





Comparison of the clinical effectiveness of Class IV Laser therapy and therapeutic ultrasound in patients with chronic neck pain: a randomized controlled trial

Comparação da eficácia clínica da terapia a laser Classe IV e do ultrassom terapêutico em pacientes com dor cervical crônica: um estudo controlado e randomizado



¹Maharishi Markandeshwar (Deemed to be University) (Mullana). Haryana, India. ²Corresponding author. Maharishi Markandeshwar (Deemed to be University) (Mullana). Haryana, India. ptsunitasharma81@gmail.com

ABSTRACT | INTRODUCTION: Chronic neck pain (CNP) is a common musculoskeletal problem that affects a large proportion of the population and lasts longer than three months. It has a high cost in terms of life, disability, and healthcare. Several modalities have effectively provided immediate and long-term relief for CNP; however, the comparative clinical effectiveness of these modalities is limited. OBJECTIVES: The study aimed to determine the clinical effectiveness of Class IV Laser therapy and Therapeutic Ultrasound (TUS) in patients with CNP. METHODS AND MATERIALS: Forty-four patients with CNP of both genders were recruited from an age range of 20-45 years from the Department of Musculoskeletal Physiotherapy of Maharishi Markandeshwar Institute of Physiotherapy, MM(DU), Ambala, India. They were divided into two groups at random: the LASER group A (n = 22) and the TUS group B (n = 22). The intervention duration was 2 weeks with 6 treatment sessions. Pre- and post-treatment outcome measures were assessed with the Visual Analog Scale (VAS), Algometer, Goniometer, and Neck Disability Index (NDI) questionnaires at baseline and after 2 weeks of intervention. The LASER group received a target dose of 10 joules per cm<sup>2</sup> at a power of 10 watts, with a continuous dosage frequency. The TUS group underwent a continuous mode ultrasound (3 MHz, 1 W/cm²) for 6 minutes. The Shapiro-Wilk test was used to assess the normality of the data. For parametric and non-parametric data analysis within the group, the paired t-test and Wilcoxon signed rank were used. The independent t-test and Mann-U Whitney test were used for the group comparison of parametric and non-parametric data, respectively. RESULTS: In both groups, there was a significant improvement in all the outcome measures (p<0.001). There was a statistically significant difference between the two interventions in VAS, Pain Pressure Threshold (PPT), and NDI (p<0.05). CONCLUSION: Class IV Laser therapy is clinically more effective than therapeutic ultrasound in treating patients with chronic neck pain.

KEYWORDS: Laser Therapy. Neck Pain. Activities of Daily Living. Ultrasound Therapy.



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RESUMO | INTRODUÇÃO: A dor cervical crônica (DCC) é um problema musculoesquelético comum que afeta uma grande proporção da população e dura mais de três meses. Ela tem um alto custo em termos de vida, incapacidade e assistência médica. Várias modalidades têm proporcionado alívio imediato e de longo prazo para a dor cervical crônica; entretanto, a eficácia clínica comparativa dessas modalidades é limitada. OBJETIVOS: O objetivo do estudo foi determinar a eficácia clínica da terapia a laser de classe IV e do ultrassom terapêutico (UST) em pacientes com DCC. MÉTODOS E MATERIAIS: Quarenta e quatro pacientes com DCC de ambos os sexos, em uma faixa etária de 20 a 45 anos, foram recrutados do Departamento de fisioterapia musculoesquelética do Instituto de Fisioterapia Maharishi Markandeshwar, MM (DU), Ambala, Índia. Eles foram divididos em dois grupos de forma aleatória: o grupo LASER A (n = 22) e o grupo UST B (n = 22). A duração da intervenção foi de 2 semanas com 6 sessões de tratamento. As medidas de resultado pré e pós-tratamento foram avaliadas com os questionários Escala Visual Analógica (EVA), Algometer, Goniometer e Índice de Incapacidade do Pescoço (IIP) na linha de base e após 2 semanas de intervenção. O grupo LASER recebeu dose alvo de 10 joules por cm² na potência de 10 watts, com frequência de dosagem contínua. O grupo UST foi submetido a ultrassom em modo contínuo (3 MHz, 1 W/cm²) por 6 minutos. O teste de Shapiro-Wilk foi utilizado para avaliar a normalidade dos dados. Para análise dos dados paramétricos e não paramétricos dentro do grupo, foram utilizados o teste t pareado e o posto sinalizado de Wilcoxon. O teste t independente e o teste Mann-U Whitney foram utilizados para comparação de grupos para dados paramétricos e não paramétricos, respectivamente. **RESULTADOS**: Em ambos os grupos, houve uma melhora significativa em todas as medidas de resultado (p<0,001). Houve uma diferença estatisticamente significativa entre as duas intervenções na EVA, Limiar de pressão de dor (PPT) e IIP (p<0,05). CONCLUSÕES: A terapia a laser de classe IV é clinicamente mais eficaz do que o ultrassom terapêutico no tratamento de pacientes com dor cervical crônica.

PALAVRAS-CHAVE: Terapia a Laser. Cervicalgia. Atividades Cotidianas. Terapia por Ultrassom.

### 1. Introduction

Neck pain is one of the most prevalent musculoskeletal pain disorders, with complete resolution of symptoms occurring in only one-third of patients.<sup>1</sup> There is localized or referred pain with point tenderness and restricted Cervical Range of Motion (CROM). In CNP, symptoms persist for more than 3 months, hampering quality of life. The main trigger is myofascial pain associated with the upper trapezius, causing intense pain.<sup>2</sup> Among the 45-54% of people who have neck pain, 19–37% develop chronic neck pain, which causes work absences and lowers quality of life.<sup>2,3</sup>

Long-term poor postures result in chronic muscular fatigue, pain, or discomfort and may lead to pathological effects and permanent disability.<sup>4</sup> Nonsteroidal anti-inflammatory medicines (NSAIDs) and pain-modulating therapy are among the medications used to treat chronic neck pain.<sup>5</sup> Low-level LASER treatment (LLLT), manual therapy, neck stretching, acupuncture, and massage are some additional non-pharmacological interventions that may be used.<sup>1</sup>

Class IV LASER devices, also known as high-intensity laser therapy (HILT), are noninvasive and painless therapeutic procedures that produce more diffuse and less concentrated photochemical and photothermic effects than class III devices. As a result, chromophores absorb light at the slowest rates, often at depths of 10 to 12 cm. It promotes nerve regeneration and stimulates immunological processes by increasing microcirculation.<sup>6,7</sup>

Therapeutic ultrasound (TUS) is made of piezoelectric crystals that convert electrical energy into mechanical oscillation energy using high-frequency, alternating currents. This mechanical oscillation energy is applied by a transducer or applicator that is placed in close contact with the patient's skin. Therapeutic ultrasound's thermal and non-thermal effects cause biological reactions such as muscle relaxation, tissue healing, and a reduction in inflammation.

Both modalities, class IV LASER therapy and therapeutic ultrasound, have proven their effectiveness in treating various musculoskeletal conditions. Till date, only one study has compared the effectiveness of these electrical modalities in patients with CNP and concluded that HILT is more effective than ultrasound in terms of pain and disability, but they have not taken outcome measures on pressure pain threshold. And along with the modalities, conventional treatment was also given. As a result, the goal of this project is to assess and compare the clinical effectiveness of class IV LASER therapy and continuous-mode therapeutic ultrasound in patients with chronic neck pain who are not receiving any conventional treatment. As no other study could be found in the literature comparing the effectiveness of therapeutic ultrasound and class IV LASER therapy without exercise in CNP, this is the first study on this subject. The objectives of the study are to compare the effectiveness of class IV LASER therapy with therapeutic ultrasound in parameters of VAS, PPT, NDI and CROM in patients with CNP.

#### 2. Materials and methods

This is a randomised clinical trial, and approval for the study was granted by the Institutional Ethics Committee (IEC-2237). This study is registered at the Clinical Trials Registry India (CTRI/2022/09/045190). All the study procedures complied with the Declaration of Helsinki. The patients were recruited from July 2022 to March 2023 in Orthopedic Physiotherapy OPD. The participants were selected from the institute's musculoskeletal physiotherapy outpatient department. Students, faculty, and residents of neighboring towns were recruited as participants. Written and verbal information regarding the study and procedures were provided, and informed consent was obtained from the study participants. The variables were assessed and documented at the institute's musculoskeletal physiotherapy outpatient department. A post-graduate musculoskeletal therapist trained in conducting the examinations assessed and recorded all of the variables.

The study included patients who had neck pain for more than three months, aged 18- 45 years with at least one trigger point in the neck region.<sup>9</sup> The diagnostic criteria for myofascial trigger points are the presence of tender points within taut bands of muscle in areas that the patient identified as painful.<sup>2</sup> The pain intensity of more than 4 on VAS. The study exclusion criteria are positive neurological examination (the presence of positive motor, reflex, or sensory abnormalities indicating spinal root compression) or abnormal neurological signs in the upper limbs relating to nerve entrapment; individuals with a previous history of trauma or fracture within the past 6 months; cervical stenosis, metabolic or systemic disorders, or cancer, as well as local anesthetic and/or steroid injections into the trigger points within the previous 6 months; any inflammatory pathology, malignancy, previous spinal surgery, or history of cardiovascular, neurological, or respiratory illness.9

#### 3. Outcome measures

## 3.1. Primary outcome measure

Visual analogue scale (VAS): VAS is a horizontal line of fixed length, usually 100 mm, used to measure pain. The extreme left is no pain, and the right is the worst pain. They are given to the patient, and the patient draws a line to represent their pain perception of their current state. The score is measured using a ruler to measure the distance (in mm) between the "no-pain" marker and the participant mark on the 10-cm line, providing a score from 0-100 mm. A higher score indicates greater pain intensity. No pain is defined as 0–4 mm, mild pain as 5–44 mm, moderate pain as 45–74 mm, and severe pain as 75–100 mm.<sup>10</sup>

Neck Disability Index (NDI): The NDI is a 10-item self-report questionnaire that asks about 10 different topics. Each response is scored from 0 (no disability) to 5 (full disability) on a 6-point scale. For a total score between 0 and 50, the numerical responses to each item are added. It can be expressed in percentage as well. A higher score indicates a higher degree of disability. Excellent reliability was demonstrated by the NDI (ICC = 0.88; [0.63 to 0.95]). The NDI's MDC was 6.9, and its MCID was 5.5 (Sn = 0.83; Sp= 0.79), respectively.<sup>11</sup>

Pain pressure threshold: Algometers are tools for applying regulated pressure to a specific body part to determine the pressure needed to evoke a pressure-pain threshold. In this study, a digitalized pressure algometer (DPA) (ALGO-DS-01) was placed on the point of greatest hyperalgesia of the trapezius muscle. PPT applied pressure to the assessment point until the patient felt pain and discomfort, and the maximum pressure was electronically recorded. The measurement was recorded in kg/cm2. PPT on myofascial trigger points has excellent inter- and intrarater reliability, with values ranging from 0.752 to 0.874 for intra-class correlational coefficient values.<sup>12</sup>

Cervical ROM: Flexion, extension, lateral flexion, and rotation were measured by a universal goniometer. Physiotherapists use the ROM measurement to measure patients' restrictions before treatment and the efficacy of treatments. The universal goniometer demonstrated excellent intra-rater reliability between sessions (ICC = 0.79 to 0.97) and within sessions (ICC = 0.83 to 0.98) and excellent inter-rater reliability (ICC = 0.79 to 0.92).<sup>13</sup>

The sample size was calculated using G\*Power 3.1.9.7 statistical software. The calculated effect size was 1.1, the significance level was 0.05, and the power set was 90%. With a 15% dropout rate, 22 samples in each group were calculated, for a total sample size of 44.9

The patients were randomly separated into 2 groups i.e. LASER group A and TUS group B via a computerized program in a ratio of 1:1. Demographic data and data about neck pain were completed for all participants. This study was single-blinded with assessor blinding. Visual analog scale (VAS) was used to determine pain intensity, Neck disability index (NDI) for disability, algometer for pain pressure threshold (PPT) of trapezius muscle and goniometer for CROM were used as outcome measures. They were evaluated before the treatment and after the 2 weeks of the intervention. The flow chart of participants is shown in Figure 1.

## 3.2. Intervention

## 3.2.1. Group A (LASER group)

Participants in the LASER group received Class IV LASER therapy on the neck taut band area three days a week for two weeks, with the dosage determined by the size of the area to be treated. Both the patients and the therapist used eyewear. The dose of LASER therapy was determined by the area to be treated in cm<sup>2</sup>. The target dose was 10 joules per cm<sup>2</sup>. Total energy was calculated by multiplying the target dosage by the treatment area. The power was 10 watts, and the dosage frequency was set to continuous.<sup>9</sup> Treatment time was calculated by dividing the total energy delivered by the average total output. The contact scanning method was used to perform treatment in a comfortable position for each area. A class IV LASER (Litecure Model No. LCT-1000H10006006) was used.

#### 3.2.2. Group B (TUS group)

Participants in the TUS group received a therapeutic ultrasound on the neck taut band area. The individuals with CNP were treated with continuous mode ultrasound (3 MHz, 1 W/cm²) for 6 minutes, 3 days a week, for 2 weeks in the sitting position in the tendered area. The Head of US was applied in a circular motion over and around myofascial taut bands.<sup>14</sup>

Both groups were advised to do all cervical movements within their normal range twice a day for 10 repetitions. The VAS score, NDI questionnaire, pain pressure threshold, and CROM measurements were recorded by the same physiotherapist, who was unaware of the research groups and conducted before the first session and after the last session.

# 3.3. Data analysis

All the data were analyzed using IBM SPSS version 20 (IBM Corp., Armonk, N.Y., USA). The normality of each demographic characteristic was analyzed for both groups using the Shapiro-Wilk test. Baseline comparison was measured through an independent t-test. For continuous numerical variables, descriptive statistics were expressed as mean ± standard deviation, median (IQR), and for categorical variables, as a number (n) and a percentage (%). A paired t-test was used to compare pre- and post-treatment results for CROM and pain pressure threshold, whereas an independent t-test was used to compare pre- and post-treatment outcomes between the two groups. The Mann-Whitney U test was used to compare baseline and post-treatment scores between groups for nonparametric measures like VAS and NDI. The Wilcoxon signed-rank test was used to compare the outcomes for each group at baseline and posttreatment. The level of statistical significance was fixed at p<0.05. Cohen's d was generated to assess the effect size of outcome measures. Cohen d ES results represent 0.8 large, 0.5 medium, and 0.2 small effects. 15

#### 4. Results

A total of 44 patients with CNP participated in this study, but three participants were excluded from the analysis as they lost follow-up. The mean (SD) age of participants was 29.31 (6.21) years. The mean (SD) age difference between the groups (LASER group =  $29.10 \pm 6.49$ ) years and (TUS group =  $29.52 \pm 6.09$ ) years was not significant (p-value = 0.830). 26 (63.4%) were female; 15 (36.5%) participants were male. Participants' demographics and baseline data of outcomes in both groups were compared in Table 1. There was no significant difference in baseline characteristics between the LASER and TUS group participants (p>0.005).

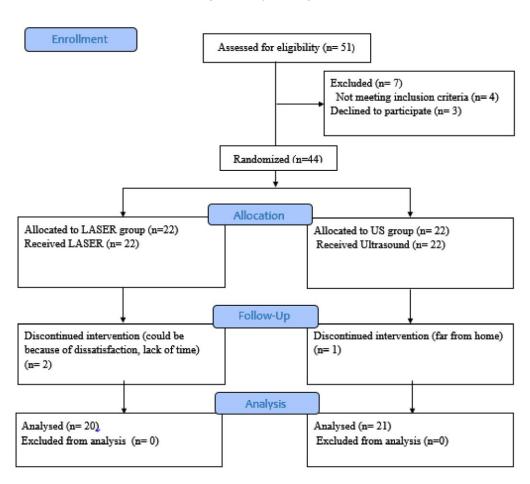


Figure 1. Study Flow Diagram

Source: the authors (2024).

Table 1. Demographic characteristics of the participants and baseline data of outcome in both the groups

	LASER group A (n=20)	TUS group B (n=21)	P value
Age (years)	29.10 ±6.49	29.52 ±6.09	0.830a
Gender		ı	1
Female	10 (50%)	16 (76.20%)	0.082 <sup>b</sup>
Male	10 (50%)	5 (23.80%)	
Weight (kg)	67.25 ±12.43	63.73 ±14.54	0.412a
Height (m)	1.66 ±0.06	1.63 ±0.05	0.169ª
BMI (kg/m²)	24.10 ±3.39	23.74 ±5.20	0.787a
VAS (cm)	6.95 (6.40 - 7.40)	6.90 (6.05 - 7.45)	0.620°
NDI (%)	43.00 (38.00 - 51.50)	42.00 (36.00 - 45.00)	0.314°
Cervical flexion	47.60±5.11	47.71 ± 4.20	0.938a
(Degrees)			
Cervical	46.45 ± 3.73	48.66 ± 3.92	0.072a
extension			
(Degrees)			
Right lateral	37.80 ± 3.28	38.66 ±3.70	0.443 <sup>a</sup>
flexion			
(Degrees)			
Left lateral	37.90 ± 4.39	36.23 ± 6.17	0.329 a
flexion			
(Degrees)			
Right rotation	70.30 ±5.91	68.42 ±4.52	0.261 a
(Degrees)			
Left rotation	67.10 ± 7.43	67.80 ± 6.07	0.739 a
(Degrees)			
Right Trapezius	13.74 ±3.57	14.58 ± 3.73	0.464 a
PPT (kg/cm²)			
Left Trapezius	16.61 ± 4.92	15.01 ± 4.40	0.280 a
PPT (kg/cm²)			

Legend: BMI - Body Mass Index; VAS - Visual Analogue Scale; NDI - Neck Disability Index; PPT - Pain Pressure Threshold. Descriptive statistics expressed as mean ± standard deviation, median (interquartile range) or number of cases and (%). <sup>a</sup> Between-groups comparison (Independent t test); <sup>b</sup> Pearson's χ2 test; <sup>c</sup> Between groups comparison (Mann–Whitney U test).

Source: the authors (2024)

Both the groups showed a significant improvement in the post-treatment pain scale, CROM, and disability of the neck as compared to baseline (p<0.001). Table 2 describes the post-treatment analysis between the groups. The table demonstrates the significant difference between the group on VAS, NDI, cervical right rotation, and left and right trapezius PPT. Also, the LASER group had a high effect size compared to the TUS group in VAS, NDI, and bilateral trapezius PPT measurements.

Table 2. Post-treatment intergroup analysis

	LASER group A (n=20)	TUS group B(n=21)	P value
VAS (cm)	3.75 (3.00 - 4.10)	4.40 (4.10 - 4.8)	0.001 <sup>c</sup>
NDI (%)	22.00 (16.50 - 29.50)	26.00 (24.00 - 30.00)	0.045 <sup>c</sup>
Cervical flexion (Degrees)	53.75 ± 3.69	52.85 ± 3.26	0.417ª
Cervical extension (Degrees)	53.00 ± 3.55	53.76 ± 3.70	0.506 a
Right lateral flexion (Degrees)	42.80 ± 2.58	43.38 ± 3.23	0.530 ª
Left lateral flexion (Degrees)	42.65 ± 3.19	42.57 ± 3.62	0.942 a
Right rotation (Degrees)	76.80 ± 3.51	73.85 ± 4.66	0.028 a
Left rotation (Degrees)	72.60 ± 6.15	74.76 ± 3.19	0.172ª
Right Trapezius PPT (kg/cm²)	29.48 ± 4.79	24.50 ± 4.81	0.002 a
Left Trapezius PPT (kg/cm²)	32.33 ± 4.90	26.25 ± 5.73	0.001 a

Legend: BMI - Body Mass Index; VAS - Visual Analogue Scale; NDI - Neck Disability Index; PPT- Pain Pressure Threshold.a Between groups comparison (Independent t-test); c Between groups comparison (Mann–Whitney U test). p-value <0.005 is considered significant.

Source: the authors (2024).

#### 5. Discussion

The main aim of this study was to investigate the clinical effectiveness of Class IV Laser therapy versus therapeutic ultrasound on pain, functional status, pain pressure threshold, and CROM in patients who had neck pain lasting more than 3 months and to find potential research gaps. This study suggests that Class IV Laser is more effective than therapeutic ultrasound on patients with CNP after 2 weeks of intervention because it is linked to better circulation and reduction of inflammation. In the present study, there were significant differences in VAS, NDI, and PPT values in the LASER group as compared to the TUS group. The findings of our study are similar to the study of Kenarah et al.<sup>9</sup>

A recent systematic review has shown that high-intensity Laser therapy is effective in treating myofascial pain syndromes of the trapezius, cervical myofascial pain, and trigger points. Another systematic review also showed the effectiveness of HILT in treating musculoskeletal conditions like plantar fascia, OA grades 2–3, carpel tunnel syndrome, lateral epicondylitis, and chronic back pain. Similar to our finding, another study has also found that Laser and ultrasound were both effective in reducing pain and disability in patients with chronic non-specific pain, and low back pain, but laser therapy was more effective. 9.18,19 One study by Kolu et al. 20 suggested that the combination of TENS and TUS was more effective than HILT in patients with chronic lumbar radiculopathy.

The amount of laser energy per square centimeter impacts the effect of laser treatment. Doses greater than 10 J/cm² have been reported to have inhibitory effects when used in conditions that require suppression, such as reducing the inflammatory response to prevent or reduce the flood of pro-inflammatory cytokines.<sup>21,22</sup> Laser therapy has analgesic effects by reducing the release of histamine and bradykinin from wounded tissues, which raises the pain threshold.<sup>23,24</sup> In addition, Laser could improve pain by altering the quantity of chemicals that resemble morphine and the pain stimuli, as well as by altering C-fiber transmission, vascular permeability, and cell metabolism.

The laser could accelerate oxidative processes in the mitochondria, which stimulate tissue. <sup>25,19</sup> Also, laser therapies enhance the production of naturally occurring opioids like  $\beta$ -endorphin, which block the central perception of pain. <sup>26</sup> Laser therapy can further help alleviate pain by boosting nitric oxide levels, which expand capillaries and arterial blood vessels, promote electrolyte exchange in cellular protoplasm, boost the synthesis of nucleic acids and proteins, and increase the consumption of oxygen. <sup>27,28</sup>

In the current study, both groups experienced a significant decrease in pain complaints and their impact on daily activities, pain pressure threshold, and CROM, with the Laser group discovering the improvement more noticeably. Neck pain and pain pressure threshold were reduced by Laser from a higher level than in the TUS before the intervention, demonstrating a very significant effect of Laser in comparison to the TUS. As a result, it is likely that the outcome was unaffected by the baseline differences between the two groups, as the laser group's mean difference was larger for nearly all variables.

This study has direct implications for physical therapy professionals dealing with individuals with CNP. There have been various management of patients with CNP. However, there is little emphasis on the PPT characteristics and treatment by class IV Laser therapy. This is probably the first study to compare the effectiveness of class IV Laser therapy in the PPT of trapezius. With adequate dosage assessment, supervision, and implementation, class IV could become a game changer in therapeutic settings for treating patients with CNP.

The lack of a control group and placebo treatment are the major limitations. A longer follow-up period with a larger sample size and multi-center studies may be recommended in the future to determine the true clinical effectiveness of these modalities.

#### 6. Conclusion

Class IV Laser is an effective physiotherapy electrical modality in treating patients with CNP compared to TUS. The use of class IV Laser therapy in patients with CNP decreases pain intensity, increases PPT and ADL activities, and also increases CROM after 2 weeks of treatment.

#### **Authors' contributions**

Sharma S contributed to study design, methodology and result processing, Shrestha D contributed to methodology, writing, result processing and manuscript preparation. All authors approved the final version to be published and agreed to be accountable for all aspects of the work.

#### **Conflicts of interest**

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

#### **Indexers**

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