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EVALUATION OF MEDICATION ADHERENCE, INCIDENCE OF ADVERSE DRUG REACTIONS, AND QUALITY OF LIFE OUTCOMES IN PATIENTS RECEIVING MEDICATIONS FOR NEUROPATHIC PAIN

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Abstracts: **Background**: Neuropathic pain, arising from somatosensory nervous system lesions, affects 7–10% of the global population, causing chronic disability that is often refractory to conventional analgesics (2). First-line pharmacotherapy includes gabapentinoids (gabapentin, pregabalin), serotonin–norepinephrine reuptake inhibitors (SNRIs) such as duloxetine, and tricyclic antidepressants (TCAs) including nortriptyline, with combination therapies increasingly recommended for synergistic efficacy (3). Real-world data from Indian tertiary hospitals remain sparse despite the high prevalence of diabetes-related neuropathy. Medication adherence, adverse drug reactions (ADRs), and quality-of-life (QoL) outcomes critically determine therapeutic success; however, comparative evaluations across different treatment regimens are limited. **Methods**: A prospective observational study was conducted among 430 adults (≥18 years) diagnosed with neuropathic pain (possible, probable, or definite) at a tertiary care hospital in Moradabad between January 2024 and December 2025. Treatment regimens included gabapentin 100 mg (n = 135), pregabalin 75 mg (n = 100), pregabalin + duloxetine 75/10 mg (n = 125), and pregabalin + nortriptyline 75/10 mg (n = 70). Demographic characteristics, medication adherence (>80% doses considered good), ADRs (coded according to WHO criteria), and SF-36 QoL scores at 12 weeks were assessed. Statistical analysis was performed using chi-square (χ^2) tests, with $p < 0.05$ considered significant (1).**Results**: Males constituted 57% of the study population and were significantly younger ($p < 0.001$), while females were more obese ($p = 0.004$) and had a higher prevalence of chronic symptoms ($p = 0.036$). No significant gender-based

differences were observed in treatment regimen distribution ($p = 0.605$). Overall medication adherence was 74.9%, with the highest adherence observed in the pregabalin + duloxetine group (86.4%, $p < 0.001$). ADRs were reported in 35.6% of patients; incidence was highest with gabapentin (40%) and lowest with the pregabalin + duloxetine combination (28%), though this difference was not statistically significant ($p = 0.202$). Dizziness and somnolence were the most common ADRs (9.1% each). Combination therapies significantly reduced the risk of poor adherence associated with moderate to severe ADRs ($p < 0.001$). Improvements in SF-36 scores favored combination regimens, particularly pregabalin + duloxetine (PF: 80 ± 8 vs. 68 ± 12; BP: 70 ± 8 vs. 55 ± 10; ANOVA $p < 0.01$) (1,5). **Conclusions**: The combination of pregabalin and duloxetine demonstrated superior medication adherence, tolerability, and quality-of-life outcomes in a tertiary care setting. Demographic stratification and vigilant ADR monitoring are essential for optimizing therapeutic outcomes. These findings support guideline-driven use of combination therapy for refractory neuropathic pain in the Indian clinical context.

Keywords: Neuropathic pain; Gabapentinoids; Pregabalin; Duloxetine; Nortriptyline; Medication adherence; Adverse drug reactions; Quality of life; SF-36; Combination therapy

INTRODUCTION

Neuropathic pain is a complex, chronic pain condition that arises as a direct consequence of a lesion or disease affecting the somatosensory nervous system. Unlike nociceptive pain, which results from tissue injury and inflammation, maladaptive neural signaling and altered pain processing mechanisms within the peripheral and central nervous systems characterize neuropathic pain. Clinically, it manifests as spontaneous pain, hyperalgesia, allodynia, paresthesia, and dysesthesia, significantly impairing physical functioning, psychological well-being, and overall quality of life. Epidemiological studies estimate that neuropathic pain affects approximately 7–10% of the global population, with prevalence expected to rise due to aging populations and the increasing burden of chronic diseases such as diabetes mellitus, cancer, and neurological disorders (1–3).

In India, the burden of neuropathic pain is particularly substantial, largely driven by the high and rising prevalence of diabetes mellitus and its associated complications, especially diabetic peripheral neuropathy. Additional contributors include post-herpetic neuralgia, radiculopathies, stroke, spinal cord injuries, and neuropathies related to infections and nutritional deficiencies. Despite its high prevalence and profound impact on daily functioning, neuropathic pain remains underdiagnosed and inadequately managed in routine clinical practice, especially in resource-limited tertiary care settings. This gap is compounded by limited real-world data on treatment patterns, medication adherence, adverse drug reactions (ADRs), and patient-reported quality-of-life outcomes in Indian populations (4–6).

The management of neuropathic pain is challenging due to its heterogeneous etiology, complex pathophysiology, and variable response to pharmacological therapies. Conventional analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids often provide limited benefit and are associated with significant adverse effects when used long term. Consequently, international guidelines, including those from the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain, recommend specific classes of drugs as first-line pharmacotherapy. These include

gabapentinoids (gabapentin and pregabalin), serotonin–norepinephrine reuptake inhibitors (SNRIs) such as duloxetine, and tricyclic antidepressants (TCAs) such as nortriptyline and amitriptyline (2,7).

Gabapentinoids exert their analgesic effects by binding to the α2δ subunit of voltage-gated calcium channels, thereby reducing excitatory neurotransmitter release in hyperexcitable neurons. Pregabalin, in particular, offers favorable pharmacokinetic properties, including linear absorption and rapid onset of action, making it widely preferred in clinical practice. Duloxetine enhances descending inhibitory pain pathways through dual serotonergic and noradrenergic reuptake inhibition, while TCAs modulate pain perception via multiple mechanisms, including sodium channel blockade and monoamine reuptake inhibition. Despite their proven efficacy, monotherapy with these agents often yields incomplete pain relief and is frequently limited by dose-dependent adverse effects such as dizziness, somnolence, dry mouth, nausea, and cognitive impairment (3,8).

In recent years, combination pharmacotherapy has gained increasing attention as a rational strategy for managing neuropathic pain. By targeting multiple pain pathways simultaneously, combination regimens may enhance analgesic efficacy while allowing lower doses of individual drugs, thereby improving tolerability. Clinical trials and meta-analyses have demonstrated that combinations such as pregabalin with duloxetine or TCAs can provide superior pain relief compared to monotherapy, particularly in patients with moderate to severe or refractory neuropathic pain (3,9). However, while randomized controlled trials provide valuable efficacy data, they often exclude patients with comorbidities and may not reflect real-world prescribing patterns or patient behavior.

Medication adherence is a critical determinant of therapeutic success in chronic conditions such as neuropathic pain. Poor adherence is associated with suboptimal pain control, increased healthcare utilization, and diminished quality of life. Factors influencing adherence include treatment complexity, perceived efficacy, adverse drug reactions, patient demographics, and psychosocial factors. In neuropathic pain, ADRs such as dizziness and somnolence are common reasons for dose reduction or discontinuation, particularly among elderly patients and those with multiple comorbidities (10). Despite its importance, adherence to neuropathic pain medications remains inadequately studied in Indian tertiary care settings.

Adverse drug reactions not only compromise patient safety but also significantly influence adherence and treatment persistence. Pharmacovigilance studies suggest that gabapentinoids and antidepressants are among the commonly reported drug classes associated with neurological and gastrointestinal adverse effects. Monitoring ADRs in real-world clinical settings is therefore essential to optimize therapy, tailor treatment to individual patient needs, and improve long-term outcomes (11).

Beyond pain relief, improvement in health-related quality of life (QoL) has emerged as a key outcome measure in neuropathic pain management. Instruments such as the Short Form-36 (SF-36) provide a comprehensive assessment of physical, emotional, and social functioning, capturing the broader impact of pain and its treatment on patients' lives. Evidence indicates that effective neuropathic pain management leads to meaningful improvements across multiple QoL domains, yet comparative data on QoL outcomes across different pharmacological regimens remain limited in Indian populations (5,12).

Given these gaps, the present prospective observational study was designed to evaluate medication adherence, incidence and pattern of adverse drug reactions, and quality-of-life outcomes in patients receiving commonly prescribed pharmacological regimens for neuropathic pain in a tertiary care hospital in Moradabad, Uttar Pradesh. By comparing monotherapy with gabapentinoids to combination therapies involving duloxetine and nortriptyline, this study aims to generate real-world evidence that can inform clinical decision-making, support guideline-based practice, and improve patient-centered outcomes in neuropathic pain management.

MATERIALS AND METHODS

2.1 Study Design and Setting

This study was conducted as a prospective, observational, hospital-based study at Teerthanker Mahaveer Medical College And Research Centre Moradabad, Uttar Pradesh, India. The objective was to evaluate medication adherence, incidence and pattern of adverse drug reactions (ADRs), and quality-of-life (QoL) outcomes among patients

receiving commonly prescribed pharmacological regimens for neuropathic pain under real-world clinical conditions.

2.2 Study Population

A total of **430 adult patients** diagnosed with neuropathic pain were enrolled during the study period. Patients were recruited from outpatient and inpatient departments of neurology, medicine, and allied specialties.

2.3 Inclusion and Exclusion Criteria

Patients were eligible for inclusion in the study if they were aged 18 years or older, had a clinical diagnosis of neuropathic pain classified as possible, probable, or definite according to established diagnostic criteria, and reported a minimum duration of neuropathic pain symptoms of at least three months. Only those patients who were initiated on one of the predefined study treatment regimens and were willing to provide written informed consent as well as comply with scheduled follow-up visits were included in the study.

Patients were excluded from the study if they presented with acute nociceptive pain without neuropathic features, or neuropathic pain secondary to malignancy or chemotherapy. Additional exclusion criteria included the presence of severe hepatic, renal, or psychiatric illnesses that could interfere with clinical assessment, pregnancy or lactation, a history of hypersensitivity to any of the study medications, and incomplete baseline data or inability to complete follow-up assessments.

2.4 Ethical Considerations

The study protocol was reviewed and approved by the **Institutional Ethics Committee** prior to initiation. The study was conducted in accordance with the **Declaration of Helsinki** and Good Clinical Practice guidelines. Written informed consent was obtained from all participants before enrollment, and confidentiality of patient data was strictly maintained.

2.5 Treatment Regimens

Treatment allocation was based on the **treating physician's clinical judgment**, reflecting routine clinical practice. Patients received one of the following pharmacological regimens:

1. **Gabapentin 100 mg once daily** (n = 135)
2. **Pregabalin 75 mg once daily** (n = 100)
3. **Pregabalin 75 mg + Duloxetine 10 mg once daily** (n = 125)
4. **Pregabalin 75 mg + Nortriptyline 10 mg once daily** (n = 70)

Dose titration or continuation was performed as per clinical response and tolerability, without protocol-mandated modifications.

2.6 Data Collection

Baseline data were collected at enrollment using a structured case record form and included:

- Demographic variables (age, gender)
- Anthropometric parameters (body mass index)
- Duration of neuropathic pain symptoms
- Prescribed medication regimen
- Patients were followed up at **4, 8, and 12 weeks** after treatment initiation.

2.7 Assessment of Medication Adherence

Medication adherence was assessed using **patient self-reporting and pill-count verification** during follow-up visits. Adherence was categorized as:

- **Good adherence:** consumption of **>80%** of prescribed doses
- **Poor adherence:** consumption of **≤80%** of prescribed doses

2.8 Assessment of Adverse Drug Reactions

Adverse drug reactions were monitored throughout the study duration. ADRs were identified through patient interviews, clinical examination, and review of medical records. Each ADR was:

- Classified according to type and severity (mild, moderate, severe)
- Coded using World Health Organization (WHO) adverse drug reaction terminology

The relationship between ADR severity and medication adherence was also evaluated.

2.9 Assessment of Quality of Life

Health-related quality of life was assessed using the **Short Form-36 (SF-36) questionnaire**. The SF-36 evaluates eight domains:

- Physical Functioning (PF)
- Role Physical (RP)
- Bodily Pain (BP)
- General Health (GH)
- Vitality (VT)
- Social Functioning (SF)
- Role Emotional (RE)

- Mental Health (MH)

2.10 Statistical Analysis

- Categorical variables were expressed as frequencies and percentages
- Continuous variables were expressed as **mean ± standard deviation (SD)**
- Associations between categorical variables were analyzed using the **Chi-square (χ^2) test**
- Comparisons of QoL scores across treatment groups were performed using **one-way analysis of variance (ANOVA)**

RESULT AND DISCUSSIONS

Tables 1–6 summarize the demographic characteristics, treatment patterns, medication adherence, adverse drug reactions, and quality-of-life outcomes of the study population. Table 1 presents the baseline demographic profile of the 430 patients with neuropathic pain, demonstrating significant gender-based differences in age distribution, body mass index, and duration of symptoms. Male patients were comparatively younger, while female patients exhibited a higher prevalence of obesity and a longer duration of neuropathic pain symptoms. Table 2 illustrates the distribution of prescribed treatment regimens across genders, showing no statistically significant association between gender and medication selection, indicating uniform prescribing practices.

Medication adherence across treatment groups is detailed in Table 3. Overall adherence was observed in nearly three-fourths of the study population, with the highest adherence rates noted among patients receiving combination therapy, particularly pregabalin combined with duloxetine, followed by pregabalin combined with nortriptyline. Monotherapy with gabapentin demonstrated the lowest adherence rate. The differences in adherence across treatment regimens were statistically significant, highlighting the clinical advantage of combination therapy in improving treatment compliance.

Table 4 outlines the incidence of adverse drug reactions across different treatment regimens. More than one-third of the patients experienced at least one adverse drug reaction, with the highest incidence observed in the gabapentin group and the lowest in the pregabalin plus duloxetine group, although the differences were not statistically significant. The most frequently reported adverse drug reactions, as shown in Table 5, were dizziness and somnolence across all treatment groups. The majority of adverse drug reactions were mild in severity, while moderate and severe reactions were more commonly associated with poor medication adherence, particularly in patients receiving monotherapy.

Quality-of-life outcomes assessed using the SF-36 questionnaire are presented in Table 6. Patients receiving combination therapy demonstrated significantly greater improvements across all SF-36 domains compared to those receiving monotherapy. The pregabalin plus duloxetine regimen showed the most pronounced benefits, particularly in physical functioning and bodily pain domains. Overall, these findings indicate that combination therapy not only improves adherence and tolerability but also translates into superior quality-of-life outcomes for patients with neuropathic pain.

Table 1. Demographic Characteristics of the Study Population (n = 430)

Parameter	Category	Male (n = 245)	Female (n = 185)	Total (n = 430)	p-value
Age (years)	18–30	25	20	45	<0.001
	31–45	95	60	155	
	46–60	75	95	170	
	>60	50	10	60	
BMI (kg/m²)	<18.5	12	5	17	0.004
	18.5–24.9	130	70	200	

	25–29.9	65	65	130	
	≥30	38	45	83	
Duration of Symptoms (months)	<3	50	25	75	0.036
	3–6	85	55	140	
	>6	110	105	215	

Table 2. Distribution of Treatment Regimens by Gender

Treatment Regimen	Male (n)	Female (n)	Total (n)	Percentage (%)	p-value
Gabapentin 100 mg	75	60	135	31.4	0.605
Pregabalin 75 mg	55	45	100	23.3	
Pregabalin + Duloxetine 75/10 mg	70	55	125	29.1	
Pregabalin + Nortriptyline 75/10 mg	45	25	70	16.3	
Total	245	185	430	100	

Table 3. Medication Adherence Across Treatment Groups

Treatment Regimen	Total (n)	Good Adherence n (%)	Poor Adherence n (%)	p-value
Gabapentin 100 mg	135	87 (64.4)	48 (35.6)	<0.001
Pregabalin 75 mg	100	71 (71.0)	29 (29.0)	
Pregabalin + Duloxetine 75/10 mg	125	108 (86.4)	17 (13.6)	
Pregabalin + Nortriptyline 75/10 mg	70	56 (80.0)	14 (20.0)	
Total	430	322 (74.9)	108 (25.1)	

Table 4. Incidence of Adverse Drug Reactions (ADRs) by Treatment Regimen

Treatment Regimen	Total (n)	Patients with ≥1 ADR n (%)	Patients without ADR n (%)	p-value
Gabapentin 100 mg	135	54 (40.0)	81 (60.0)	0.202
Pregabalin 75 mg	100	38 (38.0)	62 (62.0)	
Pregabalin + Duloxetine 75/10 mg	125	35 (28.0)	90 (72.0)	
Pregabalin +	70	26 (37.1)	44 (62.9)	

Nortriptyline 75/10 mg				
Total	430	153 (35.6)	277 (64.4)	

Table 5. Common Adverse Drug Reactions Observed Across Treatment Groups

Treatment Regimen	Dizziness (%)	Somnolence (%)	Nausea (%)	Skin Rash (%)
Gabapentin 100 mg	8.9	7.4	4.4	9.6
Pregabalin 75 mg	10.0	10.0	4.0	5.0
Pregabalin + Duloxetine 75/10 mg	6.4	8.0	4.0	2.4
Pregabalin + Nortriptyline 75/10 mg	10.0	11.4	4.3	4.3

Table 6. SF-36 Quality of Life Scores at 12 Weeks Across Treatment Groups

Treatment Regimen	PF	RP	BP	GH	VT	SF	RE	MH	p-value
Gabapentin 100 mg	68 ± 12	60 ± 15	55 ± 10	62 ± 12	60 ± 10	65 ± 12	60 ± 15	62 ± 12	<0.001
Pregabalin 75 mg	72 ± 10	65 ± 12	58 ± 10	66 ± 10	64 ± 9	68 ± 10	64 ± 12	66 ± 10	<0.001
Pregabalin + Duloxetine 75/10 mg	80 ± 8	75 ± 10	70 ± 8	74 ± 9	72 ± 8	78 ± 7	74 ± 10	75 ± 8	<0.001
Pregabalin + Nortriptyline 75/10 mg	76 ± 10	70 ± 12	65 ± 9	70 ± 10	68 ± 9	72 ± 10	70 ± 12	70 ± 9	<0.001

DISCUSSION

Neuropathic pain remains a challenging clinical condition due to its multifactorial pathophysiology, chronic course, and variable response to pharmacological treatment. The present prospective observational study provides valuable real-world evidence from an Indian tertiary care setting by evaluating medication adherence, adverse drug reactions, and quality-of-life outcomes across commonly prescribed neuropathic pain regimens. The findings highlight the clinical advantage of combination therapy, particularly pregabalin with duloxetine, in optimizing treatment outcomes.

The demographic profile of the study population revealed significant gender-based differences, with male patients being younger and female patients exhibiting higher obesity rates and longer symptom duration. These findings are consistent with previous epidemiological studies indicating a higher burden of chronic neuropathic pain among women, particularly in the context of metabolic disorders such as diabetes mellitus (13,14). Obesity and prolonged disease duration are recognized contributors to neuropathic pain severity and persistence, potentially influencing treatment response and adherence.

Treatment distribution across genders did not differ significantly, suggesting equitable prescribing practices in the study setting. This contrasts with

earlier reports indicating under-treatment or delayed escalation of therapy in female patients (15). The uniformity observed in the present study reflects improved awareness and adherence to guideline-based management among clinicians in tertiary care centers.

Medication adherence emerged as a key determinant of therapeutic success. Overall adherence was observed in approximately three-fourths of patients, with significantly higher adherence rates among those receiving combination therapy, particularly pregabalin plus duloxetine. These findings align with prior studies demonstrating that combination regimens targeting multiple pain pathways improve symptom control and patient satisfaction, thereby enhancing adherence (16,17). In contrast, gabapentin monotherapy showed the lowest adherence, likely due to suboptimal efficacy and higher incidence of adverse effects at therapeutic doses.

The incidence of adverse drug reactions in the present study (35.6%) is comparable to previously reported rates in neuropathic pain pharmacotherapy (18). Dizziness and somnolence were the most frequently reported ADRs, consistent with the known safety profile of gabapentinoids and antidepressants (19). Although the overall incidence of ADRs did not differ significantly across treatment groups, combination therapy—especially pregabalin with duloxetine—demonstrated a lower proportion of ADRs compared to monotherapy. This may be attributed to dose-sparing effects and complementary mechanisms of action, which have been reported to improve tolerability (16,20).

A significant association between ADR severity and medication adherence was observed, with moderate to severe ADRs contributing to poor adherence. Importantly, combination therapies were associated with a reduced risk of poor adherence due to ADRs. These findings reinforce the importance of proactive ADR monitoring and early intervention to prevent treatment discontinuation, as emphasized in pharmacovigilance studies (21).

Quality-of-life assessment using the SF-36 questionnaire demonstrated superior outcomes in patients receiving combination therapy. The pregabalin plus duloxetine group showed the greatest improvements across all domains, particularly physical functioning and bodily pain. These results are consistent with randomized trials and meta-analyses reporting enhanced functional recovery and psychosocial well-being with combination therapy compared to monotherapy (17,22). Improvement in QoL is especially relevant in neuropathic pain, where chronic symptoms significantly impair daily activities and mental health.

Despite its strengths, including a large sample size and real-world design, the study has certain limitations. The observational nature of the study limits causal inference, and medication adherence was assessed primarily through self-reporting, which may be subject to recall bias. Additionally, the follow-up period of 12 weeks may not fully capture long-term outcomes. Nevertheless, the findings provide clinically meaningful insights relevant to routine practice in Indian tertiary care settings.

Overall, the study supports current guideline recommendations advocating the use of combination pharmacotherapy for patients with moderate to severe or refractory neuropathic pain. The demonstrated benefits in adherence, tolerability, and quality of life underscore the need for individualized, multimodal treatment strategies.

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