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The Immediate, Short-Term and Long-Term Effects of Photobiomodulation on Chronic Post-Surgical Pain After Tympanomastoidectomy Surgery

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Abstract

Introduction: Photobiomodulation (PBM) is one of the alternatives to opioid analgesics to reduce post-operative pain. The aim of this study was to investigate the immediate, short-term, and long-term effects of PBM on chronic post-surgical pain after tympanomastoidectomy.

Methods: A total of 138 subjects who had undergone tympanomastoidectomy were selected randomly and divided into two groups: PBM and control. Patients in the PBM group (n = 64) received laser therapy (energy density of 8 j/cm^2, wavelength of 980 nm, and power of 50 mW in 8 points behind the ear during ten sessions every day) with routine drug therapy, while patients in the control group (n = 64) received only routine drug therapy (Dexamethasone, cephalexin 500 mg, acetaminophen 500 mg). The visual analogue scale (VAS) and the headache subscale of the neck disability index (NDI) were provided to both groups to assess pain intensity before the intervention, after sessions one and five, and at one- and three-month follow-ups. The between-group comparison was made through the Mann-Whitney U test, and the within-group comparison was performed using the Friedman test with pairwise comparisons.

Results: No significant differences in all variables were observed between the two groups at baseline ($P > 0.05$). The between-group comparison showed significantly lower VAS scores in PBM compared to the control group at all four time points of the study, resulting in a very large effect size at session 5, month 1, and month 3. Also, the PBM group had significantly lower NDI scores at session 5, month 1, and month 3 ($P < 0.001$). The effect size was large at session 5 and very large thereafter.

Conclusion: The combined effects of PBM and drugs may reduce pain intensity in short-term and long-term follow-ups in patients after tympanomastoidectomy. Nevertheless, PBM did not show immediate effects on pain.

Keywords: Surgery, Pain, Laser therapy, Photobiomodulation

The trial registration number: IRCT200808310011138N28

Introduction

Post-operative pain is one of the major challenges today.[1,2] During the first few days after the surgery, the incidence of acute neuropathic pain is 2 to 3%, and pain lasting more than three months is considered chronic, with an incidence of approximately 10% after surgery.[1,2] There are many reports about the amount of persistent pain in different types of surgeries.[2] In one study, the prevalence of chronic pain at the mastoidectomy incision site was 32.3 %, and although the average pain intensity was not severe, it was frequently associated with some degree of disability and sleep disturbances.[3] Also, post-operative pain after tympanomastoidectomy is prevalent, and some factors such as age, comorbidities, revision surgery, dizziness and tinnitus may affect its severity.[4] Various drugs and techniques are used to control post-operative pain.[1,5] In recent years, photobiomodulation (PBM), or low-level laser therapy, has been recognized as one of the alternatives to opioid analgesics for reducing post-operative pain and facilitating a return to normal function.[6,7] It has been revealed that PBM could treat chronic infection of the middle ear and mastoid at the same time and improve hearing loss after tympanomastoidectomy.[8,9] Furthermore, PBM is known as a safe method for reducing pain and inflammation and can accelerate the recovery of soft tissues.[10] In addition, PBM with photo-chemical effects may reduce inflammation quickly by affecting blood flow and cellular functions.[11]

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Many studies have confirmed the analgesic efficacy of PBM after different post-surgical conditions.[7,12] The effectiveness, protocols and follow-ups of PBM vary depending on the condition.[7] On the other hand, considering the vital role of tympanomastoidectomy to improve middle ear disorders, there is no research on the combined effects of PBM and drugs to decrease postoperative pain in this field.[13] In the present study, we investigated the immediate, short-term and long-term effects of PBM and drug therapy on post-operative pain after tympanomastoidectomy.

Method and Materials

The present study was a randomized, single-blinded clinical trial that was registered with the Iranian Clinical Trials Registration Center (IRCT20080831001138N28). The allocation ratio was 1:1. The Ethics Committee of Guilan University of Medical Sciences approved the study (IR.GUMS.REC.1397.159), and all patients accepted the items of the consent form. The sample size was obtained based on the previous study, in which an effect size of 89% in the intervention group and 66% in the control group, considering a type I error of 5% and a power of 80%, including a 20% dropout rate, resulted in a number of 64 people in each group.[14] The inclusion criteria were as follows: patients suffering from tumors and malignancies that underwent tympanomastoidectomy surgery; age between 20 -60 years old. Patients suffering from Bell's palsy and trigeminal neuralgia were excluded from the study. Of 138 subjects who had undergone tympanomastoidectomy and were screened for eligibility, 10 were excluded: 8 did not meet the inclusion criteria, and 2 declined to participate. Finally, 64 subjects were randomly enrolled in each group (G1 and G2). The subjects were candidates for tympanomastoidectomy at Amir-Al-Momenin University Hospital. Tympanomastoidectomy was performed by one skilled attendant surgeon (SN), with an incision behind the ear. After the mastoid bone exposure, it was removed by cortical excision, considering surgical landmarks and trying not to enter the critical anatomic adjacent spaces, such as the Fallopian canal, skull, and cochlea.[3,15] Patients were randomly divided into two groups: PBM group (G1) and control group (G2). Randomization was performed using a random number table, with even numbers in the PBM group and odd numbers in the control group. The examiner and statistical analyzer were blinded. Patients in G1 received a low-level laser therapy using a Lasermed 4098 device (CARCI, Brazil). The treatment parameters were: an energy density of 8 J/cm², a wavelength of 980 nm, a spot size of 0.19 cm², and a power of 50 mW in pulsed contact mode. Irradiation was applied to eight points behind the ear once daily for ten sessions.[7] The points of irradiation were as follows: five points placed on the surgical incision behind the ear, two points superior/inferior to the incision site, and one point inside the ear. However, the exposure time for each point was 60 seconds. During laser irradiation, the patient was given protective glasses and advised to lie on his/her side and close his/her eyes.

G2 received only drug interventions. For all the patients in the control and PBM groups, the following drugs were prescribed: dexamethasone (Decadron, corticosteroid and cortisol, Shafadaru) at a dose of 8 mg /twice in the first 24 hours after the operation and cephalexin 500 mg capsules (Cephalexin monohydrate, methyl and beta-2-amino-2-phenylacetamido, Shafadaru) taken every six hours for 5 days. In addition, one acetaminophen 500 mg tablet was prescribed every six hours for 5 days.

The Visual analogue scale (VAS) (0-10 points) and the headache subscale of the neck disability index (NDI) questionnaire were provided to both groups to assess the pain intensity.[16,17] NDI is a self-reported scale used to assess neck pain and headache.[18] Pain intensity was assessed in both groups before treatment, after sessions 1 and 5, and at the 1- and 3-month follow-ups. The blinded examiner assessed the pain intensity at all times.

Descriptive statistics, including mean, standard deviation (SD), median, and interquartile range (IQR) of all variables, were computed for both groups. The normality assumption was evaluated by the Shapiro-Wilk test, and it was not met for any of the variables. The between-group comparison was made through the Mann-Whitney U test, and the within-group comparison was performed using the Friedman test with pairwise comparisons. All analyses were performed using SPSS statistical software (version 23.0, SPSS Inc, Chicago, IL). *P*-values of less than 0.05 were considered statistically significant.

Results

Table 1 indicates the mean and SD values of demographic and main variables in the PBM and control groups. There were no statistically significant differences in terms of age ($P = 0.763$), body mass index ($P = 0.342$), and time elapsed from surgery ($P = 0.174$) between the two groups.

Descriptive statistics of VAS scores in the two groups at baseline and 4 time-points of the study are shown in Table 2. The VAS score was not significantly different between the two groups at baseline. In the PBM group, the pain intensity dramatically decreased from baseline to the end of the study ($P < 0.001$). The lowest value was recorded at month 3. A slight significant decrease was also observed in the control group from the baseline until session 5, but the trend was reversed thereafter. The between-group comparison showed significantly lower pain scores in the PBM group compared to the control group at all four time points of the study, resulting in a very large effect size at session 5, month 1, and month 3 of the study.

Table 3 shows the descriptive statistics of the NDI headache subscale in the PBM and control groups at baseline and four time points of measurements. Similarly, the NDI score gradually decreased from the baseline to month 3 in the PMB group ($P < 0.001$), while the trend was consistent in the control group, and the lowest score was observed at session 5. The between-group comparison

Table 1. Mean and standard deviation (SD) of variables in PBM and control groups before interventions

Variables	PBM group (n = 64)		Control group (n = 64)		*P*-Value
	Mean	SD	Mean	SD	
Age (year)	38.7	6.97	37.77	6.67	0.763
Body mass index (kg/m^2)	25.98	5.16	24.18	4.16	0.342
Pain (VAS)	7.59	1.19	8	1.29	0.678
Elapsed time from surgery(m)	6.95	3.89	6.67	3.67	0.174

Table 2. Within-group and between group comparison of pain severity according to VAS

Time-points	PBM group (n = 64)		Control group (n = 64)		Between-group comparison (P;BC)	Effect size
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
Baseline (T0)	7.59 (1.19)	8.00 (2)	8.00 (0.99)	8.00 (1)	0.051(0.342)	0.37
Session 1 (T1)	7.09 (1.2)	7.00 (2)	7.67 (1.04)	8..00 (1)	0.004(0.327)	0.51
Session 5 (T2)	2.92 (0.89)	3.00 (2)	6.59 (1.14)	7.00 (1)	< 0.001(0.021)	3.59
Month 1 (T3)	1.34 (0.96)	1.00 (1)	7.55 (1.09)	8.00 (1)	< 0.001(0.009)	6.05
Month 3 (T4)	0.39 (0.79)	0.00 (1)	7.25 (1.19)	7.5 (2)	< 0.001(0.015)	6.79
Within-group comparison (P; BC)	< 0.001; (0.004) T4 < T0**, T4 < T1**, T4 < T2**, T3 < T0**, T3 < T1**, T3 < T2**, T2 < T0**, T2 < T1**		< 0.001; (0.006) T0 > T1*, T0 > T2**, T0 > T3**, T1 > T2**, T2 > T3**, T2 > T4*			

SD, Standard deviation; IQR, interquartile range; *P < 0.05, **P < 0.01; BC, Bonferroni Correction

Table 3. Within-group and between group comparison of pain severity according to NDI

Time-points	PBM group		Control group		Between-group comparison (P;BC)	Effect size
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
Baseline (T0)	2.95 (0.7)	3.00 (1)	2.81 (0.73)	3.00 (1)	0.294(0.118)	0.19
Session 1 (T1)	2.94 (0.71)	3.00 (1)	2.81 (0.73)	3.00 (1)	0.361(0.541)	0.18
Session 5 (T2)	1.41 (0.95)	1.00 (1)	2.38 (0.93)	3.00 (1)	< 0.001(0.004)	1.03
Month 1 (T3)	0.66 (0.84)	0.00 (1)	2.83 (0.74)	3.00 (1)	< 0.001(0.009)	2.74
Month 3 (T4)	0.25 (0.56)	0.00 (0)	2.84 (0.80)	3.00 (1)	< 0.001(0.005)	3.75
Within-group comparison (P;BC)	< 0.001;(0.009) T4 < T0**, T4 < T1**, T4 < T2**, T3 < T2*, T3 < T1**, T3 < T0**, T2 < T1*8, T2 < T0**		< 0.001;(0.004) T0 > T2**, T1 > T2**, T3 > T2**, T4 > T2**			

SD, Standard deviation; IQR, interquartile range; *P < 0.05, **P < 0.01; BC, Bonferroni Correction

revealed that the PBM group had significantly lower values of the NDI score at session 5, month 1, and month 3 (P < 0.001). The effect size was large at session 5 and very large thereafter.

Discussion

As far as we know, this is the first study applying PBM and drug therapy to the temporal bone in patients after tympanomastoidectomy. The findings of the present study illustrated that the combined effects of PBM and drugs may cause pain reduction in short-term and long-term follow-ups in patients who have undergone tympanomastoidectomy. Nevertheless, PBM did not show immediate effects on pain.

The immediate pain relief of PBM has been shown in some studies.[6,14,19-21] On the other hand, some studies did not indicate the immediate effects of PBM.[22,23] It seems that PBM may induce direct photobioinhibitory actions on peripheral nerves, which decrease acute pain.[6] Li et al. (2019) revealed that multi-focal laser therapy has beneficial immediate effects on pain and functional parameters in patients with knee osteoarthritis.[20] Nevertheless, the exact mechanism of immediate pain reduction is not clear in their study, and they did not consider a control group for further statistical comparisons.[20] In the present study, the site of incision, mastoid bone excision, and possible infection after tympanomastoidectomy may delay the immediate effects of PBM.[7]

The present study revealed that the combined effects of PBM and drugs may reduce post-surgical pain in the short term. Some studies confirmed these findings.[24] Kaydok et al. showed that low-level laser therapy decreases pain intensity in patients with lateral epicondylitis after short-term and long-term evaluations.[24] PBM may stimulate the release of neurotransmitters such as serotonin, enhance mitochondrial adenosine triphosphate (ATP) production, and accelerate the proliferation phase of inflammation.[24] The short-term analgesic and anti-inflammatory effects of PBM may prevent fibrosis and other complications after surgery.[7] Common side effects of pain killers, such as drowsiness, dizziness, fatigue, nystagmus, nausea and memory loss, increase the need for alternative treatments.[6] Other types of pain management, such as nerve blocks, surgical treatment, and laser therapy, are suggested when drug treatment is ineffective.[6] Laser therapy is usually used in the treatment of various diseases such as trigeminal neuralgia and musculoskeletal disorders.[11] Several studies have presented the effect of laser therapy on cell function. Mitochondria are the first structures to show the primary effects of absorbing photons. An increase in the activity of cytochrome c oxidase, chromophores, and electron transfer leads to an increase in ATP production.[6,19-21]

It seems that the rate of pain reduction may influence the rate of recovery after surgery.[21] In the present study, PBM showed a greater pain reduction rate after 5 sessions of treatment (mean difference: 4.67 cm).

PBM and drug therapy together showed a long-term pain reduction in patients after surgery. A recent review emphasized that adding laser therapy to conventional treatments for neuromuscular disorders can provide more pain relief. Also, the mechanisms of PBM for long-term pain relief are through photobiomodulation, which causes a series of tissue response activation. PBM increases ATP production, vasodilation, and construction of new blood vessels, and it reduces inflammatory response and interleukin.[16,25] Other mechanisms of pain reduction included; increases the level of beta-endorphin and nitric oxide, reduces the level of bradykinin, cell ion channels regulation, increases action potential of nerve, releases acetylcholine and regenerate nerves.[26,27] Among the other effects of photobiomodulation, we can mention the increase in DNA, RNA, and collagen production.[27] The results of the long-term effects of PBM are conflicting.[28,29] Langella et al. (2018) investigated the effect of PBM on pain and inflammation after total hip replacement surgery. VAS and blood cytokines enzyme showed a significant reduction compared to the control group.[29] On the other hand, Da Silva et al. (2021) concluded that laser therapy combined with exercise or drug did not provide additional benefits for pain relief in patients with chronic pain. Different points and locations of laser therapy should be considered as a confounding factor for the negative results.[28]

There were some limitations to our study. We applied only the 50 mW laser (mentioned parameters in the method section) to the incision site. Other characteristics of PBM, such as different energy densities, power, or time, should be considered in future studies.

Conclusion

The findings of the present study illustrated that the combined effects of PBM and drugs may cause significant short-term and long-term changes in pain after tympanomastoidectomy. PBM was not effective in reducing pain intensity immediately.

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Competing Interests

The authors have no competing interests to declare that are relevant to the content of this article.

Ethical Approval

The study was approved by the ethics committee of Guilan University of Medical Sciences (IR.GUMS.REC.1397.159). All stages of this research have been performed according to the Helsinki Declaration.

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