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Effect of low level laser therapy in acute low back pain with radiculopathy: A single blinded randomized control study

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ABSTRACT

Background

The lifetime prevalence of low back pain is reported as over 70% in industrialized countries. Peak prevalence occurs between ages 35 and 55. There is increasing evidence that inflammation in association with root compression is the main pathological factor of radiculopathy. LLLT can be advantageous because its therapeutic window for anti-inflammatory actions overlaps with its ability to promote tissue repair in a dose dependent manner.

Objective

The aim of the study was to compare the effectiveness of low level laser therapy and conventional therapy in acute low back pain with radiculopathy.

Methodology

Study proceeded after ethical clearance from the central ethical committee of Nitte University. The subjects diagnosed with acute low back pain with radiculopathy by an orthopaedician fulfilling the inclusion criteria will be included in the study. An informed written consent will be collected from all the subjects included in the study.

A total of 100 patients will be included in the study and they will be randomly assigned into two groups using convenience sampling. One group will receive conventional therapy and the other group LLLT.

Visual Analogue Scale, Oswestry Low Back Pain Disability Questionnaire, Modified Schober's test will be measured pre and post following treatment for a duration of 5 days.

Results

Both groups have shown significant improvement but low level laser therapy group have shown more significant results (p value <0.001) compared to control group managed with conventional therapy.

Conclusion

Based on the above results we conclude that low level laser therapy is having a remarkable effect on pain control and tissue repair in acute back pain with radiculopathy. Further research in dosimetry and also with large sample size is recommended.

Keywords: Acute Low Back Pain, Laser, Radiculopathy.

INTRODUCTION

Low back pain with radiculopathy is defined as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with leg pain¹. Acute low back pain is usually defined as the duration of an episode of low back pain persisting for less than 6 weeks². Pain is a subjective experience, and acute pain is a warning signal which expresses that body tissue is about to be injured. If injury actually occurs, then a cascade of patho physiological events will take place in a well mapped simultaneous and chronological order². Pain intensity is usually most prevalent in the inflammatory phase during the first hours and days after injury, and in most cases, pain decreases as the tissue repair processes get under way. In peripheral nerve injury, pain may occur from persisting mechanical pressure, neurogenic inflammation, or damage to the nerve structure leading to a state of persistent central sensitization within the central nervous system^{3,4}.

The lifetime prevalence of low back pain is reported as over 70% in industrialized countries (one-year prevalence 15% to 45%, adult incidence 5% per year). Peak prevalence occurs between ages 35 and 55². Specific low back pain represents 15% of low back pain problems. About 50% of specific back pain is due to prolapsed intervertebral disc (PID), in which the nucleus pulposus herniates through a tear in the annulus fibrosis, resulting in irritation of the adjacent nerve root and causing a typical radiculopathy pain. It is commonly seen in the age group of 15- 45 years of age.³ Majority of the spinal disc herniation occurs in the lumbar region (95% in the L₄-L₅ or L₅-S₁)¹.

The clinical phenomena in acute LBP are pain and neurological disorders that affect activities of daily living. The symptoms range from mild to severe that radiate into the regions served by the affected nerve root that are irritated or impinged by the herniated material. Other symptoms may include motor and sensory changes such as muscular weakness, numbness, paralysis, paresthesia and altered reflexes⁴.

There is expanding proof that aggravation in relationship with root pressure is the fundamental neurotic element of radiculopathy. Disturbance of the annulus fibrosis causes spilling of the core pulposus into the spinal channel, which contains different aggravations to tissues including glycoproteins, nitric oxide and phospholipase A₂, which cause an incendiary reaction in and around the torment touchy nerve tissues⁵.

Hazard variables most much of the time reported are substantial physical work, regular bowing, winding, lifting, pulling and pushing, monotonous work, static stances and vibrations. Psychosocial hazard variables incorporate anxiety, trouble, tension, wretchedness, intellectual brokenness, torment conduct, work disappointment, and mental anxiety at work. Representing 75% to 85% of aggregate labourers' non-appearance². Two deliberate audits found that guidance to stay dynamic (with or without different medicines) diminished incapacity, agony, and discovered quicker rates prompting less time went through off work contrasted and bed rest. In a few rules, back particular activities (e.g., fortifying, flexion, expansion, extending) are considered not valuable amid the main weeks of a scene. Different rules express that low push oxygen consuming activities are a remedial alternative in intense low back pain^{2,5}.

LASER

The expression "laser" started as an acronym for light intensification by invigorated outflow of radiation. Low-level laser treatment (LLLTT) is a treatment procedure which utilizes a solitary wavelength light source. Laser has the accompanying qualities: collimation – it has little beam dissimilarity over separation; union – the light waves are all in stage; and monochromaticity – it has a solitary or tight band of a specific wavelength of light. The radiated laser light is noted for its high level of spatial and worldly coherence. Laser radiation and monochromatic light might adjust cell and tissue capacity⁶.

To the extent discogenic back agony is concerned, most orthopedic specialists use non-steroidal calming drugs and customary exercise based recuperation comprising of ultrasonic treatment, footing treatment, Tran’s cutaneous electrical treatment, and short-wave treatment. These types of moderate treatment modalities speak to symptomatic treatment just, without the biomodulation impacts offered by low-level lasers^{7,8}.

In spite of the fact that LLLT is presently used to treat a wide assortment of diseases. A not exactly ideal decision of parameters can bring

about lessened viability of the treatment, or even a negative restorative result⁹. Thus, a large number of the distributed results on LLLT incorporate negative results just in view of an improper decision of light source and measurements. This decision is especially vital as there is an ideal measurement of light for a specific application, and dosages higher or lower than this ideal quality might have no restorative impact. Indeed, LLLT is described by a biphasic measurements reaction: lower dosages of light are frequently more advantageous than high doses¹⁰.

CELLULAR AND TISSULAR MECHANISMS OF LLLT

Reduced PGE2 levels	Reduced IL1 levels	Reduced TNF levels	Reduce plasminogen activator	Redced neutrophil influx
Reduced hemorrhagic formation	Reduced COX-2 expression	Effects on inflammatory mediators	Reduced cell apoptosis, improved micro circulation	Reduced edema formation

Local LLLT effects occurring in less than 24 hours after first irradiation. LLLT has an extensive variety of impacts at the atomic, cell, and tissue levels. The three fundamental components by which laser produce pain relieving impacts are accepted to be: animating endogenous opioids discharge, lifting torment limits, and adjusting the arrival of harmful go betweens, for example, bradykinin and histamine. Torment balance might likewise happen because of changes in nerve conduction speed and change in the limit for myelin creation¹². LLLT backs off the transmission of agony signs through the autonomic sensory system, manages serotonin and nor epinephrine, and expansions the torment edge. Inside of the cell, there is solid proof to propose that LLLT follows up on the mitochondria to build adenosine tri phosphate (ATP) creation, adjustment of responsive oxygen species (ROS), and the affectation of interpretation elements. These interpretation variables cause protein union that triggers an expanded cell multiplication and movement, balance in the levels of cytokines, development elements and incendiary middle people, and expanded tissue oxygenation¹².

LLLT is additionally utilized for irritation, edema, swelling, and tissue mending. LLLT application is accepted to restrict the arrival of

incendiary arbiters, for example, bradykinin and histamine, diminishing the provocative reaction. Notwithstanding, it has been unequivocally conjectured that a lessening in prostaglandin action amid the provocative procedure is the principle mitigating impact of laser incitement. Prostaglandins cause vasodilation at the site of aggravation, encouraging invasion of incendiary cells to the encompassing tissue. Concentrates on have demonstrated that an abatement in prostaglandin movement because of laser incitement might advance healing.^{12,13} LLLT causes vasodilation by setting off the unwinding of smooth muscle connected with endothelium, which is very pertinent to the treatment of joint irritation. This vasodilation expands the accessibility of oxygen to treated cells, furthermore takes into account more noteworthy activity of safe cells into tissue. These two impacts add to quickened mending¹⁴.

At the most fundamental level, LLLT acts by prompting a photochemical response in the cell, a procedure alluded to as biostimulation or photobiomodulation. At the point when a photon of light is consumed by a chromophore in the treated cells, an electron in the chromophore can get to be energized and hop from a low-vitality circle to a higher-vitality circle. This put away vitality can

then be utilized by the framework to perform different cell assignments. There are a few bits of proof that indicate a chromophore inside mitochondria being the underlying focus of LLLT. Radiation of tissue with light causes an expansion in mitochondrial items, for example, ATP, NADH, protein, and RNA, and additionally an equal growth in oxygen utilization, and different in vitro tests have affirmed that cell breath is up regulated on treatment with LLLT¹².

Cytochrome c oxidase (CCO), is the pivotal chromophore in the cell reaction to LLLT. CCO is an extensive transmembrane protein complex, comprising of two copper focuses and two heme iron focuses, which is a segment of the respiratory electron transport chain. The electron transport chain passes high-vitality electrons from electron bearers through a progression of transmembrane buildings (counting CCO) to the last electron acceptor, creating a proton angle that is utilized to deliver ATP. Consequently, the utilization of light straightforwardly impacts ATP generation by influencing one of the transmembrane buildings in the chain: specifically, LLLT results in expanded ATP creation and electron transport^{12,14}. LLLT has prompted theory that CCO and NO discharge are connected by two conceivable pathways. It is conceivable that LLLT might bring about photodissociation of NO from CCO. Cell breath is down regulated by the creation of NO by mitochondrial NO synthase (mtNOS, a NOS isoform particular to mitochondria), that ties to CCO and represses it. The NO uproots oxygen from

CCO, repressing cell breath and accordingly diminishing the creation of ATP. By separating NO from CCO, LLLT keeps this procedure from occurring and results in expanded ATP creation^{12, 15}.

The wavelengths of light utilized for LLLT fall into an "optical window" at red and NIR wavelengths (600–1070 nm). Wavelengths in the reach 600–700 nm are utilized to treat shallow tissue, and more wavelengths in the extent 780–950 nm, which infiltrate further, are utilized to treat more profound situated tissues¹².

MATERIALS AND METHOD

The objective of the study was to compare the effectiveness of laser therapy and conventional treatment in acute low back pain with radiculopathy. A sample size of 100 patients were selected from Justice K. S Hegde Charitable Hospital, Department of physiotherapy, having acute back pain with radiculopathy. Patients who met the inclusion criteria were included in the study and were divided into 2 groups by computer generated random numbers. One group will receive conventional therapy and the other group LLLT. Hot pack will be given for both groups prior to treatment session for 10 minutes. Visual analogue scale (VAS), Oswestry back pain disability questionnaire (OWQ) and Schober's test (SCT) to document pain, disability and lumbar range of motion respectively, will be measured pre and post following treatment for duration of 5 days.

Inclusion Criteria	Exclusion Criteria
Age – 18 to 60 years	Previous history of spinal surgery
Sex – Male and Female	Sub-acute and chronic LBP
Patients with acute low back pain and radiculopathy diagnosed with or without the help of radiographs	Formal therapeutic or medical intervention within the last three months eg: steroid injections
Both single and multiple levels lumbar disc protrusion and prolapse	Co-existing conditions like ankylosing spondylitis, rheumatoid arthritis, spinal stenosis
VAS score more than 6	Spinal tumors or patients where secondary metastases was suspected

Laser unit of wavelength 905nm(red), frequency 5000HZ, power output 100mW, spot size 1cm, power density 20 mW/cm², energy density 3J and treatment time of 150 second in each points. Laser probe is held in contact with skin over local

transforaminal region (2.5cm and 3.5 cm laterally of the of the involved nerve root and on distal level segment). Conservative group will be receiving TENS for 10 minutes. TENS- VectroStim, bipolar, 100 HZ, 30mA.



Figure 1: Intervention group receiving LASER therapy



Figure 2: Control group receiving TENS.

RESULTS

Statistical analysis was performed with the SPSS Version. 21.0 programs. A .05% of probability was adopted as the level for statistical significance. Descriptive statistics of Age, Gender was done by using Mean and Standard Deviation. Comparison within group **A** and **B** was done by using Paired t test. Between group comparison was done by Independent t test. Since the VAS score was following the normal distribution curve Wilcoxon Signed Rank Test was not performed. Instead comparison was done by independent t test. VAS, OWQ, SCT was evaluated in this study as outcome measures. A total number of 90 patients completed the study, out of which each group contains 45 subjects. There were 10 dropouts in this study, who had taken discharge early.

In group A (intervention) mean age was (40.98±10.04.), Group B(control) mean value were(43.38±9.73.). There is no difference in the age between the groups which means subjects are equally distributed according to age. In Paired sample statistics, results of VAS test for pain had an initial mean value of control group was 1.96 ± .47 and that of intervention group was 3.96 ± .96. This data clearly shows that both the group having significant change in reduction of the pain after the treatment session. The result of OWQ test had an initial mean value of control group was 4.35±4.65 and that of intervention group was 9.97±3.73. Available data clearly shows that both the group is having significant change in reduction of the disability after the treatment session. Result

of SCT test had an initial mean value of control group was (Flexion 0.81±0.63)(Extension 0.26±0.44) and that of intervention group was (Flexion 1.42±0.49) (Extension 0.84±0.47). Available data clearly shows that both the group is having significant change in reduction of the lumbar range of motion after the treatment session. Table 2: shows the significance of $p < 0.05$ (0.001).

In Independent sample statistics, Pain difference (PD) at the end of 5 days of treatment shows differences in both group (Control 1.96 ± .47 and Intervention 3.97 ± .96), and statistically stating that there is a difference existing between the group treatment ($p = 0.001$) hence LASER is effective in reducing acute pain than conservative treatment. Low back Disability difference (OWD) at the end of 5 days of treatment shows differences in both group (control group 4.35±4.65 and that of intervention group was 9.97±3.73), and statistically stating that there is a difference existing between the group treatment ($p = 0.001$) hence LASER is effective in reducing pain and disability than conservative treatment. Schober's test difference (STD) at the end of 5 days of treatment shows differences in both group, control group was (Flexion 0.81±0.63) (Extension 0.26±0.44) and that of intervention group was (Flexion 1.42±0.49) (Extension 0.84±0.47), statistically stating that there is a difference existing between the group treatment ($p = 0.001$) hence LASER is effective in improving lumbar flexibility than conservative treatment.

Table 1: Descriptive statistics of the subjects

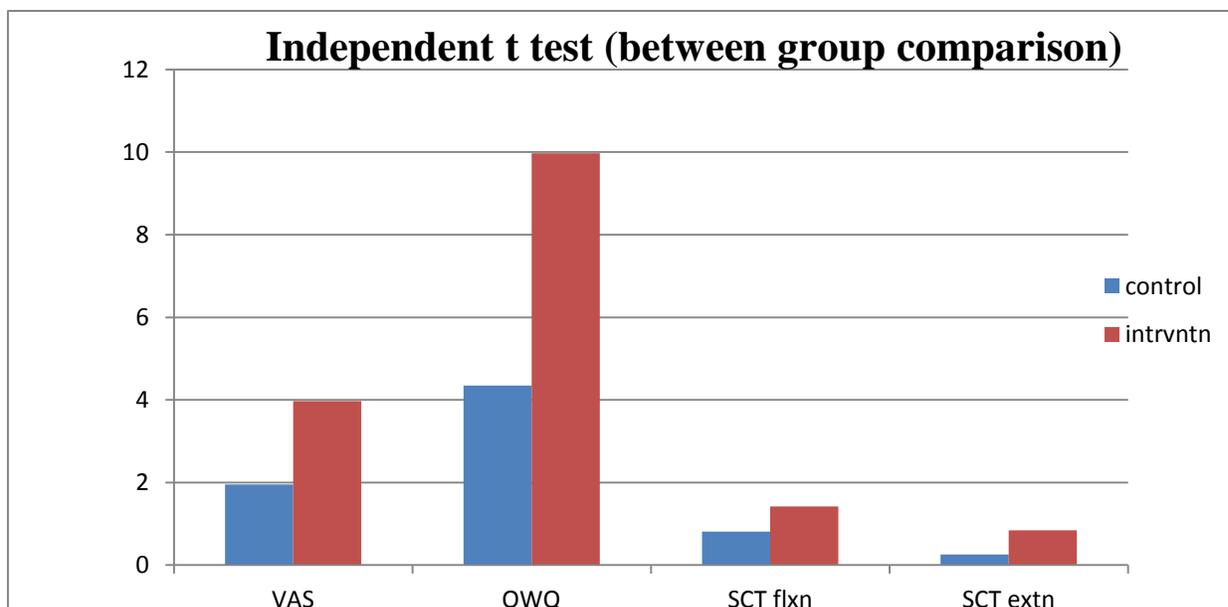
Group		Mean	Std. Deviation
Control	Age	43.38	9.733
	VAS pre	7.60	.751
	VAS post	5.64	.645
	OWQ pre	32.18	6.840
	OWQ post	27.82	6.936
	SCT pre	3.09	1.104
	Flexion		
	SCT pre	2.24	.679
	Extension		
	SCT post	3.900	.8367
	Flexion		
	SCT post	2.51	.626
	Extension		
	Intervention	Sex	1.33
Age		40.98	10.042
VAS pre		7.89	.859
VAS post		3.91	.557
OWQ pre		33.42	5.061
OWQ post		23.44	3.461
SCT pre		2.78	.765
Flexion			
SCT pre		1.93	.688
Extension			
SCT post		4.200	.7261
Flexion			
SCT post		2.78	.420
Extension			

Table 2: Paired t test (within group comparison)

Group	Variables	PAIRED DIFFERENCES			t value	Sig.(2-tailed)
		Mean ± SD	95% Confidence Interval of the Difference			
			Lower	Upper		
Control	VAS (pre -post)	1.95 ± 0.47	1.81	2.09	27.64	.001
	OWQ (pre - post)	4.35 ± 4.65	2.95	5.77	6.27	.001
	SCT Flex (pre- post)	0.81 ± 0.63	1.00	0.62	8.59	.001
	SCT Ext (pre-post)	0.26 ± 0.44	0.40	0.13	4.00	.001
Intervention	VAS (pre - post)	3.97 ± 0.96	3.68	4.26	27.65	.001
	OWQ (pre - post)	9.97 ± 3.73	8.85	11.10	17.90	.001
	SCT Flex (pre- post)	1.42 ± 0.49	1.57	1.27	19.10	.001
	SCT Ext (pre-post)	0.84 ± 0.47	0.98	0.70	11.93	.001

Table 3: Independent t test (between group comparisons)

Variable Differences		t-test for Equality of Means			95% Confidence Interval of the Difference	
		Mean ± SD	t	Sig.(2-tailed)	Lower	Upper
PD	CONTROL	1.96 ± .47	-			
	INTERVENTION	3.97 ± .96	12.614	.001	-2.34082	-1.70363
OWD	CONTROL	4.35 ± 4.65				
	INTERVENTION	9.97 ± 3.73	-6.315	.001	-7.39144	-3.85301
SFD	CONTROL	0.81 ± .63				
	INTERVENTION	1.42 ± .49	-5.083	.001	-.85005	-.37218
STD	CONTROL	0.26 ± .44				
	INTERVENTION	0.84 ± .47	-5.944	.001	-.77097	-.38459



DISCUSSION

Although low back pain is prevalent and is having a very high chance of chronicity and recurrence, there is lack of evidence on effective treatment in acute phase patients. The requirement for an effective and optimal treatment is emphasized by the fact that optimal treatment in acute phase will reduce the prevalence and prevent the chronicity and recurrence⁵. In clinical practice a broad spectrum of therapy approaches is being

used, ranging from pharmacological, physical agents to exercise and manual therapy practice. Various types of physical agents are not sufficiently supported. The general recommendation is that further studies are required, or it can be used to manage patients for whom no improvement has been achieved by previous treatments¹⁶.

This study included patients with severe pain (VAS≥6) and moderate to minimal disability during

daily activities on screening, associated with acute radiculopathy and disc herniation. Results show statistically significant improvement in all groups, with better result for all parameters measured in group A(intervention group) with other group (p value < 0.001). The analysis of parameters with more specified clinical meaning has shown significant differences between Group A and Group B, with better reduction in pain intensity and disability. The main problems in comparing the results of this study with others are the differences in the included patients and applied parameters.

Metaanalysis by Yousefi-Nooraie and colleagues considered nonspecific LBP, and there were no consistent conclusions⁴. Many other clinical studies have used LLLT for nonspecific chronic LBP, however a group of patients with nonspecific chronic LBP is very heterogenic, and the reasons of their pain caused not only by pathological changes in the spinal and paraspinal structures, but also by complex neurophysiologic and psychosomatic and psychosocial mechanisms⁴. Hypothetically, the biological actions of LLLT are multiple; the reduction of inflammation is the primary effect with consecutive improvement in neurophysiologic features of the affected nerve. The direct effect on nerve which accelerates recovery of the conduction block, changes in endorphin level; the results of clinical and experimental study has shown that the anti-inflammatory effects are more significant¹⁶.

Various studies have documented changes in biochemical markers of inflammation, distribution of inflammatory cells and the reduction in formation edema, hemorrhage and necrosis after local LASER beams ranging from 660-905nm⁵. Comparison with anti-inflammatory drugs like Meloxicam and Indomethacin has shown similar anti-inflammatory effects. The direct action or effect of LLLT on neural structures that are

damaged by compression or inflammation should be considered as an important additional effect. This additional effect is beneficial in acute lesions of neural structures, such as acute lumbar radiculopathy. A less than optimal choice of parameters can result in reduced effectiveness of treatment, or even a negative therapeutic outcome. As a result, many of the published results on LLLT include negative results simply because of an on appropriate choice of light source and dosage. LLLT is characterized by a biphasic dose response: lower doses of light are more beneficial than high doses⁵.

Evidence from this study suggests only the short term effects of LASER. Further studies could include patients randomized by levels of baseline disability and duration of symptoms. Studies which state the long term effect of LLLT should be emphasized. Further, studies should evaluate many factors such as psychosocial aspect and dosimetry that may reflect on treatment response and recovery. The complete substitution of anti-inflammatory drugs by LLLT, in patients that are at high risk, should also be targeted in future studies.

CONCLUSION

Treatment of acute low back pain with radiculopathy at 905-nm LLLT of a dose of 3J/point, proposed as an additional therapy in acute care setup has shown better short term improvement in pain, disability and quality of life, compared with patients treated with conventional physiotherapy (TENS).No side effects were noticed for LLLT throughout the study period. Hence LLLT is a viable option to treat acute radicular pain and there by arresting the promotion towards chronicity. LLLT reduces pain and disability in acute state and delay or prevents progression.

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