct methodologically rigorous research into CAM therapies for tinnitus.
- Conduct surveys to determine utilization of hearing aids for tinnitus in community and academic settings, and assess the factors that could improve compliance and acceptance of hearing aids.
- Conduct surveys to determine utilization of audiology evaluation for tinnitus with or without associated hearing loss.
- Conduct surveys to determine frequency of patient education and counseling for tinnitus in community and academic settings.
- Conduct studies on acamprosate, and other "promising" medical interventions, for tinnitus treatment.
- Conduct additional studies on anticonvulsant medications for tinnitus treatment.
- Conduct studies comparing the effectiveness of CBT, ACT, and bibliotherapy (ie, providing the person with a manual on tinnitus therapy and allowing the individual to do therapy on his or her own).
- Conduct clinical trials comparing the different types of counseling treatments available for tinnitus.
- Conduct clinical trials on new therapies for tinnitus such as cochlear implantation and deep brain stimulation.
- Conduct clinical trials on auditory treatment strategies for tinnitus that could include bone conduction devices or middle ear implants.
- Conduct studies comparing the effectiveness, as well as cost-benefits, of in-person versus Internet-based CBT for tinnitus.
- Ensure that patient cohorts are stratified by concurrent depression and anxiety when conducting controlled trials of antidepressant and anxiolytic medications for tinnitus.
- Study a variety of brain stimulation techniques, such as transcranial direct current stimulation.
- Investigate rTMS, using stimulation schedules of longer duration or in combination with other treatment methods (CBT, medications, etc) to see if more prolonged efficacy can be achieved.
- Study acupuncture for tinnitus in a rigorous methodological approach, including the study of electroacupuncture; study the response to acupuncture for tinnitus patients with somatic head and neck disorders.

Disclaimer

This clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing patients with tinnitus. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not

purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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