

Sound therapy in patients with tinnitus: traditional sound generators vs. mobile apps

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Abstract. – OBJECTIVE: Tinnitus Retraining Therapy (TRT) is a rehabilitation approach for tinnitus that is currently considered an effective treatment with an elevated response rate. TRT is usually delivered through sound generators; however, they are often difficult to find and expensive. Recently, mobile apps have been proposed for TRT. This study aims to verify the effectiveness of TRT performed using mobile apps in reducing the adverse effects of tinnitus on the quality of life.

PATIENTS AND METHODS: A total of 80 patients affected by tinnitus in category 0 (mild tinnitus) and category 1 (moderate tinnitus), according to the Jastreboff classification, were included in the study. Patients of both classes were subsequently differentiated into two homogeneous groups; the first (Group A) was treated with a traditional sound generator, and the second (Group B) using a mobile app. The Tinnitus Handicap Inventory – the Italian version of the questionnaire – was used to investigate the impact of tinnitus on the quality of life in enrolled patients and evaluate their response to TRT.

RESULTS: A significant improvement was found in THI scores in category 0 patients for both sound generator and mobile app groups; no difference was found between the two-treatment delivery technology (-1.186, $p=0.783$); conversely, tinnitus improvements in category 1 patients were only reported for subjects treated using a sound generator (-14.529, $p<0.001$), while no significant improvement was found in patients treated using the mobile app.

CONCLUSIONS: This study confirms the value of TRT, which in patients with mild tinnitus (category 0), can also be delivered through mobile apps with results comparable to traditional sound generators. Further studies are necessary to confirm the effects of the different tinnitus treatments available and improve the knowledge on this topic.

Key Words:

Tinnitus, Sound therapy, Sound generators, Mobile apps.

Introduction

Tinnitus is a subjective sound sensation perceived in one or both ears and/or in the head, not produced by an external source¹. It is a common symptom in the general population²⁻⁵ and may have a severe impact on quality of life, as it often compromises patients' daily activities with anxiety, depression, and insomnia⁶⁻¹⁰.

There is no specific pharmacological treatment for tinnitus; however, many therapeutic strategies for its management aimed at reducing tinnitus perception and related anxiety have been proposed. The purpose of this kind of treatment is to promote habituation¹¹⁻¹⁵.

Tinnitus Retraining Therapy (TRT)^{16,17} is a rehabilitation approach based on the neurophysiological model described by Jastreboff¹⁶ whose purpose is to induce the patient to get used to tinnitus. TRT is currently considered an effective treatment for tinnitus with an elevated response rate (80%)^{11,18,19}.

TRT effectiveness has increased significantly in the last 30 years, presumably due to changes in the practice of this therapy²⁰. The most significant change was to shorten the average time between one meeting and the next to create a solid therapeutic alliance between the counselor and patient¹¹. The selection of the patient is fundamental for the effectiveness of TRT, and treatable and organic tinnitus causes should be excluded. Therefore, when tinnitus does not depend on a pathology that can be solved by medical intervention, most patients may be treated with this rehabilitation approach^{21,22}.

The primary purpose of TRT is to achieve gradual desensitization towards the tinnitus, with a progressive decrease in discomfort and an increase in tolerance levels, to obtain a reduction in the subjective intensity and, finally, loudness. In addition, rehabilitation aims to have a neuroplastic re-ad-

aptation of nervous mechanisms after peripheral damage or alteration in the cochlea^{16,23}. First, the cochlear lesions cause a reduction in the cochlear nerve activity, and then, the neural activity gradually increases throughout the central auditory nervous system to compensate for this deficit^{19,24,25}. Therefore, the therapy's goal is to teach the brain to reclassify tinnitus as an unimportant sound that blends into the background. The idea is thus to decrease the contrast between the tinnitus sound and the surrounding acoustic environment¹¹.

The TRT rehabilitation protocol begins with an accurate counseling and consequent therapeutic model based on the clinical-audiological categorization of the patient, investigating the hearing loss, hyperacusis, and ambient noise effect. Then, the treatment is primarily based on sound therapy and the so-called sound enrichment^{11,16}. The most suitable acoustic stimulation for desensitization in patients who do not require prosthetic correction is the one produced by barely audible sounds applied on the affected side. These sounds can be of various types: white noise, pitch noise, modulated sounds, or Zen-type fractal sounds. The devices that allow this type of stimulation are called sound generators and include television, radio, portable music players, hearing aids, fans, sound pillows, desktop, or wearable sound generators^{20,23,26,27}.

However, available sound generators are often difficult to find and expensive, making them inaccessible to all patients. Recently, several applications have been introduced to deliver TRT; they can be downloaded on smartphones and reproduce ambient sounds and white noises. As indicated in some studies^{26,27}, these apps represent a valid, economical, and effective alternative to sound generators.

This study aims to verify the effectiveness of TRT performed using an app in reducing the adverse effects of tinnitus on the quality of life in specific patient categories (Jastreboff category 0 and 1).

Patients and Methods

Patients affected by tinnitus and treated in the Audiology Department of the Sapienza University of Rome, Italy, between October 2018 and February 2020 were enrolled in this study.

Inclusion criteria for initial enrollment required tinnitus to be the primary complaint. Participants needed to have normal hearing or

mild hearing loss without the use of hearing aids. They should have no current otological disease, no psychiatric comorbidity, no history of hyperacusis, no surgical procedures related to the ear, no previous tinnitus therapies (pharmacological or otherwise), no history of noise exposure, and no use of earplugs.

Anamnestic data of each patient were collected: demographic characteristics (age, sex, degree, job) and clinical conditions (hearing loss, dizziness, craniofacial disease, temporal-mandibular joint dysfunction, previous otological surgery, sleep disorders, history of noise exposure, earplugs use). Moreover, tinnitus characteristics (onset, probable etiology, type, side) were investigated. As per tinnitus onset, five tiers were considered: from 0 to 6 months, from 7 to 12 months, from 1 year to 3 years, from 3 to 5 years, and over five years. Comorbidities (cardiovascular, neurological, metabolic, psychiatric, respiratory, gastroenteric, traumatic, autoimmune) were tracked.

All patients underwent full otolaryngology examination, Pure Tone Audiometry (PTA), and complete immittance testing.

Following international guidelines for TRT, patients were then invited to an initial interview²⁸ with questions on tinnitus, hearing loss, hyperacusis, classifying gravity, the annoyance, and the effect on the quality of life (QoL) of tinnitus, using a Visual Analogue Scale (VAS).

In addition, the Tinnitus Handicap Inventory – Italian version (THI)²⁹ questionnaire investigating the impact of tinnitus on quality of life – was administered to patients. THI is helpful in assessing the impact of tinnitus on activities of daily living, identifying possible psychiatric comorbidity²⁹.

Using the information from the interview and the THI questionnaire scores, it was possible to divide the subjects into one of the five categories identified by Jastreboff, for each of which a different rehabilitation program is provided. Subjects were categorized according to certain factors¹¹: severity and duration of tinnitus, presence or absence of hyperacusis, the subjective value of hearing loss, and prolonged intensification of the symptom resulting from noise exposure.

According to Jastreboff classification¹¹, only patients pertaining to category 0 and category 1 were included in the study (n 80/189; 42.3%).

Patients included in the study were subsequently randomly assigned to two homogeneous groups, according to the type of technology used to deliver TRT: Group A performed TRT through

a traditional sound generator (NaturCARE, Humana Spa, Milan, MI, Italy), and Group B performed TRT using a mobile app (GN Resound Tinnitus Relief, GN Hearing A/S, Ballerup, BA, Denmark).

TRT and THI interviews were conducted at T0 (at enrollment), T1 (after three months of treatment), and T2 (after six months of treatment).

Each patient had to execute 6-8 hours of sound therapy to calibrate the sound according to the mixing point between tinnitus and white noise.

This study was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki, and all patients provided written informed consent prior to enrolment.

Statistical Analysis

Descriptive data were expressed as counts (percentage) for groups of patients. A mixed-effect model, adjusted by baseline THI values age, sex, and onset, followed by Tukey's test, was used to evaluate longitudinal changes in THI scores in the two patient groups. A p -value < 0.05 was considered significant. Statistical analysis was performed using the R Project for Statistical Computing version 4.0 (R Foundation for Statistical Computing, Wirtschaftsuniversität Wien, Austria).

Results

Eighty patients (48 males and 32 females; mean age 46.1 years) were enrolled in the study. There were no dropouts during the follow-up period. Most patients were aged between 31 and 60 years (50 patients, 62.5%), followed by older than 60 years (16 patients, 20%) and younger than 30 years (14 patients, 17.5%).

Fourteen patients reported a job with audiological risk (17.5%), with a substantial prevalence of males (71.4%, $n=10$) over females (28.6%, $n=4$).

Tinnitus was bilateral in 52.5% ($n=42$) of patients, unilateral in 35% ($n=28$), and undefined in 12.5% ($n=10$). Tinnitus was continuous in all cases (100%, $n=80$).

Familiarity with tinnitus was present only in 25% ($n=20$) of subjects, equally distributed between males ($n=10$) and females ($n=10$).

The onset of tinnitus was differentiated into five subgroups: 0-6 months (22.5%, $n=18$); 7-12 months (25%, $n=20$); 1-3 years (40%, $n=32$); 3-5 years (7.5%, $n=6$); and more than five years (5%,

$n=4$). Males and females are equally distributed within individual age groups.

A temporomandibular joint dysfunction was present in 62.5% ($n=50$) of patients, sleep disorders in 37.5% ($n=30$), and craniofacial disorders in 25% ($n=20$) of patients.

Subsequently, patients were further divided, according to Jastreboff classification, into category 0 ($n=40$) and category 1 ($n=40$). Category 0 patients were 50% ($n=20$) males and 50% ($n=20$) females; category 1 patients were 70% ($n=28$) males and 30% females ($n=12$).

Individuals with jobs at high risk of noise exposure were evenly distributed in the two categories.

The tinnitus onset, laterality and familial history were similar in both groups ($p=0.826$). Interestingly, 60% ($n=24$) of the subjects in category 0 had associated disorders such as TMJ disorders, craniocervical disorders, sleep disturbances, and dizziness. This finding is further confirmed by possible musculoskeletal comorbidity in 90% ($n=36$) of subjects in category 0, whereas in category 1, this was suspected in only 10% ($n=4$) of cases.

THI results obtained in Jastreboff categories 0 and 1 were analyzed in both the sound generator-treated and app-treated groups. Improvement was found in category 0 patients, both treated with the app and sound generator; conversely, in category 1, significant improvement was obtained only when performing sound therapy with a sound generator. A significant difference in the THI scores was found in category 1 patients between those treated with a sound generator vs. app (-14.529, $p<0.001$), while no significant differences were found in Category 0 patients according to the technology used to deliver TRT (-1.186, $p=0.783$).

Discussion

Tinnitus is a widespread symptom that often compromises the quality of life^{1,6,9}; TRT, a method based on counselling and sound therapy, may represent a notably effective treatment^{11,16,18,19}. This treatment approach has existed for about 30 years, intending to reduce the symptoms acting on the functional connections between the auditory system, the limbic, and autonomic nervous systems, improving sound tolerance of the tinnitus¹⁹.

One unique aspect of TRT is that the treatment aims to work above the source of the tinnitus and

the connections that link the auditory system and other systems in the brain. Therefore, the cause of the tinnitus is irrelevant. Therefore, any type of tinnitus, as well as somatosounds, can be successfully treated by TRT, which, as reported by several studies^{11,16-18,20,26}, offers significant help in reducing tinnitus annoyance.

In recent years, a substantial increase in mobile technology has provided additional tinnitus management options, including additional methods to deliver sound therapy, including mobile apps²². The choice of the best app should be guided by the needs and preferences of the individual patient²⁶.

Recently, smartphones and tablets have become widespread in developed countries, and healthcare-related apps are increasing dramatically in different specialties. However, their use in clinical practice is not entirely accepted since they are not medically produced. In fact, patients tend to use apps more and more to manage their tinnitus; however, this therapy is often performed independently, without a healthcare professional's proper assistance and supervision. In addition, there is evidence that most apps useful for treating tinnitus have been created without the guidance of audiologists or otolaryngologists³⁰.

Several studies²³ compared hearing aids and sound generators, combined hearing aids with simple hearing aids, and combined hearing aids with sound generators. In one study²³, patients with sound generators and those with hearing aids were compared: no difference was found, using THI as the unit of measurement at 3, 6, or 12 months, regarding the effects on tinnitus. Other studies^{23,25,30,31} compared combined hearing aids with plain hearing aids and measured tinnitus severity using the THI or TFI: comparison of the data showed no differences; furthermore, there were no adverse effects in any of the studies. However, there is no sufficient evidence to support the superiority or inferiority of the various modalities of sound therapy. In this regard, a Cochrane review demonstrated that hearing aids and sound generators could help reduce tinnitus severity in some patients³¹. However, there is insufficient evidence to recommend one device over the other or whether these devices offer improvements over a placebo treatment³¹.

Sound therapy also showed better outcomes in patients whose tinnitus frequency matched the hearing loss³². In the present study, a prevalence of males was evidenced, probably associated with the type of work activity and/or pleasure habits.

In TRT, stimulation is conventionally per-

formed with low-level broadband sound generators since the patient must receive the stimulus many hours every day. Therefore, it is essential that the sound is tolerable and pleasant. Several types of sound generators can be used with different signal power spectrums; evidence showed that they effectively reduced the discomfort caused by tinnitus in patients with normal hearing without significant differences between the different kinds of sounds³³. In addition, patients' choice of their preferred sound after short trial periods improved their satisfaction. This practice could help better tailor the treatment to each patient³³.

The present study showed that an app could be an excellent tool for improving the level of discomfort and quality of life impairment in subjects with tinnitus classified Jastreboff category 0 (mild). Thus, they would receive the same benefits as they would with traditional sound therapy.

The fact that, in category 0, both the app and sound generator are equally effective could indirectly confirm that sound therapy is not required for patients in this category, that can be treated exclusively with counseling as proposed by Jastreboff¹⁶. Furthermore, it would seem from our data that any sound therapy (app/sound generator), alone or in combination, is more effective than counseling alone. This could be the cue for more future work.

In patients with tinnitus of medium severity (Jastreboff category 1), it has been seen that significant benefit cannot be obtained when sound therapy is offered using apps, compared with what would be obtained with traditional sound generators.

However, it is worth noting that although sound generators are more effective, our results suggest that sound therapy performed through an app may also be helpful in selected cases. Therefore, in addition to obviating the high cost of sound generators, individuals with mild to moderate tinnitus may be advised and offered a protocol involving sound therapy using apps as an additional therapeutic offering.

Considering the results obtained, it is worth emphasizing the importance of individuals with tinnitus beginning treatment at an early stage. However, the underestimation of mild cases (Jastreboff category 0) can often lead to chronicization of the symptoms. Therefore, it is necessary that even individuals with mild tinnitus are treated early, also through sound therapy, to avoid the worsening of symptoms.

Another important consideration relates to the possible presence of osteoarticular and muscular comorbidities, especially in subjects belonging to category 0. This condition, if undetected, underestimated, or untreated, may contribute to the worsening of tinnitus over time, although they would not seem to affect the outcome of the therapy carried out.

Conclusions

This study confirms the value of TRT, which, in patients with mild tinnitus (class 0), can also be delivered through mobile apps with results comparable to traditional sound generators. However, a multidisciplinary approach to tinnitus patients is always recommended to better identify the causes underlying tinnitus. Further studies are necessary to confirm the effects of the different tinnitus treatments available and improve the knowledge on this topic.

Informed Consent

This study was conducted in accordance with the principles of the Declaration of Helsinki, and all patients provided written informed consent prior to enrolment.

Ethics Approval

This study was approved by the local Ethics Committee of the Department of Sense Organs, "Sapienza" University of Rome, No. 21/2018, 02/10/2018.

Availability of Data and Materials

All data and materials used in this study are available upon reasonable request.

Authors' Contributions

GA and AM design of the study, writing original draft; AP and GI data collection and data analysis; AG and GM counseling and supervision; AC data interpretation, MR writing, supervision.

Conflict of Interest

All authors declare no conflicts of interest.

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