Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com

OPEN ACCESS

Paediatrics

Effects of Oxcarbazepine versus Levetiracetam among Children with Focal Epilepsy Attending in a Tertiary Care Hospital

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DOI: https://doi.org/10.36347/sjams.2026.v14i01.008 | **Received:** 02.11.2025 | **Accepted:** 10.01.2025 | **Published:** 15.01.2026

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Abstract **Original Research Article**

Background: The incidence of epilepsy is highest in the infancy period among all age groups, affecting an estimated 70.1 out of every 100,000 in ≤ 2year old. Long term effects of pediatric epilepsy include GDD, ID, behavioral abnormalities, etc. To avoid these long-term impairments, it is crucial to treat childhood focal epilepsy with an appropriate anti-epileptic medication. ***Methods*:** This quasi-experimental study was conducted in Department of Pediatrics, Institute of Child & Mother Health (ICMH), Matuail, Dhaka, Bangladesh from January 2023 to December 2023 with newly diagnosed focal epilepsy aged 2 months to 18 years attending in outpatient and inpatient department. ***Results*:** A total number of 80 children were recruited for this study. The primary outcome was assessed in 80 children In the OXC group, the overall response rate was 75.0%, and in the LEV group, it was 60% after 3 months of treatment. Measuring frequency of seizure before and after treatment. Seizure frequency decrease after treatment with both drugs where OXC group was 4.35(±3.37) to 1.45(±0.78) and LEV group was 5.57(±4.36) to 1.57(±0.81)/month respectively. Only adverse effect irritability was found more in LEV group (in percentile), but that was not statistically significant. Statistically significant improvements in EEG were found more in oxcarbazepine group than in levetiracetam group. ***Conclusion***: In the treatment of focal epilepsy oxcarbazepine group was found to be more effective and safer than levetiracetam group, though it was not statistically significant.

Keywords: Focal Epilepsy, Oxcarbazepine, Levetiracetam, Quasi-Experimental Study.

INTRODUCTION

Epilepsy is one of the most common neurological disorders in childhood, with the highest incidence occurring during the infantile period—affecting approximately 70.1 per 100,000 children aged ≤2 years. Up to 72% of childhood epilepsy cases present as focal-onset seizures, whether or not secondary generalization occurs [1]. It is a chronic, non-communicable disease and ranks as the second most prevalent neurological condition after stroke. More than half of all epilepsy cases begin in childhood, with a lifetime cumulative incidence of about 3%. Between 4–10% of children experience at least one seizure within the first 16 years of life, and the condition is more prevalent in males than females [2].

The etiology of epilepsy is multifactorial, involving structural, metabolic, genetic, immunological, and infectious causes [3]. Because the developing brain is highly vulnerable, epileptic attacks in children can lead to neuronal damage and long-term complications such as global developmental delay (GDD), intellectual disability (ID), and behavioral abnormalities [4]. Therefore, timely and effective treatment of infantile epilepsy is crucial to prevent these adverse outcomes. The choice of anti-epileptic drug (AED) must consider various factors such as age, gender, seizure type, and epilepsy syndrome. Although many conventional AEDs are available, limitations related to bioavailability and adverse effects often restrict their use in pediatric populations. Consequently, newer-generation AEDs

have been developed to improve efficacy and minimize side effects [5].

Pharmacological therapy using AEDs remains the cornerstone of epilepsy management. Optimal treatment selection depends on the patient's clinical characteristics, seizure type, and drug tolerability, given the condition's association with increased morbidity, mortality, and cases of sudden unexplained death [6]. Among the available AEDs, oxcarbazepine (OXC) and levetiracetam (LEV) are commonly used in children with focal or generalized tonic–clonic seizures. OXC is widely accepted as a first-line or add-on treatment for partial seizures, with or without secondary generalization. Its favorable pharmacokinetic profile—such as low protein binding (40%), reduced hepatic enzyme induction, and limited drug–drug interactions—contributes to better tolerability and fewer adverse events compared to traditional AEDs [7].

Levetiracetam (LEV), a second-generation AED derived from pyrrolidone, acts by binding selectively to synaptic vesicle protein 2A, enhancing vesicle aggregation and regulating neurotransmitter release. This mechanism inhibits abnormal neuronal electrical discharges, providing broad-spectrum antiepileptic efficacy [8]. Despite the growing use of both OXC and LEV in pediatric focal epilepsy, comparative data on their efficacy and tolerability as monotherapy remain limited. Therefore, this study aims to evaluate and compare the therapeutic effectiveness, potential adverse effects, and EEG outcomes of OXC and LEV monotherapy in children with focal epilepsy.

Materials and Methods

Study Design: This quasi-experimental study was conducted at the Institute of Child and Mother Health (ICMH), Matuail, Dhaka-1362. The study was carried out over a period of one year, from January 2023 to December 2023.

Sample Size and Selection: Using 80% power and a 5% alpha error, the calculated sample size was 36 per group. After adding a 10% non-response rate, the final sample size was 40 participants in each group, totaling 80.

Preparation of Samples: Children were selected consecutively per inclusion and exclusion criteria. After IRB approval and parental consent, data were collected using a structured questionnaire. Focal epilepsy was confirmed clinically and by EEG. Participants were alternately assigned to oxcarbazepine or levetiracetam groups (10–40 mg/kg/day). EEGs were done before and 3 months after treatment. Follow-ups at 2 weeks, 1 month, and 3 months assessed seizure control, compliance, and side effects.

Data Analysis: Data were collected using a pre-designed sheet and presented in tables. Analysis was performed with SPSS version 24. Continuous variables were expressed as mean ± SD and analyzed using paired and independent t-tests, while qualitative data were assessed with Chi-square tests. Descriptive analysis summarized demographic and clinical characteristics. A p-value <0.05 was considered significant. The study protocol was approved by the IRB of ICMH.

Results

This quasi-experimental study was conducted at the Department of Pediatrics, Institute of Child and Mother Health (ICMH), Dhaka, Bangladesh. A total of 80 children (aged 2 months–18 years) with newly diagnosed focal epilepsy, meeting inclusion criteria, were enrolled (40 per group). The study aimed to compare the effects of Oxcarbazepine and Levetiracetam in these patients.

Table 1: Demographic characteristics of the study population (n=80)

Demographic characteristics	Group A (OXC)	Group B (LEV)	Total	p value
Age in month	n(%)	n(%)	(n)	
2-12 months	08 (10.0)	15 (18.75)	23	0.21[a]
13-60 months	23 (26.5)	19 (23.75)	42	
> 60 months	09 (11.25)	06 (7.5)	15	
Mean ±SD	37.22 (±32.13)	33.99 (±32.11)		0.64[b]
Gender				
Male	21 (52.50)	28 (70.0)	49	
Female	19 (47.50)	12 (30.0)	31	0.10[a]
Residence				
Rural	20 (50.0)	24 (60.0)	44	
Urban	20 (50.0)	16 (40.0)	36	0.36[a]
Average monthly family income				
Low	1 (2.50)	1(2.50)	2	
Lower middle	23 (57.50)	22 (55.0)	45	0.53[a]
Upper middle	15 (37.50)	17 (42.50)	32	
High income	1 (2.50)	0	1	

a value was determined by chi-square test
b P value was determined by unpaired t- test

Table 1 showed that children taking oxcarbazepine and Levetiracetam had a mean age of 37.22(±32.13) months and 33.99(±32.11) months, with the majority were male in both groups (52.50% vs. 70.0%) but no significant difference in demographics characteristics.

Table 2: Clinical characteristics of the study population (n=80)

Clinical profile	Group A (OXC)	Group B (LEV)	Total	p value
	n(%)	n(%)	(n)	
Age of onset of seizures (in months)	16.07 (±13.11)	12.87 (±11.93)		0.25[b]
Family history of epilepsy	09 (22.50)	06(15.0)	15	0.36[a]
Consanguinity	06 (15.0)	08 (20.0)	14	0.55[a]
H/o delay in achieving developmental milestone	15(37.50)	18 (45.0)	44	0.491[a]
Microcephaly	07 (17.50)	13(32.50)	20	0.12[a]
Types of seizures				
Only focal seizures	24 (60.0)	22 (55.0)	46	
Focal to bilateral tonic –clonic seizure	16 (40.0)	18 (45.0)	34	0.65[a]

a P value was determined by chi-square test
b P value was determined by unpaired t- test

Table 2 showed that the onset of seizures between groups were nearer. developmental delay and microcephaly were more in LEV groups. In OXC group 60.0% of patients had focal seizures, while 40.0% had focal to bilateral tonic-clonic seizures. In LEV group, 55.0% had focal seizures and 45.0% had focal to bilateral tonic- clonic seizures. No significant difference was found between the two groups.

Table 3: Therapeutic response after 2 weeks,1month and 3 months of administration of both drugs

Therapeutic Response	Group A (OXC) n (%)	Group B (LEV) n (%)	Total n	2 weeks p	1 month p	3 months p
Complete (no seizures)	17 (42.5)	18 (45.0)	35	0.70		
	23 (57.5)	22 (55.0)	45		0.85	
	30 (75.0)	24 (60.0)	54			0.31
Good (>50% seizure reduction)	10 (25.0)	8 (20.0)	18	0.70		
	8 (20.0)	10 (25.0)	18		0.85	
	4 (10.0)	8 (20.0)	11			0.31
Fair (<50% seizure reduction)	12 (30.0)	14 (35.0)	26	0.70		
	9 (22.5)	8 (20.0)	17		0.85	
	6 (15.0)	8 (20.0)	14			0.31
None (no response)	1 (2.5)	0	1	0.70		

At 2 weeks, 1 month, and 3 months, both Oxcarbazepine (Group A) and Levetiracetam (Group B) demonstrated comparable therapeutic responses. The proportions of patients achieving complete, good, or fair seizure control were similar between the two groups at each follow-up point. The p-values at all time periods (2 weeks, 1 month, and 3 months) were not statistically significant, indicating no meaningful difference in treatment efficacy between OXC and LEV throughout the study duration. (Table 3)

Table 4: Therapeutic response aged 2-12, 13-60, >60 months after 3 months of administration of both drug

Therapeutic Response (3 months)	Age Group	Group A (OXC) n (%)	Group B (LEV) n (%)	Total n	p value
Complete (no seizures)	2–12 months	5 (21.74)	6 (26.08)	11	0.58
	13–60 months	13 (28.27)	14 (30.44)	27	0.71
	>60 months	8 (53.33)	5 (33.33)	13	0.75
Good (>50% seizure reduction)	2–12 months	1 (4.35)	4 (17.39)	5	0.58
	13–60 months	3 (6.52)	6 (13.04)	9	0.71
	>60 months	0	0	0	0.75
Fair (<50% seizure reduction)	2–12 months	2 (8.69)	5 (21.74)	7	0.58
	13–60 months	4 (8.69)	6 (13.04)	10	0.71
	>60 months	1 (6.66)	1 (6.66)	2	0.75
None (no response)	2–12 months	0	0	0	0.58
	13–60 months	0	0	0	0.71
	>60 months	0	0	0	0.75

Across all age groups (2–12 months, 13–60 months, and >60 months), therapeutic responses after 3 months of treatment were similar between Oxcarbazepine (OXC) and Levetiracetam (LEV). In each age category, the proportions achieving complete, good, or fair seizure reduction did not differ significantly between the two drugs. The p-values for all comparisons were >0.05, indicating no statistically significant difference in treatment effectiveness between OXC and LEV across different pediatric age groups. (Table 4)

Table 5: Seizure frequency before and after administration of both drugs

Seizure frequency (per month)	Study group		
	Group A (OXC) n=40	Group B (LEV) n=40	p value
	Mean ±SD	Mean ±SD	
Before therapy	4.35(±3.37)	5.27(±4.36)	0.29[a]
Two weeks after therapy	1.87(±0.96)	1.90(±0.90)	0.90[a]
One month after therapy	1.65(±0.83)	1.65(±0.80)	1.0[a]
Three months after therapy	1.45(±0.78)	1.57(±0.81)	0.48[a]

aP value was determined by unpaired t- test

Table 5 showed that the mean seizure frequency was 4.35(±3.37) and 5.27(±4.36) in oxcarbazepine and Levetiracetam group before administration of drugs. After drug administration, seizure frequency decreased in both groups, 1.45(±0.78) and 1.57(±0.81) in 3 months, respectively without any significant difference between groups.

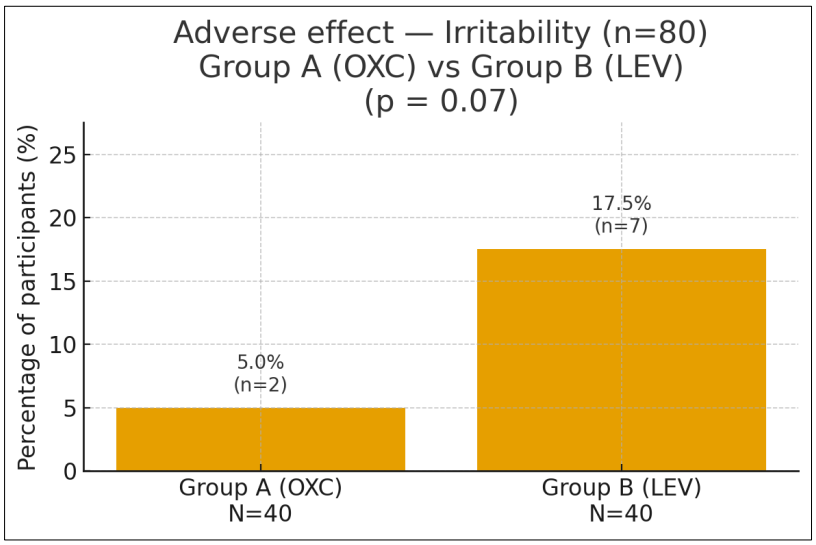

Figure Ⅰ: Adverse effects of both groups (n=80)

The figure Ⅰ showed that irritability occurred more frequently in the Levetiracetam (LEV) group (17.5%, n=7) compared to the Oxcarbazepine (OXC) group (5%, n=2). Although the LEV group reported a higher proportion of irritability, the difference did not reach statistical significance (p = 0.07).

Table 6: Comparison of EEG pattern after 3-month therapy with study group

EEG	Three months after therapy		Total	p value
	Group A (OXC)	Group B (LEV)		
	n (%)	n (%)		
Abnormal	25(62.5)	33 (82.5)	58	
Normal	15 (37.5)	07 (17.5)	22	0.04*

*P value was determined by chi-square test

Table 6 showed that statistically significant improvements in EEG were found more in oxcarbazepine group (37.5%) than in levetiracetam group (17.5%).

DISCUSSION

In the present study, the mean age of children treated with oxcarbazepine (OXC) was 37.22 ± 32.13 months, and with levetiracetam (LEV) was 33.99 ± 32.11

months. Males predominated in both groups (52.5% vs. 70.0%), consistent with findings by [8, 9], also reported male predominance [8], observed mean participant ages of 8.62 ± 2.21 years (OXC) and 8.47 ± 2.13 years (LEV). The mean age of seizure onset in the current study was 16.07 ± 13.11 months (OXC) and 12.87 ± 11.93 months (LEV). [8]) reported slightly older onset ages (7.13 ± 1.75 years vs. 6.98 ± 1.82 years), while [1], onset > 12 months in 85.5% (OXC) and 85.9% (LEV) groups. Family history of epilepsy was present in 22.5% (OXC) and 15% (LEV), similar to Zhao & Li (2022), who found 34.2% with such history. Focal seizures were predominant in both groups (60% OXC, 55% LEV), comparable to [1], who found 55.4% (OXC) and 47.4% (LEV). The overall response rate was higher in the OXC group (75%) than the LEV group (60%) after three months, though not statistically significant. This trend aligns with [1-8], who reported higher response in OXC (50% vs. 37.5% at 3 months; 78.12% vs. 53.12% at 6 months).

Seizure frequency in the OXC group declined from 4.35 ± 3.37 to 1.45 ± 0.78 after 3 months, while LEV decreased from 5.27 ± 4.36 to 1.57 ± 0.81. Similar reductions were reported by [10] in CBZ and TPM groups (6.83 ± 4.88 to 1.80 ± 1.06; 5.21 ± 2.96 to 1.86 ± 0.94). Adverse effects were mainly irritability, more frequent in the LEV group (17.5%), consistent with, who found 18% with irritability and nervousness, and [11], who reported 1% with irritability on LEV monotherapy. EEG improvement was significantly greater in the OXC group (37.5%) than LEV (17.5%), aligning with Suo *et al*., (2021), who found 40.63% and 31.25%, respectively [8]. The main strength of this study was the complete follow-up of all 80 children with both pretreatment and posttreatment EEG assessments alongside clinical evaluation.

CONCLUSION

46 In the treatment of focal epilepsy oxcarbazepine group was found to be more effective than the levetiracetam group, though it was not statistically significant. After three months of anti-epileptic therapy, statistically significant improvements in EEG were found more in oxcarbazepine group than in levetiracetam group. Only irritability was found to have adverse effects in both groups but more in levetiracetam group, which was statistically not significant.

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