ORIGINAL ARTICLE

Outcomes of Tinnitus Masking Therapy in Patients Selected Based on Audiological and Psychological Criteria

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Background: It has been shown that tinnitus can be masked with acoustic signals. These signals must be tailored for each patient and can be incorporated to a hearing aid to assist hearing loss accompanying hearing loss. Psychological criteria are as important as audiological criteria in patient selection to achieve success in tinnitus therapy.

Objective: To assess the effectiveness of wide-band acoustic signals based on tinnitus frequency for each individual patient, delivered through a hearing-aid to aid in relief of tinnitus (Tinnitus masking therapy-TMT). Tinnitus handicap scales were used to assess the degree of relief both in 42 patients with normal hearing or some degree of hearing loss.

Results: The relief from annoyance was 55.9% and decrease of negative effect on life was 67.2% after three months of treatment. Total rate for any degree of relief was 79.3% in normal hearing group, where in hearing-loss group it remained at 61.2%. Emotional, social and hearing-related scores were similar evaluated by different types of questionnaires. Intensity of masking noise was decreased gradually in all patients but two. Five patients who were completely free of tinnitus completed follow-up although they stopped using their hearing aids.

Conclusion: We conclude that the success rates, cost-effectiveness and absence of side effects makes TMT first choice treatment method in all tinnitus patients either with normal hearing or sensorineural hearing loss. The key to success is proper patient selection based on various audiological, clinical and psychological parameters. Regular follow-up is essential.

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Introduction

Tinnitus can be described as perception of sound in the absence of external acoustic or electrical stimulation. As tinnitus may also accompany other diseases, it is generally accepted as a symptom, not a disease. Although it is rare in young people, prevalence of tinnitus is estimated to be as high as one third in geriatric population [1]. Lack of consensus among many theories regarding the neurophysiological or cochlear origin and mechanism of tinnitus makes it difficult to develop an effective treatment method [2,3]. Medical treatment, tinnitus masking (TM), tinnitus retraining therapy (TRT), electrical stimulation, surgery, lasers and transtemporal magnetic stimulation are some of the treatment modalities which have been described and are still in use [4,5,6,7]. There is much controversy on these methods and there is no standard treatment for tinnitus yet. Every method has its own advantages and disadvantages. The effectiveness, cost, feasibility and side affects should be considered when developing a treatment scheme. Masking treatment is gaining acceptances in the recent years, because it has no side effects and is easy to apply.

The aim of tinnitus masking therapy (TMT) is to overcome perception of tinnitus by means of applying a masking sound at a certain intensity and frequency.

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Modern masking methods was first described and used by Jack Vernon [8]. His team developed this method being unaware of the former studies in history. In 1821, Itard had described masking for tinnitus with empiric methods [9]. He noted that tinnitus did not respond to neither medical nor surgical treatment and believed that covering the tinnitus with external sounds was the most effective method. He defended the idea that masking sound must be similar to perceived tinnitus. Listening to sounds coming from the burning fireplace or windmill was what he recommended to his patients. Today, tinnitus masking is achieved by using tinnitus maskers, combined tinnitus tools, hearing aids or low intensity white noise generators. Treatment is begun after the frequency, intensity of tinnitus and the lowest sound or noise enabling tinnitus masking is determined [6].

In this study, results of tinnitus masking (TM) therapy in our patient group is presented and discussed reviewing the treatment methods in the literature.

Materials and Methods

67 patients, ranging in age from 27 to 83 years who presented with subjective tinnitus lasting for at least three months, between March 2010 and November 2011, were recruited for this study. Patients with any diagnosed organic ear disease or previous ear surgery, as well as patients with a known diagnosis of any psychiatric illness were excluded. All patients had an experience of at least one month of treatment with various drugs, of which they had not benefited. A thorough history and otolaryngology examination was followed by tonal audiometry to diagnose any type of hearing loss. Temporal bone MRI was ordered for 23 patients based on clinical and audiological findings to rule out any retrocochlear lesion.

A tinnitus reaction questionnaire (TRQ) developed by Wilson et al [10] was carried out to assess the psychological distress associated with tinnitus. 13 patients scoring higher than 60 were referred to psychiatric evaluation and were excluded. In practice, this test has been used as a fast method for eliminating patients who need psychiatric referral before attempting a tinnitus retraining therapy [11]. Patients who accepted to begin TMT and who are eligible for further intervention are evaluated with the translated form of tinnitus handicap questionnaire (THQ) developed by Kuk et al [12]. It consists of 27 items designed to measure the handicapping effects of tinnitus on hearing, lifestyle, health and emotional status. Patients were instructed to rate their agreement from 0 to 100. The average scores for tinnitus patients in the original study for each type of handicap have a wide range.

A "tinnitus/hyperacousis initial interview form" of Jastreboff who developed a new model for tinnitus retraining therapy was also used to evaluate the patient's problem and the stress caused by it. Patient ranks severity, annoyance and effect on life on a 0 to 10 scale [13].

Determining minimum masking levels and residual inhibition levels: Frequency and intensity assessments were made at contralateral ear in unilateral tinnitus cases and at the ipsilateral ear in bilateral cases. A pure tone at 1000 Hz was presented by a clinical audiometer (Interacoustics AC40, Denmark) below hearing threshold and increased until the patient could hear a sound. The frequency was then shifted and the intensity was gradually increased. The patients selected the sound which was most similar in frequency and intensity to the tinnitus sound they perceived. Minimum masking level was measured at 500, 1000, 2000 and 4000 Hz. Earnet Nano® behind-the-ear hearing aid coupled with open-fit ear moulds was used to present selected sound stimulus. This hearing aid was selected because it can deliver masking sounds at a band tailored for each patient, while functioning as a hearing through a different program. The NOAH-based custom programming software was used for device fitting. With this hearing aid, noise generating signal level can be adjusted between 30 and 65 dB. An additional 15-20 dB gain can be added with broad-band noise setting option. At the initial fitting, stimulation was begun at the minimum intensity level and was increased to a level high enough to mask tinnitus.

Patients wore the hearing aid for 15 minutes every two hours until going to bed for seven days. At the second visit, patients were asked if they notice an absence or decrease in tinnitus for a period of time, after they took their hearing aid off. This phenomena is called

"residual inhibition"[8]. The patients were also asked about any change in frequency or any other characteristics of tinnitus. Treatment was modified according to each patient's response. Frequency band of the masking noise was shifted during each visit to find the optimal frequency and intensity to mask tinnitus, if needed.

At control visit at the end of four-week treatment, Jastreboff's "tinnitus/hyperacousis follow-up interview form" was used to evaluate patient's status and for further counseling. Scores regarding the severity, annoyance and effect on life. Final 42 patients who reported some degree of benefit from treatment were included in this study. These patients were followed-up every two week for three months, every month for the next three months and bimonthly for the next six month and masking parameters were changed when needed. Initial and 3-month scores were compared using a simple paired samples t-test. A P value of 0.05 or less was considered significant.

Results

Efficacy of TM therapy (TMT) was evaluated on 42 patients, 23 (54.8%) male and 19 (45.2%) female, ranging in age from 27 to 83 years (median=56). Five patients had normal hearing (Figure 1). 15 (40.5%) participants had bilateral tinnitus. Tinnitus was on the right ear in 17 (36.8%) patients and on the left ear in ten (23.8%) cases. Tinnitus history ranged from 3 to 180 months, with an average of 51.6 months. Average follow-up time with TMT was 4.5 months. Eight patients gave up treatment; the reason was full recovery in three of them. The other three patients did not benefit from TMT and two patients had left TMT at third and fifth month despite some degree of relief. The remaining 34 patients showed progression in relief from tinnitus based on the follow-up interview form.

Jastreboff's form: To assess the effect of the treatment, the individual differences for each subject were calculated by subtracting the initial value for each parameter from the value recorded during the following-up visit are presented as a percentage of the initial value. Average ranking for severity of tinnitus decreased from 6.9 to 3.6 (47.8% decrease). The relief from annoyance was 55.9% and decrease of tinnitus affect on life was 67.2% at three months. The changes in severity, annoyance and affect on life were shown in figure. Total rate for any degree of relief was 79.3% in normal hearing group, where in hearing-loss group it remained at 61.2 %. The scores at the first month visit were similar to two-month-scores (Figure 2). This effect is due to residual inhibition or suppression of tinnitus which provides some relief and helps the patient control the problem. No adverse effect of masking on hearing was seen in normal hearing group.

THQ scores: Patients with hearing loss scored higher in six items regarding effect of tinnitus on hearing. Social handicap scores for six related questions in THQ were parallel to that of Jastreboff's "effect on life" scores as expected. Emotional scores were similar to TRQ scores: patients scoring higher in TRQ, had higher scores in THQ questions regarding their emotional status.

Intensity of masking noise was decreased in all patients but two. Five patients who were completely

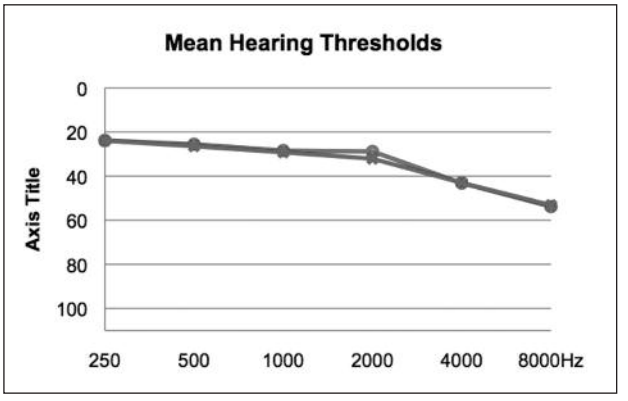

Figure 1. Mean air conduction hearing thresholds of the study population

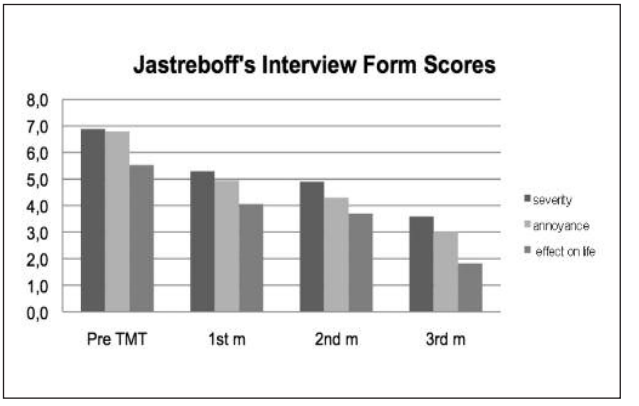

Figure 2. Pre- and post-treatment scores of based on Jastreboff's Interview Form

free of tinnitus completed follow-up although they stopped using their hearing aids. 29 patients are still followed-up beyond the limit of this study.

Discussion

Since tinnitus was first described at 15th century BC, many treatment modalities have been described. Although antidepressants are widely used in tinnitus treatment, there is no controlled study proving that they are more effective than placebo. Melatonin, a natural hormone secreted from epiphysis, was shown to be beneficial in a prospective study conducted by Megwalu on 24 patients, but in another double-blind study on 30 patients by Rosenberg, no statistically significant difference was found between placebo and melatonin [4,14]. The general belief is that melatonin does not have a direct effect on tinnitus, but it relieves tinnitus by regulating sleep. Another widely used agent especially for ischemic cases, is ginkgo biloba. In a meta-analysis, no significant difference was shown between this agent and placebo. On the other hand, Çekkeyan et al compared betahistine and ginkgobiloba both to each other and to placebo and concluded that both drugs are superior to placebo but not to each other[15]. No significant benefit was demonstrated with various agents such as GABA analogues such as gabapentin, calcium channel blockers, antilipidemics and elements like zinc. In some clinics, drug therapy is the first choice, but absence of evidence-based pharmacologic agent and possible side effects are draw-backs.

Transcutaneous electrical nerve stimulation (TENS) which is an electrotherapy method used in pain treatment, is being used in recent years with the idea of increasing cochlear functions. Steenerson reported 53% success in 500 patients using TENS[16]. He found that in 72% of these patients, relief continued for another three months. A permanent increase in tinnitus occurred in two patients and temporary increase in 13 of them. Although TENS is getting popular in recent years, because of long treatment requiring many hospital visits and no possibility of self-conduct of treatment at home, it was not able to catch superiority to masking treatment. Beriat et al compared the effect of betahistine hydrochloride, TENS and pure tone masking treatment to relief of symptoms on tinnitus in 91 patients and reported that success rate is much higher in masking treatment and that it can be recommended as the first choice treatment [17].

Jastreboff was the first researcher to put forward en electrophysiological model which pursues a clinical goal is to remove the perception of tinnitus from the patients' consciousness by initiating and facilitating the process of tinnitus habituation. He reported that the best signal is the one that provides stable, random excitation of neurons involved in processing of acoustic information in as wide frequency range as possible[18]. Such a signal is interferes with the extraction of tinnitus related activity from the background in an optimal way and provides an easy habituation. Herraiz et al found a relief rate of 80% in 158 patients undergoing tinnitus retraining treatment, in a 12-month follow-up[19]. Henry et al reported a minor difference in moderate tinnitus, comparing tinnitus retraining treatment and tinnitus masking treatment in 118 patients. The general thought was that, both tinnitus retraining treatment and tinnitus masking using a steady background sound provide similar success, and have similar advantages because they are easy to conduct and cost-effective [20].

Among all these above-mentioned modalities, masking treatment is coming forward. Tinnitus masking therapy (TMT) is gaining more acceptances today, because it is noninvasive and cost-effective. Hazell at al compared the patients with tinnitus hearing aids to those using only masking aids and noted the extra benefit of compound hearing aids in correcting the hearing loss. They also pointed out that masking component did not have any negative effect on hearing[21].

In our study, we have applied TMT to 42 patients with subjective tinnitus. Compound tinnitus aids -hearing aid and tinnitus masker- were used in all our patients. Earnet Nano® hearing aids were chosen for our study, because they can be used both as a tinnitus masker and as masker plus hearing aid.

The prevalence of tinnitus is reported to be higher between 40-70 years of age. Average age in our group is 56. Minimal male dominancy has been reported in tinnitus. Although 54% of our patients were male, the difference is not found to be statistically significant.

It was shown that the onset of tinnitus is related to emotional or stress factors in 75% of patients, rather

than a pathology of the ear [22]. Although these triggering factors are secondary, the high stress level can interfere with TMT. In our study, we have excluded patients who scored higher than 60 in tinnitus reaction questionnaire (TRQ). Although the success with TMT in our study seems to be high, the actual success based on the initial number of patients recruited is lower. The elimination of highly stressed patients by using TRQ is the reason for difference in success rates. After psychiatric evaluation or treatment, these patients may be enrolled in TMT program, if they attain lower scores in this test.

The handicapping effects of tinnitus on hearing, lifestyle, health and emotional status are very important in a patient's decision to seek for help. Tinnitus handicap questionnaire (THQ) develoloped by Kuk et al has a high internal consistency (Cronbach's alpha=0.94) and good test-retest reliability [23]. We have found that the patients who have higher emotional scores in this test had less benefit from TMT, than the patients who reported more social and hearing handicaps.

In Jastreboff's interview forms general information related to tinnitus is gathered. This interview provide information needed for choosing the appropriate protocol for treatment as well as the proper planning of the masking treatment duration and masking parameters. Although significant decrease was found on all three parameters (severity, annoyance and effect on life), most benefit was seen on effect of life. Patients who are severely affected by tinnitus possibly believe that they are perceiving tinnitus nearly all the time, and that this has a negative effect on quality of life.

The scores at the first month visit were similar to two-month-scores. This effect is due to residual inhibition or suppression of tinnitus which provides some relief and helps the patient control the problem.

The intensity of the masking sound was decreased in almost all patients, which is probable a sign for an effect on limbic system. The conditioned reflex link tinnitus signals with reactions of the limbic and autonomic nervous systems at subconscious levels. Thus, the presence of tinnitus-related neuronal activity directly activates the limbic and autonomic systems, without the need or necessity of going through the high cortical areas involved in conscious thinking about tinnitus, verbalization, beliefs, etc. [18].

Further follow-up is recommended every six months even if there is satisfactory recovery, because there might be changes in tinnitus severity depending on possible emotional alterations and ear-related pathological conditions.

Conclusion

While the etiology of tinnitus is still unclear, it is still difficult to establish a definitive treatment modality. We conclude that the success rates, cost-effectiveness and absence of side affects makes masking treatment first choice treatment method in all tinnitus patients either with normal hearing or sensorineural hearing loss. The most important step in starting a treatment for tinnitus is patient selection. This should not be based solely on audiological or ontological criteria. Besides, from audiologist's point of view, determining the tinnitus frequency precisely is not a guarantee for choosing the optimum masking band noise. Our next step in implementing the right method for masking therapy is to conduct an MMPI (Minnesota Multiphasic Personality Inventory) test to analyze which psychological factors intervene the success of TMT. Regular follow-up is crucial for the patients with hearing loss and tinnitus to reach a higher rate of success. Further studies are necessary for integrating sound therapy in TMT, in search for increasing success rate in tinnitus retraining.

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