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The Egyptian Journal of Otolaryngology (2022) 38:4
https://doi.org/10.1186/s43163-021-00196-5

The Egyptian Journal of Otolaryngology

ORIGINAL ARTICLE Open Access

Low-level laser therapy for treatment of tinnitus in Red Sea scuba divers: a randomized clinical study

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Abstract

Background: Scuba diving has become a popular hobby. However, diving puts the auditory system at the risk of a wide variety of complaints including tinnitus. Low-level laser therapy is a new modality in treatment of tinnitus. This study evaluates effect of laser therapy on tinnitus of scuba divers in Red Sea. This randomized study included 200 scuba diving patients with tinnitus without any other audiological symptoms. They were randomly divided into two groups: GI (n=100) patients were subjected to 60 sessions of laser therapy, and in the other group GII (n=100), the machine was off while doing the procedure. The Tinnitus Questionnaire (TQ) was done every 20 days to evaluate the severity of the tinnitus for both groups.

Results: Both groups were matched regarding age and sex distribution. GI group experienced significantly decreased tinnitus severity compared to GII after laser therapy. There was no relation between duration of diving and laser therapy effect in GI.

Conclusion: Laser therapy is effective in treatment of tinnitus of scuba divers and its effect is increased by number of laser sessions.

Keywords: Tinnitus-scuba divers, Laser therapy, Red Sea

Background

Tinnitus is a common otological symptoms and is defined as conscious awareness of a sound in the absence of an external auditory stimulus [1]. In this context, it was suggested that pathophysiological mechanism may be a thalamocortical lesion with decreased auditory stimulation [2]. Central theories suggest an increased activity with tinnitus in the dorsal cochlear nucleus and the inferior colliculus of the brainstem [3].

The dysfunction theory concluded that the cochlea is damaged by loud noise, drug exposure, or viral infections [4]. The outer hair cells (OHC) are damaged first and then the inner hair cells (IHC). Cochlear damage occur after acoustic trauma changes the spontaneous firing rates of neurons in the dorsal cochlear nucleus (DCN) [2]. There is no treatment recommended for tinnitus but sedatives, antihistamines, anti-depressants, local anesthetics, and antipsychotics are prescribed for treatment with different outcomes [5]. Also, low-level laser radiation was introduced as alternative modality for cochlear dysfunction and tinnitus [6].

Possible mechanisms explaining the actions of laser therapy in treatment of tinnitus include growth factors secretion, increasing cell proliferation and improvement of blood flow to inner ear [7]. The present study aimed to detect laser effect of tinnitus in scuba divers in the Red Sea

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Methods

The present randomized study was conducted at a private hospital in Kingdom of Saudi Arabia between 2017 and 2020. The study protocol was approved by the local ethical committee, and all patients gave informed consent before participation. The study is registered at clinicaltrials.gov (NCT04962750).

The study included 200 adult scuba divers. Patients had history of scuba diving for at least 5 years without history of hearing loss, vertigo, or other causes of tinnitus, The recruited patients comprised two groups: GI (n=100) treated with low-level light laser for 60 sessions. Each session is 20 min daily. In GII (n=100), the machine was off while doing the procedure.

Examination of the nose, throat, and ear by using fibro-optic endoscopy was done for all patients, audiological assessments were done including pure tone audiometry (sibelsound 400 audiometer) and tympanometry (Tympanometer 4000 Homoth GmbH&Co KG).

The laser light technical data were as follows: output power 5mW, wavelength: 650 m for 20 min pass to the cochlea through the meatus (the external auditory canal); the machine is made in Switzerland designed by COL company. Laser therapy is completely safe and painless [8].

This device consists of three parts in which laser source is placed; the tip is silicon. It was inserted inside the external ear canal, and laser ray was radiated to the inner ear and cochlea via tympanic membrane (Fig. 1). The device does not have any noise or particular vibration so the patients are not aware it is off or on, and the laser machine were off in GII group.

Randomization was performed using computer generated numbers and sealed envelope technique. Patients' allocation was achieved by an independent researcher who was not aware of the nature of the study.

Fig. 1 One of our patients during the session (picture published after his consent)

Table 1 How much of a problem is your tinnitus?

1	Not a problem
2	A small problem
3	A moderate problem
4	A big problem
5	A very big problem

Outcome parameters

Outcome parameters included the effect of laser light in the treatment of scuba diving patients with tinnitus and the Tinnitus Questionnaire (TQ) which were done 1 week pre-treatment and every 20 days of treatment for each group [9].

We asked the patients place circle at the number that best describes your tinnitus on a scale of 1 to 5 with 1 representing less tinnitus and 5 high tinnitus, all of our patients understand the questionnaire without translation (Table 1).

Statistical analysis

Results of the present study were presented as number or mean and standard deviations. Numerical data were compared using t test while categorical data were compared using chi-square test. All statistical calculations were achieved using SPSS 25 (IBM, USA). P value less than 0.05 was considered statistically significant.

Results

The present study included 200 scuba divers, they included two groups: GI (n=100) was subjected to 60 sessions of laser therapy and GII (n=100) the machine was off while doing the test, they comprised 156 males and 44 females with an age range of 23–45 years. Both groups were matched regarding age and sex distribution (Table 2).

Table 2 Baseline characteristics of the studied groups

	GI *n*=100	GII *n*=100	*P* value
Age (years)	27.1 ± 6.4	28.5 ± 7.5	0.62
Male/female	79/21	77/23	0.34

Data expressed as mean and SD or number (*n*)

Table 3 Comparison between GI and GII before and after laser therapy

	GI	GII	*p* value
Tinnitus severity	Mean (SD)	Mean (SD)	
Pre treatment	4.37±2.02	4.39±2.05	>0.05
After 20 session	4.13±1.92	2.93 ±1.02	>0.05
After 40 session	4.99±2.11	1.99 ±0.90	<0.001*
After 60 session	3.23±1.64	1.93 ±0.64	<0.001*

Data expressed as mean ± SD

* Significant *p* value

Comparison between the studied groups regarding mean of tinnitus severity pretreatment and after 20 sessions of laser therapy showed no significant difference GI 4.37±2.02 versus GII 4.39±2.05 with p >0.05, but there was significant difference between both groups after 40 and 60 sessions GI 4.99±2.11 versus GII 1.99 ±0.90 and GI 3.23±1.64 versus GII 1.93 ±0.64, p< 0.001 (Table 3).

Analysis implicated that in GI Laser therapy achieved more effect with increasing number of sessions with p < 0.001 (Fig. 2), but in the GI group, there was no difference regarding the laser therapy effect on duration of diving per years with p >0.05 (Fig. 3) and there was no difference regarding the laser therapy effect on male and females in both groups with p >0.05 (Fig. 4).

Discussion

Scuba divers report chronic disability such as tinnitus and hearing loss [10, 11], and now low-level laser light is used in its treatment as it is safe and effective. Our study comparing the tinnitus severity by using the Tinnitus Questionnaire (TQ) after laser light output can affect tinnitus recovery particularly for long time, which agree with Hahn et al. [12], who studied 100 patients suffered from tinnitus and treated by low-level laser radiation with 200mw and 650 nm wave length for 50 sessions each session10 min and recovery was reported in 59.8% of the patients.

Our results as compared to other procedures in line with the conclusions of Gungor et al. [13] who used low-level laser radiation with 5mw and 650nm for 25 min per week on 45 patients (18 females and 27 years old (mean 55.8) with chronic tinnitus, recovery percentage was increased and tinnitus frequency had significant difference comparing both under studying groups, also agree with Cuda et al. [14] and Rilana et al. [15] who assessed before and after treatment, 62% of patients in the therapy group and 36% of patients in the control group recovered.

On the other hand, Tauber et al. [16] found no effect on duration of the laser therapy on recovery of tinnitus in scuba diving using criteria visual analog scaling (VAS) and tinnitus handicap inventory (THI) between patients of both groups, we suppose that the controversial results may be due to different treatment ways, our patients received therapy in the clinic, while other

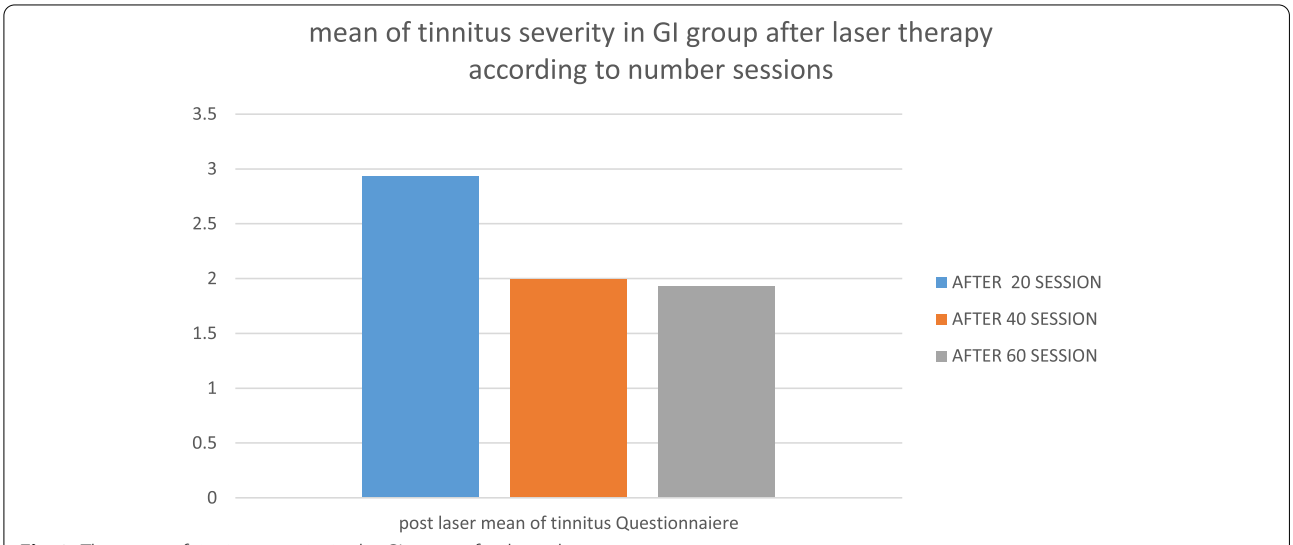

Fig. 2 The mean of tinnitus severity in the GI group after laser therapy

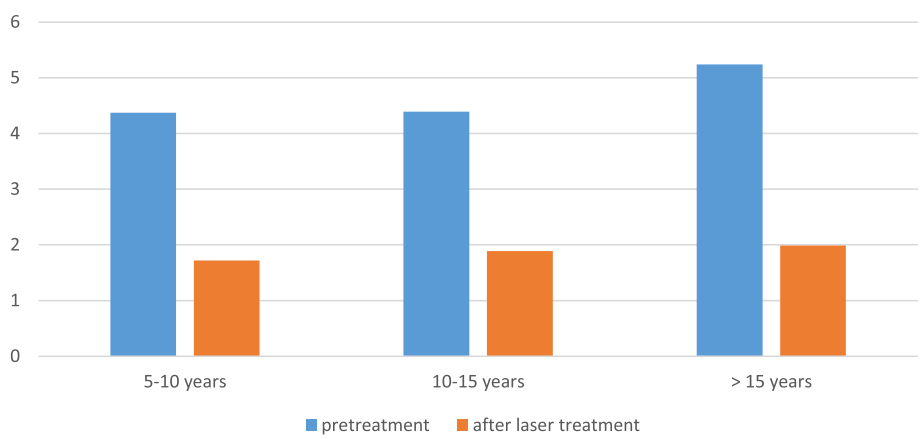

Fig. 3 The mean of tinnitus severity according to duration of diving in years in GI

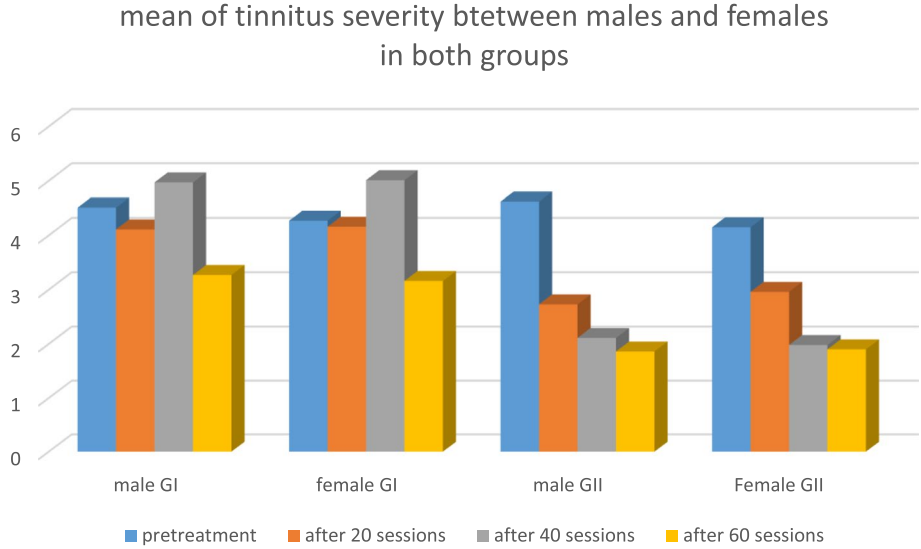

Fig. 4 The mean of tinnitus severity between males and females in both groups

study done by Simoes et al. [17] who gave the participants their course of treatment at home.

In addition, our study noted no significant difference between GI and GII before laser therapy, while there was significant difference between GI and GII groups after laser therapy which agree with Okhovat et al. [18] who concluded the same results with most similar protocol to ours, we noticed some idiopathic improvement in GII but it was not statistically significant, also no difference in results of GI according to duration of diving in years which agree with Teggi et al. [19]

Conclusions

Scuba diving is an interesting sport and becomes more popular every day, but it has many audiological hazards. Now, laser therapy is easy and safe technique in treatment of tinnitus in scuba divers and its effect is increasing by number of sessions of laser therapy.

Abbreviations

TQ: Tinnitus Questionnaire; OHC: Outer hair cells; IHC: Inner hair cells; DCN: Dorsal cochlear nucleus; LLLT: Low-level laser therapy.

Acknowledgements
None.

Authors' contributions
Conceptualization: OE and BA; Methodology: OE and B ; Formal analysis and investigation: OE and BA; Writing—original draft preparation: OE and BA; Writing—review and editing: OE and BA; Resources: OE and BA; Supervision: OE and BA. The authors revised the manuscript and approved it for publications. The authors read and approved the final manuscript.

Funding
This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Availability of data and materials
All data are owned by the institution.

Declarations

Ethics approval and consent to participate
The study protocol was approved by the ethical committee of the Saudi German Hospital in Jeddah, Kingdom of Saudi Arabia, and all participants provided written informed consent before enrollment. Approval reference number is not available.

Consent for publication
Informed consent was obtained from all individuals included in this study.

Competing interests
The authors declare that they have no competing interests.

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Received: 5 August 2021 Accepted: 10 December 2021
Published online: 10 January 2022

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