LOW LEVEL LASER THERAPY: TINNITUS SUBJECTIVE CHARACTERISTICS AND MEASUREMENTS.

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BACKGROUND/AIMS

Low-level-laser-therapy (LLLT) targeting the inner ear has been recently discussed as a therapeutic procedure for cochlear dysfunction such as chronic cochlear tinnitus or sensorineural hearing loss.

There are laser-induced effects on cell proliferation, synthesis of ATP and collagen, decrease of hypoxic injury and reductive stress, release of growth factors and enhancement of wound healing. Former studies demonstrate biological and physiological effects of LLLT such enhanced recovery of peripheral nerve injuries, which could be of therapeutic interest in cochlear dysfunction. In the inner it promotes the local blood flow ear and activates repair mechanism through photochemical and photo- physical stimulation of the mitochondria in hairy cells.

The radiation emitted by the low-level- laser is controlled in such a way that neither generates heat nor causes a change in human tissue. The low-level- laser given rise to “bio-stimulation”, i.e. endogen function circuits and regulating systems are stimulated to encourage the regeneration of damaged or out- of- balance microstructures such as nerve fibres for instance and to restore their functions. In addiction, mitochondria for various metabolism processes can be formed at an increased rate and made available in the treated cells.

Variations of the energy of electromagnetic radiation go to show that proof of the effects of laser light on cells can only be established in certain frequency ranges. In this context, the wavelength (energy) region of electromagnetic radiation between 600 and 850 nm (red spectral region) seems to be particularly efficient. LLL radiation from the red and near infrared region corresponds exactly with the energy and absorption levels relevant to the respiratory chain. This indicates that LLL radiation directly stimulates the components of the antennae pigments of the respiratory chain and thus effect an immediate vitalization of the cell by increasing the mitochondrial synthesis of ATP. This kind of stimulation can bee seen as a biological resonance of different size and form, which resonate with a specific wavelength (energy) of electromagnetic radiation and can utilize the energy of the radiation in a functional way, that is, convert it for regulation processes in the cell.

Significant reduction of tinnitus intensity after LLT was reported by different authors in a range of 15% of patients, up to 67% of patients, whereas in other studies the relief of tinnitus by laser-irradiation was supposed to be placebo-induced too. Only Wilden described improvement of hearing threshold shifts in more

than 80% of patients, while the other studies, dealing with low-level-laser-therapy of the inner ear did not observe significant changes in auditory threshold.

The comparison of therapeutic outcome rates among all those studies is difficult, because differences in technical parameters, targets of irradiation, treatment schedules and study design are obvious. Moreover the therapeutic outcome was quantified only by self-assessment on visual analogue scale (VAS) or by changes of scale in loudness or duration or annoyance degree of tinnitus. Whereas, for a complete and peer evaluation of the patients affected by tinnitus, is necessary to collect information both, about the subjective characteristics of tinnitus described by the patients, and the characteristics of the measurement of tinnitus as described in the protocol proposed by Savastano.

Up to now, the complete evaluation of the tinnitus subjective characteristics and the tinnitus measurements after LLT treatment did not have been described.

The present study refers to the results obtained from the application of the above mentioned protocol to a tinnitus population, before and after the application of LLT, comparing the complete tinnitus data referred by patients with those obtained through audiometric measurement.

METHODS

This study considered 49 consecutive tinnitus sufferers, 24 females (mean age 57 years) and 35 males (mean age 54 years), observed by the ENT Section of the Department of Medical-Surgical Specialities of Padua University. In the study were included all tinnitus sufferers who sought help from an ENT Specialist only for this symptom.

Exclusion criteria comprised the presence of otosclerosis, acute labyrinthine damage, acoustic neuroma, chronic decompensate metabolic disorders, psychiatric disorders. Patients taking drugs with a possible influence on tinnitus status were also excluded from the study.

All patients (G1) underwent the application of a Soft Laser system, consisting in a Medical Laser with 5mW output power and 650nm wavelength and the headset EarTool (fibreglass optical fibre in the ear), applied to all the patients 1 x per day, 20 minutes, for three months. The device was conceived so that treatment could be carried out at home.

As control group (G2) were considered 10 subjects who underwent the application of a Laser placebo, without any radiation, with the same modality of the sample group.

The data have been collected before the first LLT application (=T_0) and after three months of treatment (T_3).

The following parameters were considered. The subjective discomfort caused by tinnitus, was tested using a *Visual Analogue Scale* (VAS). These levels are divided into 3 types of discomfort:0-2: slight; 3-6: moderate; 7-10: elevated. Moreover tinnitus annoyance was studies using the *Tinnitus Handicap Inventory* (THI) which

help to identify the degree of problems that tinnitus may be causing. It grades 5 categories of tinnitus severity: 1. Slight; 2. mild; 3. moderate; 4. severe; 5. catastrophic.

The audiometric evaluation was performed using liminar audiometry. The sample was divided into two groups: Group A= subjects with normal hearing; Grup B= subjects with hearing loss. Audiometric threshold was considered as the pure tone average for the frequencies 0.5-1-2-4-8 KHz and divided according to the Bureau International D'Audiophonologie as follows: normal hearing (<20 dB); light hearing loss (21-40 dB); moderate hearing loss (41-70 dB); severe hearing loss (71-90 dB); Profound hearing loss (>90 dB). Audiometric results were grouped into three categories: conductive hearing loss; sensorineural hearing loss high frequency; low frequency; flat curve; mixed loss.

Tinnitus measurements included: stimulus matched to tinnitus (pure tone, narrow band, white noise), tinnitus loudness, spectral composition, masking effectiveness and residual inhibition. The pitch of the tinnitus (high-pitched or low- pitched) was determined by a matching procedure and the difference between the hearing threshold and sensation level was considered tinnitus loudness. The masking was performed with a wide frequency band noise in the same ear affected by tinnitus. Three classes of residual inhibition (RI) were considered: negative (tinnitus still present); partial (tinnitus still present but improved for less or more than 60 seconds); complete (tinnitus completely disappeared for less or more than 60 seconds).
For the statistical analysis the Wilkoxon test for paired data has been applied.

RESULTS

As for G1 is concerned the following results has been observed.

The VAS data at T_0 showed that no one of the examined subjects had a low disturbance, while it was of medium level in 30 subjects (61,20%) and high in 19 (38,77%). At T_3 the disturbance was low in 2 subjects (4,08%), moderate in 30 (61,20%) and high in 17 (34,69%). The difference To-T_3 was not relevant (p= 0.059).

The discomfort level, evaluated with THI, resulted at T_0 very low in 8 subjects (16,32%), low in (22,48%), moderate in 18 (36,73%) very high in 10 (20,40%), catastrophic in 2 (4,08%). At T_3 15 patients (30,61%) had a very low discomfort, 12 (24,48%) low, 10 (20,40%) moderate, 10 (20,40) very high, 2 (4,08%) catastrophic. The difference T_0-T_3 is not relevant (p=0.057).

The intensity of tinnitus at T_0 ranged between 10-20 db in 6 subjects (12,24%), 25-40 db in 13 (26,53%), 40-60 db in 22 (44,89%), 60-70 db in 4 (8,16%), 70- 90 db in 4 (8,16%). At T_3 the intensity resulted between 10-20 db in 5 subjects(10,20%), 25-40 db in 17 (34,69%), 40-60 db in 19 (38,77%), 60-70 db in 3 (6,12%), 70-90 db in 3 people (6,12%), not perceived in 2 people (4,08%). The difference of the intensity T_0-T_3 is statistically significant. (p= 0.0032)

The residual inhibition at T_0 resulted < 60 sec. in 45 subjects(91,83%), >60 sec. in 4 (8,16%). At T_3 the residual inhibition resulted <60 sec. in 44 subjects(89,79%), >60 sec. in 3 (6,12%), not perceived in 2 (4,08%).The difference of the residual inhibition T_0- T_3 is not relevant (p= 0.54).

As for G2 is concerned, at T_0 no one of the examined subject showed a low discomfort evaluated with the VAS, while it was moderate in 2 (22,22%) high in 7 (77,77%). At T_3, no patients presented a low discomfort, while it was moderate in 6 (66,66%) and high in 3 (33,33%). The discomfort difference To-T_3 is not relevant (p= 0.01).

The disturbance level evaluated with THI was at T_0 was very low in 1 subject (11,11%), low in 1 (11,11%), moderate in 4 (44,44%), high in 1 (11,11%), catastrophic in 1 (11,11%). At T_3, 2 subjects have very low discomfort (22,22%), 4 (44,44%) low, 1 (11,11%) moderate, 2 (22,22%) high, no one catastrophic. The THI difference a T_0- T_3 is not relevant (p=0.017).

At T_0 no one showed an intensity ranging between 10-20db and between 70-90 db; in 3 subjects it was 25-40 db (33,33 %) in other 4 between 40-60 db (44,44%), in 2 60-70 db (22,22%). At T_3 no one showed an intensity ranging between 10-20 db and between 70-90 dB, in 3 subjects it was 25-40 db (33,33%), in 5 40-60 db (55,55%), in 1 60-70 db (11,11%). The tinnitus intensity difference T_0-T_3, is not relevant (p= 0.093)

The residual inhibition at T_0 resulted < 60 seconds per 9 subjects (99,99%), no one had total inhibition > 60 seconds. In the same group a T_3, the residual inhibition resulted <60 seconds for 7 people (77,77%), >60 seconds for 2 people (22,22%). The residual inhibition difference T_0- T_3, is not relevant (p=0.47).

CONCLUSIONS

In our study the most relevant effect of the LLT is the reduction of tinnitus intensity in the group of patients who underwent the treatment with active laser. In this group it was observed a statistically significant reduction in tinnitus intensity threshold after LLT therapy.

On the other hand, in the control group, no great difference between the intensity before and after the therapy was observed.

As for VAS, THI and residual inhibition, no relevant modifications has been observed in the sample group.

In the control group, where no relevant tinnitus measurements modifications occurred, a variation for VAS and THI was observed.

A possible explanation of these results may be the psychological aspects, which are always to be take in consideration, of tinnitus patients. In fact the psychological disorders may have an influence on subjective tests such as VAS and THI.

The present follow-up is 3 months, but the study is still going on until a follow-up of 6 months.