The Journal of International Advanced Otology

J Int Adv Otol 2021; 17(1): 42–5 • DOI: 10.5152/iao.2020.9161

Original Article

Effectiveness of Hearing Aid Treatment in Patients with Chronic Tinnitus: Subscale Evaluations Using the Tinnitus Functional Index and Factor Analysis

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Cite this article as: Noguchi M, Suzuki N, Oishi N, Ogawa K. Effectiveness of Hearing Aid Treatment in Patients with Chronic Tinnitus: Subscale Evaluations Using the Tinnitus Functional Index and Factor Analysis. J Int Adv Otol 2021; 17(1): 42-5.

OBJECTIVES: The tinnitus functional index (TFI) is becoming a new international gold standard for tinnitus assessment. This study aimed to evaluate the efficacy of hearing aids for chronic tinnitus, using the Japanese version of the TFI, while focusing on its subscales.

MATERIALS and METHODS: This is a retrospective study. A total of 21 patients with chronic tinnitus were included. All participants were treated with hearing aids for at least 12 months. They answered the TFI and tinnitus handicap inventory (THI) at the first visit and 12 months later. We analyzed each TFI subscale score and the overall scores of TFI and THI.

RESULTS: The overall TFI score decreased significantly after treatment (p=0.005) with moderate effect size (d=0.70). The scores of the intrusive, sense of control, sleep, and emotional subscales decreased significantly after the treatment. Large effect sizes were found in the intrusive and sense of control subscales (d=1.33 and d=1.25, respectively).

CONCLUSION: Hearing aids are highly effective for improving the intrusive and sense of control subscales in patients with tinnitus. Identifying better treatments for the small effect size subscales and combining these with the use of hearing aids could achieve a higher therapeutic effect with better outcomes.

KEYWORDS: Hearing aid, tinnitus, tinnitus functional index, subscale, treatment

INTRODUCTION

Tinnitus is a common syndrome that occurs in 10% to 15% of the adult population.[1,2] Michikawa et al.[3] reported that in Japan, tinnitus is prevalent in 18.6% of people aged 65 years or older. Questionnaires are essential for evaluating the severity of tinnitus and treatment-related changes. Recently, Meikle et al.[4] developed the tinnitus functional index (TFI) to measure tinnitus severity and treatment-related changes. The TFI consists of 25 questions, divided into 8 subscales addressing different domains of tinnitus severity. TFI is becoming a new international gold standard for tinnitus assessment. The Japanese version of the TFI has high reliability and reproducibility.[5]

There are many possible ways to treat tinnitus, including hearing aids, sound generators, counseling sessions, relaxation techniques, medications such as antidepressants and sedatives, and psychotherapy.[6-8] Sound therapy for tinnitus started to be widely recognized with the advent of tinnitus retraining therapy developed by Jastreboff and Hazell[9] in 1993. The effectiveness of sound therapy has been reported in several countries.[10-12] There are also reports on significant improvement in hearing loss, as evaluated by the TFI, among patients with tinnitus treated with hearing aids.[13, 14] However, these reports did not evaluate each TFI subscale. Thus, this study aimed to fill in this gap and evaluate the effectiveness of hearing aids for chronic tinnitus in Japanese patients, using the Japanese version of the TFI, with a focus on its subscales.

MATERIALS AND METHODS

Consent and Ethics Approval

The ethics committee at the Keio University School of Medicine approved this retrospective study (JPRN-UMIN000008901). Procedures that involved collecting information from the patients' medical records were performed according to the Code of Ethics of the

This study was presented at the 62nd Congress of Japan Audiological Society, Oct. 2017, Fukuoka, Japan.

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Submitted: 07.17.2020 • **Revision Received:** 10.03.2020 • **Accepted:** 10.07.2020
Available online at www.advancedotology.org

Table 1. TFI and THI scores evaluated at the first visit and 12 months after the start of treatment

		Pretreatment (mean±SD)	Posttreatment (mean±SD)	p	Effect size
Overall TFI		45.0±24.8	30.2±18.0	0.005	0.70
TFI subscales	Intrusive	17.4±6.9	10.5±5.1	<0.001	1.33
	Sense of control	19.1±6.2	11.0±5.7	<0.001	1.25
	Cognitive	12.0±8.4	9.6±7.1	0.267	0.25
	Sleep	10.1±8.8	5.8±5.9	0.004	0.70
	Auditory	14.4±9.4	10.8±8.5	0.077	0.41
	Relaxation	12.9±9.3	9.1±7.9	0.113	0.36
	Quality of life	13.9±11.2	10.6±9.4	0.198	0.29
	Emotional	12.7±9.1	8.4±7.0	0.012	0.60
Overall THI		37.3±20.9	22.4±18.1	<0.001	1.06

SD: standard deviation; TFI: tinnitus functional index; THI: tinnitus handicap inventory.

World Medical Association (Declaration of Helsinki) for experiments involving humans (http://www.wma.net/en/30publications/10policies/b3/index.html).

Informed oral consent was obtained from all participants. Information about the research, including the purpose of collecting and using the data, was explained to the participants or made public. Participants were informed that they could refuse participation or request that their data be removed at any time. All participants consented that their data could be used for future studies. Data were anonymized at the time of collection.

Study Design and Participants

The subjects were 21 patients with mild to severe hearing loss on the same side of tinnitus who visited the Otorhinolaryngology Department of Keio University Hospital between May 1, 2015, and October 31, 2017. The inclusion criterion was tinnitus lasting more than 3 months as the chief complaint. The exclusion criteria included patients with missing data for 7 or more questions of the TFI, those who received treatments other than treatment with hearing aids, and those with other diseases that required alternative treatments.

MAIN POINTS

- This retrospective study aimed to evaluate the efficacy of hearing aids for chronic tinnitus, using the Japanese version of the tinnitus functional index (TFI), while focusing on its subscales.
- Concerning the TFI subscales, our findings indicate that hearing aids are effective for improving the intrusive and sense of control subscales.
- No difference was shown between the pre- and posttreatment with hearing aids scores in the cognitive, auditory, relaxation, and quality of life subscales.
- Treatment outcomes may be improved by finding more effective treatment modalities for improving the cognitive, auditory, relaxation, and quality of life subscales and combining these modalities with hearing aids.

Treatment and Evaluation Methods

All patients underwent a pure-tone audiometry test with AA-76 or AA-H1 (Rion, Tokyo, Japan), followed by hearing aid fitting. The participants were instructed to use the hearing aids for more than 10 hours per day, starting on the first day of the treatment. The patients continued to wear the hearing aids for at least 12 months. They were examined by otolaryngologists several times during visits along this period, with adjustments to the hearing aids as required. All participants completed a series of questionnaires, including the Japanese versions of the TFI and tinnitus handicap inventory (THI).[5,15] The patients answered the questionnaires at the time of the first visit and 12 months later.

Statistical Analysis

We analyzed the total score and the score for each subscale of the TFI and the total score of the THI, using the paired sample t-test. Furthermore, the effect sizes were calculated using Cohen's d for the overall scale and each subscale of the TFI and the overall scale of the THI. Absolute values of effect size ≥ 0.20 were considered as small, ≥ 0.50 as moderate, and ≥ 0.80 as large.[16] All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) software, version 25 (IBM Corp., Armonk, NY, USA). Values for continuous variables are presented as mean ± standard deviation. Differences with $p<0.05$ were considered statistically significant.

RESULTS

Of the 21 patients, 15 were male, and 6 were female. The mean age was 62.4±11.3 years (range, 34–84 years). From the 21 patients, 13 were diagnosed with presbycusis, 6 with sudden sensorineural hearing loss, 1 with Meniere's disease, and 1 with vestibular schwannoma. Notably, 10 of the 13 patients with presbycusis exhibited bilateral tinnitus, and the remaining 3 exhibited unilateral tinnitus. The average hearing thresholds for the ear affected by tinnitus and unaffected ear are shown in Figure 1. All of the 10 patients with bilateral tinnitus and 3 of the 11 patients with unilateral tinnitus used hearing aids in both ears. The remaining 8 patients with unilateral tinnitus used hearing aid in the ear affected by tinnitus.

The score for each subscale of the TFI and the total scores for the TFI and THI at baseline and 12 months later are presented in Table 1. The

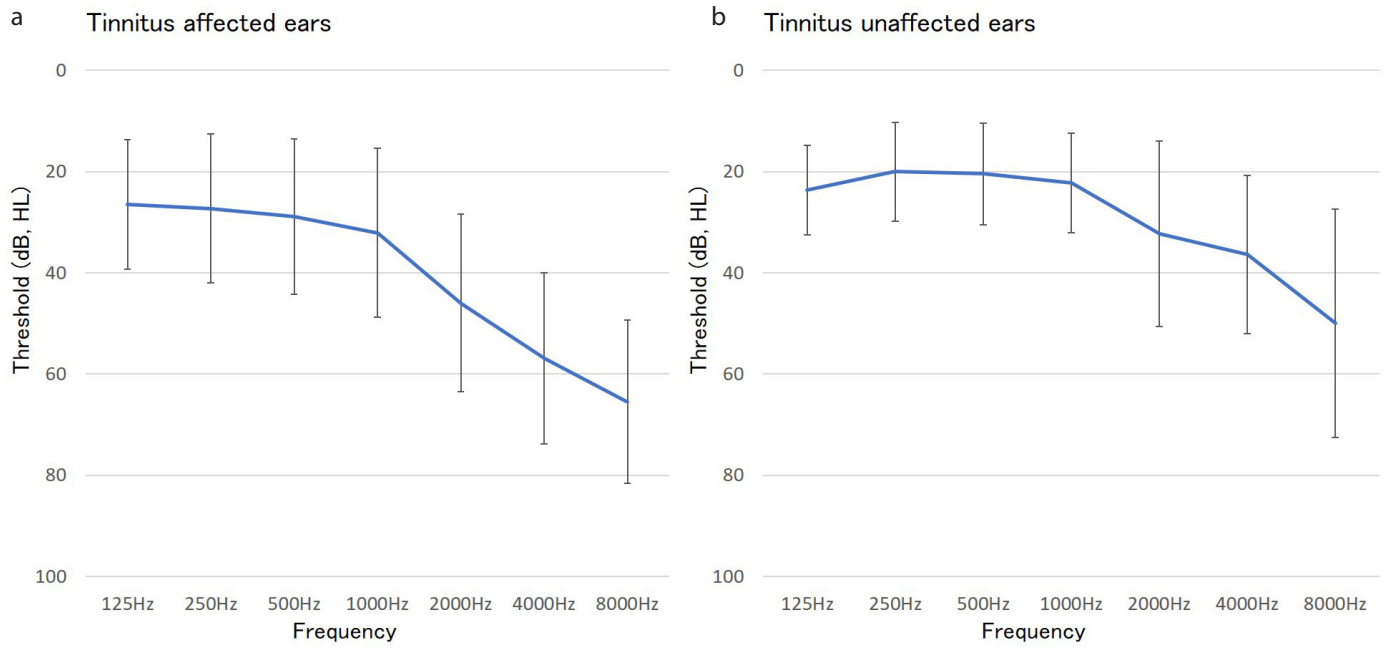

Figure 1. a, b. Average hearing thresholds in the (a) ear affected by tinnitus (n=31) and (b) unaffected (n=11) ear.

total TFI score before treatment was significantly higher than that after treatment (45.0±24.8 and 30.2±18.0, respectively; p=0.005). The effect size was moderate (d=0.70). In 10 of the 21 patients, the total TFI score decreased by at least 13 points, indicating significant improvement. The total THI score was also significantly higher at the start of the treatment than after treatment (37.3±20.9 and 22.4±18.1, respectively; p<0.001). The effect size was large (d=1.06). Among the TFI subscales, the scores of intrusive, sense of control, sleep, and emotional have decreased significantly through the treatment (Table 1). The effect sizes of the intrusive and sense of control subscales were large (d=1.33 and d=1.25, respectively). There was no difference in the TFI subscale scores in the cognitive, auditory, relaxation, and quality of life between the start and end evaluations, and their effect sizes were small.

DISCUSSION

Degree of Improvement in the Overall TFI Scale

In this study, tinnitus has significantly improved in 10 of 21 patients (47.6%), as indicated by a decrease of at least 13 points in the overall TFI score. This result is lower than in the study by Henry et al.,[14] in which 87% of patients (13/15) showed improvement. The difference might be caused by the differences in tinnitus severity among the included patients. Their study included tinnitus patients with a moderate severity level or higher and the average pretreatment TFI score was 60.5±15.3. In contrast, we included all patients with tinnitus, regardless of the severity. The average pretreatment TFI score was 45.0±24.8, and 2 patients showed 13 points or less in total TFI score at the beginning of treatment. This low initial score might explain the lower rate of improvement in the current study.

Subscales with Large Effect Size: Intrusive and Sense of Control

Focusing on the TFI subscales, the effect sizes ranged between large and small. In particular, the effect sizes for intrusive and sense of control were large. There have been no reports on the cut-off values for each subscale of the TFI. Moreover, we cannot quantify the change in each subscale score to evaluate the presence of any significant improvement. However, our results indicate that hearing aid treatment particularly improves intrusive and sense of control, as indicated by their respective large effect sizes.

Subscales with Small Effect Size: Cognitive, Auditory, Relaxation, and Quality of Life

We found no difference between the pre- and posttreatment scores in the cognitive, auditory, relaxation, and quality of life subscales, and the effect sizes in these subscales were small. These findings indicate that treatment with hearing aids had low effectiveness in these subscales. Importantly, treatment outcomes might be improved if better treatment modalities could be identified for these subscales, to be used along with the hearing aids. If this happened, it would dictate the need for a TFI-based evaluation of such treatment modalities.

The results on the subscales with small effect sizes were unexpected, especially for auditory. The 3 items evaluated in the auditory subscale are related to listening and thus were expected to improve after wearing hearing aids. However, a previous report suggested that the auditory subscale items are less relevant to tinnitus symptoms.[17] Furthermore, our previous study showed that the auditory subscale has a lower correlation with tinnitus than the other subscales. Still, we consider the auditory subscale suitable for tinnitus severity evaluation because its effect size is comparable with that of some other subscales.[5] In the current study, among the 4 subscales with small effect sizes, the largest effect size was found in the auditory subscale, indicating that it remains relevant for evaluating the effectiveness of hearing aids for tinnitus. Further studies on the correlation of the auditory subscale and tinnitus improvement are needed.

This study has some limitations. The retrospective nature of the study indicates that the possibility of selection bias cannot be ruled out. Thus, prospective studies are needed to validate our findings. Furthermore, the small sample size of this study is a limitation.

CONCLUSION

Treatment with hearing aids for chronic tinnitus significantly improves the symptoms in 48% of the patients, as evaluated by the TFI. Concerning the TFI subscales, our findings indicate that hearing aids are effective for improving the intrusive and sense of control subscales. Treatment outcomes may be enhanced by finding more effective treatment modalities for improving the cognitive, auditory, relaxation, and quality of life subscales and combining these modalities with hearing aids.

Ethics Committee Approval: The ethics committee at the Keio University School of Medicine approved this retrospective study (JPRN-UMIN000008901).

Informed Consent: Informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – M.N., N.S., N.O., K.O.; Design - M.N., N.S., N.O., K.O.; Supervision - N.O., K.O.; Resource - M.N., N.O.; Materials - M.N., N.S., N.O.; Data Collection and/or Processing - M.N., N.S., N.O.; Analysis and/or Interpretation - M.N., N.S., N.O.; Literature Search - M.N., N.S., N.O.; Writing - M.N., N.S.; Critical Reviews - N.O., K.O.

Acknowledgements: We would like to thank Editage (www.editage.jp) for English language editing.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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