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Effects of tinnitus retraining therapy involving monaural noise generators

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Abstract The aim of this study was to assess how tinnitus retraining therapy (TRT) employing monaural noise generators (NGs) affects tinnitus patients. Ninety-five patients with chronic tinnitus were included in this study. All received directive counseling and monaural NGs without any other combination treatment. Effects were evaluated with the Tinnitus Handicap Inventory (THI) 6, 12, and 24 months after the start of treatment. Multiple regression analysis was used to evaluate factors associated with improvement of THI scores. We observed a significant improvement in the average THI scores, which ranged from 59 at baseline to 36 after 6 months and were stable up to 24 months. Severely distressed (SD) patients experienced more benefits from the therapy than moderately distressed (MD) patients. Multiple regression analysis revealed that the presence of transient anxiety symptoms, measured by the state section of the State Trait Anxiety Inventory at the beginning of treatment, were associated the most to a decline in THI scores in SD patients. Pure-tone average at three mid frequencies was a negatively contributing factor. Analysis of MD patients did not provide a good model. In conclusion, TRT employing monaural NGs was an effective intervention especially for SD patients, although plateau of the effects after 6 months may be indicative of limitation of applying NGs monoaurally. Reducing the patients' hearing handicap may reinforce the effects of TRT in SD patients. Additional evaluation and interventions for both SD and MD patients might be needed.

Keywords Tinnitus retraining therapy · Monaural noise generator · Tinnitus severity · Pure-tone average at mid-frequencies · State anxiety · Duration of tinnitus

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Introduction

Tinnitus, the perception of a sound that is not present in the environment of the subject, is a common yet poorly understood symptom experienced by approximately 10% of adults in various countries [1, 2]. The number of people with bothersome tinnitus in the United States in 1990 was estimated at nearly 15 million adults [3], and approximately half of the tinnitus sufferers in another study reported problems with getting to sleep and persistence of tinnitus, as well as despair, frustration, or depression [4].

Although no established treatments to eliminate tinnitus exist so far, tinnitus retraining therapy (TRT) has prevailed as a treatment to induce habituation to tinnitus and relieve tinnitus-related distress [5, 6]. Many studies reported its efficacy in treating tinnitus patients but poorly conclusive as pointed in a recent Cochrane review [7–13]. Tinnitus retraining therapy has two principal components [5]: directive counseling based on a neurophysiological model [14]; and sound therapy. Tinnitus retraining therapy can vary widely to include treatment components that reinforce directive counseling. Modifications in directive counseling include stress management, psychotherapeutic treatment, and cognitive-behavioral elements [9, 11].

With regard to the sound therapy aspect of TRT, however, most studies on TRT have followed the original

protocol [5, 9, 15–17]. In the original protocol, patients are divided into five categories, and sound therapy is principally performed according to this categorization [5]. Patients with distressed tinnitus but without hyperacusis are classified into category one (without significant hearing impairment) or category two (with significant hearing impairment). The significance of hearing loss refers to whether such hearing loss has any impact on a person's everyday life. Hearing loss as indicated by an audiogram does not necessarily equate to significantly experienced hearing loss [18]. The original protocol recommended the binaural use of a noise generator (NG) for category one patients and the use of hearing aids or a combination of hearing aids and NGs for category two patients.

However, the principle underlying the adaptation of tinnitus control instruments (TCIs) could be changed according to the social and cultural background of the country where TRT is performed. Actually in Japan, the monaural use of NGs became the most prevalent form of sound therapy among tinnitus patients who did not experience subjective hearing handicap in daily life [19], because of the health care system, as well as the relatively limited use of hearing aids. We conducted the present retrospective study in order to elucidate the effects of TRT employing monaural NGs on patients with tinnitus. This report is unique, because there is no existing report to date on the efficacy of TRT that employs monaural TCIs. To clarify the effects of sound therapy as much as possible, we included in this study only patients that did not receive any other combination tinnitus therapy, such as psychotherapy and medication.

Methods

Patient sample

We reviewed the medical records of 184 patients with a major complaint of chronic tinnitus lasting more than 3 months. These patients received sound therapy by means of monaural NGs with adjustable volume (Siemens Hearing Instruments Ltd). They were treated at the Hearing and Tinnitus Clinic of the university hospital where the authors worked from 2001 to 2006. Of the 184 patients, we included in the study 95 patients who received no other combination therapy. Only an otolaryngologist who studied TRT carefully and knew the method well provided directive counseling; the patients received no other counseling. Directive counseling was based on a neurophysiological model [14], and the importance of general sound enrichment was fully explained to all the patients. In addition to environmental sound enrichment, a NG was recommended when the patients did not have significant hearing loss, or when the patients' tinnitus complaint was much worse than their subjective hearing handicap. The initial counseling generally lasted for 30–60 min depending on the understanding of the patients. The severity of tinnitus was also taken into consideration when NGs were recommended (see below). The other exclusion criteria for NG application were as follows: patient was under the age of 18 years; tinnitus was accompanied by fluctuating hearing loss; and hearing loss was worse than 60 dB in the speech frequency range (500, 1,000, and 2,000 Hz). Patients with severe depression and other severe tinnitus-related distress who also received treatment from psychiatrists or psychologists were not included in this study. Patients who had significant hyperacusis were not included in this study, either. Only patients with tinnitus lasting for more than 3 months were included in this study, because based on our clinical experience, spontaneous recovery from or habituation to tinnitus could happen within the first 3 months after the onset.

The characteristics of the 95 patients included in this study are summarized in Table 1. Of these, 55 were men and 40 were women; the mean age was 61 (s.d. 12) years (range 30–84 years). Tinnitus was left-sided in 22 patients, right-sided in 21 patients, bilateral in 47 patients, and within the head in five patients. Mean duration of tinnitus was 63 (s.d. 117) months (range 3–720 months). Ninety patients (95%) had already received some treatments before visiting our clinic; however, these treatments were not successful and the patients were referred to our clinic by previous clinics. In the ear experiencing tinnitus, the mean pure-tone average (PTA) at three mid frequencies (500, 1,000, and 2,000 Hz) was 28 (s.d. 10) dBHL (range from 8 to 57 dBHL), and the mean PTA at two high frequencies (4,000 and 8,000 Hz) was 45 (s.d. 17) dBHL

Table 1 Baseline characteristics of the 95 patients

Gender (men:women)	55:40
Tinnitus side (one side:both sides)[a]	43:52
	Mean ± s.d. (range)
Age (years)	61 ± 12 (30–84)
Duration of tinnitus (in months)	63 ± 117 (3–720)
Mean at three mid frequencies (dBHL)[b]	28 ± 10 (8–57)
Mean at two high frequencies (dBHL)[c]	45 ± 17 (4–85)
THI score	59 ± 19 (18–98)
SDS score	42 ± 9 (22–68)
STAI (trait) score	49 ± 8 (22–66)
STAI (state) score	49 ± 11 (22–75)

THI Tinnitus handicap inventory, *SDS* self-rating depression scale, *STAI* state trait anxiety inventory

[a] Both sides include bilateral tinnitus or tinnitus within the head

[b] Mid frequencies: 500, 1,000, and 2,000 Hz in the ear(s) experiencing tinnitus

[c] High frequencies: 4,000 and 8,000 Hz in the ear(s) experiencing tinnitus

(range 4–85 dBHL). To determine the mean PTA in patients with bilateral tinnitus or tinnitus within the head, we calculated the mean of the PTA measured from both ears for each patient. Sixty-two patients were diagnosed with presbycusis, 14 with sudden deafness, ten with idiopathic sensorineural hearing loss, seven with tinnitus without hearing loss, and two with Meniere's disease.

Patient assessment

We took the history of all the participating patients and performed physical examination on each. The pure-tone hearing thresholds of all patients were assessed. Otoacoustic emissions and auditory-evoked brain responses were performed on almost all the patients. To evaluate the severity of tinnitus, we administered the Japanese version of the Tinnitus Handicap Inventory (THI) [20–22] to each patient on the first visit to our clinic. Noise generator therapy was considered only in patients with THI scores over 18. In the original definition, THI scores of 18–36 correspond to "mild handicap", THI scores of 38–56 correspond to "moderate handicap", THI scores of 58–76 correspond to "severe handicap", and THI scores of 78–100 correspond to "catastrophic handicap" [23, 24]; however, in this study, we applied the following classification: a moderately distressed group (MD group, THI 18–56) and a severely distressed group (SD group, THI 58–100). More than 20 points of improvement in THI scores is considered to be clinically significant [23].

To evaluate the severity of comorbid depressive symptoms and anxiety symptoms in each patient before treatment, we conducted the following psychological assessments on the first visit to our clinic: the Japanese version of the Self-rating Depression Scale (SDS) [25, 26]; and the State Trait Anxiety Inventory (STAI) [27, 28]. The highest score possible for both scales is 80, and higher scores on the SDS and STAI equate to more severe depressive symptoms and anxiety symptoms, respectively. In our sample, the average scores on the SDS, the trait section of the STAI (STAI-t), and the state section of the STAI (STAI-s) were 42 (s.d. 9), 49 (s.d. 8), and 49 (s.d. 11), respectively.

We explained the clinical meaning of these instruments to all the patients. All provided their informed consent before completing the questionnaires.

Start of NG use and follow-up

Before the patients decided to purchase a NG and to keep using it, the patients were allowed to try the device for 2 weeks. Two weeks after the initial counseling, if the patients decided to purchase a NG, we spoke to them again to confirm that they understood the basis of sound therapy including the importance of environmental sound enrichment, a step that generally took about 30 min. In patients with right- or left-sided tinnitus, the NG was applied monaurally to the ear experiencing tinnitus. In patients with bilateral tinnitus, the NG was applied monaurally to the ear experiencing louder tinnitus. In patients with tinnitus within the head or with bilateral tinnitus in which the loudness of the tinnitus was the same in both ears, the NG was applied monaurally to the ear in which the patients felt more comfortable. Noise generator sound level was basically set to the so-called 'mixing point,' which is close to but below the level of total suppression [5]. The patients were instructed to keep sound level below the level which induces any annoyance or discomfort. We recommended that the patients wear their NG at least 8 h a day during waking hours.

Follow-ups for counseling and optimization of the therapy as well as evaluating auditory function were made every month for the first 3 months and every 3 months thereafter. Follow-up THIs were administered 6, 12, and 24 months after the start of NG use.

Statistical analysis

Improvement in tinnitus severity was evaluated according to changes in the THI scores. Analysis of variance (ANOVA) followed by the Dunnett post hoc test was used to evaluate changes between baseline scores and scores obtained at 6, 12, and 24 months. Dunnett post hoc test was adopted to evaluate the effects of the treatment at each time point compared with the baseline. Tukey's Honestly Significant Difference (HSD) test was also used to evaluate changes among 6, 12, and 24 months.

To evaluate what factors were related to changing THI scores, multiple linear regression analysis by forward selection was used to model the relationship between the change in THI scores and the following factors: age, gender, duration of tinnitus, location of tinnitus (one side or both sides), PTA at three mid frequencies (PTA-m), PTA at two high frequencies (PTA-h), SDS score, STAI-s score, and STAI-t score. Factors were considered to be significant at the 5% level. All statistics were calculated using JMP version 8.0.1 (SAS Institute Inc, Cary, NC).

This study was approved by the Institutional Review Board at Keio University, School of Medicine. This study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Results

Improvement in THI scores

The initial average THI score of the patients was 59 (s.d. 19), followed by 36 (s.d. 19) at 6 months ($n = 90$); 35 (s.d. 21)

at 12 months ($n = 70$); and 36 (s.d. 20) at 24 months ($n = 46$ only). These changes were statistically significant ($p < 0.0001$). The THI scores improved as early as 6 months after the start of treatment, and the significantly positive results versus baseline were also observed at 12 and 24 months ($p < 0.0001$). However, from 6 to 24 months, the THI scores did not change significantly. Fifty-seven percent of the subjects improved by more than 20 points from the baseline at 6 months, so did 56% at 12 months and 59% at 24 months, respectively.

When we divided the patients into the two aforementioned groups, there were 53 patients in the SD group and 42 patients in the MD group. Changes in the mean THI scores for both SD and MD groups are shown in Fig. 1; these changes were statistically significant (SD group, $p < 0.0001$; MD group, $p = 0.0003$). In the SD group, the mean THI scores improved from 73 (s.d. 19) at baseline to 43 (s.d. 20) at 6 months ($p < 0.0001$); 40 (s.d. 23) at 12 months ($p < 0.0001$); and 39 (s.d. 19) at 24 months ($p < 0.0001$). Sixty-seven percent of the SD patients improved by more than 20 points from the baseline at 6 months, so did 65% at 12 months and 73% at 24 months, respectively. In the MD group, the mean THI scores improved from 42 (s.d. 11) at baseline to 27 (s.d. 15) at 6 months ($p = 0.0002$); 29 (s.d. 18) at 12 months ($p = 0.0024$); and 32 (s.d. 20) at 24 months ($p = 0.0478$). Forty-five percent of the MD patients improved by more than 20 points from the baseline at 6 months, so did 43% at 12 months and 36% at 24 months, respectively. In both SD and MD groups, the THI scores did not change from 6 to 24 months.

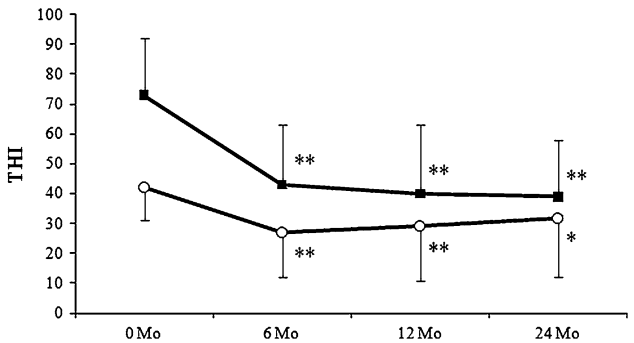

Fig. 1 Changes in THI scores in SD (*filled box*) and MD (*open circle*) patients, respectively. Data are presented as averages + s.d. (SD patients) or averages − s.d. (MD patients). In both groups, the THI scores improved as early as 6 months after the start of treatment, and the significantly positive results versus baseline were also observed at 12 and 24 months. However, from 6 to 24 months, the THI scores did not change significantly in either group. $^{**}p < 0.01$, $^{*}p < 0.05$ versus baseline (0 months after treatment). *SD* severely distressed, *MD* moderately distressed

Factors associated with changes in THI scores in each group

For the multiple linear regression analysis, we chose the change in THI scores [(ΔTHI)] (from baseline to 6 months after treatment) as the independent variable. In the SD group, the analysis showed the following significant relationship: $[\Delta\text{THI (SD)}] = -40 - 0.06 \times \text{duration} - 0.63 \times \text{PTA-m} + 0.64 \times \text{SDS} + 1.18 \times \text{STAI-s}$ ($R^2 = 0.527, p < 0.0001$). Among the dependent variables examined, the following three variables were statistically significant in this group: STAI-s ($F = 11.7$, $p = 0.002$); PTA-m ($F = 6.2$, $p = 0.018$); and duration ($F = 4.7$, $p = 0.038$). In the MD group, the following significant relationship was obtained: $[\Delta\text{THI (MD)}] = 17 - 0.06 \times \text{duration} + 7.61 \times \text{location} + 0.63 \times \text{PTA-m} - 0.56 \times \text{PTA-h} - 0.63 \times \text{SDS} + 0.45 \times \text{STAI-t}$ ($R^2 = 0.402$, $p < 0.0001$). However, among the dependent variables examined, only tinnitus duration was statistically significant in this group ($F = 5.2$, $p = 0.030$).

Discussion

Although no control group was considered in this study, our findings indicate that TRT involving monaural NGs may be effective in treating tinnitus patients, especially SD patients. We also found that the efficacy of TRT in the SD patients was negatively affected by hearing loss at mid frequencies, indicating that in the SD patients hearing handicap might need to be fought as part of TRT.

In principle, the sound therapy component of TRT should be provided binaurally whenever it is possible [5]. In that sense, our TRT method involving monaural NGs should be recognized as TRT utilizing sub-optimal sound therapy. The original protocol recommends symmetrical stimulation of the auditory system, as attempts to stimulate only one ear in patients with unilateral tinnitus frequently results in a shift of the perceived location of the tinnitus to the opposite site [5]. However, adhering strictly to the principle of sound therapy was difficult in Japan. When TRT was introduced as a treatment for tinnitus patients in Japan, TCI use was not readily accepted, partly because the use of hearing aids is not as widespread as in many Western countries. In addition, TCIs were also financially burdensome to tinnitus patients. Tinnitus control instruments are not covered by Japan's public health insurance system, even though all patients in Japan have public health insurance and many other interventions to treat tinnitus are covered by insurance. Under such circumstances, patients in Japan were more inclined to accept the monaural use of NGs, which cost less than hearing aids or binaural NGs. Consequently, in Japan the monaural use of NGs became the most prevalent form of sound therapy

among tinnitus patients who did not experience subjective hearing handicap in daily life [19]. Although our results did not address the comparison between monaural and binaural provision of NGs, they did suggest that even monaural provision of NGs may be beneficial. On the other hand, the improvement of the THI scores observed in our study reached plateau after 6 months, which was contrary to the results of other studies involving binaural sound therapy [29, 30]. This difference in results may be due to sub-optimal use of sound therapy, and a further study will be needed to compare the effects of TRT between monaural and binaural provision of NGs.

In terms of hearing loss and the effect of TRT employing NGs, the negative impact of hearing loss on the effects of TRT in the SD patients may indicate the need to reduce the hearing handicap of patients with hearing loss. This result also indicates that, although the patients in this study did not complain subjectively of significant hearing loss, detecting and treating unnoticed hearing handicap may be important, regardless of a patient's subjective awareness [18].

We have already shown previously that depressive state and state anxiety may be associated with THI scores [20]. In the present study, only state anxiety appeared to be related to the reduction in THI scores in the SD patients, indicating that the effects of TRT employing monaural NGs could be mediated through the reduction of transient anxiety symptoms, but not the reduction of depressive symptoms. Therefore, additional therapy—such as antidepressant [31] or psychological/psychiatric therapy [11]—aimed at reducing depressive symptoms might be a good co-therapy option to treat SD tinnitus patients.

The significant correlation between duration of tinnitus and reduction in THI scores in both SD and MD patients is consistent with the results of other studies [9, 16]. The duration of tinnitus had the same impact on the change of THI scores in both SD and MD patients. The multiple linear regression analyses showed that the longer duration of tinnitus reduced the effect of TRT. Proper counseling and sound enrichment at an earlier stage of tinnitus would make TRT a more effective and promising intervention.

Other studies have shown that MD patients experience fewer benefits from TRT than SD patients [15, 32], which is consistent with our results. In this study, multiple regression analysis failed to provide a good model of the MD patients. Moreover, even though the SD patients showed significant improvement due to TRT, their average final THI score indicated that they still had mild to moderate handicap. This result is also consistent with that of another study [12]. Taken together, these results indicate that mildly to moderately distressed patients, as well as severely distressed patients whose severity of tinnitus have been turned into mild to moderate, may require additional evaluation and treatment.

One problem with the present study is that we did not include a control group in our analysis. Some studies have used patients on a waiting list for treatment as a control group [11, 12]. However, in Japan it is quite difficult to put patients on a waiting list for treatment, as all patients have free access to health care. Consequently, we could not set a proper control group in this study. Even though we had no control group and observed that most of the changes in THI score were observable within the first 6 months, we are confident that the results of this study provide evidence to support the efficacy of TRT employing monaural NGs. Tinnitus retraining therapy benefited many of our patients even though most of them had been treated unsuccessfully at different facilities prior to visiting our institute, which is supposed to have limited the impact of the placebo effect involved in many tinnitus research. The significantly positive results observed after 24 months in both severely and moderately distressed groups represent a valuable argument against a strong placebo effect in our patients.

Conclusions

Tinnitus retraining therapy employing monaural NGs was an effective intervention especially for SD patients, although the plateau of the effects after 6 months may be indicative of the limitation of applying NGs monoaurally. The effect of the therapy on SD patients may be related to the presence of high state anxiety before treatment. Reducing the patients' hearing handicap may reinforce the effects of TRT in SD patients. Additional evaluation and interventions for both SD and MD patients might be needed.

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Conflict of interest The authors declare that they have no conflict of interest. The authors alone are responsible for the content and writing of the paper.

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