



EFFECTS OF OZONE THERAPY ON PAIN RELIEF IN PATIENTS WITH LOW BACK PAIN: CASE SERIES.

Rafael Pires Figueiredo¹, Letícia Faria Vilela¹, Hagner Guilherme Ribeiro dos Prazeres¹, Lais Fernandes Domingues¹, Felipe dos Santos Lourenço¹, Verônica Cristina da Silveira¹, Ana Paula Anzolin², Adriana Antônia da Cruz Furini¹.



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RESUMO

A ozonioterapia é reportada como terapia integrativa complementar que consiste em uma técnica que utiliza uma mistura constituída por gás ozônio (O³) na concentração de até 5% e o gás oxigênio medicinal (O²) na concentração até 95%. Por se tratar de um método minimamente invasivo e com raros casos de complicação, se torna uma alternativa viável, como complementar e integrativa em diversas condições, tais como aumento de imunidade, processos inflamatórios, alterações metabólicas e em processos dolorosos, particularmente em dor ciática, o que acarreta na liberação de endorfinas, mecanismo analgésicos e diminuição das liberações de prostaglandinas. O objetivo desse estudo foi de avaliar os efeitos causados pela ozonioterapia em dez pacientes com dor em nervo ciático devido a hérnia lombar, denominada lombocitalgia. O estudo foi do tipo prospectivo, com dez indivíduos com dor em nervo ciático. O projeto foi aprovado pelo Comitê de Ética em Pesquisa do Centro Universitário de Rio Preto com número do parecer: 5.543.403. A técnica foi utilizada como complementar aos tratamentos que os pacientes fazem uso. A pesquisa foi composta de dados clínicos, diagnósticos médicos, resultados de exames laboratoriais, estudo do uso de medicamentos, uso da ozonioterapia por via subcutânea e retal.

Palavras-chave: Ozônio. Ozonioterapia. Dor.

ABSTRACT

Ozone therapy is an integrative, complementary modality that employs a gas mixture composed of ozone at concentrations of up to 5 % and medical-grade oxygen (O₂) at up to 95 %. Because it is minimally invasive and associated with only rare complications, it represents a viable adjunct for several clinical situations, including immunomodulation, inflammatory disorders, metabolic dysfunctions and pain syndromes, particularly sciatica, by triggering endorphin release, activating analgesic pathways and reducing prostaglandin synthesis.

This study aimed to evaluate the effects of ozone therapy in nine patients with sciatic nerve pain caused by lumbar disc herniation (lumbosciatica). We conducted a prospective study enrolling nine individuals with sciatica. The protocol was approved by the Research Ethics Committee of Centro Universitário de Rio Preto (approval no. 5.543.403). Ozone therapy, administered subcutaneously and rectally, was used as an adjunct to each participant's standard treatment. Data collection included clinical characteristics, medical diagnoses, laboratory test results and concomitant medication use.

Keywords: Ozone; Ozone therapy; Pain; Low Back.

Instituição afiliada – ¹Centro Universitário de Rio Preto; ²Philozon

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INTRODUÇÃO

Back pain is widely recognized as the leading cause of disability, workplace absenteeism, and demand for health-care services on a global scale. Although a range of conservative treatment strategies has been developed, the condition's rising prevalence underscores the need for new therapeutic approaches (Latini *et al.*, 2024).

The vertebral column comprises 33 vertebrae, 7 cervical, 12 thoracic, 5 lumbar, 5 fused sacral, and 3 to 5 fused coccygeal segments. This structure plays a fundamental role in supporting the body: it bears the head, neck, thorax, abdomen, and pelvis, and provides mobility and flexibility through the intervertebral discs and facet joints. It also performs an essential protective function for the spinal cord and the spinal nerves that course through the vertebral canal (Andrade *et al.*, 2019).

One of the principal etiologies impairing the sciatic nerve is intervertebral disc herniation. Under physiological conditions, the annulus fibrosus (AF) contains the nucleus pulposus (NP), which expands to absorb impacts. Herniation occurs when the NP is displaced or bulges, altering its anatomical configuration and potentially rupturing the AF. The nucleus may then extrude posteriorly or posterolaterally, compressing the spinal cord and adjacent nerves (KOS, N. *et al.*; 2019). The clinical manifestations of disc herniation arise from nerve-root compression and the local inflammatory response (COSAMOLÓN-GAN, I. *et al.*; 2021).

Disc herniation is most frequent in the third and fourth decades of life, when degenerative changes develop in the intervertebral discs. Reduced proteoglycan and water content leads to dehydration, increased fibrous tissue, and loss of resilience. Excessive mechanical loading, traumatic injury, genetic predisposition, and inadequate nutritional supply also compromise disc integrity (KOS, N. *et al.*; 2019). Standard management includes medication, physiotherapy, and other procedures. Recently, ozone therapy has been reported as an integrative, complementary treatment for painful conditions, characterized by ozone application to the affected area, triggering endorphin release, activating analgesic pathways, and reducing prostaglandin release (KOS, N. *et al.*; 2019).

Ozone, a triatomic molecule of Oxygen, has been used medically since the early



twentieth century (Int J MOL SCI. 2023). Clinically, low-concentration oxygen–ozone gas mixtures serve multiple therapeutic purposes. Ozone reacts with organic compounds containing double bonds to form ozonides (Int J MOL SCI. 2023). In contact with human fluids and tissues, it reacts with polyunsaturated fatty acids to produce hydrogen peroxide (H₂O₂) and a variety of lipid ozonation products (LOPs), such as 4-HNE and 4-HHE. H₂O₂ acts as a short-lived reactive oxygen species (ROS) that functions as a cellular messenger (Int J MOL SCI. 2023). In extruded disc herniation, exposure of the NP to the immune system triggers an antigen–antibody reaction, initiating an inflammatory cascade aimed at resorbing the herniated fragment—a slow and painful process. Therapeutic ozone doses activate Nrf2-mediated antioxidant signaling, attenuate NF-κB activation (a key inflammatory regulator), and consequently reduce pain. Ozone also stimulates macrophage phagocytosis of the herniated fragment, promoting complete resorption, preserving a vitalized nucleus pulposus, and improving scar formation (Int J MOL SCI. 2023).

Oxygen–ozone therapy is considered an alternative modality because of its analgesic and anti-inflammatory effects. A retrospective study of 76 patients with chronic cervical or lumbar pain evaluated intramuscular paravertebral oxygen–ozone injections and documented pain reduction, decreased disability, improved quality of life, and lower analgesic consumption (Latini *et al.*, 2024). Improvement in sexual impairment was also reported following percutaneous intradiscal ozone therapy in patients with low-back pain from lumbar disc herniation, with faster recovery observed in older patients and in L3–L4 involvement (Somma *et al.*, 2023). Although minimally invasive oxygen–ozone therapy is commonly employed for musculoskeletal pain, most available studies focus on the lumbosacral region. One investigation described paravertebral intradiscal or intramuscular administration of an oxygen–ozone mixture in patients with myofascial pain syndrome, cervical disc herniations, and chronic cervical pain, showing significant pain reduction and functional improvement (Jandura *et al.*, 2024). However, evidence regarding its effectiveness in other spinal regions remains scarce, justifying further research.

Accordingly, the present study aims to evaluate the effects of ozone therapy (subcutaneous and rectal) on pain and disability in patients with lumbosciatalgia, to assess improvements in quality of life, and to determine reductions in analgesic



requirements. The study further seeks to investigate ozone therapy's efficacy for lumbosciatalgia, thereby contributing to the development of more effective and less invasive interventions for spinal pain.

METODOLOGIA

This prospective study enrolled nine individuals with sciatic and low-back pain who were treated between 20 March 2022 and 3 July 2022. The project was approved by the Research Ethics Committee of *Centro Universitário de Rio Preto* (approval no. 5.543.403). All procedures were performed free of charge in specialised outpatient clinics by professionals certified in ozone therapy.

A partnership with Philozon provided the Philozon Medplus MX ozone generator for all interventions. In addition to the therapeutic procedure, a comprehensive questionnaire captured clinical, therapeutic, and laboratory data, which were complemented by imaging findings and clinical diagnoses. As a safety measure, *glucose-6-phosphate dehydrogenase* (G6PD) activity was tested beforehand because G6PD deficiency is a contraindication to ozone therapy.

2.1 Participants

Nine adult patients with a confirmed diagnosis of sciatic pain were included, provided that G6PD testing revealed no contraindication. Inclusion criteria comprised documented lumbar disc herniation and persistent sciatica. Exclusion criteria were conditions that contraindicate ozone use—such as G6PD deficiency, active infection, and pregnancy.

2.2 Procedures

After written informed consent, participants underwent an initial assessment that included the aforementioned questionnaires and clinical-laboratory evaluation. Ozone therapy was delivered with the Philozon Medplus MX generator according to the protocol below. Each treatment session involved direct administration of an oxygen–ozone gas mixture to the affected region, following a standardised protocol to ensure consistency.

2.2.1 Ozone-therapy protocol

Ozone was administered through two distinct routes:

Subcutaneous route

- Concentration: 10 $\mu\text{g mL}^{-1}$
- Final volume per session: 20 mL
- The volume was divided into 2 mL per painful point.
- Injections were given with a 20 mL syringe and a 30 G needle (30 × 13 mm).

Rectal route

- Concentration: 20 $\mu\text{g mL}^{-1}$
- Total volume: 180 mL
- The gas was drawn into three 60 mL syringes.
- A lubricated 12-French urethral catheter was inserted 10 cm into the rectum with the patient in the lateral decubitus position.
- Each 60 mL aliquot was injected sequentially until the full 180 mL was delivered.
- Patients remained in lateral decubitus for 15 minutes after administration.

2.3 Outcome measures

Pain intensity was quantified with the Visual Analogue Scale (VAS), a continuous 0-to-10 metric. Disability and quality-of-life impact were assessed with the Oswestry Disability Index (Ghizoni *et al.*, 2011), validated for spinal disorders. Both instruments were applied at three time points: before the first ozone session (baseline), mid-treatment, and at the final session (after completion of all planned sessions).

2.4 Ethical considerations

The study conformed to the ethical principles of the Declaration of Helsinki. All participants provided written informed consent. Confidentiality was strictly maintained, and data were stored securely to protect participant privacy.



Figure 1. Visual Analogue Scale for pain.

Source: www.victorbarboza.com.br/medindo-intensidade-da-dor

RESULTADOS E DISCUSSÃO

Case 1

A 78-year-old male (90 kg, retired) with lumbosciatica at L4–L5 presented low-back pain radiating along the left sciatic nerve. History included treated prostate tumour and untreated anxiety. He used nimesulide 100 mg every 12 h during pain crises and did not consume alcohol or tobacco. March 2024 laboratory values were: creatinine 0.93 mg dL⁻¹, fasting glucose 103 mg dL⁻¹, PSA 0.04 ng mL⁻¹, ALT 33 U L⁻¹, AST 23 U L⁻¹, G6PD 6.9 U g⁻¹ Hb. Ten subcutaneous ozone sessions (2 mL per point, 10–20 µg mL⁻¹) plus the adapted Cuban rectal protocol reduced pain from 8 → 5 and allowed a marked decrease in nimesulide use.

Case 2

A 33-year-old female (74 kg, entrepreneur) with lumbosciatica at S1–S2 reported bilateral radiation of low-back pain. Comorbid anxiety/depression were treated with venlafaxine 75 mg (morning) and trazodone 100 mg (bedtime). She relied on ibuprofen 100 mg q12 h and intramuscular ketoprofen 100 mg 2 mL for severe crises, used polyethylene-glycol laxative, and was an alcohol and tobacco user. Baseline G6PD was 7.8 U g⁻¹ Hb. Ten subcutaneous sessions (5–15 µg mL⁻¹) plus the rectal protocol lowered pain from 7 → 5, permitting reduced analgesic intake.

Case 3

A 60-year-old female (55 kg, housekeeper) with L4–L5 lumbosciatica and left-leg



radiation had type II diabetes and hyperthyroidism (Xigduo XR, NPH insulin as needed, levothyroxine 25 µg). She neither drank nor smoked. April 2024 labs: 25-OH-vitamin D 19.6 ng mL⁻¹, HbA1c 5.9 %, fasting glucose 133 mg dL⁻¹, G6PD 7.2 U g⁻¹ Hb. Ten subcutaneous sessions (20–25 µg mL⁻¹) plus the rectal protocol reduced pain from 9 → 6.

Case 4

A 62-year-old female (50 kg, entrepreneur) with L4–L5 lumbosciatica, bilateral hand and shoulder pain, and anxiety (escitalopram 10 mg, valproate 400 mg) neither drank nor smoked. January 2024 labs: 25-OH-vitamin D 22.7 ng mL⁻¹, ALT 35 U L⁻¹, vitamin B12 600 pg mL⁻¹. Ten subcutaneous sessions (10–25 µg mL⁻¹) plus the rectal protocol reduced pain from 7 → 3.

Case 5

A 55-year-old female (60 kg, domestic worker) with L4–L5 protrusive lumbosciatica and left-leg radiation had hypertension (losartan 50 mg + HCTZ 25 mg), unmedicated anxiety, and a nutraceutical regimen (coenzyme Q10, *Curcuma longa*, resveratrol). She took ibuprofen 600 mg q6 h during crises. January 2024 vitamin D was 28.04 ng mL⁻¹. Ten subcutaneous sessions (15–25 µg mL⁻¹) plus the rectal protocol lowered pain from 8 → 2 and reduced NSAID use.

Case 6

A 90-year-old female (92 kg, retired) with L5–S1 lumbosciatica plus widespread musculoskeletal pain had fibromyalgia, left-knee prosthesis, type II diabetes (diet-controlled, glucose 130 mg dL⁻¹), hypertension (valsartan/HCTZ), depression (duloxetine 30 mg), pregabalin 75 mg q12 h, diosmin/hesperidin for venous disease, and spironolactone diuretic. Ten sessions (15–25 µg mL⁻¹) were planned, but she reported no relief and discontinued after session 7.

Case 7

A 62-year-old female (78 kg, retired) with L4–L5 lumbosciatica radiating to the left knee had no comorbidities and neither drank nor smoked. Ten subcutaneous sessions (15–20



µg mL⁻¹) plus the rectal protocol resolved pain from 6 → 0.

Case 8

A 46-year-old female (88 kg, domestic worker) with L4–L5/L5–S1 lumbosciatica radiating to the left knee had hypertension (losartan 50 mg) and no laboratory data. Eight subcutaneous sessions (15–20 µg mL⁻¹) plus the rectal protocol reduced pain from 6 → 2.

Case 9

A 53-year-old female (57 kg, entrepreneur) with isolated L4–L5 low-back pain had unmedicated anxiety and neither drank nor smoked. March 2024 labs: 25-OH-vitamin D 25.9 ng mL⁻¹, vitamin B12 650 pg mL⁻¹, CPK 85 U L⁻¹. Ten subcutaneous sessions (5–15 µg mL⁻¹) plus the rectal protocol lowered pain from 7 → 2.

Table 1 summarizes clinical characteristics and outcomes for the nine patients with lumbosciatica at different vertebral levels (L4–L5, L5–S1, S1–S2). Variables include age, sex, body weight, baseline and post-treatment pain intensity, and qualitative improvement indicators such as reduced analgesic consumption and symptom evolution. Most participants experienced clinically meaningful pain reduction, some achieving near-complete resolution, while one discontinued due to lack of benefit. These findings highlight the heterogeneous response to ozone therapy and underscore the need for individualized treatment strategies in lumbosciatica.

Patient	Age (years)	Sex	Weight (kg)	Diagnosis	Pain intensity before	Pain intensity after	Observed improvement
1	78	Male	90	Lumbosciatica (L4–L5)	8	5	Decreased nimesulide intake
2	33	Female	74	Lumbosciatica (S1–S2)	7	5	Reduced analgesic use
3	60	Female	55	Lumbosciatica (L4–L5)	9	6	—
4	62	Female	62	Lumbosciatica (L4–L5)	7	3	—

5	55	Female	60	Lumbosciatica (L4–L5)	8	2	—
6	90	Female	92	Lumbosciatica (L5–S1)	—	—	No pain improvement
7	62	Female	78	Lumbosciatica (L4–L5)	6	0	—
8	46	Female	88	Lumbosciatica (L4–L5 / L5–S1)	6	2	—
9	53	Female	57	Lumbosciatica (L4–L5)	7	2	—

Table 1 Clinical profile, baseline and post-treatment pain scores, and qualitative improvement in nine patients with lumbosciatica treated with ozone therapy.

A significant reduction in pain intensity was observed between the first session ($M = 7.55 \pm 0.44$) and the tenth session ($M = 3.88 \pm 0.99$; $p = 0.0005$) (Figure 2).

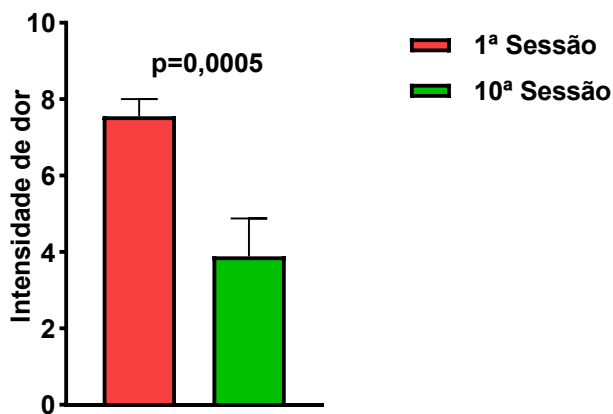


Figure 2. Mean \pm standard deviation of pain intensity in patients with lumbosciatica. p values calculated with paired t -test.

The findings of this study indicate that ozone therapy may represent a promising therapeutic modality for the management of lumbosciatalgia, effectively reducing pain intensity and the requirement for pharmacological analgesia in the majority of patients. Case analysis revealed a favorable response in eight of the nine participants, as evidenced by diminished self-reported pain scores at the conclusion of the treatment sessions.

Clinical response exhibited inter-patient variability, potentially influenced by factors such as age, comorbidities, concurrent medication use, and lifestyle variables. Patients with fewer comorbidities and no history of chronic diseases,



exemplified by Case 7, demonstrated significant improvement, achieving complete pain remission. Conversely, Case 6, an elderly patient with multiple comorbidities including fibromyalgia, type II diabetes, and venous insufficiency, did not exhibit a satisfactory response to treatment, which led to the premature discontinuation of therapy.

Analysis of vitamin D levels showed that patients with a deficiency in this vitamin (Cases 3, 4, and 5) still demonstrated a positive therapeutic response, suggesting that ozone therapy may confer analgesic benefits irrespective of serum vitamin D concentrations. Nevertheless, the influence of vitamin D on musculoskeletal pain is well-documented in the literature, and further investigation is warranted to elucidate this specific interaction in the context of ozone therapy.

A noteworthy outcome of this study was the observed reduction in the utilization of anti-inflammatory drugs and analgesics. Specifically, Case 1 showed a decreased intake of nimesulide, while Case 2 reported reduced use of ibuprofen and intramuscular ketoprofen. This finding is clinically relevant, as the prolonged administration of non-steroidal anti-inflammatory drugs (NSAIDs) is associated with adverse events, including renal and gastrointestinal damage, particularly in elderly or comorbid populations.

The applied ozone concentrations were titrated according to patient-reported pain intensity. Higher concentrations (20-25 µg/mL) were generally administered to patients presenting with higher baseline pain scores, as observed in Cases 3 and 5. The therapeutic efficacy observed at these dosages underscores ozone's analgesic and anti-inflammatory potential, whilst also highlighting the necessity for individualized treatment protocols to optimize therapeutic outcomes. An adapted Cuban rectal insufflation protocol was employed adjunctively in all cases, complementing subcutaneous ozone administration. This multimodal approach may have contributed to the positive results, as rectal ozone therapy is reported in the literature to modulate systemic inflammatory processes and enhance tissue oxygenation.

The present findings align with existing literature. Magalhães, Dotta *et al.* (2012) concluded from their analysis of ozone therapy for low back pain



secondary to disc herniation that there is a high level of evidence supporting its efficacy and therapeutic excellence, yielding favorable patient outcomes. Furthermore, its low cost facilitates broader application for lumbosciatalgia and other etiologies of lumbar pain. Consequently, this method can be considered an integrative complementary option, either in conjunction with other treatments or for patients refractory to conventional therapies.

Andreula *et al.* (2003) reported on a study involving 600 patients, comparing a group (A, n=300) treated with CT-guided intradiscal and periganglionic ozone injections against a group (B, n=300) receiving corticosteroids and anesthetics plus ozone therapy. After a 6-month follow-up, therapeutic success rates were 70.3% for group A and 78.3% for group B, thereby demonstrating the therapy's efficacy. Justin, Arend, and Gouveia (2020), encompassing 35 articles, addressed the effectiveness and safety of medicinal ozone for treating low back pain and lumbosciatalgia, affirming its therapeutic profile. This supports the technique's role as an adjunct in managing various health conditions, offering an alternative to reduce dependence on medications such as corticosteroids, anti-inflammatory drugs, analgesics, and antipyretics. Oliveira Junior and Lages (2012), through a literature review of 54 selected articles, affirmed that ozone therapy for low back pain, with or without sciatica, proved effective and was associated with few adverse events. Similarly, Sampaio, Cruz, and Medrado (2018), after a literature review based on four distinct studies, concluded that ozone application could be considered a promising tool for pain management in patients with chronic inflammatory processes associated with conditions like low back pain and lumbosciatalgia.

When considering the outcomes of this study, certain methodological aspects are important to acknowledge. The initial insights are drawn from a sample size of nine participants; while valuable, further studies with larger cohorts would enhance the generalizability of these results and the capacity to identify more subtle therapeutic effects. As this was an observational study without a concurrent control group, the observed clinical improvements provide positive indications for ozone therapy, though the specific contributions relative to potential placebo effects or the natural history of lumbosciatalgia would be



further elucidated by future controlled research. The clinical diversity among participants (regarding age, comorbidities, and baseline pain levels) and the individualized ozone concentrations administered, characteristic of tailored patient care, are factors to bear in mind when developing standardized conclusions. Additionally, the concurrent application of rectal ozone insufflation with subcutaneous administration, while potentially beneficial, means that discerning the precise impact of each modality individually invites further investigation. These observations offer a valuable foundation, and subsequent research employing larger, randomized controlled trials with standardized protocols and extended follow-up periods will be instrumental in building upon these preliminary findings and more definitively establishing the efficacy of ozone therapy for lumbosciatalgia.

CONSIDERAÇÕES FINAIS

This case series provides preliminary evidence that ozone therapy can attenuate pain intensity in patients with lumbar disc herniation–related sciatica. Within the Brazilian public-health framework, the National Policy for Integrative and Complementary Practices, ozone therapy is already listed among 29 sanctioned integrative modalities, and its proposed mechanisms of action (analgesia, anti-inflammatory modulation, immunoregulation) are increasingly supported by experimental and clinical data. The present findings reinforce those mechanistic expectations: eight of nine patients reported meaningful pain relief accompanied by decreased dependence on non-steroidal anti-inflammatory drugs.

From a public-health perspective, ozone therapy is attractive because it is inexpensive, technically straightforward, and rarely associated with adverse reactions when administered at appropriate concentrations, volumes, and via validated routes. Nevertheless, the current study is inherently limited by its descriptive, uncontrolled design and small sample size; causal inference cannot be established, and the observed heterogeneity in treatment response underscores the need to identify patient-level predictors of efficacy.



Accordingly, rigorously designed randomised, sham-controlled trials with larger cohorts and longer follow-up are essential to confirm therapeutic benefit, delineate optimal dosing algorithms, and characterise long-term safety. Such investigations will determine whether ozone therapy should be incorporated into evidence-based guidelines for the management of discogenic sciatica and, more broadly, chronic spinal pain syndromes.

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