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Treatment of Chronic Tinnitus with Low Level Laser Therapy

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Abstract: Tinnitus causes disability associated with concentration deficits, insomnia, hypersensitivity to sounds, anxiety and depression. Often a combination of several complaints leads to a diminished quality of life. The purpose of the study was to determine the effect of the Low Level Laser Therapy (LLLT) in the treatment of chronic tinnitus. Sixty patients with chronic subjective tinnitus were included in this study and were randomly divided into two equal groups: (study group and control group). Study group received Low Level Laser Therapy, 3 times per week for 1 month while control group received placebo laser, 3 times per week for 1 month. The clinical findings of the patients were analysed before and after the treatment via the Visual Analogue Scale (VAS) and Tinnitus Severity Index (TSI) Questionnaire. All sixty patients completed the study. There were no adverse effects observed. The Visual Analog Scale (VAS) score difference before and after the treatment was statistically significant ($p = 0.0001$). Also statistical difference was found before and after the treatment in the Tinnitus Severity Index (TSI) Questionnaire score ($p = 0.0001$). In relation to the VAS and TSI Questionnaire scores, the study revealed that the results obtained in the study group were superior to that of control group. It was concluded that Low Level Laser Therapy (LLLT) was considered an effective treatment modality for the treatment of chronic subjective tinnitus.
Keywords: Tinnitus, Low Level Laser Therapy.

Introduction

Tinnitus is a perception of sound without a real external source. Roughly 14 % of the grown-up populace tenaciously experiences tinnitus and 20% of those with such side effect experience extensive trouble.[1]

Common causes of tinnitus are: presbycusis, prolonged noise exposure, acoustic trauma, otosclerotic, infections, genetic predisposition, autoimmune hearing loss, meniere's disease or endolymphatic hydrops, tumors/growths (e.g., acoustic neuroma, cholesteatoma), ototoxicity, vascular problems, metabolic problems and side effects from medications.[2]

Regardless of its commonness and grimness, tinnitus still remains a dark manifestation. Principally in light of the subjective way of the issue and our absence of information of its mechanisms. Treatment of tinnitus has been restricted, dubious and all the time unsuccessful.[3]

Tinnitus can be separated in two general classes. 'subjective tinnitus', the patient perceives a "phantom" sound, refers to the significantly more common form in which the source of the auditory sensation can't be

distinguished [4]and the 'objective tinnitus' or "somatosound", refers to the uncommon number of cases in which a sound source can be recognized. Cases incorporate abnormal blood stream throbs in vessels adjoining the middle ear or abnormal muscle contractions as in palatal myoclonus.[5]

Acute tinnitus, which can last days or weeks may be caused by ear infection, medications, head or neck injury, excessive exposure to loud sounds, impacted earwax, and changes in blood pressure or metabolism. With appropriate evaluation, such underlying conditions usually can be identified and treated, often with resultant resolution of tinnitus. Chronic tinnitus which persisted for 6 months or more can also result from these conditions and is more likely to occur in people who have hearing loss. [2]

Notwithstanding distinctive standard strategies, Low Level Laser Therapy has been presented as an option methodology for cochlear dysfunction.[6]

Low level laser treatment (LLLT) as a restorative methodology in cochlear dysfunction, such as, chronic cochlear tinnitus or sensorineural hearing loss is still questionable. Notwithstanding distinctive pathophysiological systems of inner ear pathologies and assorted hypotheses on the mechanisms of tinnitus, the contrasts in study plan, treatment calendars and irradiation parameters could bring about extensive variety of results.[7]

So, the purpose of this study was designed to detect the therapeutic effect of Low Level Laser Therapy in chronic subjective tinnitus.

Patients: Sixty patients suffered from chronic subjective monolateral or bilateral tinnitus (more than 6 months prior to entry) with or without sensorineural hearing loss were included in the study.

Their age ranged from (30-50) years. Patients didn't have any concomitant treatment for tinnitus and previous pharmacological treatment did not have any effect on tinnitus.

They were randomly assigned into two groups. All participants were informed about the purpose of the study and signed a consent form before participation in the study. Group A (Study group) composed of thirty patients who had chronic subjective tinnitus, and they received Low Level Laser Therapy, infrared laser (wavelength 904 nm) for 1 month, 3 sessions per week, and twenty minutes per session. Group B (Control group) composed of thirty patients who had chronic subjective tinnitus, and they received placebo laser for 1 month, 3 sessions per week, and twenty minutes per session.

Those who were not diagnosed as mentioned before were excluded from the study. The Ethical Committee of Physical Therapy College of Cairo University approved the study.

Materials and Methods

Evaluation Procedures: Tinnitus was assessed by:

1- Visual Analogue Scale: Figure (1): The VAS consisted of 100 mm lines with endpoints (extremes) that indicated the words "total absence" and "maximum" of tinnitus loudness. The pretherapeutic degree of tinnitus was defined on the VAS for each patient (baseline) and 1 month after treatment. The VAS model used in the study was accompanied by a simple graphics showing face grimaces according to patient amount of hardship.[8]

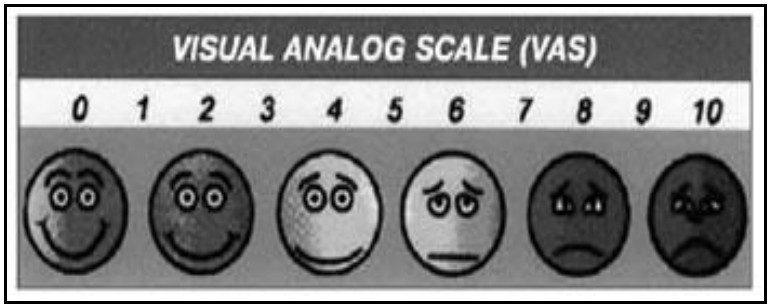

Fig (1): Visual Analogue Scale.[8]

2- Tinnitus Severity Index (TSI) questionnaire: Table (2): TSI was administered to each patient before and 1 month after treatment. Each patient answered its 12 questions and circle the number that best describe him/her tinnitus.[2]

Table (1): Tinnitus Severity Index (TSI) questionnaire. [2]

	Never	Rarely	Sometimes	Usually	Always
Does your tinnitus: 1. Make you feel irritable or nervous?	1	2	3	4	5
2. Make you feel tired or stressed?	1	2	3	4	5
3. Make it difficult for you to relax?	1	2	3	4	5
4. Make it uncomfortable to be in a quiet room?	1	2	3	4	5
5. Make it difficult to concentrate?	1	2	3	4	5
6. Make it harder to interact pleasantly with others?	1	2	3	4	5
7. Interfere with your required activities (work, home& care or other responsibilities)?	1	2	3	4	5
8. Interfere with your social activities or other things you do in your leisure time?	1	2	3	4	5
9. Interfere with your overall enjoyment of life?	1	2	3	4	5
10. Interfere with your ability to sleep?	1	2	3	4	5
11. How often do you have difficulty ignoring your tinnitus?	1	2	3	4	5
12. How often do you experience discomfort from tinnitus?	1	2	3	4	5

Treatment Procedures:

Group A (the study group) received Low Level Laser Therapy, infrared laser (wavelength 904 nm) for 1 month, 3 sessions per week, twenty minutes per session.

Group B (the control group) received placebo laser for 1 month, 3 sessions per week, twenty minutes per session.

Each patient was instructed to wear goggles each time on laser irradiation to protect his/her eyes. Place the patient in a suitable comfortable sitting position. Before beginning the treatment check device and be sure that it was switched off, Switch device on. The prope of the laser device was fixed on the processus mastoideus.

Just the influenced ear was treated. In the event that the patient had bilateral tinnitus, the side with the higher tinnitus was treated. In the event that patients couldn't spatially determine their tinnitus, the study convention was by default treating the right ear.

Statistical Analysis:

Descriptive statistics and t-test were conducted for comparison of subjects mean age between both groups. T test was conducted to compare mean values of VAS between both groups. Paired t test was conducted to compare between pre and post treatment mean values of VAS in each group. Mann–Whitney U test was conducted for comparison of TSI between both groups. Wilcoxon signed ranks test was conducted for comparison of TSI between pre and post treatment in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical tests were performed through the statistical package for social studies (SPSS) version 19 for windows (IBM SPSS, Chicago, IL, USA).

Results

3.1.1. Descriptive data of both groups (study and control):

Patient demographic data as observed in table (2) and demonstrated in figure (2), showed the mean ± SD age of group A and B. There was no significant difference between both groups in the mean age ($p > 0.05$)

Table (2): Comparison of mean age between groups A and B:

	x̄±SD		MD	t- value	p-value
	Group A	Group B			
Age (years)	38.43 ± 6.42	40.1 ± 6	-1.67	-1.03	0.3*

x̄: **Mean, SD: Standard deviation, MD: Mean difference, t value: unpaired t value, p value: Probability value, *: Non significant.**

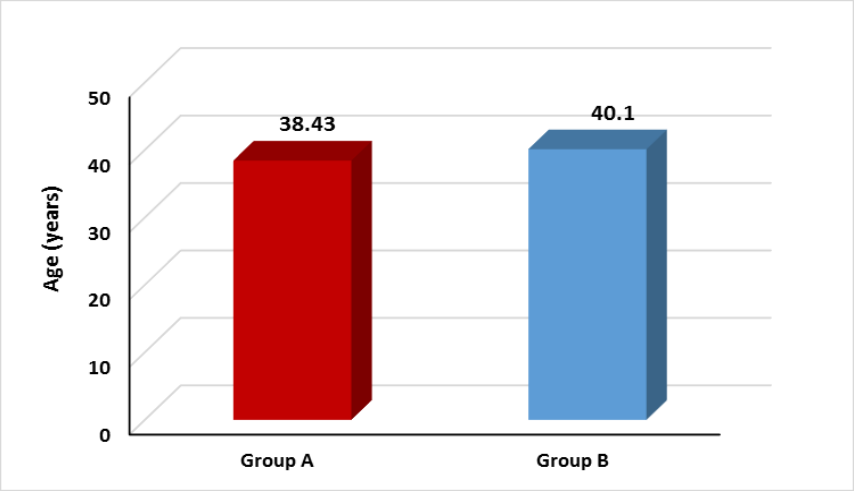

Fig (2). Mean age (years) of study group and control group.

3.1.2. Comparison between characteristics of patients regarding sex, unilateral and bilateral, affection side, and associated sensorineural hearing loss:

Characteristics of patients as observed in table (3), showed that there was no significant difference between both groups in the distribution of sex, unilateral or bilateral, affection side, and associated sensorineural hearing loss between groups A and B ($p > 0.05$).

Table (3): Comparison of sex, unilateral and bilateral, affection side, and associated sensorineural hearing loss distribution between groups A and B:

	Group A	Group B	χ^2	p-value
Females	15 (50%)	16 (53%)	0.06	0.79*
Males	15 (50%)	14 (47%)		
Bilateral affection	23 (77%)	22 (73%)	0.08	0.76*
Unilateral affection	7 (23%)	8 (2%)		
Right ear affected	20 (67%)	18 (60%)	0.28	0.59*
Left ear affected	10 (33%)	12 (40%)		
With sensorineural hearing loss	18 (60%)	18 (60%)	0	1*
With sensorineural hearing loss	12 (40%)	12 (40%)		

χ^2 : Chi squared value, p value: Probability value, *: Non significant.

3.2. Comparison within group:

Results of group A:

There was a significant decrease in the mean value of Visual Analogue Scale (VAS) post treatment compared with pre treatment (p >0.0001). The VAS decreased post treatment by 55.55%. Also, there was a significant decrease in median value of Tinnitus Severity Index (TSI) questionnairepost treatment compared with pre treatment (p > 0.0001). (Table 4,5) and (Figures 3,4).

Results of group B:

There was a significant decrease in the mean value of VAS post treatment compared with pre treatment (p >0.001). The VAS decreased post treatment by 11.75%. Also, there was a significant decrease in median value of TSI post treatment compared with pre treatment (p > 0.001). (Table 4,5) and (Figures 3,4).

Table (4): Comparison of Visual Analogue Scale (VAS)between pre and post treatment in group A and B:

	Pre	Post	% of change	t-value	p-value
	x̄±SD	x̄±SD			
Group A					
VAS	7.2 ± 1.73	3.2 ± 2.68	55.55	7.43	0.0001**
Group B					
VAS	7.4 ± 1.97	6.53 ± 2.28	11.75	5.06	0.0001**

x̄: **Mean, SD: Standard deviation, MD: Mean difference, p value: Probability value, **: Significant.**

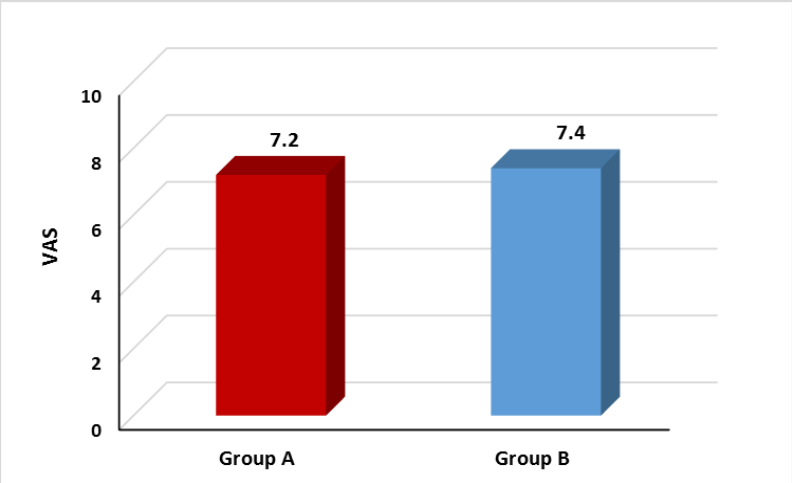

Fig (3).Pre treatment mean values of VAS of study group and control group.

Table (5): Comparison of Tinnitus Severity Index (TSI) questionnaire between pre and post treatment in group A and B:

	Pre	Post	z-value	p-value
	Median (range)	Median (range)		
Group A				
TSI	40 (27)	25 (28)	4.28	0.0001**
Group B				
TSI	43.5 (28)	41 (27)	3.24	0.001**

p value: Probability value, **: Significant.

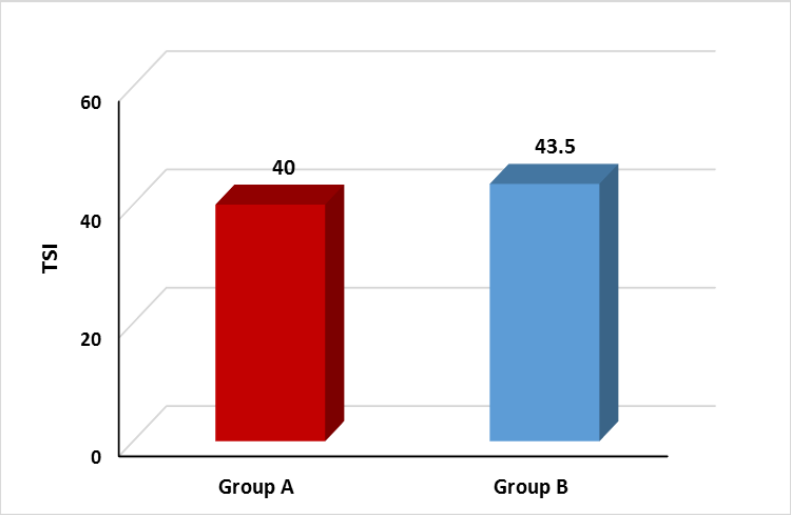

Fig (4).Pre treatment median values of TSI of study group and control group.

3.3. Comparison between groups:

There was no significant difference between group A and group B in VAS, and TSI pre-treatment ($p > 0.05$). Comparison between groups post treatment revealed a significant decrease in VAS and TSI in group A compared to group B ($p < 0.05$). (Table 6,7) and (Figures 5,6).

Table (6): Comparison of Visual Analogue Scale (VAS) between group A and B pre and post treatment:

	Group A	Group B	t-value	p-value
	x̄±SD	x̄±SD		
Pre treatment				
VAS	7.2 ± 1.73	7.4 ± 1.97	-0.41	0.67*
Post treatment				
VAS	3.2 ± 2.68	6.53 ± 2.28	-5.18	0.0001**

x̄: **Mean, SD: Standard deviation, MD: Mean difference, p value: Probability value *: Non significant,**: Significant.**

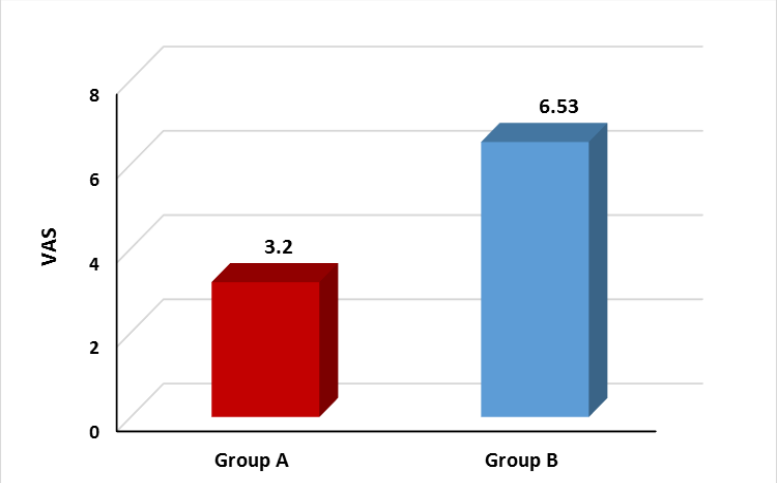

Fig (5). Post treatment mean values of VAS of study group and control group.

Table (7): Comparison of Tinnitus Severity Index (TSI) questionnaire between group A and B pre and post treatment:

	Group A Median (range)	Group B Median (range)	U-value	p-value
Pre treatment				
TSI	40 (27)	43.5 (28)	419	0.64*
Post treatment				
TSI	25 (40)	41 (27)	160	0.0001**

p value: Probability value *: Non significant, **: Significant.

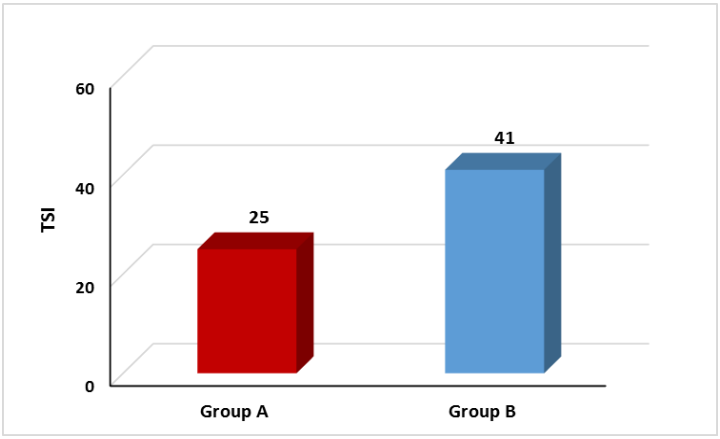

Fig. (6): Post treatment median values of TSI of study group and control group.

Discussion

Tinnitus is the perception of sound inside the human ear or head without outside source.[9]Tinnitus is a common however heterogeneous otologic manifestation. Its wide occurrence in the populace was shown by epidemiologic studies.[10]

The best accessible evaluations showed that 10–15% of adults report tinnitus crosswise over Europe, the United States (US), Japan and a few African nations.[11,12]

A sum of 10% to 15% of patients reported that they had encountered tinnitus that endured longer than 5 minutes and 1% to 5% had troublesome tinnitus that meddled with rest or even prompted inability and lessened personal satisfaction. The clinical presentation of tinnitus as a side effect and issue may rely on upon an assortment of variables. Huge individual contrasts exist with respect to audiologic, medical and mental qualities. [13]

Regularly endorsed drugs for tinnitus include: antidepressants, anticonvulsants, antihistamines, local anaesthetics, narcotics, antipsychotics, and botulinum toxin A, all giving blended or conflicting advantages.[3] Non pharmacologic and surgical helpful methodologies have been utilized as a part of selected cases. These routines have not demonstrated significant restorative impacts. [14]

Low Level Laser Therapy (LLLT) is a type of Phototherapy which includes the use of monochromatic light over organic tissue to evoke a biomodulative impact within that tissue.[15,16]

Toward the end of the most recent century, low level lasers (with around 50mW power) which has been fruitful in treatment of healing of wounds and painful conditions [17]have been utilized on tinnitus patients, accepting an athermic incitement of biochemical processes in the inner ear actuated by light.[18]

Clashing studies haves been published going from achievement rates more than 75%[7,19]to no huge change by any means.[20,21]

Since the rise of the lower level laser treatment for tinnitus in the late 1980s just a few reports of its effectiveness have been published. A large portion of them joined laser with Gingko Biloba, an acclaimed vasodilator.[18]

Improvement of tinnitus in 75% and improvement in hearing in 80 % of patients was reported in one uncontrolled study.[19]

Two other uncontrolled studies still found tinnitus relief in 55% [22]and 25% [2020], respectively. In one controlled single- blind study beneficial results were shown in 50 % of the active treatment group while 5% in the placebo group.[23]Two other studies, one single–blind [24]and one double–blind concluded no statistical significant differences between active treatment and placebo groups.[21]

The treatment techniques in every one of these studies were the same, He-Ne and/or Ga-Al-AS laser with wavelength somewhere around 630 and 900nm and most power output somewhere around 10 and 50 mW have been pointed at the mastoid or the external auditory meatus. The bias intrinsic to single–blind and particularly to uncontrolled studies has restricted the estimation of a portion of these trials and traded off their results.[18]

The therapeutic effect of the low level laser Therapy is not totally clear; a few hypotheses are: increasing cell proliferation, ATP and collagen synthesis, growth factors secretion, enhancing the inner ear blood stream and stimulating the hair cell mitochondria. [7]Distinctive studies with distinctive treatment interventions have been performed to evaluate the efficacy of the low level laser therapy and these studies indicated assorted results. [9]

The present study for treatment of tinnitus resulted in subjective tinnitus improvement in55.55% in study group while only 11.75% in control group measured via the VAS. Comparison between groups post treatment revealed a significant decrease in VAS and TSI in study group compared to control group ($p < 0.05$).

Conclusion

In this study, it could be concluded that low Level Laser Therapy has significant improvement in chronic subjective tinnitus as evidenced by VAS and TSI questionnaire scores. Low level laser therapy was considered as a safe and effective treatment modality for the treatment of chronic subjective tinnitus.

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