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High- and Low-Frequency TENS with Paravertebral Ozone Therapy for Chronic Low Back Pain and Radiculopathy: A Pilot Study

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Abstract

Background: Chronic low back pain (CLBP) with radiculopathy is a leading cause of disability worldwide. Conventional treatments generally have limited efficacy, high costs, and associated adverse effects.

Objective: To evaluate the efficacy and safety of high-and low-frequency TENS (HLF-TENS) with paravertebral ozone therapy (POT)in chronic low back pain (CLBP) and radiculopathy.

Methods: This non-randomized pilot study was conducted with 88 consecutive patients meeting the inclusion criteria. Participants underwent 12 sessions of combined HLF-TENS and POT, without a control group. Pain intensity, neuropathic symptoms, and disability were assessed using the Numeric Rating Scale (NRS); the modified Michigan Neuropathy Screening Instrument (MNSI), and the modified Oswestry Disability Index (ODI), respectively. Assessments were performed at baseline, midpoint, and post-treatment, with long-term follow-up (1–2 years) via telephone interviews.

Results: The study included 35 men (40%) and 53 women (60%), mean age of 51.3 years (range 20–80). Post-treatment, 80% of participants showed statistically significant improvements in pain, neuropathic symptoms, and disability. Pain NRS scores decreased from 8.58 to 1.64, neuropathic symptom scores from 7.34 to 1.14, and ODI scores from 8.05 to 2.12 ($p< 0.001$). At long-term follow-up (1–2 years), 80% of respondents remained asymptomatic, with no adverse effects reported.

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Conclusions: The combination of HLF-TENS and POT significantly reduced pain, neuropathic symptoms, and disability in CLBP patients with radiculopathy. These findings suggest a promising, non-invasive treatment option; however, randomized controlled trials are necessary to confirm efficacy.

Keywords: High-and low-frequencystimulation, Transcutaneous electrical nerve stimulation, Paravertebral Ozone Therapy, Chronic low back pain, Radiculopathy.

1. Introduction

Low back pain is one of the leading causes of disability, affecting approximately 9.4% of the global population (1-2). CLBP with radiculopathy represents a significant public and occupational health challenge, imposing major professional, economic, and social burdens (3). A 2006 review estimated that the total annual cost of LBP in the United States exceeded $100 billion (4).Patients with LBP experience moderate to severe pain, physical limitations, and a substantial decline in their quality of life, which have significant consequences, including financial and social repercussions (5).

CLBP, defined as pain persisting for at least 12 weeks, is a multifactorial condition involving mechanical, inflammatory, compressive, immunological, and degenerative processes (6). Radiculopathy, a common comorbidity in this condition, results from neural compression associated with inflammatory processes, which causes sensory deficits and motor dysfunctions (7).

This study investigates a novel therapeutic approach by combining HLF-TENS and POT targeting the lumbar region and sciatic nerve with the primary objective of alleviate symptoms while assessing the potential for reverse the condition.

2. Hypothesis

The combined treatment with HLF-TENS and POT will significantly reduce pain intensity, neuropathic symptoms, and disability in patients with CLBP and radiculopathy, reversing the causes of the condition as much as possible, with minimal adverse effects.

3. General Objective

- To evaluate the efficacy and safety of HLF-TENS wit POT in patients with CLBP and radiculopathy.

3.1 Specific Objectives

- Quantify pain, neuropathic symptoms, and disability using the Numerical Rating Scale (NRS) (8).
- Assess improvements in pain,neuropathic symptoms using the modified Michigan Neuropathy Screening Instrument (MNSI) (9).
- Measure changes in disability using the modified Oswestry Disability Index (ODI) (10).
- Determine the long-term effectiveness (1–2 years) of the treatment protocol.

4. Justification:

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This clinical trial introduces a novel, non-invasive, and cost-effective treatment alternative for CLBP with radiculopathy, utilizing the combined application of HLF-TENS and POT. This dual approach directly targets the affected lumbar disc(s) and sciatic nerve, addressing both symptoms and underlying causes. While various therapies have been used individually for this condition, their combined use remains largely unexplored (16-17-18-19-26-29-30). If successful, this strategy could provide significant benefits to patients and healthcare systems by improving outcomes and reducing associated costs.

Advancements in the understanding of CLBP with radiculopathy have evolved considerably since Mixter and Barr's 1934 landmark publication, which linked the condition to neural compression resulting from intervertebral disc degeneration (IDD)(11). Contemporary research acknowledges CLBP with radiculopathy as a complex, multifactorial disorder involving mechanical, inflammatory, compressive, immunological, and degenerative processes (12).

The intervertebral disc (IVD), the largest avascular organ in the human body, plays a crucial role in spinal function. Its specialized structure protects the nucleus pulposus (NP) from the host's immune system, making the IVD an immune-privileged organ. Maintaining this immune privilege is essential for IVD homeostasis and is facilitated by the blood-NP barrier (BNB), a robust protective system that prevents immune responses to NP antigens. However, when the BNB is disrupted due to trauma, degeneration, or other factors, NP antigens become exposed to the immune system, triggering autoimmune responses that exacerbate intervertebral disc degeneration (IDD), a condition associated with pain and disability (13).

IDD is driven by the abnormal secretion of proinflammatory molecules from NP and anulus fibrosus (AF) cells, further compounded by the involvement of immune cells such as macrophages, T cells, and neutrophils. These cytokines initiate a cascade of pathological responses within disc cells, resulting in autophagy, senescence, and apoptosis, manifesting clinically as varying degrees of pain (14).

Radiculopathy arises from the mechanical compression of nerve roots caused by IDD and is further exacerbated by inflammatory and immunological interactions.This complex pathology manifests clinically as neuropathic symptoms: burning, numbness, tingling, among others (15). In turn, damage to the axons or nerve roots results in nerve root dysfunction, leading to both sensory and motor abnormalities (16).

We believe that treatment strategies should address the underlying pathophysiological mechanisms of the condition, focusing on restoring the immune privilege of the IVD disc and relieving root compression to the extent possible.

5. Proposed Treatment Protocol

Considering the multifactorial pathophysiology of CLBP with radiculopathy, we propose a treatment protocol combining two complementary therapies to address both symptoms and underlying causes at the intervertebral disc(s) and sciatic nerve levels:

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1. HLF-TENS. This non-invasive technique applies electrical impulses to stimulate the affected peripheral nerves recovery as it enhances nerve- motor and sensory functions while decreasing disability (17).
2. POT. Aims to reduce oxidative stress, suppress proinflammatory cytokine levels, and facilitate contraction and reabsorption of herniated disc material (18-19).

This treatment protocol presents a novel and cost-effective alternative to conventional treatments by integrating two complementary therapies. To our knowledge, no previous study has explored the combined application of HLF-TENS and POT for the treatment of CLBP and radiculopathy. Our hypothesis suggests that this dual therapy, designed to address the pathophysiological changes of the disease, offers an innovative noninvasive therapeutic strategy.

6. Methods

6.1 Study Design and Participants

This prospective, single-center, nonrandomized pilot study was conducted between August 2018 and July 2020 at the Neuropathy and Disc Herniation Clinic in Durango, Mexico. A total of 88 consecutive patients diagnosed with chronic low back pain (CLBP) with radiculopathy (pain intensity ≥6 on the Numeric Rating Scale [NRS]) were included. These patients had not responded to prior conservative or surgical treatments. Exclusion criteria consisted of the presence of a pacemaker, mechanical instability, vertebral fractures, or malignant vertebral lesions confirmed through imaging studies.

6.2 Intervention

Each participant underwent 12 treatment sessions over four weeks (three sessions per week), incorporating the following therapies:

- HLF-TENS. Administered using the Neurogenx 4000 Pro device (Synaptic Corp., Aurora, Colorado, USA). FDA-approved for pain control, utilizing high and low frequencies with a modified variable A waveform and wide sweep frequency (40,000 to 400 Hz). Peak current per pulse: 57 milliamps. Session duration: 20 minutes.
- POT. Injection of 10 mL of an oxygen-ozone mixture (27 µg/mL) into the affected area using a 23-gauge needle. Administered with the Ozone Generation MED-80 equipment, utilizing Corona Effect/Silent Discharge technology. Ozone concentration range: 0–80 µg/mL (gammas, mg/L, g/m³). Equipment provider: OZONO CARBAR'S, Mexic

6.3 Outcome Measures

- Pain Intensity, Neuropathic Symptoms, and Disability assessed using the Numeric Rating Scale (NRS).

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- Neuropathic symptoms: Evaluated using the modified Michigan Neuropathy Screening Instrument (MNSI).
- Disability levels: Measured with the modified Oswestry Disability Index (ODI).
- Assessment timeline: Conducted at baseline, midpoint, post-treatment, and long-term follow-up (1–2 years).

6.4 Patient Assessment

Participants underwent a clinical examination and completed standardized questionnaires at three critical time points: pre-treatment, mid-treatment, and post-treatment. Additionally, long-term follow-up assessments (1–2 years post-treatment) were conducted via telephone interviews by the research director to evaluate sustained treatment effects.

6.5 Assessment Domains

Neuropathic Symptoms were assessed using a modified version of the Michigan Neuropathy Screening Instrument (MNSI), examining the following key symptoms:

- Numbness
- Burning sensations
- Muscle cramps
- Stabbing pain
- Discomfort from feet rubbing against sheets

Additionally, five supplementary questions evaluated

- Pain severity
- Tingling sensations
- The sensation of feet dragging while walking
- Balance difficulties
- The feeling of walking on uneven surfaces

Disability Assessment was measured using the modified Oswestry Disability Index (ODI), evaluating limitations in:

- Walking
- Sleeping
- Sitting or standing
- Dressing or bathing

Additional activities assessed:

- Climbing stairs

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- Performing daily tasks
- Work-related function

Pain Severity and Neuropathic Symptoms were quantified using the Numeric Rating Scale (NRS), ranging from 0 (no symptoms) to 10 (most severe). Disability scores reflected functional impairment, with higher scores indicating greater disability.

6.7 Treatment Protocol

The treatment involved the simultaneous application of two complementary therapies over 12 sessions, administered three times per week to target pain relief, neuropathic symptom reduction, and neural recovery.

1. HLF-TENS was applied to the lumbar region and along the sciatic nerve pathway to alleviate pain, reduce neuropathic symptoms, and promote recovery of affected neural structures.

Electrode Placement:

- One electrode positioned on the skin at the affected lumbar disc level.
- Three electrodes placed along the posterior midline, tracing the sciatic nerve pathway from the thigh to the calf and sole.
- For patients with bilateral low back pain and radiculopathy, electrodes were placed on both extremities using the same method.
- Session duration: 20 minutes.

2. POT was administered to the affected lumbar region to dehydrate and induce contraction of the intervertebral disc, thereby reducing radicular compression and suppressing the production of inflammatory molecules associated with IDD.

6.8 Procedure:

- Patient positioned prone, with the upper edge of the iliac crest palpated for anatomical reference.
- L4 level identified via an imaginary horizontal line drawn between the iliac crests.
- Asepsis performed using povidone-iodine.
- 10 mL of an oxygen-ozone mixture (27 µg/mL concentration) was slowly injected into the paravertebral lumbar muscles on each side.

Injection Details:

- 23G x 60 mm needle (or 80 mm, depending on patient's subcutaneous fat thickness) used for injection.

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7. Data Analysis and Sample Size Considerations

Data were analyzed using SPSS version 17.0, with normality tested before applying appropriate descriptive and inferential statistical methods, including: Student's t-test ANOVA with Bonferroni correction Chi-square test. Although this pilot study did not include a formal sample size calculation, feasibility and preliminary outcome trends justified the sample size. Future studies should incorporate power calculations to optimize statistical reliability. Additionally, stratification by sex and multivariate analyses were considered to control for potential confounders.

7.1 Ethical Considerations

The study was approved by the Research and Bioethics Committee of the Scientific Research Institute Dr. Roberto Rivera Damm, Juarez University of the State of Durango. It complies with the General Health Law on Research. Informed consent was obtained from all participants, with the consent form outlining: Study objectives and procedures, potential risks, including minor injection discomfort; expected benefits, data confidentiality protocols. Participants' right to withdraw at any time without penalty, and arrangements for any additional medical expenses.

8. Results

A total of 88 patients participated in the study, comprising 35 males (40%) and 53 females (60%). The mean age was 51.3 years (range: 20–80 years). The largest age group consisted of 68 patients (77%) aged 52 years or older, including 26 men (40%) and 42 women (60%) (Fig. 1).

8.1 Improvements Observed

Significant improvements were recorded in pain, neuropathic symptoms, and disability:

- **Pain**: Mean Numerical Rating Scale (NRS) scores decreased from 8.58 to 1.64 ($p< 0.001$).
- **Neuropathic Symptoms**: Mean scores decreased from 7.34 to 1.14 ($p< 0.001$) (Fig. 2).
- **Disability**: Mean scores decreased from 8.05 to 2.12 ($p< 0.001$) (Fig. 3).

8.2 Duration of Symptoms

The average symptom duration was:

- 4.8 years for patients who achieved significant benefits.
- 7.5 years for patients who did not achieve significant improvements.

8.3 Long-term Outcomes

To evaluate long-term outcomes, patients were contacted by telephone 1–2 years after treatment (Fig. 4). Of the 60 patients successfully contacted (68.1% of the cohort):

- 80% remained asymptomatic.

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- 20% experienced symptom recurrence, with 3 reporting milder symptoms and 9 experiencing symptoms comparable to baseline.

No adverse effects were reported during or after treatment

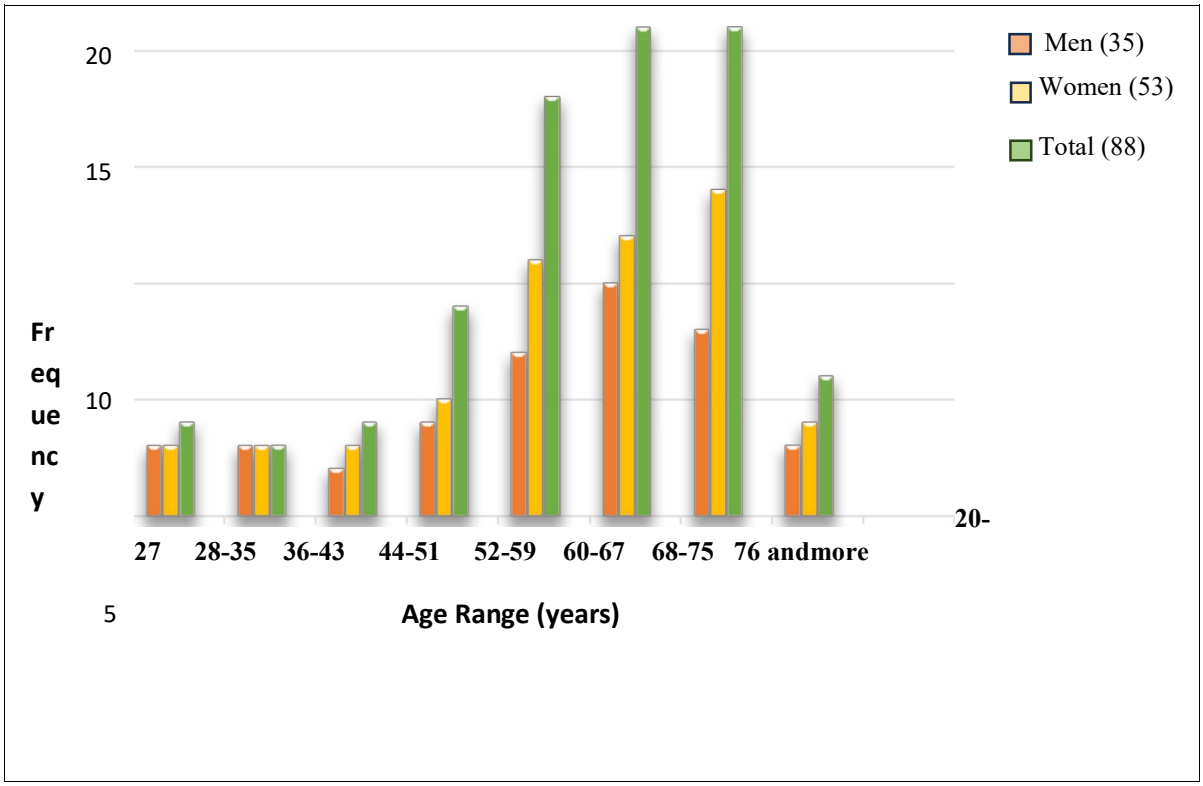

Figure 1: Frequency groups by age and sex (N=88)

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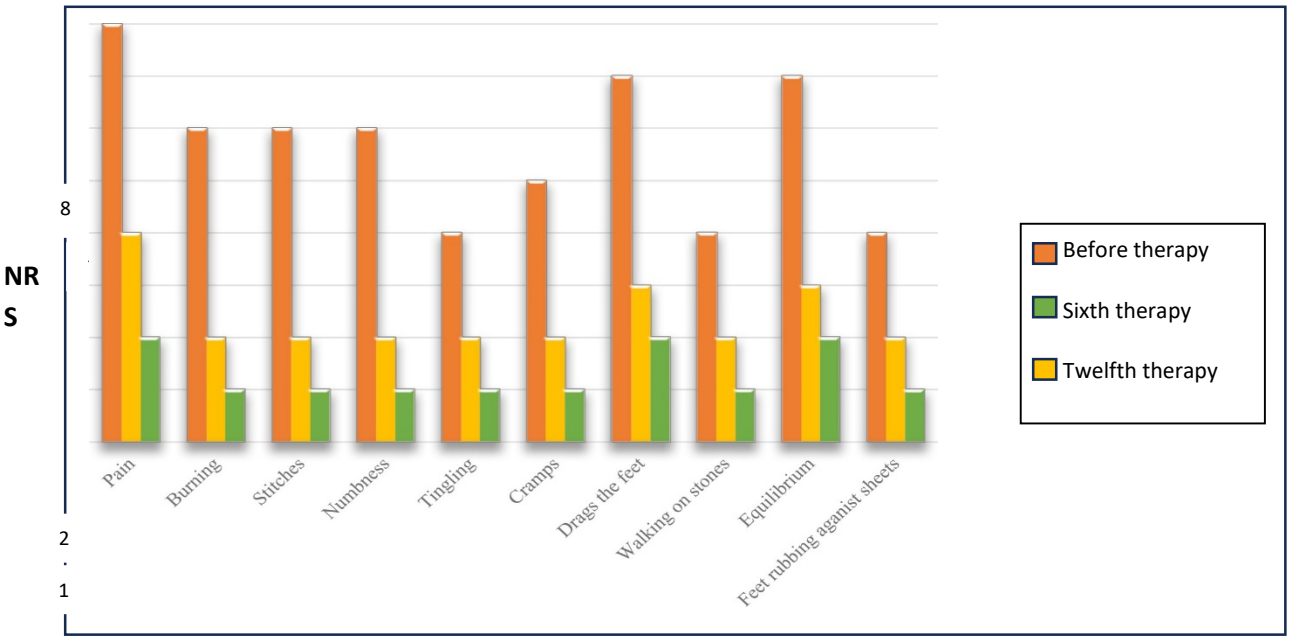
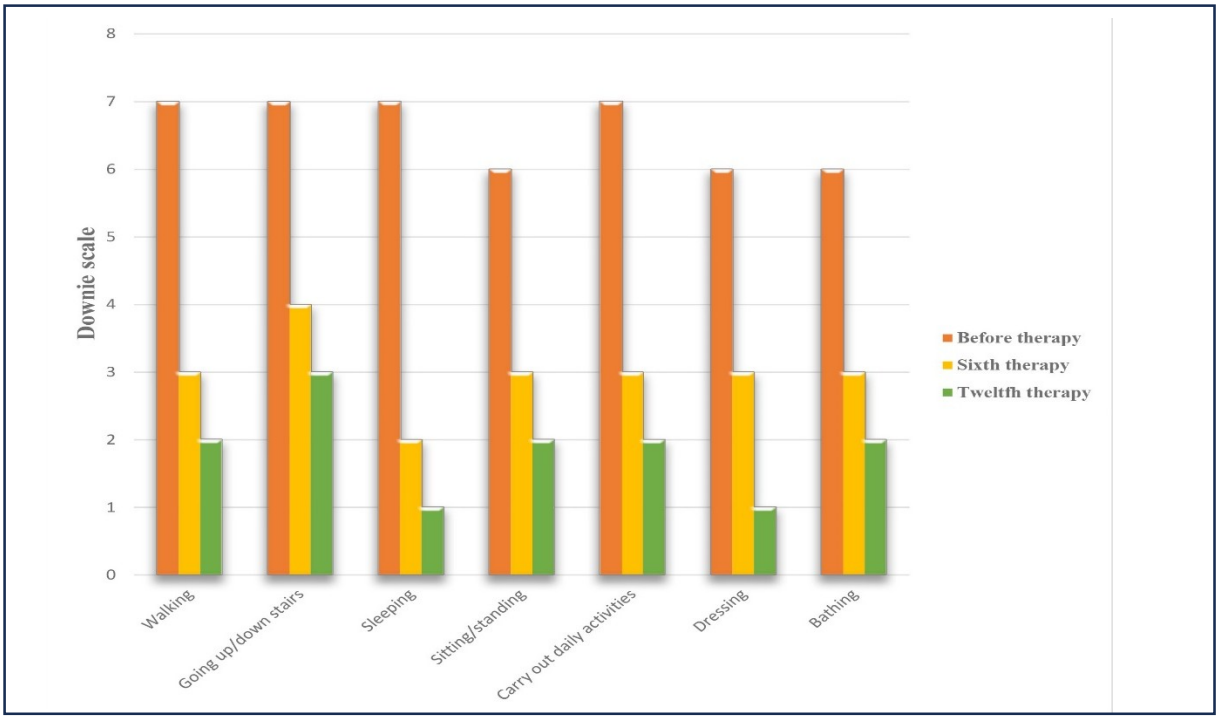


Figure 2: Pain and neuropathic symptoms intensity using Numeric Rating Scale (NRS)



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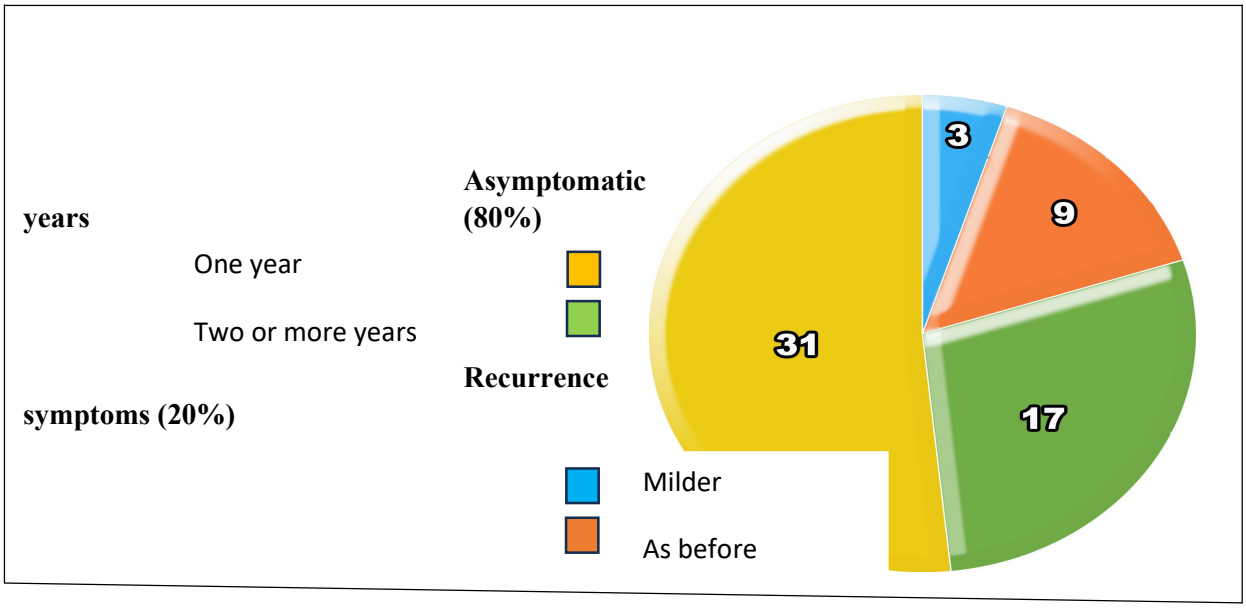

Figure 4: Long-term outcomes (N=60)

9. Discussion

CLBP with radiculopathy is a multifactorial condition, involving mechanical, inflammatory, compressive, immunological, and degenerative processes that primarily affect the IVDand sciatic nerve. Despite advancements in pain management, effective treatment remains challenging, as many current interventions provide only partial relief, carry risks, or lead to adverse effects.

The results of this pilot study suggest that combining HLF-TENS with POT may be an effective approach for managing CLBP with radiculopathy. Patients experienced significant reductions in pain, neuropathic symptoms, and disability, with sustained improvements observed in long-term follow-up assessments.

While conventional treatments for CLBP with radiculopathy, such as physical therapy, medication, and surgical intervention, often provide partial or temporary relief, they are associated with high costs, potential complications, and inconsistent outcomes. In contrast, the HLF-TENS and POT approach presents a non-invasive, cost-effective alternative that appears to address both symptoms and underlying pathophysiological mechanisms.

Previous research has explored the individual efficacy of HLF-TENS and POT in pain management and neural recovery (15, 16, 17, 18, 25, 28, 29). However, this study is among the first to examine their combined therapeutic effect, supporting the hypothesis that dual therapy may enhance overall treatment efficacy.

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Conventional medical treatment, which uses nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol, muscle relaxants, and even opioids for short periods, only provides temporary symptomatic relief without addressing the underlying causes of the condition (20).

Additionally, anticonvulsants such as gabapentin and pregabalin, though widely prescribed, have demonstrated limited therapeutic efficacy and increased risks of adverse effects. A systematic review by Enke et al. supports this, concluding that anticonvulsants are largely ineffective for low back and radicular pain and pose considerable safety concerns (21).When conservative treatments fail, surgical intervention is often considered. However, surgical approaches present significant challenges and limitations, particularly in achieving consistent, long-term success. Failed Back Surgery Syndrome (FBSS) first identified by Follett and Dirks in 1993 (22), highlights the difficulty of achieving predictable and lasting relief through surgical intervention. FBSS affects approximately 20% of spinal surgery cases, with some studies reporting rates as high as 40%. A systematic review of lumbar discectomies in patients under 70 years of age found that 5–36% experienced recurrent back or leg pain within two years post-surgery (23).

Patients diagnosed with FBSS often require additional spinal surgeries to manage persistent pain or complications. However, these follow-up procedures frequently yield disappointing outcomes. Instrumented spinal fusion, commonly recommended for FBSS management, has shown limited efficacy. Arts et al. reported satisfactory results in only 35% of cases, while 65% led to suboptimal outcomes (24).

On the other hand, the economic impact of spinal surgery is considerable. A study by the Mexican Social Security Institute (IMSS) reported that preoperative and postoperative disability of workers undergoing spinal surgery reached 212 days, a situation that significantly affects their work capacity. Furthermore, two years after surgery, only 37% of them had returned to active employment, highlighting the long-term economic consequences. The study concluded that spinal surgery does not guarantee return to work (25).

Spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS) are FDA-approved therapeutic approaches that have demonstrated significant efficacy in alleviating chronic pain. SCS delivers electrical currents to spinal tissues, modulating pain perception and has been successfully utilized for over three decades to manage moderate-to-severe pain in the trunk and limbs, significantly enhancing patients' quality of life. Similarly, PNS targets neuropathic pain caused by peripheral nerve dysfunction, providing an effective alternative for pain management (26).

Among TENS and PNS are increasingly recognized as promising non-invasive options for pain relief. Notably, high-frequency electrical stimulation (HFES) has shown potential in regulating neuroinflammatory mediators, offering substantial relief from chronic pain (27). The Neurogenx 4000 Pro device, employed in this study, integrates high- and low-frequency stimulation in a non-invasive manner, effectively mitigating risks associated with invasive procedures, such as lead migration or infection (28). This technological advancement further supports the growing recognition of electrical stimulation as an effective non-invasive strategy for neuropathic and chronic pain management.

Ozone therapy represents an innovative strategy for addressing both the inflammatory and degenerative aspects of intervertebral disc degeneration (IDD). Through its ability to induce lipid peroxidation and

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proteoglycan degradation, ozone therapy facilitates the contraction and reabsorption of herniated disc material, effectively reducing radicular compression and inflammation (29). Grangeat AM and Erario MLA (30) identified medical ozone as a promising treatment for intervertebral disc pathologies. Unlike conventional therapies that primarily target symptom relief, ozone therapy operates at an etiological level, stimulating the immune system to absorb the herniated nucleus pulposus and resolve disc extrusion. Furthermore, their study suggests that ozone may function as an epigenetic regulator, addressing the root causes of IDD while simultaneously promoting the repair of intervertebral spaces. This dual mechanism supports ozone therapy's potential role in neuroinflammatory modulation and disc regeneration, highlighting its therapeutic value as a non-invasive alternative in spinal care.

This study aligns with the recommendations of The Lancet Low Back Pain Series Working Group (31–33), which emphasizes the importance of cost-effective, evidence-based interventions to address the global burden of LBP. By advocating for a non-invasive, outpatient-based approach, this research offers a promising alternative to conventional treatments, effectively reducing pain, neuropathic symptoms, and disability while minimizing adverse effects. This strategy ultimately supports better patient outcomes and enhanced quality of life.

The combination ofHLF-TENS and POT introduces a novel, multidimensional approach targeting both structural and neurological contributors to CLBPwith radiculopathy. HLF-TENS modulates neurochemical signaling, promoting neuropathic symptom relief and enhancing nerve recovery while POT reduces inflammatory activity, suppresses oxidative stress, and stimulates tissue repair, directly addressing underlying disease mechanisms. This integrated approach presents an effective, non-invasive alternative to conventional therapies, combining neuromodulation and anti-inflammatory effects to enhance long-term clinical outcomes.

10. Conclusion

This combined therapy may represent a promising, non-invasive treatment option. However, study limitations including the absence of a control group and potential selection bias underscore the need for further research. To establish a solid evidence base for clinical application, future randomized controlled trials (RCTs) are essential to validate these promising findings.

Conflicts of Interest

The authors declare no conflict of interest

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