DO COMBINATION INSTRUMENTS REDUCE THE EFFECTS OF TINNITUS?

Harvey Abrams, Ph.D.,[1] Melissa Frederick, Au.D.,[2] Susan Griest, MPH;[2] Sara Sell, Au.D.,[2] James Henry, PhD[2]

[1]Starkey Hearing Technologies [2]VA National Center for Rehabilitative Auditory Research

Overview

Rationale & Objective

- Numerous clinical studies have reported positive outcomes from various interventions for tinnitus; however, because there is no consensus on how to best measure the outcomes of tinnitus treatment, statistical evidence supporting the effectiveness of these treatments remains inconclusive[1,2].
- Sound therapy, or use of any sound for the purpose of tinnitus management, is widely accepted as one treatment for tinnitus. Sound therapy may be provided by hearing aids, noise generators (or "tinnitus maskers"), or combination instruments that provide both amplification and generate a sound stimulus. While it is known that hearing aids can be beneficial for alleviating the effects of tinnitus[3,4,5], research has not been conducted to evaluate whether combination instruments provide greater benefit than the use of hearing aids alone.
- Thus, the objective of this study was to evaluate the efficacy of hearing aids versus combination instruments for tinnitus management.

Methods

- Thirty qualified participants (hearing aid candidates with bothersome tinnitus) were randomized into two groups:
  "Control" Group – Hearing Aid amplification only
  "Experimental" Group – Hearing Aid + noise generator.
- Both groups were fit with the same commercially-available receiver-in-canal (RIC) combination instruments (Xino Tinnitus; Starkey Hearing Technologies). However, for the Experimental group only, the noise generator was activated, and the FM/AM broad band noise stimulus was fine-tuned across 16 channels to optimize relief from tinnitus for each participant.
- All participants received tinnitus counseling and returned 1-2 weeks later for a follow-up appointment to confirm proper fit and make any programming adjustments to the instruments.
- Outcomes were assessed at baseline and after 3 months of intervention using the Tinnitus Functional Index (TFI)[6] and Hearing Handicap Inventory for the Elderly (HHIE)[7].

Results

- Both groups revealed significant improvement, as indicated by reductions in mean TFI index scores. Differences between groups at 3 months were not statistically significant. However, the Experimental group showed a mean reduction in the TFI score that was 6.4 points greater than for the Control group. The difference approached significance (p=.09), suggesting that a larger group of participants may have resulted in a significant difference between groups. This possibility is tempered by the fact that effect sizes, which control for variation, were very similar between groups.

Conclusions

- Results of this study suggest that the use of hearing aids alone or hearing aids plus the use of sound generators both provide significant benefit with respect to alleviating effects of tinnitus.

Methods

Outcome Measures

- Tinnitus Functional Index (TFI): The TFI includes 25 questions and provides an index score from 0-100 (higher numbers reflect a greater problem with tinnitus). A score of at least 25 suggests a clinically significant problem with tinnitus, and a 13-point reduction in the TFI index score is considered a meaningful reduction in outcome scores.
- Hearing Handicap Inventory for the Elderly (HHIE): The HHIE is a 25-item questionnaire that measures the effect of hearing loss on social/situational functioning and the emotional impact of hearing loss. A 19-point change in the HHIE is suggestive of a meaningful change in perceived handicap[8].
- Outcome measures were completed at baseline and at 3 months. At 3 months, participants completed the HHIE and TFI twice, to indicate their responses with respect to when they were: (1) using their hearing aids ("*with* hearing aids"), and (2) not using their hearing aids ("*without* hearing aids").

Participant Screening

- Candidates were screened for the following criteria: (1) at least 18 years of age; (2) English-speaking; (3) perceived hearing difficulties; (4) no hearing aid experience within the previous 12 months; (5) no mental, emotional, or health conditions that would prevent participating in the study; and (6) "clinically significant" tinnitus based on responses to the Tinnitus and Hearing Survey (THS)[9,10].

Visit 1: Evaluation

- Candidates completed four questionnaires: The Mini Mental State Exam (MMSE)[11], a general tinnitus survey, the TFI, and the HHIE. Individuals passing the MMSE and a minimum TFI index score of 25 underwent standard audiologic testing.
- Candidates were required to have a mild to moderately-severe, symmetrical, sensorineural hearing loss, with no medical contraindications for a hearing aid fitting.
- Candidates were also asked about their level of motivation to try hearing aids and find relief from tinnitus.
- Thirty qualifying candidates were enrolled and scheduled for Visit 2. Participants were randomized to the hearing-aid-plus-noise (Experimental) or the hearing-aid-only (Control) group. Figure 1a,b shows audiometric data for the Experimental and Control groups.

Visit 2: Device Fitting

- Participants were fitted binaurally with commercially-available receiver-in-the-canal (RIC) combination instruments. Real ear measures and patient feedback were used to verify and adjust the amplification settings.
- Tinnitus counseling from *Progressive Tinnitus Management: Counseling Guide*[9] was provided. For the Experimental group, the noise generator, incorporating a FM/AM broad band noise adjustable across 16 channels, were turned on and adjusted to the participants' individual preferences to achieve "maximum relief from tinnitus."

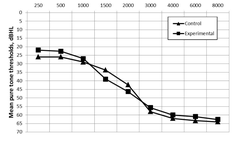

Figure 1a: Right Ear mean pure-tone thresholds by Experimental and Control group.

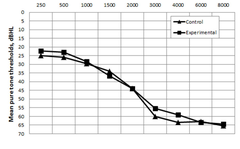

Figure 1b: Left Ear mean pure-tone thresholds by Experimental and Control group.

Results

Demographics

Table 1 shows the breakdown of demographic characteristics for the overall group and separately for the Experimental (n=15) and Control (n=15) groups.

- Mean age for the overall group was 67 years with 67% male.
- 22 participants reported their tinnitus to be "always" present, and 27 had experienced their tinnitus for 3 or more years.
- 40% of the overall group reported a "big" to "very big" problem with their tinnitus, 57% reported a "moderate" problem, and 3% reported a "slight" problem with their tinnitus.
- A Chi-Square analysis revealed no significant differences (p>0.05) between the two groups within each of the demographic characteristics.

Characteristic	Overall Group	Control	Experimental
Age	67.2 (9.2)	67.9 (11.0)	66.5 (7.4)
Gender:			
Male	67%	80%	53%
Female	33%	20%	47%
Veteran:			
No	57%	40%	73%
Yes	43%	60%	27%
Tinnitus present:			
Some of the time	17%	13%	20%
Most of the time	10%	13%	7%
Always	73%	74%	73%
Tinnitus duration:			
< 1 year	3%	0%	7%
1 - 2 years	7%	7%	7%
3 - 5 years	3%	0%	7%
6 - 10 years	10%	13%	7%
11 - 20 years	27%	27%	26%
> 20 years	40%	46%	33%
Unsure	10%	7%	13%
Tinnitus problem:			
Slight problem	3%	0%	7%
Moderate problem	57%	53%	60%
Big problem	33%	33%	33%
Very big problem	7%	14%	0%

Table 1. Demographic characteristics of participants.

Data Logging

- Differences in device usage between Experimental and Control groups were not significant at either of the visits (p>.05) (Table 2).

	Visit 3			Visit 4		
Ear	**Control (n=15)**	**Experimental (n=15)**	**Combined (N=30)**	**Control (n=15)**	**Experimental (n=15)**	**Combined (N=30)**
Right	**8.5**	**9.0**	**8.7**	**6.9**	**7.0**	**7.0**
Left	**8.7**	**8.9**	**8.8**	**6.9**	**6.9**	**6.9**

Table 2. Average number of hours per day devices were used, based on data-logging capability of the devices. Data were retrieved at Visits 3 and 4.

Tinnitus Functional Index (TFI)

- For the overall sample, paired t-tests showed the mean 3-month reductions of 36.1 points (*with* hearing aids) and 13.5 points (*without* hearing aids) as both significant (p<.0001).
- For the Control group, the mean 3-month reductions of 32.9 points (*with* hearing aids) and 16.2 points (*without* hearing aids) were both significant (p<.0001 and p=.002, respectively). (Table 3).
- For the Experimental group, the mean 3-month reductions of 39.3 points (*with* hearing aids) was significant (p<.0001) but the 3-month reduction of 10.8 points (*without* hearing aids) was not significant (p=.034). (Table 3).
- Repeated measures ANOVA revealed a significant main effect between baseline and 3-month mean scores *with* hearing aids [F(1,28)=66, p<.0001] and *without* hearing aids [F(1,28)=18.8, p<.0001], but no significant interaction between the groups.
- Paired t-tests showed that the differences between the two 3-month conditions (*with* hearing aids vs. *without* hearing aids) were significant for both the Control (difference=28.5; p<.0001) and Experimental group (difference=16.6; p<.0001). That is, for both groups, TFI scores with respect to when they were wearing hearing aids were significantly better than when they were not wearing hearing aids.
- For the *with* hearing aids condition, 87% of the Control participants and 87% of the Experimental participants showed at least a 13-point improvement in TFI scores. For the *without* hearing aids condition, 53% of the Control participants and 40% of the Experimental participants had at least a 13-point improvement in TFI scores. (Table 4)

	TFI Mean (SD) Index Score			TFI Effect Size	
Group	**Baseline**	**3 mo *with* hearing aids**	**3 mo *without* hearing aids**	**3 mo *with* hearing aids**	**3 mo *without* hearing aids**
Control	60.5 (15.3)	27.6 (16.1)*	44.3 (14.6)*	2.1	1.1
Experimental	56.1 (16.5)	16.8 (19.8)*	45.3 (18.8)	2.2	0.6

Table 3. Means, standard deviations, and effect sizes for the TFI at baseline and 3-month follow up.

	Control		Experimental	
3-Month Condition	**Range of Change**	**Number (%) Improved by ≥13 Points**	**Range of Change**	**Number (%) Improved by ≥13 Points**
***With* Hearing Aids**	-5 to -83	13 (87%)	+15 to -82	13 (87%)
***Without* Hearing Aids**	+7 to -51	8 (53%)	+19 to -46	6 (40%)

Table 4. Within-group changes and ranges in TFI scores between baseline and 3 months.

- Within-group changes are shown in Figure 2a (*with* hearing aids) and 2b (*without* hearing aids). Non-parametric testing showed no significant differences between the groups in either condition.

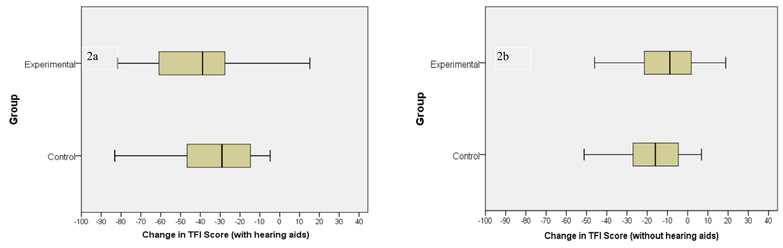

Figure 2. Within-group changes in TFI score from baseline to 3 months (Box = median, 25th and 75th percentiles; Whisker = minimum, maximum values). 2a. *With* hearing aids. 2b. *Without* hearing aids.

Results

Hearing Handicap Inventory for the Elderly (HHIE)

- For the overall sample, paired *t*-tests showed the mean 3-month reduction of 29 points (*with* hearing aids) as significantly different (p<.0001). The mean 3-month reduction of 5.1 points (*without* hearing aids) was not significantly different (p>.05).
- For the Control group, the mean 3-month reduction of 28.4 points (*with* hearing aids) was significant (p<.0001); the mean reduction of 7.8 points (*without* hearing aids) was not (p=.04). (Table 5)
- For the Experimental group, the mean 3-month reduction of 29.3 points (*with* hearing aids) was significant (p=.001); the mean reduction of 1.8 points (*without* hearing aids) was not (p=.04). (Table 5)
- Repeated measures ANOVA revealed a significant main effect between baseline and 3-month mean scores *with* hearing aids [F(1,7)=50; p <.0001] but no significant differences in HHIE scores *without* hearing aids. There was no overall difference from baseline to 3 months, or between groups for the HHIE *without* hearing aids.
- Differences between the two 3-month conditions (*with* hearing aids vs *without* hearing aids) were significant for both the Control (difference=20.6; p=.001) and Experimental group (difference=25.7; p=.004). That is, for both groups, HHIE scores with respect to when they were wearing hearing aids were significantly better than when they were not wearing hearing aids.
- For the *with* hearing aids condition, 60% of the Control participants and 67% of the Experimental participants showed at least a 19-point improvement in HHIE scores. For the *without* hearing aids condition, 20% of the Control participants, and 7% of the Experimental participants had at least a 19-point improvement in HHIE scores. (Table 6)

	HHIE Mean (SD) Index Score			HHIE Effect Size	
Group	**Baseline**	**3 mo *with* hearing aids**	**3 mo *without* hearing aids**	**3 mo *with* hearing aids**	**3 mo *without* hearing aids**
Control	55.3 (13.9)	26.9 (17.9)*	47.5 (19.0)	1.8	0.5
Experimental	49.3 (13.5)	20.0 (18.7)*	47.5 (18.0)	1.8	0.1

Table 5. Means, standard deviations, and effect sizes for the HHIE at baseline and 3-month follow up.

	Control		Experimental	
3-Month Condition	**Range of Change**	**Number (%) Improved by ≥19 Points**	**Range of Change**	**Number (%) Improved by ≥19 Points**
***With* Hearing Aids**	-2 to -62	9 (60%)	+30 to -80	10 (67%)
***Without* Hearing Aids**	+20 to -30	3 (20%)	+28 to -24	1 (7%)

Table 6. Within-group changes and ranges in HHIE scores between baseline and 3 months.

- Within-group changes are shown in Figure 3a (*with* hearing aids) and 3b (*without* hearing aids). Non-parametric testing showed no significant differences between the groups in either condition.

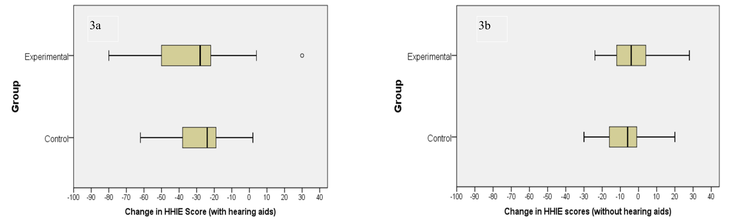

Figure 3. Within-group changes in HHIE score from baseline to 3 months (Box = median, 25th and 75th percentiles; Whisker = minimum, maximum values). 3a. *With* hearing aids. 3b. *Without* hearing aids.

Conclusions

- 86.7% of participants in both groups reported meaningful reduction in their tinnitus.
- There were no statistically significant differences in the amount of tinnitus reduction as measured by the TFI between the Experimental and Control groups
  -The Experimental group showed a mean reduction in the TFI score that was 6.4 points greater than the Control group. This difference approached statistical significance (p=.09), suggesting that a larger group of subjects may have resulted in a significant difference between groups.
- There were no statistically significant differences in the amount of hearing handicap reduction between the Experimental and Control groups suggesting that reduction in hearing handicap was not affected by the addition of the noise stimulus.
- There were no statistically significant differences in device usage as measured by data logging between the Experimental and Control groups
- It is possible that the noise stimulus has some beneficial effects that were not captured by the measures used in this study
- It is possible that participants may have experienced additional perceived benefit if they could adjust the sound therapy parameters themselves.

Financial Disclosures

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