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A RETROSPECTIVE STUDY TO ASSESS EFFECTIVENESS AND SAFETY OF BRIVARACETAM IN INDIAN EPILEPSY PATIENTS (BESURE STUDY)

Neurology

Nitin Kapure* Department of Medical Affairs, Alkem Laboratories, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra 400013*Corresponding Author

Mayur Mayabhate Department of Medical Affairs, Alkem Laboratories, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra 400013

Akhilesh Sharma Department of Medical Affairs, Alkem Laboratories, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra 400013

ABSTRACT

Background: Epilepsy is one of the most prevalent neurological disorders globally, affecting approximately 50 million people worldwide, with India contributing a substantial proportion (~12 million) to this burden. Brivaracetam (BRV) is a third-generation antiseizure medication (ASM) that exhibits selective and high-affinity binding to synaptic vesicle protein 2A (SV2A), demonstrating broad-spectrum antiseizure activity. Though widely approved for focal and generalized epilepsies, real-world data on its use in Indian clinical settings remain limited.

BOX 1: Key highlights.

- Largest Indian real world BRV cohort
- 66.1 percent responder rate
- 29.2 percent seizure freedom at 3 months
- Low psychiatric adverse event burden
- Good adherence in over 75 percent patients
- Physician rated efficacy excellent or good in 93.5 percent

Note: Data from the study.

Objective : To evaluate the effectiveness and safety of brivaracetam in Indian patients with epilepsy in routine clinical practice under real-world conditions. **Methods :** This was a multicentre, retrospective, observational study (BESURE study) conducted across India. A total of 8,634 patients who had received brivaracetam were included. Demographic data, epilepsy type, seizure frequency at baseline and 3-month follow-up, treatment adherence, adverse events, and physician global efficacy assessments were analyzed. **Results :** The study enrolled 8,634 patients (mean age: 40.7 ± 13.3 years; 61.0% male). Focal epilepsy was the most common type (55.7%). The mean duration of epilepsy was 4.0 ± 4.7 years. At 3-month follow-up, 87.4% of patients showed a decrease in seizure frequency, and 29.2% achieved seizure freedom. The ≥50% responder rate was 66.1%. Treatment adherence was good in 77.2% of patients. Only 30 patients (0.35%) reported adverse events, the most common being dizziness. The physician global efficacy assessment was excellent or good in 93.5% of patients. **Conclusion :** Brivaracetam demonstrated clinically meaningful seizure reduction, a high seizure-freedom rate, favourable tolerability, and good adherence in a large cohort of Indian epilepsy patients under routine clinical practice conditions. These findings support the effectiveness and safety of brivaracetam as an important therapeutic option for epilepsy management in India.

KEYWORDS

INTRODUCTION

Epilepsy is a chronic neurological disorder characterized by recurrent unprovoked seizures, affecting an estimated 50 million individuals worldwide [1,2]. Antiseizure medications (ASMs) remain the cornerstone of epilepsy treatment. Despite the availability of more than 30 approved ASMs, approximately 30% of patients continue to experience drug-resistant epilepsy. The development of newer ASMs with novel mechanisms of action is therefore clinically significant [3].
Brivaracetam (BRV); is a high-affinity, selective synaptic vesicle glycoprotein 2A (SV2A) ligand with approximately 15–30 times higher binding affinity for SV2A compared to levetiracetam [4]. It is approved as adjunctive therapy for focal onset seizures in adults and adolescents aged 4 years and above [6].

Phase III randomized controlled trials and subsequent post-marketing studies in Western populations have established the clinical efficacy, favourable tolerability, and improved behavioural/psychiatric profile of BRV compared to levetiracetam [5,12]. However, real-world evidence from Indian clinical practice — incorporating a diverse patient population with varying comorbidity profiles, concomitant medications, and healthcare-seeking behaviours — is limited [7,9].

India alone bears a significant burden, with approximately 12 million people living with epilepsy — nearly one-quarter of the global total. The management of epilepsy is challenging due to the heterogeneity of seizure types, comorbidities, and individual patient variability in drug response and tolerability [10].

The BESURE (Brivaracetam Effectiveness and Safety in a Real-world Indian Epilepsy) study was designed to address this gap by retrospectively characterizing the real-world effectiveness and safety of BRV in Indian epilepsy patients across multiple centres.

METHODS

Study Design and Setting

The BESURE study was a multicentre, retrospective, observational study conducted at epilepsy clinics and neurology outpatient departments across India. Data were collected from patient medical records. The study was conducted in accordance with the Declaration of Helsinki and applicable national regulatory guidelines. Institutional ethics committee approval was obtained prior to study initiation.

Study Population

Adult and paediatric patients (age ≥1 year) with a confirmed diagnosis of epilepsy who had received brivaracetam for at least one clinic visit and had at least one follow-up assessment at or around 3 months were included. Patients with incomplete records or those who had received BRV for indications other than epilepsy were excluded.

Data Collection

Data extracted from medical records included: demographic information (age, gender, height, weight); clinical characteristics (epilepsy type, duration of epilepsy, age at epilepsy onset, baseline seizure frequency, family history of epilepsy); medical history (comorbid conditions); previous Antiseizure Medication (ASM) treatment history; BRV treatment details (dose, adherence); and 3-month follow-up outcomes (seizure frequency, change in seizure frequency, adverse events, and physician global efficacy assessment).

Study Outcomes

The primary effectiveness outcomes were:

1. Change in seizure frequency at 3 months compared to baseline
2. ≥50% responder rate (patients achieving ≥50% reduction in monthly seizure frequency)
3. Seizure freedom rate (0 seizures at 3 months)

Secondary outcomes included: physician global efficacy assessment, treatment adherence, and safety (incidence and nature of adverse events).

Statistical Analysis

Descriptive statistics were used to summarize patient demographics and clinical characteristics. Continuous variables are presented as mean ± standard deviation (SD) and median with interquartile range (IQR). Categorical variables are presented as frequency (n) and percentage (%). Change in seizure frequency between baseline and 3-month follow-up was analyzed among patients with available numeric

seizure frequency data at both time points. No formal hypothesis testing was performed due to observational design.

RESULTS

Patient Demographics

A total of 8,634 patients were included in the analysis. The demographic characteristics are summarized in Table 1. The mean age was 40.7 ± 13.3 years (median: 40 years; range: 1–90 years). The study population was predominantly male (61.0%; n=5,269), with females comprising 38.4% (n=3,315) and other gender 0.6% (n=50). The mean BMI was 25.1 ± 4.2 kg/m². The majority of patients were in the 31–45year age group (43.1%), followed by the 46–60year group (26.8%).

Family history of epilepsy was present in 1,130 patients (13.1%). A total of 3,682 patients (42.7%) had at least one comorbid condition. The most frequently reported comorbidities were depression and anxiety disorders (684 patients, 7.9%), migraine (324 patients, 3.8%), sleep disorders (302 patients, 3.5%), and autoimmune disorders (284 patients, 3.3%).

Table 1: Baseline Demographic and Clinical Characteristics (N=8,634)

Parameter	n / Mean ± SD	Percentage / Range
Total patients	8,634	—
Age, years (mean ± SD)	40.7 ± 13.3	—
Age, years (median [IQR])	40 [32–50]	—
Gender – Male	5,269	61.0%
Gender – Female	3,315	38.4%
Gender – Other	50	0.6%
BMI, kg/m² (mean ± SD)	25.1 ± 4.2	—
Family history of epilepsy	1,130	13.1%
Duration of epilepsy, years (mean ± SD)	4.0 ± 4.7	—
Focal epilepsy	4,809	55.7%
Generalized epilepsy	3,168	36.7%
Unknown epilepsy type	657	7.6%
Baseline seizure frequency (mean ± SD, per month)	3.1 ± 2.4	—
Any comorbidity present	3,682	42.7%

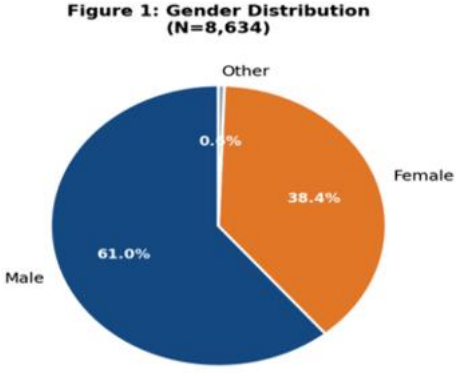

Figure 1: Gender Distribution of Study Patients (N=8,634)

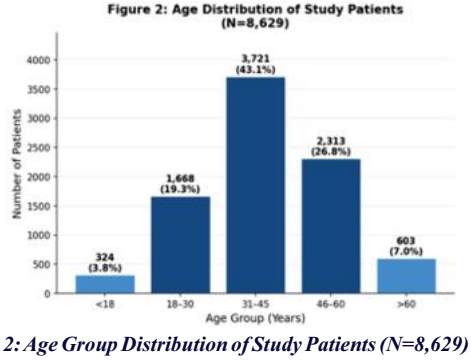

Figure 2: Age Group Distribution of Study Patients (N=8,629)

Clinical Characteristics

Focal epilepsy was the most prevalent type, accounting for 55.7% of patients (n=4,809), followed by generalized epilepsy in 36.7% (n=3,168) and unknown type in 7.6% (n=657; Figure 3). The mean duration of epilepsy at study entry was 4.0 ± 4.7 years (median: 3 years; IQR: 1–5 years). The mean age at epilepsy onset was 35.6 years. The mean baseline monthly seizure frequency was 3.1 ± 2.4 (median: 3 per month).

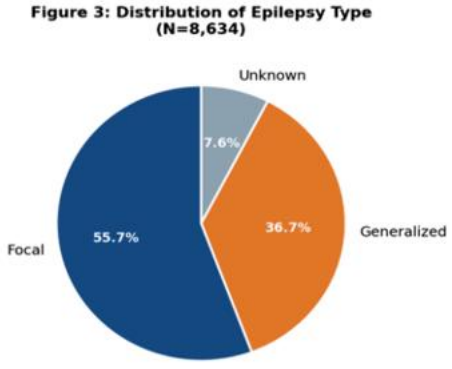

Figure 3: Distribution of Epilepsy Type (N=8,634)

Previous Antiseizure Medication Use

The majority of patients had been previously treated with at least one antiseizure medication prior to initiating or using brivaracetam concurrently. The most commonly documented prior ASMs included levetiracetam (various formulations), sodium valproate, clobazam, and phenytoin sodium. Brivaracetam was used in both add-on and switch settings, reflecting the real-world practice of the treating neurologists.

Brivaracetam Treatment Details

The most frequently prescribed BRV dose was 50 mg/day (either once daily or in divided doses), followed by 100 mg/day and 75 mg/day. Dosing was individualized per treating physician judgment based on clinical response and tolerability. Treatment adherence was rated as good in 77.2% of patients (n=6,664), fair in 20.6% (n=1,776), and poor in 1.3% (n=111).

Table 2: Brivaracetam Dosing and Adherence

Characteristic	n	%
Most common dose: 50 mg/day	2,486	28.8%
100 mg/day	1,544	17.9%
75 mg/day	413	4.8%
Other doses	4,191	48.5%
Treatment Adherence – Good	6,664	77.2%
Treatment Adherence – Fair	1,776	20.6%
Treatment Adherence – Poor	111	1.3%

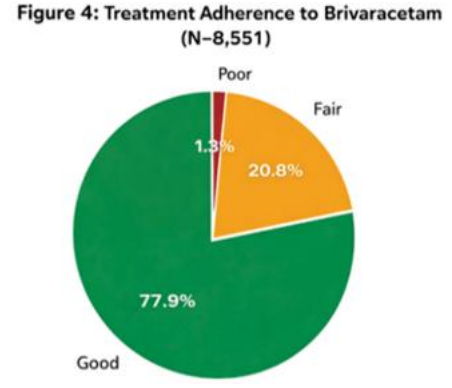

Figure 4: Treatment Adherence to Brivaracetam (N=8,551)

Effectiveness Outcomes at 3-Month Follow-up

Change in Seizure Frequency

At 3-month follow-up, seizure frequency had decreased in 87.4% of patients (n=7,548), remained unchanged in 10.5% (n=903), and increased in 1.2% (n=100). When analyzed among the 7,760 patients with available numeric seizure frequency data at both baseline and follow-up:

- ≥50% responder rate: 66.1% (n=5,130)
- Seizure-freedom rate: 29.2% (n=2,267)
- Mean seizure frequency decreased from 3.1 ± 2.4 at baseline to 1.5 ± 2.6 at 3 months

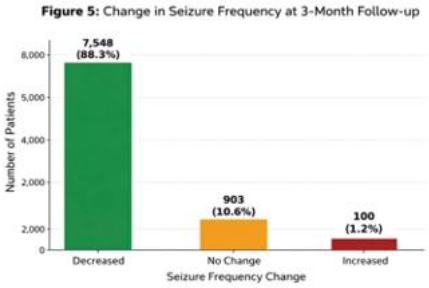

Figure 5: Change in Seizure Frequency at 3-Month Follow-up (N=8,551)

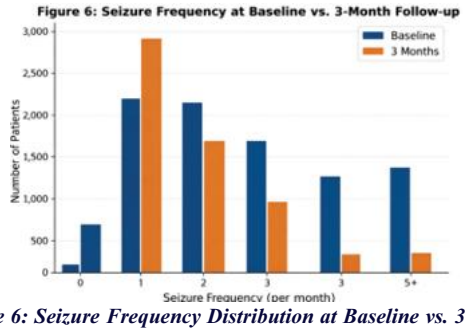

Figure 6: Seizure Frequency Distribution at Baseline vs. 3-Month Follow-u

Table 3: Effectiveness Outcomes at 3-Month Follow-up

Outcome	n	%
Decrease in seizure frequency	7,548	87.4%
No change in seizure frequency	903	10.5%
Increase in seizure frequency	100	1.2%
≥50% seizure frequency reduction (responders)	5,130	66.1%
Seizure freedom (0 seizures at 3 months)	2,267	29.2%
Mean baseline seizure frequency (per month)	3.1 ± 2.4	—
Mean 3-month seizure frequency (per month)	1.5 ± 2.6	—

Physician Global Efficacy Assessment

The physician's global efficacy assessment at 3 months was rated as excellent in 34.9% (n=2,985) and good in 59.5% (n=5,086) of patients, yielding a combined excellent/good response in 93.5% of patients. Average and poor ratings were reported in 5.2% (n=442) and 0.4% (n=38) of patients, respectively (Figure 7).

Figure 7: Physician's Global Efficacy Assessment at 3-Month Follow-up (N=8,551)

Safety and Tolerability

Brivaracetam was well-tolerated in the vast majority of patients. Adverse events were reported in only 30 patients (0.35% of the total cohort). The most commonly reported adverse event was dizziness (n=17, 0.20%), followed by irritated mood (n=1), suicidal tendency (n=2), mood changes (n=1), weight gain (n=1), aggression (n=1), and vomiting (n=1). No serious adverse events leading to hospitalization or death were reported. There were no reports of psychiatric adverse events at a rate higher than those seen with older ASMs.

Table 4: Adverse Events Reported at 3-Month Follow-up

Adverse Event	n	%
Total patients with any adverse event	30	0.35%
Dizziness	17	0.20%
Suicidal tendency	2	0.02%
Mood changes / Irritated mood	2	0.02%
Aggressive behaviour	1	0.01%
Weight gain	1	0.01%
Vomiting	1	0.01%
Other	6	0.07%

DISCUSSION

This large-scale, multicentre, retrospective, real-world study — the BESURE study — enrolled 8,634 epilepsy patients across India who had received brivaracetam and had a 3-month follow-up. The study provides important and clinically meaningful real-world evidence supporting the effectiveness and safety of BRV in an Indian patient population.

The demographic profile of our cohort — predominantly middle-aged adults (mean age 40.7 years), majority male (61%), and most frequently with focal epilepsy (55.7%) — is consistent with the broader epidemiology of epilepsy in India and aligns with published data from clinical trials and observational studies of BRV [5,7,9,12].

The primary effectiveness finding of this study was highly encouraging. At 3-month follow-up, 87.4% of patients demonstrated a decrease in seizure frequency from baseline, a ≥50% responder rate of 66.1%, and a seizure-freedom rate of 29.2%. These outcomes compare favourably with the results of pivotal Phase III trials of BRV, where responder rates ranged from 38% to 55% at therapeutic doses (50–200 mg/day) [5,12], and are consistent with real-world observational data from European and Asian cohorts [7,9]. The higher responder rates in our study may be attributable to the uncontrolled nature of observational designs, physician optimization of therapy over the follow-up period, and the inclusion of patients switched from levetiracetam to BRV with potentially improved tolerability driving better adherence and outcomes.

The safety profile of BRV in this large real-world Indian cohort was favourable. Only 0.35% of patients reported adverse events, which appears lower than rates reported in controlled clinical trials and real-world studies from other populations (15–30%) [5,7,9,12]; however, this observation should be interpreted with caution given the retrospective design and potential for underreporting. The most common adverse event was dizziness, observed in 0.20% of patients. Importantly, psychiatric adverse events such as irritability, aggression, and mood changes — which are a significant concern with levetiracetam and represent a key reason for drug switching — were exceedingly rare in this cohort. This supports the established evidence that BRV has a more favourable neuropsychiatric tolerability profile than levetiracetam [4,6], attributable to its lower affinity for non-SV2A targets.

Treatment adherence was rated as good in 77.2% of patients, reflecting the favourable tolerability profile of BRV and once-or twice-daily dosing convenience. Good adherence is a critical determinant of long-term seizure control in epilepsy and BRV's tolerability advantages appear to translate into improved real-world adherence [10]. The physician global efficacy assessment — rated excellent or good in 93.5% of patients — further corroborates the clinical effectiveness observed in this cohort.

Comorbidities were prevalent in this cohort, with depression and anxiety disorders, migraine, sleep disorders, and autoimmune disorders being most common [11]. This reflects the well-known association between epilepsy and psychiatric comorbidities. The favourable neuropsychiatric profile of BRV is particularly advantageous in this population, and the low rate of psychiatric adverse events in our study further supports its use in patients with comorbid psychiatric conditions [4,6].

The BESURE study has several strengths: large sample size (N=8,634), multicentre design spanning diverse Indian clinical settings, comprehensive data capture including seizure frequency, adherence, and safety outcomes, and a patient population representative of real-world epilepsy management in India.

This study has few inherent limitations. First, the retrospective observational design limits causal inference and is subject to selection and documentation bias. Second, the absence of a comparator or control arm restricts direct comparative evaluation of effectiveness and safety. Third, missing or incomplete data, particularly for adverse event reporting, may have influenced outcome estimates.

CONCLUSIONS

The BESURE study demonstrates that brivaracetam is an effective and well-tolerated antiseizure medication in Indian patients with epilepsy in real-world clinical practice. At 3-month follow-up, a substantial majority of patients (87.4%) experienced a reduction in seizure frequency, with a ≥50% responder rate of 66.1% and a seizure-freedom rate of 29.2%. Adverse events were rare (0.35%), and treatment adherence was good in 77.2% of patients. Physician global efficacy assessment was excellent or good in 93.5% of patients.

These real-world findings from a large, diverse Indian cohort substantiate the role of brivaracetam as a clinically important therapeutic option in Indian epilepsy management, offering a compelling combination of efficacy, tolerability, and adherence.

DECLARATIONS

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional ethics committee approval was obtained prior to study initiation. Patient data were anonymized and de-identified prior to analysis. The requirement for written informed consent was waived given the retrospective nature of the study.

Conflict of Interest: The authors declare no conflicts of interest.

Funding:
This study was supported by Alkem Laboratories Limited. All authors have declared that no additional financial support was received from any other organization for the submitted work.

Data Availability:
Data supporting the findings of this study are available from the corresponding author upon reasonable request.

SUPPLEMENTARY MATERIAL

Supplementary Table S1: Comorbidity Profile of Study Patients

Comorbid Condition	n	%
Depression & anxiety disorders	684	7.9%
Migraine	324	3.8%
Sleep disorders	302	3.5%
Autoimmune disorders	284	3.3%
Psychotic conditions	272	3.2%
Diabetes	172	2.0%
Cardiovascular diseases	60	0.7%
Gastrointestinal conditions	34	0.4%
Asthma	12	0.1%
No comorbidity	4,952	57.3%

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