COMBINED LOW POWER LASER THERAPY AND EXTRACTS OF *GINKGO BILOBA* IN A BLIND TRIAL OF TREATMENT FOR TINNITUS

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Tinnitus is an annoying and often debilitating condition of neuro-otologic origin but of uncertain aetiology. Many treatment methods have been tried, but to date none has been consistently successful. The present preliminary study presents a blind trial of laser therapy (c/w HeNe 632.8 nm and pulsed GaAs 904 nm) combined with doses of an extract of *Ginkgo biloba* (50 mg) in two groups of 20 patients, one experimental and one control. All 40 patients received the biloba extract injection, but only the 20 experimental patients received real laser irradiation, 8 days, 8 min per day. The control group received sham irradiation in a blind arrangement. Fifty percent of the experimental group was assessed to have a reduction in tinnitus of more than 10 dB, compared with 5% in the control group in both self-assessment and audiometric findings. Although only a preliminary report, the results are very encouraging, and the authors suggest that this combined photochemotherapy is a promising treatment for tinnitus.

KEY WORDS LLLT Biloba extract Ginkgo extract Photochemotherapy Helium-neon-infrared laser combined

Introduction

Since the end of the seventies several reports have suggested, that low power laser therapy is effective on the improvement of wound-healing. Later on a combined therapy with a low power laser and extracts of *Ginkgo biloba* in the treatment of neurootologic diseases gained increasing consideration because of the need for conservative but intensive treatment of tinnitus as an extremely debilitating neurootologic disease.

From September 1991 to June 1992 we accomplished a study designed as a blind trial of the efficacy of low power laser therapy combined with extracts of *Ginkgo biloba* in the treatment of tinnitus.

According to pharmacology of *Ginkgo biloba* extracts and physical bases of low power laser therapy we have to refer to other relevant publications.

Methods and Materials

From September 1991 to June 1992 40 patients, 25 males and 15 females, with chronic tinnitus were admitted to the trial. All patients had been suffering from tinnitus for at least six months up to five years. Beside the tinnitus all patients showed a

sensorineural hearing loss, partially after sudden sensorineural deafness.

Patients with dysfunction of the thyroid gland, cardiovascular diseases or alteration of the upper vertebral column were not admitted to the study.

All patients had shown little or no response to a wide range of treatments including infusion therapy with hemorheological drugs, iontophoresis, acupuncture and others before the trial.

Pre-Treatment Analysis

Subjects were patients who were referred to the ORL-Department of Prosper-Hospital at Recklinghausen, Germany because of problematical tinnitus. The patients were randomly divided into two groups.

Group A (laser group) underwent a treatment with a low power laser after injection of 50 mg of *Ginkgo biloba* extract. Group B (control group) received an identical treatment with injection of *Ginkgo biloba* extract, the laser was positioned, but switched so as not to transmit the laser beam.

Before treatment all patients underwent a

detailed physical analysis;
electrocardiography and blood chemistry;
tympanometry;
pure-tone audiometry;

comparison of the tinnitus to a pure tone or narrow-band noise and matching for frequency, intensity and masking;
brainstem electrical response audiometry (BERA), partially CCT or NMR in order to exclude a retrocochlear process;
computer aided vestibulometry.

Procedure and Post-Treatment Analysis

Following the pattern of Witt¹ all patients received an identical treatment, beginning with an injection of 50 mg of *Ginkgo biloba* extract followed by low power laser therapy of the corresponding ear. The laser used was a combined helium neon (continuous wave, 632.5 nm, 12 mW output) and gallium arsenide laser (5 impulse regulated gallium arsenide infrared laser diodes, 904 nm, rated impulse power 30 W, frequency 100–2800 Hz).

The distance between laser head and skin was 2 cm, the direction of the laser beam lead from 4 cm above the point of the corresponding mastoid to the lateral rim of the opposite orbita. The initial impulse frequency was 800 Hz with a daily increase of 100 Hz.

Treatment sessions for both groups were performed daily for altogether eight days and lasted 8 min on each occasion.

The control group too received an injection of 50 mg of *Ginkgo biloba* extract, the laser was positioned but switched so as not to transmit the laser beam.

In addition to audiometry both groups received a scale for self-assessment, ranging from 0 ('tinnitus as severe as before treatment') to 10 ('complete relief'). Audiometry and tinnitus matching were carried out after the 4th and 8th session.

Results

According to a normal fluctuation of hearing, a reduction of tinnitus less than 10 dB was not acceptable to be valued as a success. Also a reduction between 10 and 20 dB is too little small

Figure 1. Tinnitus reduction in dB after therapy

Figure 2. Tinnitus reduction beyond 20 dB after therapy

Figure 3. Tinnitus reduction beyond 20 dB + frequency shift

to be assumed as a significant difference. However a reduction beyond 20 dB can surely be considered as a success.

After treatment the laser group showed a marked tinnitus reduction more than 10 dB of 50% compared with a reduction of only 5% in the control group. A reduction more than 20 dB was found in 30% of the laser group, including two cases of complete relief. In the control group only one person showed a tinnitus reduction of 10 dB, higher reductions could not be achieved in this group. Student's *t*-test values at 99% level of confidence were highly significant.

Together with a reduction of tinnitus more than

Figure 4. Frequency shift without tinnitus reduction

Figure 5. Laser group: self-assessment compared with audiometry

Figure 6. Control group: self-assessment compared with audiometry

20 dB a frequency shift to lower frequencies could be found.

A relevant hearing improvement more than 20 dB could not be achieved in both groups.

Self-Assessment in Comparison with Audiometry

Comparing the self-assessment scale with the audiometric results, a very good correlation could be found. In the laser group, 12 patients declared a reduction of tinnitus in the subjective scale compared with only five patients in the control group.

Discussion

Tinnitus, a subjective sensation of noise in the ears, is a very common otological symptom. The

assessment is a difficult problem as it is subject to individual psychological and emotional influences. Patients with long-standing tinnitus frequently demonstrate symptoms of depression and in its most severe form tinnitus can even induce suicidal tendencies.

From our point of view the combined treatment of low power laser and *Ginkgo biloba* extracts is able to obtain some relief from tinnitus in single cases. Further follow-ups and trials containing a greater number of patients should follow.

If our results will be confirmed, this combined therapy offers a new method of effectively treating tinnitus.