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Research Article

Injectable Levetiracetam in the Management of Acute Neonatal Seizures: Evidence from Term and Preterm Neonates

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Abstract

Background: Acute neonatal seizures are a neurological emergency and a frequent marker of serious brain injury during the first 28 days of life. Injectable levetiracetam is increasingly used in neonatal units because it can be administered intravenously and has a favorable short-term cardiorespiratory tolerability profile. *Objective:* To present injectable levetiracetam as a management option for acute neonatal seizures and to describe clinical evidence from term and late-preterm neonates using the author's original clinical dataset. *Methods:* This original clinical manuscript was revised from the existing word file into an IMRAD format. The clinical data were derived from neonates aged 0-28 days admitted with acute seizures to the Special Care Baby Unit of Dhaka Medical College Hospital. Eligible mature and late-preterm neonates had gestational age above 34 weeks and below 42 weeks and birth weight above 2000 g. Injectable levetiracetam was administered as the active treatment arm, and outcomes were assessed by seizure control, need for additional antiseizure medication, time to seizure control, adverse effects, treatment outcome, and hospital stay. The original randomized dataset included a comparator arm, but the present manuscript is framed around the levetiracetam management profile in term and preterm neonates. *Results:* Among 50 neonates who received injectable levetiracetam, 44 (88.0%) were term and 6 (12.0%) were preterm. Mean gestational age was 38.00 ± 1.43 weeks and mean birth weight was 2776.00 ± 267.50 g. Seizure control was achieved in 33 neonates (66.0%), while 17 (34.0%) required additional antiseizure medication. Forty neonates (80.0%) achieved seizure control within 12 hours, and the mean time to seizure control was 6.88 ± 15.47 hours. Adverse effects were reported in 5 neonates (10.0%), mainly somnolence and irritability. Mean hospital stay was 6.22 ± 2.20 days. *Conclusion:* Injectable levetiracetam showed clinically useful seizure control and acceptable short-term tolerability in this cohort of term and late-preterm neonates with acute neonatal seizures. The findings support its role as a structured component of neonatal seizure management, with careful attention to gestational age, renal maturity, seizure etiology, and local neonatal protocols.

Keywords

Neonatal Seizures, Injectable Levetiracetam, Term Neonate, Preterm Neonate, Acute Seizures, Antiseizure Medication, Neonatal Intensive Care

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1. Introduction

Neonatal seizures are among the most urgent neurological presentations in neonatal intensive care. They commonly indicate an acute insult to the developing brain and may be associated with mortality, later epilepsy, cerebral palsy, developmental delay, prolonged hospitalization, and complex family counseling needs. Recognition is challenging because neonatal seizures may be subtle, intermittent, or electrographic-only, while many bedside movements are nonepileptic [1, 2].

The clinical profile of neonatal seizures differs between term and preterm neonates. In term neonates, hypoxic-ischemic encephalopathy, perinatal arterial ischemic stroke, intracranial hemorrhage, central nervous system infection, metabolic disturbances, structural malformations, and neonatal-onset epilepsies are important causes. In preterm neonates, germinal matrix-intraventricular hemorrhage, white matter injury, infection, metabolic instability, respiratory compromise, and complications of prematurity are particularly relevant [3-5].

Phenobarbitone remains widely used as initial antiseizure therapy in many neonatal settings; however, incomplete response, sedation, respiratory depression, hypotension, and concerns about neurodevelopmental exposure have encouraged increasing clinical use of injectable levetiracetam [6, 8-16]. Levetiracetam is pharmacologically attractive because it has low protein binding, minimal hepatic enzyme interaction, and predominant renal elimination. These features are relevant in sick neonates who frequently receive multiple medications and may have cardiorespiratory instability [7].

The present manuscript retains the original title of the submitted word file and changes the article type from an overview-style manuscript to an original clinical article format. The purpose is not to retitle the work as a comparative drug paper, but to present clinically organized evidence for injectable levetiracetam in the management of acute neonatal seizures among term and late-preterm neonates.

2. Materials and Methods

2.1. Study Design and Setting

This was an original clinical article based on an author-owned randomized clinical dataset of neonates with acute seizures. The study was conducted in the Special Care Baby Unit of Dhaka Medical College Hospital. The source clinical study enrolled neonates between July 2013 and June 2014 after approval from the local ethics committee and written informed consent from parents or guardians.

2.2. Study Population

Neonates aged 0-28 days with a clinical presentation of acute neonatal seizures were considered for enrollment. Mature and late-preterm neonates were eligible when gestational age was more than 34 weeks and less than 42 weeks, birth weight was more than 2000 g, and acute neonatal seizures were present. Neonates with seizures attributed to correctable hypoglycemia, hypocalcemia, dyselectrolytemia, or sepsis were excluded in the original clinical protocol. Neonates who had received more than one loading dose of phenobarbitone or any other antiseizure medication before enrollment were also excluded.

2.3. Intervention and Clinical Management

The levetiracetam treatment arm received injectable levetiracetam as the active management strategy for acute neonatal seizures. In the original protocol, levetiracetam was administered as an intravenous loading dose of 50 mg/kg, followed by maintenance dosing of 10 mg/kg/dose every 8 hours. Neonates were examined clinically, monitored continuously, and assessed for seizure frequency, response to therapy, need for additional antiseizure medication, adverse effects, discharge status, and hospital stay. If seizure control was not achieved within 48 hours, the event was considered treatment failure according to the study protocol.

2.4. Outcome Variables

The primary clinical outcome was seizure control after injectable levetiracetam. Secondary outcomes included time required to control seizures, requirement for more than one antiseizure medication, adverse effects, treatment outcome during admission, and duration of hospital stay. The term and preterm profile was also described to show the clinical scope of the levetiracetam evidence in newborns of different gestational maturity.

2.5. Statistical Analysis

Categorical variables were summarized as frequency and percentage. Continuous variables were summarized as mean ± standard deviation and range where available. The original dataset used chi-square testing for categorical comparisons and p values for group-level assessment. In this revised manuscript, the comparator arm is not used to define the article title; instead, it provides contextual support while the results are presented primarily around injectable levetiracetam management.

2.6. Ethical Considerations

The original clinical study was approved by the local ethics committee, and written informed consent was obtained from parents or guardians. No identifiable patient information is included in this revised manuscript.

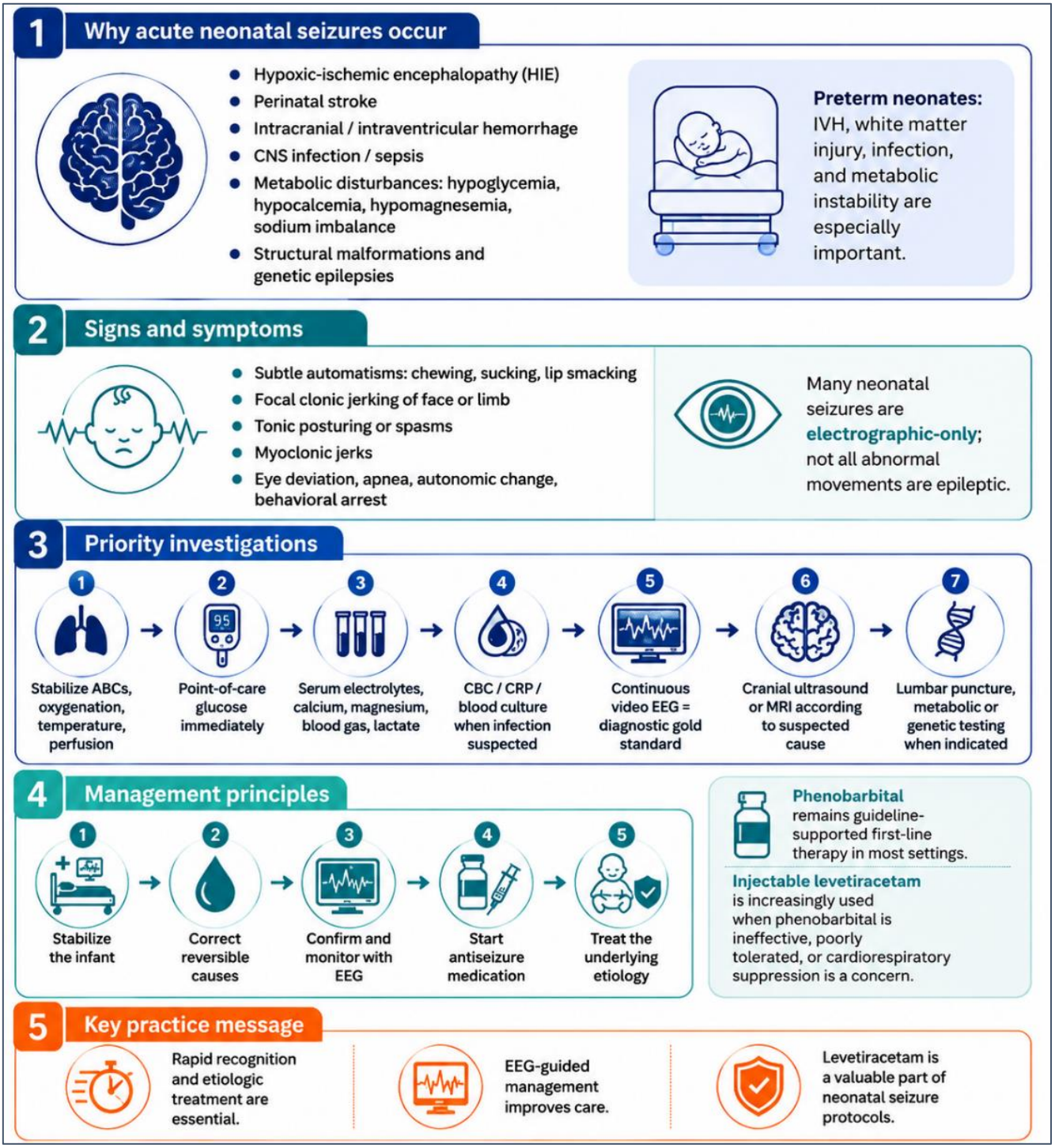

Figure 1. *Practical pathway for recognition, investigation, and management of acute neonatal seizures with injectable levetiracetam integration. [17].*

3. Results

3.1. Baseline Profile of Neonates Receiving Injectable Levetiracetam

A total of 50 neonates in the levetiracetam arm were analyzed for the levetiracetam-centered outcomes. Male neonates represented 60.0% of this group. Most neonates were term, while a smaller late-preterm subgroup was also included. Baseline gestational age and birth weight are summarized in Table 1.

Table 1. Baseline profile of neonates managed with injectable levetiracetam (n=50).

Variable	Category	Finding
Sex	Male	30 (60.0%)
Sex	Female	20 (40.0%)
Gestational age	Preterm (<37 weeks)	6 (12.0%)
Gestational age	Full-term (37-42 weeks)	44 (88.0%)
Gestational age	Mean ± SD	38.00 ± 1.43 weeks
Birth weight	2000 to <2500 g	8 (16.0%)
Birth weight	2500-4000 g	42 (84.0%)
Birth weight	Mean ± SD	2776.00 ± 267.50 g
Birth weight	Range	2300.03-3200.0 g
Hospital-delivered neonates	Apgar score <7	26/26 (100.0%)
Outside-hospital delivery	No breathing within 1 minute	19/24 (79.2%)
Outside-hospital delivery	Breathing within 1 minute	5/24 (20.8%)

3.2. Clinical Seizure Profile

Most neonates presented early after seizure onset. The majority of neonates in the levetiracetam arm had seizure onset within 12 hours of birth. Clonic and subtle seizures were the most common seizure types recorded clinically. No continuous EEG monitoring was available at diagnosis and enrollment in the original protocol; therefore, outcomes reflect clinical seizure assessment [18-20].

Table 2. Clinical seizure profile in the levetiracetam arm (n=50).

Variable	Category	Finding
Age on admission after seizure onset	≤12 hours	35 (70.0%)
Age on admission after seizure onset	>12-24 hours	9 (18.0%)
Age on admission after seizure onset	>24-36 hours	3 (6.0%)
Age on admission after seizure onset	>36-48 hours	2 (4.0%)
Age on admission after seizure onset	>48 hours	1 (2.0%)
Age on admission after seizure onset	Mean ± SD	10.10 ± 12.69 hours
Age at seizure onset	≤12 hours	38 (76.0%)
Age at seizure onset	>12-24 hours	8 (16.0%)
Age at seizure onset	>24-36 hours	1 (2.0%)
Age at seizure onset	>36-48 hours	3 (6.0%)
Age at seizure onset	Mean ± SD	8.97 ± 11.93 hours
Type of seizure	Subtle	18 (36.0%)
Type of seizure	Clonic	22 (44.0%)
Type of seizure	Tonic	6 (12.0%)
Type of seizure	Myoclonic	4 (8.0%)

3.3. Levetiracetam Treatment Outcomes

Seizure control was achieved in 33 of 50 neonates who received injectable levetiracetam. Most neonates achieved clinical seizure control within 12 hours. Additional antiseizure medication was required in 17 neonates. Reported adverse effects were limited mainly to somnolence and irritability [21-23].

Table 3. *Treatment outcomes after injectable levetiracetam (n=50).*

Outcome	Category	Finding
Seizure control	Controlled	33 (66.0%)
Seizure control	Not controlled / required escalation	17 (34.0%)
Need for more than one antiseizure medication	Yes	17 (34.0%)
Need for more than one antiseizure medication	No	33 (66.0%)
Time required to control seizures	≤12 hours	40 (80.0%)
Time required to control seizures	>12-24 hours	6 (12.0%)
Time required to control seizures	>24-36 hours	2 (4.0%)
Time required to control seizures	>36-48 hours	1 (2.0%)
Time required to control seizures	>48 hours	1 (2.0%)
Time required to control seizures	Mean ± SD	6.88 ± 15.47 hours
Adverse effects	Any adverse effect	5 (10.0%)
Adverse effects	No adverse effect	45 (90.0%)
Type of adverse effect	Somnolence	3/5 (60.0%)
Type of adverse effect	Irritability	2/5 (40.0%)
Treatment outcome	Discharged with advice	37 (74.0%)
Treatment outcome	Left against medical advice	11 (22.0%)
Treatment outcome	Expired	2 (4.0%)
Hospital stay	<5 days	9 (18.0%)
Hospital stay	5-7 days	29 (58.0%)
Hospital stay	8-10 days	10 (20.0%)
Hospital stay	>10 days	2 (4.0%)
Hospital stay	Mean ± SD	6.22 ± 2.20 days

3.4. Evidence from Term and Preterm Neonates

The levetiracetam arm included both term and late-preterm neonates. Term neonates formed the majority of the cohort, while the preterm subgroup was small. Therefore, the manuscript supports levetiracetam use in a mixed term and late-preterm neonatal population, but it should not be interpreted as a separately powered preterm efficacy analysis. In very preterm or extremely low-birth-weight neonates, renal maturation, volume of distribution, seizure etiology, cardiorespiratory instability, and EEG background may differ substantially from the infants represented in this dataset [24-26].

Table 4. Term and preterm interpretation of the levetiracetam evidence.

Gestational group	Representation in dataset	Interpretation for management
Term neonates	44/50 (88.0%) in the levetiracetam arm; 89/100 (89.0%) in the full original dataset	Findings are most directly applicable to term neonates with acute clinical seizures meeting the study eligibility criteria.
Late-preterm neonates	6/50 (12.0%) in the levetiracetam arm; 11/100 (11.0%) in the full original dataset	Findings provide supportive inclusion of late-preterm infants, but subgroup-specific efficacy cannot be claimed from this small sample.
Very preterm neonates	Not represented because the original eligibility required gestational age above 34 weeks and birth weight above 2000 g	Management should be individualized and guided by renal function, illness severity, EEG/aEEG monitoring where available, and specialist neonatal neurology input.

4. Discussion

This revised manuscript presents injectable levetiracetam in an original article structure rather than as an explanatory overview. The central clinical finding is that two-thirds of neonates who received injectable levetiracetam achieved seizure control, and most clinically controlled events occurred within the first 12 hours. These findings support the practical value of levetiracetam as part of acute neonatal seizure management in a resource-conscious neonatal unit.

The safety profile was also clinically relevant. Most neonates in the levetiracetam arm did not develop reported adverse effects. The observed events were mainly somnolence and irritability, and no major cardiovascular adverse effect was highlighted in the levetiracetam arm. This is important because neonates with acute seizures often have hypoxic-ischemic injury, infection, respiratory compromise, or hemodynamic instability, where excessive sedation or cardiorespiratory suppression may complicate care [27, 28].

The term and preterm framing of this article should be interpreted carefully. The dataset included term and late-preterm neonates, with term neonates forming the majority. The small preterm subgroup supports inclusion of preterm evidence but does not permit a strong independent conclusion for preterm infants. Preterm neonates have distinct etiologies, renal maturation, pharmacokinetics, EEG backgrounds, and vulnerability to adverse effects; therefore, dosing and escalation should remain individualized [5, 15, 16].

The clinical management of neonatal seizures should not rely on antiseizure medication alone. Stabilization, oxygenation, glucose correction, electrolyte correction, sepsis evaluation, neuroimaging where indicated, and cause-directed therapy remain essential. Continuous video EEG is the diagnostic standard when available, although it was not available at diagnosis and enrollment in the original clinical protocol. This limitation is common in many low-resource neonatal settings and should be clearly acknowledged.

Compared with the previous overview format, the current structure gives the article a clearer original research identity: defined objective, study design, setting, population, intervention, outcomes, results tables, discussion, limitations, and conclusion. The title remains focused on injectable levetiracetam in the management of acute neonatal seizures rather than being rewritten as a comparative drug article.

5. Clinical Implications

1) Injectable levetiracetam may be considered a useful component of acute neonatal seizure protocols, particularly when a rapid intravenous option with favorable short-term tolerability is desired.
2) Term neonates are best represented by the present dataset; late-preterm neonates were included but require cautious interpretation because of small subgroup size.
3) Seizure response should be assessed clinically and, where available, by EEG or aEEG to avoid missing electrographic-only seizures.
4) Underlying etiologies such as hypoxic-ischemic encephalopathy, intracranial hemorrhage, infection, stroke, hypoglycemia, hypocalcemia, and electrolyte disturbance must be investigated and treated alongside antiseizure medication.
5) Very preterm neonates and neonates with renal impairment require individualized dosing and specialist input because pharmacokinetics and illness severity may differ substantially.

6. Limitations

1) The original protocol used clinical diagnosis and clinical seizure control; continuous EEG monitoring was not performed at diagnosis and enrollment.
2) The preterm subgroup was small and was limited to infants above 34 weeks of gestation and birth weight above 2000 g; therefore, the findings should not be generalized to very preterm or extremely low-birth-weight neonates.

3) The manuscript focuses on short-term inpatient outcomes. Long-term neurodevelopmental outcome and later epilepsy risk were not assessed in this revised article.
4) The original dataset included a comparator arm, but the present revision intentionally frames the manuscript around injectable levetiracetam management to match the requested title and article aim.

7. Conclusion

Injectable levetiracetam was associated with clinically useful seizure control, rapid response in most controlled cases, and acceptable short-term tolerability in this cohort of term and late-preterm neonates with acute neonatal seizures. The revised manuscript now follows an original article format while retaining the title Injectable Levetiracetam in the Management of Acute Neonatal Seizures: Evidence from Term and Preterm Neonates. The findings support levetiracetam as a structured option in neonatal seizure management, provided that stabilization, cause-directed therapy, gestational maturity, renal function, and EEG/aEEG monitoring where available are considered in clinical decision-making.

Author Contributions

Mohammed Mahfuzur Rahman: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing

Saiful Islam: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Supervision, Visualization, Writing – original draft

Farhana Alam: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Visualization

Data Availability Statement

The manuscript is based on the author's original clinical dataset. Availability of data should be stated according to the target journal's policy.

Conflicts of Interest

The authors declare no conflicts of interest.

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