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Correlation Analysis Between Pain Intensity, Functional Disability and Range of Motion Using Low-Level Laser Therapy in Patients With Discogenic Lumbar Radiculopathy: A Cross-sectional Study

Ishaq Ahmed[1*], Mohammad Ali Mohseni Bandpei[2], Seyed Amir Gilani[3], Ashfaq Ahmad[4], Faryal Zaidi [1,5]

[1]University Institute of Physical Therapy, Ibadat International University Islamabad, Pakistan
[2]Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences: Tehran, Iran
[3]Dean Faculty of Allied Health Sciences, The University of Lahore, Pakistan
[4]University Institute and Clinics of Physical Therapy, Faculty of Allied Health Sciences, The University of Lahore, Pakistan
[5]Research Coordinator at University Institute of Physical Therapy, Ibadat International University Islamabad, Pakistan

***Correspondence to**
Ishaq Ahmed, Assistant Professor/Head of Department, University Institute of Physical Therapy, Ibadat International University Islamabad, Pakistan.
Email: ishaqpt786@gmail.com

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Abstract

Introduction: Low-level laser is a pain-free and non-invasive treatment modality. It is used in many acute and chronic painful conditions. This study aimed to determine the correlation between pain intensity, functional disability, and range of motion using low-level laser therapy (LLLT) in patients with discogenic lumbar radiculopathy.

Methods: This cross-sectional study was conducted as a part of a randomized controlled trial of LLLT to treat patients with discogenic lumbar radiculopathy in physical therapy departments of three different hospitals in Islamabad, Pakistan, from August 2021 to September 2021. The study was conducted according to STROBE guidelines. Fifty-Five patients from the experimental group of the trial were invited to participate in this study. The outcomes of the treatment were recorded on a semi-structured questionnaire on the first day and last day of their treatment from each patient's pain intensity, functional disability, and Lumbar range of motion (L-ROM) (flexion and extension) by using the visual analogue scale (VAS) for pain intensity, Oswestry Disability Index (ODI) for functional disability, and dual inclinometer for L-ROM. The data were analyzed through SPSS version 26.0.

Results: The results of the correlation coefficient/Pearson's correlation of VAS, ODI, and dual inclinometer were varied. The strength of correlation between variables was weak to moderate ($r=0.033$ to 0.425) with statistically insignificant correlation coefficient ($P > 0.05$, 95% CI) except for lumbar flexion ($P<0.05$, 95% CI).

Conclusion: For acute *low back pain* (LBP) with discogenic lumbar radiculopathy, LLLT at a wavelength of 830-nm and a dose of 3 J/point in conjunction with conventional physical therapy had no significant correlation, but rather weak to moderate values with pain intensity, functional disability, and L-ROM.

Keywords: Low-level laser therapy; Acute discogenic lumbar radiculopathy; Visual analogue scale; Oswestry Disability Index; Dual inclinometer.

Introduction

Lumbar disc prolapse is considered a hallmark of low back pain (LBP). Typically, the pain is located bilaterally at the posterior beltline with a sharp, shooting pain running down the low back, buttocks, and the thigh along with numbness" or tingling.[1,2] The pain is aggravated by sitting, prolonged standing, bending, or twisting movements and is relieved by walking, lying down, rest, and a recumbent position.[3,4] The diagnostic tools are history, symptoms, and physical examination of the patient.[4]

The "majority of disc prolapses occur in the lumbar region (L4-L5 or L5-S1).[2,3] The majority of disc prolapse pains are self-limiting and short-lived.[4] The ratio of men to women is approximately 1:1.[5-7]

Most people affected by disc prolapse are between 25 and 55 years of age.[2] Risk factors include age, degeneration, activity level, disc trauma, smoking, vibration (e.g. when driving a car), congenital predisposition, obesity, improper lifting technique, etc.[3,5,8]

Radiculopathy caused by lumbar disc prolapse occurs at a lower rate between 17% and 50% according to validated instruments.[9] Using strict criteria in two studies, a herniated lumbar disc was associated with the lifetime prevalence of radiculopathy in 4% of females and 5% of

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males.[10,11] The overall discogenic lumbar radiculopathy was estimated at 4.8 per 1000 person-years.

Discogenic lumbar radiculopathy can be treated via multiple approaches, such as decreasing intra-discal pressures, increasing fluid and nutrient exchange, promoting disc regeneration, and retracting nucleic material of bulging discs.[10-13] There are several possible approaches, such as soft tissue manipulation, taping, lumbar corsets, therapeutic exercises, analgesics and anti-inflammatory drugs, electrotherapy, and surgery as a last resort.[8,9,14]

Researches have shown that low-level laser therapy (LLLT) modulates the inflammatory process and helps relieve pain caused by disc lesions.[15] Reduced nerve conduction, the release of endogenous opioids, an increase in angiogenesis, and a consequent increase in local microcirculation are responsible for this alteration. Additionally, it might inhibit prostaglandin production, cytokine production, and cyclooxygenase activity, while increasing cell proliferation, collagen production, and tissue regeneration.[15,16]

As per the renowned disablement model by Ngai,[17] whenever there is a pathology, pain, and impairments always come which produce functional limitations and disability in return, but the pain does not necessarily result in impairment, and not all impairments result in functional limitation and disability.[18] In order to treat the impairments related to functional limitation and disability, a clinician should be target-oriented. Therefore, an effective assessment and management of LBP and sound knowledge of the relationships between pain, impairment, and disability are required.

Multiple studies have investigated the direct relationship between measures of pain intensity, impairments, and disability. These studies show some discrepancies in the level of correlation between measures of pain, impairment, and disability.[14,16,18] We hypothesize that a strong correlation exists between measures of pain, functional disability, and lumbar range of motion (L-ROM) using LLLT and conventional physical therapy as a mode of treatment. The aim of this study is to find the correlation between pain intensity, functional disability, and L-ROM using LLLT in patients with discogenic lumbar radiculopathy.

Materials and Methods

Patients

This cross-sectional study was conducted according to STROBE guidelines as a part of a randomized controlled trial of LLLT to treat patients with discogenic lumbar radiculopathy at the Physical therapy departments of Polyclinic hospital, National Institute of Rehabilitation Medicine hospital and Rawal hospital in Islamabad, Pakistan, from August 2021 to September 2021. In this study, 55 patients from the experimental group of the trial with a mean age of 39.00 ± 7.49 years (Table 1) were invited to participate if they had unilateral leg pain greater than LBP, leg pain below the knee to foot or toes following a dermatomal pattern,[7,10] paresthesia and numbness in the same affected area, a moderate to severe score (21%-60%) on ODI,[1,5,6] positive score on the Straight Leg Raise (pain between 35 degrees and 75 degrees),[3,4] pain limiting functional ability, and scores at least 3/10 on the VAS, restricted lumbar range of motion - 25% flexion, 20% extension. As a measure of results of the treatment, patients' pain intensity, functional disability, and L-ROM (flexion and extension) were measured on the last day of the study through a semi-structured questionnaire, using the visual analogue scale (VAS) to measure pain intensity, the Oswestry Disability Index (ODI) to measure functional disability, and the dual inclinometer to measure L-ROM. An informed consent form was duly signed by every patient, and the Institutional Review Board/Ethical Committee of the University of Lahore deemed it valid. Thus, every patient's rights were protected.

Treatment Procedure of RCT

Upon acceptance into the study, patients were randomly assigned by the Sealed Envelope Method to one of the two treatment groups, either an "experimental group (LLLT – 830 nm, 0.67 W/cm² or 300 mW/cm² and conventional physical therapy – back extension exercises, hot pack, hold relax with sustained stretches in SLR, sciatic nerve mobilizations) or a control group (conventional physical therapy alone)". In either group, a patient was equally likely to be selected. As a precaution for skin hygiene, the laser probe was held stationary in skin contact for 2.5 and 3.5 cm laterally of the spinous processes of the involved nerve roots (L4 or L5 or S1) and at one distal level segment as well.[19] The parameters[14] of the low-level laser beams are listed in Table 2. The hot pack was applied to the lower

Table 1. Basic Characteristics of Patients

Age	BMI (kg/m²)	Gender
Mean ± SD	Mean ± SD *P* Value)	Male: Female
37.24 ± 7.414	26.9 ± 3.65 (0.878)	30: 25

Table 2. Characteristics of Laser Beams

Wavelength	830 nm (near infrared)
Laser frequency	5000
Power output	100 mW
Power density	300 mW/cm² or 0.67 W/cm²
Energy	3 J/point
Energy density	3 J/cm² on each point
Number of points	4
Spot size	1 cm
Treatment time	30 sec on each point
Daily energy delivered	12 J

lumbar area (L3-S2) for 10 minutes.[5,7] The patients were instructed to perform lumbar extension exercises in a prone lying position in three sets of five repetitions each.[1,5] There were three sets of five repetitions of the hold-relax technique for the hamstrings, gluteus maximus, and calf muscles, followed by sustained stretching for 15 seconds of hold each for all three sets of five repetitions.[1,2,5,7] Sciatic nerve mobilizations were done five times in one set with 15 seconds of hold.[5,7]

The patients in both groups had received a series of 18 treatment sessions (3 sessions per week for 6 to 8 weeks). The treatment days for the experimental and control groups were alternate in nature.

Measurable Outcome Variables

A semi-structured questionnaire which assessed each patient's pain intensity, functional disability, and L-ROM (L-flexion and L-extension) was administered on the first day of therapy and then after 18 sessions. Pain intensity in the affected leg was assessed using a VAS.[8] This was a horizontal scale ranging from 0 (no pain at all) to 10 (the worst pain imaginable). L-ROM was measured using posterior superior iliac spine to 15 cm cephalad landmarking technique using a dual inclinometer. On a piece of adhesive tape, a horizontal line marked the upper and lower spinal landmarks. For each set of data, the adhesive marks were removed and re-labeled. At each low landmark along the spine, there were two heads of the dual inclinometer, the MASTER head was positioned at the upper landmark, and the SLAVE head was located at the lower landmark. A change in degree was recorded while the patient bent forward maximally. For L-flexion and L-extension, the intra-rater reliability of this method is 0.73 and 0.85 respectively.[15] The functional disability was measured using the ODI. This questionnaire measures how pain impacts daily activities on a scale of 0 to 5 for each section, with higher scores indicating more severe impacts. The ODI was assessed as being Cronbach α reliable with a score of 0.877.[15]

Data Analysis

The statistical analyses were performed using SPSS version 26.0 on the basis of "intention to treat". As the Shapiro-Wilk test (P value < 0.05, 95% CI) showed no normal distribution of the data, the results were presented as median (25% and 75% percentiles). The Wilcoxon signed Test for intra-group analysis was used as a test of significance, and a two-tailed P value of 0.05 (95% CI) was calculated to either accept or reject the null hypothesis. Effect size (Cohen's d) analysis was done for evaluating the importance of measured changes in pain intensity, disability, and L-ROM as post hoc power analyses. Correlation coefficient/Pearson's correlation was used to determine the correlation between pain intensity, L-ROM, and functional disability.

Results

Statistical Analysis

The results from intra-group statistical analysis (Table 3 and Figure 1) showed a statistically significant

Table 3. Median Values (25 % and 75% Percentiles), Paired Sample Statistics & Effect Size of Measured Outcomes

Outcomes	Pre-Therapy	Post-Therapy	Wilcoxon Signed Test Score		d*
			Z-score	Asymp. Sig. (2-Tailed)	
VAS	7 (6; 8)	1 (0; 2)	-6.457	0.000	3.49
ODI	32 (29; 35)	17(16; 19)	-6.457	0.000	3.39
LFLEX	32 (29; 36)	47 (44; 49)	-6.461	0.000	3.11
LEXT	12 (9; 13)	18 (17; 20)	-6.46	0.000	2.51

d* (Cohen effect size: d < 0.2, small; 0.2 < d < 0.8, medium; d > 0.8, large).
LFLEX, lumbar flexion range of motion; LEXT, lumbar extension range of motion

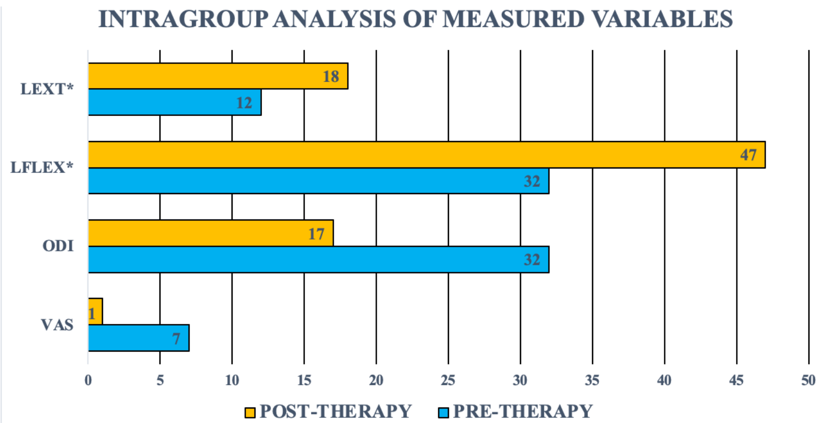

Figure 1. Intragroup Analysis of Measured Variables. Abbreviations: LFLEX, lumbar flexion range of motion; LEXT, lumbar extension range of motion; VAS, visual analogue scale; ODI, Oswestry Disability Index .

improvement within the groups ($P < 0.05$ in all instances). The median values with 25% and 75% percentiles for the Experimental group had shown significant differences in values with respect to pain intensity, functional disability, lumbar flexion and extension that were obtained over time. Hence, the group had shown clinical improvements that were statistically significant. These statistically significant changes on each measured outcome through the Wilcoxon signed rank test were consistent (Z-score = -6.457, $P = 0.000$, 95% CI) during the entire treatment period, based on measurements taken at the beginning and end of the session. Analysis of effect size statistically revealed that measured differences were large for pain intensity, functional disability, and lumbar flexion and extension (d = 2.51 to 3.49). Overall, the largest effect size was for pain intensity, and the smallest was for lumbar extension (Table 3 and Figure 2).

It is evident from the median values with 25% and 75% percentiles of measured outcomes (shown in Table 3 and Figure 1) that LLLT along with conventional physical therapy had produced a great improvement in all quantitative variables.

The analysis of correlation through Pearson correlation coefficient (shown in Table 4 and Figure 3) showed that the strength of correlation between variables was weak to moderate (r = 0.033 to 0.425) with a statistically insignificant correlation coefficient ($P > 0.05$, 95% CI) except for lumbar flexion ($P < 0.05$, 95% CI). It is concluded that only 0.7% ($r^2 = 0.007$, $P = 0.55$) of the variation in functional disability, 18% ($r^2 = 0.18$, $P = 0.00$) in lumbar flexion and only 5% ($r^2 = 0.051$, $P = 0.09$) in lumbar extension are explained by pain intensity. However, only 0.1% ($r^2 = 0.001$, $P = 0.80$) of the variation in lumbar flexion and 0.4% ($r^2 = 0.004$, $P = 0.66$) in lumbar extension are explained by functional disability.

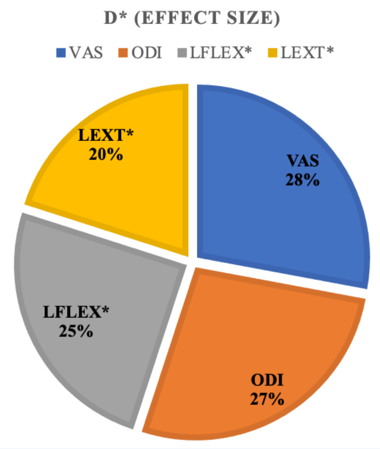

Figure 2. Effect Size of Measured Outcomes. Abbreviations: LFLEX, lumbar flexion range of motion; LEXT, lumbar extension range of motion; VAS, visual analogue scale; ODI, Oswestry Disability Index.

Discussion

In the current study, a correlation analysis was done among pain intensity, functional disability, and L-ROM using LLLT combined with conventional physical therapy in patients with discogenic lumbar radiculopathy. This study found remarkable changes between the 0th day and 45th day of the intervention. A similar mean age of 38.12 ± 7.14 was found for the study participants aged between 25 and 55 years (Table 2). 25-55 years of age is the restriction because discogenic lumbar radiculopathy tends to be more prevalent in this age range. Kreiner et al also adopted this age restriction of 25-55 years for the same reasons.[1] Freburger et al found a mean age of 34 years where 50% of the participants were 25-40 years of age.[4] This study had a greater ratio of men about 52%, which is usually because of the higher prevalence of lumbar radiculopathy, that is 2%-5% in men and 1%-3% in women.[4,6,9] The BMI score (Table 2) was found to be 26.9 ± 3.65 with a p-value = 0.878

The significant changes were found in pain intensity, disability levels, and L-ROM. Most notable are the results pertaining to reducing functional disability (from moderate to minimal disability) and increasing the lumbar flexion range (28%) (based on the difference in the percentage between pre- and post-median values). Even with the large effect size, the pain intensity was reduced (from severe to moderate level). In terms of the lumbar extension range, there was not much improvement.

There is no such golden rule to define a strong versus a moderate versus a weak relationship. However, Colton[19] suggested some general guidelines for health science studies that we used in this study. That is, correlations ranging from 0.00 to 0.25 indicate little or no relationship; those from 0.25 to 0.50 suggest a fair degree of relationship; values of 0.50 to 0.75 are moderate to good, and values above 0.75 are considered good to excellent.

The results of the analysis of correlation showed weak to moderate strength of correlation between outcome variables; a large negative linear correlation (18%) was

Table 4. Correlation Analysis Between Pain Intensity, Functional Disability & ROM Outcomes

Outcomes	Pain Intensity			Functional Disability			Lumbar Flexion			Lumbar Extension		
	r	Sig. (2-Tailed)	R^2 Linear	r	Sig. (2-Tailed)	R^2 Linear	r	Sig. (2-Tailed)	R^2 Linear	r	Sig. (2-Tailed)	R^2 Linear
Pain intensity	1			-0.081	0.55	0.007	-0.425	0.00	0.18	0.227	0.09	0.051
Functional disability	-0.081	0.55	0.007	1			-0.033	0.80	0.001	-0.059	0.66	0.004

Note. Pearson correlation coefficient: r < 0.4, weak or no relationship; 0.5 < r < 0.7, moderate relationship; r > 0.7, strong relationship.

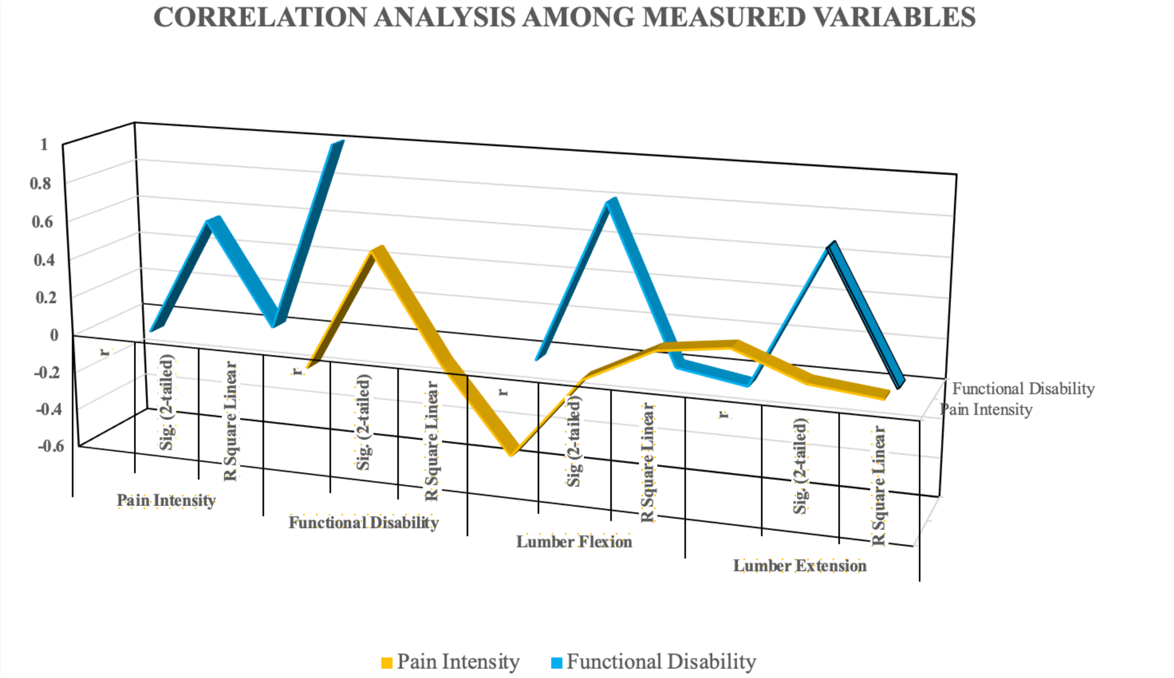

Figure 3. Correlation Analysis Among Measured Outcomes Variables.

observed between pain intensity and lumbar flexion and the least (0.7%) with functional disability, while very weak to no linear correlation (0.1 to 0.4%) was found between functional disability and L-ROM. All the variables have some interdependence to some degree, so any change in one variable has an impact on the other, whether a positive or negative one.

Several studies[20,21] have evidenced a diminished LBP and disability post-treatment but failed to record correlation coefficients between these 2 outcome measures. As pain intensity is only 1 area addressed on the back-pain questionnaire, a moderate relationship between these 2 variables (pain, disability) was expected. The longitudinal significant improvement in VAS and ODI and dual inclinometer scores suggested that intensity of pain was more closely related to the degree of disability and ROM as the condition became more chronic in patients with acute LBP with discogenic lumbar radiculopathy. Clinicians should be aware of this and the intensity of pain should be addressed seriously in the early stages before the condition becomes chronic.

Ay et al[22] applied LLLT doses with laser beam sources NdYAG36, which was recommended by WALT, to a group of patients suffering from nonspecific LBP.[23] Jovičić et al conducted a study aiming to give additional anti-inflammatory effects to patients with acute LBP.[14] Due to the heterogeneity of the patients and their pathophysiological factors, it was difficult to compare the results in these studies. In a study of patients with acute LBP with radiculopathy, a laser with an 830-nm wavelength was used at a dose of one joule to study the effects of different therapies. Ultrasound and traction therapy did not significantly change the results obtained when compared to LLLT.[18]

LLLT has multiple biological effects including the stimulation of nerve fibers, ensuring rapid recovery from conduction block, decreasing inflammation as a primary effect, improving neurophysiology features of nerve structures, and changing in the Endorphin level. The anti-inflammatory effects are the most notable of all, recorded in many experimental studies. Studies using local lasers with different wavelengths of 660, 684,[15] 780,[23] and 904 nm[24] have found different changes in biochemical markers of inflammation, cellular chemotaxis, as well as decreased oedema formation, hemorrhage and necrosis respectively. There is a positive correlation between this mode of reduction and the decrease in the tumor necrosis factor alpha level, and the effect is dose-dependent.[25] LLLT directly impacts neural structures in acute lesions, such as acute lumbar radiculopathy which causes neuropathic pain. Laser therapy at an 840-nm wavelength, used on injured peripheral nerves, has been shown to have a marked effect on nerve recovery in clinical studies.[18] There may be a potential for positive interactions between LLLT and COX-2 inhibitors as these enzymes increase the nonspecific resistance of cells to oxidative damage.[25,26]

A condition which occurs as frequently as degenerative lumbar radiculopathy lacks sufficient evidence for diagnostic procedures and treatment interventions. Published trials suffer from factors such as imprecise selection of patients, lack of additional MRI and EMG investigations, varying clinical characteristics, undefined clinical stage, and often no description of treatment.

Strengths and Limitations

A major strength of this study is the diversity of the sample that was recruited from a variety of surgeons, making our findings generalizable. A major weakness of correlational research is the inability to establish causal relationships. However, given the lack of documented evidence supporting these outcomes, it is critical to determine how these variables are related in patients with acute, discogenic LBP.

Recommendations

Further studies are required to determine the relationship between pain, fear-avoidance belief, and muscle strength. We found that as the condition of the patient improves, the outcome measures show improvement and change in their correlation. Further investigation is required to elucidate this.

Conclusion

For acute LBP with discogenic lumbar radiculopathy, LLLT at a wavelength of 830-nm and a dose of 3 J/point in conjunction with conventional physical therapy had no significant correlation, but rather weak to moderate values with pain intensity, functional disability, and L-ROM. It means that all the variables are interrelated to each other to some extent; any change in one variable brings about change in other variables whether in a positive or negative direction. LLLT was also observed to have no significant side effects during and after use.

Acknowledgement

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Availability of Data and Materials

The datasets used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Conflict of Interests

All authors declare that they do not have any competing interests.

Consent for Publication

A written informed consent was obtained from all participants in the study that if data is used for publication in the literature or for the teaching purpose, no names will be used and other identifiers, such as photographs, audio or videotapes, will not be used without my special written permission.

Ethical Considerations

The study was approved by the Institutional Review Board/Ethical Committee of The University of Lahore, Pakistan. A written informed consent to participate in the study was obtained from all participants which was approved from an Institutional Review Board/Ethical Committee of The University of Lahore, Pakistan. Therefore, the rights of every patient were protected. All procedures in the study were performed in accordance with the relevant guidelines.

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