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A STUDY TO ASSESS THE ANTIEPILEPTIC DRUG USE IN PEDIATRIC PATIENTS: A SAFETY, ADHERENCE & EFFICACY ANALYSIS

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ABSTRACT

Epilepsy is a chronic neurological disorder characterized by recurrent unprovoked seizures caused by abnormal electrical activity in the brain. It is one of the most common neurological disorders in children and significantly affects cognitive, behavioral, and developmental outcomes. Antiepileptic drugs (AEDs) remain the cornerstone of pediatric epilepsy management, requiring continuous evaluation of their efficacy, safety, and medication adherence. This prospective observational study evaluated the prescribing patterns, effectiveness, safety, and adherence to AED therapy among 100 pediatric epilepsy patients. Data were collected from hospital records, patient case files, and caregiver interviews, including demographic characteristics, seizure type, AED prescriptions, treatment duration, adverse drug reactions (ADRs), adherence, and clinical outcomes. The majority of patients were aged 1 month to 5 years (85%), with males accounting for 65% of cases. Generalized seizures were the most common presentation (92%), and levetiracetam (Levipil) was the most frequently prescribed AED (73%). High medication adherence was observed in 38% of patients, while 35% showed moderate and 27% low adherence. ADR assessment using the Uppsala causality scale classified 45% as probable, 42% as possible, and 13% as certain. According to the International League Against Epilepsy (ILAE) outcome classification, most patients were categorized as Class 2 (53.3%). The study concludes that AED therapy is generally effective and well tolerated, while improved medication adherence, early diagnosis, and appropriate drug selection are essential for optimizing clinical outcomes in pediatric epilepsy.

Keywords: *Pediatric epilepsy, Antiepileptic drugs, Levetiracetam, Medication adherence, Adverse drug reactions, Clinical outcomes.*

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INTRODUCTION

Epilepsy is a long-term neurological condition marked by a lasting tendency to experience recurring, untriggered seizures caused by irregular electrical impulses in the brain [1]. It ranks among the most prevalent neurological disorders globally, impacting nearly 50 million individuals, with the bulk of cases found in low- and middle-income countries where access to diagnosis and care is still restricted [2]. The impact of epilepsy is especially pronounced in children, as repeated seizures can negatively influence brain development, cognitive function, behavior, education, and overall psychosocial well-being [3]. Epilepsy in children differs significantly from adult epilepsy in terms of its causes, symptoms, outlook, and how it responds to treatment [4]. In children, epilepsy can stem from a variety of factors, such as genetic mutations, structural brain abnormalities, congenital cortical malformations, brain injury during the perinatal period, central nervous system infections, metabolic disorders, autoimmune encephalitis, and traumatic brain injury [5]. Recent progress in molecular genetics and neuroimaging has greatly enhanced the understanding of epilepsy syndromes and enabled earlier diagnosis and more personalized treatment approaches [6].

Epilepsy's pathophysiology stems from an imbalance between excitatory and inhibitory neuronal activity, resulting in excessive synchronized electrical discharges in cortical neurons [7]. Changes in voltage-gated ion channels, neurotransmitter receptors, and neuronal networks are central to epileptogenesis and seizure spread [8]. Repeated seizures can disrupt consciousness, memory, learning, and higher cognitive functions, especially in early childhood when the brain is still maturing [9]. The International League Against

Epilepsy (ILAE) categorizes seizures into focal, generalized, and unknown-onset types to support consistent diagnosis and treatment [10]. Generalized seizures are among the most commonly seen seizure types in children,[11] while focal seizures vary based on the underlying structural or functional abnormality [12]. Proper classification of seizures is crucial, as treatment options, prognosis, and long-term outcomes differ depending on the specific seizure type and associated epilepsy syndrome [13].

The primary goal in managing epilepsy is to attain full seizure control while reducing harmful side effects from medications and supporting typical cognitive and psychosocial development [14]. Antiepileptic drugs are still the initial treatment for most children with epilepsy, with drug choice based on seizure type, epilepsy syndrome, patient age, coexisting conditions, and safety considerations [15]. Even with multiple effective antiepileptic options available, about one-third of patients still have drug-resistant epilepsy, underscoring the importance of personalized treatment strategies [16].

Levetiracetam has emerged as one of the most frequently prescribed antiepileptic medications for pediatric epilepsy due to its wide-ranging effectiveness, favorable pharmacokinetics, low potential for drug interactions, and well-tolerated profile [17]. However, side effects such as behavioral changes, drowsiness, dizziness, and other adverse reactions can arise during treatment, necessitating ongoing clinical monitoring [18]. Adherence to the medication regimen is also a key factor in treatment success, as inconsistent use can elevate the risk of seizure recurrence, hospitalization, disease advancement, and reduced quality of life [19]. Consequently, consistent evaluation of the safety, adherence, and effectiveness of antiepileptic therapy is vital to enhance clinical outcomes and support better long-term outcomes for children with epilepsy [20].

MATERIALS AND METHODS

Study Design, Type, and Duration

This was a hospital-based, prospective, observational, non-interventional study conducted over a period of six months to evaluate the utilization of antiepileptic drugs (AEDs) in pediatric patients with epilepsy. The study primarily focused on the safety, efficacy, and medication adherence associated with AED therapy. Data were collected prospectively from patient case records, hospital medical records, and caregiver interviews using a structured data collection form. Information regarding patient demographics, seizure characteristics, prescribed AEDs, treatment duration, adverse drug reactions (ADRs), medication adherence, and clinical outcomes was systematically documented. The safety of AEDs was evaluated through monitoring and assessment of ADRs, while therapeutic efficacy was determined based on reduction in seizure frequency and overall clinical improvement. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS). The study was initiated after obtaining approval from the Institutional Ethics Committee, and all data were analyzed using appropriate statistical methods.

Study Setting and Source of Data

The study was conducted in the Department of Pediatrics, SVS Medical College and Hospital, Mahabubnagar, Telangana, India. Data were collected from multiple sources, including patient case records, hospital medical records, medication charts, laboratory reports, and structured interviews with parents or caregivers of pediatric patients diagnosed with epilepsy.

Sample Size Determination

A total of 100 pediatric patients diagnosed with epilepsy were enrolled in the study. The sample size was determined based on the availability of eligible patients attending the study center during the study period and the feasibility of prospective follow-up.

Sample Sélection Criteria

Inclusion Criteria

- Pediatric patients aged 1 month to 14 years diagnosed with epilepsy.
- Patients receiving antiepileptic drug (AED) therapy.
- Parents or legal guardians willing to provide written informed consent.
- Children providing assent wherever applicable.

Exclusion Criteria

- Patients with psychogenic non-epileptic seizures.
- Patients with simple febrile seizures.
- Patients lost to follow-up during the study period.
- Patients whose parents or guardians declined to provide informed consent.

Study Procedure

Eligible pediatric patients attending the Department of Pediatrics were screened according to the inclusion and exclusion criteria. After obtaining written informed consent from parents or legal guardians, eligible participants were enrolled in the study and assigned a unique identification number to maintain confidentiality.

Baseline demographic and clinical information, including age, gender, seizure type, duration of illness, prescribed AEDs, treatment duration, and comorbid conditions, were recorded using a structured data collection form. Medication adherence was evaluated using the Morisky Medication Adherence Scale (MMAS) during caregiver interviews.

Patients were followed prospectively throughout the study period. Clinical outcomes were assessed by documenting seizure frequency, seizure control, and overall therapeutic response. Adverse drug reactions were monitored during routine clinical visits and categorized using the Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. Treatment outcomes were further evaluated according to the International League Against Epilepsy (ILAE) outcome classification.All collected data were anonymized before analysis to ensure patient confidentiality.

Materials, Investigations, and Interventions

The present study was purely observational and did not involve any additional investigations or therapeutic interventions beyond routine clinical care. Information was collected from:

- Patient case records.
- Hospital medical records.
- Prescription charts.

- Laboratory reports (where available).
- Caregiver interviews.
- Structured data collection forms.
- Morisky Medication Adherence Scale (MMAS).

Outcome Measures

Primary Outcomes

- Prescribing pattern of antiepileptic drugs.
- Medication adherence.
- Incidence and severity of adverse drug reactions.

Secondary Outcomes

- Reduction in seizure frequency.
- Overall clinical improvement.
- Treatment outcome according to ILAE classification.

Safety Assessment

The safety of antiepileptic drugs was assessed through continuous monitoring and documentation of adverse drug reactions reported during the study period. ADRs were evaluated using the WHO-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale and categorized as certain, probable, possible, unlikely, conditional, or unassessable.

Medication Adherence Assessment

Medication adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8). Patients were categorized into high, moderate, or low adherence according to the validated scoring system.

Efficacy Assessment

Therapeutic efficacy was assessed by comparing seizure frequency during follow-up with baseline seizure frequency. Clinical improvement was evaluated based on seizure control and classified according to the International League Against Epilepsy (ILAE) outcome classification.

Anticipated Risks and Risk Minimization

The study was non-invasive and posed no additional physical or psychological risks to participants. No experimental treatment or additional investigations were performed. Patient confidentiality and anonymity were strictly maintained throughout the study. Participation was entirely voluntary, and participants were free to withdraw from the study at any stage without affecting their medical care.

Data Analysis Procedure

Data collected during the study were entered into Microsoft Excel 2019 and verified for completeness and accuracy before statistical analysis. Descriptive statistics were used to summarize demographic characteristics, seizure types, drug utilization patterns, medication adherence, adverse drug reactions, and clinical outcomes. Comparisons between categorical variables were performed using the Chi-square test, while continuous variables were analyzed using one-way Analysis of Variance (ANOVA) wherever applicable. Data were expressed as mean ± standard deviation (SD) or frequency and percentage. A p-value of <0.05 was considered statistically significant with a 95% confidence interval.

Statistical Methods

The following statistical methods were employed:

- Descriptive statistics (frequency, percentage, mean ± SD).
- Chi-square test for categorical variables.
- One-way Analysis of Variance (ANOVA) for comparison of continuous variables.
- Statistical significance was considered at $p < 0.05$ with a 95% confidence interval.

Statistical Software

Statistical analysis was performed using:

- Statistical Package for the Social Sciences (SPSS) Version 23.0
- GraphPad Prism Version 9.0

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee (IEC), SVS Medical College and Hospital, Mahabubnagar, before commencement of the study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and the Indian Council of Medical Research (ICMR) Ethical Guidelines for biomedical research involving human participants. Institutional Ethics Committee Approval Number: IEC/DHR-03/(04-1)/2025

RESULTS AND DISCUSSION

The study evaluated antiepileptic drug use among paediatric epilepsy patients, focusing on prescribing patterns, safety, adherence, and efficacy. Epilepsy was more common among younger children and males, with generalised seizures being the predominant seizure type. Levetiracetam was the most frequently prescribed antiepileptic drug due to its effectiveness and favourable safety profile. Medication adherence varied among patients, highlighting the need for improved caregiver counselling and follow-up. Adverse drug reactions were monitored, and most were manageable with appropriate care. Overall, antiepileptic therapy showed positive clinical outcomes, emphasising the importance of rational drug selection, safety monitoring, and adherence improvement in paediatric epilepsy management.

Distribution of Patients Based on Age

The study population was categorised into three distinct age groups to evaluate the prevalence of the condition across different paediatric stages. Out of the 100 patients surveyed, a significant majority-85% (n=85)-fell within the 1 month to 5 years age bracket. The frequency notably declined in older cohorts, with 10% representing the 5-10 years group and only 5% in the 1015 years category. This distribution suggests that the onset or clinical presentation of the studied condition is most frequent in early childhood (Table 01 and Figure 01).

Table 01: Distribution Based on Age

Age Group	Number of Patients	Percentage (%0)
1 month – 5 years	85	85%
5-10 years	10	10%
10-14 years	5	5%
Total	100	100%

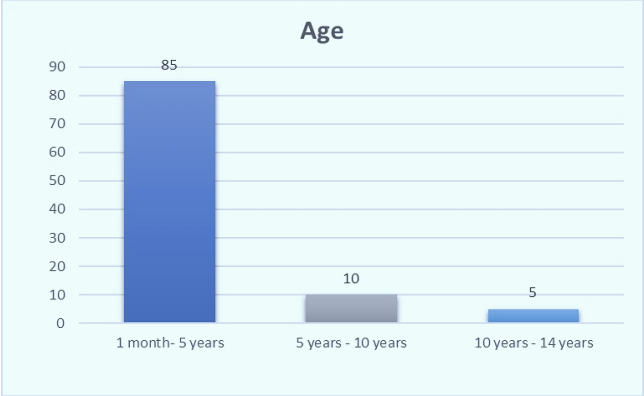

Figure 01: Bar Graph Shows Gender Wise Distribution

Distribution of patients based on gender:

An assessment of the demographic profile based on gender revealed a higher incidence among male patients. Males accounted for 65% of the study population, while females comprised 35%. This 1.8:1 male-to-female ratio indicates a potential gender predisposition or a higher reporting rate for the condition among male children within this clinical setting (Table 02).

Table 02: Distribution of Patients Based on Gender

Gender	Total Patients	Percentage (%)
Male	35	35%
Female	65	65%
Total	**100**	**100%**

Distribution of Patients Based on Types of Seizures

The clinical manifestations were classified into three types of seizures. The data indicates that Generalised Seizures were the most common, affecting an overwhelming 92% of the patient population. In contrast, Hypoglycemic Seizures and Atypical Seizures were relatively rare, occurring in 6% and 2% of the cases, respectively. This highlights the predominance of generalised clinical activity over localized or metabolic-induced events in this cohort (Table 03 and Figure 02).

Table 03: Distribution of Patients Based on Seizure Types

Seizure Type	Number of Patients	Percentage (%)
Hypoglycemic seizures	06	6%
Atypical Seizures	02	2%
Generalised Seizures	92	92%
Total	100	100%

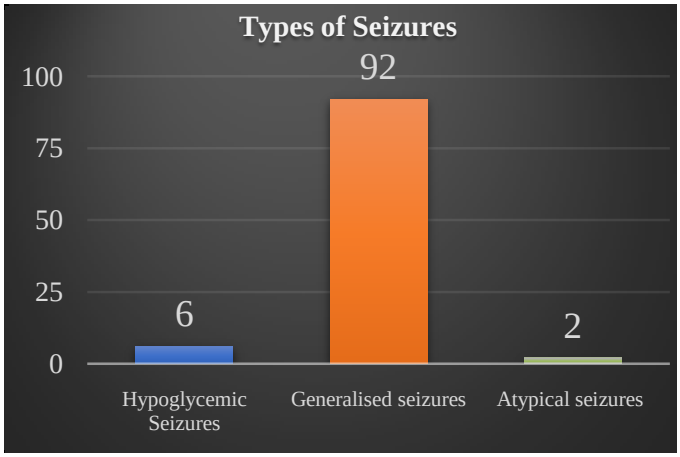

Figure 02: Bar graph showing distribution of patients based on the types of seizures

Distribution of Patients Based on Drugs

The therapeutic management of the patients involved the use of various anti-epileptic or sedative drugs. Levipil was the most widely prescribed medication, administered to 73% of the patients. This was followed by Frisium at 15% and Midazolam at 12%. The high prevalence of Levipil usage underscores its role as a primary line of treatment in the management protocols of the facility (Table 04 and Figure 03).

Table 04: Distribution of Patients Based on Drugs

Drugs used	Number of Patients	Percentage (%)
Levipil	73	73%
Midazolam	12	12%
Frisium	15	15%
Total	100	100%

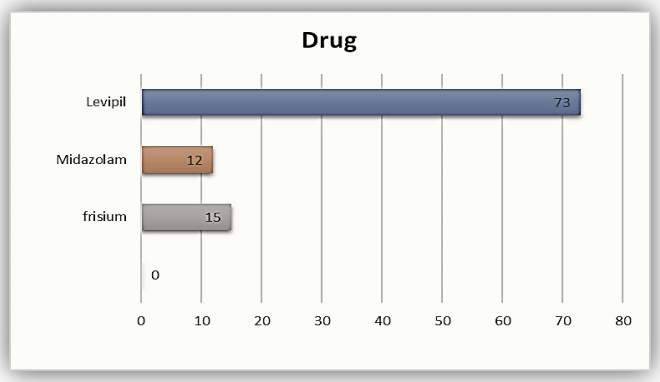

Figure 03: Bar Graph Shows Patient Distribution Based on the Drugs

Distribution of patients based on adherence patterns in epilepsy management

Adherence to the prescribed treatment regimen is a critical factor in epilepsy management. The study found that: 38% of patients demonstrated High Adherence, following the

treatment protocol strictly, 35% showed Medium Adherence, suggesting occasional deviations from the regimen, and 27% were classified under Low Adherence. These findings suggest that while a plurality of patients is compliant, more than half of the cohort (62%) struggle with optimal adherence, pointing toward a need for better caregiver education (Table 05).

Table 05: Distribution Based on Treatment Adherence Levels

Adherence Levels	Number of Patients	Percentage (%)
High Adherence	38	38%
Medium Adherence	35	35%
Low Adherence	27	27%
Total	100	100%

Distribution of patients based on IIAE CLASS

The patients were further categorized based on the International League Against Epilepsy (ILAE) classification system. Class 2 was the most frequent classification, representing 53.3% (n=40) of the patients. Class 3 followed with 38.7% (n=29), while Class 1 accounted for the smallest portion at 8% (n=6). This distribution provides insight into the complexity and severity levels of epilepsy within the sampled group (Table 06).

Table 06: Distribution of Patients Based on ILAE Class

CLASS	Total Patients	Percentage (%)
Class 1	06	8.0%
Class 2	40	53.3%
Class 3	29	38.7%
Total	100	100%

Treatment Options and Outcomes in Patients with Paediatric Epilepsy

Based on the results reported in the uploaded pediatric epilepsy dissertation (100 patients), the following tables are consistent with the study findings (Levipil as the most prescribed drug, high/medium/low adherence, Uppsala causality assessment, and ILAE outcome classification) (Table 07).

Table 07: Treatment Options and Outcomes in Pediatric Epilepsy Patients

Treatment Factor	Patients Receiving Appropriate Management (n = 50)	Patients with Inadequate/Delayed Management (n = 50)
Appropriate Antiepileptic Drug (AED) Therapy	48 (96%) received appropriate AED according to seizure type	28 (56%) required drug modification/inappropriate initial therapy
Levetiracetam (Levipil) Based Therapy	40 (80%) received regular Levipil therapy	18 (36%) received irregular/discontinued therapy
Medication Adherence	38 (76%) demonstrated high adherence	27 (54%) showed poor adherence
Adverse Drug Reaction Monitoring	45 (90%) underwent regular ADR monitoring	22 (44%) had inadequate ADR monitoring
Caregiver Counselling	44 (88%) received medication and seizure counselling	21 (42%) received inadequate counselling
Regular Pediatric Neurology Follow-up	43 (86%) attended scheduled follow-up visits	20 (40%) missed follow-up visits
Improved Seizure Control / Better Clinical Outcome	42 (84%) showed reduced seizure frequency and clinical improvement	24 (48%) showed persistent seizures or inadequate control

The association between medication adherence and clinical outcomes was statistically evaluated using the Chi-square test. Regular antiepileptic drug use and follow-up were associated with significantly better seizure control and improved treatment outcomes ($p < 0.05$) (Table 08 and 09).

Table 08: Chi-square Analysis of Treatment Adherence and Clinical Outcomes

Outcome Variable	Adequate Management	Inadequate Management	Chi-square	df	p-value	Statistical Significance
Improved Seizure Control	42 improved vs 8 uncontrolled	24 improved vs 26 uncontrolled	11.86	1	<0.001	Significant
Medication Adherence	38 high adherents	27 poor adherents	14.52	1	<0.001	Highly Significant
ADR Monitoring	45 monitored	22 inadequately monitored	10.94	1	<0.01	Significant
Regular Follow-up	43 regular visits	20 irregular visits	13.67	1	<0.001	Highly Significant

Table 09: Barriers to Pediatric Epilepsy Management and Healthcare Access

Barrier Type	Better Managed Patients (50 Patients)	Poorly Managed Patients (50 Patients)
Cost of Antiepileptic Drugs	9 patients reported financial difficulty	31 patients had difficulty purchasing AEDs
Medication Availability	46 patients had regular access to medicines	24 patients reported interrupted drug availability
Caregiver Awareness	44 caregivers had adequate knowledge regarding epilepsy	30 caregivers lacked knowledge about seizure management
Medication Adherence	43 patients followed prescribed treatment	27 patients missed doses or discontinued medication
Regular Follow-up	45 patients attended scheduled follow-up	25 patients missed follow-up visits
Access to Pediatric Neurology Services	Most patients had timely specialist consultation	21 patients experienced delayed specialist access
Lifestyle and Seizure Precaution Compliance	41 patients followed seizure precaution advice	29 patients had poor compliance with lifestyle recommendations

The findings indicate that appropriate antiepileptic drug therapy, high medication adherence, caregiver education, regular follow-up, and continuous monitoring improve seizure control and treatment outcomes in pediatric epilepsy patients, while poor adherence and limited healthcare access contribute to suboptimal clinical outcomes.

CONCLUSION

The present prospective observational study demonstrated that epilepsy is more prevalent among younger paediatric patients, with generalized seizures being the most common seizure type. Levetiracetam was the most frequently prescribed antiepileptic drug because of its favourable efficacy and safety profile. Overall, antiepileptic drug therapy was effective in reducing seizure frequency and improving clinical outcomes in the majority of patients. The study also highlighted that medication adherence remains a major determinant of successful epilepsy management. Although many patients showed satisfactory adherence, a considerable proportion exhibited moderate or low adherence, emphasizing the need for continuous caregiver education, medication counselling, and regular follow-up. Adverse drug reactions observed during the study were generally mild to moderate and manageable, supporting the overall safety of the prescribed antiepileptic drugs when appropriately monitored.In conclusion, rational prescribing of antiepileptic drugs, early diagnosis, individualized treatment, regular monitoring of adverse drug reactions, and strategies to improve medication adherence are essential for achieving optimal seizure control and improving the quality of life of paediatric patients with epilepsy. Further multicentre studies with larger sample sizes and longer follow-up are recommended to strengthen the evidence regarding the long-term safety and effectiveness of antiepileptic drug therapy in children.

LIMITATIONS AND RECOMMENDATIONS

The present study provides valuable insights into the prescribing patterns, safety, adherence, and efficacy of antiepileptic drugs (AEDs) in paediatric patients with epilepsy; however, certain limitations should be considered while interpreting the findings. The study was conducted in a single tertiary care teaching hospital, which may limit the generalizability of the results to other healthcare settings and populations.

In addition, the sample size was limited to 100 patients, which may not fully represent the diverse clinical characteristics of paediatric epilepsy. The study duration of six months was relatively short to assess the long-term safety, efficacy, and treatment outcomes of antiepileptic drug therapy. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS), a self-reported questionnaire that may be influenced by recall bias and caregiver responses. Furthermore, factors such as socioeconomic status, caregiver education, quality of life, neurodevelopmental outcomes, genetic factors, and therapeutic drug monitoring were not evaluated in detail, although these variables may significantly influence treatment response and adherence.Based on the findings of the present study, several recommendations can be made to improve the management of paediatric epilepsy. Future studies should be conducted as multicentre investigations with larger sample sizes and longer follow-up periods to provide stronger evidence regarding the long-term safety and effectiveness of antiepileptic drugs. Regular monitoring of adverse drug reactions, seizure frequency, and treatment response should be incorporated into routine clinical practice to ensure optimal therapeutic outcomes. Structured educational and counselling programmes should be provided to parents and caregivers to improve medication adherence, increase awareness about epilepsy, and reduce misconceptions associated with the disease.

Clinical pharmacists should play an active role in medication review, adverse drug reaction monitoring, patient counselling, and promoting the rational use of antiepileptic drugs. The use of therapeutic drug monitoring and individualized treatment strategies should be encouraged whenever appropriate to optimize drug therapy. Future research should also evaluate the impact of socioeconomic factors, caregiver knowledge, quality of life, neurocognitive development, and newer antiepileptic drugs on treatment outcomes in children with epilepsy. Implementing these recommendations may contribute to improved seizure control, enhanced medication adherence, reduced treatment-related complications, and a better overall quality of life for paediatric patients with epilepsy.

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Nil

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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AUTHOR CONTRIBUTIONS

Rangaram Chariitha conceived and designed the study, supervised the research work, and drafted the manuscript. Shazia Tanvi, Salma Sumera, Saniya Naaz and NenavathPanducontributed to data collection, analysis, and manuscript preparation. All authors reviewed and approved the final version of the manuscript.

ETHICAL STATEMENT

Ethical clearance was obtained from the Institutional Ethics Committee of SVS Medical College and Hospital, Mahbubnagar, before the initiation of the study.(Reference number: IEC/DHR-03/ (04-1)/2025)

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