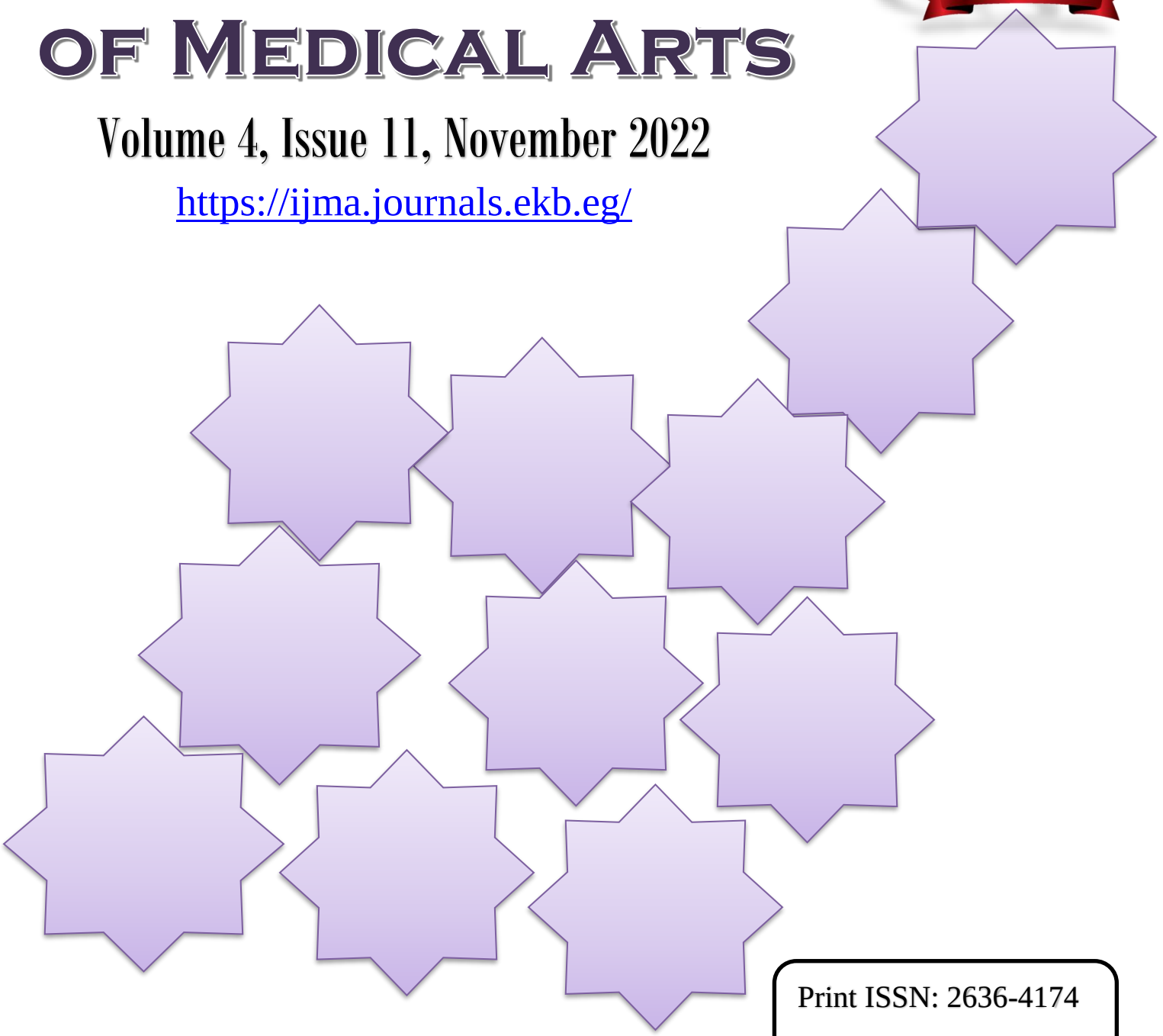
International Journal of Medical Arts

Volume 4, Issue 11, November 2022

https://ijma.journals.ekb.eg/



Print ISSN: 2636-4174

Online ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Otorhinolaryngology]

Original Article

Comparative Study Between Low Level Laser Therapy and Intra Tympanic Steroids Injection in Treatment of Tinnitus

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Article information

Received: 01-11-2022

Accepted: 02-03-2023

DOI: 10.21608/IJMA.2023.172313.1542

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Citation: Kadah SMS, Elkholy TA, Behairy R, Elneklawy NEA, Eltobgy MA. Comparative Study Between Low Level Laser Therapy and Intra Tympanic Steroids Injection in Treatment of Tinnitus. IJMA 2022 November; 4 [11]: 2835-2842. doi: 10.21608/IJMA.2023.172313.1542.

ABSTRACT

Background: Persistent tinnitus can result in serious problems and morbidity, especially at the psychological and socio-professional levels. Although many treatments exist for the resolution of tinnitus symptomatology, total eradication of symptom rarely occurs.

The aim of the work: To compare the effectiveness of two new promising techniques in treating tinnitus; low level laser therapy versus intra tympanic dexamethasone injection.

Patients and Methods: A comparative randomized clinical trial included 40 patients suffering from tinnitus for more than 6 months. They were divided into two groups randomly with every other patient consecutively; group [1] included 20 patients received steroids injection [0.5 ml of 4 mg\ml dexamethasone] on six sessions twice weekly, and group [2] included 20 patients who obtained low level laser therapy transmeataly with wave length 650 nm and laser output 5 mW for 7 sessions. Assessment of treatment included tinnitus handicap inventory [THI], visual analogue scale of loudness [VAS-L], pure tone audiometry and tympanometry for evaluation before and after therapy.

Results: THI after treatment was lowered in group 2 more than group 1, but this result did not reach statistical significance [P=0.076]. Quality of life in group 2 after treatment was statistically significantly better than in group 1 [better results after treatment as regard questions assessing sleeping at night, interfering with daily work and concentration].

Conclusion: Low level laser therapy is more effective and safer than intratympanic steroid injection in treating chronic tinnitus with duration more than 6 months.

Keywords: Tinnitus; Laser Therapy; Tympanic; Steroids

INTRODUCTION

The aware experience of noise in the absence of external acoustic stimulation is known as tinnitus. Tinnitus can be either bilateral or unilateral, with or without hearing impairment, and it might sound like rings, crackling, blowing, roaring, vibrating, or whistling noises [1]. Additionally, tinnitus can be classified as either non-pulsatile [perceptual] or pulsatile [objective]. When compared to objective pulsatile tinnitus, which is typically brought on by an inner vibration or noise, perceptual non-pulsatile tinnitus only can be experienced by the subject [2].

The most prevalent type of tinnitus, known as subjective tinnitus, affects around 10% of the general population. The cochlea is the most frequently identified locus for subjective tinnitus, but any other problem in the auditory system may also be to blame [3]. Age-related increases in perceived tinnitus frequency are typical, and hearing loss is the main contributing factor. Tinnitus can be caused by a lot of other factors, including exposure to noise, head trauma, middle ear problems, ototoxic medications, and Meniere's disease, but idiopathic instances are the most common type [4].

At the psychological and social/professional levels, persistent tinnitus can result in severe disruptions and morbidities. Counseling, psychotherapy, meditation, tinnitus retrain therapy, cognitive-based approaches, and sound enhancement are a few of the numerous potential tinnitus treatments that may reduce the loudness and irritation produced by the symptom [5]. However, the complete elimination of the symptom rarely occurs, therefore, tinnitus is constantly being studied, and there are always promising treatment approaches, such as the low-level laser therapy [LLLT] and intra tympanic steroids injection [6].

Low-level laser therapy [LLLT] is a recent therapy, which alters cellular activity by using low-energy lasers or light-emitting diodes [7]. Although the exact pathophysiology has yet to be investigated and discussed, it is most likely photochemical rather than thermal effects [8].

In contrast to high power lasers that are used to cut or destroy tissue, LLLT applies lasers with lower power to the surface of the body. LLLT acts by increasing blood microcirculation through sympathetic neural inhibition, prompting an increase in cell proliferation and enhancing adenosine triphosphate [ATP] synthesis in mitochondria. Together, it speeds up the repair and decreases the damage of cells and tissue [5, 9]. However, it was not until **Moon *et al*.** [10] assessed the safety of LLLT in an animal model that a laser power of less than 200 mW could be safely administered to the tympanic membrane without adverse effects such as edema, vascular congestion and inflammation.

On the other hand, intra tympanic injection medication, particularly when combined with steroids, offers promising effects. Steroids are one of the most often utilized medications for intra tympanic therapy because of their anti-inflammatory and electrolyte-modifying properties [11].

Drugs injected into the tympanic cavity are assumed to work by diffusing through the round window, the annular ligament of the oval window, capillaries, or the inner ear lymphatics [12].

There have been conflicting results about the effects of LLLT and intra tympanic steroids on tinnitus [13]. Therefor in our study we are comparing results of both low-level laser therapy and intra tympanic steroids injection in treatment of tinnitus.

THE AIM OF THE WORK

This study aims to compare the effectiveness of two new promising techniques in treating tinnitus; low level laser therapy versus intra tympanic dexamethasone injection using tinnitus handicap inventory, visual analogue scale of loudness and pure tone audiometry for evaluation before and after therapy.

PATIENTS AND METHODS

A comparative randomized clinical trial, included 40 patients with chronic tinnitus [> 6 months], was conducted at Al-Zahraa University Hospital during the period from November 2021 to August 2022. Patients with or without sensory neural hearing loss were included.

Ethical consideration: The study protocol, manual of procedures, informed consent form and translated form of tinnitus handicap

inventory were approved by the ethical committee of Al-Azhar faculty of medicine for girls on November 2021. Written informed consent was taken for the patients.

After detailed tinnitus evaluation, a complete otorhinolaryngology examination was performed in all patients. Also, audiometric examinations were conducted including tympanometry to exclude middle ear pathologies, and pure tone audiometry for exclusion of conductive hearing loss and detection of sensory neural hearing loss. All cases with unilateral tinnitus and/or unilateral hearing loss were imaged using MRI and all cases with neurological pathologies were excluded. Laboratory investigations [CBC-Thyroid profile] were done for exclusion.

Patients with conductive hearing loss, pulsatile tinnitus, tinnitus due to autoimmune diseases, and those with positive focal neurological findings were excluded.

This comparative study included 40 Patients [22 male and 18 females] aged between [20-75] years. Patients were randomly divided into 2 groups.

- **Group 1 [20 patients]:** received steroids injection [0.5 ml of 4 mg\ml dexamethasone] on six sessions twice weekly.

- **Group 2 [20 patients]:** underwent low level lase therapy transmeataly with wave length 650 nm and laser output 5 mW for 7 sessions [once daily for one week, each session lasts for 15 minutes].

All patients were evaluated using tinnitus handicap inventory [translated to Arabic by the author], visual analogue scale of loudness and pure tone audiometry before treatment and after treatment.

Interventions

I. Group 1

Patient lies flat with the affected ear facing the ceiling. The external ear canal is cleaned of debris. Emla cream 5% or xylocaine 10% spray applied to tympanic membrane for 30 minutes [14-16]. 0.5 to 1 mL of dexamethasone 4 mg\ml is injected slowly using a 25-gauge spinal needle or 3 cm syringe through the postoinferior region [14] into the middle ear space until full and the patient stayed in the same position for about 30 minutes. A total of six injections six injections [twice weekly] were performed according to **Yener *et al*.** [13].

II. Group 2

Patient sets in a chair looking forward wax and debris in the external auditory canal were removed. Low level laser device [LASPOT] giving a laser beam through an ear piece inserted through the external auditory canal with a wave length of 650 nm and an output power of 5 mw with time sets ranges from 15-60 minutes. Each patient receives 7 sessions [once daily for one week, each session lasts for 15 minutes] [17]. The device probe is inserted in the external auditory canal, and is adjusted on mode B [so only applicant work] time adjusted for 15 minutes.

Outcomes

All participants were evaluated one month after last treatment session by visual analog scale of loudness [18, 19], tinnitus handicap inventory [13, 19] and pure tone audiometry. Adverse events and any notes were assessed at all study visits. Successful treatment is defined as complete recovery or an improvement of THI score, visual analog loudness score. Changes in tinnitus perception [nature of sound, loudness and continuity] were considered a type of improvement.

Statistical analysis: Data were analyzed using Statistical Program for Social Science [SPSS] version 24. Quantitative data were expressed as mean ±SD. Qualitative data were expressed as frequency and percentage. Quantitative data were presented as mean and standard deviation [SD]. Mann Whitney [u] test [MW] was used when comparing between two means [for abnormally distributed data]. Chi-square test was used when comparing categorical data. P-value < 0.05 was considered significant.

RESULTS

There was no significant difference between studied groups regarding age [p-value 0.565], sex [p-value 0.057], smoking [p-value 0.465], family history [p-value 0.327], etiology of tinnitus [p-value 0.171] and tinnitus side [p-value 0.746] [table 1].

Table [2] shows statistically significant [P=0.003] increased percentage of changed sound nature after treatment in group 2 [17 patients; 85%] when compared with group 1 [8 patients; 40%]. No statistically significant difference was found between studied groups regarding continuity of tinnitus before and after treatment and sound nature before treatment.

Regarding measured outcomes, there was statistically significant [p < 0.001] decreased THI in group 1 after treatment [44.8 ± 17.5] when compared with THI before treatment [54 ± 17.5]. In addition, there was a statistically significant [p-value < 0.001] decreased THI in group 2 after treatment [32.3 ± 16.1] when compared with THI before treatment [58.8 ± 11.8]. Comparison between both groups revealed no statistically significant difference regarding THI before [P = 0.289] and after treatment [P= 0.076]. Regarding VAS of loudness, there was a statistically significant [p-value < 0.001] decreased VAS-L in group 1 after treatment when compared to before treatment in the same group. Furthermore, there was a statistically significant [p-value < 0.001] decreased VAS-L in group 2 after treatment when compared to before treatment in same group. Comparison between both groups revealed that VAS-L was significantly [P < 0.001] decreased after treatment in group 2 [4.45 ± 2.01] when compared with group 1 [6.4 ± 1.04] [table 3].

Regarding severity of tinnitus questionnaire, patients in group 2 showed significant decrease in the frequency of symptoms regarding trouble sleeping [P=0.016], working responsibilities [P=0.03] and concentration efforts [P=<0.001] as shown in table [4].

Regarding post-treatment complaints, all patients in group 1 experienced pain and transient increase in tinnitus loudness compared to none in group 2. Transient vertigo was reported among 60% in group 1 versus none in group 2 [P=<0.001]. Three patients in group 2 felt transient external canal itching versus none in group 1 [table 5].

Table [1]: Comparison between studied groups as regard demographic and etiological data

		Group 1 [n= 20]	Group 2 [n = 20]	Test	P-value
Age [years]	Mean±SD	43.8±10.1	46.5±17.2	178[&]	0.565
Sex	Male Female	8 [40%] 12 [60%]	14 [70%] 6 [30%]	3.6[#]	0.057
Smoking	No Yes	16 [80%] 4 [20%]	14 [70%] 6 [30%]	0.53[#]	0.465
Family history of tinnitus	Negative Positive	14 [70%] 6 [30%]	11 [55%] 9 [45%]	0.96[#]	0.327
Etiology	Meniere's disease Idiopathic Acute noise exposure Head trauma	4 [20%] 8 [40%] 4 [20%] 4 [20%]	6 [30%] 11 [55%] 0 [0%] 3 [15%]	5.01[#]	0.171
Tinnitus side	Right Left Bilateral	4 [20%] 4 [20%] 12 [60%]	6 [30%] 3 [15%] 11 [55%]	0.58[#]	0.746

*: significant; DM: Diabetes Mellitus; HTN: Hypertension; [&]: Mann Whitney U test; [#]: Chi-square test.

Table [2]: Comparison between studied groups as regard tinnitus

		Group 1 [n= 20]	Group 2 [n = 20]	Test	P-value
Continuity of tinnitus before treatment	Continuous Intermittent	20 [100%] 0 [0%]	20 [100%] 0 [0%]	----	----
Continuity of tinnitus after treatment	Changed Not changed	8 [40%] 12 [60%]	6 [30%] 14 [70%]	0.44[#]	0.507
Sound nature before treatment	Humping Whistling Roaring Ocean waves	4 [20%] 12 [60%] 4 [20%] 0 [0%]	3 [15%] 11 [55%] 3 [15%] 3 [15%]	3.3[#]	0.344
Sound nature after treatment	Changed Not changed	8 [40%] 12 [60%]	17 [85%] 3 [15%]	8.6[#]	**0.003***

*: significant; [&]: Mann Whitney U test; [#]: Chi-square test

Table [3]: Comparison between studied groups regarding different outcome measurements

		Group 1 [n= 20]	Group 2 [n = 20]	Test	P-value
THI [before]	Mean ± SD	54±17.5	58.8±11.8	160	0.289
THI [after]	Mean ± SD	44.8±17.5	32.3±16.1	134	0.076
P value*		**< 0.001**	**< 0.001**		
VAS [before]	Mean ± SD	8±0.9	7.75±1.3	182	0.640
VAS [after]	Mean ± SD	6.4±1.04	4.45±2.01	66	**< 0.001**
P value*		**< 0.001**	**< 0.001**		

*: significant P value on comparing values before and after treatment

Table [4]: Comparison between studied groups as regard studied questionnaire

		Group 1 [n= 20]	Group 2 [n = 20]	Test	P-value
Because of your tinnitus, do you have trouble falling to sleep at night? [Before]	Sometimes Yes	4 [20%] 16 [80%]	2 [10%] 18 [90%]	0.78	0.376
Because of your tinnitus, do you have trouble falling to sleep at night? [after]	No Sometimes Yes	0 [0%] 12 [60%] 8 [40%]	6 [30%] 11 [55%] 3 [15%]	8.3	**0.016**
Does your tinnitus interfere with your job or household responsibilities? [Before]	No Sometimes Yes	4 [20%] 4 [20%] 12 [60%]	6 [30%] 6 [30%] 8 [40%]	1.6	0.449
Does your tinnitus interfere with your job or household responsibilities? [after]	No Sometimes Yes	4 [20%] 12 [60%] 4 [20%]	12 [60%] 5 [25%] 3 [15%]	7.02	**0.03**
Because of your tinnitus, is it difficult for you to concentrate? [Before]	Sometimes Yes	8 [40%] 12 [60%]	6 [30%] 14 [70%]	0.44	0.507
Because of your tinnitus, is it difficult for you to concentrate? [after]	No Sometimes Yes	0 [0%] 12 [60%] 8 [40%]	9 [45%] 11 [55%] 0 [0%]	17.04	**< 0.001**

Table [5]: Comparison between studied groups as regard sequelae

	Group 1 [n= 20]	Group 2 [n = 20]	X^2	P-value
Pain	20 [100%]	0 [0%]	40	**< 0.001**
Transient Vertigo	12 [60%]	0 [0%]	17.1	**< 0.001**
Headache	4 [20%]	4 [20%]	0.0	1.0
Transient increase in tinnitus loudness	20 [100%]	0 [0%]	40	**< 0.001**
Transient external canal itching	0 [0%]	3 [15%]	3.2	0.072

DISCUSSION

Since there is now no single method of tinnitus treatment that will completely eradicate the condition everywhere, individuals are left attempting to live with untreated tinnitus. Different approaches have been devised by various doctors in an effort to give tinnitus suffers a good quality of life [14].

Tinnitus handicap inventory [THI] is a questionnaire involving 25 questions with 3 possible answers, yes with a score 4, sometimes with a score 2 and no with a score 0. It is a tool of evaluation of patients before treatment and one month after treatment [13, 19]. In the current study, the mean THI for group 1 before treatment was 54 ± 17.5, which dropped after treatment to 44.8 ± 17.5 [p < 0.001]. This was in agreement with the results of **Yener *et al.*** [13] who reported that the comparison of the THI total score mean between the groups [control and intratympanic injection] revealed significantly lower scores in the study group [p=0.05] after 7 sessions of 0.5 ml of 4 mg/ml steroid injection every day for 1 week. **Karabulut *et al.*** [20] also reported significant decrease in the mean total THI score after 3 sessions of 0.5 ml of 4 mg/ml steroid injection every other day. **Elzayat *et al.*** [21] also agreed that mean total THI score was lowered in study group after treatment with 4 sessions of 1ml injection of 8 mg/2ml dexamethasone once weekly for one month. Furthermore, **An *et al.*** [22] reported that 74.6% of cases improved according to evaluation with THI score with a

parameter that improvement occurs with 20 points of THI score or more decrease after treatment with after 4 sessions of 0.5 ml of 5 mg/ml steroid injection.

On the other hand, **Shim *et al*.** [23] findings were against our study with only 35% of cases achieved the improvement parameter, 20-point decrease or more after treatment after 4 sessions of 0.5 ml of 5mg/ml steroid injection. This difference in results may be a result of lower sessions, different dose or different parameters of improvement. Also, **Choi *et al*.** [24] showed similar findings, who considered improvement when total THI score decreases 5 or more after treatment after 4 sessions of 0.4 ml of 5 mg/ml steroid injection twice weekly for two weeks. This difference in results may be a result of lower sessions, different dose or different parameters of improvement.

Regarding the mean THI for group 2 before treatment, it was 58.8 ± 11.8, which turned after treatment to 32.3 ± 16.1 [P < 0.001]. Our results came in agreement with **Chen *et al*.** [5] in their systematic review with meta-analysis, who concluded that the THI scores were significantly lowered after LLLT in 2 studies with different measurements [25, 26]. Also, **Gungor *et al*.** [27] came with the same results, where THI was significantly lowered two weeks after treatment with 7 sessions each for 15 minutes once daily for one-week 5 mw and 650 nm laser. **Cuda *et al*.** [28] also agreed with our results reporting significant decrease in THI score after treatment with 20 min session daily for a total of 90 sessions with 5 mw and 650 nm laser.

However, **Teggi *et al*.,** [29] came against our results reporting non-significant difference in THI score after treatment with 20 min session daily for a total of 90 sessions with 5 mw and 650 nm laser. Similarly, **Mirvakili *et al*.** [30] was against our results as they reported non-significant change in THI score 3 months after treatment [p-value 0.85] with 20 minutes session 3 times weekly for seven weeks with total 20 sessions. This may be explained that a relapse may had occurred after 3 months in follow up as all previous studies had an immediate, 2 week or one month follow up after treatment.

Comparing both modalities revealed non-significant difference regarding THI after treatment, which indicates that none of the two treatment methods came prior to the other.

Visual analog scale of loudness score was collected before and one month after treatment. The mean VAS-L in group 1 before treatment was 8 ± 0.9 and after treatment became 6.4 ± 1.04 [p < 0.001]. Our results also came in agreement with **Sakata *et al*.** [31] and **Karabulut *et al*.** [20] who reported significant decrease in mean VAS-L after treatment in injection groups when compared with control groups. **Yoshida *et al*.** [32] also agreed with our study and found significant decrease in VAS-L after treatment [P-value 0.05] with a parameter of improvement, 2 point or more decrease in VAS. **An *et al*.** [22] also agreed with our study reporting 74.6% of cases improved with the same previous improvement parameter.

Cesarani *et al*. [33] agreed with our study even when their study considered improvement when complete resolution for grade 0 as regard VAS occurs and they reported 74% improvement after treatment with 9 sessions of 4 mg/ml steroid injection 3 times per month for 3 months.

In contrast, **Shim *et al*.** [23] came against our results as he reported only 35% of cases improved with non-significant results as he considered improvement when VAS was lowered 2 or more points after treatment. This difference in results may be a result of lower sessions, different dose or different parameters of improvement.

In group 2, the mean VAS-L before treatment was 7.75 ± 1.3. and after treatment was 4.45 ± 2.01 [p < 0.001]. These results came in agreement with **Ferreira *et al*.** [19], a systemic review reported two studies [25, 34], and found a significant decrease in VAS-L after treatment when compared to before treatment in study groups [LLLT]. **Gungor *et al*.** [27] and **Teggi *et al*.** [29] also agreed with our results.

On the contrary, **Mirvakili *et al*.** [30] reported non-significant changes in VAS at three months after treatment [p-value 0.522]. This may be explained that a relapse may had occurred after 3 months in follow up as all previous studies had an immediate, 2 week or one month follow up after treatment.

Regarding sequelae, only 7 patients in group 2 had a sequel after treatment; 4 had headache [20%] and 3 had transient external canal itching [15%]. These data revealed that intra tympanic steroid injection had more sequel as there was

statistically significant [p-value < 0.001] increased percentage of pain, transient vertigo and transient increase in tinnitus loudness in group 1 [20 patients, 100%] when compared with group 2 [0 patients, 0%].

Ferreira *et al*. [19], a systemic review included 7 studies agreed with our results that low-level laser therapy had minimal side effects on patients and four studies reported almost no side effects. **Yener *et al*.** [13] was against as they reported no side effects with intratympanic injection, while all patients in group 1 in our study had at least 2 significant side effects.

Limitations of our study: This was a short-term study of a limited number of cases so long term follow up was difficult. Chronic tinnitus cases were difficult to collect as they mostly lose hope of treatment and seek no help so most of them were collected from the audiology units [for a hearing aid] rather than outpatient clinic.

Conclusion: Low level laser therapy is more effective and safer than intratympanic steroid injection in treating tinnitus [chronic tinnitus with duration more than 6 months]. Trying a different protocol of laser therapy with bigger number of sessions may give better results even till tinnitus disappearance.

Conflict of Interest and Financial Disclosure: None.

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International Journal of Medical Arts

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Print ISSN: 2636-4174
Online ISSN: 2682-3780