

# Tinnitus Retraining Therapy (TRT): outcomes after one-year treatment

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## Abstract

The aim of the study is to present our results regarding the efficacy of TRT for tinnitus relief in patients with clinically significant tinnitus compared to a group treated with vasoactive agents. In a nonrandomized prospective study, 63 patients with disabling tinnitus were recruited. Greek translation of the Tinnitus Handicap Inventory (THI) and visual analogue scale (VAS) for annoyance caused by tinnitus when conducting four major activities of everyday life (work, sleep, relaxation and concentration) were examined in a 12-month period. The THI score was significantly improved in the TRT group, as well as mean VAS scores, in all measures. Comparison of the mean improvement of THI and VAS scores after treatment showed significant differences between the two groups, favoring TRT treatment. Our data suggest that TRT is an effective treatment. It reduces the level of annoyance induced by tinnitus and improves the ability of patients to work, sleep, relax or be concentrated.

**Keywords:** tinnitus, sound generator, directive counseling.

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## BACKGROUND

TRT has been presented as a new approach to tinnitus management. It is based on the neurophysiological model of tinnitus described by Jastreboff in 1990 postulating that tinnitus results from the interaction of several subsystems in the nervous system<sup>1</sup>. According to the model, tinnitus, a phantom auditory perception, is usually generated in the cochlea, while the limbic and sympathetic part of the autonomic nervous systems are responsible for the development of tinnitus annoyance. Tinnitus is responsible for anxiety, problems with concentration, panic attacks and suppression of the ability to enjoy activities in life in 20% of patients who experience the symptom<sup>1-3</sup>. It has been reported that tinnitus causes sleep disorders in 57% of tinnitus patients<sup>4</sup>. Symptoms of anxiety and depression in cases of clinically significant tinnitus are attributed to the inappropriate activation of the conscious cortex and subcortical level by tinnitus signal through existing connections between the auditory pathways and the cortical and subcortical areas. The connections between the auditory, limbic and autonomic nervous systems are governed by the principles of conditioned reflexes<sup>2-3</sup> which can explain why significant tinnitus may be the result of nonacoustic factors, e. g., retirement and divorce<sup>5</sup>.

According to the neurophysiological model of tinnitus, the perception of tinnitus is not necessarily the key element causing tinnitus to be problematic. It is even possible for the patient to have reactions to stimuli which are not consciously perceived<sup>6-7</sup>. Habituation is the cornerstone of TRT which aims to alter the mechanisms that transfer the signal from the auditory to the limbic and autonomic nervous systems and thereby remove tinnitus-induced reactions<sup>8</sup>. It is apparent that TRT neither attempts to eliminate the source of tinnitus signal, nor to directly affect the neuronal symptoms responsible for reactions; therefore, TRT is effective regardless of the etiology of tinnitus<sup>8</sup>.

TRT is achieved by directive counseling and exposure to low-level broad band noise. The first component of TRT, directive counseling, may change the way tinnitus is perceived. The patient is taught the basic knowledge about the auditory system and its function, the mechanism of tinnitus generation and the annoyance associated with tinnitus. The repetition of these points in the follow-up visits helps the patient to perceive the signal as a non-danger.<sup>9</sup>

The second element of TRT therapy, sound therapy, aims to decrease the sound contrast between tinnitus and silent environment leading to a reduced detection of tinnitus. According to Weber-Fechner's law, a sound is perceived as less intense whenever it is presented to the nervous system together with a noise background.<sup>9</sup> The

therapy employs long-term use of sound, the level of which is adjusted at or just below the mixing point (the point at which the tinnitus and the noise begin to mix together). Sound can be provided by enrichment of background sound (TV, radio, CDs) and further amplified by hearing aids, sound generators and combination instruments (sound generator and hearing aid in one shell).<sup>8</sup> The process of tinnitus habituation requires approximately 12 months, and the patients are advised to continue for another 6 months to ensure that plastic changes within the brain are established.<sup>10</sup>

Several independent centers have presented clinical results of TRT with success rates of about 80% and higher.<sup>2, 11-17</sup> The objective of our study is the evaluation of TRT for clinically significant tinnitus after 1 year of treatment. We compare TRT patients with a group of patients who refused TRT when recommended and were administered vasoactive agents instead.

## MATERIAL AND METHODS

A prospective nonrandomized study was conducted. Sixty-three patients with disabling tinnitus referred to the ENT Departments of the Ippokratio Hospital of Athens and Tzanio Hospital of Piraeus between January 2005 and July 2009 were examined.

At the intake assessment, a full history evaluation was taken. In addition, a physical examination of ear, nose and throat was performed by an otolaryngologist. Then, an audiological assessment including pure-tone audiogram (PTA) and tympanogram were conducted in all cases. Auditory evoked potentials and magnetic resonance imaging with gadolinium were performed in order to rule out retrocochlear disease if required.

Tinnitus evaluation consisted of a Greek validation of the THI. The total THI score varied from 0 to 100, with 0 being asymptomatic and 100 being the strongest complaint. A score  $\geq 58$  indicates severe tinnitus, almost always heard, which leads to disturbed sleep patterns and can interfere with daily activities.<sup>18</sup> On the contrary, a score  $\leq 36$  correlates with mild tinnitus, easily masked by environmental sounds and easily forgotten with activities<sup>18</sup>. Additionally, based on the TRT Initial Interview<sup>19</sup>, the patients were particularly asked if tinnitus prevented four major activities of everyday life: work, sleep, relaxation and concentration. A VAS of 0 to 10 was used to assess the tinnitus-induced annoyance.<sup>9, 19, 20</sup>

Subjects were classified into two groups: (1) Group 1 consisted of TRT patients who received a complete TRT (study group,  $n = 33$ ). The participants were further classified as either Category 1 ( $n = 4$ ) or Category 2 ( $n = 29$ ) patients according to Jastreboff's classification.<sup>21</sup> Category 1 patients experienced tinnitus as a significant subjective problem but did not have hearing difficulties. On the contrary, category 2 patients reported

both tinnitus and hearing problems.<sup>2</sup> Group 2 consisted of patients who refused TRT despite our recommendation and were treated with vasoactive medications (control group, n= 30). All patients of this group were administered trimetazidine (20 mg three times daily).

All TRT patients received directive counseling; each participant was reassured for the absence of brain tumor accounted for tinnitus emergence, while the neurophysiological model of tinnitus was explained in a concise way. On the basis of the audiometric threshold, category 1 patients (n= 4) were fitted with wearable ear-level sound generators, while category 2 patients (n= 29) were fitted with combination devices that incorporated both hearing aids and sound generators. They were applied for at least 8 hours a day, preferably during the waking hours. Volume adjustment was carried out at the mixing point.

Both groups were regularly checked at 3, 6 and 12 months. A Greek translation of the THI was administered in order to assess treatment a year after therapy initiation. A reduction in the score of 20 or more was regarded as indicating effective relief from the tinnitus.<sup>22</sup>

Furthermore, the patients were particularly examined if treatment had an effect on the annoyance caused by tinnitus when conducting certain activities of daily living (sleep, concentration, relaxation, work). All patients reported the level of problems in the 0-10 scale of the structured interview form<sup>20</sup> that was used to assess the annoyance. Improvement meant a difference of at least 2 points.<sup>9</sup>

Data were imported into a statistical computer program (SPSS 15.0) for further evaluation and analysis. A paired t-test was performed to evaluate the statistical significance of a difference between the mean THI and VAS scores before and after treatment. Two-tailed t-test for independent groups was used to compare baseline THI and VAS scores between groups, and mean differences after treatment. The adopted level of statistical significance was 0.05.

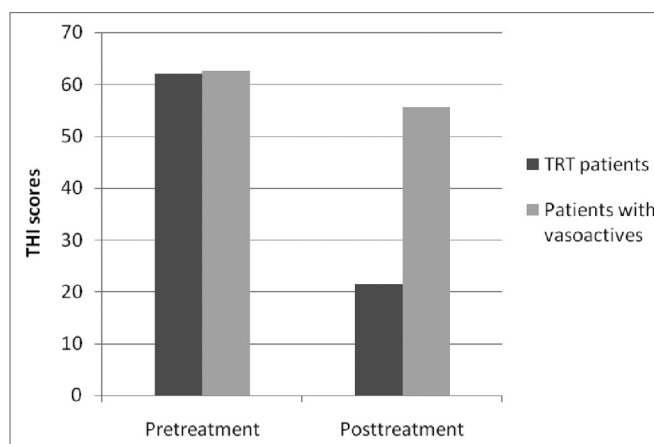
## RESULTS

Sixty-three subjects were included in the study. The average age was 63.9 years ( $\pm 13.2$ ) (range, 29 to 88 years). The 33 TRT patients included 18 males and 15 females with a mean age 63.7 ( $\pm 13.4$ ) years (range: 29-88 years). Hearing impairment ( $\geq 25$  dB in at least 1 frequency) was present in 29 out of 33 patients (87.9%). The 30 subjects from the control group treated with vasoactive agents included 15 males and 15 females. The mean age of the control group was 64.1 ( $\pm 13.2$ ) years (range: 39-87 years). Hearing impairment ( $\geq 25$  dB in at least 1 frequency) was present in 25 out of 30 subjects of the control group (83.3%). Presbycusis was the most common diagnosis in both groups (Table 1).

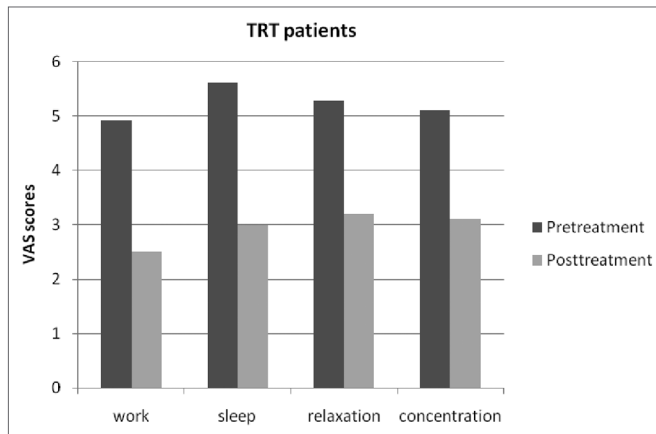
**Table 1.** The etiology of tinnitus by gender in TRT patients and in patients treated with vasodilators.

| Diagnosis                  | TRT patients |        |       | Patients with vasodilators |        |       |
|----------------------------|--------------|--------|-------|----------------------------|--------|-------|
|                            | Male         | Female | Total | Male                       | Female | Total |
| Presbycusis                | 8            | 6      | 14    | 7                          | 8      | 15    |
| Sudden deafness            | 2            | 2      | 4     | 1                          | 2      | 3     |
| Noise-induced hearing loss | 1            | 1      | 2     | 4                          | 2      | 6     |
| Ménière's disease          | 0            | 1      | 1     | 1                          | 1      | 2     |
| Idiopathic                 | 7            | 5      | 12    | 2                          | 2      | 4     |
| Total                      | 18           | 15     | 33    | 15                         | 15     | 30    |

Baseline comparison of THI and VAS scores for work, sleep, relaxation and concentration did not reveal any significant differences between the study group and the control group. No statistical significant differences in pre- and post-treatment THI scores were detected between genders. However, on final evaluation the THI score was statistically significantly improved in the study group ( $p < 0.001$ ,  $t = 12.76$ ) and marginally improved in the control group ( $p = 0.049$ ;  $t = 2.05$ ) (Figure 1). Additionally, mean VAS scores were statistically improved in the study group, in all measures (work:  $p < 0.001$ ,  $t = 7.00$ ; sleep:  $p < 0.001$ ,  $t = 6.66$ ; relaxation:  $p < 0.001$ ,  $t = 5.74$ ; concentration:  $p < 0.001$ ,  $t = 5.74$ ). On the contrary, in the second group of controls, none of these measures was found significantly improved (work:  $p = 0.34$ ,  $t = 0.96$ ; sleep:  $p = 0.13$ ,  $t = 1.55$ ; relaxation:  $p = 0.22$ ,  $t = 1.24$ ; concentration:  $p = 0.33$ ,  $t = 0.98$ ). Mean pre- and post-treatment VAS scores for both groups are shown in Figure 2. Finally, comparison of the mean improvement of THI and VAS scores after treatment showed significant differences between the two groups, favoring



**Figure 1.** Mean pretreatment and post-12-month treatment THI scores for TRT patients and patients treated with vasoactive medications.



**Figure 2.** Mean pretreatment and post-12-month treatment VAS scores for work, sleep, relaxation and concentration for patients treated with TRT (upper panel) and patients treated with vasoactive medications (lower panel).

TRT treatment (THI:  $p < 0.001$ ,  $t = 7.26$ ; VAS for work:  $p < 0.001$ ,  $t = 4.48$ ; sleep:  $p < 0.001$ ,  $t = 3.57$ ; relaxation:  $p < 0.005$ ,  $t = 2.91$ ; concentration:  $p < 0.005$ ,  $t = 3.20$ ).

## DISCUSSION

In our series, a statistically very significant decrease in average THI and VAS scores after a year of TRT ( $p < 0.001$ ) was documented. The mean THI score was lowered by more than 20 points and the level of annoyance when our TRT patients were working, concentrating, relaxing, and sleeping was reduced. Several independent centers have reported results indicating that TRT is an effective treatment for tinnitus.<sup>2, 9, 11-17, 23-24</sup> Herraiz et al. (2005) showed the efficacy of TRT for tinnitus relief compared to a waiting list group and a partially treated group (patients that refused prosthesis adaptation), as THI score was reduced from 48% to 32% and VAS for intensity decreased from 6.6 to 5.3 after one year of treatment ( $p < 0.05$ ).<sup>23</sup> To our knowledge, our study is the first one conducted between TRT patients and a control group of patients treated with vasoactive medications.

Tinnitus coincided with serious emotional disorders in some of our cases. An increased frequency of non-specific neurotic symptoms like worrying and tension has been reported in Greek patients.<sup>25</sup> A genuine and general North-South difference in the expression of psychological distress may be present, while cultural differences in terms of personality traits and culturally sanctioned child rearing practices might account for the findings.<sup>25</sup> Concomitant psychiatric diseases and stress are the most important factors in resistance to TRT results and treatment of these conditions before or simultaneously with TRT application would be mandatory.<sup>26</sup> A modified TRT enhanced by a variety of psychological approaches is advocated by some authors in order to re-

duce tinnitus-related distress and psychometric stress.<sup>27</sup> It comprises Jacobson's progressive muscle relaxation, physiotherapy, education via lectures and training of selective attention, as well as changes of appraisal, mental attitude and behavior towards tinnitus.

The majority of patients in both groups suffered from presbycusis (42.4% of TRT patients, 50% of patients treated with vasodilators). Other diagnoses included sudden deafness, noise-induced hearing loss, Ménière's disease and idiopathic. It has been reported that diagnosis could influence TRT results.<sup>23</sup> It seems that older patients with presbycusis start tinnitus habituation when they understand the benignity of the process and the good prognosis for this habituation.<sup>23</sup> On the contrary, patients with Ménière's disease and sudden deafness should be given exhaustive medical counseling and a sound therapy program.<sup>23</sup>

Our TRT patients received TRT comprised by directive counseling and sound therapy. Both elements of TRT are regarded as important in order to achieve optimal results.<sup>2</sup> In a review article, it appears that in the Anglo-Saxon countries counseling is the dominant element and that additional acoustic measures only bring minor additional improvement whereas in German-speaking countries complementary psychotherapeutic measures, such as anti-stress therapy, hearing perception training, various relaxation techniques and music and sound therapy can increase the effectiveness of the therapy even more.<sup>28</sup> A significant improvement was found in 83% in those treated with a TRT protocol involving counseling and the use of noise-generators, whereas the success ratio was only 18% in the group with counseling alone.<sup>10</sup> A significant improvement in 70% of patients treated with the use of hearing aids was reported.<sup>10</sup>

In our study, we documented a satisfactory response obtained at 12 months after the beginning of TRT. There is some controversy regarding the time required to achieve optimal effects. It has been reported that the first improvements appear 3 months after TRT and that they increase with time.<sup>29</sup> Some authors advocate that treatment should continue for 18 months in order to obtain stable results.<sup>9</sup> It has also been documented that improvement may continue for a long time after the end of 18-month TRT.<sup>24</sup> However, the time of 12–18 months was considered to be too long by some of the patients.<sup>30</sup> We believe that patients should be encouraged to attend TRT for at least a period of a year in order for optimal and stable improvement to be achieved.

## CONCLUSIONS

TRT achieved by directive counseling and exposure to low-level broad band noise is an effective approach to tinnitus management. Sound therapy decreases the



sound contrast between tinnitus and silent environment leading to a reduced detection of tinnitus. Directive counseling changes the way tinnitus is perceived. The objective of this study was to present the results regarding the efficacy of TRT for tinnitus relief in patients with clinically significant tinnitus. We conclude that although TRT is not a cure, since it does not remove tinnitus, it reduces the level of annoyance induced by tinnitus and improves the ability of patients to work, sleep, relax or be concentrated.

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