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Combined tinnitus therapy with laser and EGb 761: further experiences

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Abstract

Objective: To verify the effect of lasertherapy in a combination with administration of Ginkgo bilobae extract (EGb 761) in the treatment of patients with chronic tinnitus. **Background data:** Tinnitus is a symptom signifying the disturbances of a hearing system. The treatment is difficult due to the multiple aetiology and great psychological influence of tinnitus. Studies concerning EGb 761 or laser and their biological effect suggest their use in the treatment of tinnitus. Nevertheless, the results of clinical studies applying these methods vary, making their general clinical application rather controversial. **Methods:** We performed a simple prospective study involving 420 patients (16-77 years of age; 53.7 years mean, SD 14.2) with chronic tinnitus (duration 3 months to 40 years, 7.7 mean, SD 7.8). A soft laser BTL 10 type was used with an 830 nm/200mV probe, applied with transmastoidal and transmeatal approach as a continuous and pulse beam, after 3 weeks of oral use of EGb 761. The objective effect of the therapy was measured by tinnitus masking; the subjective effect was evaluated on the visual analogue scale (VAS). **Results:** 238 patients (56.7%) displayed an objective improvement in tinnitus masking, the average improvement of the intensity being 30 dB. 196 patients (46.7%) marked a subjective improvement on VAS. The conformity of objective and subjective evaluation was found in 79% of cases. **Conclusion:** Compared with the findings of other authors, our results show relatively higher rates of positive changes in tinnitus status and a greater conformity between audiometric and subjective findings.

Keywords: hearing loss, questionnaires, sensorineural, tinnitus.

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INTRODUCTION

Tinnitus is a symptom of a disturbance of the auditory system. About ten percent of the population suffers from tinnitus and tinnitus is present in about 70% of patients with a hearing disorder. There are many known etiologic factors that could induce and influence tinnitus including the inner ear or auditory pathway disorders themselves, cardiovascular diseases, neck spine disturbances, dyslipidaemia and other metabolic dysfunctions, endocrine disorders (thyroid dysfunction, diabetes mellitus), stress and psychic disorders, etc. The causes of tinnitus often remain unknown. Although we have diagnostic tools to evaluate tinnitus (audiology and tinnitus masking), various aetiologic factors make the treatment of tinnitus difficult in individual patients, causing further predominantly psychic and social problems.

There are various modalities in the treatment of the chronic tinnitus (pharmacotherapy, physiotherapy, psychotherapy, surgery etc), targeted at improving tinnitus and the quality of patients' lives. As the effectiveness of the therapy is, in most cases, very poor, some alternative treatment is applied more often[1] in the patients suffering from chronic tinnitus. The disappearance of tinnitus occurs very rarely among the patients with chronic tinnitus and according to the literature these patients do not represent a statistically significant group.

The aim of the therapy is to reduce the perception of tinnitus. In the evaluation of the efficacy of the therapy, changes of tinnitus frequency and intensity are assessed. Visual analogue scales are used to describe subjective changes in loudness and annoyance of the tinnitus.

Among various combined approaches to the patient with tinnitus, it is also possible to combine a soft laser with Ginkgo biloba extract (EGb 761). EGb 761 has a polymodal effect on the cell metabolism. The extract from the leaves of Ginkgo biloba has been used for centuries primarily in the therapy of respiratory disorders[2]. The defined alcoholic extract of EGb 761 contains a mixture of flavonoid glycosides and terpenoides. The properties of EGb 761 include an antioxidant effect diminishing free radical damage[3,4,5,6] and an antagonistic effect on platelet activating factor (PAF)[7].

Lasers emit beams of electromagnetic wave motion exerting analgesic (reducing the irritability of the peripheral nervous system), anti-inflammatory (activating all cells participating in the anti-inflammatory reaction - granulocytes, monocytes, fibroblasts, polymorphous cells - enhancing their chemotactic activities), stimulation (activating enzymes of the respiration chain and simultaneously amplifying anti-oxidative effects in mitochondria), thermal, and photochemical effects. The wave motion emitted enhances the metabolism in tissues and cells. After being irradiated with laser, the cells acquire additional energy, their renewal becomes more rapid and their protective mechanism is amplified[8].

For otoneurologic purposes, lasers of the red light spectrum are most feasible. Thus the effect is mainly based on the support of the oxidative processes in the cell and stimulation of the cellular metabolism.

Soft laser has been used as a therapy for tinnitus since the beginning of the 1990's. Soon after, studies evaluating its therapeutic potential have followed[9-12]. The results have not been encouraging, either for soft laser alone[9,11,12] or in the combination with EGb 761[10]. On the other hand, some recent results prove mostly positive effects[13-16]. The controversy could be explained by different approaches made by the researchers, concerning the study design, the topography and the physical parameters of the laser beam applied, as well as the duration and the schedule of the therapy. The more recent results are supported by dosimetric and functional magnetic resonance imaging studies[14,15].

Following a previous publication[17], the authors present the actual results on a larger group of patients.

MATERIALS AND METHODS

A simple prospective study involving 420 patients suffering from chronic tinnitus of the cochlear type was performed at the ENT Clinic of the 3rd Medical Faculty, Charles University in Prague between September 1998 and May 2006. The mean duration of tinnitus was 7.7 years (range 3 months to 40 years). The group consisted of 200 women and 220 men, with a mean age 53.7 years (range 16-77 years) (Table 1).

Table 1. Research group, demographic data.

420 patients (200 women, 220 men)		
Age - group	16-77 years	(53.7 mean; SD = 14.2)
women	16-77 years	(54.1 mean; SD = 14.1)
men	16-77 years	(53.3 mean; SD = 14.2)
Tinnitus persistence group	0.25-40 years	(7.7 mean; SD = 7.8)
women	0.5-32 years	(7.8 mean; SD = 7.9)
men	0.25-40 years	(7.6 mean; SD = 7.7)

Exclusion criteria comprised otosclerosis, acute labyrinthine damage, statoacustic neurinoma, serious problems with cervical spine and heavy and/or decompensated metabolic disorders. Patients taking drugs with a possible influence on tinnitus were also excluded from the study.

The patients underwent a thorough anamnestic interview, basic ENT examination and a complete battery of audiologic tests i.e.: pure tone audiometry, speech

audiometry and objective audiometry (if necessary). With regard to tinnitometry, the intensity (dB) and frequency (Hz) were recorded. The annoyance caused by tinnitus was also estimated with a visual analogue scale.

Application of EGb 761 was begun three weeks before starting the soft laser therapy. Patients were given 80 mg Tanakan and/or Tebokan in a form of drops or tablets, three times daily. Patients visited our department for at least 3 weeks for 10 sessions of laser therapy, each lasting 10 minutes. A soft laser BTL 10 type was used with an 830 nm/200 mV probe. A continuous beam was applied initially, followed by a pulse beam, each for 5 minutes. Laser beams were targeted to the mastoid and to the cochlea (via the external auditory meatus).

RESULTS

In order to measure the improvement of tinnitus, two methods of evaluation were used in this study: (I) changes in the frequency and intensity of tinnitus; and (II) changes in the subjective evaluation rating.

The mean audiometric improvement of tinnitus was 30 dB (range 10 to 50 dB). Tinnitus disappeared in one case and in one case worsened by approximately 10 dB. 31 patients improved by 10 dB, 73 patients improved by 20 dB, in 48 patients the improvement of 30 dB was measured, in 38 cases it was 40 dB of improvement and finally in 48 cases it reached an improvement rate of 50 dB (from a total of 238 patients) (Table 2).

Table 2. Objective changes on tinnitus masking.

Change	Count	%
by 10 dB	31	13.0
by 20 dB	73	30.6
by 30 dB	48	20.2
by 40 dB	38	16.0
by 50 dB	48	20.2
∑	238	100.0

It is very interesting that one woman, with an objective improvement of 50 dB, reported no subjective improvement of tinnitus. Audiometric improvement was found in 238 cases (56.7%), tinnitus remained unchanged in 182 cases (43.3%). Subjective improvement of tinnitus was reported by 196 patients (46.7%) (Table 3).

Table 3. Improvement rate.

Objective parameters		
audiogram confirms improvement	audiogram with no change	Subjective improvement
238 patients 56.7%	182 patients 43.3%	196 patients 46.7%

Conformity between audiometric and subjective evaluation was as follows: in 79% of cases total conformity was reported, in 11% of cases audiologic improvement of tinnitus parameters was measured, but no subjective improvements were reported by the patients. In 10% of cases suffering from chronic tinnitus subjective improvement was reported, but no measurable reduction in tinnitus was confirmed (Table 4).

Table 4. Subjective and objective evaluation correlation.

Correlation patient	count	%
conformity of an audiogram and the subjective evaluation	332	79
audiogram improvement, same subjectively	46	11
subjective improvement, same audiogram	42	10
∑	420	100

DISCUSSION

When evaluating the results of any method used in the treatment of tinnitus, not only the objective measures are relevant for the final outcome. Tinnitus is a subjective perception for each patient and the patient's estimation of it is highly individual. Therefore, we consider the subjective evaluation of the patient at least as important as the objective audiometric methods. In this study, independent on the correlation between the subjective and objective evaluation, 46.7% of patients found an positive effect of the treatment and tinnitus masking revealed the improvement in the intensity of the tinnitus in 56.7% with a relatively high mean value of 30 dB. Audiometry confirmed the subjective information of the patient in 79% of cases, indicating the importance and relevance of both evaluating methods.

In clinical praxis, it is quite a common finding that the VAS and tinnitus masking results do not match. In our research group 10% of patients expressed the improvement, but no audiometric change was found, which is a finding that may suggest a placebo effect. On the other hand, 11% percent of patients did not "realize" their audiologic improvement, a phenomenon that is difficult to evaluate and explain in an individual patient, but is commonly described as a central processing or imprinting of tinnitus - theories supported by neuroscientifical research[18,19].

There were no complications of the therapy reported by the patients, although some of them described the thermal effect of laser as unpleasant.

When compared with previously cited studies concerning low power laser therapy in tinnitus, Shiomi et al. performed a study with similar design, but without application of EGb 761, and reported similar improvement rates in patients with chronic tinnitus[9].

Gungor et al. found a single laser therapy useful in the treatment of tinnitus in a double-blinded, randomized prospective study[16]. 5mW laser with wavelength of 650 nm was used, but for 15 minutes in one session and similar results were reported. On the other hand, Rogowski et al. bring negative outcomes and so does the study performed by Partheniadis-Stumpf et al.[10,12]. This might be caused by the different physical parameters of the laser used (we used a high energy 200mW probe) and perhaps by an evaluation of a small group of patients. In contrast with the German study, which applied Tebonin intravenously before each session, we used a preliminary administration of EGb 761, for as it could be expected, the effect of nootropics would be accentuated with the time of administration.

CONCLUSION

Tinnitus patients usually tend to try different therapeutic possibilities in the time of their illness in a search for alleviation of the annoyance and stress caused by their tinnitus. According to data collected in this study, we recommend combined soft laser and EGb 761 therapy as a suitable and safe modality in the treatment of the patients with chronic tinnitus of a cochlear type.

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