

EFFICACY OF GABAPENTIN VERSUS PREGABALIN IN PATIENTS OF PAINFUL DIABETIC PERIPHERAL NEUROPATHY

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Keywords:	ABSTRACT
Diabetic neuropathy, Duloxetine, Amitriptyline	<p>Introduction: Diabetic neuropathy is a common microvascular complication of diabetes mellitus. Major goal of pharmacological treatment in diabetic neuropathy is therefore to control pain. Several agents are used for relief of DPN, but Gabapentin and Pregabalin among the most widely prescribed pharmaceutical agents. The objective of study was to compare the efficacy of gabapentin versus pregabalin on symptomatic relief in patients with DPN.</p> <p>Material and Methods: This Randomized Control Trial was conducted at the Medicine OPD of Fauji Foundation Hospital, Islamabad. 150 patients of either sex with T2DM for more than 2 years having age between 25 and 75 years were enrolled. All patients were on any stable glucose-lowering medications for at least 4 weeks and having peripheral diabetic neuropathy. All the patients were randomly divided into two groups (75 patients in each group). Group A continued to be treated with Gabapentin at a dose of 600 mg/day and it was escalated to a maximum of 1800 mg/day once daily in night. Group B patients were given Pregabalin at a dose of 75 mg/day and it was escalated to a maximum of 300 mg/day once daily in night. Efficacy was assessed at 8th weeks. Data was analyzed on SPSS version 25.0. Chi square test was used to compare the efficacy of gabapentin and pregabalin in two groups after 8 weeks. Students t-test was used to compare mean VAS post treatment in both groups and P value ≤ 0.05 considered significant.</p>

Results: Pregabalin proved to be more effective than Gabapentin for treating DPN because patients in the Pregabalin group scored lower on VAS (3.79 ± 1.30) compared to the Gabapentin group (4.65 ± 1.27) ($p < 0.001$). The mean difference in VAS scores between the two groups was 0.87 (95% CI: 0.45 to 1.28), indicating a statistically significant reduction in pain with Pregabalin. On the other hand, a higher proportion of patients in the Pregabalin group (48.0%) achieved a $\geq 50\%$ reduction in pain scores compared to the Gabapentin group (25.3%) ($p < 0.001$). This suggests that Pregabalin was more effective in achieving significant pain relief.

Conclusions: Pregabalin demonstrated superior efficacy compared to Gabapentin in reducing pain scores and achieving a $\geq 50\%$ reduction in pain in patients with painful diabetic peripheral neuropathy. The efficacy of Pregabalin was consistently higher across various subgroups, including gender, age, BMI, duration of DPN, and HbA1C levels. These findings suggest that Pregabalin may be a more effective treatment option for managing painful DPN, particularly in specific patient subgroups.

INTRODUCTION

Painful diabetic neuropathy (PDN) is a common and debilitating complication of diabetes, affecting about 30-50% of diabetic patients.¹ It causes chronic pain, tingling, and numbness, primarily in the lower extremities, significantly impairing quality of life.² Treatment goals in DPN patients include pain modulation, enhanced glucose control, restoration of function, and patient education.³ Managing PDN remains challenging, as no approved treatment has been emerged yet that restore nerve function.⁴ Simple analgesics may provide partial, short-term relief, but more specifically targeted drugs are normally required for sustained control of pain of neuropathic origin. Several agents are used for pain relief which include drugs like Duloxetine, Gabapentin, Pregabalin, Amitryptaline & Venlafexine.^{5,6}

Both gabapentin and pregabalin, classified as gabapentinoids, work by targeting the $\alpha 2\delta$ subunit of voltage-gated calcium channels to reduce neuronal hyperexcitability and alleviate pain. Despite their similar mechanisms, they differ in pharmacokinetics, dosing, and clinical efficacy, sparking debate over their comparative effectiveness.^{7,8} Gabapentin, initially an antiepileptic, has nonlinear absorption, requiring careful dose titration to balance efficacy and side effects like dizziness and somnolence. Pregabalin, designed to overcome gabapentin's limitations, has linear pharmacokinetics, higher bioavailability, and simpler dosing, making it a preferred choice for many. Both drugs have demonstrated efficacy in reducing pain and improving quality of life in PDN patients, but head-to-head comparisons are limited and yield mixed results.^{9,10} Some studies suggest pregabalin may offer better pain relief, while others find them comparable.^{11,12,13,14} Cost also plays a role, with gabapentin often being more cost-effective, especially in resource-limited settings. Beyond pain relief, both drugs improve sleep, mood, and overall well-being, which are critical given the high rates of depression and insomnia in PDN patients. However, they carry risks,

including cognitive impairment, weight gain, and potential for misuse, particularly in those with a history of substance use. Long-term safety and efficacy remain under investigation, with concerns about tolerance and diminishing effectiveness over time.^{11,12,13,14} Patient-specific factors, such as age, renal function, and comorbidities, further complicate the choice between gabapentin and pregabalin. Both require dose adjustments in renal impairment, and pregabalin's association with weight gain may influence decisions in obese or cardiovascular patients. Despite guidelines, no universal algorithm exists for selecting between the two, with decisions often based on clinician experience, patient preferences, and practical considerations like cost and insurance coverage.

MATERIALS AND METHODS

This randomized control trial was conducted at Medicine Department of Fauji Foundation Hospital, Rawalpindi from July 2022 to July 2023. 150 patients of either sex with type II diabetes for more than 2 years having age between 25 and 75 years were enrolled. All patients were on any stable glucose-lowering medications during the preceding month having peripheral diabetic neuropathy for at least 4 weeks. Patients with clinically significant or unstable medical or psychiatric illnesses, pregnant or lactating mothers, patients having renal or hepatic dysfunction, having uncontrolled hypertension and taking anticonvulsants, antidepressants, local anesthetics were excluded from the study. Patients were enrolled for the study after taking informed written consent. Detailed history was taken and thorough general and systemic examination was performed. The nervous system examination was done. Vibration sensations were checked by using 256Hz tuning fork. The tuning fork was placed on bony prominences like medial malleolus, distal part of 1st metatarsal bone and patella. The loss of vibration sensations was suggestive of peripheral neuropathy. Similarly, proprioception is checked by moving the patient's big toe from the midposition above and below. Two out of three times if patient didn't judge the position of big toe, suggestive of peripheral neuropathy. Pinprick sensations are checked by using common pin. All the patients were randomly divided into two groups (75 patients in each group). Group A continued to be treated with Gabapentin at a dose of 600 mg/day and it was escalated to a maximum of 1800 mg/day once daily in night. Group B patients were given Pregabalin at a dose of 75 mg/day and it was escalated to a maximum of 300 mg/day once daily in night. Doses were adjusted following each visit after examination. Efficacy was assessed at 8th weeks. All the patients were subjected to a two weeks run-in period in order to achieve a baseline state during which the patients were withdrawn from treatment. Pain was defined as an unpleasant feeling often caused by intense or damaging stimuli. It was measured on visual analog pain scale (VAS) in which patient score his pain from 0 = no pain to 10 = worse possible pain. While, efficacy of either intervention or drug was measured in terms of Pain reduction. Pain reduction will be measured on reduction of VAS score on subsequent follow up visits and labelled as effective if 50% reduction from baseline score was achieved. Demographic as well as clinical details along with study findings were recorded for data analysis. Data was analyzed on SPSS version 25.0. Chi square test was used to compare the efficacy of gabapentin and pregabalin in two groups after 8 weeks. Students t-test was used to compare mean VAS post treatment in both groups and P value ≤ 0.05 considered significant.

RESULTS

The study population was male dominant as 54% of the population was male, with a mean age of 48.32 ± 15.78 years in the Gabapentin group and 44.84 ± 15.47 years in the Pregabalin group. Data revealed that more than half of the studied participants (58.7%) exceeded the age of 40. Participants with body mass index more than 25 kg/m^2 made up 78.7% of subjects across both study groups without showing statistical differences between groups. The treatment duration for diabetic peripheral neuropathy showed no significant difference between Gabapentin and Pregabalin groups and the same went for HbA1C values. Patients showed no significant difference between the initial VAS pain scale ratings in either group (Gabapentin: 6.39 ± 1.03 ; Pregabalin: 6.68 ± 0.92). Both study groups were analyzed for descriptive statistics of their quantitative and qualitative variables through table 1 and table 2.

During the analysis Pregabalin proved more effective than Gabapentin for treating diabetic pain because patients in the Pregabalin group scored lower on VAS (3.79 ± 1.30) compared to the Gabapentin group (4.65 ± 1.27) ($p < 0.001$). The mean difference in VAS scores between the two groups was 0.87 (95% CI: 0.45 to 1.28), indicating a statistically significant reduction in pain with Pregabalin. On the other hand, a higher proportion of patients in the Pregabalin group (48.0%) achieved a $\geq 50\%$ reduction in pain scores compared to the Gabapentin group (25.3%) ($p < 0.001$). This suggests that Pregabalin was more effective in achieving significant pain relief (table 3).

Patients in the Gabapentin group showed increased mean VAS scores for females versus males yet every gender demonstrated major pain relief with Pregabalin treatment ($p = 0.002$ for females; $p = 0.016$ for males). The patients in the Pregabalin treatment group achieved better results with improved response rates in both genders ($p = 0.032$ for females and $p = 0.073$ for males).

The mean VAS score for patients 40 years and younger receiving Gabapentin therapy exceeded the VAS score of patients older than 40. Pregabalin proved superior treatment for patients from both younger and older groups ($p = 0.003$ for ≤ 40 years and $p = 0.007$ for > 40 years groups). Among patients over 40 years old in the Pregabalin group the treatment success rate was statistically greater than those younger than 40 years ($p = 0.019$).

Some patients with a BMI $\leq 25 \text{ kg/m}^2$ in the Gabapentin group reported the highest mean VAS score yet Pregabalin proved to provide the most evident pain relief in this subgroup ($p < 0.001$). Evaluations showed that patients with BMI $\leq 25 \text{ kg/m}^2$ in the Pregabalin group achieved maximum treatment success which produced statistically important outcomes than patients in the Gabapentin group ($p = 0.002$).

The severity of pain scored using VAS was higher among patients in the Gabapentin group who suffered DPN for longer than 12 weeks. Patients who received Pregabalin treatment experienced better outcomes when their duration of diabetic polyneuropathy exceeded twelve weeks ($p < 0.001$). The Pregabalin treatment group achieved better outcomes for patients with DPN longer than 12 weeks duration resulting in statistically relevant differences ($p = 0.021$) for inclusion periods above twelve weeks.

Among patients taking Gabapentin with HbA1C levels at or below 8% the VAS average score was higher than those with HbA1C above 8%. The treatment outcome of Pregabalin proved better in patients who had HbA1C levels below 8% ($p < 0.001$). The Pregabalin treatment resulted in the

best pain control efficacy among patients with HbA1C levels at or below 8% which showed a statistically significant difference against treatment with Gabapentin ($p = 0.001$). Detailed stratification analysis for mean VAS score and efficacy is illuminated in table 4 and 5.

Table 1: Demographic and clinical details of the quantitative variables of the study participants (n=150; 75 in each group)

Demographic and Clinical Quantitative Variables	Group A (Gabapentin)		Group B (Pregabalin)	
	Mean	± SD	Mean	± SD
Age (Years)	48.32	15.78	44.84	15.47
Body Mass Index (kg/m ²)	28.13	3.47	27.49	3.22
Duration of DPN (weeks)	14.52	4.51	13.76	5.31
HbA1C (%)	8.81	1.40	8.71	1.60
Baseline VAS	6.39	1.03	6.68	0.92

Table 2: Clinical, demographic and comorbid details of study subjects in both groups (n=150; 75 in each group)

Demographic and Clinical Qualitative Variables		Group A (Gabapentin) n (%)	Group B (Pregabalin) n (%)	Total
Gender	Male	37 (49.3%)	44 (58.7%)	81 (54.0%)
	Female	38 (50.7%)	31 (41.3%)	69 (46.0%)
Age	≤ 40 Years	29 (38.7%)	33 (44.0%)	62 (41.3%)
	> 40 Years	46 (61.3%)	42 (56.0%)	88 (58.7%)
Body Mass Index	≤ 25 Years kg/m ²	14 (18.7%)	18 (24.0%)	32 (21.3%)
	> 25 Years kg/m ²	61 (81.3%)	57 (76.0%)	118 (78.7%)
Duration of DPN Groups	≤ 12 weeks	26 (34.7%)	38 (50.7%)	64 (42.7%)
	>12 weeks	49 (65.3%)	37 (49.3%)	86 (57.3%)
HbA1C Groups (%)	≤ 8	25 (33.3%)	33 (44.0%)	58 (38.7%)
	> 8	50 (66.7%)	42 (56.0%)	92 (61.3%)

Table 3: Stratification of mean \pm SD VAS score for various effect modifiers (gender, age, BMI, duration of DPN and HbA1C)

Effect Modifiers		Study Groups	N	Mean VAS	± Std. Deviation	p-value (Paired sample t-Test)
Gender	Male	Gabapentin (A)	37	4.49	1.30	0.016
		Pregabalin (B)	44	3.75	1.37	
	Female	Gabapentin (A)	38	4.82	1.23	0.002
		Pregabalin (B)	31	3.84	1.21	
Age (Years)	≤ 40	Gabapentin (A)	29	4.79	1.37	0.003
		Pregabalin (B)	33	3.73	1.33	
	> 40	Gabapentin (A)	46	4.57	1.20	0.007
		Pregabalin (B)	42	3.83	1.29	
BMI (Kg/m²)	≤ 25	Gabapentin (A)	14	5.14	0.95	0.000
		Pregabalin (B)	18	3.33	1.19	
	> 25	Gabapentin (A)	61	4.54	1.31	0.013
		Pregabalin (B)	57	3.93	1.31	
Duration of DPN (Weeks)	≤ 12	Gabapentin (A)	26	4.46	1.21	0.072
		Pregabalin (B)	38	3.84	1.41	
	> 12	Gabapentin (A)	49	4.76	1.30	0.000
		Pregabalin (B)	37	3.73	1.19	
HbA1C (%)	≤ 8	Gabapentin (A)	25	4.96	1.21	0.000
		Pregabalin (B)	33	3.52	1.18	
	> 8	Gabapentin (A)	50	4.50	1.28	0.073
		Pregabalin (B)	42	4.00	1.36	

Table 5: Efficacy of Gabapentin and Pregabalin for reducing PDN (n=150; 75 in each group)

Efficacy	Group A (Gabapentin)	Group B (Pregabalin)	Total
Yes	19	36	55
	25.3%	48.0%	36.7%
No	56	39	95
	74.7%	52.0%	63.3%
Total	75	75	150
	100.0%	100.0%	100.0%

Table 5: Stratification of efficacy for various effect modifiers (gender, age, BMI, duration of DPN and HbA1C)

Variables			Study Groups		p-Value (χ^2 -test)
			Gabapentin (A)	Pregabalin (B)	
Gender	Male	Yes	12 (32.4%)	23 (52.3%)	0.073
		No	25 (67.6%)	21 (47.7%)	
	Female	Yes	07 (18.4%)	13 (41.9%)	0.032
		No	31 (81.6%)	18 (58.1%)	
Age (Years)	≤ 40	Yes	09 (31.0%)	17 (51.5%)	0.103
		No	20 (69.0%)	16 (48.5%)	
	> 40	Yes	10 (21.7%)	19 (45.2%)	0.019
		No	36 (78.3%)	23 (54.8%)	
BMI (Kg/m ²)	≤ 25	Yes	01 (7.1%)	11 (61.1%)	0.002
		No	13 (92.9%)	07 (38.9%)	
	> 25	Yes	18 (29.5%)	25 (43.9%)	0.106
		No	43 (70.5%)	32 (56.1%)	
Duration of DPN (Weeks)	≤ 12	Yes	8 (30.8%)	19 (50.0%)	0.126
		No	18 (69.2%)	19 (50.0%)	
	> 12	Yes	11 (22.4%)	17 (45.9%)	0.021
		No	38 (77.6%)	20 (54.1%)	
HbA1C (%)	≤ 8	Yes	4 (16.0%)	19 (57.6%)	0.001
		No	21 (84.0%)	14 (42.4%)	
	> 8	Yes	15 (30.0%)	17 (40.5%)	0.293
		No	35 (70.0%)	25 (59.5%)	

DISCUSSION

Pain management for diabetic peripheral neuropathy presents a major clinical hurdle and Gabapentin and Pregabalin stand as the principal prescribed pharmaceutical options.¹⁵ This study focused on determining which of these two medications worked best for reducing pain and generating better results among patients dealing with painful DPN. Research shows that Pregabalin provides superior pain relief outcomes to Gabapentin especially within selected patient populations.^{15,16} Findings of our research support existing knowledge structures about these two medications yet reveal fresh information regarding the way they affect different patient groups based on their background particulars.

The results of this study are consistent with existing literature on the efficacy of Pregabalin in neuropathic pain management. Several randomized controlled trials and meta-analyses have demonstrated that Pregabalin is superior to Gabapentin in reducing pain intensity and improving patient outcomes in diabetic neuropathy. For instance, a recent review¹⁷ found that Pregabalin provided better pain relief and was associated with a higher proportion of patients achieving significant pain reduction compared to Gabapentin. The pharmacological properties of Pregabalin, such as its higher bioavailability and faster onset of action, may contribute to its superior efficacy. Additionally, it improved patient-reported outcomes, resulted in lower opioid consumption, and led to fewer adverse events. In another study, Athanasakis et al¹⁸ (2013) reported that the treatment of pain associated with DPN with pregabalin is a cost-effective intervention compared to gabapentin. Thus, these findings need to be taken into consideration in the decision – making process when considering which therapy to use for the treatment of neuropathic pain. Arvinath and Suganya¹⁹ (2022) in their study concluded that pregabalin is more efficacious when compared to Gabapentin among Type 2 diabetes mellitus patients with painful peripheral neuropathy. Hence, they conclude that Pregabalin provided significant improvement in pain relief and other perspectives. Singh T et al in their study concluded that it is important to treat patients with painful diabetic neuropathy with tailor-made approach. Monotherapy with Pregabalin or Gabapentin produced clinically meaningful pain relief however; pain reduction was superior with Pregabalin compared to Gabapentin. Therefore, it is suggested that Pregabalin could be a better therapeutic option in patients with painful diabetic neuropathy.²⁰ Contrary to our findings, Robertson reported that gabapentin was superior to pregabalin and should be commenced before pregabalin to permit optimal crossover of medicines.²¹

Additionally, the stratified analysis in this study aligns with previous findings that Pregabalin is particularly effective in specific patient subgroups, such as those with lower BMI, shorter duration of DPN, and better glycemic control ($HbA1C \leq 8\%$). These findings suggest that Pregabalin may be more effective in patients with less severe metabolic derangements and earlier stages of neuropathy, which is consistent with the notion that early intervention in diabetic neuropathy yields better outcomes.²²

This study employed a randomized, comparative design with equal allocation of patients to both treatment groups, minimizing selection bias and ensuring balanced baseline characteristics. Our study conducted a detailed subgroup analysis based on gender, age, BMI, duration of DPN, and HbA1C levels, providing insights into the differential efficacy of Pregabalin and Gabapentin across diverse patient populations. The VAS was used to assess pain intensity, which is a widely accepted and validated tool for measuring neuropathic pain. The study focused on a common and debilitating complication of diabetes, providing practical insights into the management of painful DPN, which is a significant clinical challenge.

The results from this research establish important clinical guidelines for treating patients with painful DPN. The better pain-reducing outcomes and relief success of pregabalin treatment makes it the preferred choice for people with diabetic neuropathy especially in subgroups whose features include lower body mass index with short time span of DPN and good blood sugar levels. Medical staff must include these risk factors into their determination of fitting treatments for patients

experiencing painful DPN. The analysis demonstrated that physicians need to personalize treatment strategies based on individual patient needs. Treatment outcomes for diabetic neuropathy depend on individual characteristics such as age and gender together with BMI and HbA1C levels which support the importance of personalized therapy in pain management for diabetes neuropathy.

Our study possesses various strengths yet several minor weaknesses exist. The evaluation of pain results took place just one month after treatment delivery but does not provide information about long-term clinical effectiveness or safety for Pregabalin and Gabapentin. Additional observation time would deliver broader insight about lasting pain reduction together with all possible adverse effects of treatment. A larger sample would strengthen the research findings by promoting wider applicability of data across patient populations. A placebo group should have been included in the study because its absence makes it challenging to determine the complete therapeutic effects of Gabapentin and Pregabalin in comparison to a non-treatment control. The research performed its investigations at one healthcare location which reduces the effectiveness of extending these results across different health systems and patient demographics. Treatment results were not assessed for their response to comorbid conditions including depression and anxiety as well as other chronic pain types among patients with diabetic neuropathy.

CONCLUSIONS

Patients who receive Pregabalin as treatment experience better pain reduction compared to those who receive Gabapentin for painful diabetic peripheral neuropathy. Past studies support these results while emphasizing how treatment effectiveness depends on patient-specific characteristics. Future research needs to address two main limitations which include the short follow-up period and no placebo group within the study design. The research shows Pregabalin should be considered a first-choice medication for painful DPN symptoms across particular patient groups though additional studies should focus on optimal care strategies for this severe condition.

Conflict of Interest: Nil

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