

A Prospective Study to Assess the Predictors of Neonatal Mortality among very Low Birth Weight Neonates in Neonatal Intensive Care Unit at Teaching Hospital of Raipur, Chhattisgarh, India

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ABSTRACT

Introduction: Around 4-7% of the live births are Very Low Birth Weight (VLBW) neonates and their mortality is very high (50%). The survival of this population of infants is closely related to various factors which include maternal factors (significant obstetric problems, use of antenatal steroids etc.), gestational age, Apgar Scores and Respiratory Distress Syndrome (RDS). With identification of predictors, it is possible to prevent, particularly aiming the improvement of newborn children care.

Aim: To determine the predictors of neonatal mortality among VLBW neonates in Neonatal Intensive Care Unit (NICU) at teaching hospital of Raipur, Chhattisgarh.

Materials and Methods: This was a hospital-based prospective study carried out among all premature newborns weighing less than 1,500 grams and more than 26 weeks admitted to NICU with a sample size of 129. The data was prospectively recorded on a standard proforma and their outcome was monitored post birth till 28 days. If the neonate was discharged prior to 28 days, telephonic follow-up was done weekly to monitor the newborn outcomes at home. A bivariate analysis using the Chi-square test or Fisher-exact test, where appropriate, was performed to evaluate

differences between groups for categorised variables. All tests were performed at a 5% level of significance; thus, an association was significant if the p-value was less than 0.05. Multivariate logistic regression analysis was used to calculate adjusted Odds Ratio with 95% CI (association between mortality and qualitative variables) to eliminate confounders.

Results: The binominal multivariate logistic regression analysis of predictors of neonatal mortality and adjusted odds ratio with 95% CI was obtained and most of birth and maternal variables such as birth weight, gestational age, foetal distress and non use of antenatal steroids were statistically significant except sex, required assisted ventilation, initiation of enteral feeding, maternal fever and premature rupture of membrane.

Conclusion: The present study identifies the risk factors associated with mortality in VLBW neonates and helps in prioritising them so that health care workers can intervene and prevent mortality in these neonates. There is therefore a need of such infants requiring care at centers, which have adequately trained staff with appropriately developed support infrastructure.

Keywords: Apgar score, Eclampsia, Enteral feeding, Pregnancy induced hypertension, Resuscitation

INTRODUCTION

The World Health Organization (WHO) defines VLBW as birth weight <1,500 grams at birth irrespective of gestational age [1]. VLBW neonates constitute approximately 4-7% of all live births and their mortality is very high (50%) [2]. The workload of Special Newborn care units is increased as the majority

of VLBW babies are preterm who require intensive care [3]. Since, the investigators all over the world have continuously been searching for factors (clinical and physiological) which could help in prediction of mortality in VLBW neonates, hence it could be acknowledged that the prospect of the survival of infant population is closely related to factors [4]. Birth weight,

gestational age, Apgar scores, RDS and various maternal factors (like maternal medical illness, significant obstetric problems, use of antenatal steroids, etc) are some of these predictors [5]. Various efforts for defining physiological, laboratory and imaging parameters have been done in recent times which would help predicting neonatal mortality [6]. With identification of predictors, it is possible to prevent, particularly aiming the improvement of newborn children care. Here, the NICUs are one of the most effective tools to reduce country's newborn mortality [7]. Furthermore, the patterns of neonatal mortality are useful indicators of the quality of obstetrical and neonatal care in a particular setting, and their assessment ensures the estimation of the quality of health care [8]. Therefore, the present study was conducted with an aim to determine the predictors of neonatal mortality among VLBW neonates in NICU at teaching hospital of Raipur, Chhattisgarh.

MATERIAL AND METHODS

Study Design and Setting

This was a hospital-based prospective cohort study carried out from June 2018 to May 2019 (one year) in NICU, Department of Paediatrics, Ekta Institute of Child Health, Raipur.

Study Population

The source and study population for this study were all premature newborns weighing less than 1,500 grams and more than 26 weeks admitted to NICU, Department of Paediatrics, Ekta Institute of Child Health, Raipur for the one-year period i.e., June 2018 to May 2019. The neonates with presence of lethal congenital malformations, death within 12 hours of life, Intra-Uterine Growth Restriction (IUGR), Leave Against Medical Advice (LAMA) and extramural newborns were excluded from the study.

Sample Size with Justification

Even though the present study included all premature VLBW newborns consecutively admitted to the NICU of Ekta Institute of Child Health during the study period, the adequacy of the sample size based on studies objectives and accordingly were checked and, the minimum required sample size was calculated using sample size formula,

$$n = \{Np(1-p)\} / \{(d^2/Z_{1-\alpha/2}^2 * (N-1) + p*(1-p))\}$$

by considering the following statistical assumptions: N= 200 as population size (no. of patients of birth weight <1,500 gm admitted to Ekta Hospital in a year), p=36.9% as prevalence of mortality in birth weight <1,500, d= 5% as margin of error, and $Z_{1-\alpha/2} = 1.96$ at 95% confidence interval [9]. This calculation yielded a sample size requirement of 129 neonates.

Study Tool

A pretested, predesigned, standardised questionnaire was prepared. The questionnaire was first prepared in English.

Then, it was translated into Hindi by an expert in that language keeping semantic equivalence. To check the translation, it was back translated into English by two independent researchers who were unaware of the first English version.

The collected questions were subjected to content validation by a panel of 10 medical experts. The purpose was to identify the items with a high degree of agreement among experts. Aiken's V was used to quantify the concordance between experts for each item. Questions that had an Aiken's V >0.7 were selected for the study. All efforts were made to keep the questions simple and unambiguous according to the objectives of the study.

The questionnaire consisted of as per the details given below:

Birth data: Birth weight, gestational age (from the maternal last menstrual period and by the modified Ballard's criteria), sex, assisted ventilation at the time of birth, Apgar scores at 1, 5, and 10 minutes, need for resuscitation at birth and initiation of enteral feeding.

Obstetrical data: Presence of significant maternal illnesses (e.g., pregnancy induced hypertension, Eclampsia, maternal fever), presence of significant obstetric problems (e.g., prolonged rupture of membranes, meconium stained liquor, fetal distress) and non use of antenatal steroid.

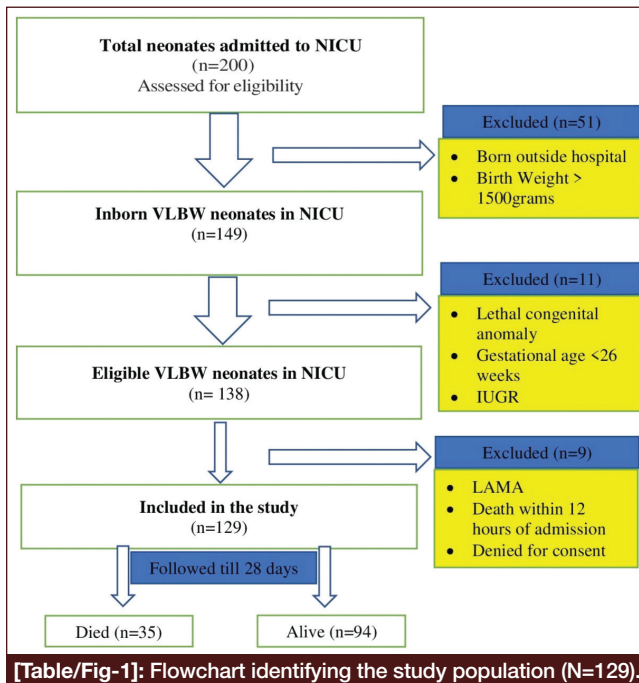
Data Collection

Ethical committee and scientific committee clearance were taken (IEC approval letter no. EICH/IEC/2017/06, dated 29/10/2017). Parents of the children were explained about the purpose of the study and ensured strict confidentiality. Written informed consents were taken prior to the study. On admission, the investigator himself interviewed the parents or guardians, and then examined the newborns. A standardised performa was maintained for recording prospective data in all VLBW neonates both at the time of birth and at the time of admission to NICU.

The study monitored their outcome till 28 days post birth period. When the neonates were discharged before 28 days, weekly phone calls were undertaken to monitor the newborn outcomes at home [Table/Fig-1].

Data Analysis

Data obtained was compiled systematically in Microsoft excel 2010 spread sheet and master table was prepared. The data set was subdivided and distributed meaningfully. The data was presented in the form of graphs and tables. Statistical analyses were performed using a personal computer with Statistical Package for Social Sciences Software (SPSS version 16.0). Categorical data were presented as percentages (%). A bivariate analysis using the Chi-square test or Fisher-exact test, where appropriate, was performed to evaluate differences between



groups for categorised variables. All tests were performed at a 5% level of significance; thus, an association was significant if the p-value was less than 0.05. Multivariate logistic regression analysis was used to calculate adjusted Odds Ratio with 95% CI (association between mortality and qualitative variables) to eliminate confounders.

RESULTS

A total of 129 subjects fulfilling the inclusion criteria were enrolled in the study and 45.75% were males and 54.25% were females and mortality was higher amongst males as compared to the females ($p < 0.05$). It is clearly evident in the [Table/Fig-2], that nearly one third of study subjects (28.7%) had birth weight below 1000 grams and the dead neonates had significantly less weight than those neonates who survived ($p < 0.05$); and nearly two-fourth (38.7%) had gestational age less than 30 weeks and the infants who died in the early neonatal period were considerably more premature than the survivors. In the study, 36 subjects required resuscitation and among them 16.7% belonged to survivor group whereas 83.3% belonged to non survival groups, these differences were statistically significant.

As [Table/Fig-3] depicts that there was significant difference between the neonates who survived and those who died with regard to the existence of maternal illnesses during pregnancy or obstetric problems encountered at the time of delivery and among these maternal fever, meconium stained liquor, fetal distress, non use of antenatal steroids and premature rupture of membrane found to be significantly associated with mortality in these newborns ($p < 0.05$). Neonatal deaths were seen in 35 (27.25%) newborns enrolled into the study. The primary causes of

Birth related variables	Survived (94)	Non survived (35)	Test of significance
	n (%) or Mean±SD		
Sex			
Male (62)	40 (42.6%)	22 (62.9%)	$\chi^2=4.21$, df=1, $p=0.041$
Female (67)	54 (54.4%)	13 (37.1%)	
Required assisted ventilation			
Yes (72)	58 (61.7%)	14 (40.0%)	$\chi^2=4.87$, df=1, $p=0.027$
No (57)	36 (38.3%)	21 (60.0%)	
Initiation of enteral feeding			
<3 days (58)	48 (39.4%)	10 (28.6%)	$\chi^2=5.21$, df=1, $p=0.022$
>3 days (71)	46 (60.6%)	25 (71.4%)	
Need for resuscitation at birth			
Yes (36)	6 (6.4%)	30 (85.7%)	$\chi^2=79.77$, df=1, $p < 0.05$
No (93)	88 (93.6%)	5 (14.3%)	
Birth weight			
<1000 gm (37)	16 (17.1%)	21 (60.0%)	$\chi^2=23.03$, df=1, $p < 0.05$
>1000 gm (92)	78 (82.9%)	14 (40.0%)	
Gestational age			
<30 weeks (50)	24 (25.5%)	26 (74.3%)	$\chi^2=25.53$, df=1, $p < 0.05$
>30 weeks (79)	70 (74.5%)	9 (25.7%)	
Apgar score at 5 min			
<7 (33)	18 (19.1%)	15 (42.8%)	$\chi^2=7.53$, df=1, $p < 0.05$
>7 (96)	76 (80.9%)	20 (57.2%)	

[Table/Fig-2]: Predictors of mortality according to neonatal birth related variables (N=129).

*Independent sample t-test assuming equal variances and excluding cases analysis by analysis

neonatal mortality are presented in [Table/Fig-4] and septicaemia was the primary contributory causing (44.95%) deaths.

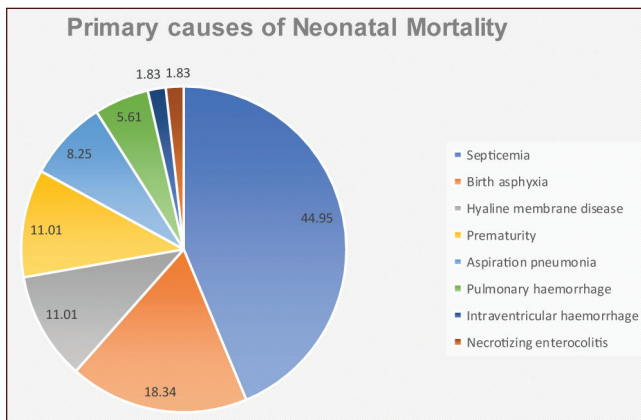
Binominal multivariate logistic regression analysis of predictors of neonatal mortality and adjusted add ratio with 95% CI was obtained and most of birth and maternal variables were statistically significant except sex, required assisted ventilation, initiation of enteral feeding, maternal fever and premature rupture of membrane [Table/Fig-5].

DISCUSSION

The present study was specifically designed to evaluate the predictors of neonatal mortality. Accuracy and reproducibility of the observations were ensured by taking great care of the methodology. In developing countries itself there is wide variations in the performance of Sick Newborn Care Units (SNCUs) and hence the survival of VLBW babies admitted to SNCUs in India is generally lower than in any developed country [9]. By considering

Maternal risk factors	Survived (94)	Nonsurvived (35)	Test of significance
	n (%)		
Pregnancy induced hypertension			
Yes (30)	23 (24.6%)	7 (20.0%)	$\chi^2=0.28, df=1, p=0.593$
No (99)	71 (75.5%)	28 (80.0%)	
Eclampsia			
Yes (27)	18 (19.1%)	9 (25.7%)	$\chi^2=0.66, df=1, p=0.415$
No (102)	76 (80.9%)	26 (74.3%)	
Maternal fever			
Yes (15)	7 (7.4%)	8 (22.9%)	$\chi^2=5.89, df=1, p=0.015$
No (114)	87 (92.6%)	27 (77.1%)	
Premature rupture of membrane			
Yes (35)	20 (21.3%)	15 (42.9%)	$\chi^2=6.00, df=1, p=0.014$
No (94)	74 (78.7%)	20 (57.1%)	
Meconium stained liquor			
Yes (30)	10 (10.6%)	20 (57.1%)	$\chi^2=30.90, df=1, p<0.05$
No (99)	84 (89.4%)	15 (42.9%)	
Fetal distress			
Yes (28)	8 (8.5%)	20 (57.1%)	$\chi^2=35.49, df=1, p<0.05$
No (101)	86 (91.5%)	15 (42.9%)	
Use of antenatal steroid			
Yes (59)	49 (52.1%)	10 (28.6%)	$\chi^2=5.70, df=1, p=0.017$
No (70)	45 (47.9%)	25 (71.4%)	

[Table/Fig-3]: Predictors of mortality according to maternal risk factor (N=129).



[Table/Fig-4]: Distribution of primary causes (%) of neonatal mortality among study participants (N=35).

the effects on outcome of pre-NICU admission risk factors, the severity of illness and the intensive care effectiveness, the present study may help to understand the reason for the existence of these differences.

A number of antenatal and intrapartum factors have been reported in the past to be significantly associated with perinatal and neonatal deaths. Most studies have not evaluated these

Variables	Adjusted odds ratio	95% confidence interval	p-value
Sex (Male)	3.399	0.829-13.939	0.089
Required assisted ventilation (Yes)	4.149	0.990-17.387	0.052
Initiation of enteral feeding (>3 days)	2.643	0.645-10.836	0.177
Need for resuscitation at birth (Yes)	110.375	25.048-486.381	<0.05
Birth weight (<1000 gm)	20.730	5.408-79.459	<0.05
Gestational age (<30 weeks)	19.928	5.282-75.188	<0.05
Apgar score (<7)	4.188	1.399-12.533	0.010
Maternal fever (Yes)	3.691	0.812-16.783	0.091
Premature rupture of membrane (Yes)	3.245	0.917-11.482	0.068
Meconium stained liquor (Yes)	11.606	3.429-39.286	<0.05
Foetal distress (Yes)	21.938	5.513-87.308	<0.05
Antenatal steroid used (No)	5.955	1.576-22.494	<0.05

[Table/Fig-5]: The binominal multivariate logistic regression analysis of predictors of neonatal mortality among study participants (N=129).

factors specifically focused on mortality in VLBW babies. In the present study antepartum factors such as maternal age or presence of maternal illness or obstetric problems at delivery were observed to be comparable in VLBW babies who survived or died. All of the above factors are known to be strongly associated with either preterm delivery or fetal growth retardation. Here by having selected a specific subgroup or preterm and low birth weight infants the bias of the above factors in contributing to mortality in this VLBW subgroup have been eliminated.

Male sex has been cited as a major risk factor for neonatal mortality in the studies done by Lim JW et al., and Basiri B et al., and numerous hypotheses have been proposed to explain the biological plausibility of the differences in the mortality existing between the two sexes and similar findings were obtained in present study on univariate analysis [10,11].

Initiation of enteral feeding within 3 days significantly reduces the neonatal mortality in VLBW neonates which was reflected in the present study. Early enteral feeding prevents nosocomial sepsis; prevent Necrotizing Enterocolitis (NEC), and neonatal sepsis and similar finding were obtained by Akhter T et al., [12]. In the present study antepartum factors such as presence of maternal medical illness or significant obstetric problems at delivery were observed to be comparable in VLBW babies who survived or died. All of the above factors are known to be strongly associated with either preterm delivery or fetal growth

retardation in studies by Verma J et al., Basu S et al., Lim JW et al., and Basiri B et al., [8-11]. The present study observed that not using antenatal steroids was significantly associated with neonatal mortality. Use of antenatal steroid significantly reduces neonatal mortality by reducing RDS, Intraventricular haemorrhage as observed in the study by Kaplan HC et al., [13]. A factor that was found to be highly significant on multivariate analysis as regards the prediction of neonatal mortality was lower Apgar scores and need for resuscitation at the time of delivery. This is of importance because this information is available to the paediatrician at the time of transfer to the SNCU, enabling the doctors to be extra cautious in taking care of this subset of neonates and such variables were utilised in the study by Muktan D et al., and Iqbal Q et al., [14,15].

Besides, in present study, more than half (61.2%) of the neonatal deaths are attributed to birth asphyxia, neonatal sepsis, and prematurity. From this finding it can be concluded that more neonatal survival interventions should be targeted towards the intrapartum period as well as in immediate and early neonatal periods. This finding aligns with the studies of Wang H et al., Sharma AK et al., and Hornik CP et al., which shows up to half of all deaths occur in the first 24 hours of life, and 75% occur in the first week, with the 48 hours immediately following birth cited as the most crucial time for newborn [16-18].

The findings obtained in the present study can be generalised because they portray similar etiologies of neonatal hospital mortality observed in other developing country setting as shown in studies by Tekleab AM et al., Orsido TT et al., Owusu BA et al., Ndombo PK et al., Alebel A et al., El Ganainy H et al. and Baqui AH et al., [19-25]. Most studies conducted in India by Pal A et al., Harinkhede A et al., Modi R et al., Sachan R et al., and Singh A et al., were retrospective in design, thus, there can be the probability that some data were not corrected noted which resulted in inaccurate outcomes on neonatal hospital mortality [26-30].

Limitation(s)

The main limitation of present study is that it is a single centre study, but the merits of this study include its prospective cohort design and robust statistical methods to provide a contribution of level II scientific evidence to the scarcity of data on neonatal hospital mortality in Indian setting.

CONCLUSION(S)

The predictors evaluated for mortality among VLBW neonates admitted in NICU include maternal, obstetric and neonatal factors. On multivariate analysis, the predictors significantly associated with early neonatal mortality were lower birth weight, lower gestation, lower Apgar scores at five min. Not using antenatal steroid was significantly associated with

neonatal mortality and initiation of enteral feeding within three days significantly reduces the neonatal mortality in VLBW. This study identifies the risk factors associated with mortality in VLBW neonates and helps in prioritising them so the health care workers can intervene and prevent mortality in these neonates. There is therefore a need that such infants require care at centres with adequately trained staff with appropriately developed support infrastructure.

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