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Original Research Article

A COMPARATIVE ANALYSIS OF EFFICACY AND SAFETY OF PREGABALIN VERSUS DULOXETINE IN MANAGING DIABETIC NEUROPATHY

GUL K*[1], KHAN Y[1], BILAL M[1], KHAN AU[2], SALMAN M[1]

[1]*Department of Medicine, Lady Reading Hospital, Peshawar, Pakistan*
[2]*Department of Medicine, Khalifa Gulnawaz Teaching Hospital, Bannu, Pakistan*
**Corresponding author email address:* khayaligull@gmail.com

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ABSTRACT

Background: *Diabetic neuropathy is a common complication of diabetes mellitus, often leading to significant morbidity and impaired quality of life. Pharmacological management includes agents such as pregabalin and duloxetine, but comparative evidence on their efficacy and safety remains limited in local populations.* ***Objective:*** *To compare the efficacy and safety of pregabalin versus duloxetine in the management of diabetic neuropathy at Lady Reading Hospital, Peshawar.* ***Study Design:*** *Randomized controlled trial.* ***Setting:*** *Department of Medicine, Lady Reading Hospital, Peshawar, Pakistan.* ***Duration of Study:*** *05-December-2024 to 05-June-2025.* ***Methods:*** *A total of 160 patients aged 30–75 years with confirmed diabetes mellitus and clinically diagnosed diabetic neuropathy were randomly assigned to two equal groups. Group A received pregabalin (300 mg/day) and Group B received duloxetine (60 mg/day). Efficacy was evaluated by improvement in neuropathic symptoms and physical examination findings. Safety was assessed based on the occurrence of adverse events, including constipation, decreased appetite, and lethargy. Statistical analysis was performed using SPSS version 25, with chi-square and t-tests applied as appropriate; p-values <0.05 were considered statistically significant.* ***Results:*** *In the duloxetine group, 77.5% of patients achieved symptomatic improvement compared to 61.2% in the pregabalin group ($p < 0.05$). Adverse event profiles were comparable between the two groups. Pregabalin was associated with a higher incidence of lethargy (11.2%), while duloxetine had slightly more cases of constipation (7.5%), with no statistically significant difference ($p > 0.05$).* ***Conclusion:*** *Duloxetine demonstrated significantly greater efficacy than pregabalin in managing diabetic neuropathy, while both drugs exhibited similar safety profiles. Duloxetine may be considered a preferred option in this patient population.*

Keywords: Diabetic Neuropathy, Pregabalin, Duloxetine, Efficacy, Safety

INTRODUCTION

Diabetes is a significant global health issue affecting roughly 500 million individuals worldwide. The worldwide incidence is increasing considerably and is expected to reach 700 million by 2045 (1). Diabetic neuropathy (DN) reflects a significant as well as prevalent complication of diabetes, showing a lifetime prevalence exceeding 50% in individuals with the condition (2). DN can manifest in various ways due to multiple potential sites of damage to nerves. This review will focus on the most common and extensively researched type, hereafter referred to as DN. DN is a progressive and often debilitating condition. Sensory symptoms demonstrate a range of manifestations, such as numbness as well as dysesthesia, typically in the feet and progressing proximally. Motor function may be compromised, resulting in weakness, gait problems, and impaired coordination that impede patients' ability to perform daily living tasks. Recent studies recognise the significant psychosocial effects as well as implications for quality of life associated with DN (3-6). Additionally, DN significantly contributes to the risk of ulceration of the diabetic foot (7).

The treatment of neuropathic pain within diabetes presents an important obstacle for clinicians, leading to the development of multiple clinical guidelines aimed at determining the most successful therapies for affected patients (3, 8). Duloxetine as well as pregabalin are recognised as initial therapies for painful diabetic neuropathy (DPN) according to international guidelines (9, 10). Duloxetine functions as a norepinephrine as well as serotonin reuptake inhibitor. The mechanism of action involves enhancing serotonergic and noradrenergic activity within the CNS's descending inhibitory pain pathways (11). Pregabalin is classified as an anticonvulsant. It reduces the discharge of excitatory neurotransmitters linked to pain perception by attaching to presynaptic neuronal calcium routes (12). Pregabalin and duloxetine are both suggested as initial treatment options for symptom management. A study compared the efficacy of pregabalin (65.1%) and duloxetine (84.1%) in managing DN (13).

Both pregabalin and duloxetine have emerged as prominent pharmacological options for neuropathic pain management; however, comparative efficacy and safety data between these two agents remain limited, especially in the context of diabetic neuropathy, due to the paucity of literature on this subject locally. The goal of this study is to compare the efficacy and safety of pregabalin versus duloxetine in managing diabetic neuropathy at our hospital setup. Understanding the relative efficacy and safety profiles of pregabalin and duloxetine is crucial for our medical professionals to optimize treatment strategies, enhance patient outcomes, and minimize adverse events associated with neuropathic pain management in diabetic patients. The findings of this study will also fill this gap by providing valuable insights into their respective roles in managing diabetic neuropathy and guiding evidence-based clinical decision-making.

METHODOLOGY

This study was conducted as a randomized controlled trial at the Department of General Medicine, Lady Reading Hospital, Peshawar, spanning from 05/December/2024 to 05/June/2025, following ethical approval from the hospital. The sample was calculated with the help of the WHO sample size calculator based on a power of 80%, 95% confidence level, and efficacy rates of 65.1% for pregabalin and 84.1% for duloxetine, as reported in prior literature (14). This yielded 160 patients with 80 assigned to each treatment group using blocked randomization. Non-probability consecutive sampling was applied.

Patients included in our study were males and females aged 30 to 75 years diagnosed with diabetes mellitus and diabetic neuropathy. These criteria encompassed laboratory confirmation of diabetes (HbA1c > 6.5% or ongoing anti-diabetic treatment for 3–5 years) and diabetic neuropathy symptoms including pain (Visual Analog Scale score > 3), tingling and numbness in the distal lower extremities, progressing proximally verified by physical examination findings such as sensory deficits, impaired ankle reflexes and foot ulcers. Patients with vitamin B12 or folic acid deficiency, abnormal thyroid-stimulating hormone levels, autoimmune disorders, or neurological conditions were not included.

Consent was obtained from all participants. Demographic details were recorded for each participant. Patients in Group A received pregabalin at a dose of 300 mg daily, while those in Group B received duloxetine at a dose of 60 mg daily, both administered for eight weeks. The efficacy of each treatment was assessed after this period based on the alleviation of neuropathic symptoms (pain, tingling, and numbness) and improvements in sensory deficits, reflexes, and foot ulcers as determined through physical examination. Safety was evaluated by monitoring the frequency of adverse effects, specifically constipation (defined as straining or passing lumpy/hard stools in at least 25% of defecations), decreased appetite (notable reduction in desire to eat), and lethargy (abnormal drowsiness or fatigue). All assessments were conducted under the supervision of a consultant with at least five years of post-fellowship experience, and data were recorded using a pre-designed proforma.

For analyzing the data, SPSS 25 was used. Age, height, weight, BMI, and duration of diabetes were summarized as means with standard deviations. Gender, efficacy, education status, safety, occupation, socioeconomic status, and residence were presented as frequencies and percentages. The efficacy of pregabalin and duloxetine was compared using a chi-square test, with a p-value of less than 0.05 considered statistically significant. Age, gender, BMI, duration of diabetes, education, occupation, socioeconomic status, and residence were stratified, and efficacy and safety were assessed using the chi-square test, maintaining the same significance threshold.

RESULTS

Group A had a mean age of 63.49±11.01 years, while Group B was slightly younger with a mean age of 60.59±11.63 years. The mean BMI was comparable between the two groups, with Group A at 26.56±1.87 and Group B at 26.48±1.72 kg/m^2. The duration of diabetes was also similar, averaging 7.49±2.09 years for Group A and 6.99±2.27 years for Group B. Both groups consisted of 80 participants. Demographic analysis revealed that Group A included 44 (55.0%) males and 36 (45.0%) females, whereas Group B had 45 (56.2%) males and 35 (43.8%) females (Table 1).

Regarding efficacy, duloxetine showed notably higher efficacy, 62 (77.5%), compared to 49 (61.2%) efficacy in the pregabalin group (P = 0.02). Safety profiles revealed that duloxetine was associated with fewer adverse effects, as 70 (87.5%) participants reported no adverse effects, whereas 64 (80.0%) in the pregabalin group experienced none. Specific adverse effects included constipation in 3 (3.8%) of Group A and 6 (7.5%) of Group B, decreased appetite in 4 (5.0%) of Group A and 2 (2.5%) of Group B and lethargy in 9 (11.2%) of Group A compared to only 2 (2.5%) of Group B. However, the safety profile did not exhibit a notable difference across groups (P = 0.09) (Table 2). Stratifications can be observed from Table No. 3 to Table No. 11.

Table 1: Demographics

Demographics		**Groups**			
		Group A (Pregabalin)		**Group B (Duloxetine)**	
		n	%	n	%
Gender	Male	44	55.0%	45	56.2%
	Female	36	45.0%	35	43.8%
Education	Educated	42	52.5%	37	46.2%
	Uneducated	38	47.5%	43	53.8%
Occupation status	Employed	41	51.2%	38	47.5%
	Unemployed	39	48.8%	42	52.5%
Residence	Urban	32	40.0%	41	51.2%
	Rural	48	60.0%	39	48.8%
Socioeconomic status	Lower class	19	23.8%	23	28.8%
	Middle class	41	51.2%	40	50.0%
	Upper class	20	25.0%	17	21.2%

Table 2: Comparison of efficacy and safety between the two groups

		Groups				**P value**
		Group A (Pregabalin)		**Group B (Duloxetine)**		
		n	%	n	%	
Efficacy	Yes	49	61.2%	62	77.5%	0.02
	No	31	38.8%	18	22.5%	
Safety	Constipation	3	3.8%	6	7.5%	0.09
	Decrease appetite	4	5.0%	2	2.5%	
	Lethargy	9	11.2%	2	2.5%	
	No adverse effect	64	80.0%	70	87.5%	

Table 3: Stratification of comparison of efficacy between both groups with demographics

				Groups				**P value**
				Group A (Pregabalin)		**Group B (Duloxetine)**		
				n	%	n	%	
Gender	Male	Efficacy	Yes	29	65.9%	31	68.9%	0.76
			No	15	34.1%	14	31.1%	

	Female	Efficacy	Yes	20	55.6%	31	88.6%	0.002
			No	16	44.4%	4	11.4%	
Education	Educated	Efficacy	Yes	20	47.6%	28	75.7%	0.01
			No	22	52.4%	9	24.3%	
	Uneducated	Efficacy	Yes	29	76.3%	34	79.1%	0.76
			No	9	23.7%	9	20.9%	
Occupation status	Employed	Efficacy	Yes	24	58.5%	25	65.8%	0.05
			No	17	41.5%	13	34.2%	
	Unemployed	Efficacy	Yes	25	64.1%	37	88.1%	0.01
			No	14	35.9%	5	11.9%	
Residence	Urban	Efficacy	Yes	17	53.1%	31	75.6%	0.04
			No	15	46.9%	10	24.4%	
	Rural	Efficacy	Yes	32	66.7%	31	79.5%	0.18
			No	16	33.3%	8	20.5%	
Socioeconomic status	Lower class	Efficacy	Yes	17	89.5%	17	73.9%	0.20
			No	2	10.5%	6	26.1%	
	Middle class	Efficacy	Yes	23	56.1%	35	87.5%	0.002
			No	18	43.9%	5	12.5%	
	Upper class	Efficacy	Yes	9	45.0%	10	58.8%	0.40
			No	11	55.0%	7	41.2%	
Age groups (Years)	30 to 45	Efficacy	Yes	7	87.5%	9	90.0%	0.86
			No	1	12.5%	1	10.0%	
	45 to 60	Efficacy	Yes	4	28.6%	16	64.0%	0.03
			No	10	71.4%	9	36.0%	
	61 to 75	Efficacy	Yes	38	65.5%	37	82.2%	0.05
			No	20	34.5%	8	17.8%	
BMI (Kg/m2)	18 to 24.9	Efficacy	Yes	10	58.8%	15	78.9%	0.19
			No	7	41.2%	4	21.1%	
	> 24.9	Efficacy	Yes	39	61.9%	47	77.0%	0.06
			No	24	38.1%	14	23.0%	
Duration of diabetes (Years)	< = 5	Efficacy	Yes	9	81.8%	13	86.7%	0.73
			No	2	18.2%	2	13.3%	
	> 5	Efficacy	Yes	40	58.0%	49	75.4%	0.03
			No	29	42.0%	16	24.6%	

Table 4: Stratification of the comparison of safety between the two groups with age

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Age groups (Years)	30 to 45	Safety	Constipation	1	12.5%	0	0.0%	0.41Z
			Decrease appetite	0	0.0%	1	10.0%	
			Lethargy	0	0.0%	1	10.0%	
			No adverse effect	7	87.5%	8	80.0%	
	45 to 60	Safety	Constipation	1	7.1%	3	12.0%	0.36
			Decrease appetite	1	7.1%	0	0.0%	
			Lethargy	0	0.0%	0	0.0%	
			No adverse effect	12	85.7%	22	88.0%	
	61 to 75	Safety	Constipation	1	1.7%	3	6.7%	0.06
			Decrease appetite	3	5.2%	1	2.2%	
			Lethargy	9	15.5%	1	2.2%	
			No adverse effect	45	77.6%	40	88.9%	

Table 5: Stratification of comparison of safety between both groups by gender

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Gender	Male	Safety	Constipation	1	2.3%	5	11.1%	0.19
			Decrease appetite	0	0.0%	1	2.2%	
			Lethargy	3	6.8%	1	2.2%	
			No adverse effect	40	90.9%	38	84.4%	
	Female	Safety	Constipation	2	5.6%	1	2.9%	0.07
			Decrease appetite	4	11.1%	1	2.9%	

			Lethargy	6	16.7%	1	2.9%	
			No adverse effect	24	66.7%	32	91.4%	

Table 6: Stratification of the comparison of safety between the two groups with education

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Education	Educated	Safety	Constipation	0	0.0%	1	2.7%	0.54
			Decrease appetite	2	4.8%	1	2.7%	
			Lethargy	3	7.1%	1	2.7%	
			No adverse effect	37	88.1%	34	91.9%	
	Uneducated	Safety	Constipation	3	7.9%	5	11.6%	0.14
			Decrease appetite	2	5.3%	1	2.3%	
			Lethargy	6	15.8%	1	2.3%	
			No adverse effect	27	71.1%	36	83.7%	

Table 7: Stratification of comparison of safety between both groups with occupation status

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Occupation status	Employed	Safety	Constipation	1	2.4%	2	5.3%	0.28
			Decrease appetite	2	4.9%	2	5.3%	
			Lethargy	6	14.6%	1	2.6%	
			No adverse effect	32	78.0%	33	86.8%	
	Unemployed	Safety	Constipation	2	5.1%	4	9.5%	0.27
			Decrease appetite	2	5.1%	0	0.0%	
			Lethargy	3	7.7%	1	2.4%	
			No adverse effect	32	82.1%	37	88.1%	

Table 8: Stratification of the comparison of safety between the two groups with residence

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Residence	Urban	Safety	Constipation	2	6.2%	3	7.3%	0.12
			Decrease appetite	2	6.2%	0	0.0%	
			Lethargy	4	12.5%	1	2.4%	
			No adverse effect	24	75.0%	37	90.2%	
	Rural	Safety	Constipation	1	2.1%	3	7.7%	0.32
			Decrease appetite	2	4.2%	2	5.1%	
			Lethargy	5	10.4%	1	2.6%	
			No adverse effect	40	83.3%	33	84.6%	

Table 9: Stratification of the comparison of safety between the two groups with socioeconomic status

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	%	n	%	
Socioeconomic status	Lower class	Safety	Constipation	1	5.3%	3	13.0%	0.74
			Decrease appetite	1	5.3%	1	4.3%	
			Lethargy	2	10.5%	1	4.3%	
			No adverse effect	15	78.9%	18	78.3%	
	Middle class	Safety	Constipation	2	4.9%	3	7.5%	0.31
			Decrease appetite	2	4.9%	1	2.5%	
			Lethargy	3	7.3%	0	0.0%	
			No adverse effect	34	82.9%	36	90.0%	
	Upper class	Safety	Constipation	0	0.0%	0	0.0%	0.27
			Decrease appetite	1	5.0%	0	0.0%	
			Lethargy	4	20.0%	1	5.9%	
			No adverse effect	15	75.0%	16	94.1%	

Table 10: Stratification of comparison of safety between the two groups with BMI

	Groups				P value
	Group A (Pregabalin)		Group B (Duloxetine)		
	n	%	n	%	

BMI (Kg/m^2)	18 to 24.9	Safety	Constipation	1	5.9%	2	10.5%	0.71
			Decrease appetite	1	5.9%	0	0.0%	
			Lethargy	1	5.9%	1	5.3%	
			No adverse effect	14	82.4%	16	84.2%	
	> 24.9	Safety	Constipation	2	3.2%	4	6.6%	0.09
			Decrease appetite	3	4.8%	2	3.3%	
			Lethargy	8	12.7%	1	1.6%	
			No adverse effect	50	79.4%	54	88.5%	

Table 11: Stratification of comparison of safety between both groups with duration of diabetes

				Groups				P value
				Group A (Pregabalin)		Group B (Duloxetine)		
				n	5	n	%	
Duration of diabetes (Years)	≤ 5	Safety	Constipation	1	9.1%	0	0.0%	0.41
			Decrease appetite	0	0.0%	1	6.7%	
			Lethargy	0	0.0%	1	6.7%	
			No adverse effect	10	90.9%	13	86.7%	
	> 5	Safety	Constipation	2	2.9%	6	9.2%	0.01
			Decrease appetite	4	5.8%	1	1.5%	
			Lethargy	9	13.0%	1	1.5%	
			No adverse effect	54	78.3%	57	87.7%	

DISCUSSION

The present study compared the efficacy and safety of pregabalin and duloxetine in managing diabetic neuropathy. The results demonstrated that both duloxetine showed notably higher efficacy (77.5%) compared to pregabalin (61.2%). Safety profiles revealed that duloxetine was associated with fewer adverse effects, such as constipation (7.5%) and lethargy (2.5%), whereas pregabalin had higher rates of lethargy (11.2%) and a lower constipation rate.

In the study by Nagra et al., duloxetine exhibited a significantly greater mean reduction in pain scores (3.23±1.38) compared to pregabalin (1.63±1.07) over 12 weeks (p=0.0001) (14). This supports our findings where duloxetine showed superior efficacy. The study also highlighted that duloxetine was particularly effective in older patients and those with longer diabetes duration, suggesting its suitability for advanced neuropathy cases.

Similarly, Shahid et al. reported a mean reduction in VAS scores from 6.81±0.91 to 4.01±1.12 with duloxetine compared to 6.99±1.12 to 4.91±0.82 with pregabalin, further corroborating duloxetine's efficacy. They also documented that constipation was more common in the duloxetine group and lethargy was more common in the pregabalin group, which aligns well with our findings. Similar to our study, they documented a similar safety profile for both drugs (15).

Another study by Warrier et al. compared pregabalin and duloxetine in combination with methylcobalamin. The results indicated that duloxetine combined with methylcobalamin provided better pain relief compared to pregabalin combination therapy with MCB. Additionally, sleep interference scores improved more with duloxetine than with pregabalin (16). These findings resonate with our observations, where duloxetine was not only more effective but also improved secondary outcomes, such as a lower incidence of adverse effects. Their study also noted fewer adverse effects with duloxetine, reinforcing its favorable safety profile.

In contrast, the study by Shah et al. (2022) reported comparable efficacy between duloxetine (81.4%) and pregabalin (74.4%), though duloxetine had a slightly higher response rate. However, the safety profile favored pregabalin with fewer severe adverse effects compared to duloxetine. This discrepancy in safety outcomes could be attributed to differences in study design or patient demographics. (17)

Gulzar et al. conducted a six-week RCT and found no notable difference in pain relief between duloxetine and pregabalin. This contrasts with our results, where duloxetine showed a clearer advantage. The shorter duration of their study (six weeks vs. our eight-week follow-up) may explain this difference, as duloxetine's effects might take longer to manifest fully. Additionally, their study reported similar adverse effect profiles with pregabalin causing more sedation and duloxetine leading to gastrointestinal disturbances. These findings suggest that while duloxetine is effective, its side effects may vary depending on the population (18).

Based on the collective evidence, duloxetine appears to be a more effective option for diabetic neuropathic pain, particularly in patients with moderate to severe symptoms. However, pregabalin remains a viable alternative, especially for those who cannot tolerate duloxetine's side effects. Future studies should explore longer-term outcomes and the impact of combination therapies, such as adding methylcobalamin, to optimize treatment strategies.

CONCLUSION

In conclusion, the efficacy of duloxetine was significantly better than that of pregabalin in the management of diabetic neuropathy; however, both drugs had a similar safety profile.

DECLARATIONS

Data Availability Statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned. (IRB-849/LRH/MTI)

Consent for publication

Approved

Funding

Not applicable

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

KHAYALI GUL **(**Postgraduate Resident**)**
Data Collection, Data Entry, Data Analysis, Study Design, Manuscript drafting, Review of manuscript, and Final Approval of Manuscript
YASEEN KHAN **(**Professor**)**
Conception of Study Design, Critical input, and Final Approval of Manuscript
MUHAMMAD BILAL **(**Associate Professor**)**
Critical Input, and Literature Search
ASIM ULLAH KHAN **(**Postgraduate Resident**)**
Literature Search
MUHAMMAD SALMAN **(**Postgraduate Resident**)**
Review of Literature.

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