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Original Research Article

COMPETITIVE STUDY OF EFFICACY AND SAFETY BETWEEN LEVETIRACETAM (500) VS BRIVARACETAM (50) IN PATIENTS WITH SEIZURE DISORDER IN A TERTIARY CARE HOSPITAL IN WEST BENGAL

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ABSTRACT

Background: Epilepsy is a common neurological disorder requiring long-term antiepileptic therapy. Levetiracetam and brivaracetam, both acting on synaptic vesicle protein 2A (SV2A), are widely used in seizure management. Brivaracetam, a newer agent, is believed to have higher selectivity and improved tolerability. This study aimed to compare the efficacy and safety of levetiracetam (500 mg) and brivaracetam (50 mg) in patients with seizure disorders. **Materials and Methods:** This prospective comparative study was conducted in a tertiary care hospital in West Bengal and included 100 patients diagnosed with seizure disorders. Patients were divided into two groups: Group A received levetiracetam (n=50) and Group B received brivaracetam (n=50). Patients were followed up for six months. Seizure frequency, responder rate (≥50% reduction), seizure freedom, adverse drug reactions, and overall tolerability were assessed. Statistical analysis was performed using appropriate tests, with $p<0.05$ considered significant. **Results:** Both groups showed a significant reduction in seizure frequency over time, with brivaracetam demonstrating a statistically significant advantage at six months (p=0.04). The responder rate was higher in the brivaracetam group (76%) compared to the levetiracetam group (68%). Seizure freedom was achieved in 48% of patients on brivaracetam versus 36% on levetiracetam. Adverse effects such as irritability and anxiety were significantly higher with levetiracetam. Brivaracetam showed better tolerability and lower discontinuation rates. **Conclusion:** Brivaracetam is an effective and well-tolerated alternative to levetiracetam, offering improved safety and comparable or superior efficacy in seizure management.

INTRODUCTION

Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures due to excessive and abnormal neuronal activity in the brain. It affects approximately 50 million people globally, with a disproportionately higher burden in low- and middle-income countries, including India.[1] The condition is associated with significant morbidity, mortality, social stigma, and reduced quality of life. Effective seizure control remains the primary goal of management, and antiepileptic drugs (AEDs) are the mainstay of therapy. Despite the availability of several AEDs, nearly one-third of patients continue to have uncontrolled seizures or experience adverse drug reactions, necessitating the exploration of newer and more effective therapeutic options.[2,3]

Levetiracetam is a second-generation AED widely used for the treatment of focal and generalized seizures. It exerts its antiepileptic effect primarily through binding to synaptic vesicle protein 2A

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(SV2A), thereby modulating neurotransmitter release and reducing neuronal excitability.[4] It is favored due to its favorable pharmacokinetic profile, minimal drug interactions, rapid onset of action, and broad-spectrum efficacy. Clinical trials have demonstrated significant seizure reduction and good tolerability with levetiracetam; however, its use is frequently associated with behavioral and psychiatric adverse effects such as irritability, agitation, and mood disturbances, which may limit its long-term use in certain patients.[5,6]

Brivaracetam is a newer analog of levetiracetam with a 10–30 times higher affinity for the SV2A receptor, resulting in enhanced anticonvulsant activity at lower doses.[7] It has been developed to improve upon the limitations of levetiracetam, particularly its neuropsychiatric side effect profile. Brivaracetam exhibits rapid brain penetration, linear pharmacokinetics, and minimal drug–drug interactions, making it a promising alternative in epilepsy management.[8] Clinical studies have demonstrated that brivaracetam significantly reduces seizure frequency and achieves ≥50% responder rates in a substantial proportion of patients with focal seizures.[9]

Comparative evidence between levetiracetam and brivaracetam suggests that both drugs are effective in seizure control; however, brivaracetam may offer better tolerability, especially in patients who develop behavioral adverse effects with levetiracetam.[10] Switching from levetiracetam to brivaracetam has been associated with improvement in psychiatric symptoms while maintaining seizure control, indicating its potential advantage in clinical practice.[11] Nevertheless, some studies report comparable efficacy between the two agents, highlighting the need for further head-to-head comparisons in different populations.[12]

In the Indian context, particularly in tertiary care settings, there is limited data directly comparing the efficacy and safety of levetiracetam and brivaracetam. Variations in genetic, environmental, and socioeconomic factors may influence drug response and tolerability. Therefore, this study aims to conduct a comparative evaluation of the efficacy and safety of levetiracetam (500 mg) versus brivaracetam (50 mg) in patients with seizure disorders in a tertiary care hospital in West Bengal. The findings of this study are expected to provide valuable insights into optimizing antiepileptic therapy and improving patient outcomes in routine clinical practice.

MATERIALS AND METHODS

A prospective, comparative, observational study conducted in the Department of General Medicine at a tertiary care hospital in West Bengal to evaluate and compare the efficacy and safety of levetiracetam (500 mg) and brivaracetam (50 mg) in patients diagnosed with seizure disorders. The study was carried out over a period of 6 months (August 2025 to January 2026) after obtaining approval from the Institutional Ethics Committee, and informed written consent was obtained from all participants prior to enrollment.

A total of 100 patients diagnosed with seizure disorders, based on clinical history, neurological examination, and relevant investigations such as electroencephalography (EEG) and neuroimaging when required, were included in the study. Patients aged between 18 and 65 years, of either gender, and newly diagnosed or requiring modification of antiepileptic therapy were eligible for inclusion. Patients with severe systemic illness, psychiatric disorders, pregnancy or lactation, history of hypersensitivity to study drugs, or those already on multiple antiepileptic drugs were excluded from the study.

The study participants were divided into two groups of 50 patients each. Group A received levetiracetam at a dose of 500 mg per day, while Group B received brivaracetam at a dose of 50 mg per day. The allocation was done based on clinician discretion and patient suitability. Both groups were followed up regularly over a period of 6 months, with assessments conducted at baseline, 1 month, 3 months, and 6 months.

Efficacy was assessed primarily by measuring the reduction in seizure frequency from baseline and the proportion of patients achieving ≥50% reduction in seizure frequency (responder rate). Secondary efficacy outcomes included complete seizure freedom during the follow-up period. Patients were instructed to maintain seizure diaries to ensure accurate recording of seizure episodes.

Safety and tolerability were evaluated by monitoring adverse drug reactions (ADRs), with particular attention to neuropsychiatric symptoms such as irritability, aggression, anxiety, and depression. Routine laboratory investigations, including complete blood count, liver function tests, and renal function tests, were performed at baseline and during follow-up to assess drug safety. All adverse events were recorded, documented, and assessed for causality.

Data were collected using a structured case record form and entered into a Microsoft Excel spreadsheet for analysis. Statistical analysis was performed using appropriate software. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The independent sample t-test was used to compare mean values between the two groups, and the Chi-square test or Fisher's exact test was applied for categorical data. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The baseline demographic and clinical characteristics of the study participants are presented in Table 1. Both groups were comparable with respect to age

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distribution, gender, duration of epilepsy, and type of seizure, indicating homogeneity between the study groups.

In Group A (Levetiracetam), the majority of patients belonged to the 31–45 years age group (40%), followed by 18–30 years (36%) and >45 years (24%). Similarly, in Group B (Brivaracetam), 44% were in the 31–45 years category, 32% in 18–30 years, and 24% in >45 years. The difference in age distribution between the groups was not statistically significant (p=0.81).

Male predominance was observed in both groups, with 56% males in Group A and 60% in Group B, while females constituted 44% and 40%, respectively. This difference was not statistically significant (p=0.68).

Regarding the duration of epilepsy, nearly half of the patients in both groups had a duration of 2–5 years (48% in Group A and 52% in Group B), followed by <2 years and >5 years categories. No significant difference was observed (p=0.72).

Focal seizures were the most common type in both groups, accounting for 64% in Group A and 60% in Group B, while generalized seizures were seen in 36% and 40%, respectively. The difference was not statistically significant (p=0.67). Overall, both groups were comparable at baseline. [Table 1]

Table 1: Baseline Demographic Characteristics

Variable	Category	Group A (Levetiracetam) n (%)	Group B (Brivaracetam) n (%)	p-value
Age (years)	18–30	18 (36%)	16 (32%)	0.81
	31–45	20 (40%)	22 (44%)	
	>45	12 (24%)	12 (24%)	
Gender	Male	28 (56%)	30 (60%)	0.68
	Female	22 (44%)	20 (40%)	
Duration of Epilepsy	<2 years	14 (28%)	12 (24%)	0.72
	2–5 years	24 (48%)	26 (52%)	
	>5 years	12 (24%)	12 (24%)	
Type of Seizure	Focal	32 (64%)	30 (60%)	0.67
	Generalized	18 (36%)	20 (40%)	

Table 2 shows the comparison of mean seizure frequency between the two groups over time. At baseline, the mean seizure frequency was similar in both groups (5.8 ± 1.9 in Group A vs 5.6 ± 2.1 in Group B; p=0.62), indicating no initial difference.

At 1 month and 3 months follow-up, both groups demonstrated a reduction in seizure frequency, with slightly lower values observed in the brivaracetam group; however, these differences were not statistically significant (p=0.18 and p=0.09, respectively).

At 6 months, a greater reduction in seizure frequency was observed in Group B (1.2 ± 0.8) compared to Group A (1.6 ± 0.9), and this difference was statistically significant (p=0.04). This suggests that brivaracetam may provide better long-term seizure control compared to levetiracetam. [Table 2]

Table 2: Comparison of Mean Seizure Frequency

Time Point	Group A (Levetiracetam)	Group B (Brivaracetam)	p-value
Baseline	5.8 ± 1.9	5.6 ± 2.1	0.62
1 Month	3.6 ± 1.5	3.2 ± 1.4	0.18
3 Months	2.4 ± 1.2	2.0 ± 1.1	0.09
6 Months	1.6 ± 0.9	1.2 ± 0.8	**0.04***

The proportion of patients achieving a ≥50% reduction in seizure frequency was higher in the brivaracetam group (76%) compared to the levetiracetam group (68%). However, this difference was not statistically significant (p=0.36). Despite the lack of statistical significance, a favorable trend towards better response with brivaracetam was observed. [Table 3]

Table 3: Responder Rate (≥50% Seizure Reduction)

Outcome	Group A (n=50)	Group B (n=50)	p-value
Responder	34 (68%)	38 (76%)	0.36
Non-responder	16 (32%)	12 (24%)	

Table 4 demonstrates that 48% of patients in the brivaracetam group achieved complete seizure freedom compared to 36% in the levetiracetam group. Although a higher proportion of seizure-free patients was observed in Group B, the difference was not statistically significant (p=0.21). This indicates a trend towards improved outcomes with brivaracetam, though larger studies may be required to establish statistical significance. [Table 4]

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Table 4: Seizure Freedom at 6 Months

Outcome	Group A (n=50)	Group B (n=50)	p-value
Seizure-Free Patients	18 (36%)	24 (48%)	0.21
Not Seizure-Free	32 (64%)	26 (52%)	

Irritability was significantly higher in the levetiracetam group (24%) compared to the brivaracetam group (10%) (p=0.04). Similarly, anxiety and depression were more frequently observed in Group A (18%) than in Group B (6%), and this difference was statistically significant (p=0.03).

Other adverse effects such as somnolence, dizziness, and headache were slightly more common in the levetiracetam group, but the differences were not statistically significant (p>0.05). Overall, neuropsychiatric adverse effects were more prominent in patients receiving levetiracetam. [Table 5]

Table 5: Incidence of Adverse Drug Reactions (ADRs)

Adverse Effect	Group A (n=50)	Group B (n=50)	p-value
Irritability	12 (24%)	5 (10%)	**0.04***
Somnolence	10 (20%)	8 (16%)	0.60
Dizziness	8 (16%)	6 (12%)	0.56
Headache	6 (12%)	5 (10%)	0.75
Anxiety/Depression	9 (18%)	3 (6%)	**0.03***

Drug discontinuation was higher in the levetiracetam group (16%) compared to the brivaracetam group (6%); however, this difference was not statistically significant (p=0.11).

Good tolerability was observed in a higher proportion of patients in Group B (80%) compared to Group A (64%), whereas moderate to poor tolerability was more common in Group A (36%) than in Group B (20%). Although this difference did not reach statistical significance (p=0.07), it indicates a trend towards better tolerability with brivaracetam. [Table 6]

Table 6: Overall Tolerability and Drug Discontinuation

Parameter	Category	Group A (n=50)	Group B (n=50)	p-value
Drug Discontinuation	Yes	8 (16%)	3 (6%)	0.11
	No	42 (84%)	47 (94%)	
Overall Tolerability	Good	32 (64%)	40 (80%)	0.07
	Moderate/Poor	18 (36%)	10 (20%)	

DISCUSSION

The present study evaluated and compared the efficacy and safety of levetiracetam (500 mg) and brivaracetam (50 mg) in patients with seizure disorders in a tertiary care hospital setting. The findings demonstrated that both drugs were effective in seizure control; however, brivaracetam showed a trend toward better efficacy and improved tolerability profile.

The baseline demographic and clinical characteristics in our study were comparable between the two groups, indicating homogeneity and minimizing confounding bias. Similar demographic distributions have been reported by Klein et al. and Ryvlin et al., who observed no significant differences in age, gender, or seizure type between treatment groups in comparative antiepileptic studies.[13,14] This comparability strengthens the internal validity of our study findings.

In terms of seizure frequency reduction, both levetiracetam and brivaracetam showed progressive improvement over the study period, with brivaracetam demonstrating a statistically significant reduction at 6 months. This finding aligns with the study conducted by Biton et al., who reported significant seizure reduction with brivaracetam compared to placebo and comparable or superior efficacy to levetiracetam.[15] Similarly, Ben-Menachem et al. observed a greater reduction in seizure frequency with brivaracetam due to its higher affinity for synaptic vesicle protein 2A (SV2A), contributing to enhanced antiepileptic activity.[9]

The responder rate (≥50% seizure reduction) was higher in the brivaracetam group (76%) compared to the levetiracetam group (68%), although the difference was not statistically significant. Comparable findings were reported by Kwan et al., who demonstrated similar responder rates between newer antiepileptic drugs but with a slight advantage favoring brivaracetam.[2] Additionally, French et al. reported responder rates ranging from 34–55% with brivaracetam in randomized controlled trials, supporting its effectiveness in clinical practice.[16]

Seizure freedom at 6 months was achieved in a higher proportion of patients receiving brivaracetam (48%) compared to levetiracetam (36%), although this difference did not reach statistical significance. This trend is consistent with findings from Niespodziany et al., who suggested that brivaracetam's higher selectivity and potency at SV2A may contribute to improved seizure control outcomes.[17] Similarly, Yates et al. reported improved seizure-free outcomes with brivaracetam in refractory epilepsy patients.[11]

Safety analysis revealed that adverse drug reactions such as irritability and anxiety/depression were

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significantly higher in the levetiracetam group compared to the brivaracetam group. This is in agreement with studies by Mula et al., who reported a higher incidence of behavioral adverse effects, including irritability and mood disturbances, with levetiracetam.[18] Likewise, Steinhoff et al. demonstrated that brivaracetam is associated with a lower incidence of psychiatric adverse effects due to its more selective pharmacodynamic profile.[19]

Other adverse effects such as somnolence, dizziness, and headache were comparable between the two groups, indicating that both drugs are generally well tolerated. These findings are consistent with previous clinical trials that have shown similar non-psychiatric adverse effect profiles for both medications.[16,19]

With regard to overall tolerability, a higher proportion of patients in the brivaracetam group reported good tolerability (80%) compared to the levetiracetam group (64%). Although not statistically significant, this clinically relevant difference is supported by findings from Villanueva et al., who reported improved patient satisfaction and tolerability with brivaracetam, particularly in patients who previously experienced adverse effects with levetiracetam.[20]

Drug discontinuation rates were lower in the brivaracetam group (6%) compared to the levetiracetam group (16%), reflecting better adherence and tolerability. Similar observations were made by Toledo et al., who reported lower discontinuation rates with brivaracetam due to improved side effect profiles and patient compliance.[21]

Overall, the findings of the present study are consistent with existing literature, suggesting that while both levetiracetam and brivaracetam are effective antiepileptic agents, brivaracetam may offer advantages in terms of better seizure control, improved psychiatric tolerability, and lower discontinuation rates. These findings support the growing preference for brivaracetam as a favorable alternative, especially in patients who are intolerant to levetiracetam.

The present study has certain limitations. The sample size was relatively small, which may limit the generalizability of the findings. The study duration was limited to six months, restricting assessment of long-term efficacy and safety. Being a single-center study, regional variations could not be accounted for. Additionally, the lack of blinding may introduce observer bias. Drug adherence was not objectively monitored, and serum drug levels were not measured, which could influence outcome interpretation.

CONCLUSION

The present study demonstrates that both levetiracetam (500 mg) and brivaracetam (50 mg) are effective in the management of seizure disorders, with significant reduction in seizure frequency over time. However, brivaracetam showed comparatively better efficacy at six months, along with a higher proportion of responders and seizure-free patients. Importantly, brivaracetam was associated with fewer behavioral adverse effects, such as irritability and anxiety, and showed better overall tolerability and lower drug discontinuation rates.

Although some differences did not reach statistical significance, the overall trend favors brivaracetam as a safer and more tolerable alternative to levetiracetam. These findings suggest that brivaracetam may be particularly beneficial in patients who experience neuropsychiatric side effects with levetiracetam. Further large-scale, multicentric, and long-term studies are recommended to validate these observations and establish definitive clinical guidelines.

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