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Original Research Article

Levetiracetam vs. phenobarbitone in neonatal seizures - a randomised controlled trial at a tertiary care hospital in Southern Rajasthan

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ABSTRACT

Background: Neonatal seizures, most commonly due to hypoxic-ischemic encephalopathy (HIE), represent a medical emergency with substantial morbidity. While phenobarbitone (PB) remains the first-line antiepileptic, its efficacy varies and adverse effects are frequent. Levetiracetam (LEV) may offer a safer and equally effective alternative.
Methods: In this randomized controlled trial conducted at RNT Medical College NICU, Udaipur, 120 EEG-confirmed neonatal seizure cases were randomized equally to receive either LEV or PB. Seizure control within 24 hours without switching was the primary outcome; secondary outcomes included drug switching, adverse events, discharge rate and mortality.
Results: Baseline characteristics were well-matched between groups. Initial seizure control was achieved in 81.6% of the LEV group and 71.6% of the PB group (p=0.195). After switching, seizure control rates significantly favored LEV over PB (96.7% vs 86.7%, p=0.048). Adverse events occurred in 11.7% of neonates receiving LEV versus 23.3% with PB (p=0.036). No significant difference was observed in mortality or discharge rates between the two groups.
Conclusions: Levetiracetam demonstrated a comparable efficacy to phenobarbitone in neonatal seizure control, with a significantly better safety profile and higher effectiveness after drug switching. LEV shows promise as a preferable first-line or adjunctive therapy for neonatal seizures.

Keywords: Hypoxic-ischemic encephalopathy, Levetiracetam, Neonatal seizures, Phenobarbitone

INTRODUCTION

Neonatal seizures are the most common neurological emergency in the newborn period, with an incidence of 0.5–0.8% in term neonates and 6–12% in those weighing less than 1500 grams.[1,2] Nearly 75% of these seizures are acute symptomatic, predominantly resulting from HIE, cerebral infarction or intracranial hemorrhage and are associated with increased risks of mortality and adverse long-term neurodevelopmental outcomes.[3,4] Neonates exhibit heightened seizure susceptibility due to an imbalance between early-developing excitatory glutamatergic pathways and immature inhibitory GABAergic mechanisms.[3] Recurrent or prolonged seizures may exacerbate neuronal injury and contribute to long-term sequelae, including epilepsy and cognitive impairment, highlighting the need for early and effective intervention.[5] PB remains the most widely used first-line antiepileptic drug (AED) in this population. However, its seizure control efficacy varies between 33% and 77% and it is frequently associated with adverse effects such as hypotension, respiratory depression and potential neurotoxicity.[6-9] LEV, a newer AED, exerts its antiepileptic action via binding to synaptic vesicle protein 2A (SV2A). It offers a more favorable safety profile, absence of neuronal apoptosis in preclinical studies and reported seizure control rates ranging from 35% to 86%.[10-14] LEV is further favored for its pharmacokinetic

advantages, including rapid absorption, minimal drug–drug interactions, non-hepatic metabolism and availability in both oral and intravenous formulations.[15-17] Although the off-label use of LEV in neonatal intensive care units (NICUs) is increasing, high-quality comparative evidence with phenobarbitone remains limited.[13] Therefore, this study was undertaken to compare the efficacy, safety and clinical outcomes of Levetiracetam versus Phenobarbitone in the management of neonatal seizures.

METHODS

This randomised control trial (crossover design with equal allocation) was conducted in the Paediatric department of RNT Medical College, Udaipur, after taking approval by the institutional ethical committee and written informed parental consent was taken before enrolment. This study was conducted at tertiary level NICU, RNT Medical College, Udaipur, Rajasthan. After getting clearance from departmental review committee and ethical committee till completion of sample size for a minimum period of 1 year. This study has been conducted on term and pre-term babies admitted in NICU with seizures. History and clinical examination have been done using a systematically designed proforma.

Inclusion criteria

EEG confirmed seizure in all term and pre-term babies admitted in NICU. Those patients whose guardian has given informed consent.

Exclusion criteria

Neonates with electrolyte imbalance (hyponatremia and hypernatremia), hypoglycemia, hypocalcemia, hypomagnesemia, any previous history of receiving ASM, family history of any seizure disorder, any congenital malformation.

Protocol

After obtaining approval from the Institutional Ethics Committee and written informed parental consent, Term and preterm neonates (total sample size 120) with EEG-confirmed seizures were enrolled. Electrographic seizures were defined as abnormal, evolving EEG patterns with peak-to-peak amplitude >2 µV and duration >10 seconds. Seizure frequency in the first 24 hours was classified as rare (<5), occasional (5–10) or frequent (>10).

Randomization and intervention

Neonates were randomized (computer-generated schedule) into two groups: LEV group: Received intravenous levetiracetam (30 mg/kg diluted to 2 mg/ml in normal saline) over 20 minutes. If seizures persisted, a second LEV dose (30 mg/kg) was given. Non-responders were switched to PB. PB group: Received intravenous phenobarbitone (20 mg/kg diluted 1:10 in saline) over 20 minutes at 1 mg/kg/min under cardio-respiratory monitoring. If seizures continued, up to two additional loading doses (10 mg/kg each) were administered. Persistent cases were switched to LEV. Routine investigations (RBS, CBC, sepsis screen, electrolytes, LFTs, KFTs, neuroimaging, etc.) were performed as indicated. Primary outcome: Seizure cessation within 24 hours after initial and second drug loading doses. Secondary outcome: Adverse events within 2 hours of drug administration (e.g., respiratory depression, bradycardia, hypotension, desaturation). Clinical seizure control was defined by the absence of abnormal movements, ocular deviation, autonomic disturbances or cardiorespiratory changes.

Statistical analysis

Data were entered in Microsoft Excel and analyzed using IBM SPSS Statistics version 26. Continuous variables were expressed as mean±standard deviation (SD) or median with interquartile range (IQR), depending on the distribution assessed by the Shapiro-Wilk test. Categorical variables were summarized as frequencies and percentages. Between-group comparisons were performed using Chi-square test or Fisher's exact test for categorical variables and independent t-test or Mann–Whitney U test for continuous variables, as appropriate. A p value<0.05 was considered statistically significant.

RESULTS

A total of 120 neonates with seizures were enrolled in this randomized controlled trial, with 60 allocated to the Phenobarbitone (PB) group and 60 to the Levetiracetam (LEV) group. In the LEV group, 65% were males and 35% females (M:F ratio 1.8:1), while in the PB group, 83.3% were males and 16.7% females (M:F ratio 5:1).

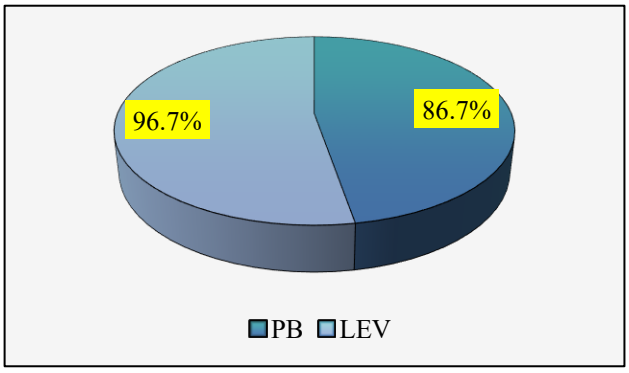

Figure 1: Distribution of final seizure control (post switch).

The gender difference between groups was statistically significant (p=0.022). Regarding gestational age, 87% of the total study population were term and 13% preterm. The PB group had 92% term and 8% preterm neonates, whereas the LEV group had 84% term and 16% preterm

(p=0.168, not significant). The mean gestational age was comparable between groups (38.05±1.254 weeks in PB vs. 37.98±1.490 weeks in LEV, p=0.791). Birth weight distribution was also similar across groups, with the majority (68%) weighing 2.5–3 kg.

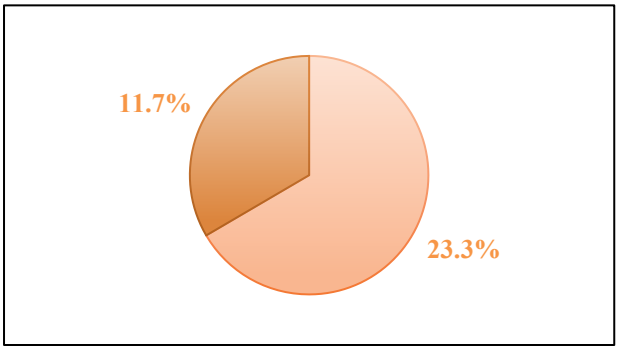

Figure 2: Distribution of adverse events in drug groups.

Mean birth weight was 2.81±0.287 kg in PB and 2.78±0.307 kg in LEV (p=0.635). Most neonates (65.9%) required resuscitation at birth, without significant intergroup difference. The distribution of APGAR scores at 1 and 5 minutes did not differ significantly. Mean APGAR at 1 minute was 4.70±1.720 in PB and 4.82±1.722 in LEV (p=0.711) at 5 minutes, it was 7.60±0.764 in PB and 7.65±0.745 in LEV (p=0.715).

Seizure profile

Tonic seizures were the most common type (45.8%), followed by tonic–clonic (35.8%) and clonic seizures (18.3%), with no statistically significant differences between groups. Among 120 EEG, 32.5% EEGs were severely abnormal (PB 25%, LEV 40%) and 67.5% mild/moderately abnormal (PB 75%, LEV 60%) with no significant difference.

Seizure frequency categorization (rare, occasional, frequent) showed no significant variation; however, the mean seizure frequency before switching drugs was significantly lower in the LEV group (4.87±2.347) than in the PB group (6.00±2.623, p=0.025). Cranial ultrasonography (USG) was normal in 56.7% of neonates, while 41.7% showed hypoxic–ischemic encephalopathy (HIE) changes and rare findings included cysts, ventricular dilatation or mild cerebral edema. Seizure frequency was significantly higher in neonates with abnormal USG findings compared to those with normal scans (6.06±2.667 vs. 4.96±2.353, p=0.018).

Table 1: Characteristics and its distribution.

Variable	Phenobarbitone (n=60)	Levetiracetam (n=60)	Total (n=120)	P value	Significance
Gender (M:F ratio)	83.3%: 16.7% (5:1)	65%: 35% (1.8:1)	74.2%: 25.8%	0.022	Significant
Gestational age (Term: Pre-term)	92%:8%	84%: 16%	87%: 13%	0.168	No
Birth weight >2.5kg	90%	88%	89%	0.785	No
Mean birth weight (kg)	2.81±0.29	2.78±0.31	2.80±0.30	0.635	No
APGAR score at 1 min (mean)	4.70±1.72	4.82±1.72	4.76±1.71	0.711	No
APGAR Score at 5 min (mean)	7.60±0.76	7.65±0.73	7.63±0.75	0.715	No
Resuscitation Required	68%	65%	65.9%	0.600	No
AGA:SGA distribution	86.7%: 13.3%	88.3%: 11.7%	87.5%: 12.5%	0.783	No
Etiology: HIE	91.6%	88.3%	90%	0.361	No

Treatment response

In the LEV group, seizure control was achieved after the first dose in 19%, after the second dose in 62%, while 19% required switching to PB. In the PB group, seizure control was achieved after the first dose in 7%, second dose in 25% and third dose in 40%, with 28% requiring switching to LEV.

Dose escalation trends were statistically significant in both groups. Before switching, seizure control rates were 81.6% in LEV and 71.6% in PB (p=0.195). After switching, seizure control was significantly higher in LEV (96.7%) compared to PB (86.7%, p=0.048). Switching requirement itself was not significantly different between groups (18.3% in LEV vs. 28.3% in PB, p=0.195).

Etiology and outcomes

HIE was the predominant etiology (90%), followed by infectious causes such as meningitis (8.3%) and bilirubin

encephalopathy (1.7%), with no significant intergroup difference. Adverse events were significantly lower in the LEV group (11.7%) compared to PB (23.3%, p=0.036), with hypotension significantly more frequent in PB (p=0.078). Overall, 93.3% of neonates were discharged and 6.7% died, with no statistically significant mortality difference between LEV (5.0%) and PB (8.3%) groups.

Table 2: Neuroimaging and distribution of seizure controlled group.

Variable	Phenobarbitone (n=60)	Levetiracetam (n=60)	P value	Significance
Abnormal EEG findings (grades)			0.119	Not significant
Severe	15 (25%)	24 (40%)		
Mild/ moderate	45 (75%)	36 (60%)		
Seizure type	Tonic 50%, Clonic 11.7%, Tonic-Clonic 38.3%	Tonic 41.7%, Clonic 25%, Tonic-Clonic 33.3%	0.168	Not significant
Seizure frequency (median, IQR)	6 (4–7)	4.5 (3–6)	0.025	Significant
seizure controlled (before switching)	71.6%	81.6%	0.195	Not significant
Seizure controlled (after switching)	86.7%	96.7%	0.048	Significant
Switching required	28.3%	18.3%	0.195	Not significant
usg abnormal (HIE, cyst, edema)	45%	41.7%	0.782	Not significant
Seizure frequency with abnormal USG (mean)	6.06±2.67	-	0.018	Significant

Table 3: Response to drugs and its adverse effects.

Outcome variable	Phenobarbitone	Levetiracetam	P value	Significance
1st Dose response	7% (4/60)	19% (11/60)	-	-
2nd Dose response	25% (15/60)	62% (38/60)	<0.00001	Highly significant
3rd Dose required	40% (24/60)	-	-	-
Switching to another drug	28.3% (17/60)	18.3% (11/60)	0.195	Not significant
Final seizure control (post-switch)	86.7%	96.7%	0.048	Significant
Adverse events	23.3%	11.7%	0.036	Significant
Hypotension	10 (16.66%)	3 (5%)	0.078	Not significant
Respiratory depression	3 (5%)	1 (1.6%)	0.611	Not significant
Bradycardia	3 (5%)	3 (5%)	1	Not significant
Discharge rate	91.7%	95.0%	0.464	Not significant
Mortality	8.3%	5.0%	-	-

DISCUSSION

This study aimed to compare the efficacy, safety and outcomes of LEV and Phenobarbitone (PB) in the control of neonatal seizures in NICU-admitted term and preterm neonates. A total of 120 neonates were randomized equally into LEV and PB groups and their clinical, demographic and treatment responses were recorded. Of the 120 neonates, 87% were term and 13% preterm. The PB group had a higher proportion of term neonates (92%) compared to the LEV group (84%), while the LEV group had more preterm neonates (16%). Similar distributions were reported in studies by Gowda et al and Battig et al.[18,19] Males were predominant in both groups (overall 74.2%). The PB group had a significantly higher male proportion (83.3%) compared to the LEV group (65%), with a statistically significant p value of 0.022. Low birth weight (1.5–2.4 kg) was more common in the LEV group (12%) than PB group (10%). Mean birth weight was comparable (PB: 2.81±0.287 kg, LEV: 2.78±0.307 kg). Similar trends were noted in studies by Gowda et al and Battig et al, while Gyandeep et al reported significantly lower mean weights[18,19,23] Resuscitation was required in 65.9% of neonates, slightly higher in PB group (68%) than LEV (65%). These findings are consistent with Gyandeep et al.[23] APGAR scores at 1 and 5 minutes were comparable across both groups (1 min: ~4.7, 5 min: ~7.6), in line with studies by Battig and Gyandeep.[18,23] In PB group, tonic seizures (50%) were most common, followed by tonic-clonic (38.3%). In LEV group, Tonic seizures (41.7%) and clonic seizures (25%). Seizure frequency was significantly lower in the LEV group

(p=0.025), suggesting better initial seizure control. Study by Toptan also reported lower seizure frequency in LEV group, while Battig noted slightly more frequent seizures in LEV (24%) compared to PB (23%).[18,24] 56.69% of neonates had normal USG findings, 43.4% had abnormalities (mostly HIE). PB group had more HIE changes (43.3%) compared to LEV group (40%). No significant difference in distribution, but seizure frequency was significantly higher in neonates with abnormal USG findings (p=0.018). Studies by Gowda et al, Battig et al and Toptan et al reported similar trends.[18,19,24] In LEV Group, 19% seizure control after 1st dose, 62% after 2nd dose, 19% switched to PB. In PB Group, 7% after 1st dose, 25% after 2nd, 40% after 3rd, 28% required switching to LEV. Seizure control was significantly better in the LEV group and even after switching (p<0.048).

Comparable findings were seen in studies by Gowda et al, Susnerwala et al and Ramantani et al.[19,20,26] In contrast, Sharpe C et al, suggested PB might be more effective, indicating ongoing debate.[22] 18.3% of LEV group and 28.3% of PB group required switching. Seizure control after switching was higher in the LEV group (96.7%) than PB (86.7%), though not statistically significant in all contexts. Studies by Charu et al and Khan et al support LEV's effectiveness post-switch, especially in HIE.[10,21,26] Majority of seizures were due to HIE (90%), followed by infections (8.3%) and bilirubin encephalopathy (1.7%).

Distribution was similar across groups and not statistically significant (p=0.361). Comparable etiology patterns noted in studies by Battig et al, Khan et al and Toptan et al.[18,21,24] Adverse events were significantly higher in the PB group (23.3%) compared to LEV (11.7%) (p=0.036). PB-related events included hypotension, respiratory suppression and bradycardia, with hypotension significantly more frequent in PB (p=0.078). These findings align with previous studies highlighting LEV's favorable safety profile.[18,22,24,25] Discharge rates were slightly higher in the LEV group (95%) compared to PB (91.7%), with a non-significant difference. In drug-switched subgroups, discharge rates were comparable (LEV: 82.4%, PB: 81.8%). Toptan et al also reported a higher discharge rate in the LEV group (75.76%) than PB (67.61%).[24]

Levetiracetam demonstrated better efficacy, faster seizure control and fewer adverse effects compared to Phenobarbitone. While both drugs were comparable in many demographic and clinical aspects, LEV showed superior safety and tolerability. Seizure control remained high even after drug switching, favoring LEV especially in asphyxiated neonates. These findings support LEV as a promising first-line or adjunctive therapy for neonatal seizures, although further large-scale randomized trials are necessary.

CONCLUSION

This randomized study evaluated and compared the efficacy, safety and clinical outcomes of LEV and PB in the management of neonatal seizures among 120 term and preterm neonates admitted to the NICU. The results demonstrated that Levetiracetam was more effective, with a higher rate of seizure cessation following treatment (96.7% vs. 86.7% after drug switching, p=0.048) and greater seizure control even before switching (81.6% vs. 71.6%, p=0.195, not statistically significant). In addition to its efficacy, levetiracetam was associated with significantly fewer adverse events compared to Phenobarbitone (11.7% vs. 23.3%, p=0.036), highlighting its favorable safety profile. It also required fewer escalations in dosing and less frequent switching to alternative therapy. Although the difference in discharge rates between groups was not statistically significant, it was higher in the LEV group (95% vs. 91.7%).

These findings are consistent with prior literature and support Levetiracetam as a safer and more effective first-line AED for the treatment of neonatal seizures, particularly in neonates with hypoxic-ischemic encephalopathy (HIE), which constituted the majority of cases in this cohort (90%). Early initiation of treatment, particularly for EEG-confirmed seizures, is crucial, as higher seizure frequencies may correlate with poorer treatment response. Given its superior efficacy and safety profile, Levetiracetam may be considered a preferable alternative to Phenobarbitone in the acute management of neonatal seizures. Further long-term prospective studies are warranted to evaluate the neurodevelopmental and cognitive outcomes associated with these antiepileptic therapies in neonates.

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