Original Article

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Evaluation of Adverse Outcome Predictors in Neonatal Seizure: A Longitudinal Study from a Tertiary Centre of Eastern India

Paediatrics Section

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ABSTRACT

Introduction: Neonatal seizures are common but can be manifestations of serious underlying disorders and sometimes have a grave prognosis. Predictors for adverse outcomes are important for early referral and advanced interventions.

Aim: To study the incidence and factors associated with neonatal seizure and to determine the predictors of adverse outcomes.

Materials and Methods: This was a longitudinal study, conducted from April 2020 to March 2021 at a Rural Medical College (Midnapore Medical College and Hospital, West Bengal) in Eastern India. All the admitted newborns (N=143) in the Special Newborn Care Unit (SNCU), who had clinically evident seizures, were included in the study. Data were collected regarding the perinatal history, gestational age, type of delivery, birth weight, APGAR score at 1 and 5 minutes, and need for resuscitation at birth. The onset of the seizure, seizure type, investigation findings, possible aetiological diagnosis, and final outcome was noted. The management of neonatal seizures was as per the institutional protocol. Babies were followed up for a minimum of 28 days or throughout their hospital stay till discharge/death. The outcome was categorised into two categories: 'favourable' when there was a normal neurological examination and 'unfavourable' when there was any neurological impairment or death. Statistical analyses were performed using the Statistical Package for Social Sciences software version 25 (SPSS Inc., Chicago, IL, USA). Risk factors were determined by analysing outcomes using simple and multivariate logistic regression analysis. The p-values less than 0.05 were considered as statistically significant.

Results: A total of 143 newborns had seizures out of 3126, making the incidence of neonatal seizures 4.57%. Males outnumbered females. Total 64.33% were preterm. Five minutes APGAR score <7 was noticed in 44.75%. The most common type was subtle seizure. Advanced resuscitation manoeuvre was required for 46.8% cases whereas mechanical ventilation was required in 11.88%. The most common aetiology was birth asphyxia (46.15%), and the cranial ultrasound showed Hypoxic Ishchaemic Encephalopathy (HIE) changes in 30.77% of cases. Multiple logistic regressions revealed only four factors, namely, preterm delivery (OR 5.82), need for extensive resuscitation manoeuvre (OR 6.21), presence of status epilepticus (OR 3.49) and abnormal cranial ultrasound (OR 1.02) to be the independent risk factors for unfavourable outcome.

Conclusion: Clinical diagnosis of neonatal seizure could be useful in resource poor centers, where video-Electroencephalogram (EEG) is not available. Premature delivery, need for extensive resuscitation, presence of status epilepticus and abnormal cranial ultrasound were associated with poor short-term outcome.

Keywords: Preterm delivery, Resuscitation, Special newborn care unit, Status epilepticus

INTRODUCTION

Neonatal seizures are common but can also be manifestations of serious underlying disorders. Incidence is usually 1-5 per 1000 live births; preterm deliveries are associated with higher rates. Neonatal brain is in a developing stage and more prone for seizures. Manifestations of neonatal seizures may be different, often subtle or sub clinical and hence challenging to diagnose [1].

Two thirds of neonatal seizures are due to HIE. Here the seizure manifests within 48 hours of birth and usually have unfavourable outcome in the long-term. Cerebro vascular disorders are also a cause of clinical seizure and have bad prognosis. Other important causes are of infectious aetiology; bacteria such as group B *streptococcus, E Coli, Listeria monocytogenes* etc., and viruses such as Herpes simplex, Coxsackie virus and Cytomegalovirus (CMV). Congenital infections such as Toxoplasma and CMV are also important cause of neonatal seizures. Cortical malformations such as lissencephaly are also cause of intractable neonatal seizures. Metabolic causes such as hypoglycaemia and electrolyte disturbances have favourable prognosis. Also, pyridoxine responsive neonatal seizures, mutation in potassium channel KCNQ2, fifth day seizure and benign familial neonatal seizures have subsequent normal development. However, inborn errors of metabolism such as hyperglycaemia and urea cycle disorder have very unfavourable prognosis [2].

Neonatal seizures are associated with epilepsy, cerebral palsy, learning disorder and other neuro developmental disorders in later life [3]. Age is the most important factor reported to determine the outcome after neonatal seizures, premature babies are more likely to suffer from long-term sequelae [4].

Though long-term effects of neonatal seizure are well known, predictors for short-term outcomes are important for early referral and advanced interventions.

Garfinkle J and Shevell MI developed a scoring system and associated following factors namely 'delivery via caesarean section, experiencing a seizure during the first 24 hour of life, presenting with a seizure other than focal clonic, showing a moderately or severely abnormal EEG background' with adverse short-term outcomes in term newborns [5].

It is known that the gestational age, birth weight, APGAR score at 5 minute, seizure onset <24 hours, status epilepticus, severely

abnormal radiological and EEG findings are significantly associated unfavourable short-term outcomes [6].

There are six independent variables and used to construct a scoring system. The variables were birth weight, APGAR score at 1 minute, neurologic examination at seizure onset, cerebral ultrasound, efficacy of anticonvulsant therapy, and presence of neonatal status epilepticus. Each variable was scored from 0 to 3 to represent the range from "normal" to "severely abnormal." The scores could help in predict neurological outcomes in the neonatal period [7].

The purpose of this study was to determine the predictors of adverse outcome of neonates admitted to SNCU. This can be an important tool for early referral and advanced intervention for long-term follow-up and rehabilitation.

MATERIALS AND METHODS

This longitudinal study was undertaken from April 2020 to March 2021 in Midnapore Medical College and Hospital, a tertiary centre of Eastern India in West Bengal catering predominantly to rural and tribal population, after approval of Institutional Ethics Committee (MMC/IEC-2000/46 dated 17/03/2020).

Inclusion criteria: All the admitted newborns in the SNCU, who had clinically evident seizures within first 28 days of life examined by atleast two doctors, either 'provoked or spontaneous', and 'not abolished by passive restraint' were included in the study thereby differentiating them from seizure mimics.

Exclusion criteria: Neonates who died before completing the investigations were excluded from the study.

To provoke seizures tactile stimulation was used. Informed consent was taken from the parents before inclusion of their babies in the study. Seizures were diagnosed by clinical observation and described according to Volpe's classification; i.e., subtle, tonic, clonic and myoclonic [8]. The EEG to confirm the clinical seizures could not be done because of non availability of the same in the SNCU.

Study Procedure

Data was collected using a structured proforma regarding the perinatal history including mode and place of delivery, birth order, birth weight, gestational age, sex of the newborn, religion of parents, socio-economic status, APGAR score at 1 and 5 minutes, need for resuscitation at birth and requirement of respiratory support [6]. The onset of seizure, type of seizure, presence of status epilepticus, possible aetiological diagnosis, cranial ultrasound and final outcome were noted.

The management of neonatal seizure was as per the All India Institute of Medical Sciences (AIIMS) Neonatal Intensive Care Unit (NICU) protocol. After i.v access and good oxygenation was ensured, the babies were screened for hypoglycaemia and treated accordingly. Next hypoclacemia was ruled out. Phenobarbital was the first line drug to be used followed by phenytoin [9].

Babies were followed-up for minimum of 28 days or throughout their hospital stay till discharge/death. Based on the available documentation, outcome was categorised into two categories: 'favourable', when there was normal neurological examination and 'unfavourable' when there was any neurological impairment or death. Normal neurological examination was defined as normal muscle tone, normal reflexes and normal functional cranial nerves.

The birth weight of an infant was the first weight recorded after birth, ideally measured within the first hours after birth, before significant postnatal weight loss had occurred. Low Birth Weight (LBW) is defined as a birth weight of less than 2500 g (up to and including 2499 g), as per the World Health Organization (WHO) [10]. Modified BG Prasad Socio-economic classification scale 2019 was used to assess socio-economic class of the studied families [11].

STATISTICAL ANALYSIS

Statistical analyses were performed using the (SPSS Inc., Chicago, IL, USA software. Chi-square (χ^2) test was used for comparative analysis of categorical variables. Risk factors were determined by analysing outcomes using simple and multivariate logistic regression analysis. The results were evaluated with a confidence interval of 95%.

RESULTS

The total number of newborns admitted during the study period was 3126 out of which 143 had seizures, thus the incidence of neonatal seizure in this study was 4.57%.

In this study, 81 (56.4%) were males and 62 (43.6%) were females with a sex ratio of 0.76:1. Total 79 (55.23%) cases were born to primigravida whereas 64 (44.75%) were born to multigravida. Total 92 (64.33%) neonates were preterm and 51 (35.66%) were term. A total of 95 (66.42%) babies were of normal birth weight and 48 (33.56%) babies were LBW, mean weight being 2.56±1.17 kg. Total 63 (44.05%) babies were from middle socio-economic class according to the modified BG Prasad Scale 2019 [11], followed by 34 (23.77%) from lower- middle, 32 (22.37%) cases from lower and 14 (9.78%) were from upper socio-economic class.

One minute APGAR score <7 was noticed in 69 cases (48.25%) and at 5 minutes APGAR score <7 was noticed in 64 (44.75%) neonates. There was onset of seizure within first 24 hours' of life in 74 (51.74%) cases and most common type of seizure was subtle seizure 62 (43.35%). Advanced resuscitation manoeuvre was required for 67 (46.85%) newborns whereas mechanical ventilation was required in 17(11.88%) new-borns. Most common identified aetiology was birth asphyxia in 66 (46.15%) whereas cranial ultrasound showed HIE changes in 44 (30.77%) cases in [Table/Fig-1]. [Table/Fig-1] also shows the outcome of neonatal seizures in various demographic and clinical conditions.

Many factors significantly associated with unfavourable outcomes, such as non institutional delivery, primigravida, preterm delivery, LBW, APGAR score of < 7 at 5 minutes, need for extensive resuscitation manoeuvre, presence of status epilepticus and abnormality in cranial ultrasound p<0.001** [Table/Fig-2].

However, multiple logistic regressions revealed four factors, namely preterm delivery, need for extensive resuscitation manoeuvre, presence of status epilepticus and abnormal cranial ultrasound to be independent risk factors for unfavourable outcome with odd's ratios of 5.82, 6.21, 3.49 and 1.02, respectively [Table/Fig-2].

DISCUSSION

Population based studies by Ronen GM et al., in Newfoundland [12] and Talebian A et al., from Iran had reported the incidence of neonatal seizure to be 2.6% per 1000 live births [12,13]. Pisani F et al., found the incidence to be 2.29 per 1000 live births [14]. By general consensus, incidence of clinical seizure varies from 0.5% to 20.2%. Clinical seizures represent only the tips of the iceberg and only one third of the neonatal EEG seizures are accompanied by clinical seizures on simultaneous video recording [15,16]. Though

Variable		Outcome		Total	p-value*
		Unfavourable outcome, n (%)	Favourable outcome, n (%)		
Modes of delivery	Normal vaginal delivery	49 (34.26)	58 (40.55)	107	0.767
	Instrumental delivery	3 (2.09)	5 (3.49)	8	
	Caesarean section	11 (7.69)	17 (11.88)	28	
Place of delivery	Non institutional delivery	19 (13.28)	12 (8.39)	31	0.029*
	Institutional delivery	44 (30.76)	68 (47.55)	112	
Birth order	Primi gravida	45 (31.46)	34 (23.77)	79	<0.001**
	Multi gravida	18 (12.58)	46 (32.17)	64	
Gestational age	Preterm	53 (37.06)	39 (27.27)	92	<0.001**
	Term	10 (6.99)	41 (28.67)	51	
Birth weight [10]	LBW (<2500g)	34 (23.77)	14 (9.79)	48	<0.001**
	Normal birth weight (>2500 g)	29 (20.27)	66 (46.15)	95	
Sex	Male	38 (26.57)	43 (30.06)	81	0.619
	Female	25 (17.48)	37 (25.87)	62	
Religion	Hindus	35 (24.47)	38 (26.57)	73	0.458
	Muslims	23 (16.08)	31 (21.67)	54	
	Others	5 (3.49)	11 (7.69)	16	
Socio-economic status [11]	Upper-middle	5 (3.49)	9 (6.29)	14	0.705
	Middle	30 (20.97)	33 (23.08)	63	
	Lower-middle	16 (11.18)	18 (12.58)	34	
	Lower	12 (8.39)	20 (13.98)	32	
APGAR Score at 1 minute	<7	28 (19.58)	41 (28.67)	69	0.418
	≥7	35 (24.47)	39 (27.27)	74	
APGAR Score at 5 minutes	<7	37 (25.87)	27 (18.88)	64	0.0028*
	≥7	26 (18.18)	53 (37.06)	79	
Resuscitation manoeuvre	Extra	44 (30.76)	23 (16.08)	67	<0.001**
	Routine care	19 (13.28)	57 (39.86)	76	
Respiratory support required	No support/O_2 hood box	21 (14.68)	41 (28.67)	62	<0.001**
	HHFNC O_2	16 (11.19)	27 (18.88)	43	
	CPAP	11 (7.69)	10 (6.99)	21	
	Mechanical ventilator	15 (10.49)	2 (1.39)	17	
Seizure onset	<24 hours	33 (23.07)	41 (28.67)	74	0.509
	≥24 hours to 72 hours	6 (4.19)	5 (3.49)	11	
	>72 hours to 7 days	21 (14.68)	25 (17.48)	46	
	>7days	3 (2.09)	9 (6.29)	12	
Seizure type	Subtle	6 (4.19)	56 (39.16)	62	<0.001**
	Multifocal clonic	39 (27.27)	12 (8.39)	51	
	Focal clonic	5 (3.49)	7 (4.89)	12	
	Tonic	6 (4.19)	4 (2.80)	10	
	Myoclonic	7 (4.89)	1 (0.70)	8	
Status epilepticus	Present	32 (22.38)	21 (14.68)	53	0.0025
	Absent	31 (21.68)	59 (41.26)	90	
Aetiology	Birth asphyxia	31 (21.68)	35 (24.47)	66	0.783
	Sepsis	19 (13.28)	23 (16.08)	42	
	Metabolic disorder	12 (8.39)	21 (14.68)	33	
	Others	1 (0.69)	1 (0.70)	2	
Cranial ultrasound	No abnormality	15 (10.48)	63 (44.05)	78	<0.001**
	HIE changes	31 (21.68)	13 (9.09)	44	
	Intra cranial haemorrhage	3 (2.09)	1 (0.70)	4	
	Hydrocephalus	9 (6.29)	1 (0.69)	10	
	Ventriculomegaly	5 (3.49)	2 ()	7	

[Table/Fig-1]: Descriptive data and outcome of neonatal seizures in various demographic and clinical conditions.
*chi-square test

Variable		Univariate analysis		Multivariate analysis	
		OR (95%CI)	p-value	OR (95%CI)	p-value
Place of delivery	Non institutional delivery	2.45 (1.08-5.53)	<0.001**		0.78
	Institutional delivery	1.000			
Birth order	Primi gravida	3.38 (1.67-6.84)	<0.001**		0.43
	Multigravida	1.000			
Gestational age	Preterm	5.57 (2.49-12.47)	<0.001**	5.82 (2.87-13.54)	0.042*
	Term	1.000			
Birth weight	LBW	5.53 (2.58-11.82)	<0.001**		0.59
	Normal birth weight	1.000			
APGAR score at 5 minutes	<7	2.79 (1.41-5.53)	<0.001**		0.36
	≥7	1.000			
Resuscitation manoeuvre	extensive	5.74 (2.78-11.84)	<0.001**	6.213 (2.54-12.54)	0.038*
	Routine care	1.000			
Status epilepticus	Presence	2.9 (1.44-5.85)	<0.001**	3.49 (1.78-6.49)	0.008*
	Absence	1.000			
Cranial ultrasound	No abnormality	1.000	<0.001**	1.02 (0.06-0.21)	0.025*
	abnormal	0.08 (0.04-0.19)			

[Table/Fig-2]: Predictors of unfavourable outcome in neonatal seizures.
*Significant

EEG/video-EEG should be the gold standards for the diagnosis of neonatal seizures, they are often not available in most of the neonatal care units of India. Many Indian studies report neonatal seizure diagnosed with clinical methods only [6,17,18]. Digra SK and Gupta A had reported incidence to be 19.2% from a hospital based study in Jammu in 2007 [17]. More recently Amudhadevi S and Kanchana P from Tamil Nadu reported incidence of 2.5% [18]. Anand V and Nair PM et al., Kerala reported the incidence to be 5.5% [6]. Above three studies did not use EEG to diagnose neonatal seizure [6,17,18]. Ghanshyambhai P et al., from Hyderabad using EEG for diagnosis reported the incidence 0.77% and 7.3% in intramural and extramural neonates, respectively [19]. Thus, the incidence of 4.57% in the present study was comparable with other hospital based studies.

In the present study, 81 (56.64%) were male and 62 (43.36%) were female neonates suggesting male preponderance. Anand V and Nair PM; Digra SK and Gupta A; and Sethy G et al., reported similar results of male preponderance (55.5%, 70.5% and 61.34%, respectively) [6,17,20]. It appears male babies were more prone to develop neonatal seizures, however, the cause is unknown.

There were four factors in this study, which were found to be significantly associated with unfavourable outcome, after multiple regression analysis was done. They were namely preterm delivery, need for extensive resuscitation, presence of status epilepticus and abnormal cranial ultrasound.

In the present study, 92 (64.33%) neonates were preterm and 51 (35.66%) were term and preterm delivery was significantly associated with unfavourable outcome with p=0.042 and odds ratio=5.82. Similar observation was reported by Anand V and Nair PMV for preterm delivery [6]. Other studies by Glass HC et al., from US, Pisani F et al., and Spagnoli C et al., from Italy also observed higher morbidity and mortality in premature babies [21-23].

Resuscitation manoeuvre was also found statistically significant for prediction of outcome. Out of 67 neonates who required extensive resuscitation, 44 (65.67%) had adverse outcome (odd's ratio 6.213 and p-value=0.038). Yildiz EP et al., had reported need for resuscitation at birth to be a strong prognostic factor for unfavourable outcome [24]. However, Anand V and Nair PM did not find any association [6].

Presence of status epilepticus was another factor for unfavourable outcome in this study (odds ratio=3.49 p-value=0.008*). Anand V and Nair PM had reported the onset of seizures <24 hours and presence of status epilepticus to be significantly associated (p<0.001**) with a bad prognosis [6]. Yildiz EP et al., also reported neonatal status epilepticus to be one of the strong predictors for adverse outcome [24].

The fourth independent predictor, cranial ultrasound abnormality was significantly associated with unfavourable outcome in this study (odds ratio=1.02, p=0.025*). Anand V and Nair PM had reported radiological abnormality was associated with adverse outcome [6]. Yildiz EP et al., also found cranial imaging findings to be a predictor of outcome [24]. Singh R et al., also found cranial ultrasound in high-risk infants to be a bad prognostic factors [25]. Abnormal cranial ultrasound findings were also associated with adverse outcomes in the study of Lai Y et al., [26].

Limitation(s)

The drawback of this study was that the diagnosis of neonatal seizures was done only by clinical means. Though EEG is considered gold standard for diagnosis of neonatal seizure, the same could not be done because of non availability of EEG in the study set-up. Attempts were made to compensate by including cases which were clinically diagnosed by two clinicians separately, though chances of over-diagnosis or under-diagnosis were not completely ruled out, particularly in preterm babies. Also, the study describes only short-term observations. Long-term follow-up could not be done, which might have resulted in different outcomes, particularly in borderline cases.

CONCLUSION(S)

Though video-EEG diagnosis is considered gold standard, clinical diagnosis of neonatal seizure could be useful resource in poor centers, when done carefully. Premature delivery, need for extensive

resuscitation, presence of status epilepticus and abnormal cranial ultrasound were found to be independent risk factors for poor short-term outcome.

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