Clinical and functional evaluation of patients with acute low back pain and radiculopathy treated with different energy doses of low level laser therapy

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Clinical and functional evaluation of patients with acute low back pain and radiculopathy treated with different energy doses of low level laser therapy

Klinička i funkcionalna ispitivanja bolesnika sa akutnim lumbalnim sindromom i radikulopatijom koji su lečeni različitim dozama laseroterapije

Milica Jovičić*, Ljubica Konstantinović†, Milica Lazović*, Vladimir Jovičić‡

***Institute for Rehabilitation, Belgrade, Serbia; †Clinic for Rehabilitation, Belgrade, Serbia; ‡Clinic for Cardiac Surgery, Clinical Centre of Serbia, Belgrade, Serbia**

Abstract

Background/Aim. The main clinical phenomena in acute low back pain (LBP) with radiculopathy are pain and neurological disorders. Although some studies show that low level laser therapy (LLLT) has the ability to modulate inflammatory processes and relieve acute pain condition, the laser therapy dose protocol has not been yet completely established. The aim of this study was to investigate the effects of three different energy doses of LLLT in patients with acute LBP and radiculopathy. **Methods.** The study included 66 patients with acute LBP and radiculopathy who had been randomly divided into three groups (22 patients each) received three different doses of LLLT. The patients were treated 5 times weekly, for a total of 10 treatments, with the following parameters: wave length 904 nm, frequency 3,000 Hz, average diode power 25 mW; energy dose of 0.1 J per point in the first group, 1 J per point in the second and 4 J per point in the third group; daily treatment time and accumulated energy were 16 s and 0.4 J in the first group, 160 s and 4 J in the second group and 640 s and 16 J in the third group, respectively. The parameters of assessment before and after the therapy were: lumbar and leg pain measured by visual analogue scale (VAS), local and general functional changes (Schober test, manual muscle test, straight leg raise test and the modified North American Spine Society-Low Back Pain Outcome Instrument–NASS LBP). **Results.** Highly significant improvements ($p < 0.01$) were noted in all the groups after LLLT with respect to all the investigated parameters. The VAS scores were significantly lower in all the groups without a difference between the groups ($p > 0,05$). Functional improvements were better in the third group treated with the dose of 4 J per point than in other two groups ($p < 0.05$). **Conclusions.** Three different energy doses of LLLT were equally effective in alleviating lumbar and leg pain without side effects, but the dose of 4 J per point seemed to be more effective in improving the activities of daily living and lumbar mobility.

Key words:
lumbosacral region; pain; pain assessment; laser therapy; treatment outcome.

Apstrakt

Uvod/Cilj. Glavne kliničke manifestacije kod bolesnika sa akutnim lumbalnim sindromom i radikulopatijom (ALR) su bol i neurološki poremećaji. Mada su neke studije pokazale da terapija laserom male snage (LMS) menja inflamatorne procese i olakšava akutna bolna stanja, protokol lečenja laserom još uvek nije kompletno utvrđen. Cilj rada bio je da se ispita efikasnost tri različite doze LMS kod bolesnika sa ALR. **Metode.** U istraživanje je bilo uključeno 66 bolesnika sa ALR. Bolesnici su metodom slučajnog izbora bili podeljeni u tri grupe, po 22 bolesnika, kojima je primenjivana laseroterapija u različitim dozama. Bolesnici su tretirani pet puta nedeljno, ukupno 10 terapija, sledećim parametrima LMS: talasna dužina 904 nm; frekvencija 3 000 HZ; izlazna snaga 25 mW; doza od 0,1 J po tački u prvoj, 1 J po tački u drugoj i 4 J po tački u trećoj grupi; dnevno trajanje terapije i primljena energija iznosili su 16 s i 0.4 J u prvoj grupi, 160 s i 4 J u drugoj grupi i 640 s i 16 J u trećoj grupi. Parametri praćenja na početku i nakon dve nedelje terapije bili su bol u leđima i nozi, mereni vizuelnom analognom skalom (VAS), lokalni i opšti funkcijski status bolesnika (pokretljivost lumbalne kičme, manuelni mišićni test, test istezanja po Lazareviću, modifikovani *North American Spine Society Low Back Pain outcome* test). **Rezultati.** Kod sve tri grupe bolesnika uočeno je statistički

Correspondence to: Milica Jovičić, Institute for Rehabilitation, Sokobanjska 17, 11 000 Belgrade, Serbia. Phone: +381 11 2131 455, Mob: +381 63 8534 633. E-mail: medi@eunet.rs

visoko značajno poboljšanje svih ispitivanih parametara posle LMS terapije ($p < 0,01$). Skorovi VAS bili su niži u sve tri grupe, ali bez statistički značajne razlike ($p > 0,05$). Značajnije poboljšanje funkcijskog statusa uočeno je u trećoj grupi bolesnika koja je lečena dozom od 4 J po tački ($p < 0,05$). **Zaključak.** Tri različite doze LMS bile su podjednako efikasne u smanjenju bola u leđima i nozi bez neželjenih efekata, ali je doza od 4 J po tački bila efikasnija u poboljšanju aktivnosti dnevnog života i pokretljivosti lumbalne kičme ispitivanih bolesnika.

Ključne reči:
lumbosakralni predeo; bol; bol, merenje; lečenje laserom; lečenje, ishod.

Introduction

The point prevalence of low back pain (LBP) is reported to be as high as 33% and 50% of people whith LBP are expected to seek care [1, 2]. Acute episode that lasts less than 4 weeks is both a major cause of temporary disability and a challenge to correct medical treatment decision [3, 4]. The main clinical phenomena in acute LBP with radiculopathy are pain and neurological disorders that affect daily activities [5].

Data strongly support the role of inflammation alone or in association with root compression in pain etiology of lumbar radiculopathy that is associated with herniated discs [6, 7].

Laboratory studies show that low level laser therapy (LLLT) has the ability to modulate inflammatory processes and relieve acute pain conditions triggered by lesions in soft tissues [8–10]. This activity may occur through the decrease in nerve conduction, release of endogenous opioids, increase in angiogenesis and, consequently, increase in local microcirculation. It may also have inhibitory effects on the release of prostaglandins, cytokine levels and cyclooxygenase (Cox) 2 and it may accelerate cell proliferation, collagen synthesis and tissue repair [9, 11–13].

One of the most important aspects of laser applications is the dose, which is defined as the quantity of radiation emitted to the tissue. With regard to clinical studies, it is agreed that dose should be express in Joules (J) [14].

The literature data and reviews show a wide range of doses that are used in the treatment of acute and chronic musculoskeletal disorders [15]. The majority of recently created studies report the use of doses ranging from 1 J to 4 J [16–23].

Despite the increase in quality and volume of clinical studies of LLLT in recent years, a laser therapy dose protocol has not been completely established. This fact is due to the variable parameters of laser light that have been used in the investigations. Moreover, different equipment, experimental designs and techniques do not allow to compare the results of the clinical trials.

In *in vitro* trials higher energy doses have been reported to suppress inflammation and this effect was also reported to be dose-dependent, ranging from 0.3 J to 19 J per cm^2 (J/cm^2). The anti-inflammatory effect was highly significant after 5 days with daily laser treatment [8].

In the same review, Bjordal et al. [8] analysed clinical trials of LLLT and acute inflammatory pain, nine studies were methodologicaly acceptable and showed the adventage of LLLT groups over placebo groups and they emphasized the anti-inflammatory effect of LLLT in clinical settings.

It was also reported that energy doses that produced an anti-inflammatory effect were 1 J/cm^2 and 2.5 J/cm^2 and the dose of 2.5 J/cm^2 produced a better anti-inflammatory effect similar to those produced by diclofenac at the dose of 1 mg/kg [24]. Laser therapy and the dose of 2.1 J/cm^2 was more effective than 0.9 J/cm^2 and 4.2 J/cm^2 in the treatment of carrageenan-induced pleurisy in rat [25].

To our knowledge, there is a missing link between the results and effects of different protocol doses from LLLT in the laboratory and the results of clinical trials.

There are many papers reporting the use of LLLT for improvement of symptomatology of chronic, nonspecific LBP patients [19, 26–29] but there are no many trials concerning acute LBP with radiculopathy and no study has been conducted to determine the effect of different doses of LLLT in the treatment of LBP patients.

Based on these findings, the aim of the study was to assess the efficacy of LLLT given at three different doses and related functional short term changes in patients with acute LBP and radiculopathy.

Methods

The prospective double-blind randomized study included 66 patients, suffering from acute LBP with radiculopathy caused by disc herniation with the duration of symptoms less than four weeks. The diagnosis was made by clinical examination and additional investigations like plain radiography, magnetic resonance imaging and standard nerve conduction study and needle myography (NCS/EMG). Clinical characteristics for inclusion in the study were lumbar and unilateral leg pain, duration of symptoms less than four weeks, clinical signs of radicular lesion in dermatomal distribution and/or myotomal muscle weekness and/or diminished reflexes in lower limbs. The main criteria for patients exclusion were chronic low back pain and a previous spinal surgery.

Also, patients with neurological, metabolic, endocrine and neoplastic diseases were excluded from the study. Individuals who had received corticosteroids in the last 30 days were also excluded. Prior to treating with LLLT and baseline examination, all patients received nimesulide 200 mg/day during 7–14 days.

Of 84 referrals, 16 patients did not meet the entry criteria, 2 patients refused to participate and 66 patients were randomly assigned to three equal laser groups (A, B and C, n = 22 each) treated with different doses of laser light during two weeks (ten therapy sessions, five times a week except weekends).

The characteristics of laser beam included: wave length 904 nm; frequency 3000 Hz; power output 25 mW; spot size 1 cm²; dose 0.1 J per point in the group A, 1 J per point in the group B, and 4 J per point in the group C; daily treatment time and energy delivered were 16 s and 0.4 J in the A group, 160 s and 4 J in the B group and 640 s and 16 J in the C group, respectively; application mode – stationary in contact with skin, anatomical site local – 4 points, 2 cm laterally from spinous process of involved and next distal spinal segment. The doses were chosen according to recommended anti-inflammatory doses for Galium-Arsenide (GaAs) lasers by the World Association of Laser Therapy (WALT) [30] and energies that were used in clinical trials for lumbar spine pain [19, 26, 29].

Prior to commencing the study, ethics approval was obtained from the Medical School, University of Belgrade, Ethics Committee, and all patients gave informed written consent to participation in the study.

The outcome measures included:

1. Functional evaluation of the patients activities of daily living (ADL) according to a modified North America Spine Society Low Back Pain Instrument (NASS LBP) [31, 32]. The questionnaire measures symptoms, functional status, expectations from the treatment and satisfaction. The patients were asked to report how pain affected their activities such as walking, sitting and standing and each item was scaled from a complete ability to complete disability.

2. The visual analogue scale (VAS) was used in the measurement of lumbar and leg pain [33]. Pain levels were scored from 0 to 10, where 10 indicated unbearable pain and 0 indicated no pain at all.

3. Physical examination of the lumbar spine and legs [34]: a) measurement of lumbar spine flexion as the distance from the top of the third finger to the floor (cm); b) the Schober test was assessed by measuring the distance between two spinal landmarks.

Marks were made on the skin at the spinous process of L5 and 10 cm above as the participant stood in a neutral position. A participant then bent forward maximally, and the change in the distance between these marks was measured in cm; c) manual muscle testing (MMT) of crucial muscles according to the American Spinal Injury Association Protocol [35].

We performed and rated MMT from 5 to 0 (5 indicated that a patient could hold the position against maximum resistance and through a complete range of motion and 0 indicated no contractile activity in the gravity eliminated position). The tested muscles were: the iliopsoas for L2 miotome, the quadriceps muscle for L3, the tibialis anterior for L4, the extensor hallucis longus for L5 miotome and the gastrocnemius for S1 miotome; d) straight leg raise test.

To identify any adverse effects of the treatment, the subjects were asked to record any new symptoms.

The data were evaluated by using SPSS Version 17.0 for Windows. The results were expressed as the mean and standard deviation for data with the normal distribution, or as median and interquartile range for data that were not distributed normally. Significant differences among pre-treatment characteristics of the patients and baseline measurements among the groups were evaluated using χ^2 test, Mann-Whitney *U* test and Kruskal-Wallis test. The pain level scores and functional status of the patients in each group before and following therapy were tested using paired samples *t*-test and Wilcoxon Signed Ranks test.

Intergroup statistical analysis and comparison of differences among the groups for all outcome measures at the beginning and the end of the therapy were tested by the General Linear Model. The differences of p value < 0.05 were considered statistically significant.

Results

The main characteristics of the patients in the groups before the therapy are outlined in Table 1. There was no statistically significant difference among the investigated groups in terms of age and body mass index (BMI) ($p > 0.05$). Moreover, there was no difference in the levels of lumbar and leg pain ($p > 0.05$). The flexion of lumbar spine among the groups was similar without a significant difference ($p > 0.05$). The groups differed in MMT before the therapy, the patients in the group C had lower muscle strength as compared with the group A ($p = 0.044$) (Table 1). Electromyographic testing did not show a difference among the groups in terms of common affected nerve root levels and there was no difference in the severity of radicular lesions ($p > 0.05$) (Table 2).

Table 1

Characteristics of the patients before the low level laser therapy (LLLT)

Characteristics	Group	$\bar{x} \pm SD$	χ^2/F	*p* value
Age (yrs)	A	47 ± 10.711	0.873	> 0.05
	B	44 ± 8.763		
	C	45 ± 6.78		
Body mass index (kg/m2)	A	23,93 ± 2.43	2.545	> 0.05
	B	25.1 ± 2.78		
	C	25.10 ± 1.75		
Lumbar pain (VAS)	A	7 ± 1	1.149	> 0.05
	B	7 ± 3.5		
	C	6.5 ± 1		
Leg pain (VAS)	A	7 ± 1.5	1.031	> 0.05
	B	6.75 ± 3		
	C	6.5 ± 2		
Flexion (cm)	A	58.7 ± 20.8	0.285	> 0.05
	B	55.0 ± 16.9		
	C	55.7 ± 14.2		
Schober (cm)	A	2 ± 2	0.068	> 0.05
	B	2 ± 0.5		
	C	2 ± 0.5		
Manual muscle test	A	3 ± 1	6.225	0.044
	B	2 ± 1		
	C	2 ± 0.5		

SD – standard deviation; A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point; VAS – Visual analogue scale

Table 2

The affected nerve root levels in the groups and severity of radicular lesions (electromygraphic study)

Affected root levels/severity of radicular lesions	Groups of patients			Statistics	
	A n (%)	B n (%)	C n (%)	χ^2	*p*
L4	6 (27.3)	5 (22.7)	0 (0)		0.085
L5	7 (31.8)	11(50.0)	13(59.1)		
S1	9 (40.9)	6 (27.3)	9 (40.9)	8.193	
Mild to moderate	3 (13.6)	0 (0)	0 (0)		
Moderate	10 (45.5)	10 (45.5)	7 (31.8)		0.162
Moderate to severe	7 (31.8)	7 (31.8)	11 (50.0)		
Severe	2 (9.1)	5 (22.7)	4 (18.2)	9.219	

A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point

The baseline examinations of ADL did not show a significant difference among the groups ($p > 0.05$). The majority of patients in all groups improved the disability and discomfort during ADL following LLLT in relation to much better walking, sitting and standing and that was highly statistically significant ($p < 0.0001$) (Table 3).

There was no significant difference between the group A and the group B ($p > 0.05$), but the patients in the group C showed some statistically significant improvements in walking (F = 5.319; $p = 0.007$), sitting (F = 5.882; $p = 0.005$) and standing (F = 4.621; $p = 0.013$) as compared to the previous groups (Table 3).

After LLLT, we noticed pain reduction measured by VAS in all of the three investigated groups treated with different doses of laser light without a significant difference among the groups. Thus, all of the three doses were equally efective in relation to reduced lumbar pain (F = 2.161, $p > 0.05$) (Figure 1).

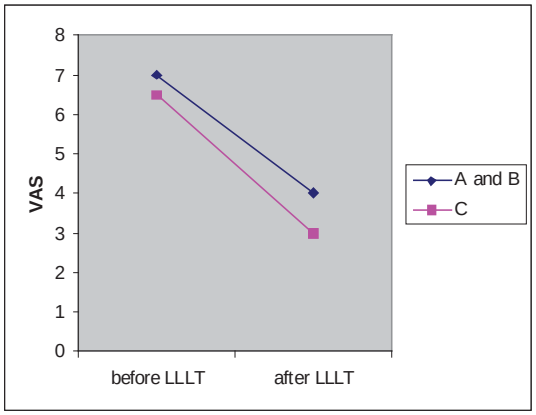

Fig. 1 – Lumbar pain in the groups before and after the low level laser therapy (LLLT)

VAS – Visual analogue scale; A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point

Table 3

The reported activities of daily living (ADL) before and after low level laser therapy (LLLT)

ADL	Groups of patients (n = 22 in each group)						Statistics
	A (%)		B (%)		C (%)		
	before	after	before	after	before	after	
Ability to walk							
I can walk	0.0	4.5	4.5	9.1	0.0	13.6	
I can not walk >1 h	9.1	27.3	9.1	22.7	4.5	45.5	(C : A and B)
I can not walk >30 min	13.6	27.3	22.7	40.9	22.7	27.3	F = 5.319
I can not walk >10 min	45.5	40.9	36.4	22.7	31.8	13.6	$p = 0.007$
I can walk a few steps only	27.3	0.0	27.3	4.5	31.8	0.0	
I can not walk at all	4.5	0.0	4.5	0.0	9.1	0.0	
Statistics	Z=3.376*		Z=3.456*		Z=4.086*		
Ability to sit							
I can sit in every chair	4.5	9.1	0.0	4.5	0.0	4.5	
I can sit in special chair	0.0	0.0	0.0	0.0	0.0	36.4	(C : A and B)
I can not sit >1 h	9.1	36.4	13.6	13.6	13.6	45.5	F = 5,882
I can not sit >30 min	22.7	36.4	13.6	63.6	13.6	13.6	$p = 0.005$
I can not sit >a few min	54.5	13.6	45.5	13.6	36.4	0.0	
I can not sit at all	9.1	4.5	27.3	4.5	13.6	0.0	
Statistics	Z=3.491*		Z=3.080*		Z=4.142*		
Ability to stand							
I can stand	0.0	9.1	0.0	0.0	0.0	13.6	
I can stand with pain	4.5	9.1	0.0	22.7	4.5	27.3	(C : A and B)
I can not stand >1h	0.0	13.6	0.0	13.6	4.5	40.9	F = 4,621
I can not stand >30 min	18.2	45.5	13.6	31.8	27.3	18.2	$p = 0.013$
I can not stand >10 min	50	18.2	50	31.8	31.8	0.0	
I can not stand at all	27.3	4.5	36.4	0.0	31.8	0.0	
Statistics	Z=3.816*		Z=3.677*		Z=4.176*		

A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point
***statistically significant difference ($p < 0.0001$)**

Similar results were noticed for leg pain (F = 1.978, $p > 0.05$) (Figure 2).

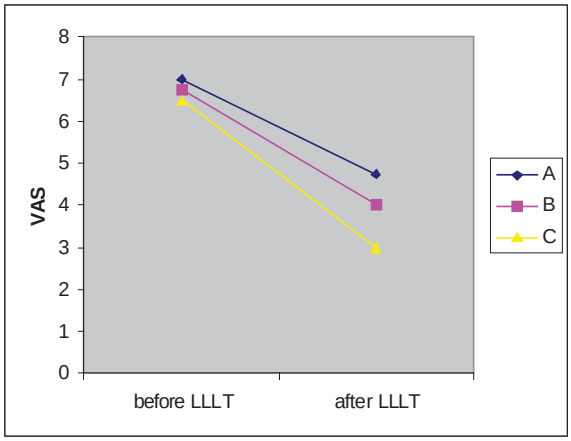

Fig. 2 – Leg pain in the groups before and after the low level laser therapy (LLLT)

VAS – Visual analogue scale; A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point

Lumbar spine flexion was improved in all the groups after LLLT that was statistically significant ($p < 0.0001$). On the other hand, the patients in the group C treated with the dose of 4 J per point had better improvements in the flexion of lumbar spine (distance from the top of the third finger to the floor in cm) compared with A and B groups (F = 12.543, $p < 0.0001$) (Figure 3). The difference between A and B groups did not exist, patients in both groups improved flexion of lumbar spine equally ($p > 0.05$).

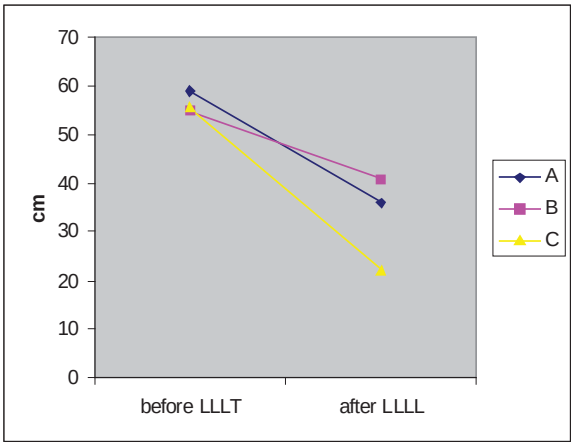

Fig. 3 – Flexion of lumbar spine before and after the low level laser therapy (LLLT)

A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point

The patients in the group B and the group C had significantly higher values of the Schober's index (F = 4.329; $p < 0.05$) than the first group treated with the lowest dose of laser light, where we did not notice such an improvement following LLLT ($p > 0.05$).

At the end of the treatment, the patients from all groups equally improved muscle strength in their legs ($p < 0.0001$; figure 4) and showed better results in straight leg raise test ($p < 0.01$) without any differences among the groups (F = 3.066; $p > 0.05$; F = 2.922; $p > 0.05$).

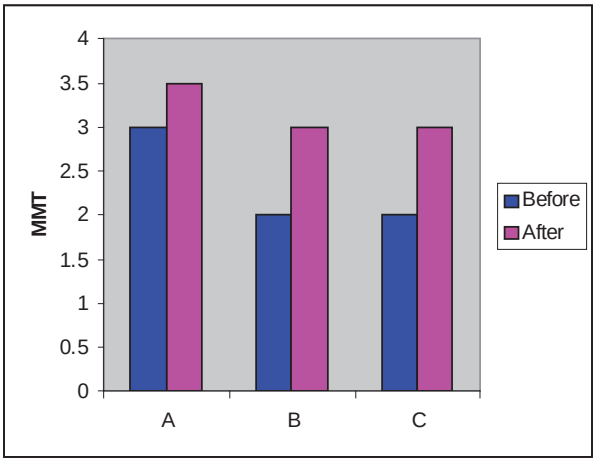

Fig. 4 – Manual muscle test (MMT) in the groups before and after the low level laser therapy (LLLT) therapy

A – group treated by energy dose of 0.1J/point; B – group treated by energy dose of 1J/point; C – group treated by energy dose of 4J/point

In this study, systemic or local side effects from laser treatment were not noticed.

Discussion

Prevention of recurrences and chronicity is identified as an important goal in the management of acute LBP [4]. Clinical guidelines recommend a series of steps in order to diagnose and treat patients presenting with LBP, including lumbar disc herniations [36]. The main criterion for judgment of treatment effectiveness includes pain and functional disability which have a considerable impact on overall health.

The present study investigated the use of different energy doses of LLLT for the treatment of acute LBP with radiculopathy. The doses of 0.1, 1 and 4 J per point showed a significant efficacy in relation to reduced pain and functional disability of the patients. Importantly, the patients treated with the dose of 4 J per point had significantly better results in terms of ADL and lumbar mobility.

The differences in the included patients and the applied regimes of LLLT were the main difficulty in comparing the results of this study with the results of other clinical LLLT trials.

Additionaly, there was no published research on the comparison of different energy doses in treating LBP. Most of the studies in the available literature included patients with non-specific chronic back pain [17, 19, 26, 28, 29]. We identified a meta-analysis by Yousefi-Nooraie et al. [37] considered nonspecific LBP, and there were no firm conclusions on the clinical effect of LLLT for LBP.

Soriano et al. [26] demonstrated the efficacy of LLLT in the treatment of chronic lumbar pain with following pa-

rameters of laser light: wave length - 904 nm, average power - 40 mW, frequency – 10,000 Hz, dose-4 J/cm^2.

Gur et al. [19] concluded that LLLT (producing energy of approximately 1 J/cm^2 improved pain and functional disability in the therapy of chronic LBP, but it did not bring any additional benefits to exercise therapy.

In the study that investigated acute lumbar pain associated with disc herniation, Gruszka et al. [27] showed positive results, improved pain relief and neurological status after LLLT with the dose of 9 J/cm^2. This study was supported by CT scans and conventional needle myography.

According to Konstantinovic et al. [18] treatment of acute LBP with radiculopathy at 904-nm LLLT at a dose of 3 J, proposed as additional therapy to nonsteroidal anti-inflammatory COX-2 drugs showed better improvement in local movements, more significant reduction in pain intensity and related disability, and improvement in quality of life, compared with patients treated only with drugs and with a placebo LLLT procedure. The study included 546 patients with symptoms for less than 4 weeks, caused by a prolapsed intervertebral disc, and confirmed by magnetic resonance imaging. The baseline characteristics, intensity of pain and functional disabilities of the patients were similar to our patients sample but the study showed positive clinical results of LLLT as additional therapy with nimesulide 200 mg/day without investigating the dose-dependent effects. Transitional worsening of pain was registered in 27 patients and 4 patients had persistent pain but the final results of side effects show the low risk nature of LLLT. In our study, the patients did not report the worsening of pain and symptoms.

Unlu et al. [38] investigated and compared LLLT (830 nm laser unit at a dose of 1 J/cm^2), ultrasound and traction therapy in the treatment of patients with acute lumbar and leg pain due to disc herniation. The study showed that all therapies were effective in reducing pain and disability scores but there was no significant difference among the 3 treatment groups. There were significant reductions in size of the herniated mass on magnetic resonance imaging after the treatment, but no differences among the groups.

The same design of the study was implemented in a a randomized controlled clinical trial by Monticone et al. [39] who compared two different methods (orthosis and exercises with a previous mesotherapy and LLLT) in treating patients with acute LBP. They found no significant pain relief in the group treated with LLLT, but treatment parameters and application technique were not reported.

In the very new prospective, placebo controlled study the Ay et al. [40] compared the effectiveness of LLLT (wave length of 850 nm and daily delivered energy of approximately 40 J) on pain and functional capacity in patients with acute and chronic LBP caused by disc herniation and found no differences between laser and placebo laser treatment. The authors did not explain precisely the clinical characteristics of the patients with acute LBP and duration of symptoms. They excluded patients with neurological deficits that was not in accordance with our study. All patients completed the study without side effects.

In summary, the results from our study suggest that LLLT given at three different doses, plays a significant role in reducing pain and functional disability in the treatment of acute LBP with radiculopathy. Although we did not find any statistically significant differences in pain intensity among groups, better improvements of physical function were observed in the group treated with the highest dose of LLLT.

The study has some limitations that must be considered. First, there was no placebo group for laser therapy. Second, the sample size was not enough to detect differences among the groups for some outcomes and evidences from this study suggest only the short-term effects.

In the evaluation of LLLT and LBP, the choice of the most optimal dosage presents a complex topic. For improved clinical results, the importance of LLLT dose as well as the pathophysiology of lumbar pain should be stressed.

Because of the positive results and different therapy regimes in the clinical evaluations of LLLT, further placebo-controlled studies with bigger homogeneous patients sample and longer follow-up periods should be performed in order to state precisely a laser therapy dose protocol and find possible interactions with other treatment modalities.

Conclusion

The results of this study show that the three investigated energy doses are equally effectve in reducing lumbar and leg pain without side effects in patients with acute LBP and radiculopathy, but the dose of 4 J per point seems to be more effective in improving the activities of daily living and lumbar mobility.

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