

Mortality and morbidity profile of preterm very low birth weight infants: A prospective longitudinal observational study

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ABSTRACT

Objective: To study the survival to discharge and immediate outcome of preterm very low birth weight (VLBW) infants. **Materials and Methods:** Design: Prospective observational longitudinal study. Setting: Level II neonatal intensive care unit in a tertiary care center. Subjects: All live born inborn babies with birth weight 401-1499 g or gestational age between 22 weeks 0 day and 31 weeks 9 days. Outcome: Key outcome was survival to discharge for preterm VLBW infants. Incidence of major morbidities was assessed. **Results:** Of 183 neonates enrolled in the study, 73.2% babies were alive at initial disposition. Respiratory distress syndrome was the most common morbidity, and infection was the most common cause of death. Lower gestational age and low APGAR score at 1 min were the most significant predictors of poor outcome. **Conclusion:** This study provides a baseline database for evaluating the efficiency of perinatal services in a tertiary care center. Further large-scale trials are needed to substantiate our findings and to study neurodevelopmental outcome of VLBW infants.

Key words: Morbidity, Mortality, Outcome, Very low birth weight

In India, very low birth weight (VLBW) infants (birth weight <1500 g) constitute only 3.4% of total live births but they are responsible for around one-third (29.7%) of neonatal deaths [1]. Furthermore, they are more likely to suffer both short-term and long-term morbidities than normal newborns [2] which expose them to additional diagnostic and therapeutic interventions, increase the duration of hospitalization and cost of treatment [3-8] and are predictive of adverse neurodevelopmental outcome at 18 months of age [9]. Hence, the outcome of these babies closely reflects the quality of neonatal intensive care and helps in identifying the birth weight and gestational age groups who are most likely to benefit from intensive care.

There are several prospective and retrospective studies from both developed [10-17] and developing [18-30] countries regarding the outcome of VLBW infants. However, there is limited published data from India. Therefore, this study was planned to evaluate the short-term outcome of VLBW infants and to compare our performance with other institutes.

MATERIALS AND METHODS

This prospective longitudinal study was conducted in a Level II neonatal intensive care unit (NICU). The research proposal was approved by the research and ethics committee of the hospital and written informed consent was obtained from the parents of enrolled neonates. All the neonates are provided free medical

services under the Janani-Shishu Suraksha Karyakram (JSSK) scheme. All live born inborn babies with birth weight 401-1499 g or gestational age between 22 weeks 0 day and 31 weeks 9 days were included in the study. Babies >32 weeks gestation were not included to exclude late preterm or term small for gestational age (SGA) babies as they have a different morbidity profile than preterm appropriate for gestation age (AGA) or preterm SGA babies. Out born babies were excluded. The study was conducted from May 2012 to January 2013.

Data were collected prospectively using the standard definitions published by the Vermont Oxford Network [31]. Gestational age was estimated on the basis of last menstrual period, antenatal ultrasound or New Ballard score [32] in that order. Bacterial sepsis was defined as recovery of bacterial pathogens from blood or cerebrospinal fluid cultures. Cranial ultrasound was performed at 72 h, day 7 and day 28 to identify intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL). Respiratory distress syndrome (RDS) was defined as PaO₂ <50 mmHg or central cyanosis in room air or a requirement for supplemental oxygen to maintain PaO₂ >50 mmHg, or a pulse oximeter saturation over 85% within the first 24 h of life and a chest radiograph consistent with RDS within first 24 h of life. A bedside echocardiography (ECHO) was performed in all babies at 72 h of age and earlier or later if baby had symptoms such as increased oxygen requirement, hyperdynamic circulation, or unexplained apnea. Hemodynamically significant patent ductus arteriosus

(PDA) (clinical features or left atrium to aortic root ratio on ECHO >1.5:1) was treated with intravenous indomethacin or oral ibuprofen. A 7 days course of paracetamol was tried for babies in whom PDA did not respond to three courses of indomethacin or ibuprofen.

Necrotizing enterocolitis (NEC) was diagnosed if the baby had bilious gastric aspirate, emesis, abdominal distension or occult or gross blood in stool (no fissure), and at least one of the radiographic findings, i.e., pneumatosis intestinalis, hepatobiliary gas, or pneumoperitoneum. Gastrointestinal perforation was diagnosed if there was evidence of pneumoperitoneum on X-ray without pneumatosis intestinalis. Indirect ophthalmoscopic examination was performed at 4 weeks of age by consultant ophthalmology and retinopathy of prematurity (ROP) was classified according to International classification of ROP [33]. Chronic lung disease (CLD) was defined as need for supplemental oxygen on day 28 and classified according to National Institute for Health consensus definition. For all the definitions date of birth was taken as day 1 irrespective of the time of birth. No additional intervention was involved in the study.

Outcome measures were survival to discharge for VLBW neonates and incidence of major morbidities, i.e., RDS, PDA, pneumothorax, sepsis, NEC, gastrointestinal perforation, IVH, cystic PVL, ROP and CLD. Data were entered in a Microsoft access database and analyzed with Stata 11.1 software (StataCorp, TX, USA). Categorical data are presented as number and proportion. Numerical data are presented as mean±SD or median and interquartile range.

RESULTS

Table 1 shows the baseline demographic characteristics of study subjects. 183 VLBW babies were born alive during the study period, 86 boys and 97 girls. Of these 121 (66.1%) babies survived to discharge home. Mean birth weight was 1228±234 g and mean gestational age was 31±2.7 weeks with 28.4% being SGA. Only 10% of the babies were <1000 g birth weight and/or <28 weeks gestation. Table 2 shows morbidity profile of VLBW babies and Table 3 shows interventions done for these morbidities. 56 babies required delivery room resuscitation with maximum number (33.3%) requiring bag and mask ventilation only. 25 babies had 1 min APGAR score <3 and only 11 had 5 min score <3.

A total of 37 babies (20.5%) had RDS, only 9 were administered surfactant (early rescue). In 7 patients, parents could not afford surfactant and surfactant was not available under JSSK, in 3 others, surfactant treatment was not offered due to nonavailability of ventilator and NICU bed while remaining 18 had mild disease (Grade I-II hyaline membrane disease) which responded to continuous positive airway pressure (CPAP) only. Mean age at first dose of surfactant was 7.4 h and repeat course was required in 3 babies. 101 required some form of respiratory support, the most common being nasal CPAP in 90 babies followed by conventional ventilation in 50 and humidified high flow nasal cannula (HHFNC) in 49. HHFNC was primarily

Table 1: Baseline characteristics of study subjects

Characteristic	n=183 (%)
Birth weight* (g)	1228±234
Gestational age* (weeks)	31.4±2.7
SGA	52 (28.4)
Birth head circumference* (cm)	27.6±1.9
Gender	
Male	86 (47)
Female	97 (53)
Babies admitted to NICU	115 (62.8)
Prenatal care	158 (86.3)
Antenatal steroids	110 (60.1)
Antenatal magnesium sulfate	31 (16.9)
Vaginal delivery	117 (63.9)
Multiple births (twins)	31 (16.9)
APGAR score	
1 min*	7±2.6
<3	25±13.7
5 min*	8±1.9
<3	11±6
Admission temperature**	36.2±0.6

*Mean±standard deviation, **n=115 since 68 babies were not admitted to NICU. SGA: Small for gestational age, NICU: Neonatal intensive care unit

Table 2: Major morbidities observed in VLBW babies

Morbidity	n=183 (%)
IVH	
Grade 0	104 (56.8)
Grade I	34 (18.6)
Grade II	13 (7.1)
Grade III	3 (1.6)
Grade IV	1 (0.6)
RDS	37 (20.5)
Pneumothorax	3 (1.7)
PDA	19 (10.4)
NEC	4 (2.2)
Gastrointestinal perforation	2 (1.1)
Early bacterial sepsis	3 (1.6)
LOS	10 (5.5)
Bacterial pathogen	9 (4.9)
Fungal sepsis	1 (0.6)
BPD	3 (1.6)
Mild BPD	2 (1.1)
Moderate BPD	1 (0.6)
ROP	
Stage I	3 (1.6)
Stage II	4 (2.2)
Stage III	5 (2.7)
Stage IV	2 (1.1)
Cystic PVL	17 (9.3)

IVH: Intraventricular hemorrhage, RDS: Respiratory distress syndrome, PDA: Patent ductus arteriosus, NEC: Necrotizing enterocolitis, BPD: Bronchopulmonary dysplasia, ROP: Retinopathy of prematurity, PVL: Periventricular leukomalacia, VLBW: Very low birth weight, LOS: Late-onset sepsis

used as an alternate method of providing continuous distending pressure only when it was not feasible to provide CPAP by ventilator or bubble CPAP due to nonavailability. 38 babies required nasal intermittent positive pressure ventilation mainly for postextubation cases and apnea of prematurity not responding to CPAP and methylxanthines. High frequency oscillatory ventilation (HFOV) was used in 19 subjects, indication being air leaks, refractory hypoxemia and hypercarbia. Pneumothorax was found in 3 subjects, of which 2 were on mechanical ventilation and were managed with insertion of chest drain while 1 had pneumothorax on CPAP and was managed conservatively. 1 baby each had pneumomediastinum and pulmonary interstitial emphysema both managed on HFOV. 3 babies were dependent on supplemental oxygen on day 28 of life but only 1 required 30% FiO₂ at 36 weeks postmenstrual age necessitating the use of steroids.

PDA was diagnosed in 19 (10.4%) babies out of them 14 were hemodynamically significant and all 14 responded to medical management with ibuprofen or paracetamol. 3 babies had definite early onset sepsis (EOS), organisms being two *Acinetobacter*

and one *Escherichia coli*. Late-onset sepsis was diagnosed in 10 babies – 1 fungal and 9 bacterial. Of bacterial sepsis, 3 were positive for *Klebsiella*, 3 methicillin resistant *Staphylococcus aureus*, 2 carbapenem-resistant *Acinetobacter* species (managed with injection colistin), and 1 case of methicillin sensitive *S. aureus*.

Cranial ultrasound was performed in 155 subjects - 34 cases of Grade I IVH, 13 Grade II, 3 Grade III, and 1 case of Grade IV IVH. Out of these 155 cases, 19 died within 12 h of life, and 9 left against medical advice before 24 h of life. None of the babies with severe IVH (Grade III-IV) survived to discharge home. Follow-up ultrasound on day 28 of life among survivors revealed cystic PVL in 17 babies (9.3%). 4 (2.2%) babies developed NEC, of which, 2 responded to conservative management, 1 was transferred to higher center for surgical management in view of pneumoperitoneum and 1 died of fulminant sepsis. 2 babies were diagnosed with spontaneous intestinal perforation of which 1 died and the another baby was transferred to higher center.

Retinal examination was performed in 120 babies, of which 5 babies had Stage III and 2 had Stage IV disease, managed with laser therapy.

Table 3: Treatment received by VLBW babies

Intervention	n=183 (%)
Delivery room resuscitation	
Oxygen	36 (19.7)
Bag and mask ventilation	61 (33.3)
Endotracheal intubation	22 (12)
Epinephrine	7 (3.8)
Chest compression	8 (4.3)
CPAP	5 (2.9)
Respiratory support	
Oxygen	76 (41.5)
Conventional ventilation	50 (27.3)
High frequency ventilation	14 (7.6)
High flow nasal cannula	49 (26.8)
Nasal IMV	38 (20.8)
CPAP	90 (49.1)
Surfactant	9 (4.9)
Delivery room	1 (0.6)
NICU	8 (4.4)
Age at 1 st dose of surfactant* (h)	7.4±4.9
Indomethacin for PDA	3 (1.6)
Ibuprofen for PDA	11 (6)
Paracetamol for PDA	3 (1.6)
Surgical ligation for PDA	0
ROP surgery (laser)	7 (3.8)
Oxygen on day 28	3 (1.6)
Respiratory support (oxygen) at 36 weeks PMA	1 (0.6)
Steroids for BPD	1 (0.6)
TPN	9 (4.9)

*Mean±standard deviation. CPAP: Continuous positive airway pressure, IMV: Intermittent mandatory ventilation, NICU: Neonatal intensive care unit, PDA: Patent ductus arteriosus, ROP: Retinopathy of prematurity, PMA: Postmenstrual age, BPD: Bronchopulmonary dysplasia, TPN: Total parenteral nutrition, VLBW: Very low birth weight

Final Outcome and Predictors of Poor Outcome

A total of 121 (66%) babies survived to discharge home. Mean weight at discharge was 1350±241 g and mean head circumference was 28.5±1.9 cm. Mean duration of hospital stay was 17.4 days. 43.2% babies were discharged home on exclusive breast feed, 26.8% on human milk with fortifier or formula, only 2 were discharged on exclusive formula feed that too because their mothers were retrovirus positive and they opted for exclusive formula feeding for their babies (Table 4). Table 5 shows survival with major morbidity.

Table 4: Final outcome of VLBW babies

Outcome	n=183 (%)
Death (total)	45 (24.6)
Death in delivery room	12 (6.6)
Death within 12 h of NICU admission	7 (3.8)
Alive at initial disposition	134 (73.2)
Survival to discharge home	121 (66.1)
Left against medical advice	13 (7.1)
Transfer to other hospital	4 (2.2)
Enteral feeding at discharge	130 (71)
Exclusive breastfeed	79 (43.2)
Formula feed	2 (1.1)
Breast milk+fortifier/formula	49 (26.8)
Oxygen at discharge	1 (0.6)
Monitor at discharge	1 (0.6)
Weight at initial disposition* (g)	1350 (241)
Head circumference at initial disposition* (cm)	28.5 (1.9)
Length of hospital stay* (days)	17.4±12.6

*Mean (standard deviation). NICU: Neonatal intensive care unit, VLBW: Very low birth weight

Mortality rate was 24.6% (45), of which 12 died in the delivery room and 7 died within 12 h of NICU admission. The most common cause of death was infection accounting for 24% cases followed by perinatal asphyxia (22%) and extreme prematurity (15.6%). None of the babies with birth weight <750 g survived; likewise, mortality rate was maximum for babies with gestation 25-26 weeks (80%).

On univariate analysis (Table 6), decreasing birth weight and gestational age were associated with increased probability of death (odds ratio: 0.995 and 0.91, respectively). Furthermore, lower APGAR score at 1 min was associated with significantly higher risk of death (odds ratio: 0.65). In logistic regression model, lower gestational age (regression coefficient -0.278; 95%

confidence interval [CI]: -0.44-0.12) and low APGAR score at 1 min (regression coefficient -0.05; 95% CI: -0.45--0.12) most significantly predicted the likelihood of poor outcome (Table 7). Birth weight has been ignored in this model because both birth weight and gestation have a linear correlation and birth weight is not known before birth. Hence, gestational age may be a better antenatal predictor of adverse outcome. Using this model, poor neonatal outcome can be correctly classified to the extent of 85.14% with the specificity of 95.4%. p value on applying goodness of fit test was 0.0639 suggesting good fit. Pseudo R² for this model was also the highest, i.e., 0.3051.

DISCUSSION

Outcome of VLBW babies is an index of efficiency of perinatal services in a particular area. In this prospective longitudinal study, all live born VLBW babies were observed for mortality and major morbidity. Perinatal factors responsible for increased mortality were computed using univariate analysis and a logistic regression model was developed to ascertain the most important factors associated with poor outcome.

Overall mortality of VLBW babies was 24.6% which is much higher than that of developed countries, whereas survival with major morbidity is much lower for study subjects than Vermont Oxford Network (VON) group [32]. This can be explained by decreased survival of extremely low birth weight babies (birth weight <1000 g) in our study as none of the babies with birth weight <750 g survived compared to 63.4% in VON group [34]. Another important factor influencing survival may be lesser use of antenatal steroids (60% against 79% reported from developed countries [19], although higher than that reported from other developing countries (48%) [30]. Cochrane collaboration systematic review has already concluded that use of corticosteroids before preterm birth reduces neonatal mortality [35].

Incidence of PVL was significantly higher in our study group (9.3%) when compared to developed countries (~3%) [11-19]. IVH, intrauterine infection and immature cerebral blood flow autoregulation are known to predispose the preterm brain to white-matter injury and subsequent development of PVL. Hence, higher incidence of EOS reflecting intrauterine infection (2.5% vs. 1.7% [11]) and slightly higher percentage of babies with IVH Grade I-IV (29% vs. 27% [20]) might explain this difference to some extent.

Furthermore, mortality rates reported in our study are comparable to those of AIIMS (p=0.48) [29] and definitely lower than the reported rates from other developing countries, viz., West Indies [34] and Bangladesh [27] (Fig. 1). This comparison suggests that although, there is a definite scope for improvement in perinatal care of VLBW babies to reach the bar set by developed countries, even the current outlook is not so grim when compared to other developing nations.

Late-onset septicemia particularly by Gram-negative organisms is the most common cause of death in the study population. Study by Stoll et al. [36] from NICHD network has also suggested that infection with Gram-negative organisms or fungi is responsible

Table 5: Survival with selected neonatal morbidity

Outcome	Study group n=183 (%)
Overall survival	121 (66.1)
Survival with morbidity*	
Overall	4 (2.2)
BPD alone	2 (1.1)
Severe (Grade III/IV) IVH	0
NEC alone	2 (1.1)
BPD and severe IVH	0
BPD and NEC	0
NEC and severe IVH	0
BPD and severe IVH and NEC	0

*Morbidity is defined as diagnosis of BPD, Grade III-IV IVH or NEC.
BPD: Bronchopulmonary dysplasia, IVH: Intraventricular hemorrhage,
NEC: Necrotizing enterocolitis

Table 6: Predictors of poor outcome in VLBW babies—univariate analysis

Outcome	Mortality n	No mortality n	p value
Birth weight (g)	45	138	0.00
Gestational age (weeks)	45	138	0.00
Vaginal delivery	36	81	0.007
Gender: Male	19	78	0.067
1 min APGAR score	45	138	0.00
5 min APGAR score	45	138	0.00
DR oxygen	25	11	0.00
DR bag and mask ventilation	27	34	0.00
DR intubation	14	8	0.00
DR epinephrine	6	1	0.001
DR chest compression	7	1	0.00
DR CPAP	4	1	0.015

DR: Delivery room, CPAP: Continuous positive airway pressure, VLBW: Very low birth weight

Table 7: Final model for prediction of mortality in VLBW babies – multivariate analysis

Parameter	Odds ratio	95% CI	Regression coefficient
Gestational age (weeks)	0.76	0.65-0.89	-0.28
1 min APGAR	0.77	0.64-0.85	-0.31

CI: Confidence interval, VLBW: Very low birth weight

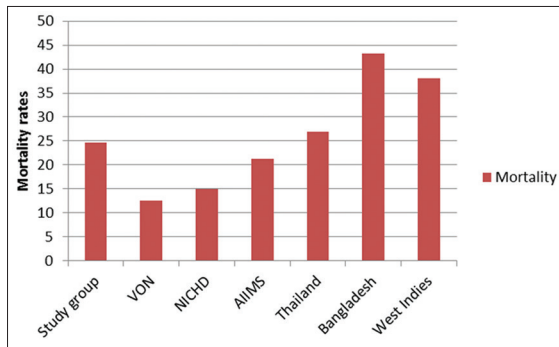


Figure 1: Comparison of mortality of very low birth weight infants among different studies

for increased risk of death and prolonged hospital stay in VLBW neonates. However, infection as an important cause of mortality suggests need for improvement in nursing care, prevention of overcrowding and strict aseptic precautions as these measures have been suggested to be of utmost importance in prevention of infection outbreaks in sick newborn units [23].

In logistic regression analysis, lower gestational age, birth weight and 1 min APGAR score turned out to be the most important predictors of poor outcome which is in agreement with a Thailand study [30] wherein birth weight <1000 g, congenital anomalies and APGAR score <5 at 1 min were the significant perinatal risk factors of mortality.

This is one of the few prospective studies from India reporting the outcome of VLBW babies in detail. A logistic regression model with fair specificity has also been drawn to ascertain the predictors of poor outcome so that necessary measures may be taken to prevent them. As each additional week of gestation is associated with improved survivals and reduced cost of treatment prolongation of gestation in these patients seems to be a cost-effective intervention. Furthermore, perinatal asphyxia has turned out to be an important predictor of mortality in this study suggesting the need for increased access to antenatal care and timely referral of at risk cases to higher centers for appropriate intervention.

However, this study is limited to short-term outcome of VLBW babies. Due to time constraint, we could not include neurodevelopmental outcome of these babies at 18 months and 5 years.

CONCLUSION

This study provides a comprehensive review of outcome of very low birth babies from a developing country. It provides baseline information for establishing more comprehensive and preferably, multicentric database for evaluating the outcome of this vulnerable group of infants and study the regional differences in their outcome. This study also indicates that although scenario is not very dismal, there is definitely a scope for improvement.

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