

Tinnitus Suppression Effect of Hearing Aids in Patients With High-frequency Hearing Loss: A Randomized Double-blind Controlled Trial

*Natalia Yakunina, †Woo Hyun Lee, ‡Yoon-Jong Ryu, and ‡Eui-Cheol Nam

**Institute of Medical Science, Kangwon National University, School of Medicine; †Department of Otolaryngology, Kangwon National University Hospital; and ‡Department of Otolaryngology, Kangwon National University, School of Medicine, Chuncheon, Republic of Korea*

Introduction: Hearing aids (HAs) with frequency lowering have been used for high-frequency hearing loss (HFHL), but their effects on tinnitus relief have not been studied extensively. This randomized double-blind trial was performed to investigate and compare tinnitus suppression effects of conventional type HAs and frequency-lowering HAs in patients with HFHL.

Methods: A total of 114 patients were randomized into three groups: conventional HA using wide dynamic range compression, HA with frequency translation, and HA with linear frequency transposition. Participants wore HAs for 3 months and then discontinued their use. The final evaluation was performed at 3 months after cessation of wearing HA (6 mo after the initial visit). The Tinnitus Handicap Inventory (THI) score and additional variables, such as matched tinnitus loudness and visual analog scale scores of subjectively perceived tinnitus loudness, daily awareness, and annoyance, were measured at the initial visit and at 3- and 6-month follow-ups.

Results: THI score and most of the additional outcomes were significantly improved at 3 and 6 months (3 mo after

HA removal) compared with their initial values in all three groups. The incidence rates of patients with improvements in the THI score by 20% or more were 71.0, 72.7, and 74.3% at 3 months, and 54.8, 51.6, and 59.4% at 6 months for the three groups, respectively. There were no significant differences in primary or additional variables between hearing aid types at either 3 or 6 months.

Conclusion: This is a consolidated standards of reporting trials-guided study providing direct evidence for tinnitus suppression effects of HA alone, without accompanying counseling or any other treatments, which lasted for at least 3 months after patients stopped using HAs. HAs effectively suppressed tinnitus in patients with HFHL regardless of the amplification strategy type. **Key Words:** Frequency lowering—Hearing aid—High-frequency hearing loss—Long-term effect—Tinnitus.

Otol Neurotol 40:865–871, 2019.

Tinnitus, a perception of sound without an external source, is usually associated with and often comes as a direct result of hearing loss. Hearing aids (HAs) have been used for tinnitus management for more than 60 years (1), as it was thought that hearing aids may act as maskers to decrease tinnitus awareness and could facilitate better communication and reduce stress. It has also been suggested that the increased level of environmental sounds may reduce the contrast between tinnitus and silence

caused by hearing loss, making tinnitus less intrusive, and less annoying (2,3). Additionally, compensation for peripheral hearing deficit could theoretically normalize the elevated central gain or hyperactivity or maladaptive neural plastic changes (3–5).

Nevertheless, scientific evidence to support the clinical effectiveness of HAs on tinnitus suppression has been weak. In particular, the standalone HA effect and long-term HA effects after cessation of their use have not been established. The 2018 Cochrane review found only seven randomized controlled trials (RCTs) that explored the effects of HAs on tinnitus among 1,202 studies (6). Three studies compared HA with combined use of HA+sound generator (SG) and concluded that HA alone or HA+SG seemed equally effective in improving Tinnitus Handicap Inventory (THI) or Tinnitus Functional Index scores (7–9). Parazzini et al. (10) reported equal effectiveness of tinnitus retraining therapy (TRT) using HA or SG. Although most of the RCTs in the Cochrane review suggested positive

Address correspondence and reprint requests to Eui-Cheol Nam, M.D., Ph.D., Department of Otolaryngology, School of Medicine, Kangwon National University, 1 Kangwondaehak-gil, Chuncheon 200-701, Korea; E-mail: birdynec@kangwon.ac.kr

This research was supported by the Ministry of Science and ICT Program of the NRF funded by the Korean government, MSIP (2016M3A9F1941022).

The authors disclose no conflicts of interest.

Supplemental digital content is available in the text.

DOI: 10.1097/MAO.0000000000002315

tinnitus-suppressing effects of HAs, the review concluded that their quality of evidence was low and unreliable due to small sample sizes and poor blinding (6).

Furthermore, even in well-designed controlled studies, HAs were supplementary to counseling or alternative to SG, and they have rarely been assessed separately. Some TRT studies concluded that the tinnitus-suppressing effect of counseling alone is almost as effective as that of the complete TRT package, which combines counseling with SG, or less often with HAs (11,12). Taken together, there is a lack of quality evidence to support the effectiveness of wearing HAs for tinnitus, particularly the standalone effect of HAs.

High-frequency hearing loss (HFHL) is the most common type of hearing loss, and tinnitus is most frequently comorbid with this descending-slope type of hearing loss (13). However, simple linear or compression-type amplification has not yielded satisfactory effects in restoring the audibility of high-frequency sounds (14–16), as more gain is required at high frequencies to achieve speech audibility, which may lead to distortion and acoustic feedback (17,18). Furthermore, hearing deficit >70 dB is commonly associated with dead cochlear regions, which makes simple amplification in high-frequency bands useless (19–21). To overcome these obstacles, frequency lowering (FL) techniques, which relocate high-frequency auditory input to lower frequencies, have been developed as a novel type of signal processing for HFHL (17). Currently, several FL approaches are commercially available, including frequency translation (FT), linear frequency transposition (LFT), and nonlinear frequency compression (FC). In LFT, sound signals at frequencies up to two octaves above the designated “start frequency” are transposed linearly down to one octave below the start frequency. The FT strategy applies a combination of conventional amplification and linear transposition in the high-frequency region.

Only two nonrandomized studies to date have investigated the effects of FL type HAs on tinnitus. One reported that LFT type HAs reduced tinnitus in 81% of subjects with HFHL, which was better than the conventional wide dynamic range compression (WDRC) method (20). However, this study had no control group, variable duration of wearing HAs (a few weeks to two and a half years), and the results were presented for only half of the participants. Another study, a crossover HA trial comparing the traditional WDRC with nonlinear FC, reported that WDRC reduced tinnitus in 44% of participants, while FC relieved tinnitus in 19%, and suggested that WDRC should be the first choice HA strategy for tinnitus patients with HFHL. However, small sample size, lack of a washout period between crossing over to the alternative treatment, and accompanying counseling reduced the reliability of this study.

The present study was performed to isolate and evaluate the effects on tinnitus of HA alone without accompanying counseling or any other therapy, following consolidated standards of reporting trials (CONSORT) to provide high-quality reliable evidence. We also

investigated whether HAs provide long-term tinnitus suppression that lasts after cessation of their use. Additionally, we explored how FL techniques (LFT and FT) performed compared with conventional WDRC in the same open-fit HA device in terms of tinnitus suppression for patients with HFHL.

METHODS

Study Design

This was a double-blind randomized controlled clinical trial in which participants were fit with receiver-in-the-canal HAs with and without FL. Participants were randomly divided into three groups to receive HAs with WDRC, FT, or LFT, and asked to wear the HAs for three consecutive months. Assessment of hearing function and tinnitus was performed initially at enrollment, after wearing HAs for 3 months, and after a further 3 months after HAs were removed (6 mo after the initial evaluation). The study protocol was reviewed and approved by the Institutional Review Board of K*** National University Hospital. Written informed consent was provided by all participants in accordance with the Declaration of Helsinki.

Participants

Participants were recruited through our hospital by advertising posters or from the otolaryngology outpatient clinic. Inclusion criteria were age over 18 years, sensorineural hearing loss with pure-tone average (PTA) of 250, 500, and 1000 Hz frequencies ≤ 25 dB, PTA of 2000, 4000, and 8000 Hz frequencies ≥ 40 dB, symmetric hearing loss (difference between PTA of the right and left sides ≤ 15 dB), word recognition score $\geq 50\%$, tinnitus duration ≥ 3 mo, VAS score of tinnitus perceived daily $\geq 50\%$, and THI score ≥ 18 . Exclusion criteria were previous HA usage, hyperacusis, history of neuropsychological disorders, and history of taking antidepressants or other psychotropic medications. The study took place in our hospital from March 2017 to November 2018.

Hearing and Tinnitus Assessment Procedures

Hearing assessment was performed in a double-walled sound-proof room (ISO 6189). Pure-tone air (0.25–8 kHz) and bone (0.25–4 kHz) audiometry, speech audiometry, tinnitus frequency, and loudness matching were performed using a two-channel AC40 audiometer (Interacoustics, Assens, Denmark) and HAD 300 calibrated headphones (Sennheiser, Wedemark, Germany). Real ear measurement during the period of wearing HA was performed using an Aurical Visible Speech system with a wireless SpeechLink 100 binaural measurement unit (Madsen, GN Otometrics, Taastrup, Denmark). The rest of the assessment was performed using THI (0–100) and VAS (0–10) of subjectively perceived loudness, annoyance, and awareness (duration perceived during a day) of tinnitus.

Blinding

All subjects were fitted with open-fit receiver-in-canal devices (Widex, Lyngø, Denmark) of the same shape for perfect blinding. The participants and the audiologist performing hearing and tinnitus assessment were not aware of the HA type being used throughout the study. Group allocation and the corresponding HA fitting were performed by a different audiologist.

Randomization Procedure

Permuted block randomization with variable block length and 1:1:1 ratio was performed by an independent researcher

using a web-based random number generator. At the time of the participant's group allocation, the audiologist responsible for HA fitting contacted the researcher responsible for randomization to inquire about the next allocation.

HA Fitting

HAs were fitted on the side of tinnitus unilaterally or bilaterally. In the LFT and FT groups, the start frequency was initially decided based on participants' audiograms using the default setting of the device and then modified according to the HA wearers' preference for listening the Ling six sounds ([m], [ah], [oo], [ee], [sh], and [s]) and additional environmental sounds, such as the sound of article being crumpled or flowing water. In the LFT group, the frequency region two octave bands above the start frequency was transposed octave-linearly to the low-frequency area and all other frequencies were amplified following WDRC. FT HA amplified the signal in the high-frequency region and simultaneously transposed the original signal to the lower-frequency area.

Each participant's daily duration of HA wearing time was automatically recorded and saved in an online system.

Outcome Measures

We used total THI score as a primary outcome measure because it reflects the impact of tinnitus on everyday life, function, and emotion more comprehensively than tinnitus loudness or daily duration of awareness. Additional outcomes were matched tinnitus loudness and VAS scores, including subjectively perceived tinnitus loudness, annoyance, and awareness, at 3 and 6 months.

After a 2-week HA fitting, adaptation, and adjustment period, the participants were asked to wear HA daily for 6 hours or more. After 3 months, their tinnitus was evaluated and HAs were removed, and the participants were asked if they would like to continue wearing HAs because they thought that wearing HAs relieved their tinnitus. The final tinnitus evaluation was made at 6 months after the initial visit, 3 months after cessation of wearing HAs to investigate the HA long-term effects.

Sample Size Determination

Sample size calculation assumed a 5% two-tailed α , 80% power, 1:1:1 allocation ratio, a standard deviation of THI score of 19.1, and mean THI scores of 35.9, 23.2, and 37.5 for the three groups (the mean and standard deviation were determined during the interim data analysis after 22 to 23 patients were recruited in each group). The necessary number of patients in each group was estimated to be 30. Considering a 20% dropout rate, the total sample size was calculated to be 113. The actual standard deviation and dropout rates were 19.4 and 17.5% (20 of 114), respectively.

Data Analysis

All statistical analyses were performed using SPSS software (version 22.0; IBM Corp., Armonk, NY). Intention-to-treat and per-protocol analyses were performed. The patients' initial profile data, and the final values of the primary variable at 3 and 6 months were compared by one-way analysis of variance for continuous variables, and the χ^2 test for nominal variables. Progression data from the initial profile to 3 and 6 months within each group were compared using the paired *t* test. In all analyses, $p < 0.05$ was taken to indicate statistical significance after Bonferroni correction for multiple comparisons.

The incidences of patients with no improvement and improvement of tinnitus were calculated for each group at each

time point. Patients who had the same or higher THI scores compared with the initial value were counted as not improved. Patients who had a THI score at least 20% lower than the initial value were counted as improved.

RESULTS

In total, 190 patients were screened through the otolaryngology outpatient clinic of our hospital. After excluding 76 patients, 114 were randomized as follows: 38, 37, and 39 subjects were divided into the WDRC, FT, and LFT groups, respectively (Fig. 1). Twenty patients withdrew from the study or were lost to follow-up, so 31, 31, and 32 subjects in the WDRC, FT, and LFT groups, respectively, completed the study at 6 months. Per-protocol analysis was performed in 94 subjects who completed the 6-month follow-up.

All three groups were evenly matched and there were no significant differences in initial demographics, tinnitus, or hearing characteristics, or daily HA wearing time (Table 1). The mean THI scores were 48.6, 49.5, and 50.3 at the initial visit, 31.6, 30.3, and 33.3 at 3 months, and 38.3, 35.2, and 35.6 at 6 months for WDRC, FT, and LFT groups, respectively (Fig. 2). All variables improved significantly at 3 months. At 6 months, THI, VAS awareness, and VAS annoyance scores were significantly improved in all three groups, while matched loudness was only improved in the WDRC group. However, there were no differences in THI score or any additional variables at either 3 or 6 months between groups (Table 2).

The incidences of subjects with a $\geq 20\%$ improvement in THI score compared with the initial value were 71.0, 72.7, and 74.3% at 3 months and 54.8, 51.6, and 59.4% at 6 months in the WDRC, FT, and LFT groups, respectively (Fig. 3). The rates of patients who did not show improvement were 16.1, 21.2, and 14.3% at 3 months, and 35.5, 19.4, and 18.8% at 6 months in the WDRC, FT, and LFT groups, respectively.

At the 3-month follow-up, 80.6, 66.7, and 80.0% of participants in the WDRC, FT, and LFT groups, respectively, reported that they wanted to continue wearing HAs because they thought that the HA relieved their tinnitus.

Intention-to-treat analysis was performed for all of the 114 subjects. For subjects who dropped out, their last available data were used. The results of intention-to-treat analysis are presented in the Supplementary Materials, <http://links.lww.com/MAO/A806> and are not discussed in the manuscript.

DISCUSSION

All three types of HA improved tinnitus perception and distress in our study. After 3 months of wearing HAs, the primary and all additional tinnitus-related variables were significantly improved, and $>70\%$ of the patients had a $\geq 20\%$ improvement in their THI (Figs. 2 and 3, Table 2). HAs have been recommended for tinnitus management for several decades, but few randomized blinded controlled trials have evaluated their effectiveness for tinnitus.

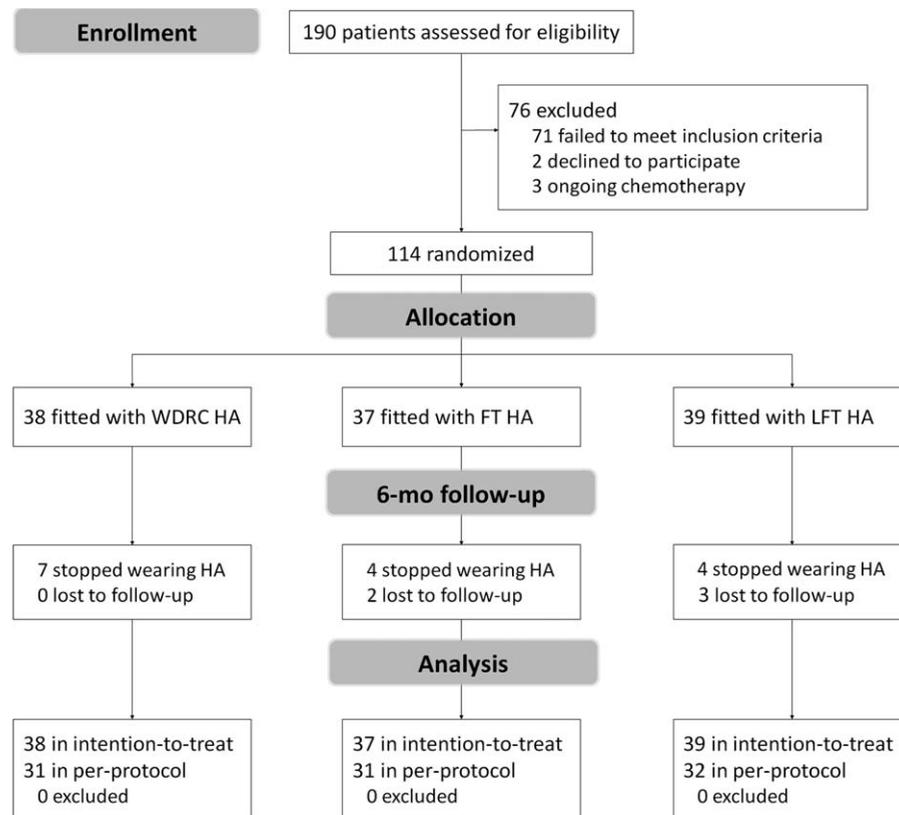


FIG. 1. Flow diagram of this study following the CONSolidated Standards of repORTing trials (CONSORT) guidelines. HA indicates hearing aid.

Additionally, the quality of evidence of the few RCTs in the recent Cochrane review was weak, particularly resulting from lack of blinding and insufficient sample size (6). Furthermore, most RCTs (including numerous TRT

studies) for HAs or SG provided counseling to the patients (7–10,12,22–26), and to our knowledge there have been no single studies on the effect of HA on tinnitus that did not apply at least one session of counseling. No studies have

TABLE 1. Initial demographic, hearing, and tinnitus profiles of the participants

Variable Name	WDRC Group n = 38	FT Group n = 37	LFT Group n = 39	<i>p</i> Value
Age	55.5 ± 9.2	57.2 ± 9.1	55.7 ± 10.0	0.683
Sex (male: female) (%)	79: 21	84: 16	77: 23	0.747
Tinnitus laterality (B: R: L) (%)	60: 24: 16	65: 8: 27	64: 15: 21	0.395
Tinnitus duration (mo)	119.9 ± 104.3	96.6 ± 92.6	98.9 ± 96.3	0.522
Average PTA of tinnitus ear (dB HL)	39.8 ± 7.6	42.3 ± 8.0	41.9 ± 7.5	0.320
PTA low (dB HL)	16.5 ± 4.4	17.4 ± 4.0	16.9 ± 3.9	0.649
PTA mid (dB HL)	35.5 ± 9.7	37.6 ± 8.5	38.3 ± 9.6	0.388
PTA high (dB HL)	67.4 ± 15.9	71.9 ± 17.5	70.5 ± 13.9	0.458
THI	48.1 ± 20.7	46.9 ± 21.1	53.4 ± 20.2	0.347
Loudness (dB HL)	71.7 ± 20.2	66.4 ± 22.5	69.2 ± 19.2	0.543
Pitch (Hz)	5.7 ± 3.1	5.1 ± 3.5	5.5 ± 2.9	0.712
VAS loudness	6.1 ± 2.0	5.7 ± 2.0	5.9 ± 2	0.604
VAS maintenance	87.4 ± 17.0	87.0 ± 18.5	88.2 ± 15.7	0.953
VAS annoyance	6.1 ± 2.4	5.6 ± 2.3	5.6 ± 2.1	0.586
WRS	88.2 ± 8.0	85.7 ± 7.2	85.1 ± 7.7	0.168
HA daily wearing time (h)	5.3 ± 1.5	5.4 ± 1.7	5.9 ± 1.8	0.257

All continuous variables are expressed as means ± standard deviation.

B indicates bilateral; HL, hearing level; L, left; PTA high, average of 4000 and 8000 Hz frequencies; PTA low, average of 250 and 500 Hz frequencies; PTA mid, average of 1000 and 2000 Hz frequencies; R, right.

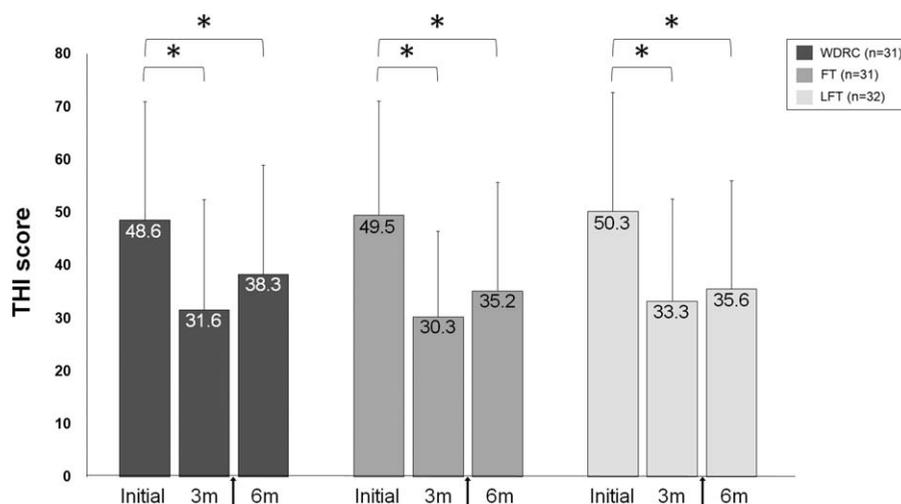


FIG. 2. Mean tinnitus handicap inventory (THI) scores at initial, 3 and 6-mo visits. THI was significantly decreased at both follow-up visits for all groups. No differences were found between groups. *, Significant improvement compared with the initial value, $p < 0.05$, paired t test with Bonferroni correction. ↑, Cessation of wearing hearing aids after 3 months. FT indicates frequency translation; LFT, linear frequency transposition; WDRC, wide dynamic range compression.

attempted to isolate and evaluate the standalone HA effect, which was one of the strong motivations for this study. We followed the CONSORT guidelines for blinding, randomization, and sample size calculation, among other factors, and demonstrated that HAs alone are effective in alleviating tinnitus.

Another motivation for our study was the common belief that tinnitus generally relapses immediately after removing HAs (27). We wished to examine whether long-term tinnitus suppression could develop and continue following HA application. In the present study, the primary variable and VAS awareness and annoyance scores were significantly improved at 6 months (i.e., 3 mo without wearing HAs) in all three groups compared with the initial level (Table 2). Additionally, at 6 months more than 50% of participants in all three groups had improvements of $\geq 20\%$ in THI score from the initial value, which is a substantial incidence considering that

the subjects did not undergo any tinnitus treatment for the last 3 months (Fig. 3). These observations suggest that the mechanism of HA tinnitus suppression extends beyond temporary masking and distraction. Our findings may suggest that HAs compensate for deprived auditory input (28–32), and subsequently reverse the tinnitus-related central plastic changes. However, the mechanisms underlying the long-term effects of HAs observed in the present study are not yet clear. Cortical tonotopic reorganization has been suggested to occur in tinnitus patients (31–33), but tinnitus can also develop without this cortical reorganization (34), and the cortical reorganization was reported to be related only to hearing deficit, not to tinnitus (35). Cortical reorganization mostly develops when severe hearing deficit occurs in extensive frequency areas (36), but tinnitus can be generated immediately after a slight change in hearing threshold at only a single measured frequency, e.g., acute tinnitus after a brief noise exposure, such as a single episode of gun shooting on a weekend, and therefore there is no time for cortical reorganization. In the present study, LFT HAs did not provide auditory input to the high-frequency area where the sensory input had the greatest deficiency, and even WDRC could not compensate for the sensory deficit if this area were the cochlear dead region that cannot be stimulated by any strong sound to induce a response. Therefore, the simple idea of compensation for deficient auditory input may not be the case.

The FL strategy was designed to avoid stimulating the tinnitus frequency area in patients with HFHL. Stimulation with pure tones stripped of the tinnitus frequency, combined with vagus nerve stimulation, successfully reversed tinnitus in noise-exposed rats (37). Tailor-made notched music therapy, which involves stimulation with music missing the tinnitus frequency, also reportedly diminishes tinnitus symptoms (38–41). These heterogeneous

TABLE 2. Additional measures at initial, 3-mo and 6-mo visits

Variable	Group	Initial	3 Mo	6 Mo
Matched loudness (dB HL)	WDRC	69.9	52.3	58.6
	FT	67.0	52.7	63.1
	LFT	72.0	52.2	66.0
VAS loudness	WDRC	6.1	3.3	5.6
	FT	5.8	4.0	5.3
	LFT	5.6	3.8	5.0
VAS awareness	WDRC	87.4	46.5	69.7
	FT	86.1	52.6	64.8
	LFT	86.9	50.6	63.1
VAS annoyance	WDRC	6.0	2.6	5.2
	FT	6.0	3.2	4.8
	LFT	5.3	3.1	4.4

Significant changes are indicated in bold (paired t test with Bonferroni correction, $p < 0.05$).

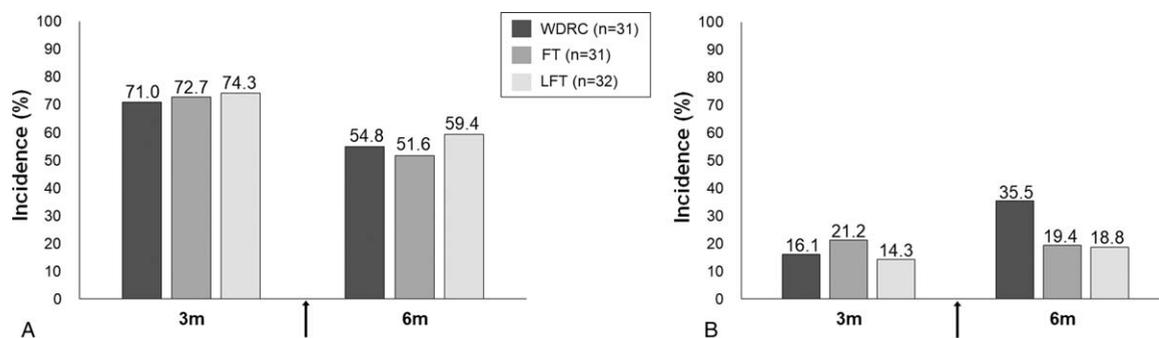


FIG. 3. Incidences of patients with $\geq 20\%$ reduction in Tinnitus Handicap Inventory (THI) scores (A) and with no improvement in THI score (B). The linear frequency transposition (LFT) group had the highest incidence of improved patients, and the lowest incidence of nonimproved patients. \uparrow , The subjects stopped wearing hearing aids after 3 mo. FT indicates frequency translation; WDRC, wide dynamic range compression.

treatment modalities have a common mechanism of action involving enhancement of lateral inhibition through stimulation of frequencies other than the tinnitus frequency area. In the present study, there were no significant differences in any of the variables between the HA groups. However, it is noteworthy that the WDRC group had double the incidence of nonimproved patients after removing HA, while the two FL groups had relatively low incidences of nonimproved patients (Fig. 3B). During the HA-wearing period, masking and distraction prevailed and no differences were observed in outcome measures between HA groups, but a significant difference was observed 3 months after removing the HAs.

We selected THI score as the primary outcome for a number of reasons. A decrease in tinnitus perception (i.e., intensity) does not automatically translate into a decrease in severity of tinnitus, and there is no relation between tinnitus loudness and the perceived severity of the tinnitus (42,43). In a survey with almost 5,000 participants, psychological complaints, such as feeling low/depressed, being highly affected by tinnitus, and considering oneself as victim of the noise, were strongly associated with tinnitus annoyance but had little correlation with loudness (44). THI is known to be a robust measure for quantifying tinnitus; it is highly correlated with tinnitus symptom rating scales, while having little correlation with loudness (45–47). However, the observation that the tinnitus loudness in the WDRC group remained consistently reduced until the final visit in our study may be useful for tinnitus management using HAs.

It should also be noted that participants in our study had normal hearing at lower frequencies, and therefore otologists or audiologists would not strongly recommend wearing HAs to improve communication function in such patients with hearing loss limited to high frequencies. However, our observations suggested that HAs, with or without FL, could be helpful for tinnitus in patients whose hearing does not necessarily require rehabilitation or assistive devices for HFHL.

There were a few limitations in our study. First, we did not recruit a negative control group, and therefore could not completely exclude the possibility of a placebo effect or spontaneous recovery. Second, we did not specifically investigate changes in tinnitus-related psychoemotional

status, such as depression, anxiety, stress, sleep disturbance, etc., which may be another important aspect of tinnitus-related disability issues. Finally, further studies involving the wearing of HAs for periods longer than 3 months and also longer than 3 months after removal of HAs are required.

CONCLUSIONS

This is the first study following the CONSORT guidelines demonstrating the effectiveness of using HAs alone to treat tinnitus. We obtained strong evidence for a long-term tinnitus-suppressing effect of HAs that lasted for at least 3 months after cessation of their use. No significant differences were found between conventional HAs and FL-type HAs in terms of tinnitus relief among patients with HFHL. Our results suggest that HAs, with or without FL, seem to be effective for longer-term relief of tinnitus among patients with HFHL, and not only for the period of their use.

REFERENCES

1. Saltzman M, Ersner MS. A hearing aid for the relief of tinnitus aurium. *Laryngoscope* 1947;57:358–66.
2. Del Bo L, Ambrosetti U. Hearing aids for the treatment of tinnitus. *Prog Brain Res* 2007;166:341–5.
3. Shekhawat GS, Searchfield GD, Stinear CM. Role of hearing AIDs in tinnitus intervention: A scoping review. *J Am Acad Audiol* 2013;24:747–62.
4. Moffat G, Adjout K, Gallego S, Thai-Van H, Collet L, Norena AJ. Effects of hearing aid fitting on the perceptual characteristics of tinnitus. *Hear Res* 2009;254:82–91.
5. Gabriel D, Veillet E, Vesson JF, Collet L. Rehabilitation plasticity: influence of hearing aid fitting on frequency discrimination performance near the hearing-loss cut-off. *Hear Res* 2006;213:49–57.
6. Sereda M, Xia J, El Refaie A, Hall DA, Hoare DJ. Sound therapy (using amplification devices and/or sound generators) for tinnitus. *Cochrane Database Syst Rev* 2018;12. CD013094.
7. dos Santos GM, Bento RF, de Medeiros. et al. The influence of sound generator associated with conventional amplification for tinnitus control: Randomized blind clinical trial. *Trends Hear* 2014;18. 2331216514542657.
8. Henry JA, Frederick M, Sell S, Griest S, Abrams H. Validation of a novel combination hearing aid and tinnitus therapy device. *Ear Hear* 2015;36:42–52.

9. Henry JA, McMillan G, Dann S, et al. Tinnitus management: Randomized controlled trial comparing extended-wear hearing aids, conventional hearing aids, and combination instruments. *J Am Acad Audiol* 2017;28:546–61.
10. Parazzini M, Del Bo L, Jastreboff M, Tognola G, Ravazzani P. Open ear hearing aids in tinnitus therapy: An efficacy comparison with sound generators. *Int J Audiol* 2011;50:548–53.
11. Bauer CA, Brozoski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: A controlled trial. *Ear Hear* 2011;32:145–55.
12. Goebel G, Rübler D, Stepputat F, Hiller W, Heuser J, Fichter M. *Controlled prospective study of tinnitus retraining therapy compared to tinnitus coping therapy and broad-band noise generator therapy. Proceedings of the Sixth International Tinnitus Seminar*. Cambridge, United Kingdom: Tinnitus and Hyperacusis Centre; 1999.
13. Davis A. *Hearing in Adults: The Prevalence and Distribution of Hearing Impairment and Reported Hearing Disability in the MRC Institute of Hearing Research's National Study of Hearing*. London: Whurr Publishers; 1995.
14. Hogan CA, Turner CW. High-frequency audibility: Benefits for hearing-impaired listeners. *J Acoust Soc Am* 1998;104:432–41.
15. Ching TY, Dillon H, Byrne D. Speech recognition of hearing-impaired listeners: Predictions from audibility and the limited role of high-frequency amplification. *J Acoust Soc Am* 1998;103:1128–40.
16. Murray N, Byrne D. Performance of hearing-impaired and normal hearing listeners with various high-frequency cut-offs in hearing aids. *Aust J Audiol* 1986;8:21–8.
17. McCreery RW, Venediktov RA, Coleman JJ, Leech HM. An evidence-based systematic review of frequency lowering in hearing aids for school-age children with hearing loss. *Am J Audiol* 2012;21:313–28.
18. Miller CW, Bates E, Brennan M. The effects of frequency lowering on speech perception in noise with adult hearing-aid users. *Int J Audiol* 2016;55:305–12.
19. Moore BC. Dead regions in the cochlea: Conceptual foundations, diagnosis, and clinical applications. *Ear Hear* 2004;25:98–116.
20. Ricketts TA, Dittberner AB, Johnson EE. High-frequency amplification and sound quality in listeners with normal through moderate hearing loss. *J Speech Lang Hear Res* 2008;51:160–72.
21. Aazh H, Moore BC. Dead regions in the cochlea at 4 kHz in elderly adults: Relation to absolute threshold, steepness of audiogram, and pure-tone average. *J Am Acad Audiol* 2007;18:97–106.
22. Caffier PP, Haupt H, Scherer H, Mazurek B. Outcomes of long-term outpatient tinnitus-coping therapy: Psychometric changes and value of tinnitus-control instruments. *Ear Hear* 2006;27:619–627.
23. Henry JA, Schechter M, Zaugg T, et al. Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Otolaryngol* 2006;126 (sup556):64–9.
24. Westin VZ, Schulin M, Hesser H, et al. Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: A randomised controlled trial. *Behav Res Ther* 2011;49:737–47.
25. Zhang M, Zhou H, Zhang J, Guo Y, Wang X, Wang N. Evaluating the effects of hearing aids combined with psychological counseling on tinnitus in patients with deafness. *Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi* 2013;27:461–4.
26. Bauer CA, Berry JL, Brozoski TJ. The effect of tinnitus retraining therapy on chronic tinnitus: A controlled trial. *Laryngoscope Investig Otolaryngol* 2017;2:166–77.
27. Peltier E, Peltier C, Tahar S, Alliot-Lugaz E, Cazals Y. Long-term tinnitus suppression with linear octave frequency transposition hearing AIDS. *PLoS One* 2012;7:e51915.
28. Schaette R, Kempter R. Development of tinnitus-related neuronal hyperactivity through homeostatic plasticity after hearing loss: A computational model. *Eur J Neurosci* 2006;23:3124–38.
29. Norena AJ. An integrative model of tinnitus based on a central gain controlling neural sensitivity. *Neurosci Biobehav Rev* 2011;35:1089–109.
30. Rauschecker JP. Auditory cortical plasticity: A comparison with other sensory systems. *Trends Neurosci* 1999;22:74–80.
31. Norena AJ, Eggermont JJ. Changes in spontaneous neural activity immediately after an acoustic trauma: Implications for neural correlates of tinnitus. *Hear Res* 2003;183:137–53.
32. Eggermont JJ, Roberts LE. The neuroscience of tinnitus: Understanding abnormal and normal auditory perception. *Front Syst Neurosci* 2012;6:53.
33. Eggermont JJ, Komiya H. Moderate noise trauma in juvenile cats results in profound cortical topographic map changes in adulthood. *Hear Res* 2000;142:89–101.
34. Langers DR, de Kleine E, van Dijk P. Tinnitus does not require macroscopic tonotopic map reorganization. *Front Syst Neurosci* 2012;6:2.
35. Ghazaleh N, Zwaag WV, Clarke S, Ville DV, Maire R, Saenz M. High-resolution fMRI of auditory cortical map changes in unilateral hearing loss and tinnitus. *Brain Topogr* 2017;30:685–97.
36. Rajan R, Irvine DR. Neuronal responses across cortical field A1 in plasticity induced by peripheral auditory organ damage. *Audiol Neurootol* 1998;3:123–44.
37. Engineer ND, Riley JR, Seale JD, et al. Reversing pathological neural activity using targeted plasticity. *Nature* 2011;470:101–4.
38. Okamoto H, Stracke H, Stoll W, Pantev C. Listening to tailor-made notched music reduces tinnitus loudness and tinnitus-related auditory cortex activity. *Proc Natl Acad Sci U S A* 2010;107:1207–10.
39. Pape J, Paraskevopoulos E, Bruchmann M, Wollbrink A, Rudack C, Pantev C. Playing and listening to tailor-made notched music: cortical plasticity induced by unimodal and multimodal training in tinnitus patients. *Neural Plast* 2014;2014:516163.
40. Stein A, Wunderlich R, Lau P, et al. Clinical trial on tonal tinnitus with tailor-made notched music training. *BMC Neurol* 2016;16:38.
41. Argstatter H, Krick C, Bolay HV. Music therapy in chronic tonal tinnitus. Heidelberg model of evidence-based music therapy. *HNO* 2008;56:678–85.
42. Monzani D, Genovese E, Marrara A, et al. Validity of the Italian adaptation of the Tinnitus Handicap Inventory; focus on quality of life and psychological distress in tinnitus-sufferers. *Acta Otorhinolaryngol Ital* 2008;28:126–34.
43. Jastreboff PJ, Hazell JW. *Tinnitus Retraining Therapy: Implementing the Neurophysiological Model*. Cambridge: Cambridge University Press; 2008.
44. Hiller W, Goebel G. When tinnitus loudness and annoyance are discrepant: Audiological characteristics and psychological profile. *Audiol Neurootol* 2007;12:391–400.
45. Newman CW, Jacobson GP, Spitzer JB. Development of the tinnitus handicap inventory. *Arch Otolaryngol Head Neck Surg* 1996;122:143–8.
46. Newman CW, Sandridge SA, Jacobson GP. Psychometric adequacy of the Tinnitus Handicap Inventory (THI) for evaluating treatment outcome. *J Am Acad Audiol* 1998;9:153–60.
47. Baguley D, Humphriss R, Hodgson C. Convergent validity of the tinnitus handicap inventory and the tinnitus questionnaire. *J Laryngol Otol* 2000;114:840–3.