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RESEARCH ARTICLE
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COMPARATIVE STUDY OF EFFICACY AND SAFETY OF SODIUM VALPROATE AND LEVETIRACETAM IN THE TREATMENT OF CHILDHOOD EPILEPSY

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ABSTRACT

Background: Epilepsy is one of the most common neurological disorders in children. Sodium Valproate and Levetiracetam are widely used antiepileptic drugs (AEDs) with differing mechanisms of action, efficacy profiles, and side effect spectra. This study aims to compare the efficacy and safety of these two drugs in the management of childhood epilepsy**.**

Material and Methods: A prospective, comparative clinical study was conducted on 100 children aged 2–16 years diagnosed with epilepsy. Participants were randomly assigned to receive either Sodium Valproate (n=50) or Levetiracetam (n=50). They were followed over a period of 6 months to assess seizure frequency reduction, treatment response, and incidence of adverse effects. Efficacy was evaluated based on seizure control (complete, partial, or no control), while safety was assessed through clinical monitoring and laboratory investigations.

Results: Both groups showed significant reduction in seizure frequency. Complete seizure control was achieved in 60% of the Sodium Valproate group and 78% of the Levetiracetam group ($p>0.05$). Partial control was noted in 26% and 18%, respectively. Adverse effects were more common in the Sodium Valproate group (32%) compared to the Levetiracetam group (12%), with weight gain and gastrointestinal symptoms predominating in the former, and behavioral changes in the latter.

Conclusion: Both Sodium Valproate and Levetiracetam are effective in managing childhood epilepsy. While their efficacy is comparable, Levetiracetam demonstrated a more favorable safety profile, making it a potentially better first-line option, especially in children sensitive to side effects.

KEYWORDS: Childhood epilepsy, Sodium Valproate, Levetiracetam, Antiepileptic drugs, Seizure control, Safety profile

INTRODUCTION

Epilepsy is one of the most common chronic neurological disorders in children, affecting approximately 0.5–1% of the pediatric population worldwide[(1)]. It is characterized by recurrent, unprovoked seizures that can significantly impact cognitive, behavioral, and psychosocial development[(2)]. Early and effective treatment is crucial to minimize seizure burden and improve quality of life[(3)].

Sodium Valproate has long been a mainstay in the treatment of generalized and focal seizures due to its broad-spectrum antiepileptic properties[(4)]. However, its use is often limited by side effects such as weight gain, hepatotoxicity, and teratogenicity. Levetiracetam, a newer antiepileptic drug, has gained popularity for its favorable pharmacokinetic profile, minimal drug interactions, and relatively mild side effect spectrum, though concerns have been raised about behavioral disturbances in some pediatric patients[(5)].

Given the importance of both efficacy and safety in the long-term management of childhood epilepsy, this study was designed to compare Sodium Valproate and Levetiracetam in a pediatric population[(6)]. By evaluating seizure control and treatment tolerability over a 6-month period, this study aims to provide evidence-based guidance for selecting optimal first-line antiepileptic therapy in children[(7)].

MATERIALS AND METHODS:

This was a prospective, randomized, open-label, comparative clinical study conducted in the Department of Pediatrics at GGH,Kadapa, over a period of 6 months.A total of 100 children aged between 2 and 16 years, newly diagnosed with epilepsy according to the International League Against Epilepsy (ILAE) criteria, were enrolled after obtaining informed consent from parents or guardians. Children with structural brain lesions, metabolic disorders, prior antiepileptic drug use, or significant hepatic/renal dysfunction were excluded from the study.Participants were randomly assigned into two equal groups (n = 50 each) using a computer-generated randomization list.Group A was given Sodium Valproate 15-30 mg/kg/day in two divided doses and Group B was given Levetiracetam 10-30 mg/kg/day in two divided doses.Dose was titrated based on individual patient needs.Patients will be given seizure dairy which they fill weekly and will be evaluated at 1st, 3rd and 6th month for follow up.

Ethical Committee Permission:

The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from the parents or legal guardians of all participants prior to enrollment.

Statistical Analysis:

Data were analyzed using SPSS version 26.Categorical variables were expressed as percentages and compared using Chi-square test. Continuous variables were expressed as mean ± standard deviation and compared using Student's t-test. A p-value < 0.005 was considered statistically significant.

RESULTS:

Table 1: Baseline Characteristics of Study Population

Parameter	Sodium Valproate (n = 50)	Levetiracetam (n = 50)	*p*-value
Mean Age (years)	8.2 ± 3.4	8.5 ± 3.1	> 0.05
Male : Female	28 : 22	30 : 20	> 0.05
Generalized Seizures (%)	70%	68%	> 0.05
Focal Seizures (%)	30%	32%	> 0.05
Baseline Seizure Frequency (per month)	5.4 ± 2.3	5.1 ± 2.5	> 0.05

Table 2: Seizure Control After 6 Months

Seizure Outcome	Sodium Valproate (n = 50)	Levetiracetam (n = 50)	*p*-value
Complete Control (%)	60% (30/50)	78% (39/50)	< 0.05
Partial Control (%)	26% (13/50)	18% (9/50)	> 0.05
No Response (%)	14% (7/50)	4% (2/50)	< 0.05

Table 3: Adverse Effects Observed

Adverse Effect	Sodium Valproate (n = 50)	Levetiracetam (n = 50)	*p*-value
Any Adverse Effect (%)	32% (16/50)	12% (6/50)	< 0.05
Weight Gain	10% (5/50)	0%	—
Gastrointestinal Symptoms	8% (4/50)	0%	—
Lethargy	6% (3/50)	0%	—
Elevated Liver Enzymes	4% (2/50)	0%	—
Hair Loss	4% (2/50)	0%	—
Behavioral Changes	0%	8% (4/50)	—
Somnolence	0%	4% (2/50)	—

DISCUSSION:

The present study compared the efficacy and safety of Sodium Valproate and Levetiracetam in the treatment of childhood epilepsy in a cohort of 100 children over a 6-month period. Both drugs demonstrated good seizure control, but Levetiracetam showed significantly better outcomes in terms of both efficacy and tolerability.

In terms of seizure control, 78% of children in the Levetiracetam group achieved complete seizure freedom, compared to 60% in the Sodium Valproate group ($p < 0.005$). This difference was statistically significant and clinically relevant. These findings align with previous studies that have reported Levetiracetam to be an effective broad-spectrum antiepileptic agent, particularly favourable for its rapid onset of action and dose flexibility.

Partial response rates were slightly higher in the Sodium Valproate group (26%) compared to the Levetiracetam group (18%), though the difference was not statistically significant ($p > 0.05$). The rate of non-responders was notably higher in the Sodium Valproate group (14% vs. 4%), further emphasizing Levetiracetam's superior efficacy in this study population.

Regarding safety, adverse effects were significantly more common in the Sodium Valproate group (32%) compared to the Levetiracetam group (12%) ($p < 0.05$). The most frequent side effects associated with Valproate included weight gain, gastrointestinal disturbances, lethargy, and mild hepatotoxicity—all consistent with its known safety profile. In contrast, Levetiracetam was associated primarily with mild behavioral changes and somnolence, which were self-limiting and did not require drug discontinuation.

These results support the growing preference for Levetiracetam in pediatric epilepsy due to its favorable pharmacokinetic profile, minimal drug interactions, and better tolerability, making it an attractive first-line option, especially in children who are at risk of metabolic or hepatic complications.

However, it's important to note some limitations of this study. The follow-up period was limited to 6 months, which may not capture long-term efficacy or delayed adverse effects. Additionally, the open-label design could introduce observational bias. Further multicenter studies with longer follow-up durations and blinded protocols would help validate these findings.

CONCLUSION:

This comparative study demonstrates that both Sodium Valproate and Levetiracetam are effective in the management of childhood epilepsy. However, Levetiracetam showed superior efficacy, with a higher percentage of children achieving complete seizure control, and a more favorable safety profile with significantly fewer adverse effects. Given these findings, Levetiracetam may be considered a more suitable first-line antiepileptic drug for children, especially in cases where tolerability and long-term safety are key considerations. Further large-scale, long-term studies are recommended to confirm these results and guide clinical decision-making in pediatric epilepsy management.

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