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Recent Experience with the Neuromonics Tinnitus Treatment

John C. Goddard, Karen Berliner, and William M. Luxford
House Clinic, Los Angeles, California, USA

Abstract: This study examines the outcomes of patients undergoing the Neuromonics tinnitus treatment protocol at a single, tertiary referral center over a 2-year period. A retrospective review of patient records was performed with the objective of collecting demographic and audiological information and identifying changes in score on an established tinnitus questionnaire (Tinnitus Reaction Questionnaire [TRQ]) after treatment. Forty-seven patients initiated treatment with the Neuromonics device during the study period. Fourteen patients completed treatment, and another 18 were actively undergoing treatment at the end of the study period. The mean pure-tone average for the study group (N = 47) was 23.4 dB for the involved ear. Of those who completed the treatment, the mean posttreatment TRQ score was significantly lower than the pretreatment score ($p \sim .001$). Fifteen patients (31.9%) returned the device or did not complete treatment. Across all 47 patients, 48.9% achieved a successful reduction of 40% or greater in TRQ score. There was no correlation among pure-tone average, initial TRQ score or duration of use, and percentage change in TRQ score for those with at least one follow-up test. Based on these preliminary findings, treatment with the Neuromonics device is successful in reducing TRQ scores in appropriately selected patients with tinnitus.

Key Words: desensitization; Neuromonics; tinnitus; treatment

Tinnitus, defined as head noise in the absence of an acoustic stimulus, is a complex symptom affecting 40–60 million people in the United States [1]. Though the precise etiology in most cases is unknown, an abnormal interaction between peripheral and central auditory pathways is believed to play a role in tinnitus development [2]. Various therapies have been proposed for the treatment of tinnitus, including the use of masking devices, hearing aids, cognitive behavioral therapy, habituation programs, acupuncture, transcranial magnetic stimulation, and various herbal and vitamin-based supplements [3–10]. Though some of these treatments have proven beneficial for select patients, a definitive treatment for tinnitus remains to be discovered. The Neuromonics tinnitus treatment protocol (Neuromonics Pty Ltd., Sydney, Australia) is a relatively recent therapeutic option that was developed to target both the auditory and behavioral components involved in an individual's perception of tinnitus [2]. This therapy involves the use of a specialized acoustic stimulus aimed at targeting the effects of auditory deprivation and relaxing music to reduce involvement of the limbic and autonomic nervous systems in the perception of tinnitus. Systematic desensitization is also used to combat the attention-related component of an individual's perceptive response to tinnitus.

Various questionnaires, such as the Tinnitus Handicap Questionnaire, Tinnitus Effects Questionnaire, Tinnitus Handicap Inventory, and Tinnitus Reaction Questionnaire (TRQ), have been developed as a means of quantitatively assessing the effect tinnitus has on an individual's quality of life [11–13]. The TRQ has been used extensively in research protocols and is useful as a means of measuring a change in a subject's tolerance of tinnitus [2,11].

This study evaluated our experience with the Neuromonics device in suitable patients from August 2007 to July 2009. Historical, demographic, and audiological information was reviewed, and the percent change in TRQ score was calculated for those patients completing the treatment course. We hypothesize that the Neuromonics device can aid in tinnitus desensitization and lessen

Reprint requests: William M. Luxford, MD, House Clinic, 2100 West Third Street, Los Angeles, CA 90057. Phone: 213-483-9930; Fax: 213-484-5900; E-mail: wluxford@hei.org.

patient symptomatology and, thus, is a unique therapeutic option.

PATIENTS AND METHODS

Patients

All patients who initiated treatment with the Neuromonics device at our clinic between August 2007 and July 2009 were included in this study. A total of 47 patients underwent the initial assessment and went on to receive the Neuromonics device. All patients were referred by physicians in our clinic to audiologists within the clinic specializing in tinnitus treatment. For analysis, patients were divided into three groups: completed, active, and incomplete. The completed group consisted of 14 patients who completed the 6- to 8-month course of treatment with the Neuromonics device. The active group consisted of 18 patients who were actively undergoing treatment but had not yet completed the planned course at the end of the study period. The incomplete group was made up of 15 patients who returned their device or chose not to complete the course of treatment during the study period.

Table 1 shows the characteristics of the three groups, including initial TRQ score. There were no significant differences between the three groups in any of these variables. There was a wide range of duration of tinnitus prior to using the Neuromonics device, with the majority of patients having had tinnitus for 5 years or less. A few patients had experienced tinnitus for more than 20 years. Although the incomplete group appeared to have a larger percent of patients in this long-duration category, there were only a very small number of such patients (n = 3), and the difference from the other two groups (each n = 1) was not statistically significant. Most of the patients (72%) had reported trying prior treatments, including hearing aids (n = 8), maskers (n = 10), music (n = 9), vitamins (n = 11), biofeedback (n = 2), tinnitus retraining therapy (n = 1), and other therapeutic options (n = 7). Twelve patients reported using multiple other treatments. Mean pure-tone averages (PTAs) for the affected ear ranged from 20.4 dB in the incomplete group to 28.0 dB in the active group.

Individual PTA in the tinnitus ear ranged from as low as 2.5 dB to 85 dB in the active group, with maximums of 51 dB and 49 dB in the other two groups. Mean initial TRQ scores ranged from 46.2 in the completed group to 61.2 in the active group, with the incomplete group between the other two groups at 53.9.

Procedures

Treatment with the Neuromonics device involves two components: soft, relaxing music of varying amplitude and a separate wideband noise similar to white noise. At different stages in the treatment protocol, the white noise is added or taken away to help mask the tinnitus or aid in desensitization, respectively. Treatment with the Neuromonics device is designed to be received through the use of individual earphones.

An initial patient assessment was performed on the first visit. Each patient completed the TRQ, a 26-question survey designed to measure patient attitudes and thoughts about their tinnitus over the previous week (Table 2). For each question on the TRQ, a score from 0 to 4 is possible, with a total TRQ score that may range from 0 (no bothersome tinnitus) to 104 (maximally bothersome tinnitus). Patients subsequently completed a tinnitus history questionnaire that included demographic information and information about prior ear surgeries, duration of tinnitus, affected ear(s), any prior treatments aimed at

Table 1. Patient Characteristics for the Three Groups Treated with the Neuromonics Device

	Completed (n = 14)	Active (n = 18)	Incomplete (n = 15)	Statistical Significance
Gender (M/F)	6/8	10/8	11/4	NS
Ear (L/R/B)	8/5/1	10/6/2	6/6/3	NS
Age in years [mean (SD)]	55.5 (8.2)	52.2 (13.0)	51.9 (10.1)	NS
Duration tinnitus				NS
≤1 yr	14.3%	38.9%	40.0%	
1–5 yr	64.3%	33.3%	26.7%	
6–20 yr	14.3%	22.2%	13.3%	
>20 yr	7.1%	5.6%	20.0%	
Prior treatment	71.4%	66.7%	80.0%	NS
PTA* in decibels [mean (SD)]	20.8 (15.7)	28.0 (19.7)	20.4 (12.8)	NS
Initial TRQ [mean (SD)]	46.2 (20.0)	61.2 (17.1)	53.9 (23.7)	NS

NS = not significant; PTA = pure-tone average at 0.5, 1, 2, and 3 kHz via air conduction; SD = standard deviation; TRQ = Tinnitus Reaction Questionnaire.
* For the involved ear. If bilateral, poorer hearing ear.

Table 2. Tinnitus Reaction Questionnaire

1. My tinnitus has made me unhappy.
2. My tinnitus has made me feel tense.
3. My tinnitus has made me feel irritable.
4. My tinnitus has made me feel angry.
5. My tinnitus has led me to cry.
6. My tinnitus has led me to avoid quiet situations.
7. My tinnitus has made me feel less interested in going out.
8. My tinnitus has made me feel depressed.
9. My tinnitus has made me feel annoyed.
10. My tinnitus has made me feel confused.
11. My tinnitus has "driven me crazy."
12. My tinnitus has interfered with my enjoyment of life.
13. My tinnitus has made it hard for me to concentrate.
14. My tinnitus has made it hard for me to relax.
15. My tinnitus has made me feel distressed.
16. My tinnitus has made me feel helpless.
17. My tinnitus has made me feel frustrated with things.
18. My tinnitus has interfered with my ability to work.
19. My tinnitus has "led me to despair."
20. My tinnitus has led me to avoid noisy situations.
21. My tinnitus has led me to avoid social situations.
22. My tinnitus has made me feel hopeless about the future.
23. My tinnitus has interfered with my sleep.
24. My tinnitus has led me to think about suicide.
25. My tinnitus has made me feel panicky.
26. My tinnitus has made me feel tormented.

Note: Each question is scored on a 0–4 scale: 0 = not at all; 1 = a little of the time; 2 = some of the time; 3 = a good deal of the time; 4 = almost all the time.

tinnitus relief, and any history of medical problems or comorbid conditions. Pure-tone audiometry with supra-aural headphones was performed at inter-octave frequencies from 250 to 8,000 Hz, with additional high-frequency testing from 10 to 12.5 kHz. Tinnitus pitch matching; broadband masking threshold; measurement of loudness sensitivity (loudness discomfort levels) at 500, 1,000, and 4,000 Hz; and residual inhibition at the narrow-band frequency of the tinnitus were also performed during the initial assessment. All patients were counseled regarding the nature and course of tinnitus as a complex symptom and their candidacy for the Neuromonics device. Other available treatment options (i.e., hearing aid) were discussed.

During the second visit, the patients were fitted for the Neuromonics device. The audiologist set the minimum volume of the device, determined the levels for use at different stages in the protocol, and discussed device usage and management with the patient. Patients were counseled to use the device for 2 to 4 hours per day. This initial portion of the treatment protocol was called *phase 1*. During this phase, the background wideband noise was consistently present while the intensity of the relaxing music was periodically altered.

After 1 week of using the device, patients were provided a courtesy call. They were questioned about their response to the treatment up to that point. At 2 weeks after the initial assessment, patient use time was uploaded from the device to a computer. Discussion about device use ensued, and questions regarding interaction with the treatment and relief obtained were asked and recorded. Counseling about the device and the treatment strategy was also provided at this time.

At 2 months after initiation, patients repeated audiological testing, completed a new TRQ, and were subsequently transitioned to the next phase of treatment (phase 2). Again, they were asked questions regarding the level of interaction with their tinnitus and any relief experienced up to this point. Counseling was provided as needed. During phase 2, the wideband noise was dropped completely, and the patient listened only to the relaxing music during Neuromonics use.

At 4 months after initiation of treatment, patients completed another TRQ. The broadband masking threshold, loudness discomfort levels, and residual inhibition levels were retested. At this point, patients were counseled to turn the volume of the device down so that they could hear their tinnitus 60% of the time and the music the remaining 40% of the time (with the device on) for desensitization purposes. They were also instructed to decrease use of the device to 2–4 hours per week and, eventually, to use it only when needed (maintenance phase). At 6 months after initiation of treatment, patients completed a new TRQ. They also underwent a repeat of the audiological test battery.

Data Analysis

Descriptive and inferential statistical analyses were performed (SPSS 12.0.1). Chi-square was used to compare categorical variables between groups, and analysis of variance was used to test differences between group means. Paired samples *t*-tests were used to evaluate the difference in initial, final and initial, and second TRQ scores, whereas independent samples *t*-tests were used to examine differences between patients with and without prior treatment. Pearson correlation coefficients were computed to examine the relationships between PTA, initial TRQ, and percent change in TRQ. For all analyses, criterion for statistical significance was set at $p \sim .05$, two-tailed.

RESULTS

There was no appreciable change in hearing levels during the course of the treatment for any of the patients (data not provided). Table 3 shows the mean TRQ scores for each of the three groups and all patients at each test interval. It also shows the percent change from the initial TRQ to the later intervals. The initial average TRQ score across all patients was 54.4 (ranging from 13 to 96). Of

Table 3. Mean Tinnitus Reaction Questionnaire Scores for Three Groups of Patients Treated with the Neuromonics Device

	Completed	Active	Incomplete	All
Duration of use (mo)	8.7 (2.2)	3.4 (2.9)	1.5 (0.7)	4.4 (3.7)
Initial TRQ	46.2 (20.0)	61.2 (17.1)	53.9 (23.7)	54.4 (20.7)
Second TRQ[a]	21.7 (15.5)	26.6 (12.7)	15.5 (3.5)	23.5 (13.8)
Final TRQ	16.8 (13.2)			
Percent change				
Initial–final	61.6 (24.9)			61.6 (24.9)
Initial–second	51.4 (32.3)	52.6 (25.6)	60.9 (15.4)	52.6 (27.8)
Initial–last[b]	61.6 (24.9)	56.0 (24.0)	60.9 (15.4)	59.1 (23.5)

[a] Completed and active groups, each n = 13; incomplete, n = 2.
[b] Last = second, third, or final TRQ, whichever was the last test completed.

course, duration of device use differed significantly between groups ($F = 41.5$, $p \leq .001$). For the completed group, the change from initial (mean, 46.2) to final (mean, 16.8) TRQ score was statistically significant (paired *t*-test, $p \leq .001$). This group experienced an average reduction in TRQ score of 61.6%, and 78.6% of the group had a reduction of 40% or greater (the common definition of success). Although only the completed group had final TRQ scores, some patients in the other groups had one or more follow-up tests. For the 13 patients in the active group with at least one follow-up, the mean reduction in TRQ score from the initial to the last recorded test was 56.0%, whereas the two patients in the incomplete group with a second test showed a similar mean improvement of 60.9%. Across all 28 patients with a second TRQ test, the change from initial (mean, 52.8) to second (mean, 23.5) test was statistically significant (paired *t*-test, $p \leq .001$), and 75% had a reduction in TRQ score of at least 40%.

Thirteen of the 15 patients in the incomplete group returned their device within 3 months of initiation. The average device use time in this group was 1.5 months. Nine patients felt that the device was of no help, whereas four patients felt it made their tinnitus worse. Of the two patients who did complete a second TRQ, the percent changes in the TRQ scores were 71.2% and 50.0%, respectively, for a "success" rate in this group of 13.3%. Across all 47 patients, 48.9% achieved a successful reduction of 40% or greater in TRQ score, and 27.7% discontinued use early.

Table 4. Mean Percent Change from Initial to Last Tinnitus Reaction Questionnaire (TRQ) Score as a Function of Initial Score

Initial TRQ Score	Completed Group No.	Completed Group % Change	Active Group No.	Active Group % Change	Incomplete Group No.	Incomplete Group % Change	All
0–26	2	33.5	0	—	0	—	33.5
27–52	6	65.4	4	39.0	2	60.9	55.9
53–78	5	68.6	7	62.4	0	—	65.0
79–104	1	60.2	2	67.5	0	—	65.1

The average percent change in TRQ score from initial to last test was also examined as a function of the initial TRQ score. There was no significant correlation between initial score and percent change ($r = .21$: $p =$ NS). Table 4 shows the breakdown of mean change to last test by group and initial score category. The few patients in the lowest initial TRQ score category had the smallest average change, but score categories beyond that showed little difference. We also examined initial TRQ score and percent change in TRQ score at last test as a function of reported duration of tinnitus symptoms (Table 5). The number of patients in any one group and duration category are too small for statistical analysis, but there appears to be a tendency for those with a very short duration of symptoms to show the most improvement. Across all patients, the mean percent improvement declines slightly with each increment in duration, although this did not achieve statistical significance. Finally, we found no significant difference in the percent change in TRQ scores between those who had prior treatment (mean, 62.9%, SD = 22.3) and those who did not (mean, 50.5%, SD = 25.0).

Table 5. Initial Tinnitus Reaction Questionnaire (TRQ) Score and Percent Change to Last Test as a Function of Duration of Tinnitus

Duration	Completed Group No.	Completed Group Initial TRQ	Completed Group % Change to Last Test	Active Group No.	Active Group Initial TRQ	Active Group % Change to Last Test	Incomplete Group No.	Incomplete Group Initial TRQ	Incomplete Group % Change to Last Test	All (%)
<1 yr	2	49.5	83.1	7	58.6	58.6	6	61.7	50.0	64
1–5 yr	9	48.9	60.2	6	69.5	55.4	4	48.5	—	59
6–10 yr	1	33.0	72.7	3	47.0	41.5	1	46.0	71.7	57
11–20 yr	1	13.0	46.2	1	57.0	—	1	24.0	—	46
>20 yr	1	62.0	35.5	1	76.0	55.2	3	58.3	—	45

DISCUSSION

Tinnitus is not a disease but rather a complex symptom believed to result from abnormalities in central and peripheral auditory pathways. Significant research efforts have been undertaken over the last two decades to better understand the causes of tinnitus and to examine the effects of various proposed treatments [3,4,14–17]. Recently, a customized acoustic stimulus delivery system, the Neuromonics device, was introduced as a means of promoting neural plasticity within the auditory system in hopes of minimizing or abolishing tinnitus-related symptomatology [2,14]. Preliminary data reported on the use of the Neuromonics device have shown that more than 80% of patients achieve clinically significant reduction in their tinnitus, defined as a greater than 40% reduction in tinnitus disturbance as measured by the TRQ [18]. However, owing to its recent introduction, there are a limited number of studies evaluating the therapeutic effectiveness of the Neuromonics device in clinical practice.

In this study, 47 patients were enrolled in a treatment protocol with the Neuromonics device over a 2-year period. Of these, 14 completed the treatment protocol by the end of the study period. The average reduction in TRQ score for this group was 62%, similar to that found in earlier studies [2]. Moreover, 11 of 14 (78.6%) had a greater than 40% reduction in TRQ score over the course of the treatment, a definition for success that has been used in prior studies [2]. The two additional groups in our patient population were those patients who were still actively undergoing treatment at the end of the study period (active group) and those who returned their device (incomplete group). Of all patients with at least one follow-up TRQ, 75% had a greater than 40% reduction in TRQ score.

Though these results provide evidence of potentially successful treatment with the Neuromonics device, there was also a large group of nonresponders. Fifteen of the 47 patients (32%) enrolled in the treatment protocol eventually returned their device and did not complete treatment. Most reported that the device was of "no help" and felt that the device may have made their tinnitus subjectively worse. The average initial TRQ score for this group was 53.9, a value that fell between the average initial scores for the completed and active groups.

Candidacy criteria for the Neuromonics tinnitus treatment protocol have not been firmly established, though some basic guidelines have been proposed by the manufacturing company (*Neuromonics Clinician's Guidelines, Client Candidacy Guide,* Neuromonics Pty Ltd., Sydney, Australia). Unlike those with a specific disease process, patients with tinnitus need not necessarily go through a series of progressively more involved treatments. Consequently, the Neuromonics protocol may prove equally effective in patients who have and have not tried other treatments. Most patients in this study received some form of prior treatment, but the mean percent reduction in TRQ score for patients in the completed group without any prior treatments ($n = 4$) was not significantly different from that of those with prior treatments ($n = 10$). There is a need for continued research to examine whether a single treatment modality or multiple treatment methods, either simultaneously or in succession, is necessary for optimal relief of tinnitus.

The extent of a patient's reaction to his or her tinnitus, as measured by the initial TRQ score, might be an important variable to consider when determining treatment efficacy. In the current study, we found no significant correlation between final percent change in TRQ score and initial TRQ score, although patients with initial TRQ scores higher than 26 had a larger percentage reduction in TRQ score (see Table 4). This is not unexpected, as individuals with TRQ scores of less than 26 likely represent patients who are less affected by their tinnitus and consequently are less likely to have a substantial change in their symptoms with any treatment modality. We also found no significant correlation between initial TRQ score and duration of use of the device. That is, initial score was not predictive of who found the device of no help and gave up its use early. Nevertheless, it will be important to delineate which candidates are more likely to benefit from treatment with the Neuromonics device, and initial severity of symptoms is a factor warranting further study. Our data were somewhat limited, as the number of patients who successfully completed the protocol with initial TRQ scores at either extreme was small. Further clinical information will be needed to determine whether patients with extremely high initial TRQ scores, and thus more bothersome tinnitus, are perhaps more likely to benefit from treatment.

Though hearing considerations are certainly important in deciding on treatment strategies for patients with tinnitus, the current study did not demonstrate any differences in hearing threshold levels among those who were successful in completing the Neuromonics protocol and those who were not, nor was there a correlation of PTA to percentage change in final TRQ score. Hearing aids must still be considered a valuable and successful therapy for patients suffering from hearing loss and tinnitus and should be discussed as a treatment option for appropriately selected patients. Further studies will be necessary to determine whether there is a minimum threshold level that is required for patients undergoing treatment with the Neuromonics device, because issues related to maximum device amplitude may arise with more profound hearing losses.

CONCLUSIONS

Tinnitus is a common, yet complex, symptom that affects millions of individuals worldwide. Though research efforts continue to try to understand the mechanisms and causes of subjective tinnitus, new treatments are being developed to aid those suffering from this difficult problem. The Neuromonics tinnitus treatment protocol was designed to target both the auditory and behavioral components involved in an individual's perception of tinnitus. Its specialized acoustic stimulus targets the effects of auditory deprivation while its relaxing music is intended to reduce involvement of the limbic and autonomic nervous systems in the perception of tinnitus. Based on the results of our study, the Neuromonics device appears to be useful as a means of significantly reducing the effects of tinnitus on an individual's daily life. Future clinical studies are needed regarding the precise candidacy criteria and longer-term efficacy of this novel treatment device.

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