Brivaracetam And Levetiracetam In Clinical Practice: Assessment Of Safety And Effectiveness Using An Observational Study Design

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ABSTRACT

Plan: The present study aims to provide an overview of the data about the relative clinical safety and effectiveness of levetiracetam (LEV) and brivaracetam (BRV) in treating epileptic patients.

Preface: Epilepsy is a chronic non-communicable disease of the brain characterized by recurrent seizures. Levetiracetam is a second-generation antiepileptic drug, and Brivaracetam is a new third-generation drug in the pyrrolidine class of anticonvulsants and an analogue of LEV. The prospective observational study was conducted in the Neurology department of a tertiary care multi-speciality hospital in Coimbatore between the period of 2024 and 2025. Written informed consent from each patient or the patient's caregiver was obtained for conducting the study. Safety and efficacy data were collected during patients' visits and follow-up. The population will be screened based on inclusion criteria, which include patients with epilepsy aged 16 years or older with current and previous mental health conditions, and exclusion criteria, which exclude patients with a history of alcoholism or drug abuse.

Method: In this study, 116 patients were evaluated, ranging in age from adolescents to older adults, and the majority were between 16 and 29 (44%). The study observed that the incidence of epilepsy is highly age-dependent. Children are at higher risk than other age groups, and it remains prevalent in old age. The risk in children is often due to genetic causes, malformations of cerebral development and hypoxic-ischemic encephalopathy. Observation found that the male patient population (58%) was higher than the female population (42%).

Outcome: An indirect treatment comparison found no statistically significant differences between levetiracetam and brivaracetam in terms of safety and adverse events (AE). Behavioural adverse events (BAE) appear to be less prevalent with brivaracetam than with levetiracetam. The most common TEAEs reported in patients receiving levetiracetam were *headache*, and in patients receiving brivaracetam were *dizziness*. Levetiracetam monotherapy was associated with significantly higher odds of experiencing a greater number of seizure episodes compared with brivaracetam monotherapy, and levetiracetam used in combination with other antiepileptic drugs showed significantly higher efficacy.

Conclusion: Results from the study indicate that both drugs have similar safety and tolerability in the epileptic population, and efficacy analyses showed seizure reduction and seizure frequency are comparatively better with the brivaracetam group over time.

Keywords: Brivaracetam, Levetiracetam, Epilepsy, Safety, Efficacy, Tolerability

How To Cite This Article: Martina Jenifer M, Andhuvan G, Vedhanayagam N, Sriram S, Afrith Mohamed H, Madhu C Divakar. Brivaracetam And Levetiracetam In Clinical Practice: Assessment Of Safety And Effectiveness Using An Observational Study Design. Int J Drug Deliv Technol. 2026;16(26s):778-785. Doi: 10.25258/ijddt.16.26s.82

1. INTRODUCTION

Epilepsy is a chronic neurological condition in which clusters of nerve cells, or neurons, in the brain transmit incorrect signals, resulting in seizures. Normally, neurons transmit electrical and chemical signals to other neurons, organs, and muscles, producing human thoughts, emotions, and behaviours [1,2]. Epilepsy involves recurrent seizures, with or without convulsions [3]. A convulsion is characterised by violent, involuntary contractions of the voluntary muscles [2]. It is among the most common neurological diseases, affecting people of all ages. Although treatments for epilepsy are becoming more varied, doubts remain regarding their effectiveness and potential side effects, especially in managing childhood epilepsy. Patients with epilepsy may also experience neurodevelopmental delays, memory problems, and cognitive impairments [1]. Seizures are triggered by an excessive release of activity from cortical neurons, which can be observed as changes on an electroencephalogram (EEG) [2]. Abnormal neuronal discharges, which can be caused by various brain conditions affecting the cortical layer, lead to epileptic seizures. One-third of new epilepsy cases are likely idiopathic, meaning they have a hereditary basis. However, in many cases, the cause remains unknown; these are called cryptogenic epilepsies [3].

Most epilepsies in young children and adolescents are idiopathic, though trauma and illness can also be factors [3]. Epilepsy resulting from birth trauma and idiopathic epilepsy can both begin in early adulthood. Other significant causes include brain tumours, alcoholism, cortical dysplasias, head injuries, and cerebrovascular illnesses [3,5].

Since epilepsy lacks a pathognomonic lesion, it differs from the majority of neurological illnesses. Any typical brain can readily trigger a seizure in response to a wide range of distinct electrical or chemical inputs. An electroencephalogram (EEG) shows a rhythmic, repetitive, hypersynchronous discharge of neurons, either localised to a specific region of the cerebral cortex or generalised throughout the brain [3,5].

The male population is more at risk than the female population. This is due to steroid hormones, fluctuations in neurosteroids (neurosteroids are powerful modulators of synaptic and extrasynaptic GABA receptors, exhibiting greater antiseizure potency in females), and neuroplasticity in receptor signaling [5].

The present work focused on studying the safety and efficacy of pyrrolidine anticonvulsants, brivaracetam and levetiracetam in clinical settings. The protocol for the work includes designing a structured data entry format, preparation of a patient consent form, preparation of a patient information form, obtaining permission from the hospital ethical committee, data collection, documenting collected data using the data entry format, analysing all the collected data, and interpreting the collected data.

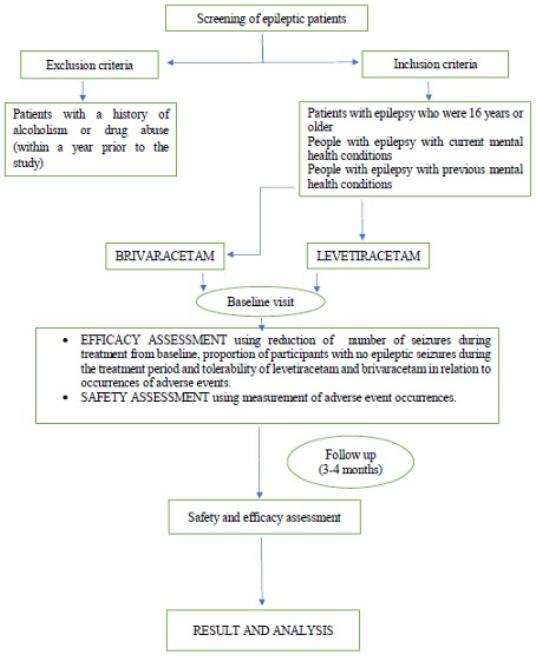
2. METHODS

2.1. STUDY DESIGN

The prospective observational study was conducted in the Neurology department of a tertiary care Multi-speciality Hospital, Coimbatore, during the period of 2024-2025. The number of patients observed during the study period was 116. Hospital ethics committee approval and written informed consent from each patient/ patient's caregiver were obtained for conducting the study.

2.2 . SELECTION CRITERIA

The population were screened based on inclusion and exclusion criteria. Data concerning the necessary demographic and clinical details of the patient identified were collected (such as age, gender, height, weight, past medical history, past medication history and laboratory investigations). The data were collected during their follow-up. The outcome was measured based on efficacy parameters like seizure freedom and seizure frequency, and by safety parameters like occurrence of adverse drug reactions and tolerability of Levetiracetam and Brivaracetam.



2.3.DATA ANALYSES

Descriptive analyses and comparative analyses using post hoc analysis were performed to assess efficacy and safety parameters. Safety parameters were incidence of TEAEs, and efficacy parameters includes number of patients who remained seizure-free for years/months during treatment (monotherapy and combination therapy), Reoccurrence of seizures and Seizure frequency status during the observation period.

3. RESULTS

3.1 PATIENT DISPOSITION AND BASELINE CHARACTERISTICS

Data collected from 116 patient population during 2024-2025 were summarised using descriptive statistics. The variables were expressed as mean, median, standard deviation, and percentage using IBM SPSS statistics version 24.0. The patients were categorised according to their age into 8 groups. The largest number of the population was in group 16-19 (22%), 20-29 (22%) and 40-49 (22%). Followed by 50-59 (11%), 60-69(8%), 30-39(6%), 70-79(6%) and 80-89(3%). Almost more than half of patient population falls below 30 years of age. The age distribution shows decline in emergence of seizures with increasing in age (Table 1). Among the 116-patient population, 54 % were female (n=63) and 46% were male (n=53). Gender distribution was near- equal distribution with 8.6% difference where male population are slightly higher. The first episode of seizure occurred in patient group of 10-19 age range with 44.8%. Cumulatively 77.5% fall under the age <40 years. The observed data showed the occurrence of first episode was relatively declined with increasing age. Among the study patient population generalized seizures accounts for 60.3% and predominant here. Other types of seizures observed was focal seizure 37(31.8%) and post stroke seizure 9(7.7%) (Table 1). The selected study drug distribution was levetiracetam {71 patients (61.21%)} and brivaracetam {45 patients(38.79%)} (Table 2). Duration of therapy ranged from less than 1 year to more than 6 years. Mean of the treatment duration was 3.24±2.23 years with the median of 3 years. Large number of treatment population fall under 2 -3-year duration category (Table 1).

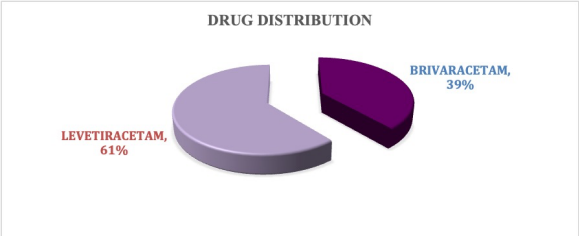
Table 1 PATIENT DISPOSITION AND BASELINE CHARACTERISTICS

1. Baseline Demographics and Clinical Characteristics		
Age (years)	*Statistics*	*Value*
	N	116
	Mean	32.79
	SD	16.90
Sex *n(%)*	*N*	*%*
	Male	53(45.7)
	Female	63(54.3)
Age at the time of first seizure *range;n(%)*		
	10-19	52(44.8)
Seizure classification *n(%)*		
Focal seizure	37	31.8
Generalized seizure	70	60.3
Post stroke seizure	09	7.7
Number of anti-epileptic drugs taken by a single patient		
1	65	56.03
2	42	36.2
3	6	5.1
>3	3	2.5
Concomitant AEDs taken		
Lacosamide	29	35.8
Oxcarbazepine	15	18.5
Zonisamide	4	4.9
Clobazam	21	25.9
Perampanel	4	4.9
Phenytoin	4	4.9
Gabapentin	4	4.9

Concurrent therapeutic drug class taken with LEV		
Anti-pyretics		
NSAIDs		
Anti-emetics		
Vitamin supplement		
Proton pump inhibitors		
Statins		
Neuro protectives		
Sedative & hypnotics		
SSRI		
Neutraceuticals		
Synthetic thyroid hormones		
Concurrent therapeutic drug class taken with BRV		
Anti-pyretics		
Antibiotics		
Anti-emetics		
Vitamin supplement		
Proton pump inhibitors		
Anti-histamines		
Anti-parkinsons		
Steroids		
Medical history (ongoing)		
Cancer	4.9	5
Stroke	18.8	25
Hypothyroidism	3.9	5
DM	26.7	35
HTN	18.8	25
CAD	3.9	5
CLD	3.9	5
Auto immune encephalitis	3.9	5
Autism spectrum disorder	3.9	5
PRES	3.9	5
BPPV	3.9	5
PTCA	3.9	5
Treatment duration	*Years*	%
Less than 1 year	9	8
1 year	22	19
2 years	26	22
3 years	16	14
4 years	13	11
5 years	3	3
6 years	7	6
More than 6 years	20	17
Treatment duration with study drugs		
	Mean	3.24
	Median	3
	SD	2.23

Table 2: Study drug distribution

Study drugs	Number of patients N=116	Percentage (%)
Brivaracetam	45	38.79
Levetiracetam	71	61.21
Total	116	100



1.2 POST HOC ANALYSIS SUMMARY

Table 3: Post hoc analysis of safety and tolerability parameter summary

TEAE category	LEV	BRV	†OR	95% CI	*p*-value
Neurological	61	56	2.25	1.30-3.89	0.0033**
Psychological	45	23	0.75	0.41-1.38	0.31
Respiratory	0	3	9.92	0.51-193.1	0.047
Metabolism and nutritional	0	3	9.92	0.51-193.1	0.047
Gastrointestinal	3	0	0.29	0.02-5.66	0.56
Others	33	4	0.16	0.06-0.47	<0.001***

LEV= Levetiracetam, BRV= Brivaracetam, †OR = Odds Ratio, Cl= Confidence Interval, *p < 0.05; ** p < 0.01; *** p < 0.001.

Table 4 Post hoc pairwise comparisons of seizure-free and recurrence status

Drug		Monotherapy *n(%)*		Combination with other AEDs *n (%)*	
BRV		13(81.3)		3(18.8)	
LEV		3(30.0)		7(70.0)	
	Treatment comparison	x^2(df=1)	*p* value a=0.025	†OR	95%CI
Seizure-free status					
	BRV vs LEV (monotherapy)	6.83	0.0015*	10.11	1.73-59.1
	BRV vs LEV (combination therapy)	6.83	0.0015*	10.11	1.73-59.1
Reoccurrence status (>3 episodes)					
	BRV vs LEV (monotherapy)		<0.025*	31.0	1.7-560
	BRV vs LEV (combination therapy)		<0.025*	41.0	2.3-720

4. DISCUSSION

The purpose of this report is to summarise the evidence on the comparative clinical safety and efficacy of Brivaracetam (BRV) versus Levetiracetam (LEV) in patients with epilepsy and mental health conditions, and in patients with epilepsy who experienced adverse events with previous treatment.

In this prospective observational study, 116 patients were evaluated. The study population ranged from adolescence to old age, with the majority aged 16-19 and 20-29 (44%). This observation is similar to the results reported by Gregory L Holmes et al. The incidence of epilepsy increases with age. Children are at higher risk than other age groups, and this prevalence is also observed in old age, as observed in this study [5]. It was found that the male patient population (54%) was higher than the female population (46%). This is similar to the results reported by Doodipala Samba Reddy et al, which summarise that men are more susceptible to excitability episodes and epileptic seizures than females. The age and sex results in this study are similar to those reported by Mary Nolan et al. A larger proportion of patients in the study population indicates that the age at the time of the first seizure episode is during the childhood-to-adolescent period (33%).

In the overall population, the frequency of seizures within a certain period of time and the time gap between seizures in a patient are more or less equally distributed across various time periods [6] (Table 1).

The brivaracetam population, prescribed doses were 50mg and 25mg. The usual dose prescribed in the epileptic population taking levetiracetam was 500mg, with a few prescribed 250mg and 750mg [7]. Inoue Y et al clinical trial suggests BRV was well tolerated in the Asian population [8].

The study observed a generalised type of seizures-GTCS [generalised tonic-clonic seizures] (60.3%), including late onset seizure disorder and breakthrough seizures, which are predominantly seen in epileptic patients than focal seizures (31.8%), including facial seizures and gelastic seizures. A significant number of patients are affected by post-stroke epilepsy (7.7%).

In the overall study population, 56.03% of patients received monotherapy with the study drugs, brivaracetam (27.5%) and levetiracetam (27.5%). Dual therapy of AEDs were taken by 42(36.2%), triple therapy in 6(5.1%) and multiple AEDs (more than 3) were taken by 3 patients (2.5%). The concomitant AEDs taken with study drugs in 43.8% of the population include lacosamide (35.8%), clobazam (25.9%), oxcarbazepine (18.5%), zonisamide (4.9%), perampanel (4.9%), phenytoin (4.9%), and gabapentin (4.9%). Concomitant drugs taken along with levetiracetam[9] in patients include antipyretics (acetaminophen), NSAIDs (naproxen, aspirin), anti-emetics (domperidone), vitamin supplements, proton pump inhibitors (pantoprazole), statins (atorvastatin), neuroprotective (citicoline, piracetam, Cerebro protein hydrolysate), sedatives and hypnotics (phenobarbital, melatonin, zolpidem), SSRIs (sertraline),

nutraceuticals, synthetic thyroid hormones (thiamine HCl) and with brivaracetam, antipyretics (paracetamol), antibiotics (amoxicillin + clavulanic acid), anti-emetics (domperidone), vitamin supplements, proton pump inhibitors (esomeprazole), anti-histamines (dimenhydrinate + cinnarazine), anti-parkinsons (levodopa, carbidopa) and steroids (methyl prednisolone).

In the study, analysis shows prior/ongoing medical conditions reported (medical history) as the highest comorbid conditions, along with epilepsy, are found to be Diabetes mellitus (26.7%), Stroke (18.8%) and Hypertension (18.8%) (Table 1). The distribution of study drugs in the overall study population was Brivaracetam (38.79%) in 45 patients and Levetiracetam (61.21%) in 71 patients (Table 2).

The duration of epileptic treatment with AEDs in the patient population with <1 year of treatment (newly diagnosed with epilepsy) is around 8%. A higher number of treatment durations are between 1 to 4 years [1 year- 19%, 2 years -22%, 3 years-14%, 4 years-11%] followed by patients who are epileptic for > 6 years (17%). The least distribution is 5 years (3%) and 6 years (6%).

A descriptive statistical analysis was conducted to evaluate treatment-emergent adverse events (TEAEs) among patients treated with levetiracetam and brivaracetam. The most common [56(62.9%)] Treatment-emergent Adverse Effects (TEAEs) reported in study subjects treated with brivaracetam were neurological disorders [fatigue (7), headache (10), dizziness (16), imbalance (3), tiredness (10), amnesia (3), somnolence (7)]. Psychological TEAEs were reported by [23(25.8%)] of patients [anxiety (6), depression (7), insomnia (10)] respectively. Respiratory, thoracic and mediastinal disorders like throat burning sensation [3(3.3%)], Metabolism and nutritional disorders like decreased appetite [3(3.3%)]and other disorders like learning difficulty [4(4.4%)] were reported by 11% of patients. The results from a post hoc pooled analysis by Brian D Moseley et al concluded the same result showing similar neurological and psychiatric disorders on using BRV, with the most predominant TEAEs are found to be headache, dizziness, somnolence, fatigue, convulsion and other psychiatric disorders like irritability, insomnia, depression, anxiety and aggression [10-13] (Table 3).

The most common [45(42.9%)] TEAEs reported in study subjects treated with levetiracetam were neurological disorders [headache (23), numbness (10), tiredness (19), amnesia (3), sedation (3), somnolence (3)]. Psychological TEAEs were reported by [45(31.6%)] of patients [anxiety (13), depression (13), insomnia (16), agitation (3)] respectively. Gastrointestinal disorders [nausea] were reported [3(2.1%). Other disorders reported were body pain (17), speech disturbance (3), altered sensorium (3), eye twitching (7) and lack of concentration (3) in 23.2% of the population [7,11,14]. The similar adverse effects are seen in the article by Bong Su Kang et al. This article mentioned the common adverse effects of LEV as irritability, dizziness, headache and somnolence (Table 3).

Post hoc analyses were conducted using SPSS Crosstabs to examine the association between treatment group (levetiracetam; brivaracetam) and treatment-emergent adverse event (TEAE) categories, with Bonferroni correction applied for six comparisons (adjusted $\alpha = 0.008$). A significant association was observed for neurological disorders, with brivaracetam associated with higher odds of neurological adverse events than levetiracetam, indicating a small-to-moderate effect size (Cramer's $V = 0.19$). Significant treatment-related differences were confined to neurological and other adverse event categories, with small-to-moderate effect sizes observed (Table 3).

Post hoc pairwise comparisons using Fisher's exact test with Bonferroni correction revealed significant differences between the levetiracetam and brivaracetam treatment groups. Levetiracetam monotherapy was associated with significantly higher odds of experiencing more seizure episodes than brivaracetam monotherapy, and this was also observed in combination therapy with other antiepileptic drugs (Table 4) [7,9,14-19]. These findings suggest that treatment efficacy differs not only by drug but also by therapeutic strategy [2,11,20-23]. Brivaracetam monotherapy was associated with a significantly higher seizure-free rate than levetiracetam monotherapy. Conversely, in combination therapy, levetiracetam showed superior seizure-free outcomes than brivaracetam [10,24,25,26,27].

The confounding factors affecting the safety and efficacy of both drugs were found to be lack of sleep, drug withdrawal (non-compliance), and mental stress.

Drug switches between the study drugs were made for safety and efficacy reasons.

During the observation period, levetiracetam was switched to brivaracetam in three patients due to intolerable giddiness, and brivaracetam was switched to levetiracetam in another three patients due to a lack of efficacy (recurrence of multiple seizures) [28,13].

CONCLUSION

The current study concluded that the brivaracetam group had significantly greater efficacy than the levetiracetam group when used as monotherapy. However, levetiracetam demonstrated comparatively better efficacy when administered as part of combination therapy. Both drugs exhibited a similar safety and tolerability profile, and neurological adverse effects were more commonly observed with both medications, highlighting the need for careful monitoring during treatment.

Conflicts of interest: The authors have declared no conflicts of interest.

Acknowledgement

The authors are grateful to Dr. T. K Ravi, Principal of Sri Ramakrishna College of Pharmacy, Coimbatore, for providing facilities for the conduct of the clinical study.

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