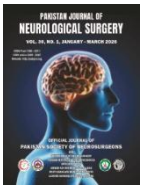

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Original Research

Short-Term Clinical Efficacy of Lacosamide in Orthopedic Spine Patients with Acute Sciatica: A Prospective Observational Study at Akhtar Saeed Trust Teaching Hospital, Lahore

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ABSTRACT

Objective: To evaluate the short-term clinical efficacy and tolerability of intravenous lacosamide in orthopedic spine patients presenting with acute sciatica.

Materials and Methods: This prospective observational study was conducted at the Department of Orthopedic Surgery, Akhtar Saeed Trust Teaching Hospital, Lahore, from January 2023 to January 2024. One hundred adult patients (20–65 years) with acute lumbosacral radiculopathy were included. All patients received intravenous lacosamide 200 mg diluted in 100 mL normal saline, administered twice daily for three consecutive days. Clinical outcomes were assessed at baseline and on day 4 using the Numerical Rating Scale (NRS) for pain, Oswestry Disability Index (ODI), Straight Leg Raise (SLR) test, and Claudication Distance (CD). Statistical analysis was performed using paired t-tests.

Results: After 4 days of treatment, significant improvements were observed across all outcome measures. Mean NRS decreased from 8.2 ± 1.1 to 3.1 ± 1.4 ($p < 0.001$), and mean ODI reduced from 58.7 ± 11.3% to 29.6 ± 10.8% ($p<0.001$). Mean SLR angle increased from 42.6 ± 10.5° to 68.3 ± 11.9° ($p<0.001$), while mean claudication distance improved from 145.2 ± 48.3 m to 266.4 ± 59.8 m ($p < 0.001$). Adverse effects were mild and included dizziness (8%), nausea (5%), and somnolence (4%), with no serious events.

Conclusion: Short-term intravenous lacosamide significantly improved pain, functional disability, and objective neurological parameters in patients with acute sciatica and was well tolerated, supporting its role as an adjunct in acute radicular pain management.

Keywords: Lacosamide; Sciatica; Radiculopathy; Neuropathic Pain; Spine.

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INTRODUCTION

Sciatica—pain radiating along the sciatic nerve distribution—is a common and often disabling condition encountered in orthopedic and neurological practice.[15–17] Its principal causes include lumbar intervertebral disc herniation, foraminal stenosis, and, less commonly, piriformis syndrome or nerve entrapment. The natural history ranges from spontaneous improvement to chronic radicular pain with persistent functional limitation.[15,16]

Conservative management, including patient education, activity modification, analgesics, and targeted physiotherapy, remains first-line for most patients, while invasive interventions such as epidural injections or surgery are reserved for those with severe, progressive, or refractory symptoms.[15–18] Contemporary clinical guidance emphasizes multimodal and phenotype-guided care, as single-modality approaches frequently provide incomplete relief for neuropathic radicular pain.[18,22,24]

Pharmacologic options for radicular and neuropathic pain include tricyclic antidepressants, serotonin–norepinephrine reuptake inhibitors, gabapentinoids, topical agents, and certain anticonvulsants that modulate neuronal excitability.[18,22] Lacosamide, a third-generation anticonvulsant that selectively enhances slow inactivation of voltage-gated sodium channels and modulates collapsin response mediator protein-2 (CRMP-2) interactions, has been investigated for several neuropathic pain syndromes due to its plausible mechanism of reducing ectopic neuronal firing in injured peripheral nerves.[5,7,8,14,20,21]

Early randomized trials and analyses in painful diabetic neuropathy and other peripheral neuropathic conditions have shown variable efficacy: some reported clinically meaningful pain reduction, while others failed to meet primary endpoints, yielding mixed but meaningful evidence base.[5,8,10,14,19] Over the last five years, systematic reviews and meta-analyses have re-examined lacosamide's role, suggesting a modest reduction in pain scores versus placebo, tempered by heterogeneity in study design, populations, and endpoints.[5,10,14,19,23]

Real-world and adjunctive-therapy reports have contributed additional insights into safety and tolerability, supporting lacosamide's use as an adjunct in neuropathic presentations refractory to first-line agents.[6,7,20,21] However, high-quality, phenotype-stratified randomized trials specifically addressing radicular sciatica remain limited, and few studies have reported short-term objective outcomes such as Straight Leg Raise (SLR) angle or claudication distance, parameters of direct orthopedic relevance.[1,13,17]

Preliminary investigations into lacosamide for acute radicular pain and sciatica, including combination-therapy designs, show promising but inconclusive results, highlighting the need for pragmatic, clinically grounded evidence in orthopedic settings.[2,9,24] This uncertainty rationalizes the prospective observational evaluation of lacosamide's short-term effects on pain, disability, and measurable functional parameters.

Therefore, this prospective observational study was designed to assess the efficacy and short-term outcomes of lacosamide using validated tools for pain, disability, and physical function (including SLR and claudication distance) in patients with acute sciatica presenting to Akhtar Saeed Trust Teaching Hospital, Lahore.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was

conducted at the Department of Orthopedics, Akhtar Saeed Trust Teaching Hospital, Lahore, between January 2023 and January 2024. The objective was to assess the short-term clinical efficacy and tolerability of intravenous lacosamide in patients presenting with acute sciatica of less than 6 weeks' duration.

Ethical Approval

The study was approved by the Ethical Approval Committee of Akhtar Saeed Trust Teaching Hospital (Ref. No. 3035/ASTH). All participants provided written informed consent prior to enrollment.

Study Population

A total of 100 adult patients (aged 20–65 years) admitted under orthopedic care with a clinical diagnosis of acute lumbosacral radiculopathy (sciatica) were included. Diagnosis was based on characteristic pain radiating along the sciatic nerve distribution, a positive Straight Leg Raise (SLR) test, and compatible radiological findings on MRI or CT. The sample size of 100 patients was determined based on convenience sampling within the study period (January 2023–January 2024). consistent with comparable observational studies in acute sciatica and neuropathic pain populations.[2,7,9]

Inclusion Criteria

Adult patients between 20 and 65 years of age presenting with acute sciatica of less than six weeks' duration were included in the study. All participants had a baseline Numerical Rating Scale (NRS) score of at least 4, along with clinical features of lumbosacral radiculopathy characterized by pain radiating along the sciatic nerve distribution, a positive Straight Leg Raise (SLR) test, and corroborative imaging findings on MRI or CT scan. None of the included patients had prior exposure to lacosamide or other anticonvulsant medications within the preceding month.

Exclusion Criteria

Patients were excluded if they had chronic sciatica lasting more than six weeks, spinal deformities, or peripheral neuropathy secondary to diabetes or trauma. Individuals with a history of epilepsy, cardiac arrhythmias, hepatic or renal impairment, or known hypersensitivity to lacosamide were also excluded. Pregnant or lactating women were not enrolled in the study. These exclusion parameters were applied to ensure patient safety and to maintain the homogeneity of the acute sciatica cohort.

Treatment Protocol

All patients received Inj. Lacosamide 200 mg diluted in 100 mL of normal saline, administered intravenously twice daily for three consecutive days. Standard supportive therapy (analgesics, rest, and physiotherapy advice) was continued as per institutional protocol. No additional neuropathic pain agents (gabapentinoids or tricyclics) were prescribed during the study period.

Outcome Measures

Clinical assessment was performed at baseline (day 0), and the patients were followed during their inpatient stay for 4 days. All primary and secondary outcomes were recorded at these two points in time. No long-term follow-up was included in this analysis.

a. ***Numerical Rating Scale (NRS) for Pain:***
A 0–10 scale (0 = no pain, 10 = worst possible pain).
Clinically meaningful improvement was defined as ≥ 30 % reduction in NRS.

b. ***Oswestry Disability Index (ODI):***

c. A 10-item questionnaire evaluating pain and daily-activity limitations.
ODI score = (total ÷ 50) × 100%.
Disability was classified as: minimal (0–20%),

moderate (21–40%), severe (41–60%), crippled (61–80%), bedbound (> 80%).

d. ***Straight Leg Raise (SLR) Test:***

Passive leg elevation with the knee extended. The angle at which pain began was recorded.

Improvement was expressed as a change in mean angle (°) from baseline.

e. ***Claudication Distance (CD):***

Walking distance before the onset of sciatic pain (Intermittent Claudication Distance, ICD) and maximum achievable distance (Absolute Claudication Distance, ACD) were recorded using the Gardner Walking Test.

Statistical Analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., USA).

Continuous variables were expressed as mean ± standard deviation (SD).

Paired t-tests were applied to compare pre- and post-treatment scores.

A *p-value* < 0.05 was considered statistically significant.

RESULTS

Demographic Profile

Of the 100 enrolled patients, 54 % were male and 46% female, with a mean age of 44.3 ± 11.2 years. The most common etiologic factors were lumbar disc herniation (62%), degenerative lumbar spondylosis (25%), and post-traumatic lumbar strain (13%). **(Figure 1).**

Baseline characteristics (pain duration, BMI, comorbidities) were comparable across subgroups.

The results were interpreted based on the assessment of the following parameters pre- and post-treatment **(Table 2 &Figure 2).**

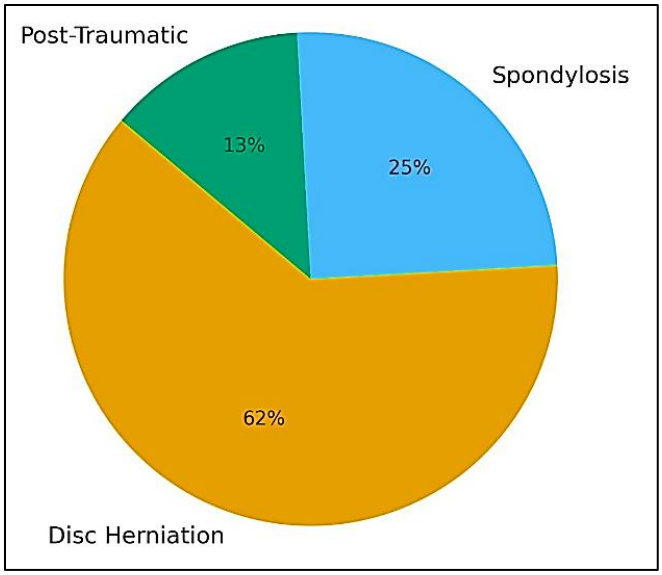

Figure 1: *Etiological Factors of Acute Sciatica.*

Table 1: *Demographic and Baseline Characteristics of Patients (n = 100).*

Variables	Mean ± SD / n (%)
Age (years)	44.3 ± 11.2
Sex (Male/Female)	54 / 46
Duration of Symptoms (days)	19.8 ± 6.3
Etiology	
• Lumbar disc herniation	62 (62%)
• Degenerative spondylosis	25 (25%)
• Post-traumatic lumbar strain	13 (13%)
Baseline values of Variables	
Baseline NRS	8.2 ± 1.1
Baseline ODI (%)	58.7 ± 11.3
Baseline SLR (°)	42.6 ± 10.5
Baseline ICD (m)	145.2 ± 48.3
Baseline ACD (m)	312.7 ± 84.1

Pain Intensity (NRS)

Mean baseline NRS score was 8.2 ± 1.1, which decreased to 3.1 ± 1.4 on day 4.

The mean reduction of 5.1 ± 1.6 points (62.2% improvement) was statistically significant (p < 0.001).

82% of patients achieved a reduction of 30% or more in pain.

Functional Disability (ODI)

Mean baseline ODI was 58.7 ± 11.3 %, improving

Table 2L *Pre- and Post-Treatment Comparison of Outcome Measures.*

Parameter	Baseline (Mean ± SD)	Day 4 (Mean ± SD)	Mean Change	*p*-value
Numerical Rating Scale (NRS)	8.2 ± 1.1	3.1 ± 1.4	-5.1 ± 1.6 (-62.2 %)	< 0.001*
Oswestry Disability Index (%)	58.7 ± 11.3	29.6 ± 10.8	-29.1 ± 9.7 (-49.6 %)	< 0.001*
Straight Leg Raise (°)	42.6 ± 10.5	68.3 ± 11.9	+25.7 ± 9.8	< 0.001*
Intermittent Claudication Distance (m)	145.2 ± 48.3	266.4 ± 59.8	+121.2 ± 38.1	< 0.001*
Absolute Claudication Distance (m)	312.7 ± 84.1	551.3 ± 97.5	+238.6 ± 76.4	< 0.001*

*Statistically significant

to 29.6 ± 10.8% after therapy — a 49.6% mean relative reduction ($p < 0.001$*).

According to ODI categories, 67 % of patients improved from "severe" to "moderate" or "minimal" disability within four days.

Straight Leg Raise (SLR)

The mean SLR angle improved from 42.6 ± 10.5° at baseline to 68.3 ± 11.9° post-treatment, indicating a mean gain of 25.7 ± 9.8° ($p < 0.001$*).

This corresponds to functional improvement and reduction in sciatic nerve irritation.

Claudication Distance (CD)

Mean Intermittent Claudication Distance (ICD) increased from 145.2 ± 48.3 m to 266.4 ± 59.8 m, and Absolute Claudication Distance (ACD) increased from 312.7 ± 84.1 m to 551.3 ± 97.5 m after treatment ($p < 0.001$*).

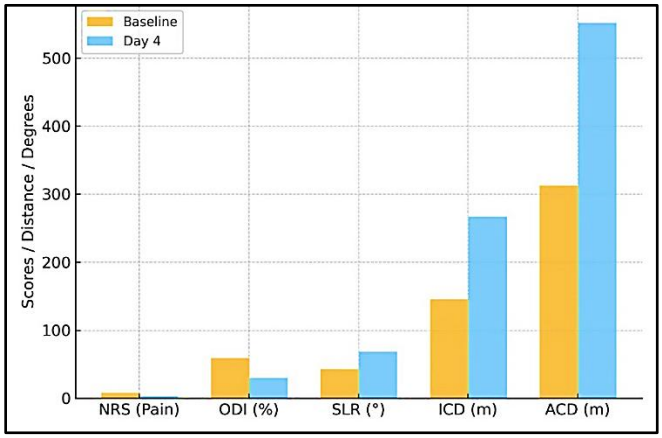

Figure 2: *Pre- and Post-Treatment Comparison of Outcome Measures.*

Safety and Adverse Events

Lacosamide was well-tolerated.

Minor side effects included dizziness (8%), mild nausea (5%), and transient somnolence (4 %).

No serious adverse events or cardiac conduction abnormalities were observed.

Table 3: *Adverse Events Observed during Lacosamide Therapy.*

Adverse Event	n (%)
Mild Nausea	5 (5%)
Dizziness	8(8%)
Transient Somnolence	4(4%)
Serious Adverse Events	0(0%)

Summary

Collectively, lacosamide administration produced statistically significant short-term improvements across pain, function, and neurological parameters in patients with acute sciatica, with good tolerability.

DISCUSSION

In this prospective observational cohort of orthopedic patients with acute sciatica, short-term administration of intravenous lacosamide was associated with clinically and statistically significant reductions in pain intensity (NRS) and functional disability (ODI) at 4 days. Objective parameters relevant to orthopedic assessment—Straight Leg Raise (SLR) angle and claudication/ walking distance—also improved early during treatment. The drug was generally well tolerated,

with an adverse-event profile consistent with previously reported experiences in neuropathic pain populations.[5–8,14,19–21,25] These findings suggest that lacosamide may provide meaningful short-term symptomatic benefit in acute radicular pain when used within the inpatient orthopedic setting.

Our results align with the broader neuropathic pain literature, in which lacosamide has demonstrated modest but significant analgesic efficacy versus placebo in meta-analyses and systematic reviews.[5,10,14,19,23] Across these studies, pain reduction was typically small to moderate in magnitude, and substantial heterogeneity existed regarding underlying neuropathic etiology, dosing regimens, and treatment duration. Consequently, direct extrapolation to acute radicular sciatica is limited. The present study contributes novel data by focusing specifically on acute radicular presentations in orthopedic patients and by incorporating functional and examination-based endpoints (SLR, claudication distance) that are rarely captured in prior randomized trials.[1,13,15–18]

Where randomized controlled data in sciatica remain sparse, real-world and observational studies have reported symptomatic improvement when lacosamide is used as an adjunctive therapy in neuropathic pain, particularly in cases refractory to first-line agents such as pregabalin or gabapentin.[7,9,11,12,19,24] The early improvements in walking tolerance and SLR observed in our cohort echo these findings and suggest that functional recovery may accompany neuropathic pain relief in radicular syndromes. However, causation cannot be inferred from the present observational design.

Lacosamide's pharmacologic mechanism—enhancement of slow inactivation of voltage-gated sodium channels and modulation of CRMP-2—is mechanistically relevant to neuropathic and radicular pain, where hyperexcitable neurons and ectopic firing contribute to sustained symptoms.[5,14,20,21,26] Stabilization of neuronal firing and improved axonal conduction may underlie the rapid analgesic and functional effects observed. While this mechanistic rationale supports biological plausibility, confirmatory randomized controlled trials focused on sciatica-specific outcomes are still needed.

For orthopedic clinicians managing acute radicular pain, lacosamide may represent a viable adjunctive pharmacologic option, particularly for patients with pronounced neuropathic features or suboptimal response to standard conservative therapy. The observed short-term gains in pain and mobility may help bridge patients through the acute phase, potentially reducing early reliance on invasive interventions such as epidural injections or discectomy.[16–18] Nevertheless, routine use should be weighed against the limited sciatica-specific randomized evidence, medication cost, and local availability of intravenous formulations.

The strengths of this study include:

a) A prospective design with prespecified short-term endpoints directly relevant to orthopedic practice (NRS, ODI, SLR, claudication distance).
b) The real-world inpatient context, enabling evaluation of IV lacosamide's early therapeutic effect.
c) Systematic safety and tolerability monitoring, consistent with prior pharmacovigilance data.[20,21,25,26]

Adverse effects in our cohort—dizziness, mild somnolence, and transient nausea—were consistent with the known lacosamide safety profile.[20,25,26] Although no cardiac conduction abnormalities were observed, clinicians should remain aware of potential PR-interval prolongation with use of Lacoasmide, and caution should be observed in patients with pre-existing conduction disorders or concomitant cardiac medications. Larger comparative studies and continued post-marketing surveillance will be essential to better define lacosamide's safety and risk–benefit profile in non-epileptic orthopedic populations.

RECOMMENDATIONS

Based on our findings, we recommend future

randomized controlled trials comparing intravenous lacosamide plus standard supportive therapy (analgesia, physiotherapy, muscle relaxants, and rest) versus standard therapy alone, to determine its additive benefit in acute radicular sciatica. In addition to randomized trials, placebo-controlled and multicenter trials are also required, which can compare lacosamide as monotherapy and as an adjunct to first-line agents such as gabapentinoids or SNRIs. Given promising signals in meta-analyses of neuropathic pain and accumulating real-world safety data, a pragmatic randomized design (e.g., add-on lacosamide vs add-on placebo in patients with refractory radicular neuropathic pain) can be performed in the future.

LIMITATIONS

This study lacked a control group for comparison, and the follow-up period was limited to three months. Future studies with longer follow-up and control cohorts are warranted to validate the long-term effects of Lacosamide.

CONCLUSION

In summary, this prospective observational study suggests that short-term IV lacosamide may reduce pain and improve function in orthopedic patients with acute sciatica, with an adverse-event profile consistent with prior reports, and thus can be used as a treatment for sciatica.

However, well-designed randomized trials are needed to confirm efficacy, define optimal dosing/ regimens, long-term efficacy, and establish lacosamide's place within multimodal sciatica treatment algorithms.

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Additional Information

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Other Relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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AUTHORS CONTRIBUTIONS

Sr. No	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Syed Ahmad Bilal Bukhari	1. Study conception, Data collection
2.	Syed Ahmad Faizan Bukhari	2. Manuscript writing
3.	Syeda Mah-e-Noor Zahra	3. Result assessment and compilation
4.	Sara Zaheer	4. Result compilation, Manuscript writing
5.	Abdul Moiz Ahmed	5. Data Collection
6.	Muhammad Waqas	6. Literature Review