Original Paper

Effectiveness of the Combined Hearing and Masking Devices on the Severity and Perception of Tinnitus: A Randomized, Controlled, Double-Blind Study

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Key Words

Tinnitus treatment · Hearing aids · Masking devices · Betahistine dihydrochloride

Abstract

Objective: The aim of this study was to evaluate the effect of combined hearing and tinnitus masking devices that are appropriately programmed for acoustic stimulations using wide-band noise over the specific frequency range of tinnitus. **Material and Methods:** A total of 21 patients were randomly divided into 2 groups. Group I (12 patients) was managed with betahistine dihydrochloride (2HCl) and fitted either with a combined hearing aid or a sound generator, and group II (9 patients) was treated with betahistine 2HCl for 3 months. Audiological tests, pitch matching to determine the frequency of tinnitus, an assessment of tinnitus severity, and subjective scores (visual analog scale, VAS; Mini-Tinnitus Questionnaire) were used to assess the patients in both groups, and a loudness scale was also analyzed in group I. The results were evaluated in a double-blinded manner. **Results:** Significant decreases in the severity of tinnitus, Mini-Tinnitus Questionnaire score and VAS were observed in both groups. No significant differences were obtained in pitch-matched frequency of tinnitus in the two groups. **Conclusion:** The findings obtained using either the combined devices or the masking devices with wide-band masking demonstrate that these devices are an effective tinnitus treatment alternative.

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Introduction

Tinnitus is an involuntary sound perception without any external stimulus that affects approximately 17% of the population worldwide [1]. Tinnitus ranges from hardly noticeable to serious and life affecting. Tinnitus symptoms create distress and affect negatively the quality of life in approximately 4% of the population [1, 2]. The quality of perceived sounds can vary enormously from simple sounds such as whistling or humming, to complex sounds, such as music. Tinnitus may be perceived in one or both ears, within the head or outside the body [3]. The risk of tinnitus increases in patients over 55 years old who suffer from metabolic conditions [4].

Tinnitus may originate at any location along the auditory pathway, from the cochlea to the auditory cortex. Jastreboff [1] suggested a neurophysiological model for tinnitus. In this model, tinnitus could be generated at different levels within the auditory processing system [1]. Furthermore, some leading theories include outer hair cell damage, pathological changes affecting the receptor potentials of the inner hair cells, disturbances of calcium channels within the cochlea, and in cochlear neurotransmission [5–7].

Numerous management strategies have been tested for this potentially debilitating, heterogeneous symptom. Tinnitus treatment is divided into two broad categories. The first treatment category is based on directly reducing the severity of or eliminating tinnitus, and the second category includes treating the response of the patient to the tinnitus [8].

Medications are utilized in both treatment categories. Numerous pharmaceutical options have been investigated [9]. Pharmacological interventions include cortisone, vasodilators [10], anticonvulsants [11], antidepressants [12], *Ginkgo biloba* [13], and zinc [14]. Betahistine dihydrochloride (2HCl) is useful to reduce or eliminate tinnitus. Betahistine 2HCl increases the permeability by capillary dilatation with the H₁ receptor agonist activity and is used to treat tinnitus. Betahistine 2HCl is preferable for clinical use based on the results of controlled studies [15–17]. Possible adverse events arising from betahistine use include headache and epigastric discomfort. Betahistine is contraindicated in patients with gastrointestinal ulcers, asthma, pheochromocytoma and hypersensitivity to the drug [17].

The appropriate external sounds have also been used as a management tool for tinnitus. Sound therapies and retraining therapies constitute the most common treatment strategies since the 1980s [18]. The initial approach to sound therapy involves ‘complete masking’ in which the masking noise is raised in intensity until the tinnitus becomes inaudible [19]. Tinnitus patients are divided into five treatment categories to determine the choice of sound therapy. These treatment strategies include the application of ear level sound generators or partial masking devices in patients who have normal hearing, and combined hearing devices (which combine the sound generator with a single attachable device) in patients with loss of hearing [20]. Narrow-band noise is often used in the tinnitus-masking therapy to quickly suppress the perception of tinnitus, and masking is achieved using sound generators, hearing devices or combined devices (masking and hearing device). Although more effective treatment is achieved by providing the masking sound below the level of tinnitus, the exact mechanism is unknown, and the effectiveness may be due to the suppression of a psychophysics event [8, 16, 21].

The relationship between tinnitus and hearing loss was previously proven. Many tinnitus patients have a certain degree of hearing loss [2, 21]. Acoustic stimulations in the hearing devices produce outputs up to frequencies of 5–6 kHz, but their efficiency is limited in patients with high-frequency tinnitus. In their study, Schaette et al. [2] demonstrated that masking with an acoustic stimulation using narrow-band noise in the tinnitus frequency range is more efficient in patients with tinnitus-matched frequencies under 6 kHz.

Table 1. Tinnitus laterality, duration, frequency, loudness and VAS pre- and posttreatment results of group I patients

No.	Name	Age years	Gender	Tinnitus laterality	Duration months	Frequency, kHz		Loudness, dB		VAS	
						before	after	before	after	before	after
1	Z.A.	47	F	L	12	8	8	70	70	5	3
2	R.Ö.	54	M	R	12	4	1	35	35	6	5
				L	12	1	1	50	50	7	5
3	G.C.	57	M	R	8	6	4	70	55	8	7
				L	8	8	4	70	55	8	7
4	K.A.	49	F	L	6	6	1	70	70	7	6
5	K.B.	69	M	L	6	6	6	105	90	7	5
6	H.Ç.	51	F	L	60	0.25	0.25	25	20	7	4
				R	8	4	6	45	65	7	6
7	H.K.Ö.	51	M	L	60	4	4	25	20	6	4
				R	8	4	6	45	65	9	6
8	Ş.K.	52	F	L	48	8	4	110	70	8	6
9	M.F.A.	45	M	L	24	6	6	65	50	5	4
				R	24	6	6	70	60	6	4
10	S.D.	54	M	R	8	4	4	80	70	6	3
11	Z.T.	51	F	L	24	0.125	0.125	15	15	8	6
				R	24	0.125	0.125	20	20	3	2
12	B.A.	60	M	L	24	0.25	0.25	25	20	6	3

In our study, we applied wide-band noise instead of narrow-band noise using a behind-the-ear partial masking treatment accompanied by betahistine 2HCl 2 × 24-mg tablet treatment in the patient group and administered betahistine 2HCl treatment with the same doses in the control group. We evaluated the tinnitus severity and perception with audiological evaluations, loudness perception tests and subjective scores between both groups.

Materials and Methods

This study was approved by the ethical committee of Baskent University's Institutional Review Board (IRB No. KA09/387), and all participants gave informed consent.

Patients

Our prospective study cohort consists of 21 adult patients who were admitted to the Ear Nose Throat Department of Baskent University (Turkey) with a primary complaint of tinnitus. All patients underwent a standardized intake assessment including history and physical examination by an otolaryngologist. Subjects with major health diseases and coexisting vascular, neurological, psychiatric disorders, conductive or retro-cochlear hearing loss, Ménière's disease, with signs of degenerative disease of the cervical spine, and patients with temporomandibular joint disorder of bruxism were excluded. Twenty-one patients (10 female, 11 male, mean age 56.9 ± 10.7 years, range 40–80) at screening with a clinical diagnosis of persistent, subjective, moderate to severe, unilateral or bilateral tinnitus present for at least 6 months were included.

Patients were randomized into two groups in order to evaluate the effectiveness of the two different treatment conditions. The study group comprised 12 patients (5 female, 7 male, 18 ears) with a mean age of 54 ± 6.4 years (range 45–69; table 1), managed with coadministration of betahistine 2HCl (24-mg capsules, twice a day, per os) and fitted either with a hearing aid and/or a noise device depending on the severity of their hearing loss for 3 months. The control group comprised 9 patients (5 female, 4 male, 13 ears) with a mean age of 61 ± 14.16 years (range 40–80), who were treated with betahistine 2HCl alone (24-mg capsules, twice a day, per os) for 3 months.

Treatment Schedule

All patients underwent a standardized intake assessment including history and physical examination, pure-tone audiogram, tinnitus assessment [pitch matching, tinnitus questionnaire, visual analog scale (VAS) and loudness scaling test] during the first appointment prior to receiving their treatment. In addition, a loudness scaling test was performed in the patients in group I. During the first visit, a counseling session of approximately 30 min was performed. During the follow-up visits after 3 months, the patients underwent the same assessment again and received an additional short counseling session (10–15 min).

Audiological Evaluation

The pure-tone audiometric evaluation was performed using an AC40 clinical audiometer (Interacoustics, Denmark). The audiometric threshold was considered as the pure-tone average for the frequencies 0.125, 0.25, 0.5, 1, 2, 3, 4, 6, and 8 kHz. Pure tones were presented repeatedly and were varied by the experimenter until the subject indicated a close match to the pitch of the tinnitus.

Comparison sounds were presented to the contralateral ear for unilateral tinnitus, and for subjects with bilateral tinnitus, each ear was tested separately. The subject was asked to concentrate on the predominant pitch of their tinnitus.

Acoustic Stimulation: Combined Devices and Masking Devices

Depending on the severity of their hearing loss, group I patients were fitted either with personalized, programmed combined devices that fit behind the ear or partial masking devices with wide-band noise. All patients were instructed to use the combined device or the partial masking device for at least 6 h per day. Hearing aids were fitted using a modified strategy based on the NAL-NL1 rule. For unilateral hearing loss, one combined device was fitted, and for bilateral hearing loss, two were fitted. The masking devices (Earnet Nano 34, Turkey) had 8 adjustable channels (0.25, 0.5, 0.75, 1, 1.5, 3, 4, and 6 kHz). By adjusting the gain factor for each channel, the spectrum of the therapeutic noise was individually adapted to the hearing loss of each patient.

Questionnaires

To evaluate the impact of tinnitus on daily life, VAS and the Mini-Tinnitus Questionnaire were administered to the patients before and 3 months after treatment as assessed by Hiller and Goebel [22]. The VAS (range 1–10) evaluates the intensity of the tinnitus, the annoyance level, the impact of the tinnitus on the patient's life and the overall problems caused by tinnitus. Subjects were asked to rate the perceived loudness of their tinnitus on a VAS, with 'inaudible' and 'very loud' as the ends of the scale.

The Mini-Tinnitus Questionnaire consisted of 12 sentences that had 3 possible options: true (2 points), partially true (1 point), and false (0 points). The final score provides the severity index (0–24).

Loudness Scaling Tests

Loudness scaling tests were only performed in patients in group I. Test signals of different levels were submitted with a loudness scale earphone (K 1000, AKG, Austria). Loudness levels of wide-band noise with signals in frequencies of 0.5, 1, 2, 3, 4, and 6 kHz were classified as 7 different categories: 'cannot hear', 'very quiet', 'quiet', 'normal', 'loud', and 'very loud'. The responses were converted into numbers from 0 (cannot hear at all) to 50 (excessively loud). The perception of the degree of loudness of the sounds was identified. In addition, a broadened dynamic range was identified, and equipment settings were set accordingly.

Data Analyses

Because of the small number of subjects in each gender subgroup, nonparametric tests were used. To calculate significances, the Wilcoxon signed-rank test was used for differences before and after treatment within a group. We performed Student's *t* test for tinnitus frequency and loudness. Errors are expressed as $\pm$ the standard error of the mean. The data were analyzed using the IBM® SPSS® Statistics 20.0 program. A *p* value of <0.05 was considered statistically significant.

Fig. 1. **a** Mean audiograms of group I divided by treatment devices: all patients (green line), patients fitted with combined devices (red line), and patients fitted with masking devices (blue line; colors visible in the online version). **b** Mean audiograms of patients grouped by treatment with betahistine 2HCl.

Results

In this study, we randomly divided 21 patients (32 ears, 10 females, 11 males, mean age 57 ± 10.7 years) into two groups and investigated the change of tinnitus severity and perception, to determine the effect of a masking treatment that utilizes wide-band noise. The 12 patients (18 ears, 5 females, 7 males, mean age 54 ± 6.4 years) in group I received betahistine 2HCl 2×24 -mg tablet treatment simultaneously with the behind-the-ear tinnitus masking device. In group II, betahistine 2HCl 2×24 -mg tablets alone was administered (9 patients, 13 ears, 5 female, 4 male, mean ages 60.9 ± 14.2 years) for 3 months.

The tinnitus duration was quantified in months, with a minimum of 6 months, a maximum of 60 months and an average of 20.8 ± 17.7 months in group I (table 1); in group II, the durations were a minimum of 6 months, a maximum of 96 months and an average of 25.07 ± 32 months. Tinnitus was localized in 7 right ears and 11 left ears in group I (table 1) and 5 right ears and 8 left ears in group II.

The mean audiograms are shown in figure 1a. There was no hearing loss in 6 patients (10 ears) in group I, but all except 1 patient (2 ears) had hearing loss in the high frequencies. There was a very mild sensorineural type hearing loss in 4 ears, mild loss in 3 ears and moderate loss in 1 ear. Of the 18 ears in group I, the masking device alone was placed in 10 ears, and the combined hearing device and sound generator were placed in 8 ears.

Nine patients (13 ears) in the control group were assessed. Two patients (3 ears) showed mild hearing loss and the others had normal hearing on the audiogram; all patients had a decrease in the ability to hear high frequencies (fig. 1b).

The tinnitus pitch-matched frequency was assessed before treatment and after 3 months. There was no significant difference in group I or II before and after treatment ($p = 0.088$ and $p = 0.157$, respectively).

Tinnitus severity was re-evaluated after 3 months of the masking treatment. The severity index of group I decreased from 55.3 ± 28.2 to 53.8 ± 26 , and the severity index of group II decreased from 62.7 ± 19.4 to 61.5 ± 16.1 . These differences were significant ($p = 0.155$ and $p = 0.593$, respectively, Wilcoxon signed-rank test). The decrease in the severity between both groups was not significantly different ($p = 0.147$, fig. 2).

On the VAS, a decrease from 6.6 ± 1.4 to 4.8 ± 1.5 was observed in group I, and a decrease from 6.8 ± 1.8 to 5.9 ± 2.0 in group II. These decreases were significant ($p = 0.00$ and $p = 0.01$,

Fig. 2. Group averages of tinnitus loudness before and after treatment.

Fig. 3. Group averages of VAS before and after treatment.

Fig. 4. Group averages of the Mini-Tinnitus Questionnaire tests before and after treatment.

respectively, Wilcoxon signed-rank test). When comparing these decreases between the two groups, there was no significant difference ($p = 0.694$, fig. 3).

The Mini-Tinnitus Questionnaire was administered to all patients. The questionnaire had 12 questions and a total score of 24. The initial mean score of patients in group I decreased from 13.4 ± 4.1 to 7.3 ± 4.5 after treatment, and this decrease was significant ($p = 0.002$). The initial mean score of group II decreased from 14.7 ± 2.3 to 8.7 ± 3.0 after treatment, and this decrease was also significant ($p = 0.007$). When comparing the decreases between both groups, there was no significant difference ($p = 0.482$, fig. 4).

Fig. 5. The mean loudness levels of group I patients before and after treatment.

The additional loudness scaling test and threshold values of the pure-sound audiometry performed on the patients in group I were in agreement with the tinnitus frequency values before and after the treatment (fig. 5). Furthermore, hyperacusis was identified in all patients, with intensity values (30, 50, 65, 80 dB HL) above the threshold. To decrease the gain in the auditory pathways as a result of the hyperacusis obtained, the use of the sound generators was deemed suitable, and the noise was adjusted so it was not fully masking. In addition, decreases in the loudness values were found in all frequencies after treatment and there was a significant correlation ($p < 0.005$). Based on these data, the acoustic stimulation given in the masking treatment was adjusted to be within the normal loudness range, and the devices were adjusted.

Discussion

Tinnitus masking therapy is used worldwide [2, 21, 22]. Protocols that aim to partially or completely mask tinnitus aim to establish a masking level that patients find more acceptable than their tinnitus. It is always important to adjust a tinnitus masker or tinnitus instrument to generate the lowest level of masking sound that is capable of masking or relieving the tinnitus [23]. In this study, we tested the effectiveness of the treatment with partial masking using wide-band noise.

Varying degrees of hearing loss have been identified in the majority of patients with tinnitus [22]. Increases in the auditory nerve activities are demonstrated with acoustic stimulations given with masking treatment in tinnitus related to mild to moderate hearing loss [3, 24]. Some studies reported that after receiving a hearing aid, one half [25] to two thirds [26] of the tinnitus subjects reported improvement of their tinnitus. Schaette et al. [2] examined the influence of acoustic stimulation treatments to a set of pure tones or narrow-band noises and chose the closed match within the stimulated frequency range. They observed that the group of patients with a tinnitus pitch of less than 6 kHz showed a significant reduction in perceived tinnitus loudness, and tinnitus-related distress was significantly decreased after

6 months of treatment. Pure tones or narrow-band noises were used in these studies [2]. It is difficult to mask patients with high-frequency tinnitus with a narrow-band noise. In our study, we applied masking therapy to patients with normal hearing, and minimal, mild, and intermediate sensorineural-type hearing loss. In addition, high-frequency hearing loss was present in most of our patients. We observed that masking therapy with wide-band acoustic stimulation is effective in patients with high-frequency tinnitus.

We provided behind-the-ear masking equipment to all patients in group I. Masking with a sound generator was performed on 10 ears, and combined devices were used on the other 8 ears. We preferred wide-band noise because when adjusted to the frequency and severity of the tinnitus, wide-band noise is more convenient for the patients' tolerance compared to narrow-band noise, and a desirable level of partial masking was obtained by intervening with a greater number of channels. In addition, because the dynamic range is narrow in levels higher than threshold in patients with hearing loss, narrow-band noise, compared to wide-band noise, affects speech discrimination levels with much less masking. We created a wide-band noise using all channels in the sound generators of the behind-the-ear masking equipment and adjusted its loudness according to the hearing threshold, pure-sound audiogram and loudness scale tests.

In previous studies, a decrease in the tinnitus severity was demonstrated using hearing aids and sound generator [2, 27]. In our study, both groups showed a significant difference in the severity of tinnitus after a 3-month treatment protocol. Tinnitus pitch-matched frequency is important for the efficiency of the treatment. The validity of the results is dependent on the reliability of the tinnitus frequency. Variable results may be obtained when determining the tinnitus frequency due to the method of measurement or because the tinnitus sound is generally formed from complex sounds [28]. Our patients showed no significant difference in frequency after 3 months, which indicates that the method we used is reliable.

The Mini-Tinnitus Questionnaire was used along with various surveys that evaluated psychosomatic perception related to tinnitus. The 12-question survey that Hiller and Goebel [22] created in 2004 was compared with other tests and was a more comfortable test to use. According to the results of this questionnaire, the decreases in both groups were significant. In addition, a significant decrease in the VAS results was demonstrated in both groups; thus, both treatments were effective.

The loudness scale identifies the degree of loudness in auditory dynamic range by decreasing the levels of stimuli in different categories [29]. We used this test only in patients who would be using masking equipment. Hearing thresholds were compatible with the pure-sound audiometric threshold, tinnitus frequency, and tinnitus loudness levels according to loudness scale tests. We identified the loudness scale of the patients using 30, 50, 65 and 80 dB HL severity in more than 0.5 and 6 kHz. All patients identified the predetermined supra-liminal sounds as louder than normally anticipated. According to the data obtained, hyperacusia was detected in all patients. A significant decrease was identified in the loudness scale values after masking treatment; thus, the equipment was an efficacious treatment method.

In a variety of masking equipments, the efficiency of the equipment is limited to 5–6 kHz [30, 31]. Therefore, the acoustic stimulation given in this frequency range is more successful. We masked the tinnitus by applying a less severe wide-band noise, and the frequency range was adjusted for all patients in group I.

There are studies showing that betahistine 2HCl or combined devices may provide symptom relief for tinnitus [15–21]. However, a comparison of these two treatments for their effectiveness has not been conducted. The data from the present study showed that both methods were effective in the 3-month period. No statistical difference was found between both groups. However, a slight difference in favor of the tinnitus masker group is seen in figures 2 and 3. Considering that this data has been obtained after only 3 months of treatment,

we may be hopeful for the effectiveness of maskers in the long term. Also, patients with hearing loss using the combined hearing devices showed that the latter contribute to providing better hearing and a decrease in the severity of tinnitus.

Observing a significant decrease in our subjective tests of our patient group, we conclude that wide-band noise masking and betahistine 2HCl therapy is an effective method. A combined device should be recommended for the tinnitus patient with hearing loss. This is the first study on evaluating a masking therapy with betahistine 2HCl with regard to the severity and perception of the tinnitus, and due to the small number of patients, further prospective, double-blind, and placebo-controlled studies with a larger number of patients are needed for a more conclusive answer.

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