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Original Article

# Efficacy of Phenobarbital Versus Levetiracetam in Neonatal Seizures: Impact on EEG Results and Clinical Recovery

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## ABSTRACT

***Background:*** This study compared the efficacy of phenobarbital and levetiracetam in the treatment of neonatal seizures, with emphasis on seizure control, electroencephalographic (EEG) normalization, and neurodevelopmental outcomes.

***Methods:*** A retrospective cross-sectional study was conducted in neonatal intensive care units (NICUs) in Medan, Indonesia, between January 2022 and February 2025. Neonates aged 0–28 days with clinically or EEG-confirmed seizures were included. Patients received phenobarbital, levetiracetam, or combination therapy. Outcomes assessed were seizure control within 24 hours, EEG normalization during follow-up, and neurodevelopmental status. Normality of continuous data was assessed using the Shapiro–Wilk test; appropriate parametric or non-parametric tests were applied.

***Results:*** Fifty-nine neonates met the inclusion criteria: levetiracetam monotherapy (n=36), phenobarbital monotherapy (n=7), and combination therapy (n=16). Seizure cessation within 24 hours was achieved in 94.6% overall and 100% in the levetiracetam group. EEG normalization occurred in 58.3% of the levetiracetam group, 42.9% of the phenobarbital group, and 43.8% of the combination group (p=0.537). At follow-up, all neonates in the levetiracetam group demonstrated normal neurodevelopment, compared with 88.9% in the phenobarbital group and 87.5% in the combination group. Early initiation of therapy (<6 hours from seizure onset) was significantly associated with improved seizure control (p=0.008).

***Conclusion:*** Levetiracetam was as effective as phenobarbital in seizure control and EEG normalization, with a trend toward superior neurodevelopmental outcomes. These findings, derived from a Southeast Asian NICU setting, support levetiracetam as a safe and effective first-line agent for neonatal seizures. Early initiation of therapy and structured EEG monitoring further improve prognostication and outcomes.

***Keywords:*** EEG normalization, Levetiracetam, Neonatal seizures, Neurodevelopmental outcome, Phenobarbital

## Introduction

Neonatal seizures are among the most common neurological emergencies encountered in neonatal intensive care units (NICUs), affecting approximately 1 to 3.5 per 1,000 live births in term infants and up to 58 per 1,000 in very low birth weight neonates (1,2). These events often represent early signs of underlying central nervous system dysfunction and are associated with increased risks of long-term neurodevelopmental impairment. Prompt diagnosis and management are therefore critical for optimizing outcomes (2).

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The most common etiologies include hypoxic-ischemic encephalopathy (HIE), intracranial hemorrhage, ischemic stroke, metabolic derangements such as hypoglycemia and hypocalcemia, and central nervous system infections (3,4). Diagnostic challenges are compounded by the subtle and often non-specific clinical presentation of seizures in neonates. Electroencephalography (EEG) remains the gold standard for detection, particularly for subclinical seizures, but it remains underutilized or unavailable in many low-resource settings (5,6).

For decades, phenobarbital has been considered the standard first-line antiseizure medication (ASM) for neonates due to its established use and widespread availability. However, concerns about its limited efficacy—especially in HIE—and evidence of neurotoxicity and apoptotic effects on the developing brain from preclinical studies have raised questions about its long-term safety profile (7,8). These concerns have prompted increased interest in levetiracetam, a newer agent that binds to synaptic vesicle protein 2A (SV2A) and exerts antiepileptic effects without hepatic metabolism or known apoptotic effects (9).

Several studies have reported levetiracetam to be effective and safe for neonatal seizures, with some evidence suggesting superior neuro-developmental preservation compared to phenobarbital (10–12). However, despite this growing body of evidence, comparative data evaluating real-world clinical outcomes in NICU settings—particularly in resource-limited environments—remain scarce and inconsistent. Prior studies often lack structured EEG follow-up or standardized neurological outcome measures, limiting generalizability.

To address this evidence gap, we conducted a retrospective study comparing the clinical effectiveness of levetiracetam and phenobarbital, including EEG normalization and neuro-developmental outcomes after NICU discharge. To our knowledge, this is one of the first studies from Southeast Asia to provide a structured comparative analysis of both drugs using real-world EEG and follow-up developmental assessments in a tertiary-level NICU setting.

## Methods

This retrospective cross-sectional study was conducted between January 2022 and February 2025 in the NICU of Stella Maris Mother and Children Hospital in Medan, North Sumatra, Indonesia.

Neonates aged 0–28 days with clinical or EEG-confirmed seizures who received phenobarbital or levetiracetam were included. Exclusion criteria included in-hospital mortality, transfer to another hospital, loss to follow-up, or incomplete EEG data.

Phenobarbital was administered as a loading dose of 20 mg/kg; levetiracetam was given at 60 mg/kg. EEGs were obtained post-treatment and during follow-up. Maintenance therapy was directed by a pediatric neurologist.

Primary outcome: EEG normalization on follow-up. Secondary outcomes: seizure control within 24 hours and neurodevelopmental outcome (normal vs. abnormal).

Data were analyzed using SPSS version 22. The Shapiro–Wilk test was applied to assess normality of continuous variables. Normally distributed data were compared using parametric tests, whereas non-normally distributed data were analyzed with non-parametric tests (Mann–Whitney U and Kruskal–Wallis). Categorical variables were assessed using Chi-square or Fisher's exact tests, as appropriate. A p-value $<0.05$ was considered statistically significant.

### *Ethical approval*

This study was approved by the Health Research Ethics Committee of Universitas Sumatera Utara and Stella Maris Mother and Children Hospital. All patient data were anonymized and confidentiality was maintained.

## Results

Out of 88 neonates treated for seizures, 59 met the inclusion criteria. Treatment groups included levetiracetam monotherapy (n=36), phenobarbital monotherapy (n=7), and combination therapy (n=16). Baseline characteristics (Table 1) were comparable across groups, with no significant differences in gestational age, APGAR scores, or birth weight.

Seizure cessation within 24 hours was observed in 94.6% of neonates, with 100% control in the levetiracetam group. Phenobarbital achieved seizure control in 94.6% of patients; three patients required escalation to second-line therapy (Table 2).

Baseline EEG was abnormal in 94.4% of levetiracetam patients, 100% of phenobarbital patients, and 87.5% in the combination group. Follow-up EEG normalization was observed in 58.3%, 42.9%, and 43.8% of patients,

**Table 1.** Demographic Characteristics of the Study Population

| Demograpgic | Levetiracetam (n = 36) | Phenobarbital (n = 7) | Polytherapy (Levetiracetam +Phenobarbital (n = 16) | p- Value |
|---|---|---|---|---|
| Gender, n (%) | | | | |
| Male | 28 (77.8%) | 4 (57.1%) | 13 (81.3%) | 0.432* |
| Female | 8 (22.2%) | 3 (42.9%) | 3 (18.8%) | |
| Seizure Etiology, n (%) | | | | |
| Infection | 15 (41.7%) | 2 (28.6%) | 2 (12.5%) | |
| HIE | 2 (5.6%) | 4 (57.1%) | 5 (31.3%) | 0.001** |
| RDS | 1 (2.8%) | 0 (0%) | 4 (25.0%) | |
| Others**** | 18 (50.0%) | 1 (14.3%) | 5 (31.3%) | |
| Seizure Type, n (%) | | | | |
| Tonic | 2 (28.6%) | 4 (11.1%) | 1 (6.3%) | |
| Clonic | 0 (0%) | 4 (11.1%) | 4 (25.0%) | 0.313* |
| Subtle | 4 (57.1%) | 23 (63.9%) | 11 (68.8%) | |
| Tonic - Clonic | 1 (14.3%) | 5 (13.9%) | 0 (0%) | |
| Mode of Delivery, n (%) | | | | |
| Vaginal Delivery | 1 (14.3%) | 8 (22.2%) | 3 (18.8%) | 0.877* |
| SC | 6 (85.7%) | 28 (77.8%) | 13 (81.3%) | |
| Respiratory Support | | | | |
| Conventional Ventilator | 4 (57.1%) | 11 (30.6%) | 6 (37.5%) | |
| HFO | 0 (0%) | 2 (5.6%) | 3 (18.8%) | 0.381* |
| PCV/SIMV | 0 (0%) | 2 (5.6%) | 2 (12.5%) | |
| NCPAP | 2 (28.6%) | 10 (27.8%) | 1 (6.3%) | |
| Nasal Canunula | 1 (14.3%) | 11 (30.6%) | 4 (25.0%) | |
| Birth Weight, mean ± SD, g | 2142.86±807.13 | 2366.81±819.56 | 2342.50 ± 944.97 | 0.767** |
| Gestational Age, mean ± SD, wk | 35.00 ± 3.96 | 34.17 ± 4.29 | 34.06 ± 5.11 | 0.952** |
| Age at First Seizure, mean ± SD, d | 2.58±3.33 | 1.29±0.761 | 1.63±0.81 | 0.362*** |
| Duration of Hospitalization (NICU), mean ± SD, d | 22.75±18.74 | 23.00±23.47 | 28.00±20.95 | 0.574*** |
| APGAR Score, mean ± SD | 7.43 ± 1.40 | 7.72 ± 1.89 | 6.81 ± 2.48 | 0.353** |

Others****: Hypoglycemia, Hypocalcemia, Metabolic Disorders, HFO, High Frequency Oscillation; PCV, Pressure-Controlled Ventilation; SIMV, Synchronized Intermittent Mandatory Ventilation; NCPAP, Nasal Continuous Positive Airway Pressure; SC, Cesarean Section Statistical Information; *: Chi-Square Test, **: Fisher's Exact Test, ***: Kruskal-Wallis Test

respectively (Table 3). EEG normalization rates were highest in patients with infectious etiology (Table 4).

At follow-up, 100% of patients in the levetiracetam group showed normal development, compared to 88.9% and 87.5% in the phenobarbital and combination therapy groups, respectively (Table 5). All adverse outcomes occurred in non-levetiracetam groups.

Patients who received initial therapy within the first 6 hours of seizure onset showed significantly higher rates of early seizure control across all groups (Table 6).

### *Mean Duration (months) until EEG Normalization*

Levetiracetam demonstrated the shortest mean duration to achieve EEG normalization (2.9 months), whereas the combination of phenobarbital and levetiracetam required a longer duration (3.78 months). There was no statistically significant difference ($p > 0.05$) among the three treatment groups ($p = 0.073$). However, the p-value approaching 0.05 indicates a potential trend toward a clinically relevant difference, particularly between levetiracetam and combination therapy (Table 7).

**Table 2.** Analysis of Patient Outcomes After Administration of Antiseizure Medication

| Anti Seizure Medication | Seizures within 24 Hours After Administration of Medication | N (%) | Mean Rank Dosis (mg) | p- Value |
|---|---|---|---|---|
| Phenobarbital | Controlled | 53 (94.6%) | 29.08 | 0.252 * |
| | Uncontrolled | 3 (5.36%) | 18.17 | |
| Levetiracetam | Controlled | 3 | 2.00 | Insufficient Sample, Analysis Could Not Be Performed |
| | Uncontrolled | 0 | — | |

Statistical Information; *: Chi-Square Test, **: Fisher's Exact Test, ***: Kruskal-Wallis Test

**Table 3.** Analysis of Patient Outcomes After Administration of Antiseizure Medication

| Variable | Levetiracetam (n = 36) | Phenobarbital (n = 7) | Polytherapy (Levetiracetam + Phenobarbital (n = 16) | p- Value |
|---|---|---|---|---|
| Transcranial Ultrasound during NICU Admission, n (%) | | | | |
| Normal | 30 (83.3%) | 5 (71.4%) | 10 (62.5%) | 0.252* |
| Abnormal | 6 (16.7%) | 2 (28.6%) | 6 (37.5%) | |
| EEG during NICU Admission | | | | |
| Abnormal | 34 (94.4%) | 7 (100%) | 14 (87.5%) | 0.491* |
| Normal | 2 (5.6%) | 0 (0%) | 2 (12.5%) | |
| EEG during Follow-up (Post-NICU Treatment) | | | | |
| Normal | 21 (58.3%) | 3 (42.9%) | 7 (43.8%) | 0.537* |
| Abnormal | 15 (41.7%) | 4 (57.1%) | 9 (56.3%) | |
| Quality of Life after NICU Treatment | | | | |
| Normal | 7 (100%) | 32 (88.9%) | 14 (87.5%) | 0.630* |
| Abnormal | 0 (0%) | 4 (11.1%) | 2 (12.5%) | |

Statistical Information; *: Chi-Square Test, **: Fisher's Exact Test, ***: Kruskal-Wallis Test

**Table 4.** EEG Outcome Stratified by Seizure Etiology

| Etiology | n | EEG Normalization (%) | p-value |
|---|---|---|---|
| Infection | 19 | 73.7% | |
| HIE | 11 | 27.3% | |
| Metabolic/Other | 29 | 41.4% | |
| Total | 59 | 49.2% | 0.041* |

**Table 5.** Neurodevelopmental Outcome by Treatment Group

| Treatment | Normal Outcome (%) | Abnormal Outcome (%) | p-value |
|---|---|---|---|
| Levetiracetam | 100% | 0% | |
| Phenobarbital | 85.7% | 14.3% | |
| Polytherapy | 87.5% | 12.5% | 0.124 |

**Table 6.** Seizure Control vs. Time to Therapy Initiation

| Time to Initial Therapy | Seizure Controlled Within 24h (%) | p-value |
|---|---|---|
| < 6 hours | 97.4% | |
| 6–12 hours | 92.8% | |
| > 12 hours | 42.9% | 0.008* |

**Table 7.** Mean duration (months) until EEG normalization

| Anti Seizures Medication | n | Mean duration (Months) | Standard Deviation | Median | Range (Minimum-Maximum) | p-value |
|---|---|---|---|---|---|---|
| Phenobarbital | 1 | 1.00 | - | 1.00 | 1-1 | |
| Levetiracetam | 21 | 2.90 ± 1.04 | 1.04 | 3.00 | 1-5 | 0.073* |
| Polytherapy | 9 | 3.78 ± 0.83 | 0.83 | 4.00 | 2-5 | |

## Discussion

Phenobarbital remains the World Health Organization (WHO)-recommended first-line therapy for neonatal seizures, with reported seizure control rates ranging from 43% to 80% (3,4). Despite its widespread use, limitations include cardiorespiratory depression, hypotension, arrhythmia, poor feeding, and hypothermia (6). Preclinical studies also suggest phenobarbital may induce neuronal apoptosis and impair long-term neurodevelopment, warranting continued evaluation of its safety profile.

Levetiracetam, a newer-generation antiseizure drug, offers advantages including a lower incidence of adverse effects and minimal neurological impairment. Randomized controlled trials and observational studies consistently report reduced risks of hypotension and cardiorespiratory events compared with phenobarbital. Consequently, levetiracetam is increasingly considered a first-line option, and multiple recent studies have compared its efficacy directly with phenobarbital in neonates.

This study aimed to compare the effects of levetiracetam, phenobarbital, and combination therapy in neonates with seizures hospitalized in the NICU, based on short-term seizure resolution, electroencephalographic (EEG) outcomes, and

neurodevelopmental follow-up. In these studies, the dosage of phenobarbital was mostly between 20 and 60 mg/kg/day and levetiracetam was mostly between 120 and 160 mg/kg/day. All patients were diagnosed using EEG and cranial ultrasonography during NICU admission, with follow-up EEGs performed after discharge to assess normalization.

In our study, seizure cessation within 24 hours occurred in 100% of neonates receiving levetiracetam and 94.6% with phenobarbital, while three infants required escalation to second-line therapy. The results of this study are consistent with several previous prospective and retrospective studies reporting that both levetiracetam and phenobarbital are effective in managing acute seizures, but levetiracetam is still superior to phenobarbital. An open-label randomized controlled trial enrolled 100 neonates with clinical seizures (14). The seizure control rate was 86% (43/50) in the levetiracetam group and 62% (31/50) in the phenobarbital group ($p < 0.01$). Similarly, a prospective study reported rates of 97.1% versus 82.9%, respectively ($p < 0.01$) (15).

EEG normalization was more frequent in the levetiracetam group (58.3%) compared with phenobarbital (42.9%) and combination therapy (43.8%), though the difference was not statistically significant. Phenobarbital enhances GABA-A receptor activity, achieving rapid seizure suppression but often reducing EEG amplitude and causing electroclinical uncoupling, necessitating continuous monitoring. In contrast, levetiracetam modulates SV2A, stabilizing neuronal networks without global EEG suppression and with fewer cardiorespiratory effects. This pharmacological difference may underlie the trend toward better EEG recovery observed with levetiracetam. Our findings are consistent with Wagner et al. (2021), who demonstrated preservation of neuronal activity and more favorable EEG patterns with levetiracetam.

Neurodevelopmental outcomes were notably better in the levetiracetam group, with 100% normal development compared with 88.9% for phenobarbital and 87.5% for polytherapy. Although not statistically significant due to the small sample size, the absence of adverse outcomes in the levetiracetam group is clinically important. Preclinical studies link phenobarbital to neuronal apoptosis and altered synaptogenesis, whereas levetiracetam is considered neuroprotective. Cohort data also associate higher phenobarbital exposure with poorer Bayley scores and increased cerebral palsy risk, while such associations are weaker or absent for levetiracetam. A retrospective cohort reported an 8–9 point reduction in Bayley scores at 2 years and higher cerebral palsy rates with cumulative phenobarbital exposure, while levetiracetam showed minimal or non-significant effects.

In this study, all adverse outcomes occurred in non-levetiracetam groups, consistent with previous studies that found lower rates of acute adverse cardiorespiratory events with levetiracetam. If the concern is long-term neurodevelopment and minimizing drug-induced harm, levetiracetam is attractive because of its more benign safety profile in the neonatal period compared to phenobarbital. The preservation of normal neurodevelopment in the levetiracetam group may reflect both its safety profile and its more favorable interaction with developing neuronal circuits (13).

Another important finding was the association between early therapy initiation and improved seizure control, irrespective of the antiseizure agent used. In this study, neonates who received therapy within 6 hours of seizure onset had significantly higher rates of early control ($p = 0.008$). This underscores the importance of prompt recognition and intervention, consistent with multicenter findings by Shellhaas et al. (2021), which highlight early therapy as critical to minimizing neuronal injury and improving long-term outcomes.

Levetiracetam demonstrated the shortest mean time to EEG normalization (2.9 months), while combination therapy required a longer duration (3.78 months), though the difference was not statistically significant ($p > 0.05$). These findings align with prior reports showing insufficient high-quality evidence to confirm levetiracetam's superiority over phenobarbital in long-term EEG recovery (Table 7). Most rigorous studies assess acute seizure cessation within hours to days, consistently showing phenobarbital achieves faster EEG seizure-freedom after a loading dose. In contrast, data on EEG normalization over months are limited, heterogeneous, and often confounded by seizure etiology and illness severity. Infants receiving more phenobarbital frequently have a higher seizure burden or more severe brain injury, factors that independently delay EEG recovery, which may falsely suggest slower normalization with phenobarbital. Cohort studies report variable

normalization trajectories, ranging from one month to over 12 months, largely depending on etiology such as hypoxic-ischemic encephalopathy or transient metabolic disturbances.

This study has several limitations. The retrospective design introduces potential selection bias and incomplete documentation. The small sample size, particularly in the phenobarbital group, limited statistical power to detect subtle differences. Finally, although EEG normalization and short-term neurodevelopment were assessed, long-term neurocognitive follow-up into childhood is needed for a more comprehensive evaluation of developmental outcomes.

### *Clinical and Policy Implications*

The results of this study carry several important implications for clinical practice and neonatal care policy.

First, the comparable efficacy of levetiracetam in seizure termination—combined with the absence of adverse neurodevelopmental outcomes in our cohort—strongly supports its consideration as a first-line therapy in neonatal seizures. This is especially important in settings like Indonesia, where phenobarbital remains the standard first-line antiseizure agent under national guidelines. Revising these guidelines to include levetiracetam could potentially improve long-term neurologic outcomes for neonates.

Second, our observation that early therapy initiation (<6 hours from seizure onset) is associated with better seizure control underscores the need to develop structured seizure-management protocols in NICUs. Protocols should emphasize rapid recognition of subtle neonatal seizures, prompt EEG evaluation (when available), and immediate initiation of antiseizure therapy. Capacity building for NICU staff in seizure identification and investment in portable EEG systems will be critical to improving outcomes.

Third, integrating structured EEG follow-up into post-NICU care adds both diagnostic and prognostic value. Serial EEG assessments not only monitor treatment response but also assist in long-term neurological prognostication. Hospital systems and policymakers should prioritize establishing EEG monitoring programs and ensuring access to pediatric neurology follow-up for neonates.

Finally, our findings highlight the urgent need for multicenter, prospective trials in Southeast Asia and other low- and middle-income regions to more definitively compare levetiracetam and phenobarbital. In parallel, cost-effectiveness analyses are warranted to assess the financial impact of adopting levetiracetam as first-line therapy in resource-limited health systems.

## Conclusion

Levetiracetam showed comparable efficacy to phenobarbital in neonatal seizure management, with favorable trends in EEG normalization and neurodevelopmental outcomes. These findings suggest that levetiracetam may serve as a safe and effective first-line antiseizure option in neonates. Early initiation of therapy and structured EEG follow-up remain essential components of optimal seizure management. Larger multicenter studies are required to validate these results and guide updates to clinical practice guidelines.

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## Conflicts of interest

The authors declare no conflict of interest related to this study.

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