

Clinical management of tinnitus using a “progressive intervention” approach

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Abstract—Chronic tinnitus is experienced by 10%–15% of the population, of which only about 20% require clinical intervention. People requiring intervention have different levels of need, ranging from the provision of basic information to long-term, individualized treatment. We address this clinical need by outlining a five-level “progressive intervention” approach to the management of tinnitus that would provide a systematic framework for treatment by audiologists. At each level, patients must be appropriately referred—usually to otolaryngology, psychology, and/or psychiatry. Level 1 is an interview method of screening for determining if the person requires clinical intervention (and addressing basic questions). Level 2 is the provision of structured group educational counseling. If the screening determines that care is urgently required or if further help is needed following the group session(s), a tinnitus intake assessment (Level 3) should be performed. The intake assessment, which includes educational counseling, can often meet a patient’s needs. If not, then a program of continuing treatment (Level 4) would be indicated. If significant benefit were not achieved through consistent treatment over 1–2 years, longer-term treatment (Level 5) would be indicated, which could include alternate or multiple treatment modalities. At all levels, the goal is to minimize the impact of tinnitus on the patient’s life as efficiently as possible.

Key words: assessment, counseling, education, hearing disorders, quality of healthcare, rehabilitation, screening, tinnitus, treatment, triage.

INTRODUCTION

Tinnitus is an internally generated neural signal that is perceived as sound. The condition is symptomatic of some abnormal state of the auditory system and is not a disease entity in itself. Like pain, tinnitus is a personal,

Abbreviations: CBT = cognitive-behavioral therapy, CD = compact disc, MLM = multilevel modeling, NCRAR = National Center for Rehabilitative Auditory Research, PVAMC = Portland VA Medical Center, RR&D = Rehabilitation Research and Development, THI = Tinnitus Handicap Inventory, THQ = Tinnitus Handicap Questionnaire, TISI = Tinnitus-Impact Screening Interview, TMJ = temporomandibular joint, TRT = Tinnitus Retraining Therapy, TSI = Tinnitus Severity Index, VA = Department of Veterans Affairs, VAMC = VA medical center, VHA = Veterans Health Administration.

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subjective experience that cannot be measured objectively and is described mainly by patient report [1–2]. Epidemiologic studies have consistently reported that tinnitus prevalence in adults ranges from about 10 to 15 percent [3–5]. In the United States, that range would equate to 30 to 45 million Americans who have tinnitus. Fortunately, most people who experience tinnitus are not significantly bothered by it [6]. For about 20 percent of those who experience tinnitus, however, the condition is “clinically significant” [7–8]. Vernon and Sanders estimate that up to 40 million people in America have tinnitus “to a minor degree,” and that, of these, 5 to 13 million have “severe, quality-of-life-disruptive” tinnitus [9]. Tinnitus is more common in men than in women and its prevalence tends to increase with advancing age [10–12]. The gender difference is most likely due to the greater noise exposure in male than in female tinnitus patients [4,11]. Because of an aging population and an increasingly noisy society, the prevalence of tinnitus is expected to increase [7,13]. More individuals will, therefore, be seeking tinnitus management services, especially as treatments are determined to be effective and become known to the broader public.

Tinnitus and Military Veterans

The incidence of tinnitus is a widespread problem for U.S. veterans and for the Veterans Health Administration (VHA) that is responsible for providing healthcare and disability compensation to a large number of these veterans. On the basis of epidemiologic data from the general population, an estimated 3 to 4 million of America’s 25 million veterans experience chronic tinnitus, with up to 1 million of these requiring some degree of clinical intervention [14]. These prevalence estimates may be somewhat low for veterans because of their higher average age and greater general noise exposure in relation to the civilian population [4]. Veterans can claim tinnitus as a service-connected disability, which is occurring with increasing frequency. As of September 2005, 339,573 veterans had been awarded a service-connected tinnitus disability (Department of Veterans Affairs [VA] Office of Policy and Planning). For their tinnitus disability, these veterans received a combined 1-year compensation of approximately \$418,000,000. These numbers represent a 1-year increase of 50,414 veterans and over \$70,000,000.

In spite of the growing magnitude of the problem of tinnitus in veterans, most VA medical centers (VAMCs) do not provide clinical management for the condition

[14]. The VHA is committed to implementing only efficient, evidence-based practices to improve healthcare outcomes in veteran patients [15–16]. The lack of VA tinnitus services reflects the fact that research evidence for all forms of tinnitus treatment remains equivocal and that no one method is as yet proven to be any more effective than another [17–19].

Purpose

Presently, no accepted standard of practice exists for the clinical management of tinnitus, either within or outside of the VHA. Many methods are used to treat tinnitus, as reviewed in the next section, but none can claim definitively to offer anything more than “nonspecific” treatment effects. That is, many patients will improve regardless of the type of treatment, provided they perceive that expert treatment is being received [20]. This is not to say that patients cannot receive quality care from competent professionals, even if the effects are nonspecific. Certain forms of therapy are well defined and are used routinely in clinics that offer tinnitus management. The need is for randomized clinical trials to document the efficacy of the various techniques [19].

This article proposes a basic model for efficiently managing tinnitus patients at all levels of clinical need. Our clinical trials and screening methodology support the commonly reported observation that most individuals who experience tinnitus do not require intervention. A structured method of screening is needed that can rapidly and accurately determine who requires intervention. For those who do, different levels of service should range from brief counseling to individualized, long-term treatment. These different levels can be addressed with a tinnitus management protocol that follows a “progressive intervention” approach.

The proposed model is designed for application at any audiology clinic that desires to optimize resourcefulness, cost efficiency, and expedience in its practice of tinnitus management. Use of these recommendations should lead to more widespread and consistent tinnitus assessment and treatment by audiologists. Before describing the model, we will first review various methodologies that are used for tinnitus management. We will then describe results of our prospective trials that are building research support for the progressive intervention approach.

REVIEW OF TINNITUS INTERVENTION METHODS

Dobie reviewed 69 randomized clinical trials that had been conducted to assess the efficacy of various treatments for tinnitus [17]. He concluded that none of these studies demonstrated replicable, long-term reduction in tinnitus impact on lifestyle. He updated his review in 2002 and again in 2004, with essentially the same conclusions [18–19]. Most recently, Dobie stated, “The literature on randomized clinical trials does not even begin to establish a ‘standard of practice’ for patients with tinnitus, especially with respect to drugs” [19, p. 274].

The reports by Dobie reveal that the literature does not provide definitive evidence to support any particular form of tinnitus intervention. With that caveat in mind, we will now review various methods of treatment for tinnitus that are most commonly reported in the literature and have been used in clinical practice. Categories of treatment include (1) medical management, (2) drug treatment, (3) acoustic therapy, (4) counseling, (5) electrical stimulation, and (6) “complementary and alternative” therapies. Many of the individual methods contain elements of one another.

Medical Management

Numerous causes of tinnitus have been identified, many of which involve head and neck injuries or diseases or systemic diseases. An otologic evaluation is essential when symptoms are consistent with an acoustic neuroma or when the tinnitus is pulsatile or objective in nature [21]. Even when these symptoms are not present, the ideal standard for tinnitus management would be for every tinnitus patient to receive a complete examination by an otolaryngologist or otologist [22]. The attending physician should have the expertise to identify any somatic pathology, which would indicate the need for radiographic imaging, laboratory testing, and/or angiography [21]. Although test results may reveal that otologic surgery is an appropriate option, such surgery would be indicated only for a very small proportion of tinnitus patients and results are often unpredictable [23]. Cerumen impaction or significant cerumen on the tympanic membrane can cause temporary tinnitus [24], and its removal may require specialized equipment and medicine expertise. Physicians also are qualified to evaluate for drug interactions or circulatory abnormalities that could be associated with tinnitus.

Patients should also receive a general physical examination consistent with an ideal standard of tinnitus clinical management. Numerous disease processes can be associated with tinnitus and its exacerbation. A general medical examination can reveal such potential contributing factors.

Drug Treatment

The mechanism(s) of tinnitus is still unknown; thus, no rational basis exists upon which to select a drug to control tinnitus [25]. Because so many drugs have been taken for so many different conditions, anecdotal evidence of correlative tinnitus relief has accumulated. Such evidence has been the impetus to conduct controlled clinical studies to determine if these effects could be generalized. The results of these studies have been generally disappointing [19]. Many drugs have also been observed to initiate or exacerbate tinnitus. The use of drugs should be considered for tinnitus patients only when sleep disorder, depression, or anxiety are reported as significant coexisting conditions [17].

Acoustic Therapy

Many forms of tinnitus therapy recommend the use of sound in some manner to reduce the effects of tinnitus. Even patients who are treated with cognitive-behavioral therapy (CBT) (see “Psychological Treatment” section) are educated as to the potentially therapeutic application of sound [26]. Some methods use sound in a very specific fashion to achieve their treatment objectives. Regardless of the form of treatment, sound is used in one way or another to distract attention from the tinnitus and to reduce the brain’s perceived need for stimulation [27].

Hearing Aids

Hearing aids have been long recognized to reduce the bothersome effects of tinnitus [28–30]. Patients with hearing loss and tinnitus often receive the secondary benefit of tinnitus relief when using hearing aids [31]. In some cases, tinnitus relief is the primary goal of hearing aids, especially if the patient is a marginal hearing aid candidate. The “tinnitus relief” afforded by hearing aids may be due to the amelioration of communicative difficulties caused by hearing loss but attributed to tinnitus, the alleviation of stress that is associated with difficult listening situations, and/or the increase in ambient sound that can mask the tinnitus or make it less noticeable. Hearing aids are used with the methods of Tinnitus Masking and Tinnitus Retraining Therapy (TRT), although they are used less commonly

than ear-level devices that produce broadband noise (noise/sound generators, and combination instruments that combine noise with amplification) [8,32].

Tinnitus Masking

The primary treatment modality with Tinnitus Masking is the use of wearable ear-level devices—tinnitus maskers, hearing aids, or combination instruments [33–34]. The sound produces a sense of immediate relief from the tinnitus [35–37]. The relief is accomplished by (1) “covering up” the tinnitus sound (making the tinnitus inaudible by replacing it with a more acceptable sound) or (2) changing the tinnitus in some way, usually by reducing its perceived loudness and thereby mitigating its intrusive and annoying nature [32,37]. These two objectives are referred to respectively as “complete” and “partial” masking. As an adjunct to the use of ear-level instruments, all masking patients are advised to use various types of sound-generating devices (e.g., tabletop water fountains, radios, compact discs [CDs], etc.) [27,34,37]. A few patients are able to control their tinnitus through “residual inhibition,” i.e., through the reduction or elimination of tinnitus perception following removal of the masking sound.

Tinnitus Retraining Therapy

TRT is a clinical implementation of the “neurophysiological model” of tinnitus [38–40]. For TRT, the use of sound (“sound therapy”), not sound devices per se, is considered essential for achieving habituation to tinnitus [41–42]. However, patients with more troublesome tinnitus are advised to wear ear-level devices (sound generators, hearing aids, or combination instruments) to optimize the habituation process. These devices ensure a monotonous, low-level sound that reduces the relative strength of the tinnitus neural signal, which presumably makes the tinnitus signal “less detectable” by the brain [43]. Reduced detection of the tinnitus signal by the brain at subconscious (subcortical) levels is thought to facilitate habituation of tinnitus-induced reactions and, subsequently, habituation of tinnitus perception (i.e., awareness) at the conscious (cortical) level. Recognition of the importance of the contributory effects of the limbic and autonomic nervous systems is a major aspect of this treatment model.

TRT patients are advised to wear hearing aids or combination instruments rather than sound generators if their hearing loss is considered a significant problem. The objective of hearing aids in the treatment of tinnitus with TRT is the same as for sound generators: to interfere

with the process of tinnitus detection, and ultimately tinnitus perception, by “enriching” the sound environment. The secondary objective of hearing aids with TRT is to improve communication ability.

Counseling

For every type of tinnitus treatment, counseling plays an important role [44–46]. Some methods use counseling only, while others combine counseling with a different modality of treatment. Regardless of the form of treatment, certain counseling topics would be considered universal for tinnitus patients. Most importantly, all patients should be advised to avoid exposure to loud noise, which is well known to cause damage to the auditory system and to potentially cause or exacerbate tinnitus [47]. Patients should also maintain a background of constant low-level sound that can make the tinnitus less noticeable. Additional common recommendations include (1) choosing healthy lifestyles (e.g., eliminating or reducing alcohol, salt, caffeine, and tobacco; minimizing stress; sleeping 8 h/night, etc.) that might help reduce the tinnitus intensity, (2) maintaining a busy schedule of meaningful activities, and (3) becoming more educated about tinnitus. Sleep disorder is the problem most commonly reported by tinnitus patients [48–51]. Patients should be counseled to obtain treatment from a physician, mental health professional, or sleep disorders clinic if this is a concern. Further, many tinnitus patients suffer from depression and/or anxiety [6], and patients should be informed that such problems require intervention from a mental health professional. Untreated depression, anxiety, or sleep disorder can negate tinnitus rehabilitation efforts.

TRT Counseling

Counseling is the essential component of treatment with TRT. Jastreboff stated, “Proper counseling, including a clear explanation of the physiology of hearing and present knowledge about tinnitus generation and perception, is the first and essential part of any treatment” [52, p. 85]. For TRT, a specific protocol of educational counseling has been designed to “demystify” a patient’s tinnitus, i.e., to remove negative thoughts associated with the tinnitus. The premise of TRT is that these negative associations must be removed for habituation to occur, which is the primary objective of treatment.

Psychological Treatment

Psychological forms of treatment for tinnitus have included progressive muscular relaxation training, biofeedback, hypnosis, and cognitive-behavioral intervention [45,53]. These types of therapy are not intended to remove or reduce the perceived tinnitus in any way but rather to help one cope with the effects of tinnitus on quality of life. Successful coping may involve the use of several different techniques, including cognitive restructuring, attention diversion, imagery training, and relaxation training [26,53].

Electrical Stimulation

Historically, the use of electrical current to suppress tinnitus dates back to 1801. Studies have shown that direct current is generally effective but results in tissue damage [54–57]. Alternating current does not cause these damaging effects, but its effectiveness is restricted to very few patients. Electrical stimulation is not a method that is presently useful in clinical practice to treat tinnitus but is considered a promising area of investigation. [58–59]. Serendipitously, cochlear implants were found to be effective for reducing the sensation of tinnitus [59–61]. (Cochlear implants provide some measure of hearing for deaf individuals by directly stimulating the cochlea with electricity.) However, cochlear implants have also been observed to exacerbate tinnitus [62].

Complementary and Alternative Treatment Methods

Many tinnitus treatment methods would be classified as “complementary and alternative,” including methods involving acupuncture, acupressure, homeopathy, naturopathy, temporomandibular joint (TMJ) surgery, nutritional programs, hypnosis, etc. Because of the anecdotal reports of tinnitus relief with the use of these various methods, numerous studies have been conducted to attempt to verify the reports. Results of these studies have been equivocal [17,19]. Herbal remedies also have been used in the attempt to reduce tinnitus symptoms—extract of ginkgo biloba has received the greatest attention. Initial reports indicated that ginkgo provided significant improvement for many patients [63]. These early results generated considerable interest, but subsequent placebo-controlled investigations did not substantiate these reports [64–66]. To date, controlled studies have not identified any effective herbal remedies for tinnitus.

Summary

This brief review of methods used for treatment of tinnitus highlights two salient points. First, methods used for treating tinnitus are numerous and diverse. Second, no form of tinnitus treatment can claim unequivocal research evidence demonstrating consistent success. Tinnitus sufferers therefore do not have the benefit of referring to any standardized guidelines when seeking help for their condition. Their plight will not change until research produces an evidence basis for prescribing and implementing treatment. The tinnitus research program at the National Center for Rehabilitative Auditory Research (NCRAR) aims to provide evidence to support effective methods of treatment.

TINNITUS CLINICAL TRIALS AT NATIONAL CENTER FOR REHABILITATIVE AUDITORY RESEARCH

Tinnitus research has been conducted at the Portland VAMC (PVAMC) since 1995 (under the auspices of the NCRAR since 1997). Our long-term objective is to develop a tinnitus management program for veterans that is documented for treatment efficacy. Two assumptions underlie our approach. First, veterans who require clinical management for their tinnitus have widely varying levels of need, thus requiring a program that addresses these different levels. Second, the limited resources at VAMCs necessitate the development of highly efficient methods of treatment. Most VA audiology clinics operate at capacity just to meet the hearing aid needs of veterans in a timely fashion. Efficiency and economy are crucial for VA acceptance and implementation of tinnitus programs.

Our randomized clinical trials, described in the following paragraphs, are a systematic effort to develop and document structured forms of tinnitus management for veterans. The methods studied are based on existing techniques that are appropriate for audiologists to implement and that should offer the greatest potential to benefit veterans. Our efforts run in two parallel tracks to address the needs of veterans with (1) severe tinnitus and (2) mild-to-moderate tinnitus. Results of these studies are promising, but further studies are needed to validate the results, to improve efficiency of treatment, and to develop methods to most appropriately triage tinnitus patients into a management program.

Evaluation of Treatment Methods for Clinically Significant Tinnitus

This clinical trial (VA Rehabilitation Research and Development [RR&D] C2887R) was completed in late 2003 and is presently in continuation as a multi-VAMC study. The original study evaluated the clinical efficacy of Tinnitus Masking versus TRT. Study participants were veterans who required long-term, individualized treatment for their tinnitus. Qualifying veterans were quasi-randomly assigned (alternating assignment) to one of the treatment methods. Both methods were conducted according to published descriptions, with modifications made as necessary to optimize consistency within and between protocols. Consultants were the progenitors of each method (J. Vernon for masking and P. Jastreboff for TRT).

Telephone Screening for Study Participants

Over 800 veterans inquired about the study during the recruitment phase. Performing the 3- to 4-hour intake assessment with each of these veterans was impossible. It was therefore critical to select only veterans with tinnitus of enough severity to warrant the long-term treatment that would be provided. For that purpose, we developed the Tinnitus-Impact Screening Interview (TISI) [14]. Of the 800 veterans who telephoned to inquire, use of the TISI reduced this number to 172 (20%). Many of the callers expressed the common misconception that their tinnitus caused their hearing difficulties [6,67–69]. These veterans required education about this issue and about their other tinnitus concerns. The telephone screening thus doubled as a brief “informational counseling” session that was sufficient for about 80 percent of the callers to decide that no additional clinical services were needed.

Study Protocol

Before attending the intake evaluation, each of the 172 study candidates completed written tinnitus questionnaires, including the Tinnitus Handicap Inventory (THI) [70], Tinnitus Handicap Questionnaire (THQ) [71], and Tinnitus Severity Index (TSI) [72]. These are three of the more commonly used and accepted tinnitus questionnaires. Each questionnaire provides an index score, with higher scores reflecting greater perceived tinnitus handicap. The 25-item THI (range: 0–100) has been evaluated for internal consistency reliability (Cronbach's $\alpha = 0.93$) and test-retest reliability ($r = 0.92$) [73]. The 27-item THQ (range: 0–2,700) has been documented for internal consistency reliability (Cronbach's $\alpha = 0.95$) [71] and test-retest reliability ($r = 0.89$) [74]. The 12-item

TSI (range: 0–48) has been shown to have a Cronbach's α of 0.92 [72] and test-retest reliability of 0.88 (determined from the following study C2760R).

During the intake assessment, the study audiologist (T. Zaugg) performed comprehensive audiologic and tinnitus testing. In addition, candidates were interviewed by the study audiologist using the TRT Initial Interview form [75] that we modified for use in this study [76]. Following the intake evaluations, 123 of the 172 candidates qualified for enrollment and placement in one of the two treatment groups, i.e., into either TRT or Tinnitus Masking.

Treatment was provided by J. Henry (TRT) and M. Schechter (masking). After the initial treatment session, ongoing treatment was provided at 3, 6, 12, and 18 months. At each of these visits, the study audiologist collected outcome data:

1. Study patients completed the written questionnaires (THI, THQ, and TSI) before each visit.
2. The TRT follow-up interview was administered before the treatment session.
3. The tinnitus and audiologic tests were repeated (except at 3 months).

Results

Of the 123 patients, 111 (53 in masking; 58 in TRT) completed the 18-month treatment protocol. **Figures 1 to 3** show line graphs of the mean \pm standard deviation (SD) index scores from the THI, THQ, and TSI, respectively (graphs correspond with means \pm SDs shown in **Tables 1–3**). Preliminary analyses were conducted on these data [14,77]. Independent-samples *t*-tests compared mean index scores between groups at each of the outcome visits. Since multiple tests were performed, Bonferroni corrections dictated more stringent significance levels for interpretation of results ($p < 0.01$ to correspond with 0.05 level for a single *t*-test). For each of the three outcome instruments, no significant differences were found between mean scores for the two groups at 0, 3, or 6 months ($p > 0.01$) but mean scores were significantly lower for the TRT group at 12 and 18 months ($p < 0.01$).

Newman et al. assessed the test-retest reliability of the THI [73], revealing that a reduction in the total index score of at least 20 points indicates statistically significant improvement at the 0.05 level of significance. Their analysis provided the opportunity to identify patients from the present study who showed improvement according to their criterion. **Table 4** shows results of this analysis at the 6-, 12-, and 18-month outcome points. (Six patients whose baseline THI scores were less than 20 were removed from

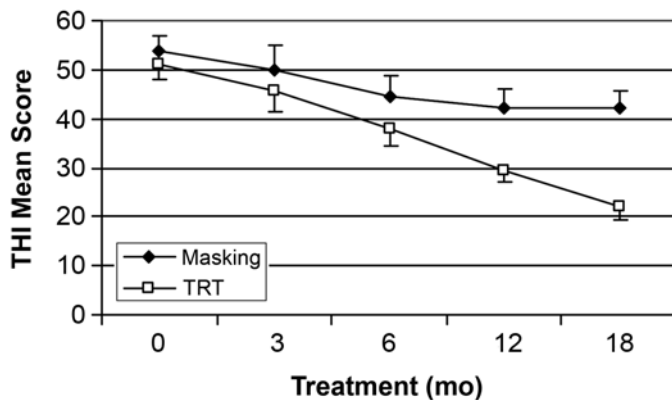


Figure 1.

Mean scores from Tinnitus Handicap Inventory (THI) for patients at baseline and ongoing treatment appointments. Each mean includes all patients who completed THI at corresponding visit (*n*'s at each visit shown in **Table 1**; error bars represent standard error of mean). TRT = Tinnitus Retraining Therapy.

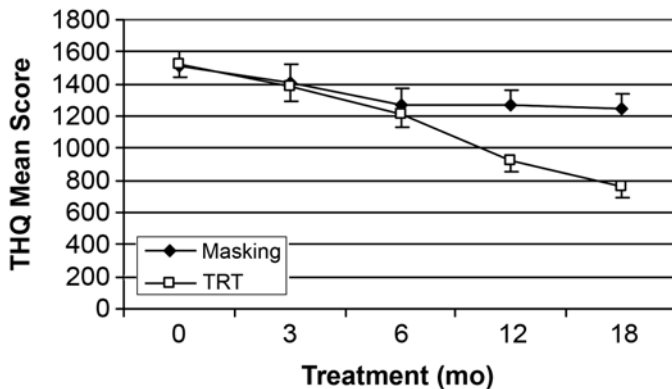


Figure 2.

Mean scores from Tinnitus Handicap Questionnaire (THQ) for patients at baseline and ongoing treatment intervals. Each mean includes all patients who completed THQ at corresponding visit (*n*'s at each visit shown in **Table 2**; error bars represent standard error of mean). TRT = Tinnitus Retraining Therapy.

this analysis because it was not possible for them to achieve a 20-point improvement). Analysis shows that 19, 30, and 33 percent of the masking patients improved by 20 points at 6, 12, and 18 months, respectively. This compares with 29, 55, and 74 percent, respectively, of TRT patients who improved by the same amount.

Discussion

Results of these preliminary analyses reveal that both groups experienced comparable improvement through 6 months of treatment. At the 12- and 18-month visits, however, the TRT group showed significantly greater

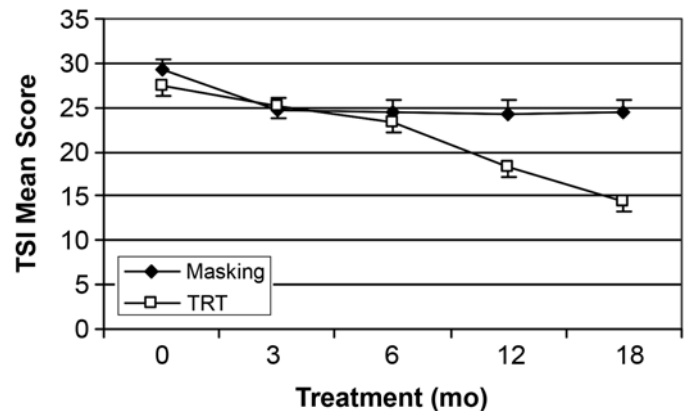


Figure 3.

Mean scores from Tinnitus Severity Index (TSI) administered at baseline and ongoing treatment appointments. Each mean includes all patients who completed TSI at corresponding visit (*n*'s shown in **Table 3**; error bars represent standard error of mean). TRT = Tinnitus Retraining Therapy.

improvement relative to the masking group. These findings were consistent across the three outcome instruments.

Further analyses have been conducted on these data (which are too extensive to include in this brief summary) on an intent-to-treat basis, using multilevel modeling (MLM) [78]. (MLM, in essence, evaluates individual trajectories of tinnitus outcomes over time—both the group average trajectory and individual variation around the average trajectory.) An important finding of the MLM analysis is that the relative improvement for TRT compared with masking occurred to a greater degree in patients who started treatment with the highest index scores (i.e., patients with the most severe tinnitus). When patients began treatment with lower index scores (reflecting a less severe tinnitus problem), the benefits of TRT compared with masking were more modest. These findings suggest that TRT may be most effective for patients who have the most serious difficulty with their tinnitus, and that treatment of 1 to 2 years may be necessary to achieve maximum benefit of therapy. Treatment with masking is traditionally provided during a single visit with minimal, if any, subsequent appointments [35–37]. The intent of masking is to provide the patient with a sense of immediate relief. This immediate-relief strategy may work best for patients with a more moderate tinnitus problem.

Although this study was well controlled, one should note that a number of variables could have influenced the outcomes. Most specifically—

1. TRT patients received more counseling time than did masking patients.

Table 1.

Mean \pm standard deviation (SD) scores from Tinnitus Handicap Inventory (THI) for patients at baseline and ongoing treatment appointments. Each mean includes all patients who completed THI at corresponding visit.*

Outcome Point (mo)	Tinnitus Masking		TRT	
	<i>n</i>	Mean \pm SD	<i>n</i>	Mean \pm SD
Baseline	54	53.8 \pm 23.2	55	51.1 \pm 21.8
3	30	49.9 \pm 26.7	32	45.7 \pm 23.4
6	49	44.7 \pm 27.8	46	37.9 \pm 22.7
12	50	42.3 \pm 26.1	52	29.6 \pm 19.3
18	52	42.1 \pm 25.6	58	22.1 \pm 22.1

*National Center for Rehabilitative Auditory Research clinical trial of evaluation of treatment methods for clinically significant tinnitus (study C2887R).

TRT = Tinnitus Retraining Therapy.

Table 2.

Mean \pm standard deviation (SD) scores from Tinnitus Handicap Questionnaire (THQ) for patients at baseline and ongoing treatment intervals. Each mean includes all patients who completed THQ at corresponding visit.*

Outcome Point (mo)	Tinnitus Masking		TRT	
	<i>n</i>	Mean \pm SD	<i>n</i>	Mean \pm SD
Baseline	45	1514 \pm 585	45	1526 \pm 551
3	32	1405 \pm 690	31	1386 \pm 533
6	49	1266 \pm 715	47	1217 \pm 556
12	50	1264 \pm 689	52	919 \pm 481
18	52	1250 \pm 612	58	757 \pm 511

*National Center for Rehabilitative Auditory Research clinical trial of evaluation of treatment methods for clinically significant tinnitus (study C2887R).

TRT = Tinnitus Retraining Therapy.

Table 3.

Mean \pm standard deviation (SD) scores from Tinnitus Severity Index (TSI) for patients at baseline and follow-up treatment intervals. Each mean includes all patients who completed TSI at corresponding visit.*

Outcome Point (mo)	Tinnitus Masking		TRT	
	<i>n</i>	Mean \pm SD	<i>n</i>	Mean \pm SD
Baseline	59	29.3 \pm 8.8	63	27.4 \pm 8.5
3	48	24.7 \pm 8.8	51	25.1 \pm 9.4
6	53	24.5 \pm 9.8	57	23.4 \pm 8.8
12	50	24.3 \pm 10.7	57	18.3 \pm 8.6
18	53	24.5 \pm 10.5	58	14.4 \pm 8.5

*National Center for Rehabilitative Auditory Research clinical trial of evaluation of treatment methods for clinically significant tinnitus (study C2887R).

TRT = Tinnitus Retraining Therapy.

Table 4.

Numbers and percentages of patients in each treatment group (Tinnitus Masking and Tinnitus Retraining Therapy [TRT]) who made statistically significant improvement (0.05 level of significance) based on a 20-point reduction in total index score of Tinnitus Handicap Inventory (THI). Patients evaluated are those who completed THI at baseline and at each outcome point.*

Outcome Point (mo)	No. of Patients Improved		Patients Improved (%)	
	Masking	TRT	Masking	TRT
6	8/43	11/38	19	29
12	13/44	23/42	30	55
18	15/46	34/46	33	74

*National Center for Rehabilitative Auditory Research clinical trial of evaluation of treatment methods for clinically significant tinnitus (study C2887R).

2. Counseling was structured for TRT and informal for masking.
3. Only one treatment audiologist conducted each method (clinician differences existed such as personality, attitude, etc.; also, the masking audiologist, unlike the TRT audiologist, had a full clinical caseload that could have affected clinician performance or patient perception of treatment).
4. Ear-level devices used for TRT broke down much more often than those used for masking.

These potentially confounding variables are being controlled for in the continuation study, which is underway at four VAMCs (Bay Pines, Florida; Portland, Oregon; San Diego, California; Seattle, Washington).

Randomized Clinical Trial to Assess Benefit of Group Therapy for Tinnitus

For this study (VA RR&D C2760R), all veterans with “clinically significant” tinnitus were included. That is, if any degree of clinical intervention was required, the veteran was considered a study candidate. Therefore, the participants in this study did not have as severe a tinnitus condition (on average) as did those in the trial just described.

The investigators hypothesized that the majority of veterans with clinically significant tinnitus would be treated effectively using group counseling that was adapted from the structured TRT counseling protocol. We have facilitated a tinnitus support/education group at the PVAMC since 1999 [14]. The group, which focuses on providing useful information for reducing tinnitus impact on lifestyle, has consistently benefited the attendees. This group, along with the availability of a structured tinnitus counseling protocol, provided the impetus for conducting this randomized clinical trial.

Development of Educational Presentations

During the initial phase, the TRT-based group counseling presentations were developed. Four sequenced presentations were created, each consisting of 1 1/4 hours of didactic material. Group sessions lasted 1 1/2 hours, which included 15 minutes for a question-and-answer period.

Pilot Study

The educational presentations were piloted with a group of 25 veterans. These participants completed questionnaires as for the main study: at baseline and at 1, 6,

and 12 months following the sessions. The pilot sessions, presented by J. Henry, provided training for the three VA audiologists (K. Anselmi, R. Coombs, J. Hensley) who would conduct the sessions for the main study. Anecdotally, these 25 veterans generally responded favorably to the group-treatment format.

Recruitment and Screening of Patients

Study patients were recruited via local (Seattle area) newspaper and radio advertisements and via flyers posted at the Seattle and American Lake (Tacoma) VAMCs. Interested veterans telephoned the research coordinator (M. Montero) who screened them for clinically significant tinnitus. Approximately 750 veterans responded to the advertisements. Of these, 549 passed the screening and were invited to attend an “open house” for further information, to sign informed consent, and to receive the baseline written questionnaires. Six open houses were held over 9 months. Of the 549 veterans invited to the open houses, 373 (68%) actually attended. Of these 373, 335 (90%) were enrolled, including 25 in the pilot study and 310 in the main study.

Study Protocol

Qualifying veterans who completed and returned baseline questionnaires were randomized into one of the three study arms: educational counseling, traditional support group, and usual care (no treatment). Patients in the education group attended the four weekly 1 1/2-hour sessions as for the pilot study. Support group patients attended four weekly 1 1/2-hour sessions of a discussion-type support group moderated by the research coordinator (no tinnitus information was provided). The usual care group received no study intervention, and they were not restricted from pursuing outside treatment. Patients in the two treatment groups completed outcome questionnaires at baseline and at 1, 6, and 12 months postintervention. Usual care patients completed their questionnaires at baseline and at 1, 6, and 12 months postbaseline. The TSI was the primary outcome instrument [72]. As previously described, individual TSI scores can range from 0 to 48 points.

Results

This study was completed in 2004, and outcomes have not yet been reported. Therefore, these findings are considered preliminary. Of the 310 patients in the main study, 269 met the strict randomization criteria and are

included in the data analysis, including 94 in education, 84 in support, and 91 in usual care. Mean TSI scores were calculated for each of the three groups at each completed outcome point (0, 1, 6, and 12 months). **Table 5** shows that for the education group the mean TSI score decreased 1.9 points from baseline at 1 month, 3.2 points from baseline at 6 months, and 2.7 points from baseline at 12 months. Each of these decreases was significant ($p < 0.01$, paired-sample t -tests). For both the support and usual care groups, mean TSI scores varied over a range of less than 1 point, and not one of the changes was significant ($p > 0.05$).

Discussion

We need to emphasize that the outcome data from this study have received only a very cursory analysis. However, the analysis does show that group educational intervention provided statistically greater benefit to veterans with tinnitus than a traditional support group or “no treatment.” Although the improvement was not as great as for the TRT patients who were treated individually, it is important to consider the per-patient “clinical contact” time: the total of 6 hours of intervention provided to each patient equates to a contact time of only 18 minutes per patient (with 20 patients attending the group sessions). In contrast, the clinical contact time for each veteran who was given individualized treatment with TRT in our controlled trial (C2887R) averaged 15.5 hours. The contact time per patient was thus about 50 times greater for individualized treatment compared with group treatment. This is certainly an improvement in efficiency from a time and/or cost perspective. Regardless of time and cost savings, however, sufficient benefit must be received from the more efficient program.

We can begin to address the question of relative benefit for group versus individualized therapy by comparing outcome data between our two studies. We can directly com-

pare TSI data for the 6- and 12-month outcome time points from both studies. For patients treated individually with TRT, mean TSI scores were 27.4 at baseline and 23.4 at 6 months, for a reduction of 4.0 points. For the patients receiving the TRT-based group education, the mean TSI score was 24.8 at baseline, and 21.6 at 6 months, for a 3.2-point reduction. These results suggest the possibility that group therapy can be as effective as individual therapy over a 6-month period. At 12 months, however, the improvement in mean TSI scores was 9.1 points for patients treated individually, and 2.7 points for patients treated in the group program. The individualized, ongoing treatment thus made a considerable difference in outcomes over the long term. The key issue in evaluating the efficiency of group therapy will be the ability to predict which patients will benefit sufficiently from group therapy and which require more intensive treatment. Our current studies, and factor analyses of existing data, will help to develop a means to triage patients into different levels of intervention.

An additional advantage of group therapy is that only education is involved; thus no expenses are incurred for audiologic testing, dispensing ear-level devices, administrative time, etc., which would normally be required for individualized treatment. Of course, the concern exists that some patients have tinnitus that requires medical attention. The educational program should therefore inform all patients of symptoms that suggest acoustic neuroma, Ménière’s disease, or tinnitus that may be correctable through medical or surgical means. Specifically, tinnitus that is unilateral, of recent onset, progressive, and/or pulsatile would indicate the need for an otologic examination.

A further possibility for tinnitus group therapy is to provide the educational program as a videotaped presentation. Such use of electronic media could decrease further the costs of administering this basic level of treatment. We

Table 5.

Mean \pm standard deviation scores from Tinnitus Severity Index (TSI) for patients in three treatment groups at baseline and 1, 6, and 12 months posttreatment (usual care received no treatment). Means include all patients who completed TSI at any of outcome points.*

Outcome Point (mo)	Education	Support	Usual Care
Baseline	24.8 \pm 8.8	22.9 \pm 9.7	22.3 \pm 9.1
1	22.9 \pm 9.6	22.2 \pm 9.2	21.6 \pm 8.6
6	21.6 \pm 10.3	23.0 \pm 9.6	22.0 \pm 9.3
12	22.1 \pm 11.0	22.9 \pm 9.3	21.5 \pm 8.9

*National Center for Rehabilitative Auditory Research clinical trial of evaluation of treatment methods for clinically significant tinnitus VA (study C2887R).

have developed videotape modules for this purpose, and they are being evaluated as a pilot project to assess their potential for clinical application in this manner.

PROPOSED MODEL OF TINNITUS PROGRESSIVE INTERVENTION

We are accumulating research evidence that supports the efficacy and efficiency of providing clinical tinnitus services with a progressive intervention approach. We can now propose a basic outline of this approach, with the caveat that much more research is needed to more specifically define the approach and to document its efficacy. **Figure 4** shows a clinical flowchart that depicts the routing of patients through the different levels of intervention. The reader should refer to **Figure 4** throughout this section.

We need to emphasize that proper implementation of this model depends critically on the audiologist making appropriate referrals to other disciplines. A section follows that outlines the most common referral concerns for tinnitus patients and describes how referrals should be handled at each of the five levels of progressive intervention.

Overview of Progressive Intervention Model

Level 1 of tinnitus progressive intervention would involve screening for clinically significant tinnitus—separating persons who do require clinical services from those who do not. Most likely, the majority of individuals who inquire about tinnitus services could have their needs met through an effective screening process. Effective screening would also identify individuals requiring immediate care versus those for whom group educational-counseling should be adequate to meet their treatment needs. Those requiring immediate care should be referred directly for a tinnitus intake assessment (Level 3), which would bypass the group education.

Group education, Level 2, may offer the most efficient means of providing basic intervention to patients who require some level of service, but whose needs are not urgent. Properly administered, the education can empower tinnitus patients by (1) removing fears and concerns about tinnitus, (2) teaching self-help strategies (especially various forms of acoustic therapy), and (3) informing them about further treatment options. Patients who complete the group education, and who feel that further clinical care is needed, should be scheduled for a tinnitus intake assessment.

The tinnitus intake assessment, Level 3 (as performed by an audiologist), should include written questionnaires, a case-history interview, audiologic testing, a tinnitus psychoacoustic assessment, and a sound-tolerance evaluation (if indicated by patient report). The intake assessment generally requires 2 or more hours, and much of the dialogue that occurs between patient and clinician amounts to personalized educational counseling. As a result, some patients at this level will decide that further treatment would be unnecessary.

If the intake assessment reveals that ongoing treatment, Level 4, is necessary, then the audiologist should implement an appropriate treatment program. Treatment methods that audiologists can readily administer include Tinnitus Masking and TRT [27]. Cognitive-behavioral therapy may also be an option if the audiologist has received special training in this psychological management technique [45,53]. Level 4 therapy should be ongoing until the patient's tinnitus problem is resolved, which can often require 1 to 2 years of treatment. For some patients, even 1 to 2 years of treatment will be insufficient, and treatment should be extended and possibly broadened to include other treatment modalities (Level 5).

Referrals

Usually, healthcare referrals are made based on results of a clinical assessment. With the tinnitus progressive-intervention model, intake assessment is the third of five potential levels of clinical management. The question then is how to address any need for referral that might be present at the other four levels. Before the intake assessment (Level 3), the main concern is that a patient could have a medical problem that requires a physician's attention. Without a clinical assessment, symptoms that would suggest a medical problem can be easily overlooked. The clinical responsibility is therefore to preface screening or group education with a statement to this effect, along with a blanket recommendation to schedule an appointment with an otolaryngologist to rule out any medical causes. Patients who exhibit obvious psychological problems should also be referred for psychological or psychiatric assessment. When patients receive continuing treatment following the intake assessment, the clinician should be highly cognizant at each appointment of the potential need for referral, especially for psychological or psychiatric management. Consideration of the potential need for referral is particularly important when 1 to 2 years of intervention does not result in significant benefit.

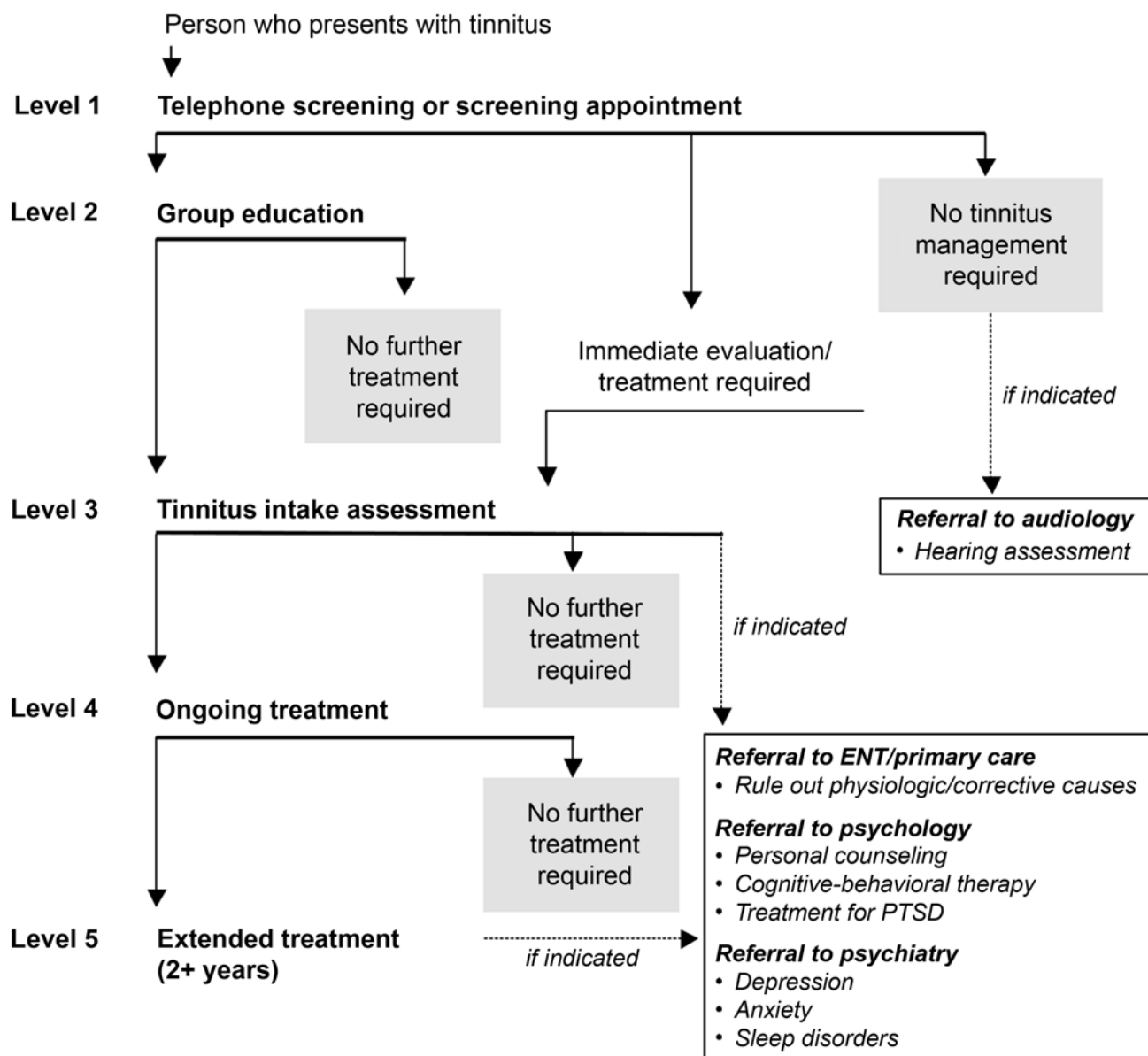


Figure 4.

Flowchart showing proposed five levels of tinnitus clinical management using “progressive intervention” approach. PTSD = posttraumatic stress disorder; ENT = ear, nose, and throat.

As part of the intake evaluation, it is essential to determine if the patient has need of a medical and/or psychological evaluation. The argument has been that anyone with tinnitus should receive a medical evaluation [22] and that tinnitus distress amounts to a psychological problem that would indicate the need for psychological management [53]. We agree that a “best practice” approach would specify that all tinnitus patients should receive medical and psychological evaluations. However, regardless of any logical basis for referring all patients, the reality is that not all

patients will be referred. In addition, patients who are referred may not comply with the recommendations. Therefore, the examining audiologist needs to be knowledgeable of symptoms that would indicate when referral is critical, rather than just routine.

Otologic Evaluation

As mentioned previously (in the “Medical Management” section), patients should be referred for an otologic evaluation whenever symptoms are consistent with acoustic

neuroma or Ménière's disease. Audiologists are trained to be alert to these symptoms. Ninety-five percent of acoustic neuromas are unilateral [79], and unilateral, progressive (occasionally sudden) hearing loss is the most common symptom. Unilateral tinnitus is the second most common symptom and is usually described as a high-frequency ringing sound. With Ménière's disease, low-pitched, fluctuating tinnitus is one of the four classic symptoms, along with low-frequency sensorineural hearing loss, aural fullness, and vertigo—all of which tend to fluctuate.

Audiologists should be aware of the distinction between tinnitus that is generated neurophysiologically versus "somatosounds," which typically have a vascular, muscular, or respiratory origin [80]. Some somatosounds are related to TMJ disorder [81]. In rare instances, somatosounds are "objective," meaning they are real noises that are audible to the examiner [82]. Somatosounds are potentially correctable by medical or surgical procedures, and their presence requires a complete head and neck examination [21–22]. Pulsatile tinnitus is the most common somatosound, which often has an identifiable site of lesion [21,83–84].

We have only briefly described tinnitus symptoms that would require referral for a medical examination. A medical examination may not be necessary, however, when the tinnitus is described as symmetric, nonpulsatile, nonfluctuating, and of long duration (minimum 6 months). These symptoms describe what would usually be neurophysiological tinnitus that is consistent with sensorineural hearing loss and a history of noise exposure. Such tinnitus is not amenable to surgical correction, nor is it life threatening.

Psychological Evaluation

Patients who require treatment for their tinnitus often suffer from depression and/or anxiety [6]. Tinnitus patients should be properly diagnosed and treated if they experience either of these conditions. It is most advantageous if tinnitus patients are referred routinely for an evaluation by a licensed mental health provider. Screening questionnaires can assist in making appropriate referrals. These questionnaires include the seven-item version of the Beck Depression Inventory [85] and the six-item version of the state scale of the Spielberger State-Trait Anxiety Inventory [86]. Psychological intervention can, in general, be helpful in reducing the debilitating effects of severe, intractable tinnitus.

Referral for Sleep Disorder

The problem that tinnitus patients most often report is sleep interference [48–51]. Patients with sleep problems also tend to report the most severe tinnitus [87–90]. Although audiologic management of tinnitus might help to mitigate sleep problems, referring the patient to a physician, mental health professional, or sleep disorders clinic may also be appropriate.

Pharmacological Intervention

Drugs are used often in the management of tinnitus. Many research studies have been conducted to evaluate the efficacy of a wide range of drugs for this purpose. Reviews of these studies reveal that none of the drugs tested showed consistent benefit for treating tinnitus [17,19,91]. However, drug treatment may be important for patients with comorbid psychological or sleep disorders. Thus, drugs may not be effective in treating the tinnitus, but they can be very helpful in treating coexisting conditions, which ultimately can make the tinnitus less of a problem.

Level 1: Screening for Clinically Significant Tinnitus

As previously described, recruitment of veterans for the clinical trial comparing TRT and Tinnitus Masking (C2887R) demonstrated the effectiveness of telephone screening those who have concerns about their tinnitus. We developed the TISI as a means to screen individuals who were interested in participating in the study—to determine if an intake assessment was warranted [14]. Although the TISI was designed specifically as a research tool, it has broader application for use with any individual to determine if a reported tinnitus condition is clinically significant.

Many of the veterans who called about our study reported difficulty hearing, which they felt was a consequence of their tinnitus. Many tinnitus professionals have the opinion that attributing hearing problems to tinnitus is a misconception that is commonly held by patients [6,67–69,92]. Clearly, however, studies have not confirmed this opinion. Bosman provides data showing no difference in speech reception thresholds between subjects with and without tinnitus [93], which contrast with Newman et al.'s study that showed specific speech deficits that could be attributed to tinnitus [94]. Lack of definitive evidence notwithstanding, hearing difficulties reported by tinnitus patients seem most likely due to comorbid hearing loss caused by cochlear pathology in combination with the

intrusive nature of the tinnitus signal on auditory perception. For the veterans in our study, the study audiologist provided education about this common misconception and addressed many of their other tinnitus concerns. The information provided was sufficient for about 80 percent of the callers to decide that clinical intervention for their tinnitus was unnecessary. If hearing loss was identified as a likely possibility, the caller learned that he or she might profit from the use of amplification and was advised to schedule a hearing evaluation for determining this.

Screening with the TISI can be a highly expeditious means of ensuring that clinical resources are used efficiently and that patients are not subjected to needless testing that can be costly and time-consuming. The TISI is certainly not the only instrument that can be used for tinnitus screening. Numerous other tinnitus questionnaires can be used, although they are generally longer than the TISI and/or are designed for self-administration. In any event, the screening clinician should use whatever best suits his or her clinic's requirements. Ideally, in the future, a screening instrument will be fully documented for reliability and validity. Such an instrument would enable standardization of tinnitus screening across clinics. Note that a complete description of the expanded TISI (which now uses eight interview questions), along with supporting data, will be provided in an upcoming publication. A copy of the TISI, along with specific guidelines for its clinical administration, is presently available from the corresponding author.

Level 2: Group Informational Counseling

Intervention for tinnitus always includes some form of counseling. The type of counseling will vary greatly between clinicians, depending on their treatment approach and level of expertise. In many cases, counseling is all that is offered. More developed forms of counseling for tinnitus will generally include a brief description of tinnitus within the context of the auditory system, advice about how to use sound to make tinnitus less bothersome, and a delineation of lifestyle factors that may affect tinnitus. This kind of generic tinnitus counseling can be presented in a group format as an efficient means of "informational counseling" [95]. Because of the commonality of much of this information, the use of educational video modules may offer an efficient mechanism for presenting the information.

Since 1999, a tinnitus education group for veterans has been conducted six to eight times a year at the PVAMC. The primary objective of these 1 1/2-hour meet-

ings is to empower veterans with information that would be useful in self-managing their tinnitus to alleviate its negative effects. Each meeting involves an educational presentation of some type. Presenters are either one of the meeting moderators or a tinnitus specialist from the surrounding area. This type of informal education/support group might represent the simplest and most cost-effective form of tinnitus intervention. The use of this group at the PVAMC has demonstrated how research and clinical functions can be complementary and can direct patients toward appropriate clinical resources. Many veterans have benefited directly from these meetings, resulting in their seeking and receiving treatment with hearing aids or maskers. Some veterans have learned how to obtain a VA service-connection disability for tinnitus and/or hearing loss.

Because of the consistent benefit provided to veterans who attended the PVAMC tinnitus support group, this group-education approach was developed into a formal research project. The project, described earlier (C2760R), was conducted to determine if structured group education, using TRT counseling principles [96], can benefit most veterans who present with clinically significant tinnitus. Preliminary results of this randomized clinical trial indicate that this is an efficient means of providing tinnitus intervention to tinnitus patients. The project has been well received by the participating research staff from the Audiology Clinic at the Seattle and American Lake VAMCs, where no tinnitus management program existed before conducting the trial. They have now instituted a clinical program for their tinnitus patients that uses a similar group-education format. Instead of conducting a series of four educational sessions, they have opted to condense the structured information into a single extended session. The fact that these patients have not been returning to the clinic indicates that attending the group session has in some way resolved their concerns.

A single session of condensed informational counseling might in fact be the most expedient method of managing tinnitus for most patients and prospective patients. With this method, any individual who complains of tinnitus would be advised to attend the single session as the first (and possibly only) step in managing his or her tinnitus. A properly conducted session would (1) inform patients of symptoms that would suggest the need for medical or psychological diagnosis, (2) provide an explanation of tinnitus and its relation to hearing loss, (3) provide a realistic description of different methods of

treatment for tinnitus, and (4) delineate specific strategies for self-managing tinnitus. The clinical application of this approach should be evaluated in a controlled trial to verify its efficacy.

Level 3: Tinnitus Intake Assessment

The next higher level in this hierarchy of clinical management is to perform a tinnitus intake assessment, which consists of a battery of hearing and tinnitus tests and of written and verbal questionnaires. We have previously published procedural details for performing a basic intake assessment for tinnitus patients [97] as well as specific procedures for the assessment of patients who will be treated with TRT [98]. The intake assessment would be performed only with a subset of patients who have completed the screening and group-education stages of intervention and whose condition warrants the full evaluation. (Some patients who are screened will bypass group education to progress directly to the assessment due to the urgency of their condition.)

The tinnitus intake assessment can result in two possible outcomes (in addition to any referrals that may result). First, it may determine that a program of continuing intervention (Level 4) is required. In this case, all the necessary clinical data will have been obtained to make informed treatment decisions. The decision to pursue treatment and the specific treatment plan should be arrived at mutually between clinician and patient. Second, some patients will not require any intervention following the assessment—the process of testing, explaining test results, and answering the patient's questions will have sufficed to mitigate any remaining concerns. Thus, in the process of performing the intake assessment (which generally requires 2 or more hours to perform), much of what the clinician says to the patient equates to educational counseling. In essence, the patient receives intervention during the assessment. This informal counseling can be sufficient for some patients such that no further intervention is needed.

Our masking versus TRT clinical trial (C2887R) demonstrated this latter result for many of our research candidates. Of the 800 veterans who underwent telephone screening, 172 were identified as requiring a comprehensive hearing and tinnitus assessment. The assessment, which included verbal administration of the TRT initial interview form [75–76,99], was sufficient for 48 of these 172 veterans to realize that no further services were required. The assessment thus served as a second, more

comprehensive level of “screening” for these 48 veterans. The information the clinician provided during the assessment process resolved their tinnitus concerns. When a patient decides that no further treatment is necessary, as was the case for these 48 veterans, the intervention provided up to that point has successfully met the patient's needs.

It is well known that some tinnitus patients have a reduced tolerance to everyday sounds [41,100–102]. This condition is generally referred to as “hyperacusis.” Unfortunately, no clear definition exists as to its manifestation [103–104]. The examining clinician should at least be aware of the potential for this condition and have the capability of evaluating patients who report a sound tolerance problem. Clinical assessment procedures for hyperacusis have been described, which can involve administration of the sound tolerance section of the TRT initial interview form [76], and the measurement of loudness discomfort levels at audiometric frequencies [97].

Level 4: Ongoing Treatment

The next level of tinnitus clinical management following the intake assessment is ongoing individualized treatment. “Ongoing” implies that treatment involves regular repeated visits over a period of up to 1 to 2 years. Patients with the most severe tinnitus condition require repeated visits to reinforce the objectives of treatment, to modify the intervention plan as necessary, and to evaluate outcomes of treatment. This type of approach reassures patients that they are not just “on their own” but are receiving a continuity of professional care for as long as it is needed. Patients in our individualized treatment trial (C2887R) attended an average of seven appointments over a period of 18 months. Results demonstrated that the effectiveness of treatment increased over time, for both the masking and TRT methods [14,77]. This result would suggest that treatment should be administered at recurring intervals to achieve continued progress.

Since counseling is important for any form of tinnitus treatment, recognizing that only about 50 percent of the information that is dispensed to patients is actually retained is important [105]. In addition, research has shown that 40 to 80 percent of counseling information is forgotten immediately [106]. For the counseling to be most effective, it must be repeated at the continuing treatment appointments [95].

Patients identified with the progressive-intervention approach as needing Level 4 long-term management should meet the following criteria:

1. Evaluation and treatment at lower levels of clinical management have been insufficient in meeting their needs.
2. They have been referred to other medical specialists as appropriate.
3. They are motivated to enter into a long-term treatment program.
4. They can comply with all requirements of treatment.

At the time of the intake assessment, these criteria should be reviewed with the patient and a treatment plan should be agreed on by both patient and clinician. The short-term schedule of return appointments should be decided at this time, and a long-term schedule should be projected. The short-term schedule will depend on the severity of the condition and on the patient's motivation to be aggressive with treatment. Some patients will need to return for multiple visits within the first month. Other patients need to return only after 1 month for the first return visit. Following the short-term flexible schedule, ongoing treatment would generally involve a fixed schedule of visits at 3 and 6 months and then every 6 months for as long as treatment is needed. All patients should be advised to telephone the clinician whenever questions or issues arise and to request special appointments if deemed necessary.

When the decision has been made to implement long-term tinnitus rehabilitation, two structured methods of treatment are suitable for clinical practice by audiologists. The method of Tinnitus Masking uses ear-level devices (maskers, hearing aids, or combination instruments that contain both) mainly to achieve immediate relief from the bothersome effects of tinnitus [27,34,37]. Masking patients are also advised to use various forms of sound (CD, radio, tabletop sound generators, etc.) to augment the ear-level devices. The method of TRT uses the same types of ear-level instruments, but choices of these instruments are much more restricted than for masking. (TRT requires that devices meet specific criteria; for masking, any type of device is acceptable if preferred by the patient.) Both masking and TRT involve counseling, but the counseling for TRT is much more structured. The differences between these methods are many, as previously described [27] and as just discussed briefly in the treatment-review section. Treatment for hyperacusis can also be accomplished as described for Tinnitus Masking [104,107] or for TRT [40,108–109].

Tinnitus patients can also be treated with CBT [53]. Although psychologists normally perform CBT, audiologists who have received the necessary training can also administer it [45,53]. CBT can be used as the only method of treatment, or it can be used to augment either masking or TRT. A book is available that describes in detail the application of CBT to tinnitus patients [53].

Level 5: Extended Treatment

Some (few) patients will progress through all the first four levels of management and will still require further care. If consistent, individualized treatment has not resulted in significant improvement after 1 to 2 years, the clinician should attempt to determine why the intervention has not been successful. Every possible contributing factor should be explored, and referrals to other practitioners may be indicated more strongly at this point. Most importantly, patients should be considered (or reconsidered) for psychological management.

For patients treated with TRT, the method is designed to produce changes in how the tinnitus neural signal is processed. When successful, these changes are thought to result in habituation to the annoyance of tinnitus and in habituation to the perception of tinnitus. This "retraining" process takes time, and patients are highly variable with respect to the amount of time required. Although most TRT patients complete treatment within 1 to 2 years, some patients have required treatment for as long as 4 years.* Habituation would of course be the goal of any form of tinnitus treatment. Regardless of what treatment is performed, the objective should always be for the patient to stop reacting emotionally to the tinnitus and ultimately to be unaware of its presence most of the time.

DISCUSSION

The lives of millions of Americans are significantly affected by intractable tinnitus. The problem is worsening because of the increasing pervasiveness of hazardous noise, especially for young people. Efforts to obtain treatment are often fruitless because no standards exist that govern the provision of tinnitus clinical services. There are certainly no guarantees that even a minimum of appropriate tinnitus care will be provided at different

*S. Gold, personal communication, June 2004.

hearing healthcare environments, primarily because of the eclectic nature of tinnitus management.

Relevance to VA Practice

Although many veterans suffer from tinnitus, few have access to high-level tinnitus treatment at a VAMC. The growing problem of tinnitus for veterans and for the VHA dictates the addition of tinnitus clinical services at VAMCs. Because of the often extreme demands on audiology clinical resources, any new implementation of services requires that they are (1) within the scope of clinical services outlined by the VA patient-care mission, (2) supported by prospective research, and (3) cost-effective for meeting the demands of veterans who experience clinically significant tinnitus. Information about tinnitus should be made readily available to veterans through a variety of media. Veterans should have telephone access to a qualified person who could answer most of their questions about tinnitus. The TISI provides an appropriate venue for answering questions about tinnitus and establishing whether clinical services are needed [97]. These services can be provided using the tiered approach of progressive intervention just described.

We have completed research (C2887R) to evaluate the clinical efficacy of Tinnitus Masking and TRT. We believe that results of this study, along with the subsequent multisite continuation study that is currently underway, will provide the evidence that the VA needs to document the effectiveness of these methods. These studies are limited to using veterans who are bothered by their tinnitus to such a degree that 18 months of individualized treatment, including the use of ear-level devices, is warranted. A less labor-intensive, more cost-effective solution is needed for veterans whose tinnitus is less severe, yet still clinically relevant. One of our randomized clinical trials (C2760R) has provided preliminary evidence that TRT counseling, presented in a group format by a trained audiologist, sufficiently alleviates the impact caused by tinnitus for many veterans with clinically significant tinnitus. Confirmation of these findings would potentially support this cost-effective treatment for implementation at all VAMCs to significantly improve the quality of life for many veterans.

Relevance to Non-VA Practice

The approach of progressive intervention for tinnitus management is suitable for any non-VA tinnitus clinic that must use its resources efficiently. Screening for clinical

relevance of tinnitus would be appropriate for any potential patient. Effective screening will, in many cases, preclude the need to schedule a clinical appointment, thus conserving clinical and administrative resources. After being screened, those patients who desire appointments in the clinic are much more likely to require clinical services than if screening were not done. Most patients can be routed into efficient group-counseling sessions to provide them with much more information than would be possible over the telephone. Some patients will demonstrate a more urgent need for treatment. These patients should bypass the group sessions and be scheduled as soon as possible for a complete hearing and tinnitus assessment. Some patients who complete the group counseling might also need further services and the assessment would be their next step. The assessment alone, which includes a degree of counseling, will be sufficient for some of these patients. Only patients with the most severe tinnitus will require a long-term treatment program.

CONCLUSION

We have outlined a progressive intervention approach to tinnitus management. This approach is based on research, but further research is needed to more specifically define the various levels of treatment methodology and how to treat patients most effectively. That research is underway at the NCRAR, with the objective to fully support an entire program of tinnitus management that addresses the needs of tinnitus patients at all clinical service levels. The progressive intervention approach not only uses clinical resources most efficiently but also addresses the needs of tinnitus patients most expeditiously. At present, a person who suffers the effects of tinnitus may have difficulty finding a professional who specializes in tinnitus management. Often these efforts are unsuccessful due to the proliferation of professionals who claim to have tinnitus expertise but only offer a form of treatment that is merely effective anecdotally, without any scientific basis. A structured, graduated approach to addressing the needs of these tinnitus sufferers will eventually become commonplace. Until that time, a systematic program of progressive intervention, as outlined in this article, could effectively manage tinnitus for all but the most intractable cases.

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