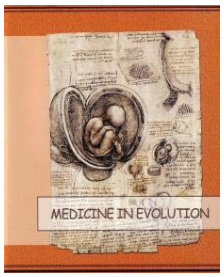
A Prescriptive Sound Amplification Method for Tinnitus Relief, Using Hearing Aids



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Abstract

Aim and objectives: To improve the quality of life of the tinnitus patients, using an innovative sound amplification algorithm, delivered via hearing aids.

Material and methods: Each subject served as his own control. Tinnitus Functional Index (TFI) questionnaire was used for tracking the progress of the therapy. Scores were calculated at the first presentation, 2 weeks, and 1, 3, 6 and 12 months after that. There were 15 adult patients with subjective tinnitus of non-tumoral etiology, 12 with tinnitus and hearing loss and 3 with tinnitus and normal hearing.

Results: After 12 months of therapy, a statistically significant decrease in TFI score was observed. The improvement was gradual for most of the patients.

Conclusion: The designed prescriptive amplification method is an efficient way of helping patients with disabling tinnitus, regardless of the fact that hearing loss is present or the hearing thresholds are normal.

Keywords: tinnitus, masking, prescriptive method, hearing aids, quality of life

INTRODUCTION

Tinnitus represents a perception of sounds in the absence of a real external source (1). Prevalence rates of tinnitus in general adult population is 8,2-20 %, rising to 18-30% in individuals over 50 years of age (2).

The quality of life of some of the tinnitus sufferers is severely affected, in areas as cognition, attention, performing daily professional and social tasks, resting and relaxing (2).

There are numerous therapies that are targeting to reduce the impact of the tinnitus on daily life of the sufferers, but none of them is offering a cure. The most commonly used therapies for tinnitus relief are sound therapies (1). These therapies include the use of maskers, TRT, music sounds etc.

For most tinnitus patients, the sounds of the noise generators, that have to be quite loud in order to be able to mask tinnitus, are producing both additional discomfort and difficulty hearing the useful environmental sounds. Also, for many of the tinnitus maskers, there is a need to change frequently the parameters of the masking sound, in order to remain effective (3).

Aim and objectives

Our aim is that by providing amplification of real environmental sounds in the frequency region of the tinnitus sound, we will obtain the masking of tinnitus, without adding the discomfort of an amplified sound that doesn't belong in the natural hearing environment of the patient.

Another aspect that we addressed is that as many as 75% of the tinnitus sufferers have an impaired capacity of speech understanding (4).

The speech intelligibility is further reduced when there is an artificial therapy sound overlapping the speech from the real sound environment of the patient. (5).

Therefore, another aim is that by amplifying the real environmental sounds situated in the frequency region of the tinnitus, we will provide a more appropriate stimulation of the classic auditory structures involved in processing and transmission of the sound signals.

MATERIAL AND METHODS

Participants inclusion criteria: the group of patients is represented by 15 adult patients, 8 men and 7 women. In order to include the patients in the study group, they have to comply with all the following inclusion criteria:

- unilateral or bilateral subjective tinnitus in the frequency range of 125-8000 Hz
- tinnitus older than 6 months, with or without hearing loss in the classic audiometry range 125-8000 Hz
- no active external or middle ear pathology at the time of first presentation
- Tinnitus Functional Index Questionnaire score in the category Moderate Problem or worse, at the first presentation
- no other parallel treatments for tinnitus

Design, equipment and method

Design: we used a single-case research design, each patient being his own experimental control for collecting and processing data at first visit in the audiology office, then at 2 weeks, 1 month, 3 months, 6 months and 12 months after the first intervention.

Equipment:

- one clinical audiometer (Harp by Inventis)
- one tympanometer (Flute by Inventis)
- one Levono laptop operating Connexx software with Audioservice hearing aids database

- 30 hearing aids, meaning 2 hearing aids per patient, operating on at least 6 frequency channels in terms of amplification and compression
- 90 Tinnitus Functional Index (TFI) questionnaires

Method: the patients presented with subjective tinnitus as main complaint, after being seen by ENT specialists that ruled out external and middle ear pathologies, as well as tumoral pathologies. For the 3 patients with normal hearing included in the study, tinnitus was the result of acoustic trauma, older then 6 months: one after 4 hours of exposure to loud music at a concert, two after military shooting training.

Each patient underwent the following audiological investigations: pure tone audiogram, speech audiogram, tympanometry, stapedius reflex. After these tests, the perceived tonality and level of intensity of the tinnitus were investigated. The patients had to match the frequency and the level of intensity of the tinnitus with warble tones provided via audiometer, in the range between 125-8000 Hz.

The patients were informed about the therapy steps and agreed to follow the protocol that consists in completing TFI questionnaire at the first presentation, then at 2 weeks, 1 month, 3 months, 6 months and 12 months after receiving the hearing aids.

All the patients received bilateral amplification, regardless of the fact that tinnitus was bilateral or unilateral. The decision was made based on the central auditory masking theory, that states that a sound coming from one ear is influencing the sounds perceived by the other ear, due to the simultaneous processing of the acoustic signals at the central cortical level (6). Also, there are studies showing that for many patients with unilateral tinnitus, that were provided unilateral sound therapy, the result was that tinnitus became evident in the contralateral ear, suggesting that tinnitus was in fact bilateral, but lateralized in the ear where it was louder (7).

The base amplification offered via hearing aids was prescribed by the NAL NL. NAL NL2 stands for National Acoustic Laboratories Non-Linear rationale and is the second release of the prescriptive methods created by this laboratory from Australia. The methods that are prescribing the gain as a function of frequency are called prescriptive methods. The NAL NL2 method is dedicated to hearing aids with Wide Dynamic Range Compression (WDRC).

The purpose of NAL-NL 2 is to amplify the frequencies found in the speech frequencial range, in order to obtain the maximum speech inteligibility, while keeping a confortable level for all the surrounding sounds (8).

To the gain prescription made by NAL NL2 rationale we added 10 dB gain for the main subjectively matched tinnitus frequency and for the frequencies within a 250 Hz interval below and above that (+/-250 Hz).

An important role in adjusting the amplification for tinnitus relief was played by the special setting of the compression system parameters of the hearing aids.

The purpose of any compression system is to adjust automatically the hearing aid gain, accordingly to changes in input levels. When properly implemented, the compression systems can maintain speech audibility over a wide range of input levels, resulting in improved speech intelligibility and quality while mainteining the loudness comfort (9).

The combinations we chose between compression threshold, compression ratio (CR) and times of attack and release were meant to allow enough amplification for the tinnitus region to be properly stimulated, and, in the same time, to prevent the loud sounds to become uncomfortably loud.

There are studies showing that the natural compression induced by the basilar membrane is having a CR between roughly 1.5:1 at 250 Hz and 3:1 at 1000 Hz and over (10).

These are the CRs that assure a natural hearing sensation and a proper speech understanding for a normal ear (11).

For the tinnitus ears, we decided to follow the natural model induced by the basilar membrane, in order to maximize the speech intelligibility potential. Therefore, we considered

that a one step compression ratio (CR) of 2, for the subjectively perceived tinnitus frequency and the frequencies in the +250/-250 Hz range from the main frequency, would prevent the patient to have unpleasantly loud hearing sensation, while not introducing additional distortions of the sound. For the rest of the frequency domains we used a one step CRs between 2 and 2.5.

We used syllabic compression attack and release times, because syllabic compression is fast. This means that it can fit the speech attributes, as syllables and even separate phonemes into the dynamic range of the hearing impaired patien. Therefore, using a syllabic compression helps to restore an abnormal loudness growth to normal. Syllabic compression is characterized by short attack and release times, smaller then 150 ms, a compression ratio under 4, and usually a threshold under 50 dB. (12).

We modified the syllabic compression using fixed thresholds of 60 dB for the tinnitus main frequency, for the +/- 250 Hz domain and the frequencies above that, and under 50 dB. for the lower frequencies.

The intended effects of the specifically designed pattern of amplification, beside bringing the hearing threshold in the normal range, are:

- the intense stimulation, retraining and remapping of the neural segments responsible for sound processing in the frequency area affected by tinnitus
- to provide a masking effect of the tinnitus using exclusively environmental sounds

The provided hearing aids used data logging. The patients were wearing the devices a minimum of 6 hours daily and a maximum of 17 hours daily in all kinds of hearing environments, without experimenting uncomfortable hearing issues: quiet, speech in noise, speech in quiet, music, traffic, party noise.

For tracking the changes of tinnitus perception, we used for each patient the Tinnitus Functional Index (TFI) developed in 2014 by Henry JA et al. (13).

TFI is a questionnaire calibrated for evaluation of the effects that tinnitus has on the quality of life of the patients. In its final shape, TFI includes eight subscales.

First subscale is referring to how intrusive tinnitus is felt by the patients, second about the feeling of keeping the control, third about cognitive impact, fourth about how tinnitus affects the sleep, fifth about impact on hearing, sixth about the capacity of the patient to relax, seventh about general perceived quality of life and the last one is about emotional impact of tinnitus.

Each subscale comprises three questions, with the exception of the Quality of Life subscale, which comprises four points.

We calculated the TFI score of each questionnaire according to the authors guidelines: we add the total points, then divide the sum by 25 and multiply it by 10.

Also, we used the score interpretation scale recommended by the authors of the TFI in order to established the categories of the tinnitus impact:

Not a problem: M=14 (range of score: 0–17)

Small problem: M=21 (range of score: 18–31)

Moderate problem: M=42 (range of score: 32–53)

Big problem: M=65 (range of score: 54–72)

Very big problem: M=78 (range of score: 73–100) (13).

The authors of TFI Questionnaire considered that a therapy can be considered succesful if the score after applying it comparing to the initial score is bigger then 13 points (13).

The National Institute for Health and Care Excellence (NICE) recommends, in the most recent guidelines, a difference of 18 points in order to consider a therapy succesful (NICE, 2018).

TFI is used both in clinical practice and in research studies, because its proven sensitivity to changes obtained as a result of different interventions methods. Also, TFI is an

excellent tool for evaluation of the general impact of tinnitus, because is covering the broad areas affected by tinnitus (13).

Therefore, we applied TFI questionnaires at the first visit of the patient, then at 2 weeks, 1 month, 3 months, 6 months and 12 months after initial fitting of the hearing aids.

Based on the score obtained at the first presentation, we selected and included in our study only the patients that falled into the categories: Moderate, Big and Very Big problem.

Clinical variables of the patients:

Table I. The 15 patients included in the study by gender

The 15 patients included in the study by gender		
	N	%
Female	7	46.7
Male	8	53.3

Characteristics of the study group:

We selected for our study only the patients that are feeling a strong discomfort caused by the tinnitus, with the total scores at TFI over 32 points (category Moderate Problem or above) at first presentation.

Table II. TFI scores over presentation

TFI scores over presentation				
	Mean ± SD	Median (range)	Percentile 5%	Percentile 95%
TFI score at first presentation (baseline)	77.2 ± 12.3	79(56 - 100.4)	56	100.4
Anova - Analysis of variance and covariance P = **0.0001**				

Most of the patients in our lot have also hearing loss beside tinnitus, with an average Pure Tone Threshold of 50 dB for both ears and an average tinnitus frequency of 2000 Hz. The patients were suffering with tinnitus from minimum 6 months, with an average of 12 months since onset, and tried up to 3 therapies until they addressed us.

Table III. Characteristics of the study group

Characteristics of the study group				
	Mean ± SD	Median (range)	Percentile 5%	Percentile 95%
Age of the 15 patients at the inclusion (years)	50.5 ± 17.9	48 (21 - 73)	21	73
Time from tinnitus onset (months)	17.4 ± 13.0	12(6 - 50)	6	50
PTA right ear (dB)	49.0 ± 30.5	50 (0 - 100)	0	100
PTA left ear (dB)	47.0 ± 16.9	50 (12.5 - 78.75)	12.5	78.75
Right ear average *tinnitus* frequency (Hz)	2192.3 ± 1797.4	2000 (500 - 6000)	500	6000
Left ear average *tinnitus* frequency (Hz)	2766.7 ± 1960.5	2000 (250 - 6000)	250	6000
Nr. of therapies tried before	0.9 ± 1.2	1(0 - 3)	0	3
Median = percentile 50%; Range = minimum – maximum; Minimum = percentile 0%; Maximum = percentile 100%				

RESULTS

The median score at the first presentation was 79 points. We applied the innovative amplification algorithm based on NAL-NL2 prescriptive method on first presentation, then made small gain and compression ratio adjustments based on the feedback received from the patients at 2 weeks, 1 month, 3 months, 6 months. The patients completed the TFI Questionnaire at first presentation, then 2 weeks, 1 month, 3 months, 6 months and 1 year after the first presentation, with the following distribution of scores:

Table IV. TFI scores over presentation

TFI scores over presentation				
	Mean ± SD	Median (range)	Percentile 5%	Percentile 95%
TFI score at first presentation (baseline)	77.2 ± 12.3	79(56 - 100.4)	56	100.4
TFI score 2 weeks	65.8 ± 10.7	68.4(44.8 - 87.6)	44.8	87.6
TFI score at 1 month	55.6 ± 13.3	56.4(21.6 - 74.8)	21.6	74.8
TFI score at 3 months	42.1 ± 12.8	42(10 - 63.2)	10	63.2
TFI score at 6 months	36.5±13.7	34(10 - 73)	10	73
TFI score at 12 months	26.8±10.7	26.4(2 - 46.4)	2	46.4
Anova - Analysis of variance and covariance P = **0.0001**				

We can observe a decreasing tendency of the overall score from one moment of presentation to the next one, with a significant median decrease of overall score already after the first month of therapy of 22.6 points. The score difference between the first presentation and the last one, after 12 months, is 52.6, which points to a significant improvement in tinnitus management.

Table V. Changes (decrease) in TFI scores

Changes (decrease) in TFI scores				
	Mean ± SD	Median (range)	Percentile 5%	Percentile 95%
TFI score at 2 weeks change from baseline	-11.4 ± 12.1	-11.4[(-44.8) - (-0.4)]	-44.8	-0.4
TFI score at 1 month change from baseline	-21.6 ± 14.6	-21.6[(-66.4) – (-10.0)]	-66.4	-10
TFI score at 3 month change from baseline	-35.1 ± 18.2	-35.1[(-78.0) – (-16.4)]	-78	-16.4
TFI score at 6 month change from baseline	-40.7 ± 16.3	-40.7[(-78.0) – (-18.2)]	-78	-18.2
TFI score at 12 month change from baseline	-50.4 ± 15.3	-50.4 [(-86.0) – (-29.6)]	-86	-29.6
Anova – Analysis of variance and covariance P = **0.0001**				

We analyzed the decrease in TFI scores with Anova – Analysis of variance and covariance (P = 0.0001) and with the Kruskal-Wallis rank testand observed the individual variability of the results.

Table VI. Percentage of decrease in TFI scores

Percentage of decrease in TFI scores					
	Median	Minim	Maxim	Percentile 5%	Percentile 95%
TFI score at 2 weeks change from baseline	-44.6%	-0.6%	-44.6%	-0.6%	-44.6%
TFI score at 1 month change from baseline	-22.1%	-75.5%	-14.2%	-75.5%	-14.2%
TFI score at 3 month change from baseline	-39.8%	-88.6%	-22.7%	-88.6%	-22.7%
TFI score at 6 month change from baseline	-47.4%	-88.6%	-20.0%	-88.6%	-20.0%
TFI score at 12 month change from baseline	-67.7%	-97.7%	-42.5%	-97.7%	-42.5%
Kruskal-Wallis rank test P = **0.001**					

The tendency of overall scores is to decrease. The nonlinear decrease of the score is due to the fact that tinnitus is affecting the individual in a complex manner. For our lot of patients, the pattern of the scores improvements did not correlate with the degree of hearing loss, the duration since the onset of tinnitus, the frequency region of the tinnitus or the subjective perceived loudness.

Table VII. TFI evolution intepretation

TFI evolution intepretation			
	TFI	N	%
Baseline	Not a problem: range of score: 0–17	-	-
	Small problem: range of score: 18–31	-	-
	Moderate problem: range of score: 32–53	-	-
	Big problem: range of score: 54–72	5	33.3
	Very big problem: range of score: 73–100	10	66.7
2-nd presentation	Not a problem: range of score: 0–17	-	-
	Small problem: range of score: 18–31	-	-
	Moderate problem: range of score: 32–53	1	6.7
	Big problem: range of score: 54–72	10	66.7
	Very big problem: range of score: 73–100	4	26.7
3-rd presentation	Not a problem: range of score: 0–17	-	-
	Small problem: range of score: 18–31	1	6.7
	Moderate problem: range of score: 32–53	5	33.3
	Big problem: range of score: 54–72	7	46.7
	Very big problem: range of score: 73–100	2	13.3
4-rd presentation	Not a problem: range of score: 0–17	1	6.7
	Small problem: range of score: 18–31	1	6.7
	Moderate problem: range of score: 32–53	10	66.7
	Big problem: range of score: 54–72	3	20
	Very big problem: range of score: 73–100	-	-
5-th presentation	Not a problem: range of score: 0–17	1	6.7
	Small problem: range of score: 18–31	2	13.3
	Moderate problem: range of score: 32–53	11	73.3
	Big problem: range of score: 54–72	-	-
	Very big problem: range of score: 73–100	1	6.7

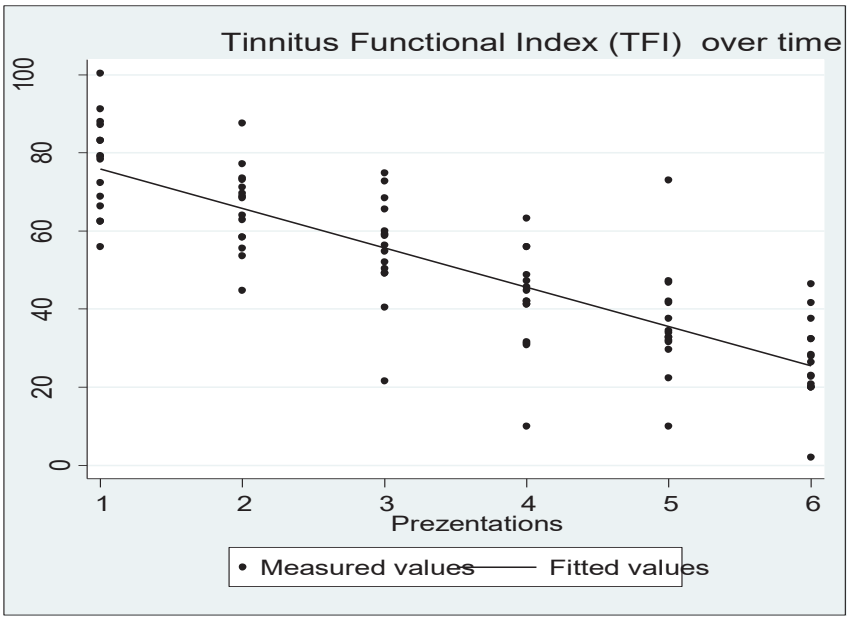

Figure 1. Tinnitus Functional Index (TFI) over time

DISCUSSIONS

Our proposed therapy is involving complex sensory and nervous structures, addressing tinnitus both by offering masking through amplifying environmental real time sounds, and by training the auditory pathways in the regions affected by hearing loss and tinnitus.

There are many studies that suggest that the atypical sensorial perceptions, as tinnitus, hyperacusis and distorted perception of the sounds, are, at least partially, the result of plastic changes at the level of central nervous system, following hearing loss or different nervous structures damage. Neural plasticity involves modified ways of processing auditory information and rerouting for transmitting it. Even more, there are imagistic proofs that neuroplasticity implies non-classical auditive structures in sound perception, creating cross-modal interactions that could explain emotional reactions of the tinnitus sufferers. (5)

Therefore, we believe that by providing additional stimulation and sound clues from the frequency region of the tinnitus, there is a possibility to decrease the tinnitus occurence, the tinnitus perceived intensity, as well as decrease the distorsion of the real sound signals and increase the speech understanding.

Our algorithm uses amplified sounds centered on the subjectively perceived tinnitus frequency, with 250 Hz above and 250 Hz below it. In this way, the masking frequency range included native frequencies of the specified domain, as well as formants of the lower frequencies, assuring a dynamic and varied composition of the masking sounds.

As the nervous plasticity and emotional response to tinnitus is different in every patient, we can also observe the variability of score improvement between individuals. All the patients that followed a full course of 12 months of therapy reported an improvement in their tinnitus management. They declared they are willing to continue to use the amplification as a longterm therapy.

CONCLUSIONS

The proposed therapy has the potential to reduce the impact that tinnitus is having on patients lives. It seems that the longer the therapy is followed, the better results are obtained. Our target for the future is to analyze the manner in which our therapy is influencing the

score for each subscale of TFI, as a function of the duration of the therapy, using a bigger lot of patients.

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