



Original Article

## Exploration of Clinical Characteristics and Treatment Patterns in Painful Neuropathy among Indian Patients: A Cross-Sectional Study

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### ABSTRACT

**Background:** Painful neuropathy is a chronic condition caused by peripheral nerve damage, characterized by burning, tingling, shooting pain, numbness, and weakness that significantly affects quality of life. Diabetic peripheral neuropathy (DPN) is the most common form worldwide, and with over 77 million people living with diabetes in India, there is a critical need for localized clinical and epidemiological data to guide targeted management.

**Methods:** In this multicenter, cross-sectional study anonymized electronic medical records of adults ( $\geq 18$  years) with confirmed painful neuropathy (including DPN and postherpetic neuralgia) were retrospectively analyzed over a 12-month period. Data on demographics, medical history, pain severity, and treatment patterns (drug, dose, adherence) were captured via secure eCRFs. Institutional Ethics Committee approval was obtained before starting of study. Descriptive and inferential statistical analyses were performed.

**Results:** The study evaluated 4,418 Indian patients with neuropathy, demonstrating a predominance of peripheral neuropathy (98.46%;  $n=4,350$ ). The cohort showed a marked male preponderance (73.83%;  $n=3,262$ ) with a relatively young mean age of  $49.31 \pm 11.26$  years. Diabetes was present in 15.07% ( $n=666$ ) of patients. Sensory symptoms were common, particularly numbness (49.39%) and paresthesia (42.08%), while motor involvement was also substantial, with weakness reported in 60.10% and muscle atrophy in 27.00% of cases. The most frequently prescribed regimen was pregabalin combined with methylcobalamin (48.53%;  $n=2,144$ ). Pain severity analysis indicated a predominance of moderate (42.67%) and mild (41.10%) pain, with severe pain observed in 16.23% of patients.

**Conclusion:** Study showed peripheral neuropathy predominates in Indian practice, commonly associated with diabetes, with most patients experiencing sensorimotor symptoms and mild-to-moderate pain and receiving primarily pregabalin-based therapy, underscoring the need for early and guideline-aligned management.

**Keywords:** Diabetic peripheral neuropathy, sensorimotor symptoms.

### INTRODUCTION

Painful neuropathy is a widespread and disabling consequence of peripheral nerve injury, marked by persistent sensory disturbances such as burning sensations, tingling paresthesias, sharp shooting pains, numbness, and motor impairments including weakness and gait instability.<sup>1</sup> These symptoms—often worsening at night and intensified by normally non-painful stimuli (allodynia)—significantly impair sleep quality, physical performance, psychological well-being, and overall productivity, thereby imposing a considerable burden on affected individuals and healthcare systems globally.<sup>2</sup> Among the various causes, diabetic peripheral neuropathy (DPN) is the most prevalent, affecting approximately 10–50% of individuals with diabetes mellitus. Its occurrence increases with advancing age, longer duration of diabetes, poor glycemic control, and the presence of associated comorbid conditions.<sup>3</sup> In India, epidemiological studies from different regions prevalence

of peripheral neuropathy, ranging from 5 to 2400 per 10,000 population. Its burden is rising due to increasing diabetes prevalence, lifestyle changes.<sup>4</sup>

Other etiologies contributing to painful neuropathy include post-herpetic neuralgia, alcohol-induced neuropathy, chemotherapy-induced peripheral neuropathy, vitamin deficiencies, and idiopathic causes. Regardless of etiology, neuropathic pain mechanisms involve peripheral sensitization, central sensitization, ectopic discharges, and inflammatory mediators, leading to chronic and refractory symptoms.<sup>5</sup>

Current management strategies focus on symptomatic relief rather than disease modification. International guidelines recommend first-line pharmacotherapies such as pregabalin, gabapentin, duloxetine, and tricyclic antidepressants, with opioids and topical agents reserved for refractory cases.<sup>6</sup> However, treatment patterns vary widely across regions due to differences in healthcare access, prescribing practices, cost considerations, and patient-related factors. In real-world settings, polypharmacy and suboptimal dosing are common, potentially affecting therapeutic outcomes and adherence.

Despite the high burden of painful neuropathy in India, there is limited contemporary real-world data describing its clinical characteristics, severity patterns, comorbidities, and current treatment practices. Understanding these factors is crucial for identifying gaps in care and optimizing evidence-based management strategies tailored to the Indian population.

Therefore, this cross-sectional study aims to explore the clinical characteristics and treatment patterns of painful neuropathy among Indian patients in routine clinical practice, providing insights into disease presentation and therapeutic approaches in a real-world setting.

## **MATERIALS AND METHODS**

### **Study Design**

This was a cross-sectional, observational, post-marketing study conducted to evaluate the clinical characteristics and treatment patterns of patients diagnosed with painful neuropathy in routine clinical practice.

### **Study Population**

#### **Inclusion Criteria:**

Adults ( $\geq 18$  years) attending outpatient clinics with a clinical diagnosis of painful neuropathy, including diabetic peripheral neuropathy, postherpetic neuralgia, or other neuropathic pain syndromes.

#### **Exclusion Criteria:**

Patients with non-neuropathic pain conditions (e.g., musculoskeletal or inflammatory arthritis), severe cognitive or communication impairment, or a history of substance abuse or addiction.

### **Study Period and Duration**

The total study duration was 12 months, conducted from April 2024 to May 2025.

### **Study Setting**

The study was carried out across 295 centers in India, reflecting a broad, multicenter representation of real-world clinical practice.

### **Data Collection**

In this multicenter, cross-sectional study (ALKPN1 protocol v1.0; dated 25 March 2024), anonymized electronic medical records of adult patients ( $\geq 18$  years) with a confirmed diagnosis of painful neuropathy were retrospectively reviewed and analyzed over a 12-month period. Data were extracted from routinely maintained clinical records without direct patient interaction, ensuring confidentiality and anonymity of patient information.

### **Ethical Approval**

The study protocol was reviewed and approved by Institutional Ethics Committees prior to initiation. The study was conducted in accordance with applicable ethical guidelines and regulatory requirements.

### **Statistical Analysis**

Descriptive statistics were used to summarize data with continuous variables expressed as mean  $\pm$  SD or median (IQR) and categorical variables as frequencies and percentages.

## **RESULTS**

The study included 4,418 patients with neuropathy, most of whom had peripheral neuropathy. The majority were males (73.83%, n=3,262), and the mean age of the participants was 49.31 ± 11.26 years, with ages ranging from 18 to 79 years (Table 1).

**Table 1: Summary of Demographic and Baseline Characteristics**

Parameter	Category	Statistics
<b>Total Patients (n)</b>	—	4418
<b>Gender</b>	Male	3262 (73.83%)
	Female	1156 (26.17%)
<b>Age (years)</b>	Mean ± SD	49.31 ± 11.26
	Range	18 – 79

Peripheral neuropathy predominated (98.46%; n=4,350), followed by mixed/combination (1.20%; n=53) and central neuropathy (0.34%; n=15) [Table 2].

**Table 2: Distribution of Neuropathy Diagnoses**

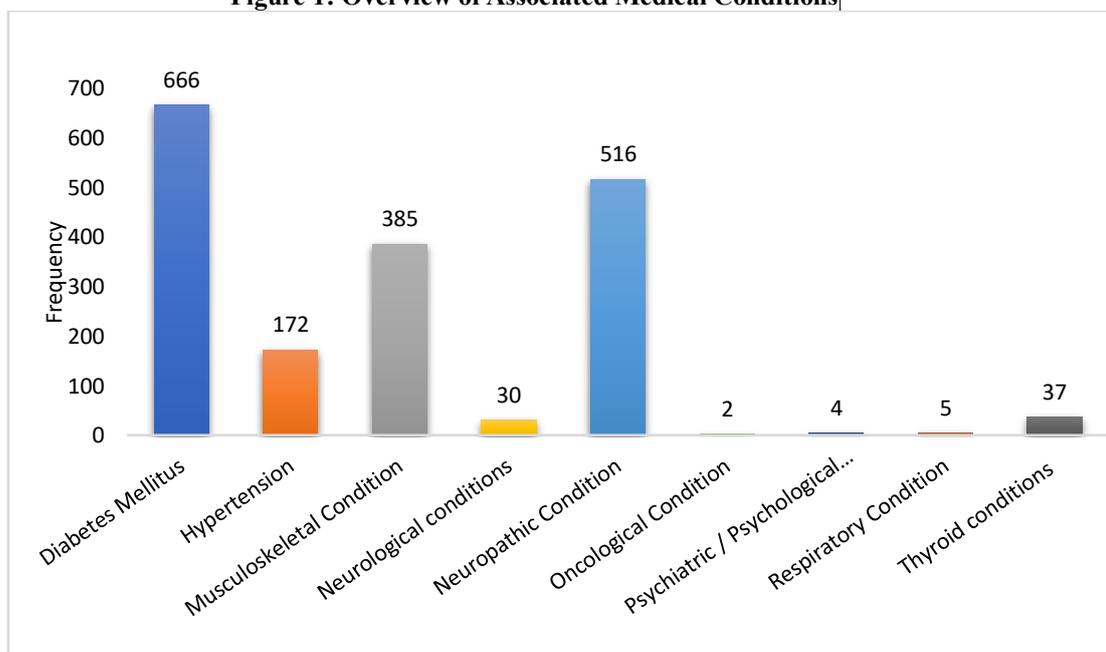
Neuropathy Diagnosis	n	%
Peripheral Neuropathy	4350	98.46
Mixed/Combination Neuropathy	53	1.20
Central Neuropathy	15	0.34

Comorbid diabetes mellitus affected 15.07% (n=666), hypertension 3.89% (n=172), and musculoskeletal conditions 8.71% (n=385) [Table 3][Figure 1].

**Table 3: Overview of Associated Medical Conditions**

Medical Condition	n	%
Diabetes Mellitus	666	15.07
Hypertension	172	3.89
Musculoskeletal Condition	385	8.71
Neurological conditions	30	0.68
Neuropathic Condition	516	11.68
Oncological Condition	2	0.05
Psychiatric/Psychological	4	0.09
Respiratory Condition	5	0.11
Thyroid conditions	37	0.84

**Figure 1: Overview of Associated Medical Conditions**



Sensory symptoms included numbness (49.39%; n=2,182) and paresthesia (42.08%; n=1,859); motor symptoms featured weakness (60.10%; n=2,655) and muscle atrophy (27.00%; n=1,193) [Table 4].

**Table 4: Distribution of Sensory and Motor Symptoms among Neuropathy Patients**

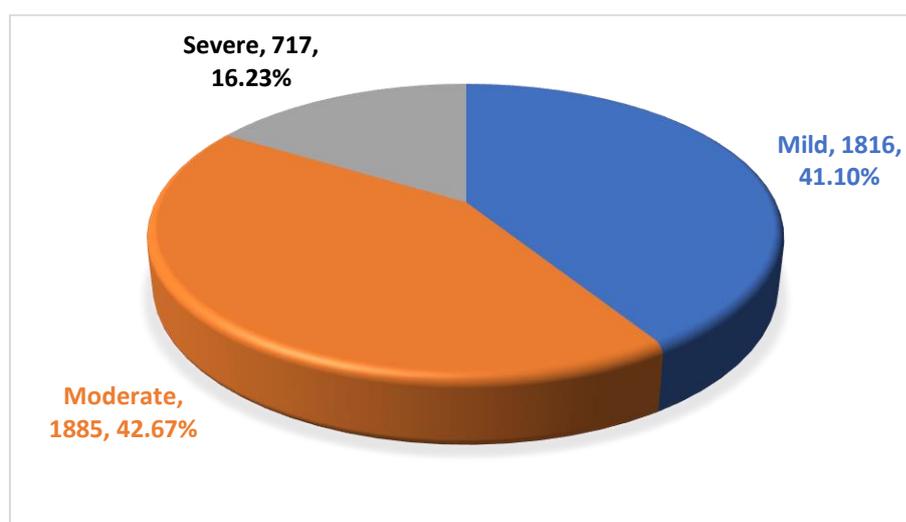
Symptoms	n	%
<b>Sensory</b>		
Allodynia	9	0.20
Burning Sensation	105	2.38
Dysesthesia	1	0.02
Hyperesthesia	94	2.13
Hypoesthesia	75	1.70
Numbness	2182	49.39
Paresthesia	1859	42.08
<b>Motor</b>		
Fasciculations	3	0.07
Gait Disturbances	5	0.11
Muscle Atrophy	1193	27.00
Thenar Atrophy	1	0.02
Weakness	2655	60.10

Neuropathic pharmacotherapy relied heavily on pregabalin + methylcobalamin (48.53%; n=2,144), pregabalin monotherapy (10.80%; n=477), and combination regimens (e.g., methylcobalamin + nortriptyline + pregabalin: 3.62%; n=160) [Table 5].

**Table 5: Overview of Neuropathic Medications**

Neuropathic Medication	n	%
Pregabalin + Methylcobalamin	2144	48.53
Pregabalin + Nortriptyline	154	3.49
Pregabalin + Duloxetine	20	0.45
Nortriptyline + Pregabalin	133	3.01
Methylcobalamin + Nortriptyline + Pregabalin	160	3.62
Pregabalin	477	10.80
Gabapentin	19	0.43
Gabapentin + Nortriptyline	2	0.05
Gabapentin + Pregabalin	1	0.02
Alpha Lipoic Acid + Benfotiamine + Biotin + Folic Acid + Methylcobalamin + Pyridoxine	139	3.15

Pain severity per Visual Analogue Scale (VAS) revealed moderate pain in 42.67% (n=1,885), mild in 41.10% (n=1,816), and severe in 16.23% (n=717) [Figure 2].

**Figure 2: Pain Severity Profile in Patients with Neuropathy**

## DISCUSSION

This large, multicenter cross-sectional study provides real-world insights into the clinical spectrum and treatment practices of painful neuropathy in Indian patients. The overwhelming predominance of peripheral neuropathy (98.46%) highlights its clinical dominance compared with mixed and central neuropathic conditions. This finding is consistent with existing literature indicating that peripheral etiologies—particularly metabolic, toxic, and compressive causes—account for the majority of neuropathic pain presentations in routine practice.<sup>7</sup>

Diabetes mellitus emerged as the most common comorbidity (15.07%), reinforcing its well-established association with peripheral nerve damage and painful neuropathic syndromes. Although the proportion of patients with documented diabetes in this cohort appears lower than that reported in some epidemiological studies, this may reflect under-documentation, inclusion of non-diabetic neuropathies, or variability in referral patterns. Hypertension and musculoskeletal disorders were less frequent but clinically relevant, as vascular and structural factors may contribute to symptom amplification and functional limitation. Nonetheless, diabetes remains a major driver of neuropathic morbidity globally, particularly in countries such as India with a high diabetes burden.<sup>8</sup>

The symptom profile in this cohort underscores the heterogeneous yet predominantly sensorimotor nature of neuropathy. Nearly half of the patients reported numbness (49.39%) and paresthesia (42.08%), classical sensory manifestations of nerve dysfunction. Notably, motor involvement was also prominent, with weakness observed in 60.10% and muscle atrophy in 27.00% of patients. The high prevalence of motor deficits suggests either advanced disease at presentation or delayed healthcare seeking, which may have implications for long-term disability and rehabilitation needs.<sup>9</sup>

Pain severity assessment revealed that the majority of patients experienced mild to moderate pain (approximately 84%), while 16.23% reported severe pain. This distribution suggests a substantial symptomatic burden, even though extreme pain was less common. Given that moderate pain can significantly impair sleep, mood, and productivity, these findings emphasize the importance of timely and optimized pain management strategies.<sup>10</sup>

Treatment patterns demonstrated a clear preference for pregabalin-based regimens, particularly the combination of pregabalin with methylcobalamin (48.53%). This reflects prevailing prescribing trends in India, where neuropathic pain agents are frequently co-administered with neurotropic vitamins, possibly to address underlying nutritional deficiencies or to enhance nerve repair. Pregabalin monotherapy (10.80%) was less common, and alternative agents such as gabapentin (0.43%) and duloxetine-containing combinations were prescribed in a minority of patients. The limited use of duloxetine and gabapentin may be influenced by physician familiarity, tolerability considerations, cost factors, or perceived effectiveness. International guidelines recommend pregabalin, duloxetine, gabapentin, and tricyclic antidepressants as first-line agents for neuropathic pain. International guidelines recommend combination therapy for neuropathic pain only when optimized monotherapy provides inadequate relief.<sup>10,11,12</sup>

The relatively modest use of tricyclic antidepressant combinations and multinutrient formulations (3.15%) further reflects selective prescribing patterns. While international guidelines recommend several first-line options—including pregabalin, duloxetine, gabapentin, and tricyclic antidepressants—the observed dominance of pregabalin suggests regional practice preferences and potential gaps in therapeutic diversification.<sup>11,12</sup>

Overall, this study highlights that peripheral neuropathy constitutes the major burden of neuropathic pain in Indian clinical settings, with diabetes as a key associated comorbidity and pregabalin-based combinations as the cornerstone of pharmacotherapy. The findings underscore the need for standardized treatment algorithms, early diagnosis, and individualized management strategies to optimize outcomes and reduce long-term disability in patients with painful neuropathy.

As a cross-sectional, retrospective analysis, the study is limited by its observational design, potential documentation bias, lack of longitudinal follow-up, and inability to establish causal relationships between clinical characteristics and treatment outcomes.

## CONCLUSION

This large multicenter cross-sectional study demonstrates that peripheral neuropathy is the predominant form of painful neuropathy in Indian clinical practice, with diabetes being the most common comorbidity. Most patients presented with sensory symptoms accompanied by significant motor involvement and experienced mild-to-moderate pain severity. Pregabalin-based combinations, particularly with methylcobalamin, were the most frequently prescribed therapies, highlighting prevailing real-world treatment preferences. These findings underscore the need for early diagnosis alignment with evidence-based guidelines to improve patient outcomes.

## Conflict of Interest

All the authors (Dr. Nishikant Madkholkar, Dr. Kushal Sarada, and Dr. Akhilesh Sharma) are full-time employees of Alkem Laboratories.

## Author Contributions

All authors contributed substantially to the study conception, data analysis, manuscript drafting, and final approval of the submitted version.

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