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Randomized Controlled Trial

Effectiveness of ultrasound-guided percutaneous needle electrolysis compared to sham needling in posterolateral lumbar disc herniation: a pilot randomized controlled trial

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ABSTRACT

Study design: A pilot randomized, sham-controlled, single-blinded clinical trial was conducted.

Participants: 20 participants with confirmed posterolateral lumbar disc herniations and tibial nerve neuropathic symptoms.

Interventions: The treatment group received three sessions of ultrasound-guided percutaneous needle electrolysis (US-guided PNE), while the control group underwent sham needling.

Objectives: This study aimed to assess the effectiveness of US-guided PNE in reducing pain and improving muscle strength in individuals with posterolateral lumbar disc herniations compared to sham needling.

Materials and Methods: Pain intensity was measured using the Visual Analog Scale (VAS), neuropathic symptoms with the Doleur Neuropatique 4 questionnaire (DN4), and muscle strength via manual muscle testing for hamstrings, triceps surae, and tibialis posterior muscles. Measurements were taken before the first session and four weeks after the third session.

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Results: The treatment group showed significant reductions in VAS and DN4 scores compared to the control group (p<0.001). Muscle strength improvements were observed in the triceps surae and posterior tibialis muscles for the treatment group (p=0.039 and p=0.049, respectively), while no significant differences were found in the hamstrings (p=0.847).

Conclusions: US-guided PNE of the tibial nerve and multifidus muscles is proposed as an effective treatment for lumbar discopathies, offering notable improvements in pain relief and muscle strength over sham needling. These results support the use of US-guided PNE as a viable option for managing symptoms associated with posterolateral lumbar disc herniations.

Keywords: Lumbar discopathy; Tibial nerve; Ultrasound-guided percutaneous electrolysis; Pain; Muscle strength; Randomized controlled trial.

1. Introduction

Lumbar discopathies are among the most frequent causes of medical consultation in Europe and Spain[1]. Worldwide, it is estimated that 2-3% of the population suffers from this pathology, which usually presents with different symptoms such as tingling, burning, or itching towards the back of the lower limb, significant muscle weakness, pain in the path of the limb or allodynia[2,3]. Those that cause greater compression in the posterolateral area of the L4-L5 and L5-S1 vertebral levels have the highest incidence among lumbar disc herniations, giving symptoms mainly to the tibial nerve[4,5]. This nerve is responsible for the motor innervation and sensitivity of the posterior aspect of the knee, leg, and foot sole. Furthermore, it is also responsible for the motor innervation of the posterior thigh[6,7].

There are multiple therapeutic options to treat this condition, including pharmacological interventions (such as pregabalin, cytokine inhibitors, analgesics, muscle relaxants, corticosteroids, non-steroidal anti-inflammatory drugs, and vitamin B12, among others), nerve root blocks, intradiscal radiofrequency ablation or spinal surgery such as discectomy[1,8-10]. However, for decades, research has been carried out into the application of different conservative physiotherapy approaches to prevent patients from undergoing these types of interventions: treatments such as therapeutic exercise, axial decompression, transcutaneous electrical nerve stimulation, or peripheral electric stimulation have emerged, which have proven to be very helpful in treating symptoms associated with discopathies of lumbar origin[11,12].

By different electrical currents, both applied directly to the nerve with needles (together with the help of ultrasound to guide the procedure) and applied non-invasively along the path of the affected nerves, physiotherapy has managed to improve the quality of life of individuals with peripheral nerve involvement of lumbar origin[13-16]. Along these lines, the application of ultrasound-guided percutaneous needle electrolysis (US-guided PNE), a galvanic continuous (not thermal) current, has begun to be studied in areas of nerve entrapment, as in the case of the proximal hamstring tendon and the sciatic nerve or median nerve in the carpal tunnel, showing promising results in improving function[15,17,18]. This effect seems to be due not only to the localized effect produced (local inflammatory response, extracellular matrix and tissue remodeling, among others) but also to the direct impact produced by this current on the modulation of pain processing and the autonomic nervous system, reconsidering the possibility that this current may be capable of depolarizing the peripheral nerve synapse and improving the state of chronic irritability present in these cases[19-21].

While Valera & Minaya[22] previously described an US-guided approach targeting the medial branch of dorsal ramus of spinal nerve for treating neuropathies of peripheral or metameric origin through the multifidus musculature, the application of PNE in proximity to the tibial nerve has not been explored. This is particularly notable given the high incidence of tibial nerve involvement in patients with lumbar discopathies[4,5]. Additionally, the dorsal ramus of the spinal nerve and the multifidus musculature are intricately associated with the innervation of the facet joints, ligaments, and stability mechanisms of the affected vertebral segment[23,24]. In light of these considerations, the primary objective of this study was to evaluate the effectiveness of US-guided PNE of the tibial nerve and multifidus muscles in reducing pain and improving muscle strength in individuals with posterolateral lumbar disc herniations at the L4-L5 or L5-S1 levels, compared to sham needling.

2. Materials and Methods

2.1 Study design

A pilot randomized, sham-controlled, single-blinded clinical trial was conducted on the application of US-guided PNE (compared to sham needling) on the tibial nerve in patients with posterolateral disc herniation at L4-L5 or L5-S1 levels. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines and applied all procedures according to the Declaration of Helsinki. The study was registered at Clinical Trials (NCT06569069).

The sample of participants was drawn from private physiotherapy clinics with agreements with neurosurgery centers in Madrid between 1 April and 1 May 2021. This study was approved by the Ethics Committee of the CEU San Pablo University (531/21/TFM). All participants signed a written informed consent form to participate in this study and were informed of the protocols that would be carried out in each group before the start of the research.

2.2 Participants

Participants of both sexes, aged between 18 and 60 years, who met the following eligibility criteria were studied. On the one hand, the inclusion criteria were: a) positive Lasegue and/or Bragard tests; b) presence of posterolateral disc herniation of the L4-L5 and/or L5-S1 vertebral segment diagnosed by magnetic resonance imaging at least three months or more after the onset of symptoms; and c) presence of neuropathic symptoms in the path of the tibial nerve. On the other hand, the exclusion criteria were: a) belonephobia (fear of needles); b) cardiovascular or nervous pathology of medical relevance; c) surgical history in the lumbar region; d) pregnant women; e) recent or current oncologic treatment (for at least 6 months); and f) poor echogenicity in the ultrasound image of the areas to be treated, following the recommendations of Valera & Minaya[22].

2.3 Interventions

The sample was randomized using the "List Randomizer" program into two groups of ten participants. US-guided PNE was applied in the treatment group, and a sham needling treatment was applied in the control group. Participants were provided with comprehensive information on both treatment modalities; however, they remained blinded to the specific intervention they would receive to minimize bias.

2.3.1. US-guided PNE group

US-guided PNE was performed with the participant in a prone position, and the therapist facing the affected homolateral side. The procedure used the General Electric Logic e BT12 ultrasound device and a 12L-RS linear probe.

First, an approach was applied in the deep multifidus, close to the medial branch of the dorsal ramus (L4-L5 or L5-S1 spinal nerve levels) according to the protocol by Valera & Minaya[22], with a transversal view of the multifidus muscles and the lumbar vertebra of the affected segment, the needle was inserted in a short axis at 80º or long axis at 45º inclination concerning the skin, depending on the presence of vessels in the area (Figure 1). Next, to treat the tibial nerve in the popliteal region, a transversal view of the tibial nerve was made along its course in the popliteal region, in a long axis at 45º concerning the skin (Figure 2).

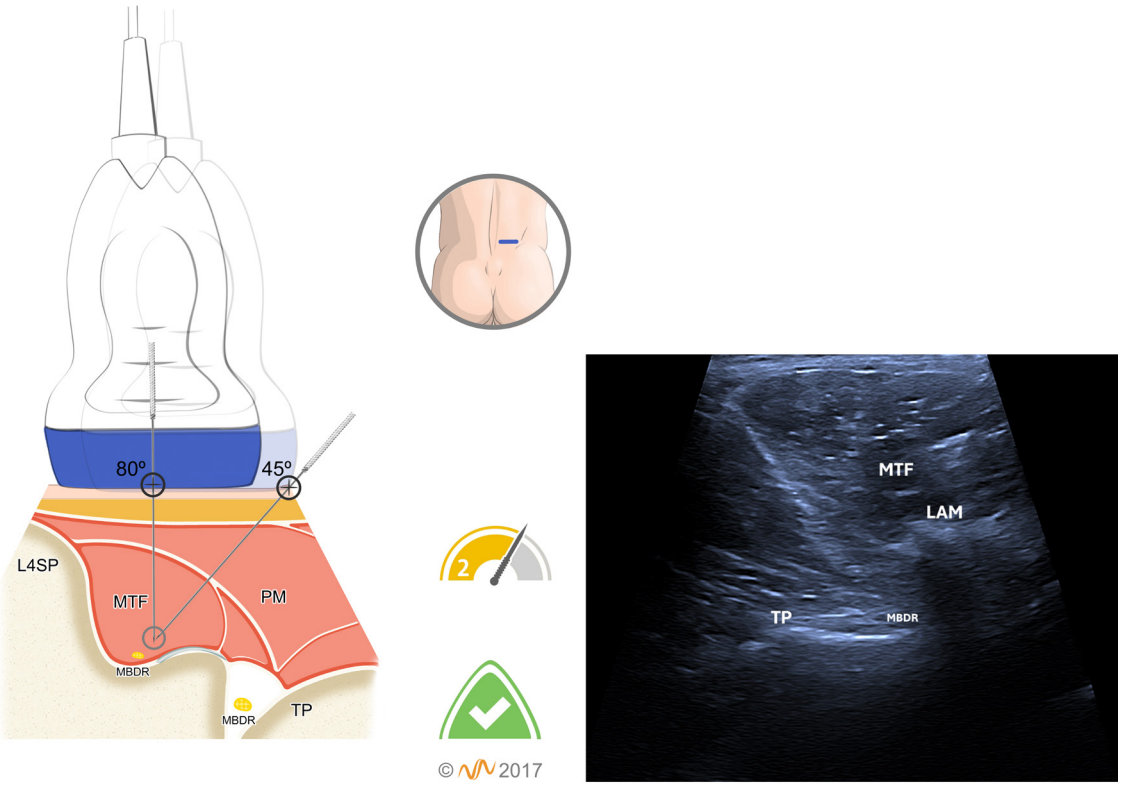

Figure 1. Approach of the medial branch of the dorsal ramus through the multifidus. LAM: Lamina; MBDR: medial branch of the dorsal ramus; MTF: multifidus muscles; PM: paraspinal muscles; TP: Transverse process.

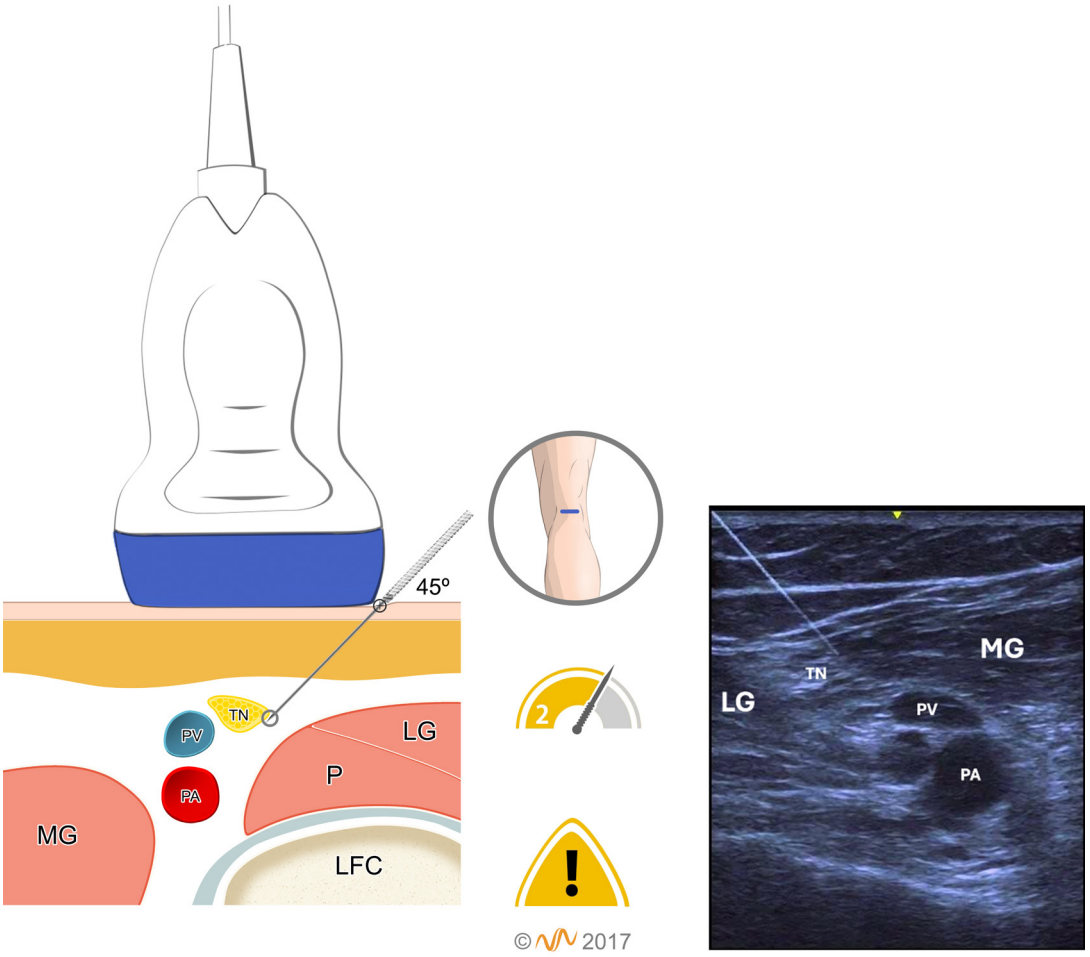

Figure 2. Approach of the tibial nerve in the popliteal region. LFC: lateral femoral epicondyle; LG: lateral gastrocnemius; MG: medial gastrocnemius; P: plantaris muscle; PA: popliteal artery; PV: popliteal vein; TN: tibial nerve.

In both areas, US-guided PNE was applied with a specific device (Physio Invasiva® 2.0, PRIM, Madrid, Spain). For the lumbar region were used needles of 0.30 x 40mm, 50mm or 60mm (Agupunt®) depending on the depth of the structure in each participant. For the popliteal region were employed needles of 0.30 x 30mm (Agupunt®) for all participants. The US-guided PNE was performed using an intensity (I) of 1.5 mA, for a time (T) of 3 seconds and 3 impacts (I) (1.5:3:3) (I:T:I), according to the protocol by Valera and Minaya[22].

Participants in the treatment group received three sessions of US-guided PNE, following a 1:7:14 periodicity[22], meaning seven days elapsed between the first and second sessions and 14 days between the second and third sessions. It is important to note that two participants did not receive the third session due to the complete resolution of pain symptoms.

2.3.2. Sham needling group

Participants in the control group were also treated in a prone position. Sham needling treatment was applied using six "Agupunt®" needles of 0.16 x 25 mm. These needles were inserted superficially in the following regions: 1) the lateral aspect of the lumbar area (L3-L4); 2) lateral gluteal region; 3) greater trochanter; 4) lateral part of the distal third of the thigh; 5) head of the fibula; and 6) and lateral aspect of the leg in its middle third. The needles were left superficially

subcutaneously for 15 minutes, performing this approach in three different sessions, again following a periodicity of 1:7:14 days.

2.4 Variables and measurement Tools

Sociodemographic data such as age, gender, time of evolution, and pathological side of each participant were obtained. In each group, the different variables were evaluated at two different times, just before the first session and four weeks after the third session. These variables were:

- Low back pain intensity. It was evaluated through the Visual Analog Scale (VAS), in which the participant describes from 0 (absolute absence of pain) to 10 (unbearable pain) the perception of pain in relation to the lumbar region and the lower limb[8,25].
- Neuropathic symptoms. This was assessed with the Doleur Neuropatique 4 questionnaire (DN4, translated as "neuropathic pain 4 questionnaire" in English), which consists of ten questions associated with the different symptoms common in neuropathic pain, scored from 0 to 10 according to which of these the patient identifies as day-to-day symptoms (confirming the presence of symptoms such as tingling in the lower limb, burning, paresthesia, hypoesthesia to touch or rubbing, etc.)[26,27]
- Muscle strength. This was evaluated in the hamstring, triceps surae, and posterior tibialis muscles using manual muscle testing (MMT). The MMT is the most widely used clinical method of muscle strength assessment. It grades muscle strength according to the ability of a muscle to act against gravity or resistance offered by an examiner. This scale scores from 0 to 5 the muscle strength of each group requested using a concentric contraction resisted by the evaluator, with “0” an absolute absence of muscle contraction (not felt) and “5” the preservation of muscle strength against resistance in the entire possible arc of movement[28]. In this study, the test was performed by placing the patient in a prone position:
    - The hamstrings muscles were evaluated from full knee extension, with the patient asked to maximally flex the knee and resist the contraction from the beginning.
    - The triceps surae muscle was assessed in the same position, but with the feet outside the stretcher, full knee extension, and the ankle in a relaxed neutral position. The patient was asked to perform maximum plantar flexion, which was resisted from the onset of muscle activation.
    - The posterior tibialis muscle was again assessed with the feet outside the stretcher and with full knee extension. On this occasion, plantar flexion with maximum foot inversion was requested.

2.5 Statistical analysis

Statistical analysis was performed with R Ver. 4.1.3. (R Foundation for Statistical Computing, Institute for Statistics and Mathematics, Welthandelsplatz 1, 1020 Vienna, Austria). The significance level was set at $p<0.05$. The qualitative variables were described in absolute values and frequencies, while quantitative variables with mean and standard deviation. The Shapiro-Wilk test was applied in each group to assess the distribution of variables. The presence of baseline differences was verified by Student's T test (after checking the assumption of homogeneity of variances with Levene's test) or with the Mann-Whitney U test for quantitative variables according to their distribution and Fisher's exact test for qualitative variables. Outcome variables were analyzed using a robust permutational analysis of covariance (ANCOVA)[29] of repeated measures with a 2x2 model with time (baseline and post-treatment) as a within-subjects factor and

group (treatment and control) as a between-subjects factor, using baseline values as a covariate to determine the effects of the treatment. The effect size was calculated with the non-parametric r statistic[30] defined as small (<0.40), moderate (0.4-0.6) and large (>0.6). In the variables with significant differences, marginal means adjusted by the baseline values in each group were calculated. The final power of the study was calculated using post-treatment VAS data adjusted for baseline values.

3. Results

Of the 31 participants recruited, 20 were ultimately included in the study. The reasons for exclusion were lumbar surgery (4 participants), poor echogenicity of the treatment areas (3 participants), belonephobia (3 participants), and pregnancy (1 participant) (Figure 3). The selected patients were randomized into two study groups: the control group (n=10, 5 men and 5 women, mean age 46.42±7.60 years) receiving sham needling, and the treatment group (n=10, 4 men and 6 women, mean age 48.82±9.47 years) receiving US-guided PNE (Figure 3). No significant baseline differences were found between the groups regarding demographic and clinical variables (Table 1).

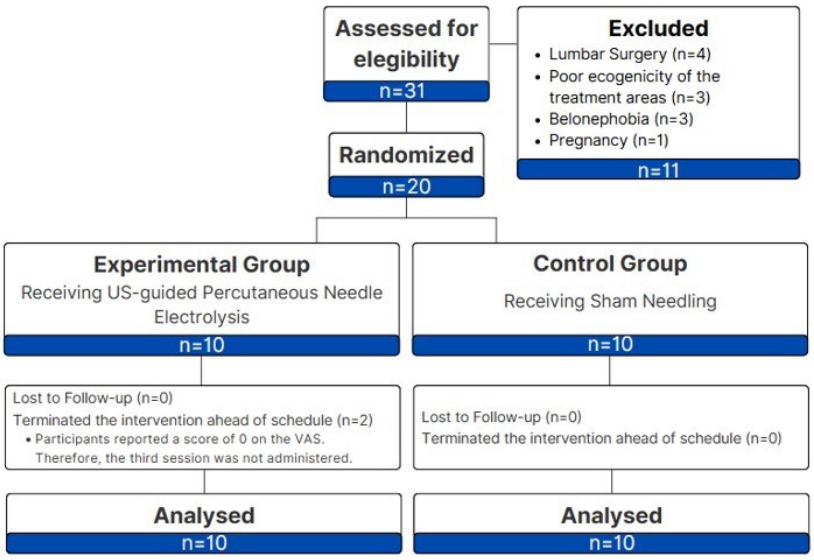

Figure 3. Participants flow diagram.

Table 1. Baseline values. Sociodemographic and study variables.

Variable	US-guided PNE	Sham Needling	Levene´s Test (P value)	P value [a]
N (male/female)	10 (4/6)	10 (5/5)		>0.999
Age (years)	48.80±9.47	48.80±9.65	>0.999	>0.999
Affected side (left/right)	7/3	6/4		>0.999
Evolution time (months)	31.30±32.08	24.30±21.76		0.820
Sessions completed	2.80±0.42	3.00±0.00		0.146
Low back pain (VAS)	7.20±1.14	6.50±1.43	0.466	0.242
Neuropathic symptoms (DN4)	5.88±1.48	5.20±1.93	0.526	0.389
Hamstrings strength (MMT)	4.22±0.64	3.75±0.44	0.407	0.069
Triceps surae strength (MMT)	3.65±0.54	4.00±0.50	0.244	0.151
Tibialis posterior strength (MMT)	3.40±0.49	3.42±0.47		0.725

Data are presented as mean and standard deviation for quantitative variables and as frequencies for qualitative variables. DN4: doleur neuropatique 4 questionnaire; MMT: manual muscle testing; PNE: percutaneous needle electrolysis; US: ultrasound; VAS: visual analogue scale; [a] Student´s T test; * Statistically significant differences (p<0.05).

3.1 Low back pain intensity (VAS)

Significant differences were found between the two groups in low back pain intensity assessed through the VAS. After treatment was applied, participants presented lower values in the mean adjusted by the baseline data in the treatment group compared to the control[0.783 95%CI(-0.095, 1.66) vs. 6.617 95%CI(5.74, 7.495)] (Table 2 and Figure 4). Based on post-treatment VAS data adjusted to baseline values, the final power of the study was 100%.

Table 2. Descriptive data and differences for all clinical variables.

Variable	Descriptive Data				Post-treatment average difference between groups (95%CI)	P value [a]	Effect size [b] (95%CI); interpretation
	US-guided PNE		Sham Needling				
	Pre-Treatment	Post-Treatment	Pre-Treatment	Post-Treatment			
Low back pain (VAS)	7.20±1.14	1.10±1.73	6.50±1.43	6.30±1.70	-5.20 (-6.81, -3.59)	F(1)=94.7 p<0.001*	0.96 (0.91,1); large
Neuropathic symptoms (DN4)	5.88±1.48	0.70±1.06	5.20±1.93	5.10±1.97	-4.40 (-5.92, -2.88)	F(1)=154.87 p<0.001*	1 (0.90,1); large
Hamstrings strength (MMT)	4.22±0.64	4.22±0.51	3.75±0.44	3.85±0.59	0.38 (-0.14, 0.89)	F(1)=0.04 p=0.847	0.43 (0.02,1); moderate
Triceps surae strength (MMT)	3.65±0.54	3.95±0.37	4.00±0.50	3.98±0.49	-0.03 (-0.44, 0.39)	F(1)=5.02 p=0.039*	0.50 (0.10,1); moderate
Tibialis posterior strength (MMT)	3.40±0.49	3.55±0.50	3.42±0.47	3.40±0.49	0.15 (-0.31, 0.61)	F(1)=4.48 p=0.049*	0.48 (0.24,1); moderate

Data are presented as mean and standard deviation. CI: confidence interval; DN4: doleur neuropatique 4 questionnaire; MMT: manual muscle testing; PNE: percutaneous needle electrolysis; US: ultrasound; VAS: visual analogue scale; [a] ANCOVA; [b] non-parametric r; * Statistically significant differences (p<0.05).

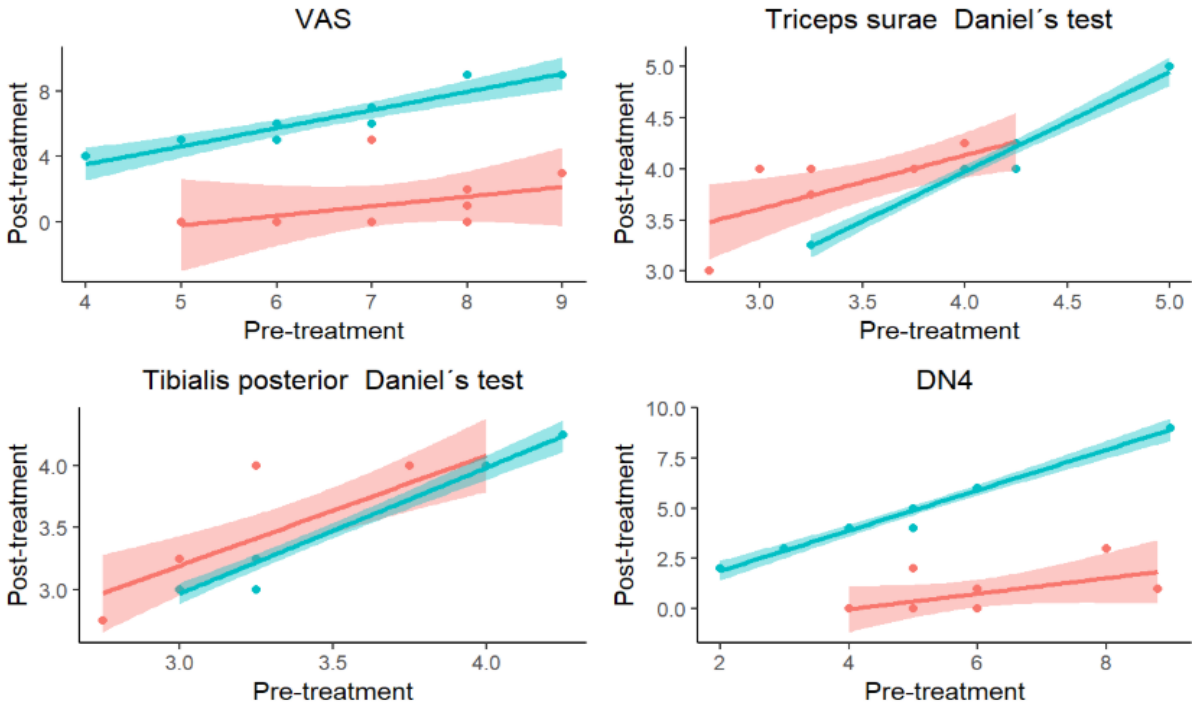

Figure 4. Scatterplots of variables with significant differences between groups. DN4: doleur neuropatique 4 questionnaire; VAS:visual analogue scale. Red refers to ultrasound-guided percutaneous needle electrolysis (US-guided PNE), while blue refers to sham needling.

3.2 Neuropathic symptoms (DN4)

Significant differences were observed between the two groups in the post-treatment scores for the DN4 questionnaire. Participants in the treatment group presented lower values in the mean adjusted by the baseline data compared to the control[0.44 95%CI(-0.149, 1.02) vs. 5.36 95%CI(4.78, 5.95)] (Table 2 and Figure 4).

3.3 Muscle strength (MMT)

Muscle strength was assessed through the MMT on different lower limb muscles. On one hand, the statistical analysis showed no significant differences between groups in the hamstrings MMT. On the other hand, significant differences were found between both groups in the triceps surae MMT and tibialis posterior MMT; after intervention, participants presented higher values in the mean adjusted by the baseline data in the treatment group compared to the control group[4.08 95%CI(3.93, 4.23) vs. 3.85 95%CI(3.70, 4.00)] and[3.56 95%CI(3.44, 3.69) vs. 3.39 95%CI(3.27, 3.51)] respectively (Table 2 and Figure 4).

4. Discussion

To date, no evidence from other studies has evaluated the effectiveness of US-guided PNE in patients with posterolateral lumbar disc herniation and tibial nerve symptoms. The primary finding of this study was the significant improvement in pain and muscle strength observed in participants who received US-guided PNE compared to those in the sham needling group.

Regarding pain reduction, our results demonstrated that the group receiving US-guided PNE experienced substantial changes in both the VAS and the DN4 questionnaire. Notably, 20% of the participants in the intervention group did not require a third session due to the complete resolution of their symptoms. This substantial analgesic effect may be attributed to applying galvanic current, which is known to stimulate the autonomic nervous system[21], thereby reducing pain associated with nerve compression from the posterolateral disc herniation. Additionally, considering the mechanisms of central and peripheral sensitization caused by disc herniations[31], the targeted treatment addressing both the affected spinal segments (L4-L5 or L5-S1) and the sensitized peripheral structure (tibial nerve at the popliteal region) likely contributed to the symptomatic improvement observed in this study.

In comparison with existing literature, Plaza et al.[32] investigated the effectiveness of combining sciatic nerve neurodynamics exercises with motor control exercises versus motor control exercises alone in individuals with lumbar herniation (L4-S1). Their findings, while significant, revealed lower baseline pain intensity in the experimental group compared to our study (5.9±1.4 vs 7.20±1.14). Despite this, our intervention achieved a greater reduction in post-treatment pain intensity (2.5±0.8 vs 1.10±1.73). These results suggest that US-guided PNE may be more effective than exercise-based interventions in reducing pain associated with lumbar disc herniations, although studies are needed to corroborate this hypothesis.

The neuropathic symptoms, often a challenging aspect of lumbar disc herniation, were also effectively addressed in our study. The existing evidence on non-pharmacological invasive interventions for neuropathic pain is limited. However, Guner & Ozcete (2023)[33] evaluated the

impact of US-guided dry needling compared to a physical exercise protocol in individuals with piriformis muscle syndrome, demonstrating a reduction in neuropathic symptoms measured by the DN4 questionnaire. Similarly, our study found that US-guided PNE significantly reduces neuropathic symptoms in patients with posterolateral lumbar disc herniation. These findings support the potential of non-pharmacological invasive interventions in managing neuropathic symptoms across different conditions, highlighting the safety and precision of these approaches when guided by US, as demonstrated by a recent study that applied invasive procedures to the posterolateral part of the intervertebral lumbar discs[34].

Muscle strength outcomes in this study revealed that US-guided PNE significantly improved the strength of the tibialis posterior and triceps surae muscles, although no significant changes were observed in hamstrings strength. This discrepancy raises questions about the effectiveness of the intervention protocol in enhancing muscle strength. One possible explanation for the lack of notable strength gains observed in our study could be related to the site of stimulation. Specifically, the proposed intervention induced mainly localized effects in the lumbar region and distal effects at the level of the tibial nerve, but the intervention did not directly target the sciatic nerve at the level of the thigh. Furthermore, evidence from previous studies[13,35] suggests that the effects observed in our study could be potentiated by combining US-guided PNE with low-frequency electrical currents. For example, Yu et al.[35] observed significant increases in lumbar extensor strength following an electroacupuncture protocol (2Hz/16Hz, 5-8 mA) in patients with lumbar disc herniation, while similarly, Álvarez-Prats et al.[13] reported substantial quadriceps strength gains following the application of percutaneous needle neuromodulation (ten 10-second stimulations at 10 Hz) targeting the femoral nerve.

In addition, one aspect of our study to consider is that participants were instructed to refrain from intense physical activity during the intervention period, which likely limited their ability to gain muscle strength. Therefore, although interventions such as US-guided PNE may be a valuable adjunct to strength training, possibly due to its role in pain modulation, which could indirectly contribute to improved muscle strength, they should not be considered a substitute.

This study has several limitations that should be acknowledged. Firstly, the comparison of US-guided PNE was conducted solely against a sham control group. This approach may not fully capture the relative efficacy of the treatment, as it does not allow for a direct comparison with other therapeutic modalities. Additionally, although the statistical power of the study was calculated post hoc and yielded robust results, these results should be interpreted with caution, as the sample size was not calculated a priori. Importantly, this study did not systematically collect data on participants' medical history or use of medications that could influence the outcomes, such as diabetes mellitus or pregabalin, both of which are known to affect neuropathic pain. Another limitation pertains to the timing of the data collection. Evaluations were performed four weeks following the final treatment session rather than immediately afterward. This temporal gap limits our ability to ascertain when the observed improvements occurred. It remains unclear whether these improvements were immediate and subsequently diminished over time or if a latency period was required for significant differences between the treatments to manifest. Moreover, the short follow-up period limits the study´s ability to assess the long-term effects and durability of the treatment. Lastly, MMT as the primary method for assessing muscle strength rather than using a more accurate and objective tool such as dynamometry is

also a constraint, in addition to the fact that muscle strength assessment with MMT is based on joint movements that involve the coordinated action of multiple muscles.

To address these limitations and provide a more comprehensive evaluation of US-guided PNE as a therapeutic option for patients with posterolateral lumbar disc herniation and associated tibial nerve symptoms, future research should incorporate several key elements. Comparative studies should include not only sham controls but also other forms of electrical stimulation, as well as established treatments like pharmacological, surgical, and physiotherapy interventions, including physical exercise and neurodynamic mobilization. Such studies would offer a clearer understanding of the relative efficacy of US-guided PNE in this condition. Additionally, future research should explore whether directly stimulating the sciatic nerve at the thigh level or combining US-guided PNE with low-frequency electrical currents represents a more effective approach to enhancing muscle strength in individuals with posterolateral lumbar disc herniation. Evaluations should be conducted immediately after each treatment session to track the progression of therapeutic effects better. This approach would help determine the optimal number of sessions required to activate maximum benefit, thus optimizing the intervention protocol. Larger, multicenter trials involving diverse populations are necessary to validate the findings and enhance their generalizability. Furthermore, extended follow-up periods should be included in future research to evaluate the long-term sustainability of the therapeutic benefits observed in this study.

5. Conclusions

US-guided PNE of the tibial nerve and multifidus muscles has emerged as an effective intervention for reducing pain intensity and neuropathic symptoms in individuals with L4-L5-S1 posterolateral disc herniations. This technique also enhances muscle strength, particularly in the triceps surae and posterior tibialis muscles. As a minimally invasive procedure, it offers a potential alternative to more invasive treatments. However, further research is warranted to confirm these results, identify the most effective methodology for US-guided PNE application in this condition, and assess the long-term outcomes and broader applicability of this technique.

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