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Low-level laser therapy effectiveness in patients with temporomandibular disorders

Ефикасност терапије ласером мале снаге код пацијената са темпоромандибуларним дисфункцијама

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SUMMARY

Introduction/Objective Low-level laser therapy has been suggested as an alternative pain relief therapy in temporomandibular disorders patients. The aim of this study was to examine the effects of Low-level laser therapy on reducing pain intensity in temporomandibular disorders patients, compared to non-steroidal anti-inflammatory drugs.

Methods A total of 63 patients diagnosed with Research Diagnostic Criteria for Temporomandibular Disorders were divided into two groups. In the first group of 35 patients low-level laser therapy was applied three times a week, 15 treatment sessions during 5 weeks (Wavelength: 780 nm; Power density: 70 mW/cm2; Radiant energy: 4.2 J; Energy density: 4.2 J/cm2; Total treatment dose: 16.8 J/cm2;). The second group included 28 participants subjected to nonsteroidal anti-inflammatory drugs therapy (ibuprofen) during two weeks (first three days 3 × 400 mg, remaining time 2 × 400 mg per day). Pain was evaluated using 100 mm Visual Analog Scale, at the baseline, during therapy, two weeks and three months after treatments.

Results Statistically significant reduction of pain intensity was achieved both, in low-level laser therapy and in nonsteroidal anti-inflammatory drugs therapy groups and remained steady in the follow-up period of three months ($p < 0.01$). Differences in Visual Analog Scale scores between observed groups were not statistically significant in each of the evaluation periods, ($p = 0.375$, $p = 0.665$, $p = 0.52$, respectively).

Conclusion The low-level laser therapy protocol applied in this research was efficient in reducing pain in temporomandibular disorders patients.

Keywords: myofacial pain; pain management; anti-inflammatory agents; visual analog scale

САЖЕТАК

Увод/циљ Терапија ласером мале снаге предложена је као терапијски модалитет у лечењу бола код пацијената са темпоромандибуларним дисфункцијама. Циљ истраживања био је да се испитају ефекти терапије ласером мале снаге на смањење интензитета бола код пацијената са темпоромандибуларним дисфункцијама, у поређењу са нестероидним антиинфламаторним лековима.

Методе Укупно 63 пацијента код којих је извршена дијагностика темпоромандибуларних дисфункција помоћу протокола за дијагностику предложеног од стране Дворкина и Лереша, подељено је у две групе. У првој групи коју је чинило 35 испитаника примењена је терапије ласером мале снаге три пута недељно током пет недеља (таласна дужина ласера: 780 *nm*; густина снаге (интензитет): 70 mW/cm^2; предата енергија по тачки: 4,2 *J*; укупна предата енергија по третману: 16,8 *J*; густина енергије (доза): 4,2 J/cm^2; доза по третману: 16,8 J/cm^2; кумулативна доза: 252 J/cm^2). Другу групу чинило је 28 испитаника код којих је спроведена терапија нестероидним антиинфламаторним лековима (ибупрофен) током две недеље (прва три дана 3 × 400mg, преосталих дана 2 × 400 mg). Евалуација интензитета бола вршена помоћу визуелно аналогне скале пре почетка терапије, током терапије ласером мале снаге, непосредно по завршетку терапије, две недеље по завршетку терапије и три месеца по завршетку терапије.

Резултати Статистички значајно смањење интензитета бола постигнуто је у обе групе испитаника и остало је стабилно током праћења од три месеца ($p < 0,01$). Разлике у интензитету бола између посматраних група нису биле статистички значајне ни у једном од периода евалуације ($p = 0,375$, $p = 0,665$, $p = 0,52$).

Закључак Протокол терапије ласером мале снаге примењен у овом истраживању био је ефикасан у смањењу интензитета бола код пасијената са темпоромандибуларним дисфункцијама.

Кључне речи: миофацијални бол; управљање болом; антиинфламаторни лекови; визуелно аналогна скала

INTRODUCTION

Temporomandibular disorders (TMDs) represent a group of musculoskeletal disorders affecting temporomandibular joints (TMJs) and masticatory muscles, including other associated structures [1]. The most commonly occurring symptom of TMDs is pain localized in the masticatory muscles and TMJs, accompanied by restricted or irregular movements and stiffness of the lower jaw, headaches, ear pain, clicking and/or crepitus sounds produced during mandibular function.

The modern treatment concept of TMDs involves different modalities that are most often applied simultaneously or successively. Therapeutic modalities include pharmacotherapy, physical therapy, occlusal, surgical, behavioral therapy and psychotherapy [2, 3].

Low-level laser therapy (LLLT) has been recently suggested as an alternative pain relief therapy in different musculoskeletal disorders, such as myofascial pain, acute and chronic neck and low back pain, osteoarthritis, etc [4, 5]. The main effects of low-level laser therapy are anti-inflammatory, analgesic and biostimulative [6]. The benefits of LLLT are its non-invasiveness, minimum contraindications, affordability and cost-effectiveness.

The results of recent studies on the application of LLLT in the treatment of TMDs are still contradictory. Many studies have confirmed the effectiveness of low-level laser therapy in decreasing pain and improving the function of orofacial system in patients with TMDs [7–12]. On the other hand, the results of some placebo-controlled studies negate the positive effects of LLLT in reducing pain and improving function of orofacial system compared to placebo [13, 14]. Since the results of previous research are inconsistent, increasing attention in the research is attributed to finding adequate radiation characteristics and LLLT protocols in TMD management.

The aim of this study was to investigate the effects of low-level laser therapy on reducing pain in TMDs patients.

METHODS

Patients

A total of 70 patients with a diagnosis of TMD examined at the Clinic for Prosthodontics, School of Dental Medicine Univer4sity of Belgrade, Serbia, participated in the study. The subjects were evaluated from December 2014 to May 2015 using the Research Diagnostic Criteria for TMD (RDC/TMD) [15]. Inclusion criteria were: pain or tenderness on palpation of the masticatory muscles; pain in the preauricular area; pain or tenderness on palpation of the lateral condyle; restricted and painful movements of the lower jaw; stiffness of the lower jaw accompanied by pain. Exclusion criteria were: ongoing treatment of TMD or treatment of TMD performed in the last 3 months; head and neck trauma; odontogenic, otogenic, neurogenic or vascular pain; pregnancy; patients younger than 20 years and patients who did not agree to participate in the study.

Patients were randomly divided into two groups: LLLT (40 patients) and nonsteroidal anti-inflammatory drugs therapy (NSAID) group (30 patients). A total of 7 subjects were excluded from the study. Five patients dropped out from LLLT group because of the irregular attendance of LLLT sessions, and two patients from NSAID group because of the irregular drug use. A final sample included 63 patients. The average age of the LLLT group was 45.77±18.72 and NSAID group 38.75±14.4. No significant differences were found between groups regarding gender and age ($p = 0.929$ and $p = 0.10$, respectively). Initial characteristics of patients in LLLT and NSAID groups are shown in Table 1.

All procedures performed in the study were in accordance with the ethical standards of the Ethics Committee, Faculty of Dental Medicine University of Belgrade, Serbia, No. 36/33 and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Pain assessment

All patients were asked to report any pain evoked by masseter muscle or condyle's lateral pole palpations, and their answers were evaluated on the 100mm Visual Analog Scale

(VAS), where left end indicates "no pain" and right end indicates "the worst possible pain". The pain evaluation was conducted by the independent investigator who was blinded to treatment groups. In LLLT group pain evaluation was performed before treatment (T0), after 5th session (T1), after 10th session (T2), after treatment (T3), 2 weeks after the last session (T4) and 3 months after the last session (T5). In the NSAID group outcome measures were taken at baseline, at the end of treatment, 2 weeks after treatment and at 3 months follow-up. The success rate of the therapeutic outcome was ranged from "minimally important changes" (<30% reduction in pain intensity), through "moderate improvement" (30–50% decrease) to "substantial improvement" (≥ 50% reduction in pain intensity), in accordance with the recommendations (IMMPACT) [16]. Successful therapeutic outcome considered any improvement ≥ 30%. All respondents in whom a successful therapeutic outcome was registered, were monitored for a period of three months after the completion of therapy.

LLLT

LLLT was conducted at the Department of Physical Medicine and Rehabilitation, Clinical Center of Serbia, using gallium-aluminium-arsenide (GaAlAs) semiconductor diode laser (Eco Medico Laser, Electronic Design, Belgrade, Serbia). A total of 15 sessions were applied three times a week for five consecutive weeks. The first three sessions were performed in three consecutive days. The application was done placing laser probe orthogonally to the skin on the four most painful tender points in the region of the masseter muscle or TMJ. In accordance with the optimal doses for the temporomandibular joint region recommended by the World Association for Laser Therapy (WALT), the applied energy was 4.2J per point [17]. The characteristics of the laser beam and LLLT protocol are presented in Table 2. All subjects wore safety goggles with protection against infrared radiation during the treatment. Testing of optical output of laser device was performed at baseline (Table 2).

Pharmacotherapy

Pharmacological treatment involved the use of NSAID, Ibuprofen (Brufen®, 400 mg Abbott Logistics, Holland) during two weeks. Dose of 400mg, 3 times per day after meal during the first three days and dose of 400 mg, 2 times per day during the rest of the

treatment period were administered. Proton pump inhibitor, Pantoprazole (Controloc Control ®, 20mg, Takeda Pharmateuticals, Japan), 1 tablet a day in the morning before meal was administered, in order to protect the gastrointestinal tract.

Statistical analysis

Statistical analysis was performed using the statistical program SPSS, version 20.0 (IBM©, Chicago, Illinois, USA). Normality of the data was tested using the Kolmogorov-Smirnov test. The level of significance was set to 5 % ($\alpha = 0.05$). For an intra-group comparison of the median values of VAS scores - repeated measures, Friedman Test was used. Wilcoxon signed-ranks tests was used for post-hoc analyses. For between-group comparison of VAS pain intensity scores Wilcoxon signed rank test was used. In the case of multiple tests of the same set of data, the Bonferroni correction α-values was used. To test the difference between the group's parameters, Fisher's exact test and the $\chi 2$-test were used.

RESULTS

Clinically significant improvement was achieved in 32 out of 35 patients in the LLLT group, and in 23 out of 28 subjects in the NSAID group. The distribution of subjects within LLLT and NSAID groups according to success rate of the therapeutic outcome is shown in Table 3. Although there were more subjects who reported clinically significant pain reduction in LLLT than in the NSAID, the between-group difference in the treatment outcome was not significant ($\chi^2 = 1.52$, $p = 0.467$) (Table 3).

Comparing LLLT and NSAID groups, no significant difference was found in variance of VAS scores at any of the treatment evaluation time points (Table 4). The repeated measures analysis of VAS pain scores in LLLT group are shown in Figure 1. Post-hoc testing (Wilcoxon test) has shown that there was a statistically significant difference in the pain intensity measured on the VAS scale in the LLLT group before the start of the treatment and after each subsequent measurement, i.e., the fifth / tenth visit, immediately after the treatment, two weeks after the treatment and three months after the treatment: $Z = -4.71$, p

<0.01; Z = -5.01 p < 0.01 ; Z = -5.09, p < 0.01; Z = -4.94, p < 0.01; Z = -4.94, p <0.01, respectively (Table 4).

DISCUSSION

The treatment of TMD is aimed at reducing or eliminating the symptoms and improving function of the orofacial system, which significantly affects the quality of patients' life. Priority is given to non-invasive methods, avoiding irreversible therapeutic procedures such as surgical therapy and occlusal adjustment. Reversible therapy of TMDs usually involves the combined use of occlusal splints, pharmacotherapy, self-management program, behavioral therapy, and physical therapy, including LLLT, LED, TENS, ultra-sound and physical exercise [1, 18]. LLLT has become the subject of many researches in recent years. In fact, many studies have investigated the application of LLLT in different types of TMDs, but the results are contradictory.

In 2011 Petrucci et al. suggested in their review that further studies are needed, since there is no evidence to support the effectiveness of LLLT in the treatment of chronic TMD pain [19]. Melis et al. concluded in their systematic review that LLLT is probably more effective for the treatment of TMD of articular origin, and less effective for the treatment of TMD of muscular origin [20]. The recent meta-analysis by Chen et al. indicated that LLLT has limited efficacy in reducing pain but can increase the function of orofacial system in patients with TMD [21]. It seems that overall conclusion of the most meta-analysis and reviews is that comparison of the results is not easy to be performed, because of the dissimilarity of wavelength, frequency and output of the laser beam and therefore, different energy dosage applied on the target site. Conclusions about the effects of LLLT on TMD signs and symptoms can be made only on the effects of the application of certain LLLT protocols, in order to establish the adequately aligned characteristics of laser radiation, dose, number and dynamics of the sessions.

This study investigated the effect of 780-nm gallium-aluminium-arsenide (GaAlAs) LLL on reducing pain in patients with TMDs, compared to pharmacological treatment with NSAID. As far as we know, this is the first study on the effects of LLLT on TMDs conducted in Serbian population.

We used an output power of 70mW with 4.2J/cm² of power density, 4.2J per point and total energy of 16.8J per session. The infrared spectrum laser has been selected, since the laser rays of the infrared spectrum penetrate deeper into the tissues than the red spectrum laser [22]. De Moraes Maia et al. stated that LLLT effectiveness is more pronounced when using the infrared laser associated with the application protocols involving higher irradiation levels (energy density and/or power density), the greater number of sessions, and the frequency of application [23]. In accordance with the optimal prescribed doses recommended by WALT for the region of the temporomandibular joint, energy applied in our study was 4.2J per point [17].

The results of the present research indicate a positive effect of the applied LLLT protocol in the reduction of the painful symptoms of TMD. Clinically significant pain intensity reduction was achieved after the applied therapeutic modalities in both groups. Also, there was no statistically significant difference between groups in the therapeutic success rate, indicating that the applied LLLT protocol was effective in reducing pain and could be proposed as adequate therapeutic procedure for treating painful TMD. Namely, 91.4% of subjects in the LLLT group and 82.1% of subjects in the NSAID group reported a decrease in intensity of pain greater than 30% after treatment. In both examined groups, more than 70% of subjects reported a decrease in intensity of pain greater than 50%, which was considered a significant improvement from a clinical aspect. Also, there was no statistically significant difference between the groups of subjects in the average intensity pain scores measured before and after the therapy.

The study that compared the effects of LLLT and naproxen pharmacotherapy in subjects with myofascial pain indicated that LLLT was effective in reducing pain intensities and increasing the range of painless mouth opening, while improvement was not observed in the group of naproxen-treated patients [24].

Wavelength is one of the important parameters of the laser beam, considered to be the most crucial characteristics that might influence the laser penetration and absorption in biological tissue [25]. In previous studies on the effects of LLLT on TMD, laser's wavelength ranged from 632.8nm to 1064nm, and the number of sessions ranged from one session to 20 sessions [21]. The results of this study are consistent with the results of several studies that used infrared 780nm laser [7, 26]. Although output power (70mW) and dose per point (4,2 J)

in this study were the same as in the study of da Silva et al., the energy density differed between studies, counting 4.2J/cm² and 105 J/cm^2, respectively [26].

In addition to the wavelengths and energy density dosages, an important parameter is also the total number of sessions and dynamics LLLT sessions. In the present study, a total of 15 sessions was applied, three times a week for 5 weeks, with the first three sessions applied three days in a row. The most of the other studies included 2-3 sessions per week [7,14, 26]. In addition to all the advantages of LLLT, one important disadvantage is that a larger number of sessions can contribute to the patients withdrawal. In our study, 40 patients started with LLLT and 35 (80%) of them attended all 15 sessions. On the other side, the necessity of attending LLLT session allows the therapist to monitor the patient during treatment and to modify the application site, since the localisation of the most painful tender point may change over time. Also, better contact between the therapist and the patient could be achieved.

Comparing groups, no statistically significant difference was registered between LLLT and NSAID group in each evaluation moments, indicating that LLLT could be an optimal treatment in patients with contraindications for NSAID pharmacotherapy.

The pain intensity of many musculoskeletal disorders varies greatly over time, from little or no pain to very painful days. This variation may occur for months. We have chosen the two weeks and three months follow-up period, starting at the end of the treatment, in order to decrease the possibility that pain variation masks the pain intensity and stability of achieved results of the LLLT. In the current study, all subjects with significant therapeutic success were followed for a period of three months after treatment, in order to evaluate the stability of the effects of the applied therapeutic modalities. The results of an analysis of repeated measurements in both groups indicate a tendency of decreasing the intensity of pain during the follow-up period. These results can in part be due to the usual fluctuation of TMD symptoms, which is particularly characteristic of muscle pain. A longitudinal study by Rammelsberg et al. indicated that in a total of 165 subjects, the symptoms and signs of myofascial pain persisted for five years in 31% of the subjects, in 33% of the respondents disappeared, while for the remaining 36% of the subjects, the recurrent course of the disease was registered [27].

Similar to present study, other authors also examined the stability of LLLT effects. Ahrari et al. [28] evaluated the effect of 810nm LLL in patients with myofascial pain one

month after treatment and concluded that the effects of reducing the intensity of the pain and the increase in the mouth opening range were maintained. Some placebo-controlled studies indicated that LLLT was not effective compared to placebo [13, 14, 29]. In contrast, a recent study by Magri et al. showed that there was no difference in the effects of active LLL or placebo on the decrease in pain intensity measured by VAS scale and sensory and affective pain components [29]. In both groups of patients, a decrease in the pain intensity measured on the VAS scale was noticed, while no significant difference in pain sensitivity measured using a digital compression algometry was noticed. The results were sustained in both groups of subjects for a period of 30 days, based on which the authors conclude that LLLT is not effective in treating TMD.

In further research on the effectiveness of the LLLT protocol used in the current study, it would be useful to extend the follow-up period, in order to minimize the impact of the usual natural fluctuation of TMD symptoms on results. A recent survival study has indicated a low maintenance rate for LLLT effects within 180 days after completion of therapy [30].

Although the results of our study indicate the positive effects of the applied LLLT protocol, there should be caution in interpreting results. One of the limitations of the present study is that pain was assessed subjectively, using VAS scale, so the results almost depend on the patients' personal responses. In addition, pain threshold was variable as well. We did not use a method for objectifying pain intensities, such as measuring sensitivity using a digital algometer. Another limitation is that the evaluation moments of the groups were different. LLLT lasted five weeks and NSAID pharmacotherapy lasted two weeks, so the evaluation moments appeared three weeks earlier for NSAID group. The use of NSAIDs in lower doses is part of the routine therapy of painful acute and chronic TMD disorders. In this regard, LLLT therapy has shown to be a more effective alternative to analgesics, both due to the shorter duration of therapy and due to the avoidance of side systemic effects of drug therapy. The depth of penetration and focus of the laser beams enables the targeting of damaged and inflamed tissue, improving the local blood supply and reparative effect. The biggest perceived disadvantage of LLLT therapy is the frequent absence of patients at the scheduled time.

CONCLUSION

According to the results of this study, it can be concluded that applied protocol of LLLT ((in duration of 15 sessions, three times per week) was effective in reducing pain in patients with TMD. LLLT was as effective as NSAID pharmacotherapy, so it could be an alternative to NSAID pharmacotherapy, both in case of contraindications or adverse events occurring during pharmacological treatment.

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Table 1. Initial characteristics of patients in LLLT and NSAID groups

Characteristics		Th		p
		LLLT	NSAID	
Limited mouth opening, n (%)	Yes	25 (71.4%)	19 (67.9%)	
	No	10 (28.6%)	9 (32.1%)	[a]0.759
Pain duration n (%)	< 6 months	14 (40%)	15 (53.6%)	
	> 6 months	21 (60%)	13 (46.4%)	[a]0.283
Diagnosis, n (%)	TMD of muscular origin	25 (71.4%)	17 (60.7%)	
	TMD of articular origin	5 (14.3%)	4 (14.3%)	[b]0.556
	TMD of muscular and articular origin	5 (14.3%)	7 (25%)	

LLLT – low-level laser therapy; NSAID – non-steroid anti-inflammatory drugs;

*statistically significant difference;

[a] χ^2-test;

[b] Fisher's exact test;

Table 2. Characteristics of laser beam and low-level laser therapy protocol

Characteristics	**Values**
Wavelength	780 nm
Output power – maximum	120 mW
Output power – operating	70 mW
Probe aperture	1 cm2
Power density	70mW/cm^2
Energy density	4.2 J/cm2
Radiant energy	4.2J per point
Time	60 sec per point
Laser Frequency	1600 Hz
Number of treatment sessions	15
Number of treated points	4
Application mode	Stationary in skin contact 16.8 J
Daily energy delivered	252 J
Total energy delivered	16.8 J/cm2
Total treatment dose	252 J/cm^2
Cumulative dose	120 mW

Table 3. Distribution of patients according to treatment success rate

Th	Minimally important changes	Moderate improvement	Substantial improvement	p
LLLT	3 (8.6%)	6 (17.1%)	26 (74.3%)	$\chi^2 = 1.52$; $p = 0.467$
NSAID	5 (17.9%)	3 (10.7%)	20 (71.4%)	

LLLT – low-level laser therapy; NSAID – non-steroid anti-inflammatory drugs

Table 4. Descriptive parameters of VAS (visual analogue scale) pain intensity scores in the low-level laser therapy and non-steroid anti-inflammatory drugs groups measured at different evaluation time points

VAS pain intensity scores	n	Med.	Min.	Max.	Range	P
VAS after treatment						
LLLT	32	16	0	50	50	0.375*
NSAID	23	20	0	50	50	
VAS two weeks after treatment						
LLLT	32	9	0	60	60	0.665
NSAID	23	10	0	40	40	
VAS three months after treatment						
LLLT	32	5	0	50	50	0.520*
NSAID	23	0	0	35	35	

LLLT – low-level laser therapy; NSAID- Non steroid anti-inflammatory drugs;

*Mann–Whitney U-test;

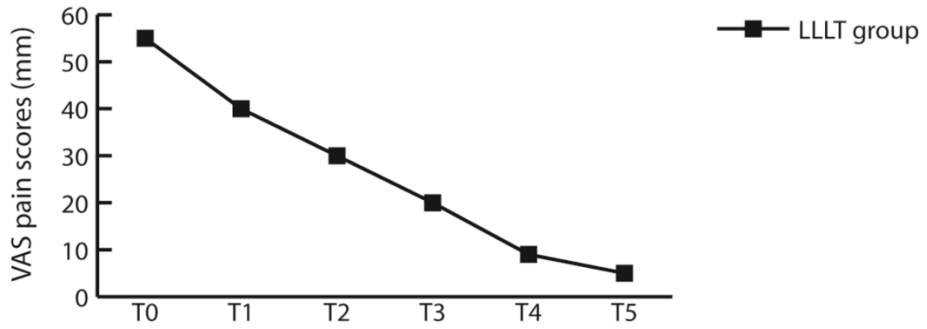

Figure 1. Line chart indicating visual analogue scale (VAS) score values in low-level laser therapy (LLLT) group at different evaluation time points

