Patient-Based Outcomes in Patients With Primary Tinnitus Undergoing Tinnitus Retraining Therapy

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Objective: To determine whether the Tinnitus Handicap Inventory (THI), a validated patient-based outcomes measure, may improve our ability to quantify impact and assess therapy for patients with tinnitus.

Design: Nonrandomized, prospective analysis of 32 patients undergoing tinnitus retraining therapy (TRT). Assessment tools included comprehensive audiology, a subjective self-assessment survey of tinnitus characteristics, and the THI. Tinnitus Handicap Inventory scores were assessed at baseline and 6 months following TRT.

Results: Baseline analysis revealed significant correlation between the subjective presence of hyperacusis and higher total, emotional, and catastrophic THI scores. Tinnitus Handicap Inventory scores correlated with subjective perception of overall tinnitus effect (P<.001). Mean pure-tone threshold average was 17.4 dB, and mean speech discrimination was 97.0%. There were no consistent correlations between baseline audiologic parameters and THI scores. Following 6 months of TRT, the total, emotional, functional, and catastrophic THI scores significantly improved (P<.001). Loudness discomfort levels also significantly improved (P≤.02).

Conclusions: There is significant improvement in self-perceived disability following TRT as measured by the THI. The results confirm the utility of the THI as a patient-based outcomes measure for quantifying treatment status in patients with primary tinnitus.


Tinnitus is a common and potentially debilitating disorder that can have a profound impact on patients’ lives. It is estimated to affect approximately 36 million Americans, or about 17% of the general population.1 Unfortunately, efforts at understanding and treating this disorder have been limited by an inability to objectively assess tinnitus and its sequelae. For example, attempts to find a relation between subjective improvement and psychoacoustical descriptions of tinnitus have not been successful.2,3 The development of patient-based outcome measures is significantly improving our ability to objectively perceive disability and better quantify the impact of conditions such as tinnitus in which manifestations are largely subjective. Furthermore, changes in these outcome measures allow a more statistically rigorous assessment of treatment efficacy. For example, the use of nonvalidated subjective tinnitus ratings scales allows assessment of improvement only within a particular patient. The use of broadly validated scales allows comparisons between patients and even between institutions.

Of the various tinnitus-specific self-assessment tools available, the Tinnitus Handicap Inventory (THI) is desirable for its ease of administration, incorporation of functional as well as emotional constructs, good construct validity, and strong internal consistency and test-retest reliabilities.4,5 The THI is a 25-item survey that provides a total score and 3 subscale scores. The functional subscale (11 items) addresses role limitations in the areas of mental, social/occupational, and physical functioning (eg, difficulty concentrating and trouble falling asleep). The emotional subscale (9 items) includes a range of affective responses to tinnitus, such as feelings of depression, anger, and anxiety. The catastrophic subscale (5 items) reflects the most severe reactions to tinnitus, such as desperation, loss of control, and failure of coping mechanisms. The THI has been used to assess response to an array of treatment modalities for tinnitus.6,8

While various surveys and questionnaires have been applied to rehabilitative treatments such as cognitive-behavioral
derwent a standardized intake assessment including a full his-
his TRT protocol as described by Jastreboff et al,11 patients un-
tween October 1999 and January 2001. Prior to initiation of

Thirty-two patients of the University of Maryland Tinnitus and

therapy,9 to our knowledge, there has been no patient-
based outcomes analysis of response to habituation-
based counseling. The following investigation ad-
dresses self-perceived disability in patients undergoing
tinnitus retraining therapy (TRT), a directive counsel-
ing method aimed at habituation of both the reaction to

The goals of this study were to quantify the impact
of tinnitus in a population of patients with primary tinni-

The mean ± SD age of the study population was 54.5 ± 11.0
years, ranging from 18 to 76 years; 78% were men. Table 1 summarizes the baseline audiologic param-
eters, THI scores, and subjective tinnitus characteristics

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All statistical analyses were performed using Statistical Pro-
gram for the Social Sciences 9.0 (SPSS Inc, Chicago, Ill). Cor-
relation analysis was performed using a linear regression model

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### Table 1. Baseline Audiologic Parameters, Tinnitus Handicap Inventory Scores, and Subjective Tinnitus Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Left (n=32)</th>
<th>Right (n=32)</th>
<th>Left/Left (n=24)</th>
<th>Right/Right (n=21)</th>
<th>Left/Right (n=25)</th>
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<tbody>
<tr>
<td>Pure Tone Average (PTA)</td>
<td>16.0 ± 10.5 (3-30)</td>
<td>18.8 ± 11.3 (9-37)</td>
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<tr>
<td>Speech Discrimination Score (SDS)</td>
<td>97.3 ± 6.4 (72-100)</td>
<td>96.6 ± 8.7 (72-100)</td>
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<tr>
<td>Loudness Matching Level (LML)</td>
<td>103.8 ± 16.3 (65-120)</td>
<td>102.7 ± 15.1 (65-120)</td>
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<tr>
<td>Minimum Masking Level (MML) left</td>
<td>51.3 ± 15.7 (32-81)</td>
<td>60.9± 15.0 (35-83)</td>
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<td>MML right (n=21)§</td>
<td>52.6 ± 13.6 (27-81)</td>
<td>64.3 ± 17.0 (32-85)</td>
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<td>Emotional Subscale (n=32)</td>
<td>19.4 ± 8.7 (2-32)</td>
<td>24.4 ± 11.5 (0-42)</td>
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<td>Functional Subscale (n=32)</td>
<td>6.0 ± 3.7 (0-14)</td>
<td>10.1 ± 5.4 (0-22)</td>
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<td>Catastrophic Subscale (n=32)</td>
<td>88.4 ± 127.4 (1-384)</td>
<td>58.0 ± 27.9 (1-95)</td>
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<td>Months tinnitus present (n=32)</td>
<td>59.4</td>
<td>40.6</td>
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<td>Percentage of time aware of tinnitus (n=32)</td>
<td>59.4</td>
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<td>Speech discrimination score (SDS)</td>
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given in Table 3. There were no consistent statistically significant correlations. A comparison of baseline THI scores and subjective tinnitus characteristics is given in Table 4. This reveals a significant correlation between the subjective presence of sound tolerance problems and higher total THI scores ($r = 0.368; P = .04$) as well as higher emotional ($r = 0.392; P < .03$) and catastrophic subscale scores ($r = 0.382; P = .03$).

**OUTCOMES FOLLOWING TRT**

A comparison of audiologic parameters at the initial visit and the 6-month follow-up after TRT intervention is given in Table 5. Right and left PTA and SDS remained within normal limits. Nine patients initially presented with tinnitus and hyperacusis (as determined by LDL scores). In these patients the LDL showed a statistically significant improvement following TRT ($P < .05$).

A comparison of THI scores between the initial visit and the 6-month follow-up is shown in the Figure. Af-
After 6 months of TRT, there was a highly significant improvement in the THI total score and all 3 subscale scores \( (P < .001) \).

**COMMENT**

**SELECTION OF PATIENT-BASED OUTCOMES MEASURES**

The need to define better the impact of tinnitus and to quantify treatment response more accurately has led to the introduction of a variety of validated, patient-based outcome measures. An initial challenge was to identify the optimal assessment tool for use in our particular study population that would most appropriately quantify the expected functional, emotional, and psychosocial improvements following TRT. While the available tinnitus-specific instruments generally demonstrate good internal consistency reliability, there are a number of limitations. The Tinnitus Cognitions Questionnaire, designed to assess negative and positive cognitions associated with tinnitus, and the Tinnitus Reaction Questionnaire, designed specifically to measure psychological distress, may be too narrow in scope.\(^{12,13}\) The Tinnitus Effect Questionnaire is relatively broad\(^{14}\) but is among those instruments that fail to differentiate clearly between tinnitus disability (functional limitations) and handicap (psychosocial impact).\(^{15}\)

The Tinnitus Handicap Questionnaire (THQ), developed in 1990 by Kuk et al.\(^{16}\) is a 27-item questionnaire that quantifies the social, emotional, and physical sequelae of tinnitus (factor 1), hearing deficiencies (factor 2), and the patient’s view of the tinnitus (factor 3). The overall internal consistency reliability was high, as determined by a Cronbach \( \alpha \) of .94; however, of the subscales only factor 1 and factor 2 had good reliability. The THI was developed in 1996 by Newman et al.\(^{17}\) to meet criteria not fulfilled by previous patient-based outcome measures. The total scale yielded excellent internal consistency (Cronbach \( \alpha \) of .93), with moderately high consistency for the emotional, functional, and catastrophic subscales. Construct validity analysis revealed low correlation between the THI results and pitch and loudness ratings and a weak but significant correlation between the total, emotional, and functional scores and both the Beck Depression Inventory and the Modified Somatic Perception Questionnaire. There was a strong correlation between the THI and subjective symptom scales for annoyance, sleep, depression, and concentration. The profile was normalized on a well-distributed mix of patients, including those with primary tinnitus and tinnitus associated with hearing loss (see Table 2 for normative values). Test-retest reliability was subsequently validated on a series of 29 patients with primary tinnitus.\(^{7}\) Correlations between the test and retest values ranged from 0.84 to 0.94. These desirable characteristics led to the selection of this outcome measure for our investigation. A recent study by Baguley et al.\(^{17}\) examined the convergent validity of the THI and the Tinnitus Questionnaire and concluded that these 2 questionnaires had good convergent validity of their total scores but the THI subscores may not be as significant.

The THI total and subscale scores in our population were higher than those obtained during initial THI development and during further validation on a primary tinnitus population (Table 2). This was not entirely surprising, since one would expect that a tinnitus and hyperacusis specialty clinic may attract a more profoundly affected group of patients than those seen in a general audiology outpatient clinic, from which the original normative values were derived.

**AUDIOLOGY, THI SCORES, AND SUBJECTIVE TINNITUS CHARACTERISTICS IN PATIENTS WITH PRIMARY TINNITUS**

Initial audiologic data revealed normal PTAs and SDs, confirming the primary nature of the tinnitus in our population. There was no association between severity of THI scores and PTA or SDS. Additionally, there were no associations between loudness matching or minimum masking level and THI scores. Thus, as previously demonstrated, the impact of tinnitus on a patient’s well-being appears to be independent of the psychoacoustical properties of the tinnitus. Alternatively, there may be insufficient sensitivity of the THI to reflect subtle changes in audiologic parameters.

**THE EFFECT OF HYPERACUSIS**

Our audiometric definition of hyperacusis is an LDL less than 100-dB hearing loss. The average LDL in our baseline population was greater than 100-dB hearing loss. In contrast, 60% of our patients subjectively complained of sound tolerance problems. The correlations between the subjective presence of sound tolerance problems and higher THI total, emotional, and catastrophic scores reiterate the significance of perceived disability in a primary tinnitus population. The disparity in psychoacoustical and subjective assessment of hyperacusis is consistent with previous studies\(^{13,13}\) and underscores the need for patient-based assessments.

**PATIENT-BASED OUTCOMES FOLLOWING TRT**

Tinnitus retraining therapy is a systematic clinical protocol that proposes that both auditory and nonauditory
centers are involved in clinically relevant tinnitus. Positron emission tomography has been used to map tinnitus-specific activity to auditory and prefrontal-temporal cortices as well as the limbic system. According to this model, the brain can be retrained to remove the negative emotional association given to the tinnitus signal (habituation of the reaction). Decreasing the contrast between the tinnitus signal and random background activity within the neural pathways with low level, broadband sound further facilitates habituation (habituation of perception). The goal of TRT is to remove the perception of tinnitus from the patient’s consciousness by initiating and facilitating the process of habituation. The therapeutic efficacy of TRT has been challenged in the past because of the lack of appropriate outcomes data.

Our results reveal a significant improvement in THI total scores following 6 months of TRT counseling and the implementation of sound generator devices. Although our sample size is small, every patient enrolled was followed up, and changes in the THI total score were significant. These prospective results thus suggest that TRT is effective in reducing some of the distressing effects associated with tinnitus. Longer duration and larger multi-institutional studies should be initiated to confirm this trend. The use of broadly validated patient-based outcomes measures such as the THI will allow accurate comparisons between patients and between institutions, which is a major limitation of other subjective, nonvalidated surveys when absent. Furthermore, such an instrument allows for the possibility of test-retest evaluation following TRT intervention. In conclusion, TRT improves self-perceived disability induced by chronic tinnitus as reflected by improved THI total score after 6 months of TRT.

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REFERENCES