# RESEARCH ARTICLE

# A comparative study on photobiological effects of low-level laser therapy and tinnitus retraining therapy in patients with acoustic trauma-induced tinnitus

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# **Abstract**

Background and Aim: Tinnitus is a subjective auditory symptom referred to the perception of sound in the absence of external stimuli, and there is no definite treatment for it. Rehabilitation methods and laser therapy have been recommended used for its management. This study aimed to investigate the photobiological effects of low-level laser therapy (LLLT) and tinnitus retraining therapy (TRT) in patients with acoustic traumainduced tinnitus.

Methods: This clinical trial was conducted on 60 patients suffering from acoustic trauma-induced tinnitus for more than six months, divided into three groups of LLLT, TRT and LLLT + TRT. The Persian version of tinnitus handicap inventory (P-THI), visual analog scale (VAS), and loudness match (LM) scale were used to collect data. The collected data were analyzed in SPSS version.22 software. The effect of time, group and time × group on the scores of VAS, LM, P-THI and its subscales were examined.

**Results:** There was a statistically significant difference between LLLT + TRT and LLLT groups after intervention in terms of LM (p = 0.002) and

\* Corresponding author: Ear, Nose and Throat Clinic, Imam Reza Hospital, Aja University of Medical Sciences, Dr. Fatemi Ave. Eatemadzade St., Tehran, 1411718546, Iran. Tel: 009821-86096354, E-mail: mostafa.cheraghipour@yahoo.com VAS (p = 0.001) variables, but no statistical significance for P-THI and its subscales (p = 0.442) was found.

**Conclusion:** Combination of LLLT and TRT, as a therapeutic protocol, is recommended due to their remarkable effects in reducing acoustic trauma-induced tinnitus symptoms. The use of LLLT method alone, however, is not recommended due to its lower effects.

**Keywords:** Tinnitus; low-level laser therapy; tinnitus retraining therapy; tinnitus handicap inventory; loudness matching; visual analog scale

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## Introduction

Tinnitus is one of the most common distressing diseases of the auditory system, especially among the personnel of military and industrial sectors. In this disorder, the person involuntarily perceives a sound with no external origin either in one or both ears. Tinnitus can lead to sleep disturbances, impaired concentration, stress,

anxiety, etc. [1,2]. The sound can stem from the middle ear, the cochlea, the brainstem or the central nervous system. Rather than a disease, tinnitus is an indicator of a problem in central or peripheral nervous systems. Exposure to sound and acoustic trauma are the most prevalent reported causes of tinnitus [3]. Tinnitus has been the subject of many studies, especially those conducted on the military personnel. In a prospective study by Nondahl et al., the prevalence of tinnitus in United States was reported 9%, of which 2% was reported intolerable [4]. Folmer et al. investigated the prevalence of tinnitus among US soldiers and veterans using the National Health and Nutrition Examination Survey data. They reported a prevalence of 8.8% and 6.1% in individuals with high and low noise exposure, respectively [5]. MacGregor et al. investigated the prevalence of tinnitus among the US soldiers who were present in Afghanistan and Iraq wars zones. They reported a prevalence of 19.1% and 31.3 % in first and second health evaluations, respectively [6]. Tinnitus is a challenging problem in patients with hearing impairments. So far, no definite treatment was introduced for it. Regarding the high prevalence of tinnitus, determining therapeutic protocols for tinnitus is essential.

Although many pharmacological treatment methods such as anxiety medications, antidepressants, sedatives and dietary supplements have been studied, their use was only able to reduce the symptoms and have not been a definitive treatment method [2,7,8]. Hence, to reduce or terminate the symptoms, therapeutic and rehabilitation methods such as tinnitus retraining therapy (TRT), sound therapy, cognitive behavioral therapy (CBT), biofeedback, electrical stimulation and laser therapy [9-11] have been proposed. By using these methods in paraclinical wards, the symptoms can somehow be mitigated or even temporarily or permanently terminated. Nowadays, laser therapy is widely used for diagnostic and therapeutic purposes. The low-level laser therapy (LLLT) is a method that is used for treatment and rehabilitation of tinnitus in patients. The LLLT is also used for sudden sensorineural hearing loss, Meniere's disease and balance impairments [12,13]. With direct effect on rapid regeneration of hair cells, the LLLT can improve the symptoms or prevent the additional cell damage. In this method, the wavelength is irradiated in a way that allows the photons to pass through the tissue and stimulate the targeted cells. In this process, the laser photons are absorbed by the cell and, since photons are biologic stimuli, stimulate the cells to induce biological responses that can help by improving blood circulation and cell regeneration [14,15]. The TRT is a rehabilitation method consisted of psychological counseling and sound therapy. By reducing the intensity of tinnitus, sound therapy facilitates the habituation process, while counseling aims to reclassify the tinnitus symptoms into either ineffective or negative effects for adaptation to tinnitus by inducing changes in the mechanisms responsible for transferring signal (tinnitus or external sound in case of misophonia) from the auditory system to the limbic and autonomic nervous systems, and through this, remove signal-induced reactions without attempting to directly attenuate the tinnitus source or tinnitus/ misophonia-evoked reactions. In counseling, the patient is trained about neurophysiological pattern of tinnitus, receives detailed information to reduce patient concerns and is prepared for the adaptation process (Fig. 1) [11,14,16,17].

Given the wide and successful application of lasers in medical fields [18], and notable effects of TRT in tinnitus rehabilitation, this study aims to investigate the effectiveness of LLLT combined with TRT in tinnitus patients. Due to the different mechanisms of the two methods (LLLT is effective in regenerating damaged cells and TRT help with the process of tinnitus habituation), their combination may have a significant effect on the treatment of tinnitus.

## **Methods**

# **Participants**

This study was conducted from March 2020 to February 2021 in the Department of Ear, Nose and Throat (ENT), Imam Reza Hospital in Iran. Participants were 60 patients with tinnitus aged 20–60 years who had experienced various levels of noise and acoustic trauma. They reported

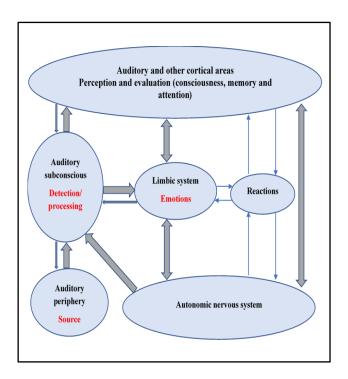


Fig. 1. The neurophysiological model of tinnitus.

either unilateral or bilateral tinnitus in the past six months due to presence in war zones and military services. The majority of them had experienced one or more sessions of medication therapy using sedatives and dietary supplements (e.g. vitamin B1 and ginkgo derivatives). Five subjects had received incomplete auditory and tinnitus rehabilitation services and 10 had not received any treatment. The inclusion criteria were normal tympanic membrane condition under otoscopy, no any complication neither in middle ear nor in the outer ear canal under otoscopy and tympanometry tests, no complications in the inner ear (e.g. Meniere's syndrome, perilymphatic fistula, and superior semicircular canal dehiscence syndrome), experiencing subjective tinnitus caused by acoustic trauma, no any health problems (e.g. neurologic diseases, severe panic disorders, mental disorders, drug/alcohol abuse), and receiving no medication or rehabilitation for tinnitus in the past three months. Violating one of inclusion criteria leads to the exclusion from the study. The hearing threshold of participants was < 25 dB HL from 500 to 2000 Hz and their hearing loss was

in a range of 25–45 dB HL (mild to moderate) at 3000–8000 Hz frequency [2].

## **Procedure**

Medical examination was first conducted by an ENT specialist to check the conditions of the outer (for earwax), and middle ears (for otitis media), medication use, family history and other diseases in patients that can affect the study outcome. Next, all eligible participants were referred to an audiologist for audiologic testing, completing questionnaires, and receiving LLLT and TRT. Audiologic tests included pure-tone audiometry using an audiometer (AT235, Interacoustics, Denmark) and TDH39 headphones, tympanometry using a tympanometer (AD229 e, Interacoustics, Denmark), ipsilateral and contralateral acoustic reflexes, tinnitus assessments, and the impact of tinnitus on social and emotional functions. Then, the tinnitus-related impairments were measured using Persian version of tinnitus handicap inventory (P-THI) [19], and visual analog scale (VAS), while the tinnitus loudness was measured by loudness match (LM) scale. Tinnitus assessments included the determination of pitch-matching (PM), minimum masking level (MML), and residual inhibition (RI) (Table 1). Most participants in the study reported a PM close to audiometry frequencies of hearing loss. Their LM was 0-10, and their MML was reported 5-30 dB SL. With a Cronbach's alpha coefficient of 0.93, the P-THI measures the impact of tinnitus on a patient's daily life. This questionnaire consists of 25 items and three subscales of functional (11 items), emotional (9 items), and catastrophic (5 items) [20]. The VAS is used for the evaluation of cognitive impairments that cannot be directly measured. Using this test, the patients were asked to rate their tinnitus on a scale from 0 to 100. All assessments were conducted before and after intervention. The audiologic tests and P-THI took 20 and 40 min to complete, respectively. Then, the participants were randomly divided into three groups of LLLT, TRT and LLLT + TRT. In the LLLT group, a low-powered laser (5 mW power and 650 nm wavelength) was irradiated to the target area for 20 min (15 min through the ear

Table 1. Pitch-matching, loudness-matching, minimum-masking-level, and residual inhibition in low-level laser therapy, tinnitus retraining therapy, and low-level laser therapy and tinnitus retraining therapy groups

	LLLT (pre/post)				TRT (pre/post)				TRT & LLLT (pre/post)			
Subject (ear)	PM (Hz)	LM (dB SPL)	MML (dB SPL)	RI (+/-)	PM (Hz)	LM (dB SPL)	MML (dB SPL)	RI (+/-)	PM (Hz)	LM (dB SPL)	MML (dB SPL)	RI (+/-)
1	6/6	6/4	10/10	+/+	3/4N	5/2	15/5	+/+	6 & 4/6N	7/2	10/10	+/+
2	4/4	5/3	15/15	+/+	4/4	5/3	10/0	+/+	6/6N	8/4	10/10	+/+
3	6/8	8/6	10/5	+/+	6/6N	6/3	15/0	+/+	4/4	7/3	15/10	+/+
4	3 & 4/4	7/5	15/10	+/+	8/8	6/4	15/0	+/+	6/4	6/2	10/5	+/+
5	4/4	5/3	5/5	+/+	6 & 8/8	6/3	10/0	-/-	3/6N	6/2	15/15	+/+
6	8/8	5/3	5/10	+/+	4/4	8/3	10/5	+/+	6/6	5/1	20/10	-/+
7	6/8	6/4	10/10	+/+	2/2N	6/3	5/10	+/+	3 & 4/4N	8/2	25/25	-/+
8	8/8	6/4	15/5	-/-	6/6	6/3	15/5	+/+	6/6	6/3	10/5	+/+
9	3/3	8/6	5/10	+/+	4/4N	6/4	20/5	+/-	6/6N	5/2	15/10	+/+
10	4 & 6/8	7/5	10/10	+/+	6/6	7/3	10/0	+/+	4/6	6/2	15/10	+/+
11	4/4	5/4	15/20	+/+	8/8	5/3	10/5	+/+	8/8	6/2	10/10	+/+
12	2 & 4/4	8/6	20/20	-/+	8N/8N	7/3	15/5	+/+	8N/8	5/1	5/5	+/+
13	4N/4	4/2	10/10	+/+	4/8N	5/3	15/5	+/+	8 & 6/8N	8/5	10/5	-/-
14	6 & 4N/6	6/4	15/5	+/-	6/6	6/4	15/5	-/-	8/8	6/2	5/10	+/+
15	3/3	7/5	10/5	+/+	4/4	6/3	10/0	+/+	8/6	6/2	15/5	+/+
16	4/4	5/3	5/5	+/+	6 & 4/4N	8/3	25/5	+/+	4/4N	8/2	15/10	+/+
17	6N/6	6/4	10/10	+/+	6/6	5/3	25/5	-/+	6/6	6/2	20/10	-/+
18	8/8	7/7	20/25	-/-	8/8	6/4	10/0	+/+	3/3	6/2	25/10	+/+
19	4N/4N	7/7	20/20	-/-	4/6	7/4	15/5	+/+	3/3N	6/3	30/25	+/+
20	4/4	6/3	15/15	+/+	8/6	7/4	30/0	-/+	6/3 & 6N	7/3	10/5	-/-
21	6/6	8/5	5/10	+/+	4/4N & 6	5/3	20/5	+/+	4/4	6/1	15/5	+/+
22	8/8N	5/5	10/5	-/+	4/4	7/7	15/5	+/+	4/4N	7/2	15/10	-/+
23	6/4N	7/5	10/10	+/+	6/	5/0	10/0	+/+	6/6N	8/2	10/5	+/+
24	6N & 4/6N	5/3	15/15	+/+					6/6	6/2	5/10	-/+
25	8/8N	3/1	10/10	+/+								

LLLT; low-level laser therapy, TRT; tinnitus retraining therapy, PM; pitch-matching, LM; loudness match, MML; minimum masking level, RI; residual inhibition, (+); complete and partial residual inhibition reports were considered positive, (-); absent and rebound residual inhibition were reported negative



Fig. 2. Low-level laser device (Tinnitool DiskMark GmbH) used in current study.

canal and 5 min through the mastoid bone) at 20 sessions over 60 days (3-day intervals) [21]. Using a portable device (TinniTool, DiskMark GmbH, Switzerland) (Fig. 2).

For the patient convenience, they received instructions on how to use the device to continue the therapy at home and were asked to report online on how and how long they used the device. In the TRT group, participants first become familiar with the neurophysiological patterns of tinnitus. The therapeutic principles for tinnitus including counseling and discussion about habituation, control and fitting of hearing aids were explained to them. A comprehensive plan to eliminate the negative associations of tinnitus and facilitate the adaptation process was also established for them by providing information about the involved mechanisms and the subsequent anxiety [22]. The predominant cause of negative associations generated by tinnitus is the unawareness of the patient or inappropriate counseling that can lead to fear and anxiety [23,24]. The counseling included: a) explaining about the results of auditory tests, b) describing the functions of peripheral and central auditory systems, limbic system, and autonomic nervous system, c) relating these

functions to the patient's condition, d) explaining about the tinnitus habituation and how to achieve it, e) explaining about the effect of sound therapy, and f) answering to the patient's questions about the neurophysiological patterns of tinnitus [22,23]. Given that all participants were suffering from a degree of hearing loss at frequencies > 3000 Hz, ranging from mild to moderate, sound therapy was carried out as a substantial part of TRT for the patients while walking using Bernafon Zerena 1 receiver-in-the-canal (RIC) model made in Switzerland. This model has the most appropriate frequency amplification and coverage with the least amount of feedback for high frequency effects and, thus, is a suitable model for the participants [22,25]. The RIC hearing aids are suitable for reducing the occlusion effect. Two hearing aid programs were used for each participant in this group. The first program consists of amplified ambient noise and speech sounds used in a noisy environment. The second program consists of a broadband white noise used in a quiet environment.

# Statistical analysis

At the end of the study, two participants failed to continue the study. The remaining 58 participants included 19 in the LLLT group, 19 in the TRT group, and 20 in the LLLT + TRT group. To examine the mean difference between the study groups before and after the intervention, repeated measure ANOVA was performed. To know where was the difference between the three groups, Tukey's post hoc test was carried out. The significance level was set at 0.05 for all analyses conducted in SPSS 22 software.

#### **Results**

Of 58 participants, 14 had unilateral tinnitus and 44 had bilateral tinnitus (32 experiencing it in the right ear and 40 in the left ear). The mean age of participants was  $41 \pm 10$  years (ranged 21-59 years) with a mean tinnitus duration of  $4 \pm 2$  years. Based on the VAS results, a total decrease of 48.4% in tinnitus loudness was observed after intervention ( $31.8 \pm 13.9$ ) compared to pre-intervention value ( $59.7 \pm 12.9$ ). The greatest tinnitus loudness reduction (75%) was observed

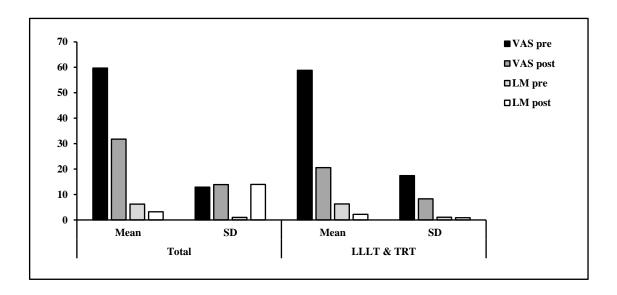


Fig. 3. Mean and standard deviation of the visual analog scale and loudness matching in two groups of total subject and subject using low-level laser therapy and tinnitus retraining therapy intervention.

VAS; visual analog scale, LM; loudness match.

in the LLLT + TRT group  $(58.8 \pm 17.4 \text{ reduced})$  to  $20.6 \pm 8.3$ ). The reduction was also observed in the LM after intervention  $(3.2 \pm 1.4)$  compared to the pre-intervention value  $(6.2 \pm 1)$ . The LM reduction was higher in the LLLT + TRT group  $(6.3 \pm 1.1 \text{ reduced})$  to  $2.2 \pm 0.9$ , which had a significant correlation with the VAS score (Fig. 3).

The results of ANOVA showed that the effect of time ( $F_{(1,69)} = 416.05$ , p < 0.001), group ( $F_{(2,69)} = 7.2$ , p = 0.001) and time × group ( $F_{(2,69)} = 23.6$ , p < 0.001) was statistically significant on the VAS score. The results of Tukey's post hoc test showed a statistically significant difference between LLLT + TRT and LLLT (p = 0.001) and between LLLT + TRT and TRT (p = 0.038) groups, while no statistically significant difference was observed between LLLT and TRT groups (p = 0.48) (Fig. 4).

Regarding the LM, the findings also showed the statistically significant effects of time ( $F_{(1,69)} = 619.9$ , p < 0.001), group ( $F_{(2,69)} = 6.5$ , p = 0.002) and time × group ( $F_{(2,69)} = 33.9$ , p < 0.001). The results of Tukey's post hoc test showed a statistically significant difference between LLLT + TRT and LLLT groups (p = 0.002), while no statistically significant difference was observed

between LLLT + TRT and TRT (p = 0.344) and between LLLT and TRT (p = 0.088) groups. Since both LM and VAS score are associated with tinnitus loudness, their Pearson correlation coefficient was measured which was positive and significant (r = 0.881, p < 0.001).

The results showed a significant decrease in the P-THI score and its subscales after intervention. The mean total P-THI score before intervention was  $52.4 \pm 14.3$  reduced to  $32.9 \pm 14.7$  after the intervention. This reduction was greater in LLLT + TRT group (54.6  $\pm$  11.7 reduced to 27.9  $\pm$  11.6) (Fig. 5). For the overall P-THI, the findings revealed that the effects of time  $(F_{(1,55)} = 202.7,$ p < 0.001) and time  $\times$  group  $(F_{(2.55)} = 9.3,$ p < 0.001) was statistically significant while the effect of group was not statistically significant  $(F_{(1,55)} = 1.1, p > 0.323)$ . The results of Tukey's post hoc test showed no statistically significant difference between LLLT + TRT and LLLT (p = 0.442) and between LLLT + TRT and TRT (p = 0.982) groups. Regarding the subscales of P-THI, the results showed that the effect of time on catastrophic  $(F_{(1,55)} = 132.1, p < 0.001)$ , emotional  $(F_{(1,55)} = 148.7, p < 0.001)$  and functional  $(F_{(1,55)} = 110.2, p < 0.001)$  responses were statistically significant. The effect of group was not

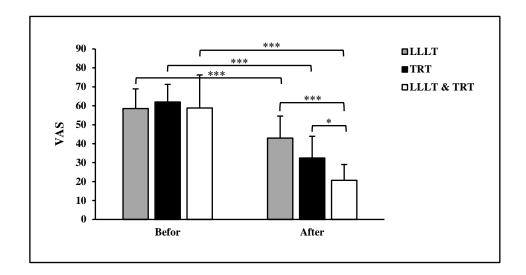


Fig. 4. Comparing the results of visual analog scale for low-level laser therapy, tinnitus retraining therapy and low-level laser therapy and tinnitus retraining therapy groups before and after intervention. As shown in the figure, there is significant difference between low-level laser therapy and tinnitus retraining therapy groups (\*\*\* =  $p \le 0.05$ ) and this difference between the low-level laser therapy and tinnitus retraining therapy groups after intervention is not significant (\* = p > 0.05). VAS; visual analog scale, LLLT; low-level laser therapy, TRT; tinnitus retraining therapy.

statistically significant on catastrophic ( $F_{(2,55)} = 0.8$ , p = 0.433), emotional ( $F_{(2,55)} = 0.3$ , p = 0.681) and functional ( $F_{(2,55)} = 0.2$ , p = 0.787) responses. However, the interaction effect of time and group on catastrophic ( $F_{(2,55)} = 3.4$ , p = 0.038), emotional ( $F_{(2,55)} = 8$ , p = 0.001) and functional ( $F_{(2,55)} = 4.5$ , p = 0.014) responses were statistically significant.

With respect to the subscales of P-THI, the results of Tukey's post hoc test showed no statistically significant difference between LLLT + TRT and LLLT ( $P_{Ca} = 0.816$ ,  $P_F = 0.847$ ,  $P_E = 0.795$ ) and between LLLT + TRT and TRT ( $P_{Ca} = 0.758$ ,  $P_F = 0.941$ ,  $P_E = 0.855$ ) groups.

## **Discussion**

The current study investigated three clinical methods of LLLT, TRT and combined LLLT and TRT in patients suffering from tinnitus caused by acoustic trauma. The participants reported various degrees of tinnitus with a duration of more than one year and loudness of > 3 dB SL under LM evaluation. Sound therapy was conducted on these patients using RIC hearing aids. The results indicated the positive effects of all three methods in removing sensitivity to tinnitus, reducing its

symptoms, and improving the psychological conditions of patients. Based on the LM and VAS score, a statistically significant decrease in tinnitus loudness was found after intervention in all three groups. Decreased loudness can reduce the annoyance caused by tinnitus, improve sleep quality, and reduce stress [16,17]. In this study, a total decrease of 48.4% in tinnitus loudness was reported in all groups after interventions. This is consistent with the findings of Dmirkol et al., Shiomi et al., Gungor et al. and Montazeri et al. who suggested that LLLT can be a valuable and effective method in improving the tinnitus symptoms [26-29]. One of the strengths of the current study was the use of higher number of LLLT sessions compared to other studies. In other words, additional routine sessions per week can be more beneficial for patient recovery.

The direct simulation effect of laser on the ions in cells increases the amount of energy or adenosine triphosphate (ATP) required to activate sodium-potassium pump. After a tissue damage, the membrane potential is rapidly declined and the neurons become depolarized quickly. This process results in pain perception and tissue dysfunction. Laser therapy improves the

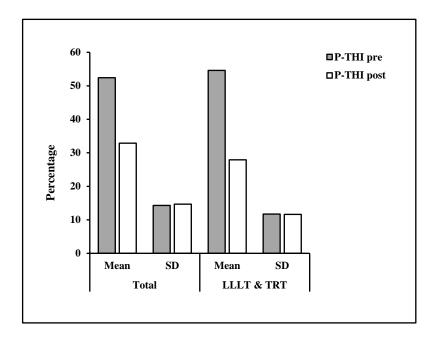


Fig. 5. Mean and standard deviation of the tinnitus handicap inventory in two groups of total subject and subject using low-level laser therapy and tinnitus retraining therapy intervention. P-THI; Persian version of tinnitus handicap inventory, LLLT; low-level laser therapy, TRT; tinnitus retraining therapy.

metabolism of body and promotes blood flow to the damaged tissue, contributing to cell regeneration [14,30,31]. Moreover, biological induction by laser therapy is conducive to cell division and activation of specific immune-defense molecules through simulation of immune system. Laser therapy, by affecting optical receivers (hemoglobin, porphyrins and cyclic nucleotides) and reacting to red light spectrum, simulates the changes in metabolism and structure of DNA, RNA and proteins. These changes subsequently lead to the synthesis of intermediate compounds such as free radicals and oxidized radicals which are essential for secondary reactions of cell regenerative process [9]. Therefore, these mechanisms underlying the cell-regeneration effects of laser may explain the effect of LLLT in improving tinnitus symptoms. It should be mentioned that a hearing loss of  $\leq$  50 dB HL was one of the inclusion criteria in our study, since the outer hair cells may be impaired at this level of hearing loss which can make the regeneration and recovery conditions difficult, terminate active augmentation of cochlea, and impair auditory efferent system

# [32].

Other study method was TRT which consists of two components, psychological counseling and sound therapy. In sound therapy, the adaptation of patient to tinnitus is facilitated using appropriate sounds. Limbic and autonomic nervous systems are involved in this adaptation process. If a person perceives tinnitus without having a negative reaction to it, the tinnitus signal will be constrained to the auditory system, but if it spreads to the limbic and autonomic nervous systems by activating the sympathetic part of the autonomic system, it will evoke several negative reactions such as annoyance, anxiety, and panic and triggers survival reflexes resulting in decreased quality of life [22,23].TRT works independent of the cause of the tinnitus, and the habituation of the reaction to the tinnitus occurs outside the central auditory pathways. Therefore, the etiology of tinnitus is irrelevant, and TRT can be successfully used for any type of tinnitus, e.g. bilateral, unilateral, continuous, or intermittent, as well as for somatosounds [22]. Habituation cannot be achieved to dangerous or threatening

stimuli or may be achieved with difficulty which evoke strong emotional reactions (negative or positive). Therefore, the primary goal of counseling in TRT is the reclassification of tinnitus signal to the category of neutral stimuli. This is achieved by teaching the mechanisms of tinnitus and its nature, although it may evoke strong negative reactions affecting the quality of life of the patients. Tinnitus patients usually have poor understanding of tinnitus and it remains a mystery for them. Therefore, demystification of tinnitus and providing patients with sufficient knowledge is important [22]. Since there is no tool for controlling unconscious areas of the brain, the negative associations of tinnitus can be reduced by providing the patient with information about the mechanisms of tinnitus and the ensuing stress [34]. Generally, the main cause of such negative associations is the lack of knowledge of tinnitus mechanism and its origin in patients. Therefore, providing patients with the right information can greatly mitigate the fear and anxiety in them, and inform them how to manage their mental problems [22]. Patients feel more relaxed after expressing their problems and receiving appropriate feedback. Perhaps, one of the reasons for the success of TRT is the use of counseling.

Sound therapy is another component of TRT [22,23] which was presented to the patients in the TRT and LLLT + TRT groups using hearing aids (two manual fitting programs using white noise presentation and sound amplification). The patients reported the significant reduction of the annoying symptoms of tinnitus. Their handicap caused by tinnitus was measured using the P-THI whose results showed a significant decrease in the P-THI score and its subscales. The study participants were not candidate to use hearing aids since their hearing loss was mild to moderate at high frequencies. Fitting hearing aids can enhance the auditory input, reduce the difficulty and efforts to hear the speech, and increase the quality of life of patients. Combination hearing devices (combining sound generators and hearing aids) are preferable option for sound therapy to be used along with enrichment of environmental sounds [22]. In people with hearing loss, sound generators are not used alone, as they can

make the understanding of speech even more difficult. Such devices can make tinnitus even worse due to an increase in the strain to hear and understand the speech [22]. According to the results of this study, achieving an optimal habituation process can be attributed to the sound therapy program using partial noise or amplifying sound [22,33]. The results of this study were consistent with the findings of Shekhawat et al., Sereda et al., Ricketts et al. and Lee et al. One disadvantage of these studies is the lack of attention to the adverse effects of tinnitus and the behavioral and psychological aspects of tinnitus patients [11,35-37]. We not only used sound therapy by acoustic tools but also considered the behavioral and psychological aspects of patients by counseling them [38]. Our results were also consistent with the findings of Nemade et al. and Reddy et al. in terms of using TRT [17,39]. One disadvantage of our study compared to these studies was the shorter duration of TRT (three months). Perhaps more permanent habituation can be achieved by using the TRT for a longer period.

## Conclusion

The low-level laser therapy (LLLT) and tinnitus retraining therapy (TRT) are beneficial, individually or combined; however, the use of LLLT alone do not have a significant advantage over TRT and combined LLLT and TRT. For treatment of tinnitus, the combined approach is more effective. Since no definite treatment is available for tinnitus, application of all safe methods that can lead to complete or partial improvement of tinnitus symptoms can be helpful for the patients, but each patient has different responses to them. Therefore, a comprehensive therapeutic protocol is needed for treatment of tinnitus caused by acoustic trauma.

## **Acknowledgments**

This study was conducted under the supervision of Iranian Military Medical Hospital and Aja University with Ethics Code of IR.Aja.FHS. 1399.054 the patient data were kept confidential as well as patient privacy.

### **Conflict of interest**

The authors declare no conflict of interest.

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