Original Article

Trends in Hearing
2014, Vol. 18: 1–9
© The Author(s) 2014
Reprints and permissions:
sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/2331216514542657
trh.sagepub.com
SAGE

The Influence of Sound Generator Associated With Conventional Amplification for Tinnitus Control: Randomized Blind Clinical Trial

Gisele Munhoes dos Santos[1], Ricardo Ferreira Bento[1], Italo Roberto Torres de Medeiros[1], Jeanne Oiticcica[1], Eleonora Csipai da Silva[1], and Silvio Penteado[1]

Abstract

Hearing aids with an integrated sound generator have been used to enhance the treatment of tinnitus. The main aim of this study was to verify whether the combined use of amplification and sound generator is more effective than conventional amplification alone in reducing tinnitus annoyance by means of the use of a new hearing aid with an integrated sound generator. A total of 49 patients underwent a blind randomized clinical trial. Tinnitus annoyance was measured by Tinnitus Handicap Inventory and numerical scales, and psychoacoustic measures of tinnitus were also performed. The sound generator was set at the lowest intensity capable of providing relief from tinnitus. Results showed that 62.5% of the patients presented a reduction in tinnitus annoyance in the combined fitting group and in the group with amplification alone, 78% showed a reduction. This difference between the groups was not statistically significant.

Keywords

tinnitus, hearing aids, sound generator

Introduction

Recent research shows that tinnitus is a disorder that originates in the brain but has its trigger in the peripheral region. This is because the damage caused by the loss of hearing in the inner hair cells causes a loss of normal auditory nerve function (Herraiz, Diges, Cobo, & Aparicio, 2009; Kaltembach, 2009; Moffat et al., 2009; Norena, 2009), which in turn leads to a reduction in afferent nerve fibers throughout the auditory system. This lack of afferents creates a change in the neuronal activity, which is thought to be responsible for causing tinnitus (Kaltembach, 2009).

For patients with tinnitus and hearing loss, the use of a hearing aid is recommended. This not only improves hearing (Ferrari, Sanchez, & Pedalini, 2007) but also stimulates the auditory cortex, which leads to permanent reductions in the neural activity responsible for causing the sensation of tinnitus (Searchfield, 2006). However, despite the hearing aid having been used as a tool for controlling tinnitus over the past 60 years (Saltzman & Ersner, 1947), a recent finding showed that the majority of people with tinnitus do not regard the hearing aid as a treatment strategy (Kochkin, Tyler, & Born, 2011).

Over the past few decades, hearing aids have been developed with an integrated sound generator as an alternative to enhance the treatment of tinnitus in patients with associated hearing loss (Henry, Zaugg, & Schechter, 2005). However, neither a well-established protocol nor sufficient scientific evidence exists to support the superiority of the combined use of tools over conventional amplification.

The main aim of this study was to verify whether the combined use of amplification and sound generator is more effective than amplification alone in reducing the discomfort of tinnitus in patients with tinnitus and a mild

[1]Department of Otorhinolaryngology, University of São Paulo, Brazil

Corresponding Author:
Gisele Munhoes dos Santos, Rua Pedroso Alvarenga, 220 Apt 101, CEP 04531-000, São Paulo, Brazil.
Email: giselemunhoes@gmail.com

to moderate bilaterally symmetrical sensorineural hearing loss, by means of the use of a new hearing aid with an integrated sound generator developed by the Department of Otorhinolaryngology of the University of São Paulo. We also wanted to check whether there was a correlation between the reduction in discomfort and the psychoacoustic measures of tinnitus.

Materials and Method

This study was developed in the form of a blind randomized clinical trial. It was approved by the Committee for Analysis of Research Projects of the Hospital das Clínicas and received financial support in the form of Research Grants by the Foundation for Research Support of São Paulo state. This study was registered on clinicaltrials.gov (NCT01857661).

To determine the sample size, the Tinnitus Handicap Inventory (THI) was considered the primary dependent variable. Based on the study of Ferreira, Cunha, Onishi, Branco-Barreiro, and Ganança (2005), a standard deviation of about 25 points on the THI scale was expected. A power analysis (Armitage & Berry, 1987) revealed that to achieve 80% power to detect a minimum difference of 20 points between the groups at a two-tailed significance level of 5%, 24 subjects were required per group, totaling 48 individuals.

The sample composed of 49 patients with mild to moderate bilateral symmetrical sensorineural hearing loss, with complaints of constant tinnitus for at least 6 months, with THI score more than 20 points, and without prior experience with hearing aids or any other type of sound therapy.

The patients were initially assessed by a *blind* evaluator, who performed a specific anamnesis, psychoacoustic evaluation of the tinnitus (tinnitus pitch, loudness, and minimum masking level [MML]), numeric scale measuring tinnitus discomfort from 0 to 10, and the THI. After this stage, the patients were randomly assigned into two groups: a combined fitting group and an amplification alone group.

The combined fitting group received bilateral fitting of hearing aids with an integrated sound generator developed by the Department of Otorhinolaryngology of the University of São Paulo (Penteado, 2009; Penteado & Bento, 2008), in combined mode or, in other words, with the combined use of amplification and sound generator. The amplification alone group received binaural fitting of the same hearing aid, but in simple mode, meaning amplification alone. This is a behind-the-ear (BTE) digital hearing aid with 16 channels of gain adjustments. It is equipped with an integrated white noise that can be used together with the amplification mode or not.

The hearing aid fitting was done by the researcher audiologist, and the individual needs, audiometric thresholds, discomfort, and observations of the patient were taken into account. Hearing aids were fitted using a modified strategy based on the NAL-NL1 rule from the software EasyFit, developed by the same University group.

In the combined fitting group, the sound generator was set at the lowest intensity capable of providing relief from tinnitus (Tyler, 2006). The level produced by the sound generator was initially very low and was adjusted upward until the patient indicated that the sound from the generator was audible. At this point, the level of the sound generator was increased further until the patient indicated some relief from tinnitus. If the patient reported any discomfort, the level from the sound generator was reduced again until a comfortable level was achieved. The noise reduction was not activated in any of the cases. Both groups received the same specific counseling about the aspects relevant to tinnitus.

The patients were advised to use the hearing aids for at least 8 hr per day, and the final evaluation, composed of the psychoacoustic measures of tinnitus (tinnitus pitch, loudness, and MML), numeric scale, and THI, was carried out after 3 months of hearing aid use, by the same blind evaluator who performed the initial evaluation and who did not know which group each patient belonged to.

For the pitch matches, patients were instructed to match to the most troublesome tinnitus percept. In cases where the tinnitus was asymmetric, the contralateral ear was used as the reference ear; in cases where the tinnitus was equal across the two ears or heard in the center of the head, the right ear was used as the reference. A pure tone was used unless a patient's description of the tinnitus suggested otherwise. The reference tone was presented at a level 5–10 dB above the hearing threshold. It began at 1000 Hz and was increased or decreased in frequency according to the patient's instruction until a match was indicated.

For loudness matches, the same ear was used as a reference as for the pitch matches, and the frequency of the tone was set at the frequency obtained from the pitch matches. The level of the tone was initially below the hearing threshold and was increased in level in 2-dB steps until the patient reported that the stimulus was equal in loudness to the tinnitus.

The MML test was designed to determine whether the tinnitus could be masked by another sound. Broadband white noise was initially presented below the hearing threshold and was increased in level in 5-dB steps, while the patient was asked to indicate whether the tinnitus was masked, partially masked, or unchanged. The procedure was stopped if the patient reported discomfort, even if no change in tinnitus was reported.

Results

Of the 49 patients who took part in the study, two did not attend the final evaluation. One of them was not located, and the other suffered a heart attack which made it impossible to attend. They were both therefore excluded from the statistical analysis for missing the follow-up.

The sample was made up of 25 women and 22 men, with a mean age of 72.1 years (26–91 years) and standard deviation of 12.6 years. The most common types of tinnitus were whistling ($n = 9$), roaring ($n = 7$), and buzzing ($n = 6$), and the most frequent location was in both ears ($n = 18$), followed by the head ($n = 15$) and in only one ear ($n = 14$). With regard to hearing loss, 26 presented a mild degree of hearing loss and 21 a moderate degree of hearing loss. A sloping hearing loss was the most frequent ($n = 36$), followed by a flat loss ($n = 11$). The most frequent diagnostic hypothesis was presbycusis ($n = 20$), followed by unknown etiology ($n = 14$), hearing loss caused by high levels of sound pressure ($n = 7$), traumatic brain injury ($n = 3$), ototoxicity ($n = 1$), hypertension ($n = 1$), stroke ($n = 1$), and radiotherapy ($n = 1$).

Comparison of Groups Before Intervention

To check whether the study groups were homogenous, the means and standard deviations of variables in the preintervention period were calculated for each of the evaluated groups, and later the difference between the means of the groups was evaluated by means of the Wilcoxon nonparametric test (Hollander & Wolfe, 1973).

According to Table 1, there is homogeneity between the study groups, with only the means of the duration of tinnitus variable showing differences, the duration of tinnitus being greater for the group submitted to the combined fitting. The groups also appeared similar for gender, location of tinnitus, and for degree and configuration of hearing loss (Table 2).

Comparison of the Groups After Intervention

After randomization, 24 patients were allocated to the combined fitting group and 23 to the amplification alone group. Calculations were made of the means and standard deviations, in the postintervention period, of the numeric scale, THI, tinnitus pitch, loudness, and MML variables for each group. Then, the difference between the means of the groups was analyzed using the Wilcoxon nonparametric test (Hollander & Wolfe, 1973).

According to Table 3, there was no difference between the groups when the variables were evaluated after intervention. To verify whether the duration of tinnitus variable interfered with the result of the study, a generalized linear regression model was constructed (Paula, 2013) using THI as the dependent variable and group and duration as the explanatory variables. There was no correlation between the duration of tinnitus and the response

Table 1. Mean and Standard Deviation by Group and *p* value of the Wilcoxon Test for the Variables in the Preintervention Period.

	Type of fitting				
	Combined		Amplification alone		
Variable	*M*		*SD*		*p*
Age (years)	74.4	10.7	69.7	14.2	.40
Duration of tinnitus (years)	12.7	8.3	7.6	6.6	.02
Numeric scale	7.8	1.9	7.8	2.2	.98
THI (points)	53.2	20.5	57.5	16.4	.62
Pitch (Hz)	5406	2161	5253	2582	.71
Loudness (dBSL)	10.2	4.7	9.0	4.5	.41
Minimum masking level (dBSL)	25.2	24.8	23.5	18.1	.62

Note. THI = Tinnitus Handicap Inventory.

Table 2. Degree and Configuration of the Hearing Loss.

	Combined	Amplification alone	*p*
Degree of hearing loss			
Mild	14	12	.46
Moderate	10	11	
Configuration of the hearing loss			
Sloping	17	19	.79
Flat	7	4	

Table 3. Mean and Standard Deviation by Group and *p* value of the Wilcoxon Test for the Variables After Intervention.

	Type of fitting				
	Combined		Amplification alone		
Variable	*M*	*SD*	*M*	*SD*	*p*
Numeric scale	5.3	3.2	3.8	4.0	.18
THI (points)	24.9	21.8	23.8	26.1	.57
Pitch (Hz)	5041	1983	4773	2207	.84
Loudness (dBSL)	7.2	3.7	8.0	4.1	.51
Minimum masking level (dBSL)	15.0	11.63	14.3	14.5	.58

Note. THI = Tinnitus Handicap Inventory.

of THI. A multiple linear regression model was also constructed (Neter, Wasserman, Kutner, & Li, 1996) using the numerical scale and tinnitus loudness as dependent variables and group and duration as the explanatory variables. Again there was no correlation between the duration of tinnitus and either the numerical scale or the tinnitus loudness.

Analysis of the Difference Between the Pre- and Postintervention Periods

In the combined fitting group, 62.5% ($n = 15$) of the patients presented a reduction of 20 points or more in the THI. In the amplification alone group, 78% presented a 20+ point reduction of discomfort with tinnitus ($n = 18$), without significant statistical difference between the groups (chi-square test; $p = .24$).

As shown in Table 4, the difference between the pre- and postintervention periods for the combined group was significant for all the variables except the tinnitus pitch.

As shown in Table 5, the difference between the pre- and postintervention periods for the amplification alone group was significant for all the variables except the tinnitus pitch and loudness.

Table 4. Mean and Standard Deviation for the Difference Between Post- and Preintervention Periods and the *p* value of the Wilcoxon Test for the Combined Fitting Group.

Variable	*M*	*SD*	*p*
Numeric scale	−2.562	3.67	<.01
THI (points)	−28.25	18.59	<.01
Pitch (Hz)	−364.67	1994.97	.15
Loudness (dBNS)	−2.96	4.09	<.01
Minimum masking level (dBNS)	−10.25	19.30	.02

Note. THI = Tinnitus Handicap Inventory.

Table 5. Mean and Standard Deviation for the Difference Between Post- and Preintervention Periods and the *p* value of the Wilcoxon Test for the Amplification Alone Group.

Variable	*M*	*SD*	*p*
Numeric scale	−3.98	4.09	<.01
THI (points)	−33.70	24.18	<.01
Pitch (Hz)	−479.75	2339.29	.27
Loudness (dBSL)	−1.02	5.40	.21
Minimum masking level (dBSL)	−9.22	21.36	.03

Note. THI = Tinnitus Handicap Inventory.

Correlations Between Discomfort and Psychoacoustic Measurements of Tinnitus

The groups were compared for the reduction of discomfort due to tinnitus, after intervention, using the following variables: numeric scale, tinnitus pitch, loudness, THI, and MML.

For the numeric scale, and tinnitus loudness variables, a multiple linear regression model was constructed (Neter et al., 1996) using the explanatory variables: group, duration of tinnitus, MML, and tinnitus pitch (Tables 6 and 7).

As shown in Figures 1 and 2, only the MML variable was significantly correlated with the numerical scale variable, with higher MML associated with higher numerical scale values. There was no difference between the two groups.

Finally, a generalized linear model was adjusted (Paula, 2013) for the THI variable, taking into account the variables: group, duration of tinnitus, tinnitus pitch, and MML as explanatory variables (Table 8).

According to Figure 3, only the MML variable proved to be significant, so that higher values of this variable are associated with higher levels of THI, without any difference between the groups.

According to the statistical analysis, it can be seen that there is no significant difference between the studied groups for the variables measured after intervention. For the numeric scale, tinnitus loudness, and THI, it was possible to detect the effect of the MML, in which higher values of MML are associated with greater discomfort due to tinnitus.

Table 6. Final Adjusted Model for Numerical Scale.

Parameter	Estimate	*SD*	*p*
Intercept	2.34	0.90	.01
Minimum masking level (effect)	0.10	0.04	.01
Group (combined)	1.40	0.99	.17

Note. Base profile: Patients of amplification alone group with minimum level of masking equal to zero.

Table 7. Final Adjusted Model for Tinnitus Loudness.

Parameter	Estimate	*SD*	*p*
Intercept	6.81	1.01	<.01
Minimum masking level (effect)	0.08	0.04	.06
Group (combined)	−0.85	1.11	.45

Note. Base profile: Patients of amplification alone group with minimum level of masking equal to zero.

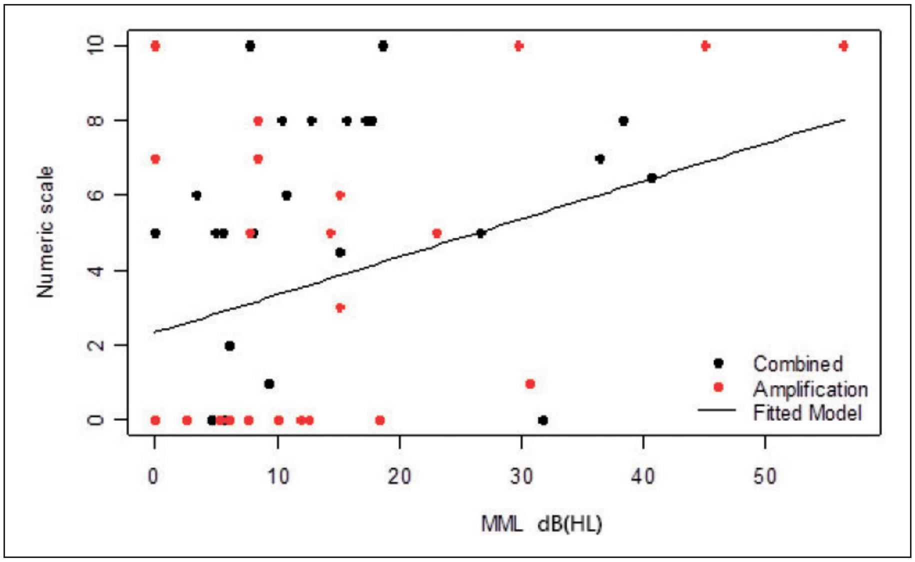

Figure 1. Scatter plot of the numeric scale and minimum masking level variables and line of adjusted model after intervention.

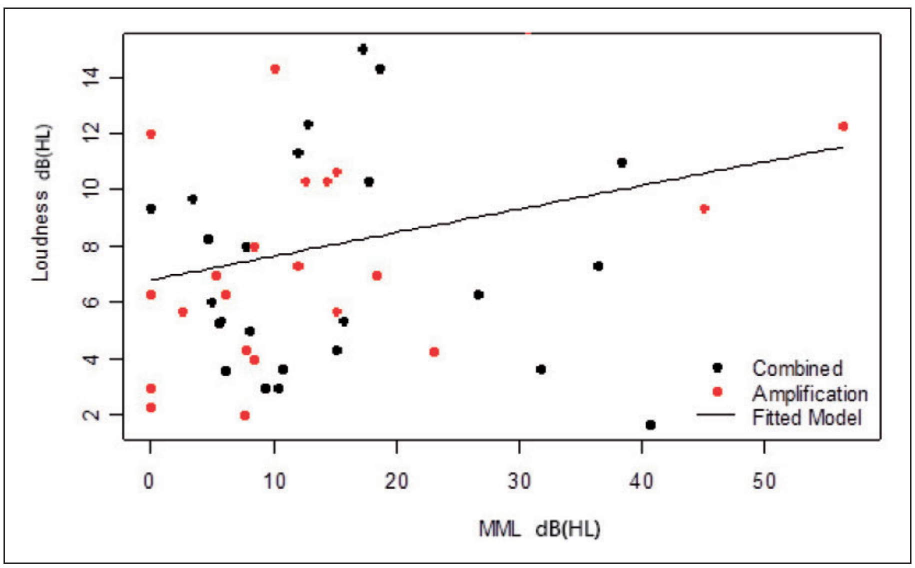

Figure 2. Scatter plot of the tinnitus loudness and minimum masking level and line of adjusted model after intervention.

Table 8. Final Adjusted Model for THI.

Parameter	Estimate	*SD*	*p*
Intercept	2.96	0.25	<.01
Minimum masking level (effect)	0.02	0.01	.08
Group (combined)	0.01	0.27	.98

Note. THI = Tinnitus Handicap Inventory.

Discussion

This study did not demonstrate a superiority of the combined use of amplification and sound generator over conventional amplification alone in reducing the discomfort of tinnitus. Both groups presented similar responses in both reduction of discomfort caused by tinnitus as measured using THI and numeric scale, and also the magnitude of tinnitus obtained by means of the MML. These findings are consistent with the findings of Schaette,

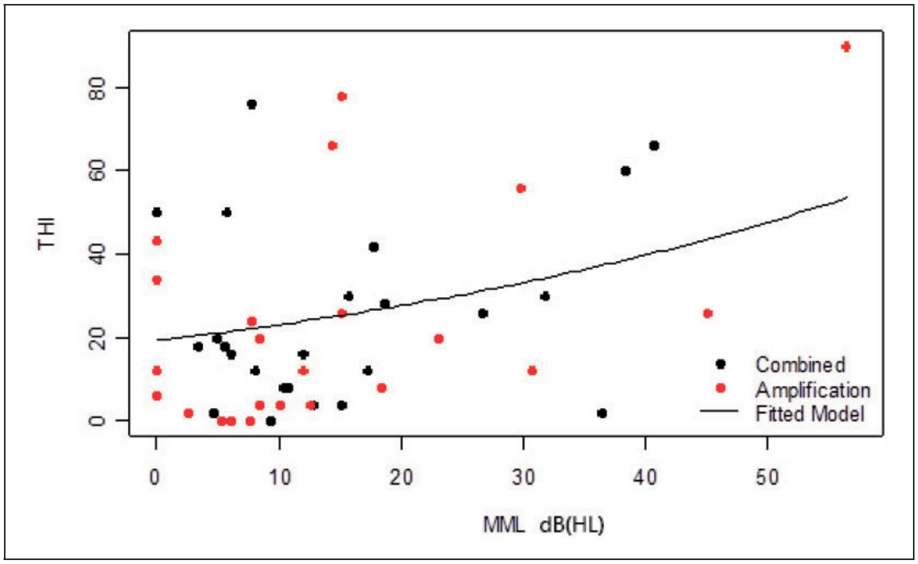

Figure 3. Scatter plot of the dispersion between the variables THI and minimum masking level (dB HL) and adjusted model after intervention.
Note. THI = Tinnitus Handicap Inventory.

Konig, Hornig, Gross, and Kempter (2010); Fukuda, Miyashita, Inamoto, and Mori (2011); and Parazzini, Del Bo, Jastreboff, Tognola, and Ravazzani (2011) that, despite using different outcome measures, these studies also found an improvement in tinnitus through the use of hearing aids, combined instruments, or sound generators, with no significant differences between instrument types.

On the other hand, in a crossover study, also comparing amplification alone with combined fitting, Frachet, Vormès, Moyse, and Vasseur (2004) observed a significantly greater reduction in the discomfort from tinnitus with the combined fitting after 24 weeks of using a hearing aid (12 weeks in simple mode and 12 weeks in combined mode).

In another recent study, Sweetow and Sabes (2010) also concluded that the discomfort from tinnitus was significantly less with the combined use of amplification with white noise or amplification with fractal sound than with amplification alone, contrary to our results.

The design of our study has possibly led to this result, as very homogenous groups with single and parallel interventions were studied. The only variable that showed a difference between the groups was the duration of tinnitus, which was significantly higher in the combined fitting group ($p = .02$). However, this fact did not interfere with the results of the study, as this variable was controlled in a multiple linear regression model, and the results were still similar in both groups. In addition, the two groups used the same hearing aid, received the same type of counseling, and were assessed by a blind evaluator, which reduces the chance of bias.

Another fact that should be mentioned relates to the type of stimulus generated by the combined hearing aid (white noise). Despite being well established in the literature that broadband noise is more effective than narrowband noise used in the past to mask tinnitus (Henry et al., 2006), some authors have suggested using other types of noise, such as speech-shaped noise, which besides accelerating the improvement of tinnitus, is better tolerated by patients (Ito, Keiko, & Reiko, 2009). Our hearing aids used only white noise, so it was not possible to compare it with other types of stimulus.

Carrabba et al. (2009) even suggest using a new combined hearing aid, which uses white noise, but with independent volume control, possibility of modulation, and a streamer that activates the sound generator only in quiet environments. The authors also observed satisfactory improvement of tinnitus after 3 months using this new hearing aid.

It is worth noting that, according to some authors, the type of therapeutic approach used can interfere in the results of the intervention. Von Wedel, Von Wedel, Streppel, and Walger (1997) point to the superiority of partial masking over total masking for reducing the discomfort of tinnitus. Henry et al. (2006) compared the effects of masking and Tinnitus Retraining Therapy (TRT) and reported that the masking showed the best results in the first 3 months. However, in the sixth month, the two approaches appeared equally effective and after 12 months, TRT appeared to be more effective than masking.

Tyler, Noble, Coelho, and Ji (2012) recently conducted a study designed to test whether the theory that audibility of the tinnitus was necessary, as proposed by Jastreboff (1990). They compared the effectiveness of TRT using a sound generator adjusted at the mixing point; a sound generator adjusted for total masking of tinnitus and with no sound generator, only with counseling. They concluded that the mixing point and total masking are equally effective for the habituation of tinnitus. In light of these findings and also from our clinical experience, we did not worry about finding the mixing point recommended for TRT (Jastreboff, 1990) nor the total masking of tinnitus (Henry et al., 2006). We sought the lowest intensity capable of providing relief from tinnitus as suggested by the Tinnitus Activities Treatment—TAT (Tyler, 2006).

It is worth remembering that any therapeutic approach using sound therapy has an optimized effect when associated with counseling (Jastreboff, 1990; Tyler, 2006), which helps break the vicious cycle of stress caused by tinnitus, helping the patients to change their behavior and way of thinking (Tyler, 2006). Searchfield, Kaur, and Martin (2010) claim that a hearing aid in tandem with counseling was more effective in reducing a patient's reaction to tinnitus than just counseling, confirming the need for an association of the two strategies.

Our approach also associated counseling and sound therapy, and our results also show satisfactory improvement of tinnitus after 3 months of using the hearing aids. In the amplification alone group, 78% of the patients presented a reduction of more than 20 points on the THI ($n = 18$), and the combined fitting group showed a 62.5% ($n = 15$) reduction, with no statistically significant difference between the groups ($p = .24$). The mean final score of the THI was 24.9 points in the combined fitting group and 23.8 in the amplification alone adaptation group, so the patients went from having a moderate level of discomfort to a mild one.

Despite the limitations of THI because of the 3-label category scale (Tyler, Oleson, Noble, Coelho, & Ji, 2007), it was used because it is the only tinnitus questionnaire certified in Portuguese language. The reduction of 20 points in THI was considered as a sign of improvement, as it represents a change in category of handicap.

In addition to the significant reduction in the score of the THI in both groups, there was also a significant reduction of the numeric scale, reinforcing the effectiveness of the simple or combined amplification in reducing the discomfort caused by tinnitus. The scores of numeric scale varied from 7.8 to 5.3 in the combined fitting group and from 7.8 to 3.8 in the amplification alone group, with no significant difference between the groups. Our results tally with several other studies that have also observed the effectiveness of using a simple or combined hearing aid to reduce the discomfort of tinnitus (Ferrari et al., 2007; Paula, 2013; Schaette et al., 2010).

Despite some authors believing that none of the psychoacoustic measures of tinnitus can be used to predict the severity of tinnitus, or the prognosis of the proposed treatment, others agree that significant changes occur in the MML over the period of treatment, reducing its intensity only in the group that presents improvements of tinnitus (Jastreboff, Hazell, & Graham, 1994; Santesso, Santos, & Samelli, 2012). In our study, there was a significant reduction in MML in both the groups evaluated, which suggests that 3 months is sufficient time for cortical plasticity to be induced by the acoustic stimulation (Herraiz et al., 2009; Kaltembach, 2009; Moffat et al., 2009; Norena, 2009) and also to reduce the magnitude of tinnitus (Tyler, 2006).

In addition to the reduction of MML, our study was also able to show a positive correlation between the MML and the reduction of discomfort from tinnitus, measured both by THI and by numeric scale, so that lower values of MML are linked to less discomfort from tinnitus. Another finding was the positive correlation between MML and the tinnitus loudness, indicating that lower loudness levels are also associated with lower values of MML.

Moffat et al. (2009) were not able to detect the effect of the hearing aids on the tinnitus loudness after 1 month of treatment. In our findings, after 3 months, it was possible to detect a significant reduction in the tinnitus loudness only in the combined fitting group. Perhaps this finding indicates that despite the combined and conventional fittings provide the same reduction in the discomfort resulting from tinnitus, it could be that the combined use is more effective in reducing the magnitude of tinnitus, in respect of the loudness. We believe that further studies are required to prove this hypothesis, as in general the tinnitus loudness varies between 5 and 10 dB and does not correlate with the degree of discomfort (Landgrebe et al., 2012). In our study, the mean was 10.2 dB (combined fitting) and 9 dB (amplification alone) before using the hearing aids, turning to 7.2 dB ($p < .01$) and 8 dB after 3 months of combined and simple fitting, respectively.

According to our results, 3 months seem to be sufficient to detect the effect of amplification on the reduction of the discomfort from tinnitus, which tallies with other reports published (Carrabba et al., 2009). Some studies ended up seeing a reduction of discomfort after 1 month of using the hearing aid (Ferrari et al., 2007; Fukuda et al., 2011). However, Ito et al. (2009) observed that the improvement of tinnitus occurred more quickly with speech noise (after 1 month of use) than with white noise (after 6 months of use). However, the group exposed to white noise had a higher degree of hearing loss and greater tinnitus than the group exposed to speech noise, introducing a potential confound.

In contrast, Parazzini et al. (2011) compared the effect of using hearing aids and sound generators to reduce the long-term discomfort of tinnitus (3, 6, and 12 months) and noticed that the tinnitus improved progressively from the third month, with no difference, however, between the groups. Therefore, we do not believe that additional time is required to show the superiority of combined use compared to the amplification alone. However, our patients continue to be monitored so that observations about the long-term effects of hearing aids can be made.

Based on the results of this study, it can be concluded that the combined use of amplification and sound generator and the use of conventional amplification alone were equally effective in reducing the discomfort caused by tinnitus in patients with tinnitus and mild to moderate bilaterally symmetrical sensorineural hearing loss. Additionally, a correlation was observed between MML and the THI, numerical scale and tinnitus loudness, suggesting that higher values of MML are associated with a greater discomfort and higher tinnitus loudness.

Some caution is required in interpreting these results, based on the relatively small number of subjects. However, as the sample size should have been sufficient to detect a large effect, any difference (if it exists) is likely to be small.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was financially supported in the form of Research Grants by the Foundation for Research Support of São Paulo state.

References

Armitage, P., & Berry, G. (1987). The planning of statistical investigations. In P. Armitage, & G. Berry (Eds.),, *Statistical methods in medical research* (2nd ed., pp. 179–185). Oxford, England: Blackwell.

Carrabba, L., Coad, G., Constantini, M., Del Bo, L., Dyrlund, O., Forti, S., & Searchfield, G. (2009, March). *Combination open ear instrument for tinnitus sound treatment*. Proceedings of the 3rd Tinnitus Research Initiative Meeting from Clinical Practice to Basic Neuroscience and Back, Stresa, Italy.

Ferrari, G. M. S., Sanchez, T. G., & Pedalini, E. B. (2007). The efficacy of open molds in controlling tinnitus. *Brazilian Journal of Otorhinolaryngology*, *73*(3), 370–377.

Ferreira, P. E. A., Cunha, F., Onishi, E. T., Branco-Barreiro, F. C. A., & Ganança, F. F. (2005). Tinnitus handicap inventory: Cross-cultural adaptation to Brazilian Portuguese. *Pró-Fono Revista de Atualização Científica*, *17*(3), 303–310.

Frachet, B., Vormès, E., Moyse, D., & Vasseur, J. (2004). Acoustic hearing aid with an integrated noise generator in hearing-impaired subjects with tinnitus. *Annales d'oto-laryngologie et de chirurgie cervico faciale*, *121*(5), 266–271.

Fukuda, S., Miyashita, T., Inamoto, R., & Mori, N. (2011). Tinnitus retraining therapy using portable music players. *Auris Nasus Larynx*, *38*, 692–696.

Henry, J. A., Schechter, M. A., Zaugg, T. L., Griest, S., Jastreboff, P. J., Vernon, J. A., . . . ,tewart, B. J. (2006). Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Oto-Laryngologica*, *126*, 64–69.

Henry, J. A., Zaugg, T. L., & Schechter, M. A. (2005). Clinical guide for audiologic tinnitus management I: Assessment. *The American Journal of Audiology*, *14*(1), 21–48.

Herraiz, C., Diges, I., Cobo, P., & Aparicio, J. M. (2009). Cortical reorganization and tinnitus: Principles of auditory discrimination training for tinnitus management. *European Archives of Oto-Rhino-Laryngology*, *266*, 9–16.

Hollander, M., & Wolfe, D. A. (1973). *Nonparametric statistical methods*. New York, NY: John Wiley & Sons.

Ito, M., Keiko, S., & Reiko, A. (2009). Association between tinnitus retraining therapy and tinnitus control instrument. *Auris Nasus Larink*, *36*, 536–540.

Jastreboff, P. J. (1990). Phantom auditory perception (tinnitus): Mechanisms of generation and perception. *Neurosciences Research*, *8*, 221–254.

Jastreboff, P. J., Hazell, J. W. P., & Graham, R. L. (1994). Neurophysiological model of tinnitus: Dependence of the minimal masking level on treatment outcome. *Hearing Research*, *80*, 216–232.

Kaltembach, J. A. (2009). Insights on the origins of tinnitus: An overview of recent research. *The Hearing Journal*, *62*(2), 26–29.

Kochkin, S., Tyler, R., & Born, J. (2011). *MarkeTrak VIII: The prevalence of tinnitus in the United States and self-reported efficacy of various treatments*. Retrieved from http://www.hearingreview.com.

Landgrebe, M., Azevedo, A., Baguley, D., Bauer, C., Cacace, A., Coelho, C., . . . ,Langguth, B. (2012). Methodological aspects of clinical trials in tinnitus: A proposal for an international standard. *Journal of Psychosomatic Research*, *73*, 112–121.

Moffat, G., Adjout, K., Gallego, S., Thai-Van, H., Collet, L.Norena, A. J. (2009). Effects of hearing AID fitting on the perceptual characteristics of tinnitus. *Hearing Research*, *254*, 82–91.

Neter, J., Wasserman, W., Kutner, M. H., & Li, W. (1996). *Applied linear statistical models* (4th ed.). Chicago, IL: Irwin.

Norena, A. (2009, March). *The long road to the neurosciences of tinnitus*. Proceedings of the 3rd Tinnitus Research Initiative Meeting from Clinical Practice to Basic Neuroscience and Back, Stresa, Italy.

Parazzini, M., Del Bo, L., Jastreboff, M., Tognola, G., & Ravazzani, P. (2011). Open ear hearing aids in tinnitus therapy: An efficacy comparison with sound generators. *International Journal of Audiology*, *50*, 548–553.

Paula, G. A. (2013). *Modelos de Regressão: Com Apoio Computacional*. Retrieved from http://www.ime.usp.br/~giapaula/texto 2013.pdf.

Penteado, S. P. (2009). *Development of digital behind-the-ear hearing aid with minimal specifications*. Retrieved from http://www.teses.usp.br/teses/disponiveis/5/5143/tde-09122009-174207/pt-br.

Penteado, S. P., & Bento, R. F. (2008). Project and development of the low-cost digital hearing aid—"Manaus.". *International Archives of Otorhinolaryngology*, *12*(3), 347–355.

Saltzman, M., & Ersner, M. S. (1947). A hearing aid for the relief of tinnitus aurium. *Laryngoscope*, *57*, 358–366.

Santesso, H. M., Santos, G. M., & Samelli, A. G. (2012). The use of conventional hearing aids for improvement of the tinnitus. *International Archives of Otorhinolaryngology*, *16*(1), 98–103.

Schaette, R., Konig, O., Hornig, D., Gross, M., & Kempter, R. (2010). Acoustic stimulation treatments against tinnitus could be most effective when tinnitus pitch is within the stimulated frequency range. *Hearing Research*, *269*, 95–101.

Searchfield, G. D. (2006). Hearing aids and tinnitus. In R. S. Tyler (Ed.), *Tinnitus treatment—Clinical protocols* (pp. 161–175). New York, NY: Thieme Medical.

Searchfield, G. D., Kaur, M., & Martin, W. H. (2010). Hearing aids as an adjunct to counseling: Tinnitus patients who choose amplification do better than those that don't. *The International Journal of Audiology*, *49*(8), 574–579.

Sweetow, R. W., & Sabes, J. H. (2010). Effects of acoustical stimuli delivered through hearing aids on tinnitus. *Journal of the American Academy of Audiology*, *21*, 461–473.

Tyler, R. S. (2006). Neurophysiological models, psychological models and treatments for tinnitus. In R. S. Tyler (Ed.), *Tinnitus treatment—Clinical protocols* (pp. 187–197). New York, NY: Thieme Medical.

Tyler, R. S., Noble, B., Coelho, C. B., & Ji, H. (2012). Tinnitus retraining therapy: Mixing point and total masking are equally effective. *Ear & Hearing*, *33*(5), 588–594.

Tyler, R. S., Oleson, J., Noble, W., Coelho, C., & Ji, H. (2007). Clinical trials for tinnitus: Study populations, designs, measurements variables, and data analysis. *Progress in Brain Research*, *166*, 499–509.

Von Wedel, H., Von Wedel, U. C., Streppel, M., & Walger, M. (1997). Effectiveness of partial and complete instrumental masking in chronic tinnitus. *Hals-Nasen-Ohrenheilkunde*, *45*, 690–694.