Original Article

Outcomes of masking and habituation therapy with the implementation of a new sound therapy protocol

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ABSTRACT

Objectives: This study aims to evaluate the outcomes of masking, counseling, and a new sound therapy protocol in subjective tinnitus patients.

Patients and Methods: This prospective study, conducted between November 2014 and November 2015, included 60 subjective tinnitus patients (33 males, 27 females; mean age 51.6±11.0 years; range, 29 to 76 years) randomly assigned to five groups. Total masking was implemented in four groups (groups 1, 2, 3, and 4), while combined habituation therapy and sound therapy were implemented in one group (group 5). Patients that did not benefit from masking therapy were offered habituation therapy. Directive counseling was applied during each session in group 5 and patients were started on a new sound protocol. Patients were evaluated with the tinnitus handicap questionnaire (THQ) in the beginning of the study (THQ1) and in the second (THQ2) and fourth months (THQ3). Patients were evaluated in the second month and regrouped: Patients that benefited from masking therapy were regrouped as group A, patients that did not benefit from masking therapy and continued with habituation therapy were group B, and patients that were only treated with habituation formed group C.

Results: Median THQ2-THQ1 and THQ3-THQ1 scores were significantly lower in group A (p=0.00063 and p=0.00109, respectively). Median THQ2-THQ1 and THQ3-THQ1 scores were significantly lower in group B (p=0.02421 and p=0.00503, respectively). Median THQ3-THQ1 and THQ3-THQ2 scores were significantly lower in group C (p=0.04685 and p=0.00506, respectively).

Conclusion: Masking with tinnitus masker could be beneficial in a limited group of patients. Further studies with longer follow-up duration for patients receiving only habituation and habituation after masking failure are warranted.

Keywords: Habituation, hyperacusis, masking therapy, tinnitus, tinnitus retraining therapy.

Tinnitus is a common otologic complaint with a prevalence of 10-15% in the adult population.[1] Tinnitus is usually classified into two groups: objective and subjective tinnitus. It is usually more possible to unveil the etiology of objective tinnitus compared to subjective tinnitus because most of the objective tinnitus patients have vascular or muscular etiologies. Although subjective tinnitus may originate from identifiable causes such as endolymphatic hydrops or cerebellopontine angle tumors, the etiology remains unclear in most of the subjective tinnitus cases. Hearing loss and cochlear damage are well known risk factors for tinnitus and it is assumed that phantom perceptions created by the neuroplastic response to the sensory loss lead to tinnitus.[2] The most widely accepted theory regarding the

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pathophysiology of subjective tinnitus is the neurophysiologic model. According to this model, tinnitus is originated from a pathology within any part of the auditory system and the neural activity is perceived as tinnitus without a vibratory stimulus in the cochlea.[3] Various therapies have been proposed for managing tinnitus; however, the most widely accepted treatment is the tinnitus retraining therapy (TRT) which is based on the neurophysiological model.[4] This technique basically combines educational counseling and sound therapy. A significant therapy success of 80% is reached with the TRT.[5] In this study, we aimed to evaluate the outcomes of masking, counseling, and a new sound therapy protocol in subjective tinnitus patients.

PATIENTS AND METHODS

This prospective study was carried out at the otolaryngology clinic of a Ege University, Faculty of Medicine, Otorhinolaryngology Department between November 2014 and November 2015. Of a total of 125 chronic subjective tinnitus patients, those with objective tinnitus, congenital anomaly of the external or middle ear, active otosclerosis, chronic otitis media, cerebellopontine angle tumors, history of neuropsychiatric disease, active Meniere's disease, severe or profound hearing loss or who were lost to follow-up were excluded. Thus, 60 subjective tinnitus patients (33 males, 27 females; mean age 51.6±11.0 years; range, 29 to 76 years) were included. Pure tone audiometry was performed in all of the patients with the Interacoustics AC-40 (Interacoustics A/S, Middelfart, Denmark, headphone: TDH39) clinical audiometer. Intensity and frequency of the tinnitus were also measured using the same clinical audiometer. The study protocol was approved by the Ege University, Faculty of Medicine Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were randomly assigned to five groups. Total masking was implemented in four groups (groups 1, 2, 3, and 4), while combined habituation therapy and sound therapy were implemented in one group (group 5). Patients that did not benefit from masking therapy were offered habituation therapy. Earnet Nano (Earnet® Hearing Systems, Istanbul, Turkey), Beltone Promise 6 (Beltone, Ballerup, Denmark), Phonak Audeo Q (Sonova AG, Staefa, Switzerland), and Widex Menu (Widex A/S, Lynge, Denmark) were used as tinnitus maskers. Personal MP3 players and smart phones were used in group 5. Directive counseling was applied during each session in group 5 and patients were started on a new sound protocol. An instrumental relaxing habituation music was combined with a background white noise slightly centered around the measured tinnitus frequency using the computer software Adobe Audition 2014 CC (Adobe Systems Incorporated, San Jose, USA). Patients were asked to apply the sound therapy throughout the day as much as they could like the tinnitus maskers.

Patients were evaluated with the tinnitus handicap questionnaire (THQ) in the beginning of the study (THQ1) and in the second (THQ2) and fourth months (THQ3). Patients who were evaluated in the second month were evaluated and regrouped as follows: Patients that benefited from masking therapy were regrouped as group A, patients that did not benefit from masking therapy and continued with habituation therapy were group B, and patients that were only treated with habituation formed group C.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Chi-square exact tests were used for the comparison of categorical data. Independent and paired sample t-tests were used for the analysis of parametric variables while Wilcoxon and Mann-Whitney U tests were used for the analysis of non-parametric variables based on the distribution pattern of the data. The Shapiro-Wilk test was used for determining the distribution pattern of the data. The distribution of the groups was non-parametric. Correlation analysis was performed via Pearson or Spearman correlation analysis based on the distribution pattern of the data. Data were expressed as median and

Table 1. Tinnitus frequency and MML scores

	Tinnitus frequency	MML
Group 1	6,000 Hz (IQR=5,000)	67.50 dB (IQR=33)
Group 2	4,000 Hz (IQR=4,000)	52.50 dB (IQR=21)
Group 3	6,000 Hz (IQR=3,500)	47.50 dB (IQR=19)
Group 4	8,000 Hz (IQR=4,000)	65 dB (IQR=18)
Group 5	6,000 Hz (IQR=5,000)	55 dB (IQR=28)

MML: Minimum masking level; IQR: Interquartile range.

interquartile range (IQR). A *p* value less than 0.05 was considered as statistically significant.

RESULTS

Three patients (5%) had otosclerosis, three (5%) had a history of sudden sensorineural hearing loss, and four (7.5%) had a history of Meniere's disease.

Tinnitus was located in the right ear in 17 patients (28.3%), left ear in 18 patients (30%), and both ears in 25 patients (41.7%). Median pure tone audiometry thresholds (500-1,000-2,000-4,000 Hz) were 25 dB (IQR=18.75) for the right ear and 24.38 dB (IRQ=22.50) for the left ear.

Median tinnitus frequency was 6,000 Hz (IQR=4,000) and median minimum masking level (MML) was 55 dB (IQR=25). Median tinnitus frequencies and MMLs of the groups were shown in Table 1. The rate of hyperacusis was 58.3%, 61.5%, 46.2%, 66.7%, and 60% for groups 1, 2, 3, 4 , and 5, respectively.

Median THQ1 scores regarding the groups were 1,450 (IQR=1083), 1,400 (IQR=1213), 900 (IQR=1,080), 1,595 (IQR=938), and 1,300 (IQR=1,279), respectively. Median THQ2 scores were 1,175 (IQR=873), 1,040 (IQR=620), 820 (IQR=648), 1,120 (IQR=773), and 1,090 (IQR=1,061), respectively (Figure 1). THQ2 scores were significantly lower compared to THQ1 scores in groups 1, 2, and 4 (p=0.010, p=0.025, p=0.031, respectively). Patients were reevaluated at the second month. Eighteen patients (group A) were satisfied with the tinnitus masker and chose to continue wearing it. However, 32 patients were not satisfied with the tinnitus masker and returned the device. These patients were offered habituation therapy (group B). Group 5 continued habituation therapy and was renamed as group C (Table 2).

The THQ1, THQ2, and THQ3 scores of groups A, B, and C were calculated (Figure 2). Median THQ1, THQ2, and THQ3 scores of group A were 1,480 (IQR=868.8), 925 (IQR=640), and 880 (IQR=800), respectively. Median THQ1, THQ2, and THQ3 scores of group B were

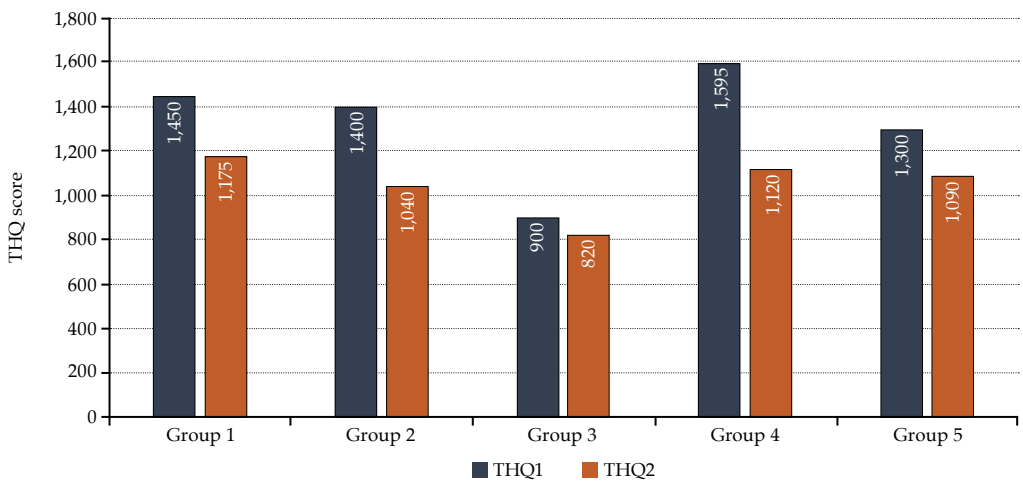

Figure 1. *Median tinnitus handicap questionnaire scores in beginning of study and in second month.*

THQ1: Tinnitus handicap questionnaire scores in beginning of study; THQ2: Tinnitus handicap questionnaire scores in second month.

Table 2. Groups and types of therapies

	Group 1	Group 2	Group 3	Group 4	Group 5	Total
Masker (Group A)	6	5	2	5	-	18
Masker + habituation (Group B)	6	8	11	7	-	32
Habituation (Group C)	-	-	-	-	10	10
Total	12	13	13	12	10	60

1,357.5 (IQR=1,087.5), 1,130 (IQR=725), and 1,075 (IQR=945), respectively. Median THQ1, THQ2, and THQ3 scores of group C were 1,300 (IQR=1,279), 1,090 (IQR=1,061.3), and 887.5 (IQR=915), respectively.

Median THQ2-THQ1 and THQ3-THQ1 scores were significantly lower in group A (p=0.00063 and p=0.00109, respectively). However, difference between THQ3-THQ2 scores did not differ significantly (p=0.06719). Median THQ2-THQ1 and THQ3-THQ1 scores were significantly lower in group B (p=0.02421 and p=0.00503, respectively). However, difference between THQ3-THQ2 scores did not differ significantly (p=0.63105). Median THQ3-THQ1 and THQ3-THQ2 scores were significantly lower in group C (p=0.04685 and p=0.00506, respectively). No significant difference was found between median THQ3-THQ2 scores (p=0.28450).

Hyperacusis was present in nine patients (50%) in group A, 20 patients (62.5%) in group B, and six patients (60%) in group C. The THQ score changes in hyperacusis-positive and negative patients were shown in Figure 3. Median THQ1-2 and THQ1-3 score differences were significantly prominent in hyperacusis-negative patients.

DISCUSSION

Tinnitus patients may experience significant psychological distress such as anxiety, depression, irritability, and sleep disorders. Thus, patients with significant distress require thorough assessment and attention to cope with their distress and tinnitus. Many pharmacologic agents were investigated to cure chronic tinnitus. Routine use of antidepressants, anticonvulsants, anxiolytics or intratympanic medications is not recommended.[6] A review investigating six trials reported that despite some slight improvement in

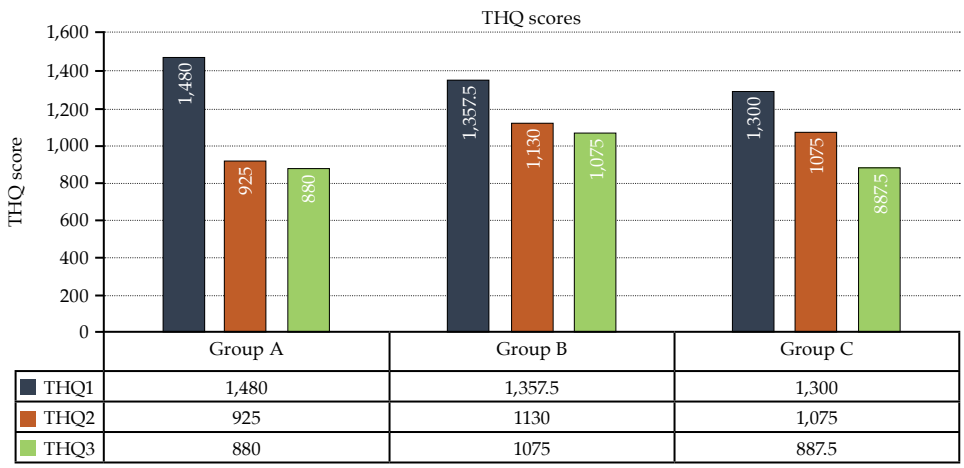

Figure 2. *Tinnitus handicap questionnaire scores in beginning of study and in second and fourth months.*

THQ: Tinnitus handicap questionnaire; THQ1: Tinnitus handicap questionnaire scores in beginning of study; THQ2: Tinnitus handicap questionnaire scores in second month; THQ3: Tinnitus handicap questionnaire scores in fourth month.

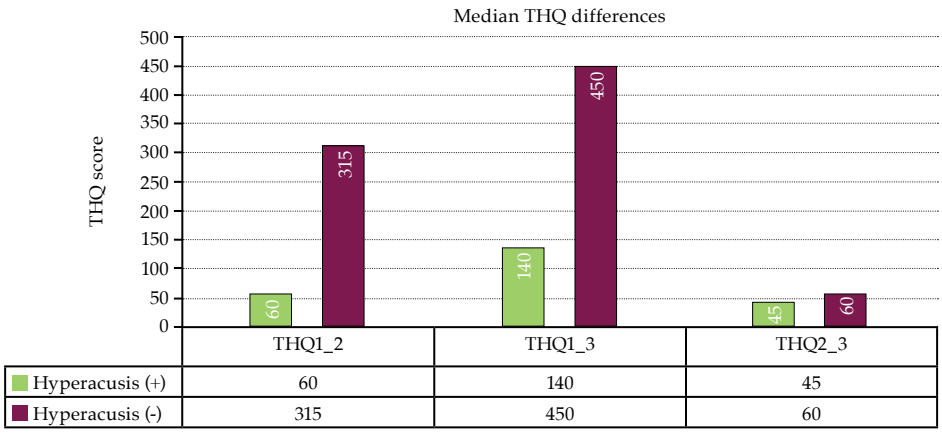

Figure 3. *Median tinnitus handicap questionnaire score differences between hyperacusis-positive and negative patients.*

THQ: Tinnitus handicap questionnaire; THQ1: Tinnitus handicap questionnaire scores in beginning of study; THQ2: Tinnitus handicap questionnaire scores in second month; THQ3: Tinnitus handicap questionnaire scores in fourth month.

tinnitus patients, there was insufficient evidence in favor of antidepressants.[7] Additionally, benzodiazepines such as alprazolam negatively affect brain plasticity and therefore are not recommended in tinnitus habituation.[8-11] Despite ongoing research, there is no licensed pharmacologic agent in Europe or North America for tinnitus.

Suppressing tinnitus with external sound stimuli has been used since the 1920s. Masking was first suggested by Vernon[12] in the 1970s for the management of symptomatic tinnitus patients. During the first years of masking therapy, special attention was given to psychoacoustic parameters and the preferred masking sound was identical to tinnitus frequency. However, more recent studies recommend wide band noise for tinnitus masking.[13,14] Hazell et al.[15] reported that tinnitus sound level and frequency were not correlated with masking properties of tinnitus. Additionally, they stated that tinnitus could not be masked in approximately 50% of the patients. They also reported that masking was problematic particularly in patients with hypersensitivity and hyperacusis because masking sound could easily pass loudness discomfort levels (LDLs) and worsen symptoms.[15] Ogut et al.[16] treated 67 patients with masking therapy and suggested that masking therapy was cost-effective, efficacious, and could be recommended as a first-line therapy in patients with normal hearing and hearing loss. A review evaluating the results of 553 patients treated with masking therapy concluded that absence of conclusive evidence should not be interpreted as evidence of lack of effectiveness.[17] However, if the sound level in partial masking therapy is low, this could potentiate habituation to tinnitus and positively affect tinnitus patients.[18] Significant THQ score reduction was present in groups 1, 2, and 4; however, the most prominent progress was in group 2. The masking sound differed from other maskers in group 2. The Zen program used in group 2 played random chime-like tones that can be used for relaxation and making tinnitus less noticeable. Sweetow at al.[19] suggested that Zen program was helpful compared to amplification alone; however, this had to be supported with consulting. Placebo had a success rate of 40%; however, this effect was short lasting (two to three months).[20] Longer follow-up time (6-24 months) is needed to justify the positive results in masking groups.

Habituation to tinnitus was developed after the neurophysiologic model was proposed in the 1970s. The TRT which is the clinical implementation of the neurophysiologic model is based on the habituation of the brain and body reactions to tinnitus.[4] Management of

tinnitus requires habituation to reactions that cause psychological distress (sleep disturbance, depression, anxiety, etc.) and habituation to perception of tinnitus.[21] This is achieved by breaking the faulty relationship between the limbic, autonomous, and auditory systems. Additionally, TRT can be used in almost all tinnitus cases regardless of etiology.

First step in habituation is counseling and patient education. Patients are informed about their auditory system and tinnitus mechanisms. Tinnitus is taught as a neutral and harmless stimulus. This helps to decrease the tinnitus-associated neuronal activity in the limbic and autonomous system. Second step in tinnitus habituation is the implementation of sound therapy, acoustic therapy or acoustic enrichment. Hearing amplification is recommended in all tinnitus patients with hearing loss requiring rehabilitation.[22,23] Amplification decreases distress and anxiety caused by hearing loss, and also amplification of the ambient noise creates masking to a certain degree. Decreased ambient noise causes amplification in the auditory system. For this reason, silence is not recommended in tinnitus patients. According to the neurophysiologic model, the level of sound therapy should not exceed the tinnitus level because tinnitus has to be audible during the sound therapy for habituation.[4]

Habituation was implemented in patients that did not benefit from masking therapy (group B) and was continued in group 5 (group C). Median THQ scores in group B were lower at the fourth month compared to the second month despite the lack of statistical significance (1,130 vs. 1,075, $p>0.05$). In group C, THQ scores were significantly decreased at the fourth month compared to the second month (1,075 vs. 887.5, $p<0.05$). According to the results of the current study, THQ scores improve after the second month. Habituation to tinnitus is gradual and requires time. In order to observe permanent plastic changes in the nervous system, a therapy of at least 12 months is required.[4,21] Given the long duration required for habituation therapy, it should not be concluded that habituation therapy was ineffective in group B.

Jastreboff categorizes tinnitus patients into five categories and patients with hyperacusis (categories 3 and 4) are deemed as the harder patients to treat regardless of tinnitus level.[4] Incidence of hyperacusis was 58.3% in this study; however, the study was designed regardless of hyperacusis presence. Incidence of hyperacusis was similar in all groups. Similar to previous reports,[4,5,21] both masking and habituation patients with hyperacusis also showed less progress. In the presence of hyperacusis, Jastreboff recommends a slow desensitization protocol and treatment of hyperacusis prior to the treatment of tinnitus.[4,21] Additionally, they recommend use of LDLs to monitor hyperacusis.[21]

This study has some limitations. Sixty out of 125 patients were able to complete the study. Almost all patients who were lost to follow-up were patients given tinnitus maskers. It was thought that patients might have thought that tinnitus masking was ineffective because counseling was not given. Another shortcoming of this study is the limited number of patients and small group sizes making the power of statistical analysis lower. Given the follow-up duration of six months to observe the plastic changes in the central nervous system, results of a longer follow-up duration would be better to support the findings of this study.

In conclusion, management of tinnitus varies significantly among regions, medical centers, and physicians. Counseling increases the adaptation of the patient to the therapy. Masking with tinnitus masker could be beneficial in a limited group of patients. However, these patients also need to receive counseling and require a close follow-up for the coherence of the therapy. Further studies with longer follow-up duration for patients receiving only habituation and habituation after masking failure are warranted.

Declaration of conflicting interests

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