Low Level Laser Effect in Treatment of Patients with Intractable Tinnitus Due To Sensorineural Hearing Loss

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Abstract:

Introduction: Tinnitus is defined as a perception of sound without an external acoustic stimulus. Due to large number of causes and limited knowledge of its pathophysiology, tinnitus still remains an obscure symptom.

Methods: This was a cross-sectional study on 120 patients with tinnitus and sensorineural hearing loss who were randomly divided into two groups; one group received low-level laser and the second group used the same instrument but off, for 20 sessions of 20 minutes. A tinnitus handicap inventory (THI) and Visual Analog Scale (VAS) were used to evaluate the severity of patients’ symptoms. Severity and frequency of tinnitus were also determined using Audiometric tests.

Results: The average age of the 120 patients in the two groups of study were not statistically significantly different. The mean difference of severity of tinnitus between the two groups was statistically significant at the end of the study and 3 month after completion of treatment. The VAS and THI mean differences after the treatment were statistically significant between the two groups but not statistically significant after 3 months of completion the study.

Conclusion: Low level laser radiation is effective for short-term treatment of Tinnitus caused by sensorineural hearing loss and its impact may be reduced over the time.

Keywords: tinnitus; laser therapy; low-level; sensorineural hearing loss

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Introduction

Tinnitus is defined as a perception of sound without an external acoustic stimulus¹. Tinnitus which is disturbing and impairs daily life activities affects 3% to 5% of individuals². Epidemiological studies show that 32% of the adult population suffers from this disease and in one third of cases tinnitus is severe and affects individual and social life of patients². Tinnitus can cause a wide range of disorders such as sleep problems, lack of concentration, anxiety, irritability and depression². Due to the large number of causes of tinnitus and limited knowledge of its physiology, tinnitus still remains an obscure symptom³. Tinnitus is classified into objective and subjective². Objective tinnitus is more common and is not audible to the observer and usually arises from neuropsychological problems. This type of tinnitus is divided into three subgroups: central, conductive and sensorineural. In contrast, objective tinnitus can be detected by an observer and arises from respiratory disorders and muscular or vascular sources². Tinnitus may be observed in patients with two type of hearing loss, sensorineural and conductive hearing loss; however, the most common causes are noise-induced hearing loss.
Different treatments have been proposed for tinnitus. However, there are no treatments specifically recommended for this purpose. Sedatives, antihistamines, anti-depressants, local anesthetics, antipsychotics and anti-convulsants have been used for treatment of tinnitus with different outcomes. Cognitive, behavioral and antioxidant therapy and also low level laser radiation have been introduced as alternative modalities for cochlear dysfunction and tinnitus.

Different usages have been known for laser in medicine, naming some of them: wound healing, pain control, and treating Meniere’s disease. Recently it has been proposed as a treatment for tinnitus. The mechanism of the effect of low-level laser therapy (LLLT) on tinnitus is not understood yet. Some theories have been proposed as probable mechanism such as increasing cell proliferation, growth factor secretion, and improvement of blood flow to inner ear.

The aim of the present study was to investigate the effect of low-level laser radiation in the treatment of patients with intractable tinnitus caused by sensorineural hearing loss.

Methods
This was a cross-sectional study on 120 patients with sensorineural hearing loss referred to our clinic between 2011 and 2012. Those older than 18 years-old with tinnitus for more than one year due to sensorineural hearing loss resistant to common medical treatments entered the study. Those with conductive or mixed hearing loss, and duration of less than one year were excluded. At first, a complete medical history and clinical examination were performed. The patients’ auditory situation was evaluated by pure-tone audiometry (PTA) before treatment. Then, the patients were randomly divided into two groups, 60 patients were placed in treatment group and another 60 patients were placed in the control group without any treatment. Before the study, at the end of treatment period and 3 months after the study, tinnitus severity was evaluated by visual analog scaling (VAS) and tinnitus handicap inventory (THI). VAS is a 10-point scale from very slight 0 to intolerable 10 tinnitus according to the patient’s opinion (Huskisson). In THI, tinnitus is graded from 1 (slight) to 5 (catastrophic) from the patient’s answers to 25 questions (Newman).

According to the previous studies, we judged that improvement was significant when a decrease of at least two scales on the VAS were reported by the patient. The patients in treatment group were treated by low-level laser radiation and patients in control group were treated by placebo (the device was inserted inside the patient’s ear in off state). A low-level laser device (TINNImed, made in Switzerland) with intensity of 5 mW and wavelength of 650 nm was used. This device consists of three sections in which laser source is placed; the tip is made from silicon. The tip was inserted inside the external ear canal and laser ray was radiated to internal ear and cochlea via tympanic membrane. This device does not have any noise or particular vibration, thus the patients are not aware of this issue that it is off or on. All patients were treated during 20 sessions, each session lasted 20 minutes (three sessions during each week). SPSS (ver 20) was used to analyze the data and P<0.05 was considered as significant.

Results
All of the patients completed the study. No complication was seen in patients due to laser radiation. The mean age of the participants was 39.78±5.49 years (range: 31 to 50 years). Mean age was 41.08±5.53 and 39.43±5.05 in treatment and control groups, respectively and the difference was not statistically significant (P=0.09). Among 60 patients in control group, 29 (48.3%) were females and 31 (51.7%) were males. In treatment group, 30 patients (50%) were males and 30 (50%) were females. No significant statistical difference was seen between two groups regarding gender (P=0.85). Table 1 shows the assessment of tinnitus severity in two groups before beginning the therapy and at the end of study in both groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Before intervention Mean (SD)</th>
<th>P-Value</th>
<th>At the end of intervention Mean (SD)</th>
<th>P-Value</th>
<th>Three months after intervention Mean (SD)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinnitus Severity</td>
<td>Control</td>
<td>6.46 (2.07)</td>
<td>0.121</td>
<td>6.27 (1.99)</td>
<td>0.001</td>
<td>6.33 (2.16)</td>
</tr>
<tr>
<td></td>
<td>Laser Therapy</td>
<td>5.69 (1.35)</td>
<td></td>
<td>4.28 (1.66)</td>
<td></td>
<td>5.10 (1.85)</td>
</tr>
<tr>
<td>THI grading</td>
<td>Control</td>
<td>2.73 (0.79)</td>
<td>0.11</td>
<td>2.35 (0.84)</td>
<td>0.01</td>
<td>2.43 (0.85)</td>
</tr>
<tr>
<td></td>
<td>Laser Therapy</td>
<td>3.01 (1.12)</td>
<td></td>
<td>1.93 (0.95)</td>
<td></td>
<td>2.40 (1.13)</td>
</tr>
</tbody>
</table>
and there was not any significant statistical difference between both groups \( (P=0.11) \). At the end of study, significant statistical difference was seen between the two groups \( (P=0.01) \) and three months after the end of therapy, the difference between both groups was not significant \( (P=0.85) \).

The obtained results from VAS criterion were investigated and measured in three time sections and then were compared between both groups. Abundance value of at least 2 degrees’ recovery was seen in end of study ratio to beginning of the therapy in 18 (30\%) patients of control group and in 34 (56\%) patients of therapy group and significant statistical difference was seen between them \( (P=0.003) \), but three months after the end of therapy there was no statistical difference between the two groups (Table 2). The obtained results from comparing the THI and VAS criteria among the patients of both groups indicate that radiation of low level laser can lead to recovery from the patients’ tinnitus situation, particularly for short time, although, following the patients’ tinnitus situation after three months from end of therapy propounds this hypothesis that its effects decreases with passing time.

<table>
<thead>
<tr>
<th>Table 2. Frequency distribution of tinnitus improvement rate per VAS (Rate of at least 2 grade improvements in VAS criterion)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At the end of the study</strong></td>
</tr>
<tr>
<td>Frequency</td>
</tr>
<tr>
<td>Control</td>
</tr>
<tr>
<td>Laser Therapy</td>
</tr>
<tr>
<td>P-Value</td>
</tr>
</tbody>
</table>

Discussion

Nowadays, low level laser radiation is used for the treatment of peripheral and central nervous system injuries and also in wound repairing \(^{11}\). Although, its influence mechanism on tinnitus has not been known well, in animal studies after direct radiation to Cochlea through Round Window, reduction in compound action potential amplitude has been seen \(^{12}\). It seems that biological effects of low level laser are more than its thermal effects on tinnitus recovery \(^{13}\). Also, lasers with various level and different wave lengths have been used. In this study, effect of low level laser radiation was investigated on patients’ tinnitus whose tinnitus has been created after sensorineural hearing loss. The results from comparing the tinnitus severity and also tinnitus situation by using THI and VAS criteria indicated that radiation of low level laser can affect tinnitus recovery particularly for short time, but its effect on tinnitus is decreased during time. Hahn et al. studied 120 patients who suffered from tinnitus and applied low level laser radiation with 200mw and 650 nm wave length for 10 sessions each session 10 minutes and recovery was reported in 50.8\% of the patients \(^{14}\). Gungor et al. used low level laser radiation with 5mw and 650nm for 15 minutes per week on 45 patients (18 female and 27 male) between 25 to 77 years old (mean 55.8) with chronic tinnitus, recovery percentage was increased and tinnitus frequency had significant difference comparing both under studying groups \( (p<0.05, \ p=0.001) \) \(^{15}\). In another study by Cuda et al. on 45 patients who suffered from tinnitus for more than 3 years, simultaneous effect of consultation and radiation of low level 5mw and 650nm laser ray on chronic tinnitus’ recovery was assessed. THI criterion was assessed before and after treatment and 61\% of patients in therapy group and 35\% of patients in control group recovered \(^{16}\). Shiomi et al. studied 38 patients with tinnitus who were resistant to medical treatments and they used low level laser with 40mw and 650nm wavelength for 9 minutes, ten times or more per week. In this study, THI criterion was also used in order to assess the patients’ tinnitus and 58\% of the under treatment patients recovered \(^{17}\). The results from these studies are concordant with the results of our study, although treatment duration, the level of the laser and also under studied patients’ community from number, type and beginning time of tinnitus are different. It seems that the effect of low level laser radiation on tinnitus recovery is not so much depending on the selected level of laser, and technical skills are more effective on tinnitus recovery, such as its correct location inside ear, rate of patients’ cooperation and also treatment duration. Mirz et al. used low level 50mw laser on 49 patients with one or two side chronic tinnitus. In this study, a mean recovery up to 18\% was achieved in subjective high situation and significant difference was not seen in THI and VAS criteria between patients of both groups \(^{17}\). Nakashima et al. also performed a study on 45 patients. In this study, 60mw laser device was used for 6 minutes one time per week during 4 weeks, and the results did not indicate significant difference between laser receiver group and placebo laser receiver group \(^{18,19}\). Tauber et al. investigated the effect of low level laser on 35 patients with chronic tinnitus and sensorineural hearing loss. After 6 months from end of treatment, only 13 patients (37\%) of 35 patients reported decreased tinnitus height and there was no significant difference between two groups. Researchers concluded that additional large, double-blind
studies are needed to evaluate the effectiveness of the low level radiation for treatment of acute and chronic cochlear tinnitus. Teggi et al. in Sanrafael center of Milan in Italy, performed a study on 60 patients with tinnitus due to sensorineural hearing loss. In this study, no significant difference was seen in patients’ tinnitus situation of both groups (p=0.9, p=0.6 respectively) 19, 6, 11. Considering the present differences in the obtained results from various studies, it seems that whatever is important in determination of laser treatment method successes is the application of proper technical parameters, correct study design method and also enough time of treatment. Also, it seems that psychological disorders such as depression, anxiety, etc have an effective role on recovery or lack of recovery of tinnitus, thus these disorders also can affect the results obtained from tinnitus recovery. In this study, and other previous studies, the role of disorders has not been assessed 20.

Conclusion
The results of this study revealed that applying low level laser radiation could effect on recovery of patients’ tinnitus caused by sensorineural hearing loss. Also, following the patients’ tinnitus situation three months after the study revealed that the effect of low level laser on tinnitus is decreased with passing time, although additional studies are necessary to prove the long term efficacy of this treatment mode and to investigate the psychological disorders in improvement of tinnitus.

References