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# ROLE OF BRIVARACETAM AS MONO-THERAPY IN FOCAL EPILEPSY AMONG CHILDREN LESS THAN 16 YEARS AGE

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**ABSTRACT**
**Objective**: To evaluate the effectiveness and safety of briveracetam (BRV) as monotherapy in managing focal epilepsy in children in a real world.
**Study design**: Quasi experimental clinical study.
**Place and duration of study**: Study was conducted in Paediatric Neurology Unit, The University of Child Health Sciences, Children's Hospital Lahore from February to August 2025.
**Methodology:** This quasi-experimental clinical study included 27 children aged less than 16 years with electroclinically diagnosed focal epilepsy enrolled through non-probability consecutive sampling. Baseline demographic, clinical, and electroencephalographic data were recorded. Brivaracetam was administered in two divided daily doses, and children were followed at 2 weeks, 1 month, and 3 months for efficacy and adverse events. Data were analyzed in SPSS version 26 using Fisher's exact test, with $p \leq 0.05$ considered significant.
**Results**: Among 27 children, the mean age was 5.22 ± 3.97 years and 17 (63.0%) were male. Focal clonic seizures were the most common seizure type, seen in 12 (44.4%) children. The mean baseline seizure frequency was 9.22 ± 9.27 per month. Complete seizure freedom was achieved in 5 (18.5%) children at the first visit, 15 (55.6%) at the second visit, and 18 (66.7%) at the third visit. No adverse effects were observed in 8 (29.6%) children. The most frequent adverse effects were irritability in 10 (37.0%), insomnia in 4 (14.8%), somnolence in 3 (11.1%), headache in 1 (3.7%), and anorexia in 1 (3.7%) child.
**Conclusion**: BRV is a reliable drug and efficacy (complete cessation of seizures) can be achieved within 3 months of treatment.

**KEYWORDS**: Brivaracetam, effectiveness, focal epilepsy, monotherapy.

## INTRODUCTION

Epilepsy is the fourth most common neurological disorder worldwide. According to estimates from the World Health Organization, 50 million people worldwide have epilepsy. Every year, about 5 million new cases are identified globally.[1, 2] The prevalence of epilepsy in pediatric population fluctuates from 7.5 to 44.3 per 1,000 in developing countries, while it is approximately 5 per 1,000 in industrialized countries. Despite the lack of adequate epidemiological research for Pakistan, the prevalence of epilepsy is estimated to be 9.99/1000.[3, 4] The majority of studies indicate that among the principal kinds of epilepsy, focal seizures (29.3–63%) are marginally more common than generalized seizures (12.9–48%).[5]
Treatment is deficient in a number of areas, including access, prevention, education, and stigma.[6] Patients with epilepsy must be treated with antiseizure medications (ASMs). The ASMs include valproate, carbamazepine, clobazam, topiramate, levetiracetam, ethosuximide, lamotrigine, and vigabatrin. Carbamazepine is the main drug used to treat focal epilepsy. Despite their remarkable effectiveness, these drugs are unable to totally control seizures about 30% of the time.[7, 8] Since BRV is associated with less clinically relevant drug-drug interactions. In the US, BRV, a third-generation ASM, is advised as a monotherapy and adjuvant for the treatment of focal epilepsy in patients one month of age and older. Response rates to BRV monotherapy and adjunctive treatment were similar to those observed in previous adult participant trials. Most of the individuals in the post-marketing trial had either previously or currently undergone therapy with LEV.[9, 10]
This study was carried out to examine the effectiveness and tolerance of BRV as monotherapy in pediatric patients with unresponsive focal epilepsy due to the gap in the literature and the need for improved documentation of the drug's safety and efficacy. The goal is to provide local clinical data on BRV as a monotherapy medication for short-term along-seizures in the Pakistani community since there is potential for substantial research on BRV.

## METHODOLOGY

The study protocol was approved by the Institutional Review Board/Ethical Committee, University of Child Health Sciences, The Children's Hospital Lahore (Approval No. 1074/CH-UCHS, 26 February 2025). This quasi-

experimental clinical study was carried out in Paediatric Neurology Unit, The University of Child Health Sciences, Children's Hospital Lahore from February to August 2025. Sample size was calculated using OpenEpi version 3.01 for estimation of a single population proportion. The expected seizure-free proportion was taken as 18% from a previous systematic review and meta-analysis of brivaracetam in children with epilepsy.[14] Using a 95% confidence level and 15% absolute precision, the minimum required sample size was 25. After adding 5% for possible non-response/loss to follow-up, the final sample size was 27 children. A total of 27 patients fulfilled the inclusion criteria and were enrolled. All the children were enrolled by using non-probability, consecutive sampling technique who fulfilled following selection criteria.

Inclusion criteria included children aged less than 16 years, either gender having focal epilepsy (diagnosed electroclinically) with or without secondary generalization if it originates from one hemisphere of the brain, having at least 1 fit per month were included.

Exclusion criteria included study participant has a history of psychogenic non-epileptic seizures, or febrile seizures, history of status epilepticus in the 30 days, any hypersensitivity to BRV or if they have been contraindicated to the medicine or any component of prescribed therapy were excluded.

Written and informed consent was taken from parents after proper guidance about research. Children's demography, medical history (including comorbidities), electroencephalographic findings were considered. Children were assessed at 3 study time points (2 weeks, 1 month and 3 months). Children with no response, worsening or serious adverse effects were shifted to other ASM as per guidelines. Children were followed for 3 months. Response to treatment and adverse events were documented. BRV (Brivera/Cubriva) oral solution or tablets were administered twice daily in 2 equally divided doses in children fall in age range from 1 month to <16 years. In children, dosing was individualized according to body weight, therapeutic response, and tolerability. Published pediatric data support weight-adjusted dosing, with regimens generally ranging from about 0.8–4.0 mg/kg/day in short-term studies and up to 1–5 mg/kg/day in longer follow-up, with a maximum daily dose of 200 mg. In the present study, the starting dose and subsequent escalation were adjusted according to clinical response and adverse effects.[14, 16] Reduction in seizure frequency by 70% in at least 50% of participants after 3 months of adding BRV as monotherapy was considered as effectiveness. An undesired effect, attributable to the use of BRV were also noted. All the data was noted in proforma.

Data analysis was performed and analyzed in SPSS software version 26. For numeric variables, mean and standard deviation were calculated like for current age of child and duration of BRV treatment. Frequency and percentage was estimated for categorical variables like gender, and efficacy and tolerability of the drug. Fischer test was used to check the significant difference in the efficacy of treatment with type of seizures, keeping p-value ≤0.05 as significance level.

**RESULT**

In this study, we enrolled total 27 children with epilepsy. The mean age of children was 5.22 ± 3.97 years. There were 17 (63%) male children and 10 (37%) female children. The most common type of seizure observed was Focal Clonic [12 (44.4%)], followed by Focal to bilateral seizures [6 (22.2%)], focal tonic [5 (18.5%)] and few others. Previous Status Epilepticus was reported in 19 (70.4%) cases. Normal EEG findings were recorded in 15 (55.6%) children while remaining 12 showed significant changes in EEG (see table-I below). The mean age of children at onset of seizures was 2.83 ± 2.71 years, while BRV treatment was started at mean age of 4.94 ± 3.79 years. Previous and Concomitant adverse events of drug (with dosages) was noted in 8 (29.6%) cases. Comorbidities (including CP, ID, DD, HD, ADHD, ASD, hyperactivity, Post-encephalitic sequelae) were noted in 15 (55.6%) cases. Table-I

**Table-I: Demographics details of children enrolled for the study (n = 27)**

| **Parameters** | **F (%)** |
|---|---|
| Age in years | 5.22 ± 3.97 |
| Gender | |
| Male | 17 (63%) |
| Female | 10 (37%) |
| Type of seizures | |
| Focal Clonic | 12 (44.4%) |
| Focal motor with impaired awareness | 1 (3.7%) |
| Focal Myoclonic | 2 (7.4%) |
| Focal non-motor (behavioral arrest) | 1 (3.7%) |
| Focal to bilateral | 6 (22.2%) |
| Focal Tonic | 5 (18.5%) |
| Previous Status Epilepticus | 19 (70.4%) |
| EEG Findings | |
| Burst suppression | 1 (3.7%) |
| Focal epileptiform discharges | 7 (25.9%) |

| | |
|---|---|
| Multifocal epieptiform discharges | 4 (14.8%) |
| Normal | 15 (55.6%) |
| Age at Onset of Seizures, years | 2.83 ± 2.71 |
| Age at Start of BRV, years | 4.94 ± 3.79 |
| Previous and Concomitant adverse events of drug (with dosages) | 8 (29.6%) |
| Comorbidities (CP, ID, DD, HD, ADHD, ASD, hyperactivity, Post-encephalitic sequelae) | 15 (55.6%) |
| BRV = brivaracetam; EEG = electroencephalogram; CP = cerebral palsy; ID = intellectual disability; DD = developmental delay; HD = hyperkinetic disorder; ADHD = attention-deficit/hyperactivity disorder; ASD = autism spectrum disorder. | |

The mean dose at the time of starting BRV was 1.33 ± 0.44 mg/kg/day. About 16 (59.3%) children were given 1 mg/kg/day dose at start, 4 (14.8%) children were given 1.5 mg/kg/day while 7 (25.9%) children were given 2 mg/kg/day as starting dose. The mean BRV Escalation Dose was 2.76 ± 1.07 mg/kg/day. Escalation dose was increased to 5 mg/kg/day in 2 (7.4%) children, while in 12 (44.4%) children, escalation dose was 2 mg/kg/day. The mean period for BRV use was 6.44 ± 3.60 months. In 24 (88.9%) children, BRV was given for 6 months only and efficacy was achieved. Table-II

**Table-II: Outcome of BRV Treatment (n = 27)**

| **Parameters** | **F (%)** |
|---|---|
| BRV Starting Dose (mg/kg/day) | 1.33 ± 0.44 |
| 1 mg/kg/day | 16 (59.3%) |
| 1.5 mg/kg/day | 4 (14.8%) |
| 2 mg/kg/day | 7 (25.9%) |
| BRV Escalation Dose (mg/kg/day) | 2.76 ± 1.07 |
| 1 mg/kg/day | 1 (3.7%) |
| 1.5 mg/kg/day | 1 (3.7%) |
| 2 mg/kg/day | 12 (44.4%) |
| 3 mg/kg/day | 6 (22.2%) |
| 4 mg/kg/day | 5 (18.5%) |
| 5 mg/kg/day | 2 (7.4%) |
| Duration of BRV therapy | 6.44 ± 3.60 |
| Used only 3 months | 2 (7.4%) |
| Used for 6 months | 24 (88.9%) |
| Used for 2 years | 1 (3.7%) |

At baseline, the mean seizures frequency was 9.22 ± 9.27 per month. After 1st visit, efficacy (complete seizures free status) was achieved in 5 (18.5%) children, while remaining 22 (81.5%) children still had episodes of seizures. After 2nd visit, efficacy (complete seizures free status) was achieved in 15 (55.6%) children, while remaining 12 (44.4%) children still had episodes of seizures. After 3rd visit, efficacy (complete seizures free status) was achieved in 18 (66.7%) children, while remaining 9 (32.3%) children still had episodes of seizures. Safety was observed in 8 (29.6%) children only. Most of the children [10 (37.0%)] had irritability, 4 (14.8%) had insomnia, 3 (11.1%) had somnolence, while one had headache and one had anorexia. Table-III

**Table-III: Efficacy and safety of BRV treatment (n = 27)**

| | | **F (%)** |
|---|---|---|
| Baseline Seizure Frequency /month | | 9.22 ± 9.27 |
| After 1st visit | Complete seizure free | 5 (18.5%) |
| | Aura without seizure | 3 (11.1%) |
| | Focal with secondary generalization | 3 (11.1%) |
| | 1 seizure/month | 6 (22.2%) |
| | 3 seizure/month | 4 (14.8%) |
| | 4 seizure/month | 2 (7.4%) |
| | 5 seizure/month | 3 (11.1%) |
| | 8 seizure/month | 1 (3.7%) |
| After 2nd visit | Complete seizure free | 15 (55.6%) |
| | Focal with secondary generalization | 6 (22.2%) |
| | Only aura no seizures | 1 (3.7%) |
| | 2 seizure/month | 4 (14.8%) |
| | 4 seizure/month | 1 (3.7%) |

| | | |
|---|---|---|
| After 3rd visit | Complete seizure free | 18 (66.7%) |
| | Focal with secondary generalization | 7 (25.9%) |
| | Occasional | 1 (3.7%) |
| | 2 seizure/month | 1 (3.7%) |
| Safety / tolerability | Yes | 8 (29.6%) |
| | No | 19 (70.4%) |
| | Adverse effects noted | |
| | Anorexia | 1 (3.7%) |
| | Headache | 1 (3.7%) |
| | Insomnia | 4 (14.8%) |
| | Irritability | 10 (37.0%) |
| | Somnolence | 3 (11.1%) |

At the 3rd visit, 18 of 27 children (66.7%) were completely seizure free. When stratified by seizure type, complete seizure freedom was seen in 7 of 12 patients (58.3%) with focal clonic seizures, 1 of 1 (100.0%) with focal motor with impaired awareness, 2 of 2 (100.0%) with focal myoclonic seizures, 1 of 1 (100.0%) with focal non-motor seizures, 5 of 6 (83.3%) with focal to bilateral seizures, and 2 of 5 (40.0%) with focal tonic seizures. The association between seizure type and complete seizure freedom was not statistically significant on Fisher's exact test (p=0.575). Regarding safety, 8 of 27 patients (29.6%) had no adverse effects. No adverse effects were observed in 3 of 12 patients (25.0%) with focal clonic seizures, 0 of 1 (0%) with focal motor with impaired awareness, 0 of 2 (0%) with focal myoclonic seizures, 1 of 1 (100.0%) with focal non-motor seizures, 1 of 6 (16.7%) with focal to bilateral seizures, and 3 of 5 (60.0%) with focal tonic seizures. The difference in safety across seizure types was also not statistically significant by Fisher's exact test (p=0.352). Table-IV

**Table IV. Final outcome according to seizure type**

| **Final outcome** | **Focal Clonic n=12** | **Focal motor with impaired awareness n=1** | **Focal Myoclonic n=2** | **Focal non-motor (behavioral arrest) n=1** | **Focal to bilateral n=6** | **Focal Tonic n=5** | **Fisher's exact p-value** |
|---|---|---|---|---|---|---|---|
| Complete seizure free | 7 (58.3%) | 1 (100.0%) | 2 (100.0%) | 1 (100.0%) | 5 (83.3%) | 2 (40.0%) | 0.575 |
| No adverse effects (Nil) | 3 (25.0%) | 0 (0.0%) | 0 (0.0%) | 1 (100.0%) | 1 (16.7%) | 3 (60.0%) | 0.353 |

Data are presented as n (% within seizure type). Fisher's exact test was used to assess the association of seizure type with complete seizure freedom at the 3rd visit and with no adverse effects)

## DISCUSSION

In this study, the mean number of seizures at baseline was 9.22 ± 9.27 per month. At the end of the study, complete seizure freedom was achieved in 18 (66.7%) children. Regarding tolerability, 8 (29.6%) children had no adverse effects, while the remaining children reported at least one adverse effect. According to a systemic analysis by Bresnahan et al., candidates who received the BRV add-on were more likely than those who received a placebo to see more than fifty percent reduction in the seizures frequency (RR:1.81, 95%CI: 1.53-2.14). Also candidates who received BRV were more likely to achieve seizure freedom status (RR:5.89, 95%CI: 2.30-15.13),. Candidates receiving BRV had a slightly higher treatment withdrawal rate than those received placebo (RR:1.27, 95%CI: 0.94-1.74).[11]

Biton et al., randomly assigned 400 individuals to either placebo or BRV dose of 5, 20, or 50 mg two times per day, in a prospective, double-blind research. When compared to a placebo, the percentage decrease in seizure frequency was -0.9% (p-value=0.885) for BRV 5 mg, 4.1% (p-value =0.492) for BRV 20 mg, and 12.8% (p-value=0.025) for BRV 50 mg twice daily. Only BRV 50 mg/day dose achieved significant difference for reduction in seizures frequency than other two doses.[12]

In a different research, Ryvlin et al., randomly assigned 399 individuals to receive 20, 50, or 100 mg per day of BRV, or placebo, for twelve weeks. For BRV 20 mg, BRV 50 mg, and BRV 100 mg, percentage decrease in seizures frequency was 6.8% (p=0.239), 6.5% (p=0.261), and 11.7% (p=0.037) as compared to placebo.[13] In this trial, 50 mg/day could not achieve significant difference than placebo, in contrast to the trial conducted by Biton et al., although the 100 mg/day demonstrated more than 50% reduction in seizures frequency than baseline.[12]

Song et al., conducted a systemic review and meta-analyses of nine trials and observed that among 503 children with epilepsy, efficacy (more than fifty percent decrease in seizures frequency) was achieved in 35% cases, with seizure free rate of 18%. Treatment-emergent adverse events were noted in 39% cases. The most common adverse

evet was somnolence observed in 9% cases, and mental or behavioral dysfunction was observed in 12% children.[14] Špilárová et al., conducted a cohort study and observed that efficacy was achieved in 25.8% children within 3 months, in 16.1% children within 6 months, and in 17.2% children within 12 months. Tolerance against drug was noted in 75.3% children reported no adverse events.[15]

The International League Against Epilepsy (ILAE) has been debating classification changes as well as basic concepts and language associated with epilepsy and seizures. Generalized seizures are defined by ILAE as tonic clonic, absence, myoclonic, clonic, tonic, and atonic seizures that rapidly activate bilaterally scattered networks.[16, 17] The development of new ASMs with more contemporary modes of action, like those that target synaptic vesicle glycoprotein 2A (SV2A), has become necessary due to the increasing incidence of therapy-resistant epilepsy during the past 20 years. [18] Compared to LEV, BRV has a higher brain permeability and a 15–30 times larger affinity for SV2A. It is far more fat soluble than benzodiazepines and phenytoin.[19-21]

In this trial, we observed few limitations due to financial and time constraints including small sample size and single centered study. Therefore, it is recommended to conduct further trials, especially randomized trial to confirm that BRV is a reliable medication for epilepsy to control seizures and improve quality of life of children.

## CONCLUSION

BRV is a reliable drug and efficacy (complete cessation of seizures) can be achieved within 3 months of treatment. BRV can be now given as a monotherapy in pediatric individuals with unresponsive focal epilepsy. Moreover, dose adjustments is recommended by considering the variations in maximum systemic concentration and comorbidities.

## ETHICAL APPROVAL:

The study protocol was approved by the Institutional Review Board/Ethical Committee, University of Child Health Sciences, The Children's Hospital Lahore (Approval No. 1074/CH-UCHS, 26 February 2025).

## PATIENTS' CONSENT:

Informed written consent was taken from the guardians of the infants.

## COMPETING INTEREST:

The authors declare no conflict of interest.

## AUTHORS' CONTRIBUTION:

**IS:** Study design, data acquisition, analysis, interpretation, and drafting of the manuscript.
**TS:** Study supervision, critical review of methodology, and final approval of the manuscript.
**SHK, SAK:** Data acquisition, patient evaluation, and contribution to clinical data.
**AA, UF:** Data analysis, manuscript revision, and literature review.
All authors approved the final version of the manuscript to be published.

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