

A Comparative Study to Evaluate the Safety and Efficacy of Gabapentin Versus Pregabalin in Neuropathic Pain

Mariam Susan Satheesh*¹, Pheba Susan Thomas¹, Dr S Vijayalekshmi²,
Dr. Santhosh M Mathews³

¹Department of Pharmacy Practice, Pushpagiri College of Pharmacy, Thiruvalla, Kerala, India

²Professor, Department of Neuromedicine, Pushpagiri Medical College Hospital, Thiruvalla, Kerala, India

³Principal, Pushpagiri College of Pharmacy, Thiruvalla, Kerala, India

Abstract

Introduction: Neuropathic pain is a chronic condition that significantly affects pain, sleep, daily functioning, and quality of life. Gabapentin and pregabalin are commonly used pharmacological treatments, but their comparative effectiveness and safety remain clinically relevant. To compare the safety and efficacy of pregabalin and gabapentin in patients with neuropathic pain, with respect to pain reduction, quality of life, sleep quality, medication adherence, and adverse drug reactions.

Methods: A prospective observational study was conducted among 94 patients with neuropathic pain, comprising 47 patients receiving pregabalin and 47 receiving gabapentin. Pain was assessed using the Short Form McGill Pain Questionnaire and pain scale, quality of life using EQ-5D, sleep quality using the Pittsburgh Sleep Quality Index, medication adherence using the Medication Adherence Rating Scale, and adverse drug reactions using the Naranjo Causality Assessment Scale.

Results: The majority (75) used insulin syringes, while 38 used pens. Baseline assessments using the BIAS scale identified administration errors. Following the educational intervention and pharmacist counselling, insulin administration accuracy improved from 83.3% to 100% in syringe users and from 81.8% to 100% in pen users. Medication adherence also significantly improved post-education.

Conclusion: Both pregabalin and gabapentin were effective in improving pain, sleep quality, and quality of life in patients with neuropathic pain. Pregabalin demonstrated significantly greater pain reduction, while medication adherence and sleep improvement were comparable between the groups. The differing patterns of adverse drug reactions highlight the importance of individualized treatment selection.

Keywords: Neuropathic pain, Pregabalin, Gabapentin, Pain reduction, Quality of life, Sleep quality, Medication adherence, Adverse drug reactions.

INTRODUCTION

This study is conducted to resolve the clinical uncertainty regarding whether Pregablin or Gabapentin is superior for treating neuropathic pain. The study is specifically comparing the drugs across four domains: analgesic efficacy (pain reduction scores), patient reported outcomes (sleep, medication adherence and quality of life), safety (incidence of side effects) [1,2]. Ultimately, the goal is to determine if Pregablin is having more predictable bioavailability and a faster pain relief with better patient tolerability as compared to Gabapentin [3,4]. Gabapentin and Pregablin are the two commonly drugs that are given to treat neuropathic pain. While Gabapentin is widely used due to its lower cost and longer history, its saturable absorption creates unpredictable blood levels, making it difficult to determine the most effective dose for a specific patient. By aggregating data from the participants, this study provides the statistical power to confirm whether Pregablin's more predictable bioavailability actually translates into superior pain relief, faster onset of action and improved quality of life [5,6].

MATERIALS AND METHODS

Study Design

A prospective observational study was conducted in the Department of Neuromedicine at Pushpagiri Medical College Hospital, Thiruvalla, Kerala.

Study Population

Neuropathic patients in the Neuromedicine department, Pushpagiri Medical College Hospital, Thiruvalla and who is meeting the inclusion and exclusion criteria.

Sample Size

A total of 47 patients from each group receiving Gabapentin and Pregablin are included in the stud.

Inclusion Criteria

Male and female inpatients and outpatients with a diagnosis of neuropathic pain who are 18 years of age or older and on either gabapentin or pregablin will be included in the trial. The study includes neuromedicine department inpatients and outpatients who willingly provide consent.

Exclusion Criteria

The study will exclude patients who do not provide consent, those admitted to departments other than Neuromedicine, and patients who are pregnant or lactating women and to those with other pain conditions, those receiving any other analgesics and those who have Psychiatric disorders.

Study Procedure

It was a 6-month study that was conducted after getting approval from the ethical committee. Patients were selected based on predefined inclusion and exclusion criteria. Informed consent was obtained from each participant. The drugs used in this study is Pregablin and Gabapentin. Initial and final data from the patients were collected with a

review period of 1 month. Demographic details and prescription information will be prospectively collected from case records and patient interviews. Various Questionnaires are included in the study. The effectiveness of drug under study under study is assessed using Short Form McGill Pain Questionnaire. The quality of life is assessed using EQ-5D Health Questionnaire and sleep quality is determined using Pittsburgh Sleep Quality Index. Medication Adherence is determined using Medication Adherence Rating Scale and the safety of drugs is assessed using Naranjo Causality Assessment scale.

Statistical Analysis

Data will be properly coded and entered in Microsoft Excel and statistically analysed using SPSS software, version 23.

RESULTS AND DISCUSSION

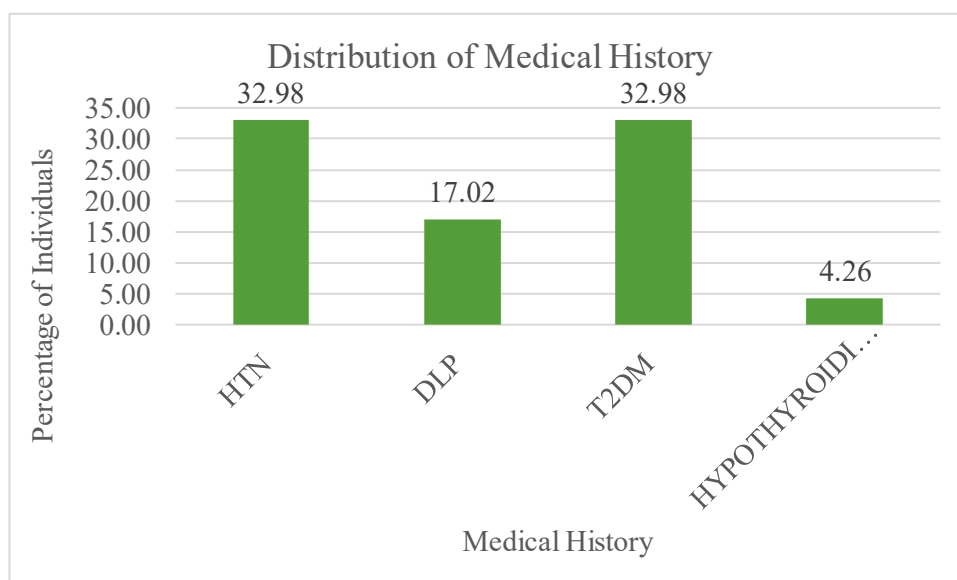
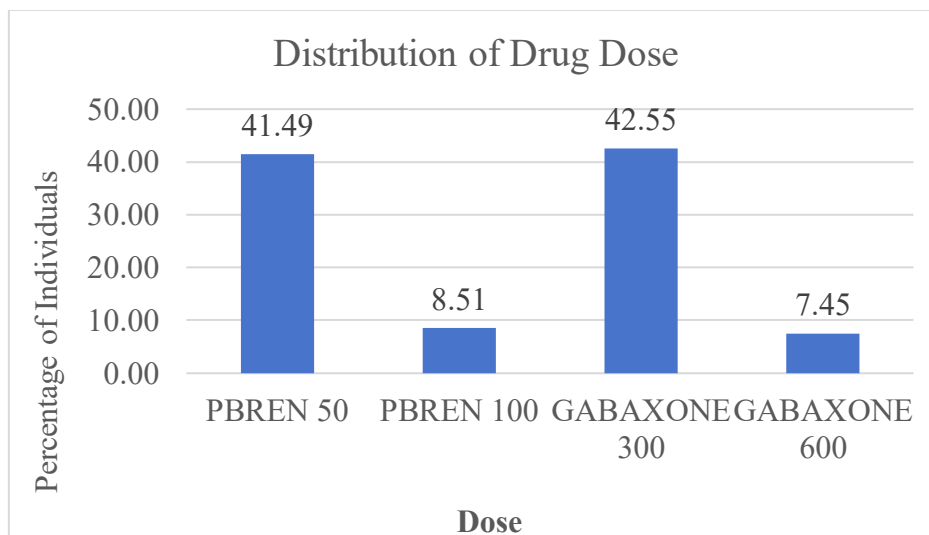
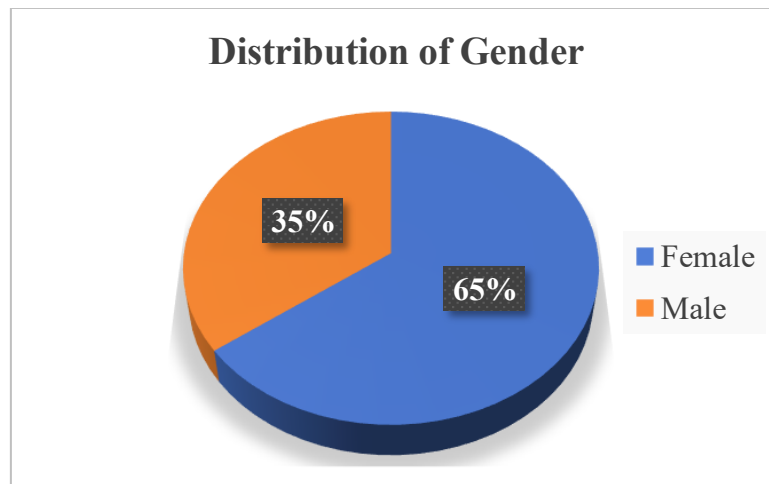
Table 1: Baseline Demographic and Clinical Characteristics of Patients

		Frequency	Percent
GENDER	Female	61	64.9
	Male	33	35.1
Type Of Drug	Pregabalin	47	50
	Gabapentin	47	50
DOSE	PBREN 50	39	41.49
	PBREN 100	8	8.51
	GABAXONE 300	40	42.55
	GABAXONE 600	7	7.45
Medical History	HTN	31	32.98
	DLP	16	17.02
	T2DM	31	32.98
	HYPOTHYROIDISM	4	4.26

A total of 94 patients with neuropathic pain were included in the study. Females constituted the majority of participants (64.9%), while males accounted for 35.1%. The study population was equally distributed between the two treatment groups, with 47 patients (50%) receiving pregabalin and 47 patients (50%) receiving gabapentin, ensuring balanced comparison between the drugs.

Regarding dosage distribution, most patients received PBREN 50 (41.49%) and GABAXON (42.55%), while smaller proportions received PBREN 100 (8.51%) and the higher dose of GABAXON (7.45%).

Among comorbid conditions, hypertension (HTN) and type 2 diabetes mellitus (T2DM) were the most common, each present in 32.98% of patients, followed by dyslipidemia (DLP) in 17.02% and hypothyroidism in 4.26%. These findings indicate that the study population had a substantial burden of metabolic and cardiovascular comorbidities, which are commonly associated with neuropathic pain conditions.



	Mean ± SD
Age	57.66 ± 14.001

The mean age of the study participants was 57.66 ± 14 years, indicating that most patients belonged to the middle-aged to elderly population commonly affected by neuropathic pain.

Table 2: Distribution of EQ-5D Quality of Life Responses Before and After Treatment among Patients with Neuropathic Pain

		Frequency	Percent
MOBILITY BEFORE	1	1	1.1
	2	3	3.2
	3	15	16
	4	67	71.3
	5	8	8.5
MOBILITY AFTER	1	2	2.1
	2	64	68.1
	3	20	21.3
	4	7	7.4
	5	1	1.1
SELF CARE BEFORE	2	9	9.6
	3	31	33
	4	54	57.4
SELF CARE AFTER	1	1	1.1
	2	51	54.3
	3	27	28.7
	4	15	16
PAIN BEFORE	2	11	11.7
	3	44	46.8
	4	37	39.4
	5	2	2.1
PAIN AFTER	1	1	1.1
	2	52	55.3
	3	29	30.9
	4	11	11.7
	5	1	1.1
ANXIETY BEFORE	2	10	10.6
	3	38	40.4
	4	42	44.7
	5	4	4.3
ANXIETY AFTER	1	2	2.1
	2	64	68.1
	3	16	17
	4	10	10.6
	5	2	2.1

USUAL ACTIVITIES BEFORE	2	9	9.6
	3	35	37.2
	4	50	53.2
USUAL ACTIVITIES AFTER	1	4	4.3
	2	39	41.5
	3	31	33
	4	20	21.3
MC GILL Before	Low	11	11.70
	Moderate	31	33.00
	High	52	55.30
MC GILL AFTER	Low	50	53.20
	Moderate	43	45.70
	High	1	1.10

The EQ-5D quality of life assessment demonstrated considerable improvement in patients with neuropathic pain following treatment with pregabalin or gabapentin. Across all EQ-5D domains, there was a noticeable shift from higher severity levels before treatment to lower severity levels after treatment, indicating enhanced quality of life and functional status.

In the **mobility** domain, the majority of patients were initially concentrated at level 4 (71.3%), reflecting severe mobility problems. After treatment, most patients shifted to level 2 (68.1%), suggesting marked improvement in movement and physical functioning.

Similarly, in the **self-care** domain, 57.4% of patients were at level 4 before treatment, whereas after treatment the majority were at level 2 (54.3%), indicating improved ability to perform personal care activities independently.

The **pain/discomfort** dimension also showed substantial improvement. Before treatment, most patients reported moderate to severe pain, with 46.8% at level 3 and 39.4% at level 4. Following treatment, 55.3% of patients were at level 2, demonstrating reduction in pain severity.

In the **anxiety/depression** domain, severe psychological distress was common before treatment, with 44.7% of patients at level 4. After treatment, most patients shifted to level 2 (68.1%), suggesting improvement in emotional well-being and reduction in anxiety-related symptoms.

For **usual activities**, more than half of the participants (53.2%) reported severe impairment (level 4) before treatment. After therapy, the distribution shifted toward lower severity levels, particularly level 2 (41.5%), indicating better performance of routine daily activities.

The **McGill Pain Score** findings further supported the improvement in patient outcomes. Before treatment, the majority of patients had high pain scores (55.3%), whereas after treatment, most patients were categorized as having low (53.2%) or moderate pain (45.7%), with only 1.1% remaining in the high pain category.

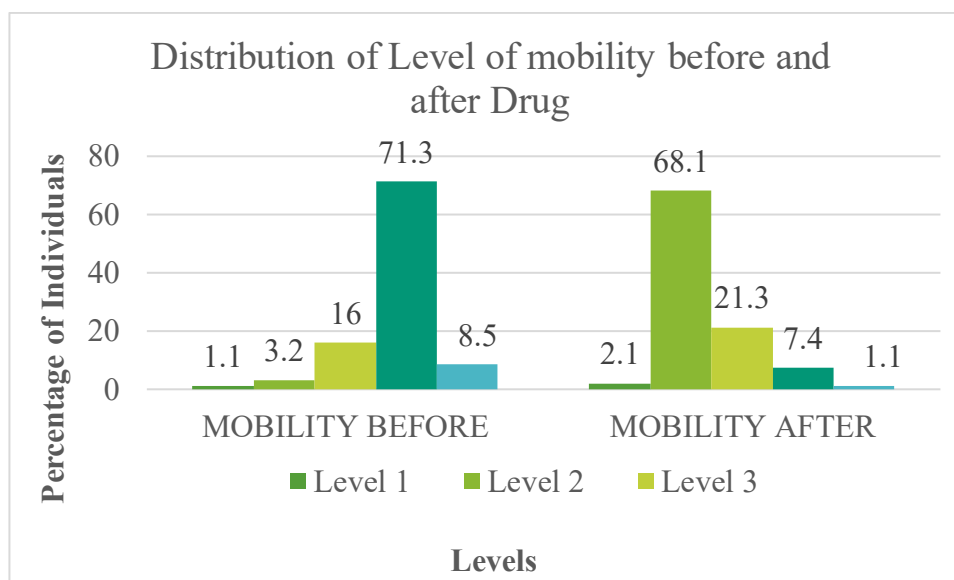


Table 3: Medication Adherence among Patients with Neuropathic Pain Receiving Pregabalin or Gabapentin

Medication adherence	Drug	Frequency	Percent
Good Adherence	Pregabalin	43	91.49
	Gabapentin	44	93.62
Poor Adherence	Pregabalin	4	8.51
	Gabapentin	3	6.38

Comparison of medication adherence between the two treatment groups showed that both pregabalin and gabapentin users demonstrated high adherence rates. Among patients receiving pregabalin, 43 out of 47 patients (91.49%) exhibited good adherence, while 4 patients (8.51%) had poor adherence. Similarly, among gabapentin users, 44 out of 47 patients (93.62%) showed good adherence and only 3 patients (6.38%) demonstrated poor adherence.

Table 4: Comparison of Adverse Drug Reaction Causality Assessment between Pregabalin and Gabapentin Users

Adverse effect of drug	Drug	Frequency	Percent
DEFINITE	Pregabalin	3	6.38
	Gabapentin	14	29.79
PROBABLE	Pregabalin	27	57.45
	Gabapentin	30	63.83
POSSIBLE	Pregabalin	17	36.17
	Gabapentin	3	6.38

Assessment of adverse drug reaction (ADR) causality revealed differences between the pregabalin and gabapentin treatment groups. Among patients receiving pregabalin, the majority of ADRs were categorized as probable (57.45%), followed by possible reactions (36.17%), while only 6.38% were classified as definite.

Similarly, in the gabapentin group, most ADRs were categorized as probable (63.83%). However, a comparatively higher proportion of definite adverse reactions was observed with gabapentin (29.79%) compared to pregabalin (6.38%). Only 6.38% of ADRs in the gabapentin group were categorized as possible.

Table 5: Comparison of Difference in Pain Scale Scores Between Pregabalin and Gabapentin Groups Using Mann–Whitney U Test

	TYPE	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig.
Difference pain Scale	Pregabalin	53.76	2526.5	810.5	0.006
	Gabapentin	41.24	1938.5		

The Mann–Whitney U test was used to compare the difference in pain scale scores between patients treated with pregabalin and gabapentin. The pregabalin group demonstrated a higher mean rank (53.76) compared to the gabapentin group (41.24), indicating greater improvement in pain scores among patients receiving pregabalin.

The obtained p-value was 0.006, which is less than the conventional level of significance ($p < 0.05$). This indicates that the difference in pain reduction between the two treatment groups was statistically significant.

Table 6: Within-Group Comparison of Pain Scale Scores Before and After Treatment in the Pregabalin Group Using Wilcoxon Signed-Rank Test

Pregabalin Group		Mean Rank	Sum of Ranks	Z	Asymp. Sig.
Pain Scale Scores Before and After Treatment	Negative Ranks	24	1128	-6.28	0.000
	Positive Ranks	0	0		

The Wilcoxon signed-rank test was used to compare pain scale scores before and after treatment within the pregabalin group. The analysis showed only negative ranks, indicating that pain scores decreased after treatment in all patients who demonstrated a change in scores. No positive ranks were observed, suggesting that none of the patients experienced worsening of pain following treatment.

The calculated Z value was -6.28 with a p-value of 0.000 ($p < 0.05$), demonstrating a statistically significant reduction in pain scores after treatment with pregabalin.

Table 7: Within-Group Comparison of Pain Scale Scores Before and After Treatment in the Gabapentin Group Using Wilcoxon Signed-Rank Test

Gabapentin Group		Mean Rank	Sum of Ranks	Z	Asymp. Sig.
Pain Scale Scores Before and After Treatment	Negative Ranks	24.83	943.5	-4.356	0.000
	Positive Ranks	20.5	184.5		

The Wilcoxon signed-rank test was used to compare pain scale scores before and after treatment within the gabapentin group. The presence of higher negative ranks (sum of ranks = 943.5) compared to positive ranks (sum of ranks = 184.5) indicates that most patients experienced a reduction in pain scores following gabapentin therapy. However, a small number of patients showed increased pain scores after treatment, as reflected by the positive ranks.

The calculated Z value was -4.356 with a p-value of 0.000 ($p < 0.05$), indicating a statistically significant difference between pain scores before and after treatment.

Table 8: Comparison of Medication Adherence Between Pregabalin and Gabapentin Groups Using Chi-Square Test

		Type of Drug		p Value
		Pregabalin	Gabapentin	
Medication adherence	Good Adherence	43	44	0.5
		49.40%	50.60%	
	Poor Adherence	4	3	
		57.10%	42.90%	

The Chi-square test was used to compare medication adherence between patients receiving pregabalin and gabapentin. Among patients with good adherence, 43 patients (49.40%) were in the pregabalin group and 44 patients (50.60%) were in the gabapentin group. Among those with poor adherence, 4 patients (57.10%) belonged to the pregabalin group and 3 patients (42.90%) belonged to the gabapentin group.

The obtained p-value was 0.5, which is greater than the level of statistical significance ($p > 0.05$). This indicates that there was no statistically significant difference in medication adherence between the pregabalin and gabapentin groups.

Table 9. Comparison of sleep score difference between pregabalin and gabapentin groups (Mann–Whitney U test)

	TYPE	Mean Rank	Sum of Ranks	Mann-Whitney U	Asymp. Sig.
Sleep Score Difference	Pregabalin	46.73	2196.5	1068.5	0.781
	Gabapentin	48.27	2268.5		

The sleep score difference between patients treated with pregabalin and those treated with gabapentin was compared using the Mann–Whitney U test. The mean rank for the pregabalin group was 46.73 (sum of ranks = 2196.5), while the gabapentin group had a mean rank of 48.27 (sum of ranks = 2268.5). The Mann–Whitney U value was 1068.5, with an asymptotic significance (p-value) of 0.781.

Since the p-value is greater than 0.05, there is no statistically significant difference in sleep score improvement between the pregabalin and gabapentin groups.

Table 10. Within-group comparison of sleep quality (Pittsburgh Sleep Quality Index) before and after pregabalin treatment using Wilcoxon signed-rank test

Pregabalin Group		Mean Rank	Sum of Ranks	Z	Asymp. Sig.
Sleep quality before and after	Negative Ranks	24	1128	-5.997	0.000
	Positive Ranks	0	0		

Within the pregabalin group, sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI) before and after treatment, and the differences were analyzed using the Wilcoxon signed-rank test. The analysis showed 24 negative ranks (sum of ranks = 1128), indicating that all participants experienced a reduction in PSQI scores after treatment, while there were no positive ranks.

The test revealed a Z value of -5.997 with a statistically significant p-value ($p < 0.001$). This indicates a highly significant improvement in sleep quality after pregabalin treatment.

Table 11. Within-group comparison of sleep quality (Pittsburgh Sleep Quality Index) before and after gabapentin treatment using Wilcoxon signed-rank test

Gabapentin Group		Mean Rank	Sum of Ranks	Z	Asymp. Sig.
Sleep quality before and after	Negative Ranks	23	1035	-5.87	0.000
	Positive Ranks	0	0		

Within the gabapentin group, sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI) before and after treatment, and the differences were analyzed using the Wilcoxon signed-rank test. The analysis showed 23 negative ranks (sum of ranks = 1035), indicating that all participants experienced a reduction in PSQI scores after treatment, while no positive ranks were observed.

The test produced a Z value of -5.87 with a statistically significant p-value ($p < 0.001$). This indicates a highly significant improvement in sleep quality following gabapentin treatment.

Table 12. Comparison of adverse drug reaction causality (pregabalin vs gabapentin) using Chi-square test

		Type of Drug		p Value
		Pregabalin	Gabapentin	
Adverse effect of drug	DEFINITE	3	14	0.000
		17.60%	82.40%	
	PROBABLE	27	30	
		47.40%	52.60%	
	POSSIBLE	17	3	
		85.00%	15.00%	

The distribution of adverse drug reactions (ADRs) classified as definite, probable, and possible was compared between pregabalin and gabapentin groups using the Chi-square test. In the pregabalin group, 3 cases (17.6%) were classified as definite, 27 cases (47.4%) as probable, and 17 cases (85.0%) as possible. In the gabapentin group, 14 cases (82.4%) were definite, 30 cases (52.6%) were probable, and 3 cases (15.0%) were possible.

The Chi-square test showed a statistically significant association between type of drug and ADR causality classification ($p < 0.001$). This indicates that the pattern of adverse drug reaction causality differs significantly between pregabalin and gabapentin groups.

CONCLUSION

The present study demonstrated that both pregabalin and gabapentin were effective in managing neuropathic pain, with significant improvements in pain scores, sleep quality, and quality of life following treatment. Pregabalin showed significantly greater pain reduction compared with gabapentin ($p=0.006$), whereas improvements in sleep quality ($p=0.781$) and medication adherence ($p=0.5$) were comparable between the groups. Good adherence was observed with both pregabalin (91.49%) and gabapentin (93.62%). A significant difference was also observed in the pattern of adverse drug reaction causality between the groups ($p<0.001$). Overall, pregabalin demonstrated greater efficacy in pain reduction, while both drugs provided comparable benefits in sleep quality and adherence. These findings suggest that pregabalin may be considered a preferable option when greater pain relief is the primary treatment goal, although therapy should be individualized based on patient characteristics, tolerability, safety, and clinical response.

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to those who have been a part of our study and to those who have guided us to publish this thesis.

Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/ publication of this article.

Funding

The authors received no financial support for the research, authorship and/ publication of this article.

Ethical consideration

Institutional Research/ Human Ethics Committee approval was obtained.

REFERENCES

- [1] Mayoral V, Galvez R, Ferrándiz M, Miguéns Vázquez X, Cordero-García C, Alcántara Montero A, Pérez C, Pérez-Páramo M. Pregabalin vs. gabapentin in the treatment of neuropathic pain: a comprehensive systematic review and meta-analysis of effectiveness and safety. *Front Pain Res (Lausanne)*. 2025 Jan 7.
- [2] Sadegh AA, Gehr NL, Finnerup NB. A systematic review and meta-analysis of randomized controlled head-to-head trials of recommended drugs for neuropathic pain. *Pain Rep*. 2024 Feb 21;9(2).
- [3] Bockbrader HN, Wesche D, Miller R, Chapel S, Janiczek N, Burger P. A comparison of the pharmacokinetics and pharmacodynamics of pregabalin and gabapentin. *Clin Pharmacokinet*. 2010 Oct;49(10):661-9.
- [4] Bockbrader HN, Radulovic LL, Posvar EL, Strand JC, Alvey CW, Busch JA, Randinitis EJ, Corrigan BW, Haig GM, Boyd RA, Wesche DL. Clinical pharmacokinetics of pregabalin in healthy volunteers. *J Clin Pharmacol*. 2010 Aug;50(8):941-50.
- [5] Bockbrader HN, Wesche D, Miller R, Chapel S, Janiczek N, Burger P. A comparison of the pharmacokinetics and pharmacodynamics of pregabalin and gabapentin. *Clin Pharmacokinet*. 2010 Oct;49(10):661-9.
- [6] Chincholkar M. Gabapentinoids: pharmacokinetics, pharmacodynamics and considerations for clinical practice. *Br J Pain*. 2020 May;14(2):104-114.