

# Tinnitus Outcome Profile and Tinnitus Control

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**Abstract:** This reports recommends the consideration of development of additional outcome measures to be used as a battery of subjective self-assessment questionnaires for patients with tinnitus. The goal is improved overall care for the tinnitus patient. Five existing outcome measurements have been incorporated into this profile, which is called the *tinnitus outcome profile*: the tinnitus intensity index, the tinnitus annoyance index, the tinnitus stress test, the tinnitus handicap inventory, and the measurement of depression scale. Frequently, there is an inconsistency between the self-report outcomes and the patient's subjective report to the doctor. This study reports outcomes based on the tinnitus outcome profile for 19 patients who were seen for evaluation and treatment of subjective idiopathic tinnitus of the severe disabling type and who completed a treatment protocol called *receptor-targeted therapy* directed to the GABA<sub>A</sub> receptor. The drugs used were gabapentin and clonazepam. Using the 0.05 significance level, the tinnitus intensity index, tinnitus annoyance index, and tinnitus stress test scores all declined significantly over time. In contrast, there was no significant change in either the tinnitus handicap inventory or the measurement of depression scale. The percent of tinnitus control reported to the doctor by the patient did not appear to be correlated with the degree of change measured on the tinnitus outcome profile.

**Key Words:** outcome questionnaires; receptor-targeted therapy; tinnitus control; tinnitus outcome profile

A definite need exists in the field of tinnitology for standards and outcome measures. *Outcome* is defined as any form of benefit resulting from a particular intervention [1]. It provides some evidence that we have made a difference in the clinical course of subjective idiopathic tinnitus (SIT) of the severe disabling type.

Critical to any form of treatment for tinnitus is the reliance placed on measures to assess the effectiveness of the intervention. In regard to tinnitus self-assessment scales, Noble [2] suggests that one needs to consider the domains of coverage and the psychometric properties of outcome measures. First, does the measurement device assess the domain that an intervention is designed to address? Second, is the device "well-behaved" in terms of its factor structure and test-retest reliability? In the development of the tinnitus handicap inventory,

Newman et al. [3] reminded us that factors that can influence test-retest studies include mood, general health, motivation, concentration of respondents, and test administration mode. Measurement tools that can be applied to the complaint of tinnitus are currently available, although not ideal.

Tinnitus is essentially a self-reported phenomenon. A battery composed of individual instruments, combinations of selected components of current scales, and new instruments targeted to specific variables can be used to measure outcomes. Subjective outcome measures include self-assessment inventories. Mueller [4] separated subjective outcome measures for hearing aid fittings into those of benefit, satisfaction, expectation, and sociological impact. These measures can also be applied to tinnitus treatment modalities. Benefit and satisfaction are two different outcome measures. Many times, patients are satisfied but the benefit achieved may not be significant.

Likewise, in treating tinnitus, the benefit achieved with a specific technique may be considered significant by a professional, but patient satisfaction may be minimal. The professional may also want to know the reason for

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the success or failure of the specific intervention. McCarthy [5] stated that satisfaction with a device—more specifically a hearing aid—may be but one outcome we want to measure. This can be compared to patient satisfaction with a device for tinnitus relief, such as a masker or habituator. Satisfaction does not always correspond to significant or quantifiable changes in impairment, activity limitations, participation, or health-related quality of life.

Self-assessment inventories are frequently influenced by patient expectations. Treatment that is available may not be what a patient wants. A patient's desires may not be in line with the treatment that can be provided currently. Patients with tinnitus want a cure; however, a cure does not exist in 2003.

In the past, we routinely reported our outcome measurements for tinnitus of the severe disabling type on the basis of two indices: the tinnitus intensity index (TII) and the tinnitus annoyance index (TAI) [6]. Both are 0- to 7-point rating scales. The benefit derived from a specific intervention using a single outcome measurement is highly dependent on the domain of coverage that the device addresses. Test results from a single instrument may be misleading, either overestimating or underestimating outcomes.

In an attempt to reduce the inconsistency in results obtained from patients' verbal expressions, from a professional's subjective observation, and from self-assessment by a patient and to provide a global profile, three additional instruments were added to the TII and TAI. These three tests are the tinnitus stress test (TST) [7], the tinnitus handicap inventory (THI) [8], and the measurement of depression scale (MDS) [9]. These were incorporated into a battery of subjective self-assessment questionnaires now called the *tinnitus outcome profile* (TOP) [10]. The domains of coverage of this profile include intensity, annoyance, stress, handicap, and depression. We expect that the TOP will be dynamic, with the profile of individual tests subject to change, including modifications, additions, or deletions.

This study reports on the results of outcome measurements and tinnitus for 19 patients who were seen for evaluation and treatment of SIT of the severe disabling type. Recommended for them was a protocol for attempting tinnitus control, called *receptor-targeted therapy* (RTT), a treatment protocol (RTT-GABA) involving medication—gabapentin and clonazepam—directed to the GABA<sub>A</sub> receptor.

## METHOD

### Patients

Included were 19 adult patients with SIT of the severe disabling type. All had tinnitus for a period equal to or

greater than 1 year. Among the patients were 13 men (mean age, 52 years; range, 35–71) and 6 women (mean age, 63 years; range, 50–76).

### Procedure

The 19 patients participated in a preliminary prospective clinical study for RTT directed to the GABA<sub>A</sub> receptor using gabapentin and clonazepam [11]. The diagnosis of a predominantly central, severe, and disabling tinnitus was established by completion of a medical audiological tinnitus patient protocol [12], which identified positive central cochleovestibular test findings. Single-photon emission computed tomography of the brain was administered both at baseline and after acetazolamide (Diamox) administration and revealed abnormalities in brain perfusion—both hypoperfusion and hyperperfusion—in multiple regions of interest highlighted by the region of the medial temporal lobe system [13].

The patients were treated with gabapentin and clonazepam for a 6- to 8-week period. The gabapentin dosage was titrated on the basis of tinnitus intensity, and the clonazepam was titrated on the basis of tinnitus annoyance. Tinnitus control was determined by self-assessment outcome questionnaires before and after taking the prescribed medication and by the patients' verbal expressions, reported to the physician, of the percentage of tinnitus control ranging from 0 to 100. Tinnitus control was monitored from January 1998 to January 2001.

Tinnitus control from 6 weeks' to 3 years' duration has been reported and ranged from 5% to 80%, with a mean of 38% [11]. The gabapentin was prescribed for the sensory component, and the clonazepam was prescribed for the affect component of the tinnitus. The sensory component relates to the sound itself, such as the intensity, whereas the affect component relates to how the patient behaviorally responds to the presence of the sound, such as the annoyance. Our goal was to achieve a level of tinnitus control and relief commensurate with the level of improvement desired by the patient; That is, the patient did not feel the need for additional tinnitus control.

### Tinnitus Outcome Profile

The TOP was developed in an attempt to improve the consistency of tinnitus intervention outcomes as reported by patients, observed by professionals, and determined by outcome instruments. The TOP is a battery of subjective self-assessment questionnaires used as outcome measures. By using multiple measures, the TOP provides a global approach. The TOP was administered to the study subjects on the initial visit and after

the establishment of tinnitus control. The TOP is currently composed of five individual tests. The TII is a point rating scale (0–7), with 0 indicating no tinnitus and 7 meaning the loudest imaginable. The TAI also is a point rating scale (0–7), with 0 representing no annoyance and 7 signifying extreme annoyance. The TST is scored by degree (none, mild, moderate, severe, and extreme), as is the THI (none, mild, moderate, and severe). Finally, the MDS too is scored by degree (none [normal], mild, moderate, severe, and extreme).

## RESULTS

Of the nineteen patients, 16 completed the entire TOP, consisting of the 5 individual tests administered both before and after treatment. The remaining three patients completed only the TII and the TAI before and after treatment.

### Tinnitus Intensity Index

Eighteen of the 19 patients reported improvement using the TII, as manifested by decreased intensity; only 1 patient reported no change. Table 1 shows the subjects' pre- and posttreatment TII scores. Test results are statistically significant using the Wilcoxon signed rank test of hypothesis of no change. The median pretreatment score was 6.1 (range, 3–7), and the median posttreatment score 3.8 (range, 1.5–5.5). The median change in scores was 2.3 (range, –4–0). The Wilcoxon test demonstrated  $p < .001$ . Of the 16 patients who completed the TOP, 15 reported an improvement on the TII as manifested by decreased intensity; only 1 patient was unchanged.

### Tinnitus Annoyance Index

Eighteen patients reported an improvement on the TAI as manifested by a decrease in annoyance; one reported increased annoyance. Table 2 shows the patients' pre- and posttreatment scores for this measure. Test results were statistically significant using the Wilcoxon test. The median pretreatment score was 7.0 (range, 3–7), and the median posttreatment score 3.6 (range, 2.0–

**Table 2.** Tinnitus Annoyance Index Results

	Median	Range
Pretreatment scores	7.0	3–7
Posttreatment scores	3.6	2.0–5.5
Change in scores	3.0	5–1

Notes:  $n = 19$ ; 0- to 7-point rating scale;  $p < .001$  (Wilcoxon text).

5.5). The median change in scores was 3.0 (range, –5–1). The Wilcoxon test revealed  $p < .001$ . Of the 16 patients who completed the TOP, 15 reported a decrease in the annoyance of their tinnitus; only 1 reported increased annoyance.

### Tinnitus Stress Test

Posttreatment results on the TST as reported by the 16 patients indicated 8 with less stress, 2 with increased stress, and 6 unchanged. Table 3 shows these patients' pre- and posttreatment scores for this measure. The Wilcoxon test showed the results to be statistically significant. The median pretreatment score was 2.5 (range, 2–4) and the median posttreatment score 2.0 (range, 1–3). The median change in scores was 1.0 (range, –2–1). The Wilcoxon test demonstrated  $p = .020$ .

### Tinnitus Handicap Inventory

Of the 16 patients who completed the THI, 4 reported an improvement with decreased handicap, and 12 showed no change. Table 4 indicates these patients' pre- and posttreatment scores. Test results were not statistically significant using the Wilcoxon test ( $p = .125$ ). The median pretreatment score was 3.0 (range, 2–3), and the median posttreatment score 2.0 (range, 1–2). The median change in scores was 0.0 (range, –2–0).

### Measurement of Depression Scale

The MDS was coded with numbers representing degrees of depression: 1, no depression; 2, minimal depression; 3, moderate depression; and 4, severe depression. Of the 16 patients, 7 scored within the range of normal,

**Table 1.** Tinnitus Intensity Index Results

	Median	Range
Pretreatment scores	6.1	3–7
Posttreatment scores	3.8	1.5–5.5
Change in scores	2.3	4–0

Notes:  $n = 19$ ; 0- to 7-point rating scale;  $p < .001$  (Wilcoxon text).

**Table 3.** Tinnitus Stress Test Results

	Median	Range
Pretreatment scores	2.5	2–4
Posttreatment scores	2.0	1–3
Change in scores	1.0	2–1

Notes:  $n = 16$ ; degree of stress measured on a 1–4 rating scale;  $p < .02$  (Wilcoxon text).

**Table 4.** Tinnitus Handicap Inventory Results

	Median	Range
Pretreatment scores	3.0	2–3
Posttreatment scores	2.0	1–2
Change in scores	0	2–0

Notes: n = 16; degree of handicap measured on a 1–4 rating scale;  $p = .125$  (Wilcoxon text).

indicating no clinical depression, at the beginning and the end of the study. Two reported the same degree of depression, 5 were less depressed, and 2 were more depressed at the end of the study.

Table 5 indicates the patients' pre- and posttreatment scores for the MDS. Results were not statistically significant using the Wilcoxon test. The median pretreatment score was 2.5 (range, 1–3), whereas the median posttreatment score was 1.0 (range, 1–3). The median change in scores was 0.0 (range, –2–1), and the Wilcoxon test showed  $p = .250$ .

### Combined Profile for All Five Test Components

Sixteen patients completed the entire TOP consisting of the TII, TAI, TST, THI, and MDS. Results of all five tests provide a more global outcome profile for individual patients.

Examination of the TII and TAI results indicates that 14 of the 16 patients had improvement as evidenced by both indices. Of the 16 patients, 15 showed improvement on the TII, and 15 showed improvement on the TAI. One patient demonstrated no change on the TII, and 1 reported increased annoyance on the TAI after treatment. With the addition of the TST, THI, and MSD, the profile has changed, as it reflects different domains of examination. For the outcome analysis of the TST and THI, variables for the degree of stress or handicap were coded with numbers: 1, mild; 2, moderate; 3, severe; and 4, extreme.

### DISCUSSION

Patient responses are divided into the sensory and the affect components. The sensory component relates to

the sound itself, such as the intensity (i.e., measured by the TII outcome). The affect component relates to how the patient behaviorally responds to the presence of the sound, as measured by the TAI, TST, THI, and MDS.

Using a .05 significance level, the TII, TAI, and TST scores all indicated a significant improvement over time. In contrast, there was no significant change seen in either the THI or MDS results. The TII revealed that 18 of 19 patients had a significant decrease in the intensity of their tinnitus; 1 was unchanged. The TAI demonstrated that 18 of 19 patients had a significant decrease in the degree of annoyance of their tinnitus; 1 reported increased annoyance.

The results for the 16 patients who completed the TOP before and after treatment showed that 15 of 16 indicated improvement on the TII and TAI. Ten of 14 who reported improvement on both the TII and TAI showed no change in the degree of handicap as measured on the THI; the other 4 showed a significant decrease in the degree of handicap, indicating improvement. This finding suggests that the domain of coverage of the THI differs from that of the TII and the TAI.

Berry et al. [14] investigated the use of the THI to measure "self-perceived disability" in 32 patients undergoing tinnitus retraining therapy (TRT). The THI scores in this report showed significant improvement in self-perceived disability after TRT. The authors concluded that these results confirmed the utility of the THI as a patient-based outcome measure for quantifying treatment status in patients with primary tinnitus. The results of our study do not support these findings. Whether the difference is due to the severity of the tinnitus experienced by our patients as compared to those in Berry's study is one possibility to be considered.

The THI, for example, has individual domains divided into three subscales, including the *functional*, a mix of intrusion in and limitation on some activities (e.g., difficulty in falling asleep and in concentrating); the *emotional*, seen in distress and annoyance and the like; and the *catastrophic*, represented by desperation and helplessness. These three combine to give a total score that is a global quantification of change in perceived tinnitus.

A critical difference of 20 points is needed for clinically significant change in an individual case. THI results are inconsistent with patient reports of subjective improvement and their desire voluntarily to continue TRT. Patients participating in the protocol for TRT were satisfied as a group—given that they felt well—and elected to continue TRT. A question arises as to why the THI does not reflect the degree of satisfaction expressed by the patients. Consideration must be given to whether this group of patients may have placed different emphasis on the catastrophic, emotional,

**Table 5.** Measurement of Depression Scale

	Median	Range
Pretreatment scores	2.5	1–3
Posttreatment scores	1.0	1–3
Change in scores	0	2–1

Notes: n = 16; degree of depression measured on a 1–4 rating scale;  $p = .250$  (Wilcoxon text).



and functional categories, thereby tipping the results in one direction and resulting in statistically nonsignificant changes. Perhaps more time is required to reduce the degree of self-perceived handicap as measured using these three categories, as compared to other outcomes. We are not suggesting that the THI be eliminated but rather that it be included as one test in a battery of measurements.

Of the 14 patients in our study who showed improvement on both the TII and TAI, 7 had a significant decrease in degree of stress as measured on the TST; 5 had no change; and 2 had an increased degree of stress. The MDS scores for these same 14 patients indicated that 2 had the same degree of depression, 2 had less depression, 2 had increased depression, and 8 reported no depression at the beginning or end of the study.

These results suggest that the domains of coverage for the TAI, TST, THI, and MDS, although all directed toward measurement of the affect component of tinnitus, are different. An interesting note is that the TST, scored by degree of stress, demonstrated that all 16 patients had some degree of stress at the outset, ranging from moderate to extreme, and all still had some degree of stress after the completion of the study. All 16 patients exhibited some degree of handicap at the beginning of the study: 10 severe and 6 moderate. At the study's conclusion, 4 showed some improvement, which translates into less handicap, but all still had some degree of handicap.

The relationships of intensity to annoyance, intensity to stress, annoyance to stress, intensity to handicap, intensity to depression, and annoyance to depression must be considered. The percentage of tinnitus control that the tinnitus patients reported to their doctor (range, 5–80%) did not appear to be correlated with degree of change measured with the TOP. For example, a patient reporting 5% control showed significant improvement on three of five outcome measures and was satisfied with the degree of tinnitus control. A patient who reported 50% control of tinnitus and had shown improvement on all five measures obtained the greatest improvement on outcome measures. The single patient who reported 80% tinnitus control did not record greatly improved outcomes.

There is an inconsistency among self-reported outcomes and patients' subjective reports to their doctors; outcome measurements; and doctors' observation and diagnostic criteria used, particularly for the measurement of depression. The analysis of the results of the MDS did not appear to reflect the observations and clinical answers to questions regarding depression by the professionals. Many patients were clinically depressed, as identified by their physicians and as verbally expressed to their physicians by the patients.

Perhaps the MDS is not the most effective measurement as a screening device for the presence or absence of depression in patients with tinnitus.

This seeming inconsistency has led us to implement the use of the criteria for depression set out in the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition [15]. We hope that the addition of this instrument—to be answered by patients before being seen by their doctors and then to be completed by their physicians during the examination—will give us more consistent information as to the presence or absence of depression. Factors to be considered include patients' personality and their individual goals. Some tinnitus patients are reluctant to accept the diagnosis of anxiety or depression (or both), let alone to accept the recommendation for psychiatric consultation.

Outcome domains must be defined, and the outcome measure must be matched to the treatment goal. The goals of treatment also should be defined. The goal of outcome measurements is to improve the overall care for patients suffering with tinnitus.

Outcomes are not a firm indication of what is going on in patients' minds and of their purpose: why they are coming and what they hope to achieve (i.e., a specific goal). Individual patient goals and their definition of improvement may not be reflected in the domain of the outcome measurements being used. What is needed is a battery of questionnaires that provide insight into the complexity of tinnitus symptoms and an understanding of the goals and character of tinnitus patients. This need is evidenced in a lack of correlation, the inconsistency among patients' clinical history, the subjectively reported abatement in degree of tinnitus complaint, and the data from the outcome measurement questionnaires. The bottom line clinically is that patients' subjective reports be clearly identified as such. The outcome measure must fit the patient, rather than the patient fitting the outcome questionnaire.

The question is not which outcome measurement is better or more reliable but rather that tinnitus, a multifactorial sensory disorder, reflects the clinical heterogeneity in the differences of the outcome questionnaires. Measurements are individual for each patient; therefore, the TOP, which provides significant increased outcome measures, greater than any one measure alone, will give us a more global understanding. Our belief is that measures must be different for different patients with tinnitus. The TOP is considered to be a dynamic battery of outcome questionnaires presently composed of five outcome measurements.

Tinnitus, a heterogeneous symptom, requires multiple measures to assess outcomes. On the basis of this study's results, we see a need for a patient-centered outcome measure. To that end, we are currently investigating the

client-oriented scale of impairment [16] for use in treating patients experiencing tinnitus. This outcome measure was originally developed to measure benefit of and satisfaction from the use of hearing aids by the hearing-impaired. Items are created by patients with their clinicians acting as facilitator. Affected patients are encouraged to list up to five situations that they consider to be most affected by their hearing impairment and that they would like to have corrected through the intervention process.

This device can be used easily and adapted to the problem of tinnitus. Patients may consider such situations as (1) inability to fall asleep at night, (2) difficulty in concentrating on conversation with clients on the telephone, (3) inability to read the newspaper while sitting quietly at home, (4) inability to tolerate sounds of their children playing, and (5) inability to go out and have dinner in a restaurant with spouse and friends. After the interventions, such patients judge the extent to which stated problems have been resolved. This approach is patient-centered: Patients are active participants in the development of their treatment goals. For the future, we are asking individual patients with tinnitus to commit themselves to defining their goals and what they would consider significant relief. Doing this will assist both them and professionals to achieve those goals.

## SUMMARY

The TOP is recommended for evaluation of outcomes for treatment methods attempting tinnitus control. It is a battery of five subjective self-assessment questionnaires, including the TII, TAI, TST, THI, and MDS. Results of the TOP in this study reveal the complexity of the symptom of tinnitus and the need for multiple instruments for outcome determinations.

Use of the five individual instruments included in the TOP provides a significantly increased profile of individual tinnitus patients' perception of their complaint prior to treatment and helps to assess these patients' progress and the effectiveness of their treatment. No single outcome can be shown to reflect the true nature of the outcome of therapy for tinnitus patients. The self-report profile of tinnitus should be based on a battery of outcome measures reflecting tinnitus, a symptom that is dynamic, fluctuant in nature, and highly individual.

## REFERENCES

1. Abrams H. Outcome measures: In health care today, you can't afford not to do them. *Hear J* 54(2):10–16, 2001.
2. Noble W. Tinnitus self-assessment scales: Domains of coverage and psychometric properties. *Hear J* 54(11):20–25, 2001.
3. Newman CW, Sandridge SA, Johnson GP. Psychometric adequacy of the tinnitus handicap inventory (THI) for evaluating treatment outcome. *J Am Acad Audiol* 9:153–160, 1998.
4. Mueller G. Outcome measures: The truth about your hearing aid fittings. *Hear J* 50:21–31, 1997.
5. McCarthy P. Value of self-assessment scales in measuring hearing aid benefit. *Semin Hear* 18(1):13–17, 1997.
6. Goldstein B, Shulman A. Tinnitus Evaluation. In A Shulman et al. (eds), *Tinnitus Diagnosis/Treatment*. Philadelphia: Lea & Febiger, 1991:293–318.
7. Malinoff R, Kisiel D, Weinstein B. The emotional aspect of tinnitus: The tinnitus stress test. Presented at the Nineteenth International Congress of Audiology, Jerusalem, Israel, June 5–9, 1988.
8. Newman CW, Jacobson GP, Spitzer JB. Development of the tinnitus handicap inventory. *Arch Otolaryngol Head Neck Surg* 122:143–148, 1996.
9. Zung WWK. A self-rating depression scale. *Arch Gen Psychiatry* 12:63–70, 1965.
10. Goldstein BA, Shulman A. Tinnitus outcome profile: Preliminary report. Presented at the Twenty-Ninth Annual Meeting of the Neurootological and Equilibriometric Society Congress, Bad Kissingen, Germany, March 22, 2002.
11. Shulman A, Strashun AM, Goldstein BA. GABA<sub>A</sub> benzodiazepine–chloride receptor–targeted therapy for tinnitus control: Preliminary report. *Int Tinnitus J* 8(1):30–36, 2002.
12. Shulman A. Medical Audiologic Tinnitus Patient Protocol. In A Shulman et al. (eds), *Tinnitus Diagnosis/Treatment*. Philadelphia: Lea & Febiger, 1991:319–322.
13. Shulman A, Strashun AM, Afriye M, et al. SPECT imaging of brain and tinnitus-neurotologic/neurologic implications. *Int Tinnitus J* 1(1):13–29, 1995.
14. Berry JA, Gold SL, Frederick EA, et al. Patient-based outcomes in patients with primary tinnitus undergoing tinnitus retraining therapy. *Arch Otolaryngol Head Neck Surg* 128:1153–1157, 2002.
15. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. Washington, DC: American Psychiatric Association, 1994.
16. Dillon H, James A, Ginis J. Client oriented scale of improvement (COSI) and its relationship to several other measures of benefit and satisfactions provided by hearing aids. *J Am Acad Audiol* 8:27–43, 1997.