The combined counselling and low level laser stimulation are effective in the treatment of disturbing chronic tinnitus

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INTRODUCTION

Tinnitus is the perception of a "phantom" sound which does not actually exist (Jastreboff, 1990). It is an often disabling symptom of different disorders affecting the auditory system and it can be associated with a wide range of pathological conditions. Tinnitus must be distinguished from real auditory hallucination which is a symptom of psychiatric or neurological disorders.

The patient's ability to tolerate tinnitus varies; those patients who seek treatment have not been able to develop the habit of living with the symptom. It is generally thought that most of the people who seek treatment for "auditory buzzing" benefit simply from clinical examination and from the doctor's reassurance about the benign nature of the symptom. Yet, for those needing further treatment, there are several different therapeutic approaches available today which are usually multidisciplinary. These are specific treatments, aimed at balancing the effects of the disorder; only in rare cases treatment leads to reduction or disappearance of tinnitus.

The present work was carried out with the objective of assessing effectiveness of the combination of two different therapeutic strategies – in perspective and in a controlled manner – for which preliminary effectiveness tests gave conflicting results. The combined strategies are: counselling and low-level laser stimulation.

MATERIALS AND METHODS

Recruitment criteria

46 adult patients (range 28-83 years; mean 56.4, sd 13.7) that consecutively sought treatment from the Authors at the tinnitus clinic of the Hospital Guglielmo da Saliceto in Piacenza were studied. 27 of them were male, while 19 were female. The recruitment criteria were the following: patients were adults who had been treated at the clinic for at least 3 months for – as main symptom – disturbing non-intermittent subjective tinnitus. Whereas patients with frank pre-existing psychiatric pathology (psychosis, major depression, etc.), those with "retrocochlear" pathology (acoustic neurinoma, etc.) and those cases involving medical-legal disputes related to tinnitus were excluded. Recruited patients received detailed information on the objectives of the trial, on its possible benefits and its potential risks. All recruited patients signed an informed consent form on the trial.

Randomization

Patients were treated with the same combined counselling protocol. However, they were subdivided into two different groups. Only one of them was subject to low-level laser stimulation. The first group was defined 'LLS –' (control group) and the second, which received the real combined treatment 'LLS+' (experimental group). Randomization was carried out by one of the authors but the real kind of stimulation applied was not revealed to the second author, until assessment on a specific patient was completed.

The **experimental** group (LLS+) was treated with **combined counselling and low-level laser stimulation**. The **control** group was instead treated with **counselling** and with a kind of stimulation which appeared identical to the active one, but which had no laser emission (placebo).

Low-level laser stimulation (LLS)

A laser device emitting cold light (TinniTool EarLaser©, DisMark GmbH, Maur, Switzerland, www.tinnitool.com) was used. The emission power was 5mW and the wavelength was 650nm. The system was composed by an emitting body equipped with a probe to be placed at the entrance of the external auditory canal from where the laser ray was directed towards the ear-drum. For more comfort during the therapy, the laser was coupled to a wearable ear hook. Patients were trained to use the device for 20 minutes a day, every day for three months.

For the placebo group, the device was identical to the active one as to appearance and weight; because the laser irradiation did not cause any sensation, it was impossible for any patient to detect the real nature of the stimulation received. The instructions were the same given to group LLS+.

Combined counselling

Each patient was subject to the same standardized protocol of combined counselling. This envisaged 10 sessions of 40 minutes each regularly distributed during the three-month treatment. Combined counselling envisaged the combination of two different approaches: a cognitive and a psychosomatic approach. Cognitive counselling was based on the Tinnitus Retraining Therapy principles (Jastreboff, 1996; Hazell, 1998). The objective was to promote habit and thus eliminate the problem, by removing any negative association to tinnitus. It comprised exhaustive discussions about the causes and the meaning of tinnitus, as well as about the anatomo-physiology of ears and auditory canals in order to understand and demystify the symptom.

The second component of combined counselling – i.e. the psychosomatic approach – focused on a particular emotional state of the interlocutor and comes from the combination of hypnotic techniques with relaxation techniques based on respiration, proprioception and insight (Colombo & De Caria 2003). The stress-causing and inhibited factors and the reactive reflexes associated to them are identified. The objective is to rehabilitate the cerebral centre responsible for the perception of the disorder by favouring filtering and blocking of the signal causing tinnitus. The hypnotic techniques used are those described by Milton H. Erickson (1992), aimed at developing higher ability to handle the symptom by increasing the patient's reactive potential and by causing a "change" in the response to the symptom. The objective of hypnosis is to change the patient's behaviour, sensorial responses and state of conscience by providing new ways of thinking, feeling and acting about the symptom. In order to meet these objectives, different resources by Erickson, such as metaphors and direct hypnosis, have been used. Moreover, relaxation techniques described by Jakobson (1952) were used. This method consists in letting the patient contract muscle segments or groups and then letting them progressively relax in a variable period of time. These exercises are effective in patients who are scarcely aware of their body and their tonic response.

Indicators

Patients were subject to a general medical-hearing assessment comprising medical history, otomicroscopy, audiometry and impedancemetry. If necessary, in order to make the hearing diagnosis, the ABR, ENG and MRI and OAE tests were carried out. Moreover, for descriptive purposes, tinnitus tests were performed and the Tinnitus Handicap Inventory (THI), developed by Newman et al (1996), was submitted to patients.

The THI score represented the basic tinnitus seriousness indicator and was taken at the beginning and at the end of the treatment. It was considered both in the form of rough scores (variable from 0 to 100) and in the form of classes of seriousness. Classes of seriousness are codified as follows (Cuda 2004): slight tinnitus (THI score 0-25), medium (score 26-50), serious (score 51-75) and catastrophic (76-100).

Data analysis

Descriptive statistics for all variables were drawn up. As to the differences between the groups, the analysis of the variance (ANOVA) was performed for continuous variables while for nominal variables a chi-square analysis was performed. Analysis was conducted through a statistics programme SPSS14.

RESULTS

Description of the sample

Tinnitus was localized in the right ear in 7 patients (15.2%), in the left ear in 10 (21.8%) while it was bilateral in 29 (63%). The symptom had been present from 3 months to 45 years (mean 6.4 sd 8.8).

From an audiometric point of view, 7 patients were normally hearing persons (15.2%) and 21 were presented with a slight neurosensorial hearing impairment (45.7%). 60.9% of patients had therefore no significant hearing impairment while the other cases were as follows: low-medium neurosensorial hearing impairment in 6 patients (13%), medium in 8 (17.4%), medium-serious serious in 1 patient (2.2%) and profound in 3 patients (6.5%). No patient presented with transmission or mixed hearing impairment. All patients affected by hearing impairment of medium or higher level regularly wore air-conduction hearing aids.

The pre-treatment THI score was 49.1 (range: 8-94; sd: 22.6). The disorder classification was as follows: Slight tinnitus 9 (19.6%), Medium 16 (34.8%), Serious 12 (26.1%), Catastrophic 9 (19.6%).

20 patients were assigned to the "LLS-" group and 26 to the "LLS+" group. All patients completed the treatment protocol and there was no abandonment.

Differences between groups

- Entire sample

No patient presented with deterioration or other significant changes in the audiometric threshold at the end of the trial. Moreover, no otomicroscopic lesion on the auditory canals or eardrums was observed.

At the end of the treatment, the average THI score was 36.2 (range 8-84; sd. 19.9). Tinnitus was classified as slight (14 cases; 30.4%); medium (21 cases; 45.7%); serious (9 cases; 19.6%); catastrophic (2 cases; 4.3%). The difference between pre- and post-treatment THI was statistically significant ($t=2.882$; $p=0.005$). The difference between this and the initial distribution was statistically significant (Chi2-test; $p<.01$).

- LLS- vs LLS+

A synthesis of the statistical analysis for continuous variables is shown in table I. The age turned out to be different in the two subgroups in a statistically significant way (ANOVA; $p<.000$) and precisely: in the experimental group LLS+ it was inferior to that of the LLS- group (50.3 vs 64.4). As to the duration of tinnitus, the pre- and post-treatment THI scores did not significantly differ between the two subgroup. On the contrary, the difference between the pre-treatment THI and the post-treatment THI (deltaTHI) scores was statistically higher in the experimental group LLS+ in comparison with LLS- (17.1 vs 7.3) (ANOVA; $p.<.05$).

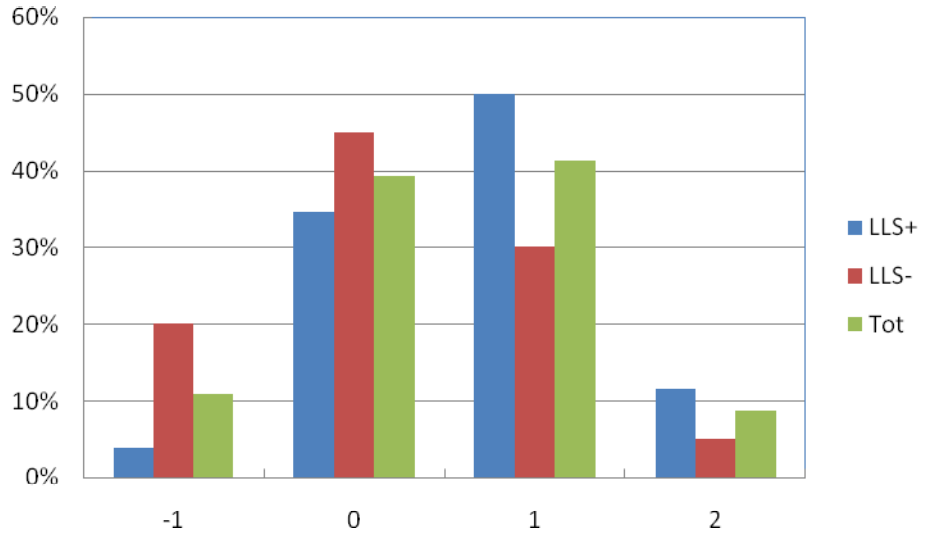
Table I

analysis of the variance (ANOVA) relative to continuous variables in a group of patients with disturbing tinnitus who underwent treatment with counselling and low-level laser (LLS+) or only counselling (LLS-)

		n	mean	sd	min	max	F	Sig.
age	LLS-	20	64,4	14,1	28	83	15,9	,000
	LLS+	26	50,3	9,8	31	76		
	Total	46	56,4	13,6	28	83		
duration	LLS-	20	8,4	10,6	,3	45	1,9	,170
	LLS+	26	4,8	6,8	,3	26		
	Tot	46	6,4	8,8	,3	45		
THIpre	LLS-	20	43,1	22,1	8	86	2,5	,117
	LLS+	26	53,6	22,3	14	94		
	Tot	46	49,1	22,6	8	94		
THIpost	LLS-	20	35,8	18,9	8	74	,02	,893
	LLS+	26	36,6	21,1	10	84		
	Tot	46	36,2	19,9	8	84		
deltaTHI	LLS-	20	7,3	15,4	-20	42	4,1	,040
	LLS+	26	17,1	16,7	-18	48		
	Tot	46	12,8	16,7	-20	48		

Intergroup differences (LLS- and LLS+) between nominal variables were analyzed with the Chi^2-test. No statistically significant difference as to tinnitus side, auditory threshold class and tinnitus classification was revealed.

In picture 1 pre-post differences of tinnitus classification are shown. Taking into consideration the total population, the tinnitus class remained unchanged in 18 cases (39.2%), improved in 23 cases (50%) and precisely, improved by one class in 19 cases (41.3%) and by two classes in 4 cases (8.7%). Only in 5 cases (10.87%) there was a one-class worsening. In the **placebo** group the class remained **unchanged in 9 cases** (45%) while it **improved in 7** (35%); a **one-class improvement in 6 cases** (30%) and a **two-class improvement in 1** (5%); the class **worsened in 4 cases** (20%). In the **experimental** group there was an **overall improvement in 16 cases** (61.6%) and precisely, by **one class in 13 cases** (50%) and by **two classes in 3 cases** (11.6%); there was a **worsening in one case** (3.8%) and the remaining **9 cases** (34.6%) **remained unchanged**.



Picture 1: improvement in the tinnitus seriousness class, in comparison with pre-treatment staging. The negative sign indicates class worsening, 0 indicates that the class is unchanged, +1 and +2 indicate an improvement by one or two classes respectively. LLS+: patients treated with active laser. LLS-: placebo group. Tot: entire group.

DISCUSSION

In the present trial a non-selected sample of patients affected by chronic disturbing tinnitus – referred to as main symptom – was treated with combined counselling method, involving an information and a psychosomatic component and associating hypnotherapeutic and muscle relaxation techniques. **The result indicator – taking into consideration the THI score – was significantly reduced thanks to the treatment**. The effectiveness of counselling on the treatment of tinnitus is already known (Jastreboff, 1996; Hazell, 1998). The effect of the various relaxation techniques in patients suffering from chronic tinnitus was assessed in a number of controlled trials (Kirsch et al. 1987; Davies et al. 1995; Kroner-Herwig et al. 1995; Winter et al. 1996; Dineen et al. 1997); although there is no final proof of their effectiveness on the perception of the tinnitus, a reduction in the symptoms associated with stress and anxiety – and thus an improvement in the acceptance of the symptoms – was observed. The effect of hypnosis was documented in different studies (Marks et al. 1985, Attias et al. 1993, Mason et al. 1996, Kaje et al. 1994, Ross et al. 2007) sometimes with conflicting results but with a general trend towards higher tolerance to symptoms by those involved in the research.

In our study, counselling and hypnotherapy had generally a good effect on the whole group observed. Relaxation techniques were used also at home, in difficult moments and to help getting to sleep which is a critical moment for patients affected by tinnitus because the perception of sounds in the ear is facilitated by silence. Elderly patients showed diligence and understanding to the therapeutic program. They enjoyed increasing care for their body, rediscovering it and finding new strategies to reduce concomitant physical disorders (dyspnoea, muscle-tension pain due to arthritis). Having more spare time, they could exercise at home more constantly. Regular exercise became an important part of their daily life and led to positive thinking. The chance to talk was perceived by them as a sign of care which balanced the lack of affection often showed to the elderly. The opportunity to know that they could benefit from a therapy which could help them relax and observe the single elements which compose their pathological "syndrome" acts as a tranquillizer: as a matter of fact, the fragmentation of symptoms reduces the impact.

The second conclusion of our trial **is a significant difference in the benefit of the treatment between group LLS+ and group LLS-**. Although the random anomalous distribution of age – which determined the group subject to laser stimulation to be younger than the placebo group – must be taken into consideration (the sampling procedure did not take into account the age of the patients), this result must be traced back to the different stimulation applied; no other difference was revealed between the subgroups LLS+ ed LLS-, as far as the characteristics of the population were concerned, such as the duration of symptoms, the distribution according to hearing loss levels, tinnitus side or perceived pre-treatment seriousness. **Therefore, 61.6% of the patients treated with laser improved by at least one class if compared to 35% of the placebo group** (pic.1). The average improvement in terms of THI score was 17.1 vs 7.3.

In the literature, the results of low-level laser stimulation are rather contradictory. For example, Partheniadis-Stumpf et al. (1993) reported an improvement in 3 cases, yet 5 were uncertain as to the results of the treatment and in 20 cases tinnitus remained unchanged. In their trial, however, the administration of a drug (Tebonin) was combined with a stimulation protocol which envisaged twelve laser applications on the top of the mastoid bone of 10 minutes each. The trial lasted three weeks and the success criterion was based only on patients' judgement. Therefore, the protocol cannot be compared to that of the present work. Shiomi et al (1997) used instead a transmeatal stimulation, though more powerful than that of the present trial (40mW with a wavelength of 830 nm). The protocol used by the Authors envisaged irradiation for 9 minutes a week for 10 or more times. The 28 patients recruited for the trial had to give a score to their symptoms on a 5-point scale before and after the end of the treatment. 55 and 58% presented with an improvement in loudness and annoyance level. So the Authors conclude that laser therapy deserves being tried on patients affected by untreatable tinnitus. Instead, the trial by Mirz et al. (1999a) led to opposite conclusions.

This was a clinical controlled trial envisaging a 50 mW laser stimulation (wavelength 830 nm) and a placebo group. The protocol envisaged the transmeatal irradiation for 10 minutes a session. No statistically significant difference was revealed between the placebo and the active group in the 49 patients recruited as to a series of indicators including VAS for loudness, annoyance and attention, as well as score THI. Similar results were described by Nakashima et al (2002). The irradiation was transmeatal also in this case and was 60-mW. It was supplied for 6 minutes once a week for a total period of four weeks. The result indicators considered were based on a questionnaire submitted to 45 recruited patients. Between the active and the placebo group no difference was reported in terms of loudness, duration, quality and annoyance of tinnitus. Moreover, a patient receiving irradiation presented with acute hearing deterioration after the third irradiation.

Unlike Nakashima et al (2002) results, no cases of deterioration of the auditory threshold were reported in our sample. Also in this case, it must be underlined that our protocol was different (higher power for shorter irradiation periods). The importance of technical aspects was emphasized by Tauber et al. (2003) who have been able to verify positive effects in a sample of 38 patients affected by chronic tinnitus through an appropriate control of dosimetric variables. Also, in this trial power emissions were lower than those used in the trials mentioned above (7.8 e 20 mW). Gungor et al. (2007) carried out a controlled trial with an application protocol similar to that of the present trial. The laser power was 5 mW and the wavelength was 650 nm. It was transmeatal and applied for 15 minutes a day for a week. A questionnaire was submitted to the 45 recruited patients where the symptoms were classified according to a 5-point scale before and after the treatment. Tinnitus loudness, duration and annoyance level improved respectively in 48.8, 57.7 and 55.5% of the patients with active laser whereas in the placebo group no significant change was reported. Indirect support to the conclusions of the trial comes from the recent study carried out by Siedentopf et al. (2007) who documented – through the functional MRI – the activation of different cerebral areas (left superior frontal gyrus, right middle frontal gyrus and right superior parietal lobe) through low-level transmeatal laser stimulation. The placebo application, randomly alternated to laser stimulation and indistinguishable by the patient, did not determine any neurological activation. Moreover, the activated cerebral areas correspond to those affected in tinnitus patients, as shown by PET surveys (Lockwood et al. 1998; Mirz et al. 1999b).
The low-level laser action mechanism is biophysiological rather than thermal (Rochkind et al 1988). The primary site of neuronal absorption is represented by mitochondria with consequent release of cytoplasm of H^+ protons. The permeability of the drum for the ions Na and K is eliminated by the result of the reduction in action potential (Karu, 1988). The effect inhibiting the action potential was shown through a trial after laser stimulation of the cochlea through the round window (Shiomi et al. 1997). Another mechanism is the increase of blood flow (Schaffer et al. 2000) due to sympathetic neural inhibition. However, there are also other different mechanisms, such as an increase in cell proliferation (Hans et al. 1992), in ATP synthesis (Passarella et al. 1984) and in collagen (Reddy et al. 1998).

The small number of case histories at disposal (in any case limited to tens of patients) and the differences in application protocols do not allow comparison of case results. The conclusions of our trial should therefore be proven through a greater multicentric controlled clinical trial with an accurate definition of the indicators, although preliminary data suggest favourable effect of the device in the otologist's therapeutic equipment.

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ABSTRACT

46 adult patients affected by disturbing tinnitus present for at least 3 years were recruited. All of them were treated with a combined counselling protocol comprising information and a psychosomatic component where hypnotherapeutic and muscle relaxation techniques were applied. 26 patients were randomly assigned to the group with low-level laser stimulation treatment and 20 to the placebo group. The laser power was 5mW and the wavelength 650nm. The irradiation lasted 20 minutes a day for three months. The THI questionnaire was submitted at the beginning and at the end of the treatment. The THI scores improved in the entire sample thanks to the treatment **but more significantly in the group subject to low-level laser stimulation. From the point of view of clinical classification, around 61% of irradiated patients improved tinnitus seriousness by one class** in comparison to 35% of the placebo group.

Key Words: Tinnitus, soft laser therapy, TinniTool, EarLaser, www.tinnitool.com, Ericksonian hypnosis.