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A study of morbidity and mortality pattern of pre-term neonates in neonatal intensive care unit of a tertiary care hospital of North East India

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ABSTRACT

Background: Pre-maturity is one of the major health problems and associated with high morbidities and mortality. According to the WHO every year, an estimated 15 million babies are born pre-term and this number is rising. **Aims and Objectives:** The objectives of the study were to know the various morbidity pattern developed during the clinical course and to identify the cause of mortality of pre-term babies admitted in neonatal intensive care unit (NICU). **Materials and Methods:** This prospective, observational study was conducted in the Neonatal Intensive Care Unit of Gauhati Medical College and Hospital, Assam, over a period of 1 year. A sample size of 150 pre-term babies selected randomly as per inclusion and exclusion criteria. **Results**: The total number of cases studied in the present study were 150 pre-term babies admitted in NICU. Male pre-term babies were 82 (54.6%) and female pre-term babies were 68 (45.3%). The various morbidities observed among the pre-term babies during the study period were neonatal hyperbilirubinemia (48%) followed by respiratory distress syndrome (RDS) (30%), neonatal sepsis (22%), hypocalcemia (16%), hypothermia (14.7%), necrotizing enterocolitis (NEC) (5.3%), and intraventricular hemorrhage (4.7%). The overall mortality among the studied cases was 12.6%. Out of 150 cases, 19 cases were expired (12.6%). The present study shows that RDS (36.8%), neonatal sepsis (26.3%), birth asphyxia (21.1%), and NEC (15.7%) were the major causes of mortality among pre-term babies. **Conclusion:** The survival rate increases significantly with increase in birth weight and gestational age. RDS, birth asphyxia, and neonatal sepsis were the leading causes of death.

Key words: Pre-term babies; Low birth weight; Respiratory distress syndrome; Sepsis; Morbidity; Mortality

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INTRODUCTION

Pre-term baby is one, which is born before 37 completed weeks of gestation. It is the single largest cause of perinatal mortality in the world.[1] According to the WHO every year, an estimated 15 million babies are born pre-term and this number is rising. This is more than 1 in 10 babies. Across countries, the rate of pre-term birth ranges from 5% to 18% of babies born.[1,2] One of the most important unresolved issues currently confronting is the prevention of pre-term birth. However, the prevention of premature delivery has been difficult and ineffective because of its multifactorial and partly still unknown etiology.[2] Although the overall rate of pre-term birth has not decreased over the past 30 years, the survival rate of pre-term babies has improved due to advanced neonatal care, use of antenatal steroids, surfactant therapy, and modern ventilatory technique.[2-4] This development results in reduced neonatal mortality rate in developing countries but concurrent increase in major neurological sequelae includes cerebral palsy, mental retardation, learning disabilities, visual and hearing problems as long-term consequences.[3,4] The

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majority of pre-term birth occurs in Africa and southern Asia, but pre-term birth is truly a global problem. India has the maximum number of pre-term births, almost 24% of the total number. An estimated 1 million babies die annually from pre-term birth and their complications.[1,4,5] Preventing deaths due to prematurity start with a healthy pregnancy. Recent WHO's antenatal care guidelines include key interventions to prevent pre-term birth, such as counseling on optimal nutrition, tobacco and substance abuse, early ultrasound, good antenatal care, antenatal steroids, and tocolytic therapy to delay pre-term labor.[5] However, the survival and outcome of pre-term neonates in different hospitals and regions vary widely.[6-9] Hence, the outcome study of pre-term babies in each population and region is essential in developing countries. Many studies were carried out by various workers on the outcome of pre-term babies in different parts of India. However, there is no such data regarding morbidity and mortality pattern of pre-term neonates in the state of Assam. Hence, this study was conducted in neonatal intensive care unit to know the various morbidity patterns developed during the clinical course and to identify the cause of mortality of pre-term babies admitted in neonatal intensive care unit (NICU).

Aims and objectives

This study aimed to determine the morbidity profile and to identify the cause of death of preterm neonates in NICU.

MATERIALS AND METHODS

This prospective, observational study was conducted in the Neonatal Intensive Care Unit of Gauhati Medical College and Hospital, Assam, over a period of 1 year from February 2019 to January 2020 after taking permission from the Institutional Ethics Committee of Gauhati Medical College. This hospital is a tertiary care hospital with well equipped, state-of-the-art NICU, having facilities of continuous positive airway pressure (CPAP), all modern ventilatory support, phototherapy units, exchange transfusion facilities, free-of-cost surfactant therapy, newborn hearing, and ROP screening facilities. The NICU has separate inborn unit, outborn unit, phototherapy unit, KMC unit, and step-down unit. Hand hygiene and all precautions are followed in NICU.

Inclusion criteria

Neonates were considered eligible for inclusion into the study if they met the following criteria: (1) Babies born before 37 weeks of gestation and admitted in NICU and (2) both inborn and outborn babies were enrolled for the study.

Exclusion criteria

(1) Babies more than 37 weeks of gestation and (2) babies having associated congenital syndrome and congenital malformations.

Study procedure

A total number of 5371 newborns were admitted in NICU during the study period. Out of this, 1987 (37%) newborns were pre-term including 26 pairs of twins. A sample size of 150 babies was randomly selected for the study, which fulfilled the above-mentioned inclusion criteria. A pro forma was designed for this study. This includes demographic profile, antenatal care, use of antenatal steroids, mode and place of delivery, gender, gestational age, birth weight, weight at admission in case of outborn baby, resuscitation needed or not, condition at birth, requirement of supplemental oxygen, surfactant therapy, etc. A written informed consent was taken from all parents and purpose of the study was explained to them in their local language. Parents were allowed to discontinue from the study at any time. The neonates were further subdivided into subgroups on the basis of gestational age and birth weight to analyze the various morbidities. Four groups according to gestation: (a) Extremely pre-term, before 28 weeks, (b) severe pre-term, 28–31 weeks, (c) moderate pre-term, 32–33 weeks, and (d) late pre-term 34–<37 weeks as described in literatures [Table 1].[3,10] Four groups on the basis of birth weight: (a) extremely low birth weight (LBW), <1 kg, (b) very LBW, 1–<1.5 kg, (c) LBW 1.5–<2.5 kg, and (d) normal birth weight, >2.5kg [Table 2].[3,10] After taking history as described, detailed clinical examination was performed and recorded. Laboratory tests such as sepsis screen, blood culture and sensitivity test, RBS, serum electrolyte, renal function test, and chest X-ray were done as per the need of the baby. These pre-term neonates were followed up in NICU throughout their stay for any development of complications. This includes complications (morbidities) of pre-term babies such as respiratory distress syndrome (RDS), neonatal sepsis, neonatal jaundice, hypoglycemia, hypocalcemia, hypothermia, and intraventricular hemorrhage (IVH) and treatment provided in NICU. The diagnosis, relevant investigations, duration of stay, and complications developed during treatment and outcome were recorded. The Statistical Package for the Social Sciences software was used to analyze the data.

RESULTS

The total number of cases studied in the present study was 150 pre-term babies admitted in NICU. Male pre-term babies were 82 (54.6%) and female pre-term babies 68 (45.3%).

In the present study, it was seen that majority babies (34.6%) were between 32 and <34 weeks, followed by 34–<37 weeks comprising 32% and below 28 weeks comprising only 4% of the cases [Table 3].

Table 1: Classification of pre-term newborns according to gestational age (as described by Goldenberg et al.)

Extremely pre-term	Born before 28 weeks of gestation
Severe pre-term	Born at 28 weeks–31 weeks of gestation
Moderate pre-term	Born at 32 weeks to before 34 weeks of gestation
Late pre-term	Born at 34 weeks to before 37 completed weeks of gestations

Table 2: Classification of pre-term newborns according to weight

Extremely low birth weight	Weight <1 kg
Very low birth weight	Weight <1.5 kg
Low birth weight	Weight <2.5 kg

Table 3: Distribution of pre-term babies according to gestational age (n=150)

Gestation in weeks	Number	Percentage
<28 weeks	6	4
28 weeks–31 weeks	44	29.3
32 weeks–<34 weeks	52	34.6
34 weeks–<37 weeks	48	32
Total	150	100

Table 4: Distribution of pre-term babies according to birth weight (n=150)

Weight	Number	Percentage
<1 kg	7	4.6
1 kg–<1.5 kg	69	46
1.5 kg–<2.5 kg	74	49.3
Total	n=150	100

Table 5: Morbidity pattern of pre-term babies (n=150)

Morbidities	Number	Percentage
Neonatal hyperbilirubinemia	72	48
Neonatal sepsis	33	22
Respiratory distress syndrome	45	30
Hypoglycemia	9	6
Perinatal asphyxia	14	9.3
Necrotizing enterocolitis	8	5.3
Intraventricular hemorrhage	7	4.7
Hypothermia	22	14.7
Hypocalcemia	24	16
Apnea of pre-maturity	13	8.7
Patent ductus arteriosus	5	3.3

In the present study, majority (49.3%) babies were LBW babies, 46% were very LBW (VLBW) babies, and only 4.6% were extremely LBW babies [Table 4].

In the present study, the various morbidities observed among the pre-term babies during the study period were as follows: Neonatal hyperbilirubinemia (48%) was the most common, followed by RDS (30%), neonatal sepsis (22%), hypocalcemia (16%), hypothermia (14.7%), necrotizing enterocolitis (NEC) (5.3%), and IVH (4.7%) [Table 5].

This study showed that hyperbilirubinemia requiring phototherapy was 100% among extreme pre-term, 61.3% among severe pre-term, and only 33% cases among late pre-term. In regard to RDS, highest number of cases was seen among extreme pre-term (66.6%) and lowest among late pre-term group (6%). Neonatal sepsis was observed 34% of cases in severe pre-term, 19% of cases in moderate pre-term, and 12.5% cases in late pre-term.

Independent two-sample T-test

The dataset [Table 6] consists of 11 observations. Each of these 11 observations is different morbidities of pre-term babies in different gestational age groups. The four are extreme pre-term, severe pre-term, moderate pre-term, and late pre-term. To see if there is any significant difference between these groups, two-sample *t*-test is used and the results are displayed in the tables below:

(1) Extreme pre-term and severe pre-term

The null hypothesis to be tested is

H_0: There is no significant difference between extreme pre-term and severe pre-term groups. Against the alternative hypothesis.

H_1: The morbidity in extreme pre-term and severe pre-term groups differs.

This is a two-tailed test.

Variable	Mean	Variance	n	Degree of freedom	P-value
Extreme pre-term	36.33	990.52	11	17	0.17
Severe pre-term	20.2	413.31	11		

Since the P>0.05, hence, null hypothesis cannot be rejected at 5% level of significance and we can conclude that there is no significant difference between the extreme pre-term and severe pre-term groups.

(2) Extreme pre-term and moderate pre-term

This is a two-tailed test.

Variable	Mean	Variance	n	Degree of freedom	P-value
Extreme pre-term	36.33	990.52	11	17	0.04
Moderate pre-term	14.83	159.08	11		

Table 6: The morbidities of pre-term babies in different gestational age groups

Morbidity feature	Extreme pre-term (%)	Severe pre-term (%)	Moderate pre-term (%)	Late pre-term (%)
Neonatal hyperbilirubinemia	6/6 (100)	27/44 (61.3)	23/52 (44)	16/48 (33)
Neonatal sepsis	2/6 (33.3)	15/44 (34)	10/52 (19.2)	6/48 (12.5)
RDS	4/6 (66.6)	24/44 (54.5)	14/52 (26.9)	3/48 (6.2)
Hypoglycemia	1/6 (16.6)	4/44 (9)	4/52 (7.7)	0
Perinatal asphyxia	0	4/44 (9)	6/52 (11.5)	4/48 (8.3)
Necrotizing enterocolitis	1/6 (16.6)	3/44 (6.8)	3/52 (5.7)	1/48 (2.1)
IVH	0	5/44 (11.3)	2/52 (3.9)	0
Hypothermia	1/6 (16.6)	6/44 (13.7)	8/52 (15.4)	7/48 (14.6)
Hypocalcemia	2/6 (33.3)	4/44 (9)	11/52 (21.1)	7/48 (14.6)
Apnea of pre-maturity	3/6 (50)	5/44 (11.3)	4/52 (7.7)	1/48 (2.1)
PDA	4/6 (66.7)	1/44 (2.3)	0	0

PDA: Patent ductus arteriosus, RDS: Respiratory distress syndrome, IVH: Intraventricular hemorrhage

Table 7: Major causes of deaths in pre-term babies in the study (n=19)

Causes of deaths	Number (n=19)	Percentage of total (n=19)
RDS	7	36.8%
Sepsis	5	26.3%
NEC	3	15.7%
Birth asphyxia	4	21.1%

RDS: Respiratory distress syndrome, NEC: Necrotizing enterocolitis

Table 8: Mortality distribution according to birth weight

Weight	Number (n=150)	Total no. of deaths (n=19)	Mortality (%)
<1 kg	7	6	85.7
1 kg–<1.5 kg	69	10	14.5
1.5 kg–<2.5 kg	74	3	4.1

Table 9: Mortality distribution according to gestation

Gestational age	Number (n=150)	Total number of deaths (n=19)	Mortality %
<28 weeks	6	5	83.3
28–31 weeks	44	7	15.9
32–<34 weeks	52	5	9.6
34–<37 weeks	48	2	4.2

Since the P<0.05, hence, null hypothesis is to be rejected at 5% level of significance and we can conclude that there exists a significant difference between the extreme pre-term and moderate pre-term groups.

(3) Extreme pre-term and late pre-term

This is a two-tailed test.

Variable	Mean	Variance	n	Degree of freedom	P-value
Extreme pre-term	36.33	990.52	11	17	0.01
Late pre-term	8.49	99.46	11		

Since the P<0.05, hence, null hypothesis is to be rejected at 5% level of significance and we can conclude that there exists a significant difference between the extreme pre-term and late pre-term groups.

(4) Severe pre-term and moderate pre-term

This is a two-tailed test.

Variable	Mean	Variance	n	Degree of freedom	P-value
Moderate pre-term	14.83	159.08	11	17	0.46
Severe pre-term	20.2	413.31	11		

Since the P>0.05, hence, null hypothesis cannot be rejected at 5% level of significance and we can conclude that there is no significant difference between the moderate pre-term and severe pre-term groups.

(5) Severe pre-term and late pre-term

This is a two-tailed test.

Variable	Mean	Variance	n	Degree of freedom	P-value
Lat pre-term	8.49	99.46	11	17	0.10
Severe pre-term	20.2	413.31	11		

Since the P>0.05, hence, null hypothesis cannot be rejected at 5% level of significance and we can conclude that there is no significant difference between the late pre-term and severe pre-term groups.

(6) Moderate pre-term and late pre-term

The null hypothesis to be tested is

Variable	Mean	Variance	n	Degree of freedom	P-value
Moderate pre-term	14.82	159.08	11	17	0.21
Late pre-term	8.49	99.46	11		

Since the P>0.05, hence, null hypothesis cannot be rejected at 5% level of significance and we can conclude that there is no significant difference between the moderate pre-term and late pre-term groups.

Treatment and intervention required in NICU during hospital stay as follows: 36% cases required supplemental oxygen for a median duration of 6 days (1–20 days), 16% cases required mechanical ventilation, 21% cases required CPAP, phototherapy (43%) cases, exchange transfusions (5.3%) cases, and 12% cases required surfactant therapy.

The overall mortality among the studied cases was 12.6%. Out of 150 cases, 19 cases were expired (12.6%). Of the expired cases, male baby comprised 11 cases (57.8%) and female babies comprised 8 (42.1%) cases. This study showed that RDS (36.8%), neonatal sepsis (26.3%), NEC (15.7%), and birth asphyxia (21.1%) were the major causes of mortality among pre-term babies [Table 7].

In the present study, it was observed that mortality percentage among extremely LBW babies was 85.7%, VLBW babies was 14.5%, and LBW babies was only 4.1% [Table 8]. Further, the highest percentage of death of pre-term babies was seen in less than 28-week gestation (83.3%), followed by 15.9% death in 28–31 weeks and lowest rate (4.2%) in 34–<37 weeks of gestation [Table 9].

DISCUSSION

This study comprises 150 pre-term babies randomly selected in the NICU, out of which 54.6% male and 45.3% female babies. Pre-mature birth is a leading and major health problem in our country despite research going on and different interventions taken to cut down the incidence of pre-term labor.[11] Accurate data on morbidity and mortality profile are important to take necessary steps for prevention and treatment in NICU. It is also useful for Local and National Health Administrators, decision-makers to design, implement, and evaluate health-care programs.[12,13] These pre-term babies develop many complications during the NICU stay and leading to increased mortality rate compared to term babies. Moreover, pre-term babies require prolong NICU stay, which is a major economic burden for the health-care facility, the concerned family and as a whole the country.[3,14,15]These complications and the different sequelae depend on the degree of pre-maturity. A review done by Goldenberg et al. described that about 5% pre-term birth occurs at <28 weeks of gestations, 15% occurs at 28–31 weeks gestation, 20% at 32–33 weeks, and about 60–70% occurs at 34–<37 weeks of gestations. In the present study, it was observed that extremely pre-term baby was 4% which is consistent with the percentage described by Khan et al.[3] and Goldenberg et al.[10] It was also found from this study that the proportion of severe pre-term was 29.3%, moderately pre-term was 34.6%, and late pre-term was 32%. This finding is comparable to the studies done by Khan et al.[3] and Shrestha and Shrestha.[15] However, percentage of late pre-term babies is very low in this study as compared to Goldenberg et al. reported 60–70% of late pre-term baby. This difference can be due to poor antenatal care, teenage pregnancy, and poor nutritional status of the mother.

With reference to various morbidities, RDS was seen in 30% of cases and similar pattern was observed by other workers in their studies, Khan et al.[3] and Shrestha and Shrestha.[15]There is decreasing trend of RDS with increased gestational age.[16-18] In this study, the incidence of RDS was extreme pre-term (66.6%), moderate pre-term (26.9%), and late pre-term (6.2%) only. Neonatal sepsis is a major concern in a NICU and it was found in 22% cases in this study. Among the sepsis cases, it was seen in 33.3% and 34% cases in extremely pre-term and severe pre-term babies, respectively, which were higher than the late pre-term babies (12.5%). Similar trends have been described in literature.[15,19,20] In the present study, hyperbilirubinemia was observed in 48% of cases. It was found in extremely pre-term (100%), moderate pre-term (44%), and late pre-term (33%). There is decreasing incidence of hyperbilirubinemia with more gestational age. These findings were comparable with Shrestha and Shrestha.[15]

In regard to mortality profile, mortality was seen in 12.6% of cases in the present study. This value is near to the values found in the studies done by various researchers from different parts of the country.[3,14,15] It was also found from this study that RDS (36.8%), neonatal sepsis (26.3%), NEC (15.7%), and birth asphyxia (21.1%) were the major causes of mortality among pre-term babies. On analysis, the present study shows that mortality percentage among pre-term babies weighing <1 kg was 85.7%, between 1 kg and <1.5 kg was 14.5%, and 1.5 kg to <2.5 kg was only 4.1%. Further, the highest percentage of death of pre-term babies was seen in less than 28-week gestation (83.3%), followed by 15.9% death in 28–31 weeks and lowest rate (4.2%) in 34–<37 weeks of gestation. This shows that survival rate improves with increased gestational age and more birth weight. Similar observations were made by various workers.[13-16,18-22]

Limitations of the study

One of the limitations of the present study was that it was an observational study. Moreover, in this study, the sample size was small and done over a short period. Hence, further study with large sample size and for a long period is needed.

CONCLUSION

Pre-term babies are at risk for early neonatal morbidities and mortality. The common morbidities are hyperbilirubinemia, RDS, hypoglycemia, neonatal sepsis, etc. The major causes of mortality are RDS, birth asphyxia, and neonatal sepsis. To prevent these morbidities and mortality, it is essential that pre-term babies should be managed in a well-equipped Neonatal Intensive Care Unit where they can be taken care of properly. This will improve the outcome of pre-term babies.

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DK- Study concept, design, study protocol, data collection, data analysis, manuscript writing, submission of article, manuscript editing, and revision; **MR-** Data collection, data analysis, manuscript writing; **DB-** Data collection, data analysis, manuscript writing.

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