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Assessment of patient contentment with pharmacological interventions for presumed diabetic peripheral neuropathic pain: a cross-sectional investigation at a medical institution in eastern India.

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Abstract

Objective:

The increasing prevalence of diabetes mellitus has led to an increased prevalence of chronic complications. Diabetic peripheral neuropathies (DPN) are the most common chronic complications. It often presents as numbness, tingling, or pain in both legs and feet. Patients may experience problems with sleep, depression, and reduced quality of life (QOL). It is an underdiagnosed condition. Patients are often unsatisfied with treatment. Multiple medicines are approved for treatment, but to date, very few studies have determined the relationship between the diagnosis of DPN and satisfaction with treatment for pain.

Methods:

A cross-sectional observational study was done in 300 patients suffering from painful diabetic neuropathy in a tertiary care hospital in West Bengal. We assessed responses with gabapentin, pregabalin, nortriptyline, duloxetine, amitryptiline alone or in combination therapy. We measured the percentage of participants who reported satisfaction with treatment for bilateral foot pain based on a scale of 1 (very satisfied) to 5 (very unsatisfied), degree of improvement in actions in daily life, and improvement in QOL.

Results:

Amitriptyline monotherapy was the most commonly prescribed treatment, received by 126 patients (42% of total), followed by pregabalin (27%) and amitriptyline-pregabalin combination (26%). In our study, the amitriptyline-pregabalin combination scored better in patient satisfaction parameters like pain relief, quality of life, and activity of daily living as compared to monotherapies with pregabalin, gabapentin, amitryptiline.

Conclusion:

Patient satisfaction is variable in diabetic neuropathic pain management. It is influenced by multiple factors. Combination therapy of amitriptyline-pregabalin provided more symptomatic relief and improved quality of life as compared to monotherapy.

Recommendation:

Combination therapy, particularly amitriptyline–pregabalin, should be considered in patients with diabetic neuropathic pain to improve satisfaction, quality of life, and functional outcomes.

Keywords: *Diabetic neuropathy, neuropathic pain, satisfaction, quality of life, activity of daily living, combination, monotherapy.*

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Introduction

Globally, the burden of diabetes mellitus (dm) continues to grow at an alarming pace. Estimates indicate that approximately 537 million adults between the ages of 20 and 70 years—roughly one in ten individuals worldwide—currently live with the condition. Projections suggest this figure will climb to 643 million by 2030 and may reach 783 million by 2045.[1] The escalating prevalence of dm has correspondingly amplified the incidence of its long-term complications. Among these, diabetic peripheral neuropathies (dpns) represent the most frequently encountered chronic sequelae of diabetes.[2] the distal symmetric polyneuropathy (dspn) variant is particularly predominant, potentially affecting up to half of all individuals with type 2 dm (T2DM) over a ten-year disease course, and at minimum 20% of those with type 1 dm (T1DM) after two decades.[3] Notably, DSPN may already be present in 10–15% of individuals at the time of T2DM diagnosis.[4]

Diabetic peripheral neuropathic pain (dpnp), a clinical manifestation of dpn, is characteristically expressed as aberrant sensations including numbness, tingling, and discomfort, predominantly affecting the lower extremities distal to the knee.[4] beyond pain itself, affected individuals frequently report disruptions in sleep architecture, psychological comorbidities such as anxiety and depressive episodes, and a measurable decline in health-related quality of life (hrqol).[5–7] epidemiological data place the incidence of DPNP in diabetic populations at approximately 28% in the United States,[8,9] between 6% and 34% across European nations,[10], and between 28% and 37% in Japan.[11–13]

Though a notable proportion of patients with dpn may be entirely asymptomatic with respect to pain, painful dpn (pdpn) has been documented in approximately 6–34% of all people diagnosed with dm.[14] the clinical and humanistic burden attributable to pdpn is closely tied to the intensity of neuropathic pain, which adversely impairs daily functioning, degrades sleep quality and quantity, and compounds emotional distress through anxiety and depression, collectively reducing overall hrqol.

In the pharmacological landscape of peripheral dpnp management, GABA analogues—specifically pregabalin and gabapentin—have been designated as first-line therapeutic agents by numerous international health authorities. The 2013 guidelines issued by the National Institute for Health and Care Excellence (NICE) recommend gabapentin, pregabalin, amitriptyline, or duloxetine as initial treatment options, with tramadol reserved as a second-line choice.[15]

According to the american diabetes association, pregabalin and duloxetine constitute the first-line regimen; gabapentin and amitriptyline represent second-line alternatives; while opioid analgesics such as tramadol and tapentadol are positioned as third-line options. The American Academy of Neurology (AAN) 2011 guidelines similarly prioritize pregabalin as the first-line agent, with gabapentin, sodium valproate, amitriptyline, duloxetine, venlafaxine, opioids, capsaicin patch, lidocaine patch, and isosorbide dinitrate spray classified as second-line interventions.[16]

Despite the well-established prevalence of bilateral foot pain among patients receiving diabetes management, a direct correlation between DPNP diagnosis and patient contentment with pain treatment has not been definitively established, nor have the determinants of treatment satisfaction been clearly characterized. Evidence from a retrospective investigation conducted in the United States revealed that nearly half of individuals receiving active DPNP treatment discontinued their prescribed regimen within the first three months, indicating suboptimal satisfaction or tolerability issues.[12] These observations underscore a potential inadequacy in the current therapeutic approach to bilateral foot pain management.

Recognizing DPNP as an underdiagnosed entity and acknowledging patient dissatisfaction as a recurring theme in its management is crucial for enabling healthcare practitioners to refine their diagnostic and therapeutic strategies, ultimately translating into improved QOL for patients.

The pharmacological agents evaluated in this study—gabapentin, pregabalin, nortriptyline, and amitriptyline—are approved for the management of diabetic neuropathic pain. This investigation assessed patient-reported outcomes with these medications administered either as monotherapy or in combination.

Given that DPNP remains underrecognized and understudied in terms of its relationship with treatment satisfaction, this study was designed to identify more effective, safer, and economically viable therapeutic strategies for diabetic neuropathic pain. To date, limited investigations have explored the correlation between dpn diagnosis and patient contentment with pain management, and the predictors of treatment satisfaction remain insufficiently defined.

The present study aimed to assess patient contentment with pharmacological interventions for diabetic peripheral neuropathic pain and to identify treatment strategies associated with improved quality of life and daily functioning.

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Material and methods

Study design and setting

This was a **hospital-based cross-sectional observational study** conducted at the **College of Medicine & JNM Hospital, Kalyani, West Bengal**, a tertiary care teaching hospital catering to a large population from urban and rural areas. The institution provides specialized diabetes care through its diabetes and lifestyle OPD.

Study duration

The study was conducted from **August 2023 to January 2024**, over a period of six months.

Study population

A total of **300 patients diagnosed with painful diabetic peripheral neuropathy (DPNP)** attending the diabetes and lifestyle OPD were included.

Inclusion criteria

- Age ≥18 years
- Diagnosed diabetes mellitus
- Presence of neuropathic pain symptoms
- Ability to understand and respond to the questionnaire

Exclusion criteria

- Age <18 years
- Presence of diabetic foot ulcer
- Severe comorbid illness affecting participation

Sample size calculation:

Formula: $N = z^2 p(1–p) / d^2$

Where: N = required sample size; $z^2 = 1.96$; p = 20; d = 0.05

Calculated n = 246

Actual enrollment: 300 patients with diabetic neuropathic pain, recruited after obtaining informed consent

Participant recruitment:

Consecutive enrollment of all eligible participants satisfying the inclusion and exclusion criteria was adopted. The primary endpoint comprised the number and proportion of participants reporting satisfaction with pain management for bilateral foot symptoms, rated on a 5-point scale ranging from 1 (very satisfied) to 5 (very dissatisfied). Secondary endpoints included: (2) perceived improvement in activities of daily living (adl) afforded by treatment, rated from 1 (very good) to 5 (very poor); (3) improvement in qol attributed to treatment, similarly rated from 1 to 5; and (4) perceived quality of communication with the treating physician, rated from 1 (very good) to 5 (very poor).

Prescription analysis was conducted to determine which therapeutic strategies yielded higher satisfaction scores. Patient responses were recorded for gabapentin, pregabalin, nortriptyline, duloxetine, and amitriptyline administered as monotherapy or in combination. Mean scores for QOL and ADL were computed across different treatment cohorts.

Participant recruitment

A total of **342 patients were approached**, of which **300 eligible patients were included** after applying inclusion and exclusion criteria and obtaining informed consent.

Variables assessed

Independent variables:

- Type of pharmacological therapy (monotherapy vs combination)

Dependent variables:

- Patient satisfaction score
- Quality of life (QOL)
- Activity of daily living (ADL)

Other variables:

- Age, gender
- Duration of diabetes
- Duration of neuropathic pain

Data collection

Data were collected using a **structured patient questionnaire** assessing satisfaction on a 5-point Likert scale. Clinical and prescription data were recorded from OPD records.

Bias

Potential biases include selection bias due to hospital-based sampling and response bias due to self-reported satisfaction scores. These were minimized by consecutive patient recruitment and standardized questionnaire use.

Ethical considerations

The study was approved by the **institutional ethics committee of the College of Medicine & JNM Hospital, Kalyani** (approval date:

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04/09/2023). The study adhered to the Declaration of Helsinki.

Informed consent

Written informed consent was obtained from all participants prior to enrollment.

Results

A total of 342 patients were screened, of which 300 eligible participants were included in the study after applying the inclusion and exclusion criteria.

A total of 300 patients with confirmed diabetic neuropathy were enrolled in this investigation, comprising 134 male and 166 female participants.

Patient-reported outcomes were captured using a 5-point scoring system across four domains: Overall pain relief, activity of daily living, quality of life, and satisfaction with physician communication. These domain-specific scores were then used to evaluate the comparative effectiveness of various treatment modalities, whether prescribed as monotherapy or in combination.

In terms of prescribing frequency, amitriptyline monotherapy was the predominant regimen, administered to 126 patients (42% of the cohort). This was followed by pregabalin monotherapy in 81 patients (27%), and the amitriptyline–pregabalin combination regimen in 78 patients (26%). Gabapentin as sole therapy accounted for 3% of prescriptions, while the pregabalin–nortriptyline combination was prescribed to 2% of the study population.

Relief of pain satisfaction score across different treatment regimens

With regard to pain relief satisfaction, the pregabalin–amitriptyline combination yielded the highest mean score of 3.58 out of 5, followed by gabapentin monotherapy (mean score 3.33), amitriptyline monotherapy (mean score 3.09), and pregabalin monotherapy (mean score 2.73). The pregabalin–nortriptyline combination recorded a mean score of 1.

Regarding satisfaction in activities of daily living, the pregabalin–amitriptyline combination again achieved the highest mean score at 3.77 out of 5, succeeded by gabapentin monotherapy (mean score 3.33), amitriptyline monotherapy (mean score 2.71), and pregabalin monotherapy (mean score 2.44). The pregabalin–nortriptyline combination registered a mean score of 1.

When evaluating QOL-based satisfaction, the amitriptyline–pregabalin combination again demonstrated superior performance with a mean score of 3.5, followed by gabapentin monotherapy (mean 3.33), amitriptyline monotherapy (mean 2.74), and pregabalin monotherapy (mean 2.44). The pregabalin–nortriptyline combination recorded a mean QOL score of 1.

Physician communication satisfaction scores revealed a different ranking pattern. Patients prescribed the pregabalin–nortriptyline combination expressed the highest level of contentment with physician interaction (mean score 5.0), followed by those on the pregabalin–amitriptyline combination (mean 4.92), gabapentin (mean 4.66), pregabalin (mean 4.56), and amitriptyline monotherapy (mean 3.81).

Chi-square analysis was subsequently applied to determine whether observed differences across monotherapy and combination groups attained statistical significance.

Table 1: Relief of pain satisfaction

Drugs	Score >3 (%)	Score =3 (%)	Score <3 (%)	Chi-square (χ^2) (>table value)	P-value
Pregabalin	36 (44%)	18 (23%)	27 (33%)	40.87 (>15.07)	<0.01**
Gabapentin	3 (33%)	0 (0%)	6 (67%)		
Amitriptyline	33 (26%)	84 (67%)	9 (7%)		
Pregabalin + amitriptyline	0	33 (42%)	45 (58%)		
Pregabalin + nortriptyline	6 (100%)	0 (0%)	0 (0%)		

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Pain relief satisfaction showed a statistically significant variation ($p<0.01$) across the different treatment groups. The highest proportion of scores ≥3 was observed in the pregabalin + amitriptyline group, identifying it as the most effective combination for patient-reported pain relief.

Table 2: Activity of daily living satisfaction level

Drugs	Score >3 (%)	Score =3 (%)	Score <3 (%)	Chi-square (χ^2) (>table value)	P-value
Pregabalin	39	33	9	45.90 (15.07)	<0.001**
Gabapentin	3	0	6		
Amitriptyline	39	84	3		
Pregabalin + amitriptyline	0	36	42		
Pregabalin + nortriptyline	6	0	0		

Table 3: Quality of life satisfaction level

Drugs	Score >3 (%)	Score =3 (%)	Score <3 (%)	Chi-square (χ^2) (>table value)	P-value
Pregabalin	39	33	9	44.54 (15.07)	<0.001**
Gabapentin	3	0	6		
Amitriptyline	36	87	3		
Pregabalin + amitriptyline	0	39	39		
Pregabalin + nortriptyline	6	0	0		

Discussion

The present study demonstrated that combination therapy, particularly amitriptyline–pregabalin, resulted in significantly higher patient satisfaction, improved quality of life, and better daily functioning compared to monotherapy. Findings from a previously conducted investigation in japan[14] showed that merely 27.9% of study participants expressed satisfaction with their foot pain and numbness management. Interestingly, satisfaction was relatively higher with respect to drug tolerability than with therapeutic efficacy or financial impact. Patients who reported functional improvements in daily activities or experienced tangible enhancements in their quality of life were more likely to express treatment satisfaction. Favourable physician–patient communication also emerged as a determinant of satisfaction.

The key predictors of treatment satisfaction identified in that study were improvements in ADL, gains in QOL, and the quality of clinical communication. These findings are consistent with a prior investigation examining satisfaction among patients receiving either non-steroidal anti-inflammatory drugs or neuropathic pain pharmacotherapy for chronic pain conditions.[21]

In the present study, the amitriptyline–pregabalin combination consistently outperformed alternative regimens across core efficacy parameters, including pain alleviation, quality of life, and activities of daily living. Statistical analysis via chi-square testing confirmed that this combination achieved significantly greater patient satisfaction compared to monotherapy with pregabalin, gabapentin, or amitriptyline alone.

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A relevant landmark study, the option-dm randomised crossover trial, compared three sequential treatment pathways: Amitriptyline followed by pregabalin, duloxetine followed by pregabalin, and pregabalin followed by amitriptyline. All three pathways produced clinically meaningful and comparable reductions in baseline pain intensity scores, with no statistically or clinically significant differences detected between them. This trial represented the first rigorous randomised, double-blind, comparator trial evaluating neuropathic pain treatment sequences.[22] A practical takeaway from this trial is that many patients initiated on monotherapy will require a second agent in combination within a short timeframe. Our study reinforces this observation, as the pregabalin–amitriptyline combination consistently produced superior outcomes relative to any single-agent regimen.

Amitriptyline was chosen as the tricyclic antidepressant for this investigation owing to its status as the most widely prescribed agent in this drug class globally and its designation as a first-line option across the majority of established clinical guidelines.[4],[5]

Notwithstanding variability in cost and accessibility of amitriptyline, duloxetine, gabapentin, and pregabalin across different healthcare systems, the comparable analgesic efficacy of all three treatment pathways offers reassurance and practical utility for informing future clinical guidelines—particularly given the conflicting recommendations currently present across international guidelines for managing diabetic peripheral neuropathic pain.[23],[24]

No clinically meaningful differences were noted in the incidence of serious adverse events across treatment groups. A potential methodological limitation of this investigation is the absence of a placebo comparator arm. However, it is important to note that the pharmacological agents under evaluation are in established clinical use worldwide, and their efficacy is well-supported by regulatory and advisory endorsements—including those from NICE—which are based on an extensive body of evidence from placebo-controlled randomized trials, systematic meta-analyses, and Cochrane reviews.

Limitations

This study has certain limitations, including its cross-sectional design, single-center setting, and reliance on subjective patient-reported outcomes. Long-term follow-up and objective clinical measures were not assessed.

Recommendations

Combination therapy should be considered in patients with inadequate response to monotherapy. Further multicentric longitudinal studies are recommended to validate these findings.

Conclusion

Patient satisfaction in the context of diabetic neuropathic pain management is heterogeneous and is shaped by a constellation of factors. While multiple pharmacological options exist for this condition, the combined regimen of pregabalin and amitriptyline demonstrated superior symptomatic relief and quality of life outcomes when compared to single-agent therapies. This positions the combination as a preferred therapeutic strategy in this patient population.

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Generalizability

The findings can be generalized to similar tertiary care settings; however, applicability to primary care settings may be limited.

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This study did not receive any external funding.

Author contribution

All authors contributed to the study design, data collection, analysis, manuscript drafting, and final approval.

Author Contributions:

1. Corresponding author; responsible for protocol development, conceptual design, data interpretation, manuscript drafting, final approval, and accountability for all aspects of the work.
2. Responsible for data collection and literature retrieval; contributed to data acquisition, manuscript review, final approval, and work integrity.

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3. Contributed to statistical evaluation, results compilation, and discussion; participated in data analysis, manuscript review, final approval, and accountability.
4. Contributed to statistical evaluation and results; participated in data analysis, manuscript review, final approval, and work accountability.
5. Responsible for data collection and reference searches; contributed to data acquisition, manuscript review, final approval, and work accountability.

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Dr. Raju Dasgupta – statistician with expertise in biomedical data analysis.
Mukta Halder – MBBS student involved in data collection and research support.

Data availability

Data are available from the corresponding author upon reasonable request.

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