



ORIGINAL ARTICLE

Effectiveness of sound therapy in patients with tinnitus resistant to previous treatments: importance of adjustments[☆]



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Tinnitus;
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Abstract

Introduction: The difficulty in choosing the appropriate therapy for chronic tinnitus relates to the variable impact on the quality of life of affected patients and, thus, requires individualization of treatment.

Objective: To evaluate the effectiveness of using sound generators with individual adjustments to relieve tinnitus in patients unresponsive to previous treatments.

Methods: A prospective study of 10 patients with chronic tinnitus who were unresponsive to previous drug treatments, five males and five females, with ages ranging from 41 to 78 years. Bilateral sound generators (Reach 62 or Mind 9 models) were used daily for at least 6 h during 18 months. The patients were evaluated at the beginning, after 1 month and at each 3 months until 18 months through acuphenometry, minimum masking level, the Tinnitus Handicap Inventory, visual analog scale, and the Hospital Anxiety and Depression Scale. The sound generators were adjusted at each visit.

Results: There was a reduction of Tinnitus Handicap Inventory in nine patients using a protocol with a customized approach, independent of psychoacoustic characteristics of tinnitus. The best response to treatment occurred in those with whistle-type tinnitus. A correlation among the adjustments and tinnitus loudness and minimum masking level was found. Only one patient, who had indication of depression by Hospital Anxiety and Depression Scale, did not respond to sound therapy.

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PALAVRAS-CHAVE

Zumbido;
Terapia sonora;
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Conclusion: There was improvement in quality of life (Tinnitus Handicap Inventory), with good response to sound therapy using customized settings in patients who did not respond to previous treatments for tinnitus.

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Eficácia da terapia sonora em pacientes com zumbido resistente a tratamentos anteriores: importância dos ajustes

Resumo

Introdução: A dificuldade em escolher a terapia apropriada para zumbido crônico encontra-se nas suas diversas formas de impacto sobre a qualidade de vida dos pacientes e requer a sua individualização.

Objetivo: Avaliar a eficácia do uso do gerador de som com ajustes individuais para aliviar o zumbido em pacientes sem resposta aos tratamentos anteriores.

Método: Um estudo prospectivo em 10 pacientes, 5 homens e 5 mulheres, na faixa etária de 41 a 78 anos com zumbido crônico e resistente a tratamentos medicamentosos. Foram utilizados geradores de som bilaterais nos modelos *Reach 62* ou *Mind 9* por no mínimo 6 horas diárias durante 18 meses. Os pacientes foram avaliados no início, depois de 1 mês e a cada 3 meses até 18 meses através da acufenometria, *Minimum Masking Level (MML)*, *Tinnitus Handicap Inventory (THI)*, Escala Visual Analógica (EVA) e *Hospital Anxiety and Depression Scale (HADS)*. Os geradores de som foram ajustados em cada visita.

Resultado: Houve uma redução do THI em 9 pacientes usando-se um protocolo com uma abordagem personalizada, independente das características psicoacústicas do zumbido. A melhor resposta ao tratamento ocorreu naqueles pacientes com zumbido do tipo apito. Encontramos uma correlação entre os ajustes e a intensidade do zumbido e o MML. Apenas um paciente com indicação de depressão HADS não respondeu à terapia sonora.

Conclusão: Houve uma melhora na qualidade de vida (THI) com boa resposta a terapia sonora com ajustes personalizados em pacientes resistentes a tratamentos anteriores para o zumbido.

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Introduction

Subjective tinnitus can be defined as an auditory perception in the absence of an external sound stimulus,¹ described as a sound like a whistle or a hiss. It is estimated that over 30 million Americans have tinnitus;² in Brazil, it is believed that this number is about 28 million.³ Thus, it is a public health problem.

It is a common-sense conclusion among researchers that symptom severity can lead to losses in quality of life. The lack of control of tinnitus and its constant presence produces a high degree of stress; indeed, the emotional effect is variable and may range from a mild irritation associated with tinnitus, to states of anxiety, depression, and insomnia, even leading to suicide.⁴

In patients with tinnitus, it is difficult to make objective measurements of emotional disorders such as anxiety and depression. However, several subjective assessment tools are available in Portuguese, and the Hospital Anxiety and Depression Scale (HADS)^{5,6} is one of the most used instruments, due to its ease of application.

Since tinnitus is a subjective symptom, it is difficult to analyze, measure, and treat. Thus evaluations such as

acuphenometry, the use of visual analog scales (VAS), and questionnaires to determine the impact on quality of life such as the Tinnitus Handicap Inventory (THI)^{7,8} are very important strategies, as are individual approaches in the treatment of these patients.

Among the therapeutic possibilities for sensorineural tinnitus, drug therapy, acupuncture,^{9,10} transcranial magnetic stimulation,¹¹ cognitive-behavioral therapy (CBT),¹² and sound therapy (masking therapy¹³ and habituation therapy) can be cited.⁴ Some patients try several resources attempting to find a treatment that brings significant relief for their tinnitus.

The process of habituation to tinnitus with the use of sound therapy consists of the stimulation of the ear by the presence of constant sounds, with the aim of reducing hypersensitivity in quiet surroundings. In this process, sound generators, with or without hearing amplification, are used with a neutral sound: music or white noise, at a low intensity in an attempt not to mask tinnitus, but to provide a reduction in its perception. Jastreboff⁴ developed Tinnitus Retraining Therapy (TRT) as a habituation therapy that uses counseling and sound therapy. Fractal Tones Therapy¹⁴ uses habituation therapy to reduce tinnitus, through a sound

generator that produces fractal sounds (music); in this manner, the melody is maintained but does not repeat itself.

To observe the effectiveness of sound enrichment in tinnitus sensation, minimum masking levels (MML) are used in order to evaluate the effect of masking the perception of tinnitus through the use of a broadband noise.¹⁵

Currently, several protocols have been used for sound therapy; however, reports on the settings used in sound generators of hearing aids were not found in the literature. The aim of this study was to demonstrate the effectiveness of sound therapy with different types of sound generators through patients' follow-up, the relationship of sequential evaluations through previously established parameters (THI, VAS, MML), and the need for individual interventions through detailing the customized settings of these generators in patients unresponsive to previous treatments for tinnitus.

Methods

This study was approved by the Ethics Committee under CEP protocol No. 1090/11. Patients were instructed about all procedures of the study and signed an informed consent.

A prospective study of 10 selected patients from the Tinnitus Outpatient Clinic was conducted by the otolaryngologists responsible for this department. For the research, 20 retroauricular behind the ear (BTE) hearing aids with an open fitting were donated to be used by patients bilaterally. Of these 10 patients, five used the Mind 9440 model with fractal sounds (Widex™) and five used the Reach 62 Model (Belton™) with white noise.

Patients were recruited sequentially from the beginning of the study, alternating the indication of Mind 9 and Reach 62 generators, according to inclusion and exclusion criteria.

Inclusion criteria: continuous chronic tinnitus complaints for over a year without improvement with drug therapies and with no specific treatment for tinnitus for at least 3 months. Hearing loss, when present, was not the main complaint of the patient.

Exclusion criteria: conductive hearing loss or changes in the external and/or middle ear.

During the use of sound generators, these patients were evaluated at the beginning of therapy, and at 1, 3, 6, 9, 12, 15, and 18 months, when the generators were switched off. In all the visits, adjustments for the generators were performed when needed, and all of the following evaluations were carried out:

Otolaryngology evaluation

Pure tone audiometry and vocal audiometry
Immittancimetry with stapedial reflex survey
HADS
VAS
THI
Acuphenometry (loudness and pitch matching)
MML

The HADS questionnaire was used because it is a simple, rapid assessment tool that provides data and identifies symptoms of anxiety and depression in individuals under no psychiatric treatment.

To better understand the effect of tinnitus in patients, the type of tinnitus presented was considered and characterized by acuphenometry: a group with whistle-type tinnitus equivalent to pure tone, a group with hissing-type tinnitus equivalent to white noise (WN) or narrow band (NB), and a group with both types of tinnitus. In all groups, evaluations and adjustments met the same criteria.

Through MML, the authors sought to ascertain the minimum intensity of tinnitus masking in ascending form by using bilateral noise: in the first instance, WN; in the second instance, NB at tinnitus frequency, and then NB at 500 Hz.

Reduction in THI score ≥ 20 points and reduced VAS were considered as improved parameters of therapy.

The five patients who used sound generators with music could choose between five types of fractal sounds, random and harmonic, known as Zen. Where necessary, the adjustments changed the rhythm (between slow and fast), frequency (between low and high), the volume in a range from 0 to 15, and, in some cases, the type of Zen sound.

The other five patients using sound generators with white noise could adjust the initial volume by sound pressure level (SPL), from 0 to 100 dB SPL; use low sound cuts between 500 and 2000 Hz and high sound cuts between 2000 and 6000 Hz; insert slight, moderate, or strong modulation; and change between slow, medium, and fast speed.

Patients with associated hearing loss were given a month of initial monitoring to adapt and adjust the sound amplification before being connected to the sound generator.

The equipment used included an AC40 audiometer (Interacoustics) and an AZ7 immittancimeter (Interacoustics).

Hearing aids with sound generator were obtained by donation from Centros Auditivos Widex and Audibel do Brasil.

Results

Of the total of 10 patients, five were female and five male, aged 41–78 years. Six patients presented with bilateral tinnitus showing more intensity on the left side; in three, the problem was unilateral on the left side; and one patient had unilateral tinnitus on the right side.

In the analysis of tonal audiometry, it was found that two subjects had no hearing loss and eight had mild-to-moderate sensorineural hearing loss at high frequencies. Of these, only four subjects had associated hearing complaints, with the necessity for placement of amplification in their hearing aids to improve speech understanding and avoid auditory deprivation.

All patients used the sound generators for at least 6 h daily throughout the treatment, regardless of the type of generator.

In acuphenometry, throughout therapy, 10 patients exhibited tinnitus between 3000 and 8000 Hz; two patients started sound therapy with whistle-type tinnitus, four with hissing-type tinnitus, and four with whistle- and hissing-type tinnitus (Table 1).

In the initial assessment with the HADS questionnaire, one patient (patient 8) had anxiety and depression, three patients had anxiety (patients 2, 3 and 9), and the other showed no such alterations.

Table 1 Visual analog scale (VAS) scores according to type of tinnitus in the beginning and at the end of sound therapy.

Patient	Baseline VAS for tinnitus		VAS for tinnitus after 18 months	
	Right	Left	Right	Left
1	Absent	Hissing 7	Absent	Hissing 5
2	Whistle 8	Whistle 10	Whistle 0	Whistle 0
	Hissing 8	Hissing 10	Hissing 3	Hissing 6
3	Absent	Hissing 8	Absent	Hissing 2
4	Whistle 5	Whistle 9	Whistle 3	Whistle 5
5	Whistle 9	Absent	Whistle 1	Absent
6	Hissing 2	Hissing 5	Hissing 2	Hissing 4
7	Absent	Hissing 6	Hissing 2	Hissing 4
8	Whistle 7	Whistle 10	Whistle 5	Whistle 6
	Hissing 7	Hissing 9	Hissing 7	Hissing 9
9	Whistle 5	Whistle 8	Whistle 0	Whistle 0
	Hissing 3	Hissing 7	Hissing 0	Hissing 3
10	Whistle 0	Whistle 8	Whistle 0	Whistle 3
	Hissing 4	Hissing 4	Hissing 3	Hissing 3

Of the 10 patients monitored, in nine a decrease of 20 points in THI score (with respect to basal levels, [Table 2](#)) and reduction in VAS ([Table 1](#)) were observed at the end of the sound therapy. Two patients, who had been consistently showing a good response to treatment, demonstrated a worse score at 15 months (patient 7) and at 18 months (patient 2).

In acuphenometry, the intensity of tinnitus was reduced or remained at the same level in all patients, when comparing the beginning and the end of sound therapy. Regarding MML with WN, volume reduction or stabilization occurred in eight patients. Compared to baseline, there was a need to increase the volume of sound generators in all patients ([Table 3](#)).

The volume of MML NB at tinnitus frequency was reduced or remained at the same level in nine patients and increased only in the patient who reported no improvement with therapy. However, when MML volume with NB at 500 Hz was evaluated, this occurred in only six patients. These responses were important in setting the characteristics of the sound generators ([Table 4](#)).

The stabilization of volume and generator characteristics required 3–12 months of sound therapy.

Of the six patients who used only the generator, two (patients 1 and 5) returned the devices; one continued with the therapy (patient 2), and three kept the generators for sporadic use (patients 8, 9, and 10). Of the four subjects presenting hearing loss, three remained only with amplification (patients 4, 6, and 7) and one with amplification and a generator (patient 3).

Discussion

Numerous proposals to determine the origin of tinnitus exist,^{4,16,17} but notwithstanding the cause, the most important aspect is when this information is interpreted as something unpleasant by the limbic system. This emotional reaction can be intensified and worsened, resulting in increasing stress and exacerbation of the tinnitus sensation, with an important impact on quality of life.

Very anxious individuals process emotional stimuli more rapidly than non-anxious people,¹⁸ and even considering that anxiety has not been established as a causal factor in tinnitus worsening, HADS showed that this condition was present in three patients (2, 3 and 9) who were already using controlled

Table 2 Tinnitus Handicap Inventory (THI) scores during sound therapy.

Patient	THI							
	Baseline	1 month	3 months	6 months	9 months	12 months	15 months	18 months
1	74	58	58	44	50	38	40	24
2	72	56	40	26	22	22	22	54
3	72	38	22	20	20	24	12	16
4	38	14	24	34	20	26	24	18
5	44	46	0	0	0	0	0	0
6	38	34	26	22	30	22	14	16
7	40	12	20	14	22	10	38	40
8	58	56	62	60	66	66	58	68
9	64	44	44	44	38	38	36	12
10	58	50	54	32	36	36	36	28

Table 3 Baseline and final intensity (dB) of tinnitus and volume (dB) of minimum masking levels (MML) with white noise (WN) in sensation level, and the number of times the generator volume was adjusted.

Patient	MML WN		Tinnitus intensity		Volume adjustment
	Baseline	Final	Baseline	Final	
1	25	15	15	05	2×
2	15	10	15	15	3×
3	20	10	10	05	2×
4	20	20	10	10	1×
5	10	0	20	0	1×
6	15	05	05	05	4×
7	15	20	15	15	3×
8	10	20	20	10	3×
9	20	20	10	0	2×
10	20	15	20	10	3×

medications for their treatment. The correlation of HADS with tinnitus showed that, despite the non-occurrence of change in anxiety characteristics throughout therapy, this fact did not hinder good responses to sound therapy.

In patient 8, characteristics of anxiety and depression in HADS were found from the beginning of therapy, but the patient reported that she was not in any specific treatment, because she had not thought that previous suggestions were beneficial. She was the only patient who did not achieve improvement of the impact of tinnitus on quality of life, which leads to the conclusion that depression, as reported by other authors,¹⁹ prevented the adaptation to tinnitus.

Several authors²⁰⁻²³ have demonstrated the efficacy of THI in monitoring tinnitus treatments, and we, used this tool as an important measure to evaluate the impact of tinnitus on quality of life. Therefore, when considering that tinnitus is dynamic and influenced by emotional and physical changes, it was important to assess THI throughout therapy, as well as to make adjustments in the intervention when necessary.

The authors observed improvement of ≥ 20 points in THI scores during therapy in nine patients, which is in line with the findings of other authors (Table 2).^{20,24} In those subjects

that worsened (patient 2 at 18 months and patient 7 at 15 months), the emotional, functional, and catastrophic aspects of tinnitus in THI were analyzed. Worsening was found in all three aspects with respect to the previous evaluation of patient 2, who had worsened emotional status due to personal factors, with no change in auditory thresholds. However, patient 7 had both worsened tinnitus and hearing thresholds after a diagnosis of cancer and the start of chemotherapy/radiotherapy. In this subject, the THI score for functional aspect was the most affected. These responses were of interest when relating the cause of worsening (emotional or functional) with the qualitative aspects of tinnitus.

There are several possibilities to treat the etiology or the effect of tinnitus. Treating the cause is more difficult, given the difficulty to determine the origin of tinnitus and also because, in most cases, there is no relationship between a cure for the disease and the elimination or reduction of tinnitus. When the neurophysiological process of habituation takes place during sound therapy, the central nervous system ceases to perceive tinnitus as an unpleasant sensation and may reduce its perception or even suppress it.^{4,14}

Table 4 Baseline and final volume (dB) of minimum masking levels (MML) with narrow band (NB) at tinnitus frequency and at 500 Hz in sensation level, and the number of times that changes were made to generator characteristics.

Patient	MML NB TF		MML NB 500 Hz		Adjustment of characteristics
	Baseline	Final	Baseline	Final	
1	45	25	70	50	3×
2	20	10	25	30	3×
3	20	10	30	35	2×
4	05	05	55	50	4×
5	20	0	25	0	1×
6	15	05	25	20	4×
7	20	15	20	20	1×
8	15	20	20	30	4×
9	20	15	30	35	1×
10	20	10	40	20	2×

TF, tinnitus frequency.

When measuring tinnitus with the use of VAS, we observed a difference in hissing- and whistle-type tinnitus reduction at the beginning and at the end of therapy (Table 1), without any change in pitch during the treatment. A significant reduction of whistle-type tinnitus occurred in six patients, with suppression of tinnitus in two patients at the end of treatment. However, in those with hissing-type tinnitus, the reduction was less noticeable, or the intensity remained the same, and in patient 7, who underwent chemotherapy, the authors even noted the onset of hissing in the side previously without tinnitus. The decrease of whistle-type tinnitus occurred even in patient 8, who did not achieve a good response to sound therapy, and whose HADS scores suggested anxiety and depression; this patient also noted no improvement on his THI, and an unaltered VAS for hissing. These findings suggest that the cortical representation of whistle-type tinnitus, expressed in acuphenometry by pure tone, can be more prone to modulation in the central nervous system. Nonetheless, considering the small number of subjects in this series, the authors cannot claim this as a hypothesis.

According to Figueiredo et al.,²⁵ there is a correlation between THI and VAS scores, which agrees with this study.

Throughout therapy, one to four adjustments of the volume and characteristics of the sound of generators were carried out until stabilization (Tables 3 and 4). New changes occurred at 15 and 18 months in both patients who worsened (patients 2 and 7).

In isolation, the intensity of tinnitus evaluated in acuphenometry did not indicate the success of the therapy. In all subjects, the baseline intensity decreased or was maintained at the same level, including in patient 8, who reported no significant improvement and did not show improvement in THI (Table 3).

Despite the reduction or maintenance of tinnitus intensity after treatment of these patients, there was a need to increase the volume of the sound generators during the therapy for all subjects (Table 3). Conversely, a reduction in MML with WN in eight patients occurred, with an increase at the end in the patient with worsening of hearing thresholds (patient 7) and also in that patient who did not improve (patient 8).

Thus, there was a correlation between intensity of tinnitus and MML WN intensity from the generator. With habituation, the tinnitus and the level of sound required to mask it quickly, as in MML WN, tended to diminish or stabilize, and the central nervous system tended to conform to the sound of generators, thus it became necessary to increase their volume (Table 3). Interventions throughout therapy were required to maintain the response.

The literature shows that the best option for habituation is broadband WN, because it is less bothersome and covers more frequencies;²³ however, the algorithms of the hearing aids enabled changes in their characteristics. Thus, this study used other support measures to evaluate and change the characteristics of sound generators: MML NB at the tinnitus frequency, and MML NB at 500 Hz.

The first had a response similar to that of MML WN, *i.e.*, volume reduction or maintenance in nine patients. However, this relationship was not observed with MML NB 500 Hz, (Table 4). Despite the fact that low frequencies are considered more relaxing compared to high frequencies, better

acceptance of changes to higher pitch was observed, but the acceptance was not good for modulation and rhythm changes.

This study also observed a relationship between THI and MML WN, which was reduced in patients with good responses to treatment and without major complications during therapy. Although Figueiredo et al.²⁶ did not observe this effect in their study, these authors did not compare THI and MML WN throughout the treatment, but only at their initial assessment.

Although several studies have demonstrated the importance of determining the mixing point for habituation of tinnitus, in the present study we did not consistently observe this, and noted it only in two patients (9 and 10) with 12 and 15 months of use of the sound generator, respectively. The findings of Tyler et al.²⁷ also showed that there was no need to determine the mixing point for habituation to occur.

Conclusion

It is possible that patients with whistle-type tinnitus have a better response to sound therapy.

A correlation of MML WN with THI during therapy was observed.

Apparently, there is a correlation of adjustments to sound generators with habituation of tinnitus, an aspect observed in these evaluations; this requires the customization of these settings, according to the patient's symptoms and their answers in matching pitch, loudness, and MML, which we performed on every patient's return.

The patient with response to HADS for depression did not respond well to treatment.

No relationship was found between the findings regarding location of tinnitus, presence of hearing loss, and type of sound generator with the other criteria evaluated in this study.

Conflict of interest

The authors declare no conflicts of interest.

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