

## CLINICAL PRACTICE

Caren G. Solomon, M.D., M.P.H., *Editor***Tinnitus**

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*This Journal feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the author's clinical recommendations.*

**A 55-year-old man reports hearing a high-pitched, static sound in both ears. He does not recall when it began, but the sound has been present for several months and is bothersome. How should this case be managed?**

## THE CLINICAL PROBLEM

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**T**INNITUS IS THE PERCEPTION OF A SOUND THAT HAS NO EXTERNAL source. The sensation is commonly described as ringing in the ear, but the sound can be perceived inside or outside the head or predominantly in one or both ears. Qualitative descriptions include humming, tonal ringing, hissing, static, roaring, or a cicada-like sound. Tinnitus can be categorized as objective or subjective. Objective tinnitus — a sound generated within the body by blood flow, muscle contractions, or spontaneous cochlear emissions that can be detected and measured by an external observer — is uncommon. This review addresses the more common variant, subjective tinnitus.

Population surveys estimate a prevalence of tinnitus of 10 to 25% among persons older than 18 years of age across various nationalities.<sup>1,3</sup> In population surveys, the sensation is reported to be severely bothersome in only a small percentage of persons with tinnitus (range, 1 to 7%).<sup>1,4,6</sup> The prevalence of persistent tinnitus increases with age, reaching a peak among persons in the seventh decade of life,<sup>1</sup> but the prevalence has increased among younger age groups over the past decade, presumably because of increased exposure to damaging recreational noise.<sup>3,7</sup> A large cross-sectional study involving children and adults who were referred to a regional otolaryngology hospital showed that 97% of those who reported tinnitus had concomitant hearing loss detected by routine audiometry.<sup>8</sup> In a population-based study, hearing impairment at frequencies between 500 and 4000 Hz was noted at baseline in two thirds of persons who reported tinnitus, as compared with 44% of persons who did not have tinnitus.<sup>5</sup> In another study, hearing loss was the strongest risk factor for tinnitus that was at least moderate in severity or that caused difficulty in sleeping (adjusted odds ratio, 3.2; 95% confidence interval, 2.3 to 4.4)<sup>9</sup>; a history of occupational noise exposure was also strongly correlated with tinnitus. Clinical experience suggests that sudden hearing loss is associated with sudden onset of tinnitus, but when hearing loss is gradual, tinnitus tends to develop over the course of months or years. Tinnitus frequently resolves or decreases considerably in severity with resolution of hearing loss — for example, after treatment of conductive hearing loss from cerumen impaction or middle-ear effusion.

Tinnitus can affect daily life in multiple domains. People with bothersome tinnitus report impaired sleep, interference with concentration, decreased social enjoy-



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## KEY CLINICAL POINTS

## TINNITUS

- Tinnitus occurs in up to one fourth of adults but is severely bothersome in less than 10%. When bothersome, tinnitus negatively affects sleep, concentration, emotions, and social enjoyment.
- Tinnitus is associated with hearing loss; audiologic testing is an important component in the evaluation of persistent tinnitus.
- Imaging is not indicated in the assessment of tinnitus except in cases in which tinnitus is localized to one ear, is pulsatile, or is associated with focal neurologic abnormalities or asymmetric hearing loss.
- Randomized, controlled trials of tinnitus treatments are limited by a lack of standardized assessments, short posttreatment follow-up, and high risk of bias.
- Treatments to reduce awareness of tinnitus and tinnitus-related distress include cognitive behavioral therapy, acoustic stimulation, and educational counseling. No medications, supplements, or herbal remedies have been shown to substantially reduce the severity of tinnitus.

ment, and difficulty hearing conversational speech.<sup>10-12</sup> In cross-sectional studies, tinnitus has been associated with increased odds of anxiety disorder<sup>3</sup> and depressive symptoms.<sup>9</sup> In a prospective study involving community-dwelling older adults in Japan, tinnitus was associated with an increased risk of subsequent development of depressive symptoms among men, even after adjustment for age and hearing impairment, although no significant association was observed among women.<sup>13</sup>

Psychophysical features of tinnitus such as loudness and pitch are not highly predictive of its psychological effect.<sup>14,15</sup> In one report, some patients who had a tinnitus loudness that matched a sensation level of less than 5 dB (as assessed by the patient identifying an external sound most consistent with the subjective tinnitus) were very disturbed by their condition, whereas other patients who had a tinnitus loudness that matched higher sensation levels were not.<sup>14</sup> This discrepancy may be explained by a person's attention to tinnitus. Whereas a majority of those with chronic tinnitus become used to it and do not pay attention to it, those who are highly disturbed by the tinnitus report constant awareness.

## NATURAL HISTORY

The loudness, severity, and effect of tinnitus are dynamic and change over time. Tinnitus can progress in severity in some persons, but it can decrease in severity and even resolve in others (Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). For example, in one longitudinal study, approximately 40% of persons who had reported mild tinnitus and almost 20% who had reported severe tinnitus at baseline

reported resolution at 5 years.<sup>5</sup> Familiarity with the natural changes in tinnitus that occur over time is important for counseling patients on expectations for improvement. Furthermore, the potential for a spontaneous reduction in the severity of tinnitus underscores the need for a control group in trials of interventions for this condition.

## STRATEGIES AND EVIDENCE

## DIAGNOSIS

Persons reporting tinnitus should be questioned about the nature of the sound (location, quality, and onset [gradual or sudden]), the duration of tinnitus, the effect of tinnitus on daily life (sleep, work, concentration, mood, and social activities), and associated symptoms, including hearing difficulties. A history of ear drainage, ear pain, or both would suggest possible infectious, inflammatory, or allergic ear disease; a history of vertigo and imbalance would suggest possible cochlear or retrocochlear disorders such as Meniere's disease, acoustic neuroma, or migraine-associated vertigo. The qualitative characteristics of tinnitus as described by patients may also suggest specific causes; for example, a roaring sound may indicate Meniere's disease, and a rhythmic clicking sound may indicate stapedial or tensor tympani muscle spasm. Acute tinnitus should be distinguished from persistent tinnitus, although there is no well-accepted definition of chronicity; in clinical trials, the definition ranges from a minimum duration of 3 months to a minimum duration of 12 months.<sup>16,17</sup>

Comprehensive audiologic evaluation for the presence, type, severity, and symmetry of hearing loss should be performed in patients with tinnitus who report hearing difficulties, persistent tinnitus

of more than 6 months' duration, or unilateral tinnitus. Audiologic evaluation of patients with new-onset tinnitus of less than 6 months' duration is also reasonable, given its frequent association with hearing loss. The results of these evaluations will determine whether additional audiometric tests (e.g., otoacoustic emissions test, high-frequency audiometry, or auditory brainstem response test) or diagnostic imaging (e.g., magnetic resonance imaging or computed tomography of the temporal bone) are indicated. Additional audiologic investigations of the qualitative characteristics of tinnitus (e.g., pitch matching, loudness matching, or tinnitus suppression with acoustic stimulation [residual inhibition]) are not diagnostic and are not used in making management decisions.

Standardized questionnaires are available for use in clinical and research settings to assess the severity of tinnitus and its effect on specific domains of a person's daily life (communication, cognition, emotion, quality of life, and sleep).<sup>18-20</sup> These instruments are useful in the initial assessment of tinnitus and in monitoring changes with treatment. The Tinnitus Handicap Inventory is a widely used assessment tool that is sensitive to changes in tinnitus severity after treatment (see the Supplementary Appendix).<sup>21</sup>

#### MANAGEMENT

Population surveys show that the majority of people with tinnitus are minimally bothered by the sensation.<sup>2,22,23</sup> Those who seek evaluation often report concern that their tinnitus is a symptom of a much worse disease, such as progressive hearing loss and deafness.<sup>24</sup> An important component of management includes educating patients about the causes of tinnitus and the natural history of the condition, including possible spontaneous reduction in severity with time. The provision of educational materials, information on support groups, and other self-help materials to facilitate coping with tinnitus may be helpful for some patients (see the Supplementary Appendix).<sup>25</sup> Treatment discussions and management goals should emphasize modulation of the patient's attention and perceptual and emotional responses to the sensation.

#### MEDICATIONS AND SUPPLEMENTS

A wide range of drug classes have been tested in the treatment of tinnitus, including antidepressants,

anxiolytics, antiepileptics, and anesthetics. Large systematic reviews have concluded that the strength of the evidence to support these agents is low.<sup>16,26,27</sup> For example, a Cochrane review of the use of antidepressants for the treatment of tinnitus identified only six trials that had sufficient quality for study, of which five were rated as "low quality," and concluded that there was no evidence of efficacy of antidepressant drug therapy in the management of tinnitus.<sup>28</sup> Whereas some studies have reported a reduction in subjective tinnitus loudness and an improvement in tinnitus-specific quality-of-life outcomes, these modest improvements are likely to reflect the modulation of depression and anxiety rather than direct effects on tinnitus. Current clinical practice guidelines do not recommend medication for management of the condition.<sup>12</sup> Nonprescription treatments such as herbal extracts, dietary supplements, and vitamins are commonly advertised as tinnitus cures, although they have no proven efficacy. Ginkgo biloba is the most commonly used supplement, and a systematic review of trials likewise did not show evidence of benefit in the alleviation of tinnitus.<sup>29</sup>

#### ACOUSTIC STIMULATION

Sound in a variety of forms and intensities has been used for centuries in the empirical treatment of tinnitus. The use of acoustic stimulation to treat tinnitus is currently based on the concept that hearing loss induces homeostatic compensatory changes within central structures (known as central auditory gain) to maintain auditory neural activity.<sup>30</sup> Tinnitus may be a maladaptive consequence of this process.<sup>31</sup> This proposed mechanism of tinnitus has been supported by findings from basic science research in animals, computational models, and functional imaging studies.<sup>32-36</sup> It has been hypothesized that acoustic stimulation may reverse the maladaptive changes by increasing neural activity in central auditory structures.<sup>37</sup>

The types of sound used for acoustic stimulation include broadband noise, amplification of speech and environmental sounds with hearing aids alone, and amplification with hearing aids in combination with broadband noise or music. Acoustic stimulation can be delivered at sound levels sufficient to make the tinnitus inaudible (masking) or at lower levels of intensity at which

the tinnitus remains audible. A review of four trials of acoustic stimulation showed a benefit with respect to tinnitus-specific and global quality-of-life outcomes from interventions that used hearing aids or sound generators but did not show the superiority of any specific form of acoustic stimulation over another; however, the studies were noted to have methodologic limitations.<sup>26</sup> More recently, a randomized trial involving adults with chronic bothersome tinnitus and hearing loss showed a significantly greater benefit with the use of combination devices (hearing aids with sound generators) and directive counseling to reduce attention and emotional response to tinnitus than with the use of hearing aids (without sound generators) and counseling with information on strategies to cope with hearing loss and improve communication.<sup>38</sup> In this trial, the intention-to-treat analysis showed that the rates of clinically significant improvement (defined as  $\geq 50\%$  decrease in Tinnitus Handicap Inventory score from baseline to the 18-month follow-up)

were greater in the group that received the combination devices and directive counseling than in the group that received hearing aids (without sound generators) and audiologic counseling (74% vs. 37%,  $P < 0.001$ ). In another trial, one that involved persons with tinnitus with minimal hearing loss, no significant difference in the rate of the same outcome (clinically significant improvement) was seen between persons who received treatment with sound generators and directive counseling and those who received audiologic counseling alone (50% and 25%, respectively;  $P = 0.16$ ), although decreases from baseline in subjective measures of tinnitus loudness were significantly greater at 12 months and 18 months in the group that received treatment with sound generators than in the group that received counseling alone ( $P = 0.04$ ).<sup>39</sup> Because counseling was different in the experimental and control groups in these trials, the effect of directive counseling versus the sound generator on the study outcomes is unknown.

**Table 1. Elements and Examples of Cognitive Behavioral Therapy for Tinnitus.**

Elements and Examples	Identify Distortions and Exaggerations	Address the Effect of Distortions and Exaggerations	Adopt Alternate Thoughts, Behaviors, and Strategies
<b>Cognitive restructuring</b>			
Example 1	<i>People think I am crazy because I have tinnitus.</i>	Recognize the inaccuracy and futility of mind reading.	<i>I can't assume others' thoughts without evidence.</i>
Example 2	<i>I wake up with my tinnitus and know it's going to be a bad day.</i>	Avoid jumping to conclusions.	<i>It is I, not the tinnitus, who controls what I do and determines how my day goes.</i>
Example 3	<i>My tinnitus is ruining my work and my life.</i>	Eliminate cognitive distortion.	Identify aspects of work and life not affected by tinnitus.
<b>Framing the problem for developing solutions</b>			
Example 1	<i>My tinnitus is making me lose my mind.</i>	Reframe: <i>I can't concentrate when there is no quiet time.</i>	Begin training exercises shown to improve concentration and refocus attention away from tinnitus.
Example 2	<i>My tinnitus is changing my personality.</i>	Reframe: <i>I get angry with people because my tinnitus keeps me from hearing conversations.</i>	Identify techniques and approaches that improve communication ability.
<b>Behavioral modification</b>			
Example	<i>Tinnitus has ruined my social life.</i>	Reframe: <i>Tinnitus ruins my ability to enjoy going out to dinner.</i>	Identify aspects of going out to dinner you can enjoy (e.g., the food, the scenery, or pleasant company) and focus on the positive.
<b>Relaxation training</b>			
		Recognize that stress and physical tension promote emotional arousal and impair coping with tinnitus.	Receive programmatic instruction on breathing exercises and progressive muscle relaxation.

**PSYCHOLOGICAL THERAPY**

The goal of psychological intervention is to decrease the negative effect of tinnitus on a patient's life and thereby improve well-being. Interventions typically address anxiety and depression because these are the most common psychological responses to tinnitus; such interventions include biofeedback training, hypnosis, and cognitive behavioral therapy.

Cognitive behavioral therapy is currently the most common psychological approach used and studied worldwide for the management of tinnitus. Cognitive behavioral therapy is a collaborative therapy that includes attention-refocusing techniques, relaxation training, mindfulness training, cognitive restructuring, and behavioral modification to change a person's reaction to tinnitus (Table 1); it can be delivered as individual therapy, as group therapy, or remotely (Internet-based therapy). The therapy is provided by a trained medical professional and typically includes once-weekly sessions of 1 to 2 hours in duration for 8 to 24 weeks.

Large systematic reviews of trials comparing cognitive behavioral therapy with either a no-treatment control (involving participants on a waiting list to receive treatment) or an active control with various combinations of yoga, education, biofeedback, relaxation, and distraction training have yielded mixed results.<sup>26,40,41</sup> Participants' subjective assessment of tinnitus loudness was not reduced from baseline in those who received cognitive behavioral therapy, those who received an active control, or those who were assigned to a waiting list to receive treatment. However, tinnitus-specific quality-of-life outcomes were significantly better with cognitive behavioral therapy than with the active or no-treatment control, with small to moderate effect sizes. Depression scores were significantly better with cognitive behavioral therapy than with the no-treatment control, but the results of comparisons between cognitive behavioral therapy and active controls (yoga or educational counseling) were inconsistent (Table S2 in the Supplementary Appendix). Overall, the strength of evidence to support cognitive behavioral therapy was considered to be low, given the high risk of bias and small sample sizes in most studies.<sup>26</sup>

**OTHER THERAPY**

Repetitive transcranial magnetic stimulation is an investigative treatment for tinnitus that in-

volves the application of strong magnetic field impulses to the scalp to induce an electrical current that alters neural activity directly in the subjacent superficial cortex and indirectly in remote brain areas. Systematic reviews of randomized trials have found conflicting results with respect to a benefit, as well as a lack of information regarding the long-term effects; determination of effectiveness is complicated by methodologic limitations of available studies, including small sample sizes and variability in design and outcome measures.<sup>42,43</sup>

**AREAS OF UNCERTAINTY**

Research suggests that an abnormal engagement of attention may be a fundamental mechanism that perpetuates tinnitus and increases tinnitus severity.<sup>44-47</sup> In small, short-term trials, attention-training programs designed to modulate awareness of tinnitus through multisensory game-based play or repetitive training in identifying and localizing other sounds have resulted in reductions in tinnitus severity and improvements in quality-of-life scores.<sup>48-50</sup> A better understanding of the mechanisms of attention might lead to more effective treatments. Further study of the relationship between mood disorders and tinnitus and of treatment strategies for patients with coexisting medical conditions is also needed. Cognitive behavioral therapy requires active engagement and commitment; a better understanding of the factors predictive of response to this approach as well as to other interventions is needed.

The subjective nature of tinnitus, its range of causes and variable effects on patients, and the reduction in severity that may occur spontaneously over time make it a challenging condition to study. The limitations of many randomized trials of tinnitus treatments include a lack of blinding, differences among trials in the definition of bothersome tinnitus, small sample sizes, a lack of attention to many variables affecting tinnitus (e.g., associated mood disorder, hearing loss, duration and severity of the tinnitus, and stability of subjective severity scores), failure to account for placebo effects, and attention to some outcomes for which results are significant but not clinically meaningful.<sup>17,51</sup> A standardized instrument has been used as the primary outcome measure of the effect of tinnitus in only 20 to 36% of clinical trials.<sup>17,51</sup> Identifying research partici-

**Table 2. Clinical Practice Guidelines from the American Academy of Otolaryngology–Head and Neck Surgery.**

Recommendation*	Comment
<b>Clinicians must:</b>	
Distinguish patients with bothersome tinnitus from patients with nonbothersome tinnitus.	This can be facilitated by the use of standardized questionnaires and patient interviews. The importance of this distinction is to identify patients who require intervention beyond the initial evaluation, assessment, and education.
<b>Clinicians should:</b>	
Perform a targeted history and physical examination at the initial evaluation of a patient with presumed primary tinnitus.	The goal is to identify conditions that — if promptly identified and managed — may relieve tinnitus (e.g., tinnitus resulting from conductive hearing loss caused by cerumen occlusion of ear canal, middle-ear effusion, or ossicular chain fixation).
Obtain a prompt, comprehensive audiologic examination in patients with tinnitus that is unilateral, persistent ( $\geq 6$ months), or associated with hearing difficulty.	Audiologic testing will facilitate identification of retrocochlear causes of tinnitus or tinnitus from sudden idiopathic hearing loss. Testing should always be performed when patients report difficulty hearing.
Distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms ( $\geq 6$ months) to prioritize intervention and facilitate discussions about the natural history of tinnitus and follow-up care.	Patients benefit from knowing about spontaneous reduction in tinnitus severity observed in population studies. Tinnitus interventions can be prioritized on the basis of duration and severity of tinnitus.
Educate patients with persistent, bothersome tinnitus about management strategies.	Patients should not be told that nothing can be done to help them.
Recommend a hearing aid evaluation for patients with hearing loss and persistent bothersome tinnitus.	The evidence for using hearing aids as treatment shows a preponderance of benefit over harm. Quality of life is improved with improved communication and decreased awareness of tinnitus.
Recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus.	It is helpful to be knowledgeable in general about the process of cognitive behavioral therapy and to have access to trained professionals with expertise in this form of therapy.
<b>Clinicians may:</b>	
Obtain an initial comprehensive audiologic examination in patients who present with tinnitus (regardless of laterality, duration, or perceived hearing status)	
Recommend sound therapy to patients with persistent, bothersome tinnitus.	
<b>Clinicians should not:</b>	
Obtain imaging studies of the head and neck in patients with tinnitus specifically to evaluate the tinnitus, unless they have one or more of the following: tinnitus that is localized to one ear, pulsatile tinnitus, focal neurologic abnormalities, or asymmetric hearing loss.	The cost and risk associated with computed tomography and magnetic resonance imaging, combined with the low diagnostic yield, do not support their application outside the noted exceptions.
Routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus.	Systematic reviews have not supported the use of antidepressants in the treatment of tinnitus. Nevertheless, it is important to recognize that mood disorders can occur in association with bothersome tinnitus and to offer treatment or referral when clinically indicated.
Recommend ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients with persistent, bothersome tinnitus.	Patients should be informed about the lack of evidence for supplements as tinnitus treatments.
Recommend repetitive transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus.	

\* No recommendation is provided regarding the effect of acupuncture in patients with persistent bothersome tinnitus.

patients willing to enroll in tinnitus studies with 12 to 18 months of follow-up is challenging.<sup>38</sup> Long-term follow-up (at least 12 months) is often lacking; in a recent systematic literature review, the median duration of follow-up in 147 clinical trials was 3 months.<sup>17</sup>

## GUIDELINES

The American Academy of Otolaryngology–Head and Neck Surgery (AAOHNS) published a clinical practice guideline for the evaluation and management of chronic bothersome tinnitus in adults.<sup>16</sup> This guideline applies to adults who have had tinnitus for at least 6 months, with no identifiable cause other than sensorineural hearing loss (Table 2). The recommendations in this article are largely consistent with those in the AAOHNS guideline; an exception is the stronger recommendation provided here for hearing aids, sound generators, and directive counseling, for which supporting data were not available at the time the AAOHNS guideline was developed.<sup>38</sup>

## SUMMARY AND RECOMMENDATIONS

The patient described in the vignette has new-onset tinnitus in both ears, and the loudness is not asymmetric. I would obtain additional history regarding vertigo or fluctuating hearing loss and examine the patient for ear disease that might suggest an underlying disorder such as otosclerosis or Meniere's disease, although symmetric tinnitus would make these conditions unlikely. I

would obtain a baseline assessment of tinnitus severity using the Tinnitus Handicap Inventory and an audiogram to determine the presence and level of hearing loss. If there is notable asymmetry in hearing, I would obtain diagnostic imaging. I would review the audiogram with the patient and discuss the relationship between hearing loss and tinnitus and what is known about the natural history of new-onset tinnitus with respect to resolution or reduction in severity over time. If hearing thresholds are outside the normal range, I would recommend hearing aids. I would discuss the potential benefit of educational counseling and acoustic stimulation with hearing aids or devices that combine hearing aids with sound generators to reduce the awareness of tinnitus and the negative effects on the patient's quality of life. If there is evidence of a coexisting mood disorder or moderate to severe distress, I would discuss the options of referral to a mental health professional and a treatment strategy of cognitive behavioral therapy.

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Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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