Short-term clinical efficacy of the pulsed Nd:YAG laser therapy on chronic nonspecific low back pain

Medicine

financial cost worldwide.^[1] Annually, the incidence of LBP is

growing approximately from 15% to 45%, whereas the

individuals who suffer from LBP are approximated 70% to

A randomized controlled study

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Abstract

Background: Chronic non-specific low back pain (LBP) is gradually increasing among populations worldwide and affects their activities. Recently, the Nd:YAG laser has been presented in the rehabilitation field.

Objectives: This study aims to explore the short-term effects of the Nd:YAG laser on chronic non-specific LBP individuals.

Methods: Thirty-five individuals with chronic nonspecific LBP were included in the study from December 2019 to March 2020. Randomly, they were categorized to Nd:YAG group (n=18) and sham laser as a control (n=17) thrice weekly for a 6-week intervention. Modified Oswestry disability index (MODI), pain disability index (PDI), visual analogue scale (VAS), and lumbar flexion range of motion (ROM) have been assessed pre and post-6 weeks of the intervention.

Results: Significant improvements were observed in the Nd:YAG group (MODI, P < .001; PDI, P = .007; VAS, P < .001; lumbar ROM, P = .002), whereas the sham group showed no significant changes (MODI, P = .451; PDI, P = .339; VAS, P = .107; lumbar ROM, P = .296) after 6-week intervention. Between-group comparisons showed significant differences in tending toward the Nd: YAG group (MODI, P < .001; PDI, P = .046; VAS, P < .001; lumbar ROM, P = .003).

Conclusions: Regarding the present study outcomes, short-term pulsed Nd:YAG laser (6 weeks) may reduce functional disabilities and pain intensity, and improve the lumbar flexion ROM in patients with chronic nonspecific LBP. Further well-designed randomized controlled studies with large sample sizes should be conducted regarding laser treatment.

Abbreviations: HILT = high-intensity laser therapy, LBP = low back pain, LILT = low-intensity laser therapy, MODI = Modified swestry disability index, Nd:YAG = neodymium-doped yttrium aluminum garnet, PDI = pain disability index, VAS = visual analogue scale.

Keywords: functional disability, laser therapy, low back pain, mobility, Nd:YAG

1. Introduction

Low back pain (LBP) is a leading health problem affecting occupational performance and quality of life and reports a great

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85% of populations at interval periods in their lifestream.^[2] Despite several researches have studied this disorder in the industrial countries, LBP is identified as a serious health problem in Arab countries.^[3] In Saudi Arabia, the prevalence of LBP is accounted for 18.8% of adult people and commonly heightens among married individuals aged >30 years.^[4] Also, another study in Jeddah city has approved that around 26% of school employees suffer from LBP.^[5]

Chronic nonspecific LBP is defined as a LBP not attributable to a detectable or recognized specific pathology with a duration of >12 weeks. It is generally related to mechanical reasons and not associated with specific pathological conditions such as fractures, infections, neoplasm, inflammatory diseases, disc spaces, or compression of nerve roots. Chronic LBP usually leads to functional disability and affects individuals' daily lives.^[6–8]

The treatment of chronic nonspecific LBP contains several intervention strategies such as patient's education, behavior modification, back schools, exercise therapy, and physiotherapy interventions including myofascial release, heat and cold applications, lumbar supports, traction, electrical stimulation, and photobiomodulation therapy.^[9]

Light amplification by stimulated emission of radiation (LASER) therapy is identified as painless, noninvasive, and simply used for many various diseases in different healthcare places.^[10] Previous documents provided that laser intervention extensively lowers severity of pain in sensitive or persistent states including fibromyalgia, osteoarthritis, rheumatoid arthritis, post-surgical pain, shoulder pain, diabetic ulcers, and carpal tunnel syndrome.^[11–13]

Although laser therapy with low intensities generates a slight temperature for body tissues,^[14] documents have reported that low-intensity laser therapy (LILT) reduces pain, inflammation, and enhance functional performance.^[15,16] LILT improves circulation, stimulates the angiogenesis process, and activates immunization and neural repair. Also, it generates analgesic influences by activation the endorphin synthesis.^[13]

Lately, the high-intensity laser therapy (HILT) in the form of a neodymium-doped yttrium aluminum garnet laser (Nd:YAG laser) has been presented in the rehabilitation field. Nd:YAG laser is working with a wavelength of 1064 nm, and an extreme power density (12W) characterizing by easily, painless, and noninvasive interventional application. It activates areas that cannot be reached by LILT including deep and large joints.^[17] Using of Nd: YAG laser therapy is growing among patients experiencing pain.^[18] Moreover, previous publications have reported that the Nd:YAG laser may reduce edema, inflammation, and pain manifestations.^[19,20] For that reason, this study was proposed to explore the short-term effects of the Nd:YAG laser therapy on chronic nonspecific LBP individuals hypothesizing that it may reduce pain severity and functional disability among those patients.

2. Materials and methods

2.1. Ethics

The study was ethically approved by the institutional review board of the physiotherapy department, Prince Sattam bin Abdulaziz University (No.: RHPT/019/040) in accordance with ethical standards of Helsinki Declaration 1964 and presented in accordance with CONSORT guidelines.

2.2. Study design and setting

The study was a prospective single-blinded randomized controlled study with a 6-week intervention and was conducted in the outpatient physiotherapy clinic, Prince Sattam bin Abdulaziz University.

2.3. Sample size estimation

According to our preliminary pilot study on 5 patients, at least 8mark differences in the Oswestry Disability Index (ODI) are required to achieve power of 90% with σ of 2, and confidence level of 95%. The required study participants were calculated 16 individuals for each group. Therefore, 36 patients were recruited in the 2 groups to account for 10% dropout.

2.4. Subjects

Thirty-six individuals experiencing chronic nonspecific LBP were included in the study from December 2019 to March 2020. They were recruited from the orthopedic outpatient clinic of the university hospital. All individuals were assessed for chronic nonspecific LBP applying physical, biochemical, radio-imaging assessments (x-ray). Randomly, they were categorized to Nd: YAG group (n=18) and sham laser as a control (n=18). Inclusion criteria were: the experiencing of LBP for 3 months at least, age range of 30 to 50 years, and the compliant ability to conduct the study program. Exclusion criteria were: orthopedic or neurological abnormalities, unacceptable biochemical investigations, positive inflammatory markers, pregnancy, cognitive dysfunction, LBP medications last 3 months, and spinal disorders, injuries, or surgeries. Before starting the study and acceptance of the participants to conduct the study program, each individual was instructed to sign a written consent form.

2.5. Randomization and blinding

Of 43 chronic nonspecific LBP patients, 36 were eligible to participate in the study procedures. Five subjects were not qualified to the inclusion criteria of the study and 2 subjects rejected to participate in the study program without any determined reason. Before commencing the study procedures, randomization was carried out by means of obscure closed envelopes, which randomly arranged by blinded examiner utilizing equal numbers of odd and even numbers inside the envelopes. Even numbers were recruited to conduct Nd:YAG program, whereas odd numbers were recruited to conduct the sham program. For blindness, because of the study design and settings, it was impossible to blind the therapists included in the program of the study. Whereas, the therapists who assessed the outcome measures pre- and post-intervention were blinded to the individual's group and the participants also were recommended to conceal their treatment program during the assessment.

2.6. Intervention

All study participants have conducted a program of easy home exercise without needs for any equipment. The exercise program consisted of mobility, flexibility, stretching, strengthening of back, pelvic, and abdominal muscles. Therapists have trained each participant to conduct properly the exercise program at the first visit before starting the home exercise. One of the family members has proved that the individual performed the home exercises regularly twice daily.

2.6.1. *Nd:YAG protocol.* Pulsed Nd:YAG laser was carried out thrice weekly for 6-week intervention using BTL-6000 HIL device with a wavelength of 1064 nm, power of 12 Watts, and hot laser source of Nd:YAG.^[17] It was applied on the lumbar region with application area of 30 cm^2 through 2-phase characteristics. During the 2 phases, HILT was applied continuously rounded movement. The first 2 weeks were characterized by an analgesic influence at the intermediating phase, pertaining a 75 seconds, power of 8 W, and energy of 6 J/cm², for a total energy density of 300 J. The subsequent 4 weeks were characterized by a biostimulant influence at the continuing phase, pertaining a 30 seconds, power of 6 W, and energy of 120 to 150 J/cm². Whereas the control group has received a sham laser (0.0 J) for same periods as active HILT within the 6-week intervention.

2.7. Outcome measures

2.7.1. *Functional disability.* Functional disability of the chronic nonspecific LBP was assessed pre and post 6-week intervention by 2 valid and reliable indices, the modified Oswestry disability index (MODI) and pain disability index (PDI). The MODI includes 10 elements: standing, sitting, walking, lifting, traveling, self-care, employing/home activities, social participation, intensity of pain, and sleep.^[21,22] The score of each element is 0 to 5, and total score of the MODI is 0 to 50, 0 suggests nothing and 50 suggest the highest disability. Regarding PDI, it comprises 7-element questionnaire involving self-care, recreation, sexual behavior, occupation, social participation, family/home activities, and life-support activities.^[21] The score of each element is 0 to 10, and the total score is 0 to 70, 0 suggests nothing, and 70 suggests the highest disability.

2.7.2. Intensity of pain. The intensity of pain was evaluated through conducting the valid and reliable visual analogue scale (VAS). Each individual was instructed mark a point on the 10-cm line of VAS, 0 suggests no pain, and 10 suggests severe pain.^[23]

2.7.3. Lumbar range of motion. Lumbar flexion range of motion (ROM) was measured pre- and post-intervention using a validated and reliable Modified-Modified Schober Test.^[24]

2.8. Statistical analysis

Data analyses were carried out using SPSS for windows, version 25 (IBM Corp., Armonk, NY) with significance level at P < .05. Continuous variables were confirmed for the normal distribution using the Kolmogorov-Smirnov test. All analyzed data were presented as mean ± SD. The paired *t* test was performed for assessing the pre-post changes within each group, whereas unpaired *t* test was performed for assessing the differences between Nd:YAG and control groups.

3. Results

From 36 patients, 1 discontinued the 6-week intervention without any defined reason, whereas 35 patients have completed the study procedures and analyzed, 18 in the ND:YAG group and 17 in the sham group. Figure 1 shows the CONSORT flow diagram of the study. By analyzing the demographic data (age, sex, height, weight, body mass index, and occupations), there were no significant differences between the Nd:YAG and sham

groups (P > .05). The employees were affected more than other occupations (40%). The duration of LBP was 7.3 ± 2.8 months in the Nd:YAG group and 6.9 ± 3.1 months in the sham group with nonsignificant difference between the groups (P = .691) as described in Table 1.

For clinical outcome measures, the preintervention mean values demonstrated nonsignificant differences between the Nd:YAG and sham groups (MODI, P=.796; PDI, P=.831; VAS, P=.706; lumbar ROM, P=.495) as described in Table 2. After 6-week intervention, significant improvements were observed in the Nd:YAG group (MODI, P<.001; PDI, P=.007; VAS, P<.001; lumbar ROM, P=.002), whereas the sham group showed no significant changes (MODI, P=.451; PDI, P=.339; VAS, P=.107; lumbar ROM, P=.296) as detailed in Table 2.

Comparison between mean values of outcome measures after 6-week intervention showed significant differences between the Nd:YAG and sham groups in tending toward the Nd:YAG group (MODI, P < .001; PDI, P = .046; VAS, P < .001; lumbar ROM, P = .003) as described in Table 2.

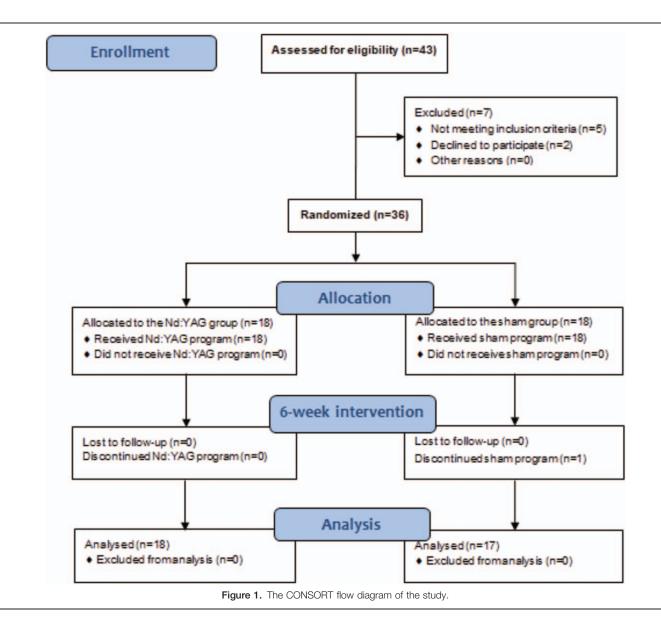
4. Discussion

This study was conducted to explore the short-term effects of the Nd:YAG laser therapy on chronic nonspecific LBP hypothesizing that Nd:YAG could reduce pain severity and functional disability. The main findings of the study showed that 6 weeks of Nd:YAG laser therapy alleviates pain, reduces functional disabilities, and improves lumbar flexion ROM.

Commonly, low-level laser is utilized to treat the individuals experiencing a chronic nonspecific LBP. This type of laser therapy is identified as a safe and useful physiotherapy intervention for improving joint mobility^[15,19] and reducing pain intensity,^[11] disabilities,^[15,19] and lumbar radiculopathy.^[25] Lately, the HILT is utilized in several medical disorders in the form of pulsed Nd: YAG. It is usually utilized in diabetic foot for healing ulcers and relieving pain.^[26] It is also utilized for relieving a symptomatic shoulder pain,^[17] long-lasting ankle pain,^[18] osteoarthritis.^[20,27] Previous study approved that HILT reduces pain greater than ultrasound intervention within a 3-week comparative study.^[28] Also, it was reported that low-intensity Nd:YAG laser may relieve pain moderately and improve functional performance in LBP patients.^[29]

The clinical effects of laser treatment have been believed to adjust cellular functions depending on laser characteristics.^[30] The 1064 nm Nd:YAG laser provides the waves to easily infiltrate and extent within the deep tissues due to inadequate meditation of the endogenous chromophore which impair the laser absorption. At the level of laser penetration, the tissue is exposed to a multidirectional light distribution increasing the oxidation response of the mitochondria and consequently proliferate the production of DNA, RNA, and ATP.^[17]

Pulsed Nd:YAG is more advantageous than LLLT in the innocent therapeutic uses with high-intensity power, 1064 nm wavelength, and short pulsed durations which help to magnify more energy and a deeper penetration to the targeted tissue with a highly cellular safety. The HILT has 3 photoenergy characteristics including photomechanical, photochemical, and photothermal effects that improve the response of the exposed tissue. Our present study suggests that ND: YAG laser has a key role in relieving pain by altering the release of bradykinin and histamine from the affected tissues^[31] and substance P from the nociceptors,^[32]



Measures	Nd:YAG (n=18)	Sham (n=17)	Р
Age, y	39.6 ± 6.7	38.9 ± 6.4	.754
Sex, male (%)	12 (66.6)	10 (58.8)	.631
Height, m	169.7 ± 7.2	171.2±7.5	.551
Weight, kg	78.4 ± 3.3	79.1 ± 4.2	.586
BMI, kg/m ²	26.5 ± 3.2	26.8 ± 2.9	.773
Duration of LBP, mo	7.3 ± 2.8	6.9 ± 3.1	.691
Occupations, n (%)			
Employees	8 (44.4)	6 (35.3)	.581
Workers	5 (27.8)	6 (35.3)	.632
Retired	2 (11.1)	1 (5.9)	.581
No work	3 (16.7)	4 (23.5)	.612

 6.9 ± 3.1 .691 The main implication of the study is that the pulsed Nd:YAG is a feasible easy and safe physiotherapy modality to relieve

tissues.^[33]

a feasible, easy, and safe physiotherapy modality to relieve chronic nonspecific LBP in a short-term duration (6 weeks). Contrariwise, some limitations were observed. The main limitation was the small sample size. Also, the study lacked for intermediate and long-term follow-up (after 6-month assessment). Lastly, home exercise has not been supervised. Future

thereby raising the pain threshold at the level of the targeted

Another theory declared that the application of laser irradiation could slow down the conduction of pain transmitters through reducing the sensory nerves conductive velocity that subsequently frustrates the transmission of C and A δ fibers.^[34] One more theory clarifies that pain could be centrally frustrated through increasing the release of beta-endogenous morphine-like substances or opioid peptides.^[35,36]

BMI = body mass index, Nd:YAG = neodymium-doped yttrium aluminium garnet.

Table 2

Changes and comparisons of the pre- and post-intervention outcome measures in the Nd:YAG and sham groups.

Measures	Nd:YAG (n = 18)	Sham (n = 17)	Р
MODI			
Pre-	39.8±14.3	38.6±12.9	.796
Post-	19.3±6.7	35.4±11.5	<.001
Ρ	<.001	.451	
PDI			
Pre-	33.5 ± 10.7	34.3±11.2	.831
Post-	24.7 ± 7.6	30.8 ± 9.8	.046
Р	.007	.339	
VAS			
Pre-	6.7 ± 1.6	6.9 ± 1.5	.706
Post-	3.7 ± 1.1	6.1 ± 1.3	<.001
Ρ	<.001	.107	
Lumbar flexion F	ROM		
Pre-	44.8±10.2	42.5 ± 9.5	.495
Post-	57.5±12.8	45.8±8.6	.003
Р	.002	.296	

MODI=Modified Oswestry Disability Index, Nd:YAG=neodymium-doped yttrium aluminium garnet, PDI=pain disability index, ROM=range of motion, VAS=visual analogue scale.

studies may include larger sample size to involve different types of laser irradiations on chronic nonspecific LBP.

5. Conclusions

Regarding the present study outcomes, short-term pulsed Nd: YAG laser (6 weeks) may reduce functional disabilities and pain intensity, and improve lumbar flexion ROM in patients with chronic nonspecific LBP. Further well-designed randomized controlled studies with large sample sizes should be conducted regarding laser treatment. Future guidelines for clinical intervention have to be considered to inspire the use of pulsed Nd:YAG laser in the treatment of musculoskeletal disorders, specifically chronic nonspecific LBP.

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