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Research Article

COMPARATIVE EVALUATION OF LEVETIRACETAM AND BRIVARACETAM IN THE MANAGEMENT OF FOCAL EPILEPSY: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Objective: Focal epilepsy accounts for the majority of epilepsy cases in the global scenario and is often intractable to therapy because of variability in etiology and drug resistance. Levetiracetam (LEV) and its more recently developed analogue brivaracetam (BRV), are widely prescribed antiepileptic drugs acting through synaptic vesicle protein 2A. The present study compares the efficacy, tolerability, and impact on the quality of life of both LEV and BRV in Indian patients with focal epilepsy.

Methods: A prospective comparative observational study was done at KIMS Hospitals, Rajahmundry for 6 months. Sixty adult patients were enrolled using purposive sampling and divided into two groups: LEV-Group A and BRV-Group B. Seizure frequency and health-related quality of life by World Health Organization Quality of Life-BREF were assessed at baseline, 3 months, and 6 months. The statistical tools used included paired and independent t-tests. Results with $p<0.05$ were considered significant.

Results: Both LEV and BRV were associated with a significant reduction in seizure frequency, with $p<0.001$. BRV was associated with a numerically greater mean reduction of 2.56 versus 2.17, though this did not reach statistical significance. Quality-of-life improvement was noted in both groups, though higher gains were realized in the BRV group in various areas: Physical and psychological. In both, the reported adverse effects were of a mild nature, though behavioral disturbances were more frequent with LEV.

Conclusion: LEV and BRV are equal in efficacy with regard to seizure control, but BRV shows better tolerability and a slightly greater improvement in quality of life, supporting its role as a preferred alternative for patients who are intolerant to LEV.

Keywords: Focal epilepsy, Levetiracetam, Brivaracetam, Synaptic vesicle protein 2A, Quality of life, Antiepileptic drugs.

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INTRODUCTION

Epilepsy is one of the most common and complex neurological disorders around the world, affecting approximately 50–70 million people of all ages, ethnicities, and socioeconomic groups. Epilepsy, which is characterized by repeated, unprovoked seizures caused by abnormal neuronal discharges in the brain, results in various neurobiological, cognitive, and psychosocial problems [1]. It has been reported that focal epilepsy accounts for nearly 60% of all cases of epilepsy and is a major therapeutic challenge due to its diverse causes and frequent drug resistance [2]. A seizure, free state with minimal side effects, continues to be the main target in clinical neurology, notwithstanding the advances in diagnostic imaging and pharmacotherapy [3]. According to the International League Against Epilepsy statement of 2017, epilepsy is a multifactorial condition, which includes the etiopathogenesis of epilepsy as well as all other aspects: Structural, genetic, metabolic, immune, infectious, and idiopathic. In focal epilepsy, a disruption in the balance of excitatory and inhibitory neurotransmission in certain neuronal circuits causes paroxysmal discharges to recur [4]. It is known that cortical dysplasia, hippocampal sclerosis, or post-traumatic lesions are the major causes of epilepsy, but there is new data showing that synaptic vesicle malfunction is one of the major factors of epileptogenesis. There are also inhibitory GABAergic and excitatory glutamatergic neurotransmissions at the synapse; their imbalance is the main reason for seizure occurrence, and thus synaptic vesicle proteins (SV2A) are potential targets for drug therapy [5].

SV2A has emerged over the past two decades as a major modulator of neurotransmitter release and neuronal excitability. In this respect, the pharmacological modulation of SV2A represents a new paradigm, which is clearly different from the classical blockade of sodium or calcium channels [6]. Levetiracetam (LEV) is the first-in-class ligand acting at SV2A, and its introduction revolutionized the treatment of focal seizures because of its broad-spectrum efficacy, favorable pharmacokinetics, and low drug–drug interactions. However, long-term therapy with LEV was associated, in a small proportion of patients, with neuropsychiatric adverse effects, namely irritability, aggressiveness, and mood disturbances, resulting in discontinuation [7].

To overcome these shortcomings, Brivaracetam (BRV) was developed as a third-generation antiepileptic agent with much higher affinity for the SV2A receptor, having a 15–30 fold higher binding affinity than LEV and a faster blood-brain barrier permeation. BRV exhibits an improved selectivity for the SV2A receptor with a minimal off-target activity, which may translate to improved tolerability and fewer behavioral adverse effects [8]. Preclinical data have demonstrated that BRV displays more potent seizure suppression and a faster onset of action, and clinical studies confirm its effectiveness both as an adjunctive and monotherapy for focal seizures in adults. Despite the close structural similarity between LEV and BRV, they are pharmacodynamically very different, which may lead to their therapeutic profiles and patient outcomes differing.

The global burden of focal epilepsy is also disproportionately higher in low- and middle-income countries (LMICs), where resource limitations prevent optimum diagnosis and treatment. Thus, the pooled incidence of

epilepsy in LMICs is over twice that of high-income countries, 139 versus 49/100,000 person-years, reflecting disparities in access to health care, infection rates, and prevalence of neurotrauma [9,10]. It is against this background that evidence-based comparison of cost-effective, well-tolerated antiseizure medications becomes essential. Given the increasing use of both LEV and BRV in tertiary care centers, direct comparative data regarding their clinical efficacy, reduction to seizure frequency, and improvement in quality of life in Indian patients are lacking.

This prospective, comparative study was performed to assess the efficacy and tolerability of LEV and BRV in patients diagnosed with focal epilepsy. Besides seizure frequency, this study evaluates health-related quality of life (HRQOL) by the World Health Organization Quality of Life- BREF (WHOQOL-BREF) questionnaire, reflecting the multidimensional nature of the impact of epilepsy management on physical, psychological, social, and environmental well-being. The integration of clinical and patient-reported outcomes in this research aims at adding real-world evidence to support the optimal choice of SV2A-targeting agents in focal epilepsy.

METHODS

Study design and setting

This is a prospective, comparative, observational study that will be conducted for 6 months, from August 2024 to January 2025, within the Department of Neurology, KIMS Hospitals, Rajahmundry, and Andhra Pradesh, India. The research has been undertaken after prior approval from the Institutional Ethics Committee of GIET School of Pharmacy (Approval No.: GSPRJY-IEC/PharmD/2024/06) and formal permission from the hospital authorities. All procedures will be in accordance with the Declaration of Helsinki (2013 revision) and institutional research policies.

Sample size estimation

Sample size estimation was performed for the primary outcome of the between-group difference in mean seizure frequency reduction. Assuming a moderate-to-large effect size (Cohen's d=0.75), with a two-sided alpha level of 0.05 and a statistical power of 80%, a minimum of 28 patients per group was required to detect a clinically meaningful difference between the LEV and BRV groups. To account for rounding and potential attrition, 30 patients were enrolled in each group, resulting in a total sample size of 60 participants.

Study population

A total of 60 adult patients diagnosed with focal epilepsy were recruited by purposive sampling from outpatient and inpatient neurology units. As this was an observational study, treatment allocation was determined by the treating neurologist and not by randomization. All provided informed written consent before enrolment. Patients were then divided into two equal groups depending on the antiepileptic medication prescribed for each patient by the treating neurologist:

- Group A (n=30): Patients receiving LEV
- Group B (n=30): Patients receiving BRV.

Both drugs were administered according to the standard dosing guidelines for routine clinical management. Clinical efficacy and effects of both drugs on HRQOL were compared.

Inclusion criteria

- Adults aged 18–80 years of either sex
- Focal epilepsy with or without secondary generalization as evidenced by clinically confirmed electroencephalogram (EEG) findings
- The patient must be receiving stable doses of either LEV or BRV for at least 2 weeks before baseline evaluation
- Willingness to participate and provide written informed consent.

Exclusion criteria

- Patients with non-epileptic or absence seizures, aura-only episodes, or acute symptomatic seizures within 14 days of brain injury or stroke
- Psychiatric disorder, substance dependence, or cognitive impairment known but impeding evaluation
- Pregnancy or lactation
- Severe hepatic or renal dysfunction, hypersensitivity to either drug.

Data collection and clinical assessment

The clinical and demographic data were obtained through a structured data collection form. In all the participants, the following baseline characteristics were analyzed: Age, gender, associated comorbidities, smoking, use of alcohol, duration of epilepsy, seizure frequency, and diagnosis of focal epilepsy and seizure classification based on the detailed clinical history and physical examination, EEG findings, and neuroimaging.

Assessment of seizure frequency

The primary outcome measure was the change in seizure frequency before and after treatment. Seizure occurrence data were derived from patient diaries, with validation by caregivers at the time of follow-up visits at baseline, 3 months, and 6 months.

All enrolled participants completed the 6-month follow-up. As no missing outcome data or protocol deviations were observed, analyses were conducted using a complete-case approach.

Quality of life assessment

The secondary outcome assessment included HRQOL, assessed using the WHOQOL-BREF questionnaire.

This validated 26-item instrument measures four essential domains:

1. Physical health
2. Psychological health
3. Social relationships, and
4. Environmental well-being.

Items were scored on a 5-point Likert scale, with higher scores reflecting better quality of life. Domain scores were transformed into a scale of 0 to 100 following the WHO guidelines for scoring. Assessment was done at baseline and after 6 months of treatment.

Medication information and administration schedules

- LEV: Initiated at 500 mg twice daily and titrated to a maximum dose of 3,000 mg/day according to clinical response and tolerability
- BRV: Initiated at 50 mg twice daily (100 mg/day), with dose adjustments up to 200 mg/day as per physician judgment.

Both drugs were administered as either monotherapy or adjunctive therapy under the supervision of a neurologist. Adherence was ensured by pill counts and interviews with the patients.

Statistical analysis

Statistical analysis was performed using IBM Statistical Package for Social Sciences Statistics version 29.0. Continuous variables were expressed as mean±standard deviation, and categorical variables as frequencies and percentages. Sample size estimation for the primary outcome assumed a moderate-to-large effect size (Cohen's d=0.75), with 80% power and a two-sided alpha of 0.05, requiring 28 patients per group; 30 per group were enrolled. Normality was assessed using the Shapiro–Wilk test. Within-group comparisons used paired t-tests and between-group comparisons used independent t-tests. Multiple quality-of-life analyses were exploratory, and p-values were interpreted with caution. A $p<0.05$ was considered statistically significant. Between-group comparisons of quality-of-life outcomes were performed using independent sample t-tests on change scores. Between-group comparisons of adverse effect frequencies were performed using the Chi-square test or Fisher's exact test, as appropriate.

Ethical considerations

All participants were notified about the purposes of the study, confidentiality, and their right to withdraw at any time without

consequence regarding medical care. No patient identifiers are included in data management and publication.

RESULTS

Baseline characteristics

A total of 60 patients with focal epilepsy were recruited and followed up for 6 months. Patients were given either LEV in Group A or BRV in Group B, consisting of 30 patients in each group. The average age was 46±17 years, ranging between 18 and 80 years. Males were predominant, 65%, compared to females, 35%. With respect to the distribution of age and sex ratio, there has not been a statistically significant difference between the groups, which means that the demographics are comparable (p>0.05).

Lifestyle characteristics showed that 18.3% were smokers, while 26.7% reported the use of alcohol. The majority of the patients, 73.3%, were non-alcoholic, and 81.7% were non-smokers. The comorbid illnesses were very prevalent; 76.7% of the patients reported at least one other medical condition, including hypertension in 5%, diabetes mellitus in 5%, and other systemic disorders. These distributions were similar for both treatments. Table 1 shows all baseline characteristics. The p-value for comorbidities reflects the overall between-group comparison across all comorbidity categories and does not correspond to any single category.

Seizure frequency before and after treatment

The primary endpoint was the mean change in seizure frequency from baseline to 6 months. Both LEV and BRV produced a statistically significant reduction in seizure episodes.

Both groups significantly reduced seizures, but BRV provided a numerically higher mean reduction of 2.56 versus 2.17, indicating superiority in clinical efficacy, though not statistically significant at p=0.09. Mean frequency of seizures before and after treatment of both comparative drugs are placed in the Table 2.

Quality of life (QOL) assessment (WHOQOL-BREF)

QOL pre- and post-treatment was assessed across four domains. Baseline quality of life was not different between groups (p>0.05). At 6 months, both groups demonstrated significant improvement. WHOQOL-BREF scores before and after treatment mean is shown in the Table 3. Graphical representation of QoL shown in the Fig. 1.

The percentage of respondents reporting "good" quality of life increased markedly. From 46.7% to 70% in the LEV group, and from 53.3% to 76.7% in the BRV group.

BRV resulted in a slightly better improvement in both the physical and psychological domains, with a greater overall mean change in WHOQOL-BREF score (Δ=4.38 vs. 3.07). Improvement in social and environmental domains is modest but consistent in both groups.

Tolerability and safety profile

Both LEV and BRV demonstrated good tolerability along with a favorable safety profile in patients. The most common mild side effects of the drugs were drowsiness, dizziness, and fatigue. Behavior changes such as irritability and mood swings were noticed in 3 patients (10%) on LEV and in only 1 patient (3%) on BRV. It should be highlighted that

Table 1: Baseline characteristics of study participants

Parameter	Category/Unit	Group A (Levetiracetam) n (%)	Group B (Brivaracetam) n (%)	Total (n=60) n (%)	p-value
Age (years)	≤20	4 (13.3)	7 (23.3)	11 (18.3)	
	21–30	2 (6.7)	6 (20.0)	8 (13.3)	
	31–40	5 (16.7)	2 (6.7)	7 (11.7)	
	41–50	4 (13.3)	4 (13.3)	8 (13.3)	
	51–60	5 (16.7)	4 (13.3)	9 (15.0)	
	61–70	8 (26.6)	4 (13.3)	12 (20.0)	
	71–80	2 (6.7)	3 (10.0)	5 (8.4)	
Age (continuous)	Mean±SD	47.6±17.8	44.9±18.6	46.3±18.2	0.21
Gender	Male	19 (63.3)	20 (66.7)	39 (65.0)	0.78
	Female	11 (36.7)	10 (33.3)	21 (35.0)	
Marital status	Married	25 (83.3)	20 (66.7)	45 (75.0)	0.11
	Unmarried	5 (16.7)	10 (33.3)	15 (25.0)	
Smoking habit	Smokers	7 (23.3)	4 (13.3)	11 (18.3)	0.32
	Non-smokers	23 (76.7)	26 (86.7)	49 (81.7)	
Alcohol consumption	Alcoholic	9 (30.0)	7 (23.3)	16 (26.7)	0.56
	Non-alcoholic	21 (70.0)	23 (76.7)	44 (73.3)	
Comorbidities	Hypertension	2 (6.7)	1 (3.3)	3 (5.0)	
	Diabetes Mellitus	0 (0)	3 (10.0)	3 (5.0)	
	Other systemic illnesses	26 (86.7)	20 (66.7)	46 (76.7)	
	No comorbidity	2 (6.6)	6 (20.0)	8 (13.3)	0.08

Data are presented as n (%) unless otherwise specified. Between-group comparisons were performed using the Chi-square test for categorical variables and the independent sample t-test for continuous age. A p>0.05 indicates no statistically significant difference between groups. The p value reported for comorbidities represents the overall comparison of the distribution of comorbidity categories between groups, rather than an individual category. SD: Standard deviation

Table 2: Mean frequency of seizures before and after treatment

Group	Mean±SD (Seizures per month) - Before treatment	Mean±SD (Seizures per month) - After 6 months of treatment	Mean reduction	p-value[†]
Group A (Levetiracetam)	2.43±1.47	0.26±0.44	2.17	<0.001
Group B (Brivaracetam)	2.96±2.09	0.40±1.47	2.56	<0.001
Between-group comparison of mean reduction	-	-	-	**0.09**[‡]

Seizure frequency is expressed as the mean (±SD) number of seizures per month over the 6-month treatment period compared with an equivalent pre-treatment period. Within-group comparisons were performed using paired t-tests ([†]). Between-group comparison of mean seizure frequency reduction was performed using an independent sample t-test ([‡]). A p<0.05 was considered statistically significant.SD: Standard deviation, [†]p-value obtained from independent samples t-test for between-group comparison of mean seizure reduction; not statistically significant (p > 0.05).

Table 3: Mean domain scores of WHOQOL-BREF before and after treatment

Quality-of-life domain	Group A (LEV) mean change	Group B (BRV) mean change	Between-group p value†
Physical health	+6.50	+8.40	0.12
Psychological health	+4.54	+7.57	0.04*
Social relationships	+0.90	+0.90	0.98
Environment	+1.60	+2.47	0.21
Overall QOL score	+3.07	+4.38	0.09

*Statistically significant at p<0.05, WHOQOL-BREF: World Health Organization Quality of Life - BREF, LEV: Levetiracet, BRV: Brivaracetam, QOL: Quality of life

Table 4: Adverse effects observed during the 6-month follow-up period

Adverse effect	Levetiracetam (n=30) n (%)	Brivaracetam (n=30) n (%)	p-value†
Drowsiness	5 (16.7)	6 (20.0)	0.74
Dizziness	4 (13.3)	3 (10.0)	0.69
Fatigue	3 (10.0)	3 (10.0)	1.00
Irritability/mood changes	3 (10.0)	1 (3.3)	0.30
Headache	2 (6.7)	2 (6.7)	1.00
Any adverse effect	11 (36.7)	9 (30.0)	0.58

no serious adverse drug reactions, liver dysfunction, or discontinuation of therapy occurred, thus confirming that both drugs are generally well tolerated. The adverse effects were under strict observation during the whole 6, month follow, up period. Adverse effects observed during the 6-month follow-up period complete data represents in Table 4.

All of the adverse events reported were of mild or moderate severity, and there was no case of serious adverse drug reaction or treatment discontinuation. The overall frequency of side effects was higher in the LEV group than in the BRV group, especially concerning behavioral symptoms.

DISCUSSION

This prospective comparative observational study investigated the efficacy, tolerability, and safety of LEV and BRV in adult patients with focal epilepsy. The results align well with the evidence already available in randomized controlled trials, meta-analyses, and real-world observational studies and thus offer a clinical context for these commonly used SV2A ligands.

Efficacy comparison

Both LEV and BRV led to significantly fewer seizures during the 6, month follow-up period. Similar responder rates for the two drugs have been demonstrated in previous studies. Zhang *et al*. performed a meta-analysis of 13 randomized controlled trials with more than 3,600 patients who had refractory focal seizures and did not find any statistically significant differences in efficacy between LEV and BRV at low, medium, and high doses. However, risk ratios for 50% responder rates slightly favored BRV [1]. BRV in this study was linked to a numerically larger average decrease in seizure frequency compared to LEV; however, this variance was not statistically significant. The two drugs' generally similar antiseizure effectiveness makes biological sense since they both work through SV2A binding and modulation of neurotransmitter release. BRV has a 1530, fold higher affinity for SV2A and penetrates the blood-brain barrier more quickly; however, clinical trials have not always shown BRV to be clearly superior to LEV, which indicates that both drugs are likely to have strong antiseizure effects in focal epilepsy [12]. The greater decrease in seizure frequency with BRV that was seen numerically but not statistically significant could be biologically reasonable given its higher affinity for the SV2A receptor

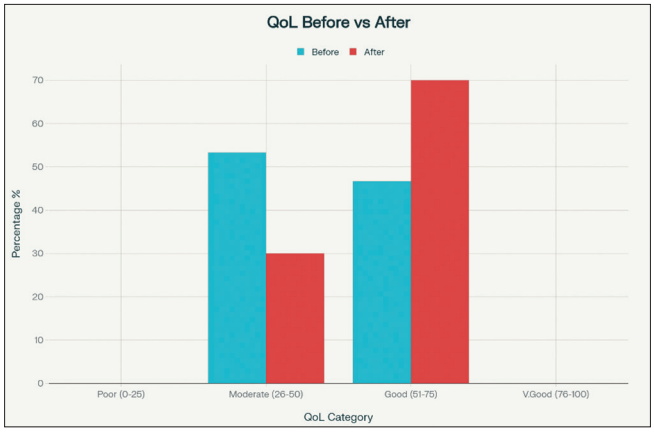

Fig. 1: Distribution of World Health Organization Quality of Life - BREF overall quality-of-life categories ("Poor," "Fair," "Good," and "Very Good") at baseline and at 6 months in the Levetiracetam and Brivaracetam groups

and its pharmacokinetic properties such as faster brain penetration.

Behavioral and psychiatric adverse effects

Behavioral adverse events carry significant clinical weight as they can impact both treatment adherence and the patient's quality of life. In this research, symptoms like irritability, mood swings, and other psychiatric manifestations were more overwhelmingly reported by patients on LEV, while those on BRV mainly exhibited somnolence. Such results parallel the real-world data of the Indian cohort study by Sivadasan *et al.* [7].

The distinct behavioral breakdown of tolerability may be explained by the pharmacodynamic differences between the two drugs. LEV is believed to have broader effects extending beyond SV2A, including potential interactions with calcium channels and neurotransmitter systems, while BRV is a more selective ligand for SV2A with a lower number of off-target effects. According to clinical studies, some patients who are not able to tolerate LEV can get a better response in terms of drug tolerance when switched to BRV without compromise in seizure control, hence, a mechanistic rationale for the drug to be used as a substitute in LEV, related behavioral intolerance cases [12,13].

Safety and hematological profile

The study demonstrated that both LEV and BRV were, in general, well tolerated. Typical side effects such as drowsiness, dizziness, and tiredness were mild or moderate and in line with the previous literature. Earlier studies have reported more dizziness and headache with BRV at higher doses but fewer psychiatric, related withdrawals. Furthermore, both drugs have been rarely linked to hematologic changes [14,15]. Thus, LEV and BRV remain promising pharmaceutical options for epilepsy, but, as earlier, individual patient monitoring becomes crucial, especially in those cases with comorbidities or polypharmacy.

Quality of life and clinical considerations

Besides the seizure control, the health-related quality of life is another very significant therapeutic outcome in the treatment of epilepsy. According to this study, administration of LEV as well as BRV led to an enhancement in overall quality of life scores. The physical and psychological areas registered the most significant changes in the BRV group, which can be explained by its better behavioral tolerability profile according to prior observational and comparative studies [13,15]. These pieces of evidence stress that the selecting of anti-seizure drugs should be individualized to best achieve patient-centered outcomes.

Limitations and future directions

Results should be interpreted considering several limitations. The relatively small sample size and short follow-up duration limit the capability to find small between-group differences and to assess the

long-term outcomes. The purposive, non-random sampling method and treatment allocation based on clinical judgment may have introduced selection bias, thus the research is limited in causal inference and generalizability. Being an observational study, the results indicate associations rather than definitive treatment effects.

These days, the assessment of short, term efficacy and tolerability with a 6, month follow, up is reasonable. However, longer-term studies of 12 months or more are necessary to look at sustained seizure control, long-term adherence, and late-onset adverse effects. Besides, not statistically correcting for multiple comparisons may have raised the risk of Type I error for secondary quality, of, life outcomes.

Future research should revolve around large-scale, head-to-head comparative trials that are stratified by age, psychiatric comorbidities, and other clinically relevant subgroups. The inclusion of pharmacogenomic profiling might enhance precision medicine approaches by fine-tuning drug selection and reducing adverse drug reactions. Utilizing combination or sequential therapeutic strategies based on different pharmacological profiles of LEV and BRV is also interesting for further investigation [12,15].

Despite baseline demographic characteristics being similar between groups, the potential for residual or unmeasured confounding remains.

CONCLUSION

This study offers data on the comparative effectiveness, safety, and impact on quality of life of LEV and BRV in the management of focal epilepsy. Both drugs exhibited a significant decrease in the frequency of seizures after 6 months, thus confirming their role as SV2A-targeting antiepileptic drugs. Even if the difference in seizure control was not significant statistically, BRV showed a greater reduction in seizure frequency by a numerical value. This matches with the earlier evidence showing that BRV has a higher affinity for SV2A and also gets into the central nervous system faster than LEV. Both drugs were well tolerated; however, behavioral side effects such as irritability and mood swings were more frequently reported with LEV.

The greater enhancement in WHOQOL, BREF facets, particularly physical and psychological well-being, was seen in patients given BRV, indicating more tolerant and satisfied patients in this group. Taken together, the data suggest that while both LEV and BRV remain therapeutic options for focal epilepsy, BRV could be a better choice for those patients who develop behavioral side effects due to LEV. More extensive and longer, duration randomized controlled trials are required to verify these findings and explore pharmacoeconomic and patient-centered outcomes of SV2A modulators in a real-world scenario.

AUTHOR CONTRIBUTIONS

Lakshmi Sai Durga Sireesha Kanithi: Conceptualization, study design, supervision, interpretation of results, manuscript drafting, and corresponding author responsibilities. Himaja Kumari Ponnada: Patient data collection, follow-up assessments, data entry, and contribution to manuscript drafting. Nakka Anusha Vara Prada: Clinical data acquisition, monitoring of therapy outcomes, and assistance in manuscript preparation. Kalam Sai Sri: Data collection, quality-of-life assessment, and literature review. Sayanthika Datta: Data curation, validation, and critical review of the manuscript. Sai Shashank Gudla: Statistical coordination, data interpretation, manuscript editing, and final review.

CONFLICTS OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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