Stapedectomy Effects on Tinnitus: Relationship of Change in Loudness to Change in Severity

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To relate poststapedectomy change in tinnitus loudness to change in tinnitus severity.

Study Design. Prospective, within-subjects.

Setting. A single otology and neurotology subspecialty referral practice.

Subjects and Methods. Forty-nine subjects undergoing stapedectomy completed the study between January 2012 and October 2013. Tinnitus instruments, audiometric data, and demographic information were collected prior to and 1 and 6 months after surgery. Tinnitus loudness was assessed using an 11-point (0 = none; 5 = conversation level; 10 = jet engine) visual analog scale, and severity was measured using the validated Tinnitus Functional Index. The relationship between change in tinnitus loudness and change in tinnitus severity was evaluated using linear regression and receiver operating characteristic (ROC) analyses.

Results. A linear regression model of change in tinnitus loudness averaged for both ears on a visual analog scale (ΔVASavg) versus change in Tinnitus Functional Index score (ΔTFI) showed a strong correlation (ΔTFI = 9.35 × ΔVASavg; R = 0.64; P < .001). An ROC analysis identified ΔVASavg between 1.5 and 2.0 as the optimal threshold for predicting a clinically significant change in tinnitus severity (ΔTFI > 13), with sensitivity and specificity of approximately 0.62 and a positive predictive value (PPV) of 0.64.

Conclusion. For poststapedectomy patients, a VAS loudness change by 1.5 to 2.0 points averaged for both ears in bilateral tinnitus or ~3 points in unilateral tinnitus has a PPV ~0.64 for a clinically significant change in tinnitus severity.

Keywords
tinnitus, stapedectomy, visual analog scale, VAS, Tinnitus Functional Index, TFI

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Introduction

Tinnitus prevalence among patients with otosclerosis is common, estimated to be 65% to 85%.1 Following surgical intervention by stapedectomy, tinnitus modulation has been reported as change in loudness using simple rating or categorical scales or complex psychometrically validated survey instruments, but infrequently both.2-5 In a recent study, 75% of otosclerosis patients with more than minor tinnitus improved by at least one category of severity on the Tinnitus Functional Index (TFI)6 within the first month of stapedectomy.2 The TFI has excellent internal consistency (Cronbach α = 0.97) and test-retest reliability (0.78), with effect sizes generally larger than its predecessor, the Tinnitus Handicap Inventory (THI).7 Whereas the aforementioned properties of the TFI are desirable, the 25-question survey instrument requires recall of symptoms over the past week and obligates a level of respondent burden that may be insurmountable for some patients.

In contrast, a 0-10 visual analog scale (VAS) of tinnitus loudness requires answering only a single question; there is no memory recall and minimal respondent burden. It would therefore be clinically useful to relate patient-reported tinnitus loudness on VAS using a simple numeric rating scale to tinnitus severity using the more elaborate and burdensome TFI instrument. VAS has been related to the Tinnitus-
for both ears separately. In accordance with the 1995 criteria, but there is not yet a study to relate change in VAS to change in TFI following treatment that modulates tinnitus. To address this objective, a prospective within-subject study of otosclerosis patients with tinnitus seeking surgical intervention was designed to collect baseline and poststapedectomy tinnitus perception data over at least a 6-month postoperative period.

**Methods**

**Study Population**

Sixty-eight patients with the clinical diagnosis of otosclerosis considering stapedectomy were enrolled in the study. Nineteen patients who either declined stapedectomy or had missing data were excluded. The remaining 49 patients were analyzed. Fourteen of the 49 patients were lost to follow-up after 1-month postoperative data were collected; thus, 6-month postoperative data were available for 35 patients. The motivation to assess the same patients at 6 months postoperatively was to evaluate the stability of 1-month results over time. The study cohort was recruited from an otology and neurotology subspecialty referral practice between January 2012 and October 2013. Demographic information was entered into a deidentified database. The study was approved by the institutional review boards of both the University of California, San Francisco (14-14680) and the University of Texas–Houston Health Science Center (HSC-MS-11-0550).

The global objective of this study was to assess the longitudinal effects of stapedectomy on tinnitus loudness and tinnitus severity. This was addressed by performing a prospective, within-subjects, repeated-measures study with a single surgeon performing all stapedectomy procedures. The effect of stapedectomy on TFI at 1- and 6-month postoperatively in a subset of patients in this trial was previously reported, with 75% and 88% of patients reporting clinically significant improvement at those time points. For this study, which includes the 26 original subjects plus 23 subsequently recruited subjects, baseline preoperative and 1- and 6-month postoperative audiometric data, VAS, and TFI scores were extracted. VAS tinnitus loudness was assessed for both ears on an 11-point rating scale (0 = none; 5 = conversation level; 10 = jet engine).

Surgical intervention consisted of a partial (one-third to two-thirds) stapedectomy with placement of a titanium bucket prosthesis over a soft tissue graft. All patients were administered 8 to 12 mg of dexamethasone intravenously for nausea prophylaxis as well as intravenous antibiotic. The presence of otosclerosis was confirmed by visual inspection. Patients were evaluated 1 and 6 months after surgery with otoscopic examination and audiological testing.

**Data Analysis**

Patient demographics, tinnitus laterality, preoperative and postoperative audiometric air-bone gap (ABG) values, VAS scores, and TFI scores were tabulated using descriptive statistics (Table 1). VAS scores were presented as raw data for both ears separately. In accordance with the 1995 American Academy of Otolaryngology Committee on Hearing and Equilibrium guidelines for the reporting of results for treatment of conductive hearing loss, air and bone thresholds at 0.5, 1, 2, and 3 kHz were averaged to compute audiometric indices. With respect to tinnitus severity, a change in the TFI score of 13 or more was accepted as the criterion for a clinically significant effect.

VAS scores reflect tinnitus loudness at the moment when patients were asked to make that particular judgment, while TFI scores reflect tinnitus severity over the antecedent week. To relate how changes in VAS scores (ΔVASavg) were related to changes in TFI scores (ΔTFI), least squares linear regression analysis was performed. ΔVASavg was calculated as change in VAS averaged for both the left and right ears. We elected this method to compute change in VAS because (1) the TFI does not distinguish contributions from the 2 ears, and (2) the nonoperated ear may experience tinnitus unmasking following hearing loss correction in the operated ear. Statistical significance was tested using linear regression analysis, with removal of a single outlier. Receiver operating characteristic (ROC) analysis was used to evaluate how different ΔVASavg thresholds affect detection of a clinically significant ΔTFI ≥ 13. We report results using standard definitions of sensitivity, specificity, and positive predictive value (PPV). An optimal ΔVASavg threshold value was determined by finding the intersection of the sensitivity and specificity curves. All analyses were performed in the GraphPad Prism computing environment. Significance was set at $P \leq .05$.

**Results**

Tinnitus loudness averaged for both ears (VASavg) and tinnitus distress (TFI) measures improved following stapedectomy (Figure 1, A and B). Using within-subject repeated-measures analyses, both VASavg and TFI were significantly improved for both ears compared to right ear (both $P < .001$). The presence of otosclerosis was confirmed by visual inspection. Patients were evaluated 1 and 6 months after surgery with otoscopic examination and audiometric testing.
decreased at 1 month after stapedectomy compared with preoperative status (*Figure 1, C* and *D*). One-month postoperative results were stable at 6 months, as 1- and 6-month data were not different. Our objective was to relate change in tinnitus loudness to change in tinnitus distress. Given that there was no change in either VASavg or TFI scores between 1 and 6 months, we focused subsequent analyses on change from the preoperative state to 1 month after stapedectomy.

Distributions of VASavg and TFI scores before and after stapedectomy were skewed to the right and distinctly non-Gaussian (data not shown). To improve our statistical power, we used within-subjects ΔVASavg and ΔTFI scores, which were normally distributed and suitable for parametric statistical testing (*Figure 2*).

We then constructed a predictive model for change in tinnitus severity based on change in tinnitus loudness (ΔTFI vs ΔVASavg) using preoperative to 1-month poststapedectomy data. A linear regression analysis is shown in *Figure 3* (ΔTFI = 9.35 × ΔVASavg; *R* = 0.64; *P* < .0001). The regression model predicted that a ΔVASavg of ~1.5 would correspond to a clinically significant ΔTFI of 13. Similar linear regression analyses for ΔTFI and ΔVASavg from preoperative to 6 months and 1 to 6 months poststapedectomy demonstrated stability of our model over a 6-month time course. Changes from preoperative to 1 month postoperative were primarily responsible for driving the predictive model. (Preoperative to 6 months postoperative: *N* = 34; ΔTFI = 7.78 × ΔVASavg; *R* = 0.47; the slope of model is not significantly different than that of preoperative to 1 month. One month to 6 months postoperative: *N* = 34; regression equation and correlation are not statistically significant.).

ROC analysis was illustrated by incrementing the preoperative to 1-month postoperative ΔVASavg threshold from 0.5 to 4.0 in steps of 0.5 (*Table 2*). With increases in ΔVASavg, sensitivity decreased and specificity and positive predictive value increased. An optimal ΔVASavg threshold was marked at the intersection of the sensitivity and specificity curves (*Figure 4*), which was between 1.5 and 2.0. Sensitivity and specificity at this intersection were ~0.62 and PPV is ~0.64.
Discussion

This is the first study to examine the correlational structure of $\Delta VAS_{avg}$ to $\Delta TFI$ in a prospective time-series manner, with the objective of benchmarking a $\Delta VAS_{avg}$ threshold to detect a clinically meaningful change in tinnitus distress.

By analyzing stapedectomy treatment effects on tinnitus using a within-subjects longitudinal study design, we have convergent evidence from our regression model and ROC analysis that a decrease by 1.5 to 2.0 points averaged for both ears in bilateral tinnitus or ~3 points in unilateral tinnitus (obtained by applying the threshold change of 1.5 for both ears to a single ear) is expected to reduce tinnitus distress in a clinically significant manner. Consistent with our findings, a related study on tinnitus VAS loudness reported test-retest reliability at 0.8 and a minimally clinically identifiable difference threshold of 1.5 on a 0- to 10-point scale to detect change to a “somewhat better” category on Clinical Global Impression.11

The predictive model in this report is in no way a substitute for assessing tinnitus severity comprehensively using validated surveys, such as the Tinnitus-Questionnaire, THI, and TFI. Those instruments require patient willingness to...
respond to a larger set of questions that query symptoms over the recent past to furnish much finer grain analysis of tinnitus distress across subcategories.

The predictive model in this report is nonetheless a clinically useful tool to relate a single response judgment of tinnitus loudness modulation by stapedectomy to its long-term impact on overall tinnitus distress referenced to the TFI. Beyond tinnitus modulation specific to stapedectomy for otosclerosis, a foreseeable application of the predictive model is to relate short-term tinnitus loudness modulation, if enduring over time, to expected long-term clinical impact. In particular, our model may be used to relate short-term changes to tinnitus loudness induced by transcranial magnetic and direct electrical brain stimulation of auditory and nonauditory structures\textsuperscript{12-17} to expected long-term outcome, recognizing that the model was derived from a stapedectomy patient population.

**Conclusion**

For poststapedectomy patients, a VAS loudness (0 = none; 5 = conversation level; 10 = jet engine) change by 1.5 to 2.0 points averaged for both ears in bilateral tinnitus or ~3 points in unilateral tinnitus has a PPV ~0.64 for a clinically significant change in tinnitus severity.

**Author Contributions**

Nicholas A. Dewyer, data analysis, manuscript writing; Ruwan Kiringoda, data collection and analysis, manuscript review; Yoseph A. Kram, data collection, manuscript review; Jolie L. Chang, study design, manuscript review; C.Y. Joseph Chang, surgeon, study design, manuscript review; Steven W. Cheung, oversaw entire process.

**Disclosures**

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