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**ORIGINAL ARTICLE**

# COMPARISON OF COMMON ADVERSE NEONATAL OUTCOMES AMONG PRETERM AND TERM INFANTS AT THE NATIONAL REFERRAL HOSPITAL IN TANZANIA: A CASE-CONTROL STUDY

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**Abstract**

***Background:*** *Neonatal period is a critical period in a child's heath because it is associated with higher risk of adverse health outcomes. The objective of this study was to assess common adverse health outcomes and compare the risk of such outcomes between preterm and term neonates, in Tanzania.*

***Methods:*** *This was a case-control study involving infants admitted at Muhimbili National Hospital between August and October 2020. About 222 pairs of preterm and term infants were followed until discharge. Logistic regression was used to compare risk of health outcomes. Statistical significance was achieved at p–value < 0.05 and 95% confidence interval.*

***Result****: Preterm neonates had increased risk of mortality (OR = 7.2, 95% CI: 3.4---- – 15.1), apnea (OR = 4.7, 95% CI: 3.4 – 15.1), respiratory distress syndrome (OR = 10.9, 95% CI: 6.1 – 19.6), necrotizing enterocolitis (OR = 5.5, 95% CI: 1.2 – 25.3), anemia (OR = 4.3, 95% CI: 2.8 – 6.6), pneumonia (OR = 2.7, 95% CI: 1.6 – 4.6) and sepsis (OR = 2.6, 95% CI: 1.7 – 3.9). No difference in risk of intraventricular hemorrhage, patent ductus arteriosus and jaundice was observed.*

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***Conclusion:*** *For promoting neonates' health, prevention and treatment of the higher risk adverse neonatal outcomes should be prioritized.*

**Keywords:** neonatal outcomes, infants, prematurity, Tanzania

## Introduction

Neonatal period is the most critical time in a child's life. This is a time of major and rapid anatomical and physiological changes required for a newborn's adaptation to extra-uterine life. The changes may also be accompanied by adverse outcomes resulting from failure to adapt or a definite high risk of infection. These outcomes put neonates at the highest risk of mortality and morbidity than infants of older age group [1].

Neonatal mortality is responsible for approximately 50% of all deaths in children under five years [2]. Around two-third of these deaths occur in only ten countries, all low or middle-income countries [3]. The predominant causes of adverse neonatal outcomes are preterm birth, infections, intrapartum-related complications and congenital anomalies. According to the World Health Organization (WHO) and the Maternal and Child Epidemiology Estimation group, it was estimated that in 2017 preterm birth, intrapartum-related complications and infections accounted for 35%, 24%, 14% and 73%, respectively, of neonatal deaths worldwide [4].

With an estimated 45,000 neonatal deaths annually and a mortality rate of 32 per 1000 live births, Tanzania ranks number ten among countries with the greatest number of neonatal deaths [5]. Preterm birth accounts for 35% of the neonatal deaths in Tanzania [6]. Nearly one out of two preterm infants experience adverse health outcomes during the neonatal period, making the risk of morbidity five times higher compared to term infants [7,8]. Although most neonatal health problems are preventable, neonatal health complications and mortality remain high in Tanzania [9]. This study aimed to assess common adverse health outcomes and compare the risk of such outcomes between preterm (born at less than 37 weeks gestation) and term infants (born at greater than or at 37 weeks gestation) within the first 28 days of life .

## Methods

### Study Site

This research was conducted at the Muhimbili National Hospital (MNH). MNH is located in Dar es Salaam-Tanzania (-6.803°S, 39.272°E) on a natural harbor on East Africa's eastern coast. MNH is a national referral and a teaching hospital for medical students, nurses and postgraduates from the Muhimbili University of Health and Allied Sciences (MUHAS). It is also a hospital that attends inpatients, outpatients and referral cases from all over the country. The hospital has a maternity block where reproductive services are offered. After delivery, newborns are admitted in the postnatal ward until discharge or may be moved to the Neonatal Intensive Care Unit (NICU) if

they are born with or develop health complications.

**Study Design**

A hospital-based case control study was conducted on newborns within the first month of life between August and October 2020. Newborns were defined as preterm or term. Preterm infants were those born at <37 weeks gestation and were regarded as cases. Term infants were those born at ≥37 weeks gestation and were regarded as controls. Gestational age was determined using the first day of last menstrual cycle and/or first trimester ultrasound. Cases were obtained through consecutive enrollement of delivered preterm babies until the desirable sample size was met. Controls were obtained through the identification of a term infant born immediately after a preterm infant was enrolled.

**Sample Size Determination**

The sample size was calculated using EPI info (7.1.3.10) matched pair formula for case-control studies. The minimum sample size at 95% confidence interval (CI), 80% power and 15% prevalence of preterm birth was 106 pairs. In this study, the sample size was increased to compensate for possible incomplete records.

**Inclusion and Exclusion Criteria**

Only live and admitted newborns who were inborn of MNH were eligible for the study. A live newborn was defined by presentation of a cry, breathing or movement after delivery and Apgar score of greater than one at one and five minutes. Newborns whose parents did not provide a written informed consent were excluded from the study. Newborns with congenital anomalies were also excluded from the study.

**Data Collection**

Infants were enrolled in the delivery room then follow up was done in the admission wards (postnatal ward or NICU). Birth details including infant's identification, gestational age, sex, Apgar score, birth weight and admission ward were recorded immediately after birth. Infants were also followed for their health outcomes and the pre-identified adverse neonatal outcomes were recorded in a pre-structured chart. Data was collected from the time of birth to discharge, death or end of the neonatal period. Generally, the allocated minimum and maximum number of days for data collection were one and 28 days, respectively.

**Statistical Analysis**

Data was recorded in hard copy then transferred and analyzed using Statistical Package for the Social Sciences (SPSS) version 20 (IBM Corp., Armonk, NY, USA) for Windows. Descriptive statistics were used to summarize outcomes as means and proportions. T–test was used to determine the statistical significance of means. For proportions, the fisher's exact test was used. Logistic regression was used to compare the risk of neonatal outcomes between the study groups. A p–value of less than 0.05 at 95% CI was considered statistically significant.

**Ethics Approval and Consent to Participate**

Neonates were included in the study after obtaining a written informed consent from their

parents. The National Health Research Ethics Committee (NatHREC) of the National Institute of Medical Research (NIMR) approved this study with reference number NIMR/HD/R.8a/Vol.IX/3006.

**Operational definitions**

**IVH**: Bleeding inside the ventriles of the brain caused by presence of fragile brain blood vessels and disturbance in the celebral blood flow. Presumptively diagnosed by neurological symptoms such as convulsion and restlessness, decrease in haemoglobin level. Diagnostic investigation was done by ultrasound of the brain.

**RDS**: A respiratory disease due to immature lungs that was clinically diagnosed by presence of fast breathing (>70 breaths per minute), grunting, severe wall indrawing, intercostal retractions, diminished breath sound and bluish discoloration of membrane and skin.

**PDA**: Failure of ductus arteriosus to close that was clinically diagnosed by presence of machinery murmur during auscultation of the heart. Diagnostic investigation involved chest x-ray and echocardiography.

**NEC**: Ischemic and inflammatory necrosis of bowel after initiation of enteral feeding. Clinical presentation included abdominal distantion and tenderness, and vomiting and stool in blood. Diagnostic investigation involved abdominal x-ray or abdominal ultrasound to show inramural gas or free air in the peritoneum.

**Jaundice**: Yellow discoloration of the skin characterized by high level of unconjugated bilirubin (>18 mg/dL).

**Anemia**: Low level of hemoglobin characterised by paleness, decreased activities, tachypnea, features of heart failure and low hemoglobin level (<10 g/dL).

**Neonatal sepsis:** A syndrome with systemic signs and symptoms of bacteremia. Presumptively diagnosed by clinical signs including fast breathing, hyperthermia (T>37.5°C), hypothermia (T<36°C), not feeding well, cyanosis, convulsion and drowsiness. Diagnostic investigation involved full blood picture.

**Results**

A total of 222 case-control pairs were recruited in this study. Sixteen (7.2%) preterm infants and five (2.3%) term infants, respectively, were excluded from the analysis due to congenital malformations or unsigned parent consent forms. Of the remaining 206 preterm infants, 9 (4.4%) were extreme preterm (less than 28 weeks gestation) who weighed more than 500 g, 63 (30.6%) were very preterm (28 –31 weeks gestation) and 134 (65.0%) were moderate to late preterm (32–36 weeks gestation).

Baseline neonatal characteristics are presented in Table 1. There were more males than females in both case and control groups, although the proportion of male to female was not statistically significantly different. Mean birth weight was 2.0±0.7 kg for preterm infants and 3.1 ± 0.6 kg for term infants. There as a statistically significant difference in the mean birth weight ( p–value < 0.001).

The proportion of preterm infants who weighed less than 2,500 g was significantly higher when compared to term infants (p–value < 0.001). There was no significant difference for less than or equal to five Apgar score at one and five minutes between the two groups.

Table 1: Baseline characteristics of preterm and term infants at Muhimbili National Hospital

| **Characteristics** | **N (%)** | | **p–value** |
|---|---|---|---|
| | Preterm (n = 206) | Term (n = 217) | |
| Sex | | | |
| Male | 110 (53.4) | 132 (60.8) | 0.140 |
| Female | 96 (46.6) | 85 (39.2) | |
| Birth weight (grams) | | | |
| ≥ 2500 | 47 (22.8) | 192 (88.5) | < 0.001 |
| < 2500 | 159 (77.2) | 25 (11.5) | |
| Apgar score ≤ 5 | | | |
| At 1 minute | 31 (15.0) | 22 (10.1) | 0.29 |
| At 5 minute | 8 (3.9) | 2 (0.9) | |

On average, the duration of hospital stay was longer for preterm than term infants (eleven vs. four days), and the difference was statistically significant (p–value < 0.05). Apnea, respiratory distress syndrome (RDS), necrotizing enterocolitis (NEC), pneumonia, anemia and sepsis were significantly common among preterm than term infants (Table 2). No significant differences were observed between the two groups for intraventricular hemorrhage (IVH), patent ductus arteriosus (PDA) and jaundice (p –value = 0.06, 0.11 and 0.20, respectively).

Table 2: Health complications among babies born at <37 (preter) and ≥37 weeks (term)gestation

| **Complications** | **Preterm (N = 206)** | | **Term (N = 217)** | | **p–value** |
|---|---|---|---|---|---|
| | N | % | N | % | |
| Death | 49 | 23.8 | 9 | 4.2 | < 0.001 |
| Apnea | 149 | 72.3 | 78 | 35.9 | < 0.001 |
| IVH | 4 | 1.9 | 0 | 0.0 | 0.055 |
| RDS | 92 | 44.7 | 15 | 6.9 | < 0.001 |
| PDA | 3 | 1.5 | 0 | 0.0 | 0.115 |
| NEC | 10 | 4.9 | 2 | 0.9 | 0.018 |
| Jaundice | 119 | 57.8 | 111 | 53.9 | 0.200 |
| Anemia | 106 | 51.5 | 43 | 19.8 | < 0.001 |
| Pneumonia | 52 | 25.2 | 24 | 11.1 | < 0.001 |
| Sepsis | 105 | 51.0 | 62 | 28.6 | < 0.001 |

Abbreviations: IVH, intraventricular hemorrhage; RDS, respiratory distress syndrome; PDA, patent ductus arteriosus; NEC, necrotizing enterocolitis

Generally, 175/206 (85.0%) preterm infants and 94/217 (43.3%) term infants had at least one adverse outcome and the difference was statistically significant (p–value < 0.001). The proportion of infants with at least one outcome increased with lower gestational ages (Figure 1). All infants born at less than 28 weeks had at least one adverse outcome. Also, 93.7% and 79.9% of those born between 28–31 weeks and 32–36 weeks, respectively, had at least adverse outcomes. However, the majority of those born at greater than or equal 37 weeks had no adverse outcome.

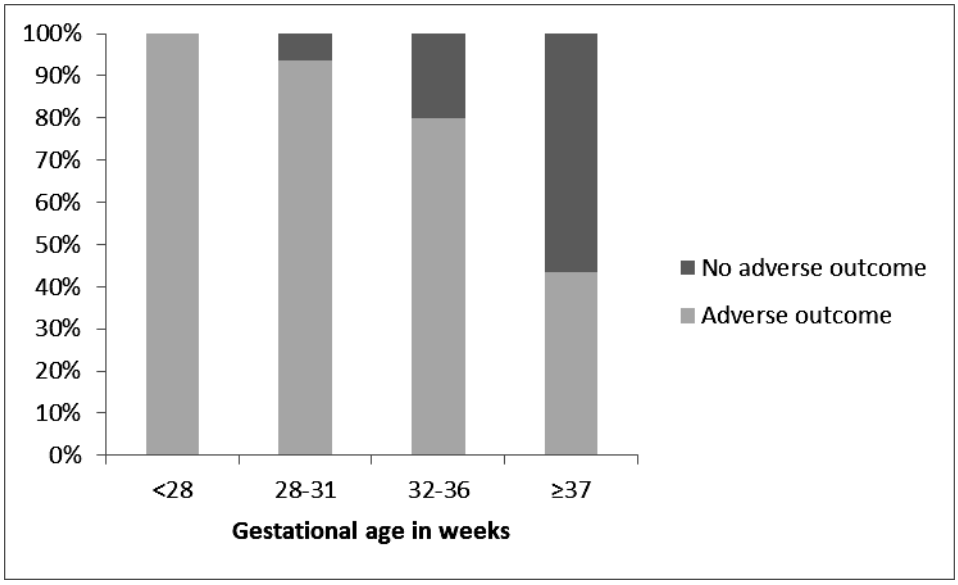


Figure 1- Proportion of infants with and without health complications across gestational age groups

Furthermore, preterm infants had a significantly higher mortality rate than term infants during the neonatal period (p–value < 0.001). There were more deaths in lower gestational ages than in higher gestational ages. Forty-nine out of 206 (23.8%) preterm infants and nine out of 217 (4.1%) term infants died within the neonatal period (Table 2). The number of deaths to the number of births increased substantially with decreasing gestational age group (Figure 2). While only 9/217 infants born at greater than or equal to 37 weeks died, all (9/9) infants born at less than 28 weeks died. For gestational ages of 28–31 and 32–36 weeks, 21/63 and 19/134 infants died, respectively.

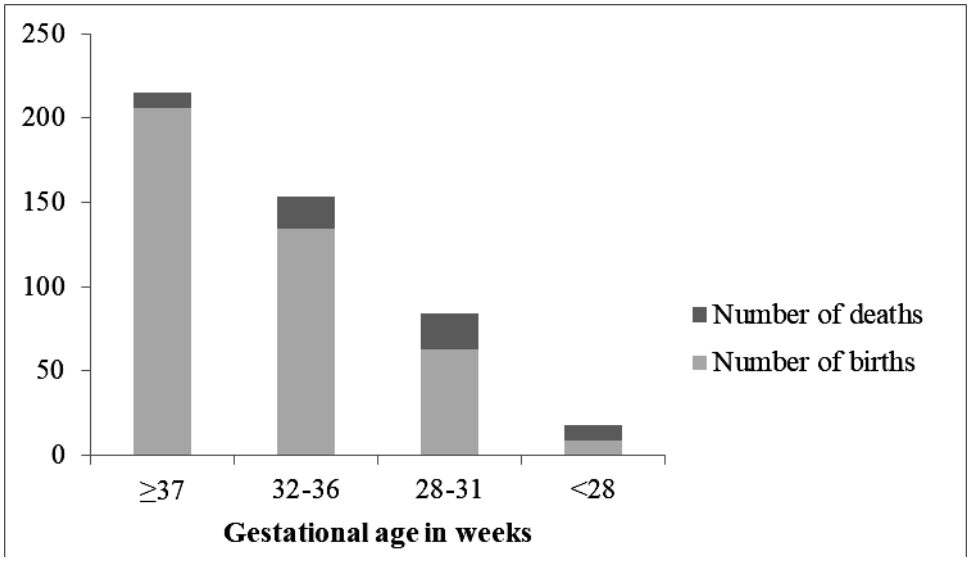


Figure 2: Number of births versus deaths at different gestational ages groups

Table 3 shows the likelihood of the significant adverse outcomes to occur among preterm and term infants. While the risk of RDS was ten times, the risk of apnea and NEC were five times higher among preterm infants than term infants. Preterm infants were four times likely to have anemia than term infants. Similarly, infections like sepsis and pneumonia were nearly three times more common among preterm than term infants. Among the adverse neonatal outcomes with greater odds of occurance. In comparison to term infants, the risk of death was seven-fold higher in preterm infants. The risk of overall morbidity was also higher in preterm infants than term infants by seven-folds.

Table 3: The odds of health complications among preterm and term infants

| Outcome | Preterm infants n = 206 | Term infants n = 217 | OR | 95% CI |
|---|---|---|---|---|
| Mortality‡ | 49 | 9 | 7.2 | 3.4–15.1 |
| Apnea‡ | 149 | 78 | 4.7 | 3.1–7.0 |
| RDS‡ | 92 | 15 | 10.9 | 6.1–19.6 |
| NEC* | 10 | 2 | 5.5 | 1.2–25.3 |
| Anemia‡ | 106 | 43 | 4.3 | 2.8–6.6 |
| Pneumonia† | 52 | 24 | 2.7 | 1.6–4.6 |
| Sepsis‡ | 105 | 62 | 2.6 | 1.7–3.9 |
| Overall morbidity‡ | 175 | 94 | 7.4 | 4.6–11.8 |

Abbreviations: OR; odds ratio, CI; confidence interval, RDS; respiratory distress syndrome, NEC; necrotizing enterocolitis
*; < 0.05, †; < 0.01, ‡; < 0.001

## Discussion

This study assessed adverse neonatal outcomes and compared the risk between preterm and term infants. The findings indicate that nearly a quarter (23.8%) of preterm infants and only 4.1% of term infants died during the neonatal period. A similar mortality rate of 28% for preterm and 6% for term infants was reported in a study conducted in Bangladesh [10]. Contrary, a lower mortality rate among preterm infants was reported in high-income countries like Australia (7.7%) and the USA (1.4%) [11,12]. These differences show that preterm infants in low and low-middle-income countries are at a greater risk of mortality than those in high-income countries. Mortality risk was seven times higher (OR = 7.21, 95% CI; 3.44–15.12) in preterm infants than term infants. Previous studies have also reported a five to 12 increased risk of mortality in preterm infants [7,13,14].

Number of deaths to live births significantly increased with decreasing gestational age and led to as high as 100% mortality rate among extreme preterm infants. A very high mortality rate among extreme preterm infants is not surprising. In a similar situation in England, a survival rate of only 2% (98% mortality rate) in extreme preterm infants was reported [15]. For moderate and late preterm infants, more than one-third and one-seventh of the infants died, respectively. A higher mortality rate among moderate (54%) than late preterm infants (13.2%) was also reported in a prospective study for causes of death and illnesses in preterm infants in Ethiopia [16].

The current study observed that, on average, preterm infants had a longer duration of hospitalization than term infants (eleven vs. four days). A comparable duration of ten days for preterm and five days for term infants was reported in a previous study comparing short-term neonatal morbidity between preterm and term infants [17]. However, a national-wide survey reported a considerably longer duration of hospitalization for preterm infants that ranged between three to 74 days depending on the degree of prematurity of an infant [11]. Fewer days of hospitalization in the present study may be due to early deaths among preterm infants. Also, in this study, there were only a few extreme preterm infants, that are usually the ones staying longer at the hospital [11].

The present study shows that the proportion of preterm infants with neonatal morbidity was nearly twice that of term infants (84.9% vs. 43.3%). In a study conducted in Bangladesh, similar proportions were observed, whereby 76% of preterm and 28% of term infants had morbidities [10]. The most common morbidity among preterm infants was apnea (72.3%). Similarly, previous studies have reported respiratory complications, including apnea, as the most common complications among preterm infants [18]. For term infants, the most common condition was jaundice (53.9%).

Respiratory complications affected only 7% of the term infants. This propotion aligns with the range 4–7% of RDS prevalence in term infants that was reported from other studies [19]. Unlike term infants, preterm infants had higher prevalence and were at a higher risk of apnea and RDS because they are more likely to have immaturity of the brain and respiratory system that may lead to weakness of the muscles that keep the airway open as well as insufficient amount of surfactant at the time of birth and are likely to have an immature nervous system [20,21].

Among the leading causes of death in children are infections such as sepsis and pneumonia [3]. In sub-Saharan Africa, for instance, pneumonia is the leading cause of mortality in under-five children [2]. In the present study, compared to term infants, preterm infants had a higher risk of both sepsis (51.0% vs. 19.0%) and pneumonia (25.2% vs. 11.1%). It was found that the odds of sepsis and pneumonia were two and three folds higher (OR = 2.60, 95% CI; 1.74–3.88 and OR = 2.72, 95% CI; 1.60–4.60), respectively, in preterm infants. A two-fold increased risk of neonatal infection among preterm infants has also been reported in other studies investigating adverse neonatal outcomes and the epidemiology of neonatal sepsis [22,23]. Immunological deficiencies among preterm infants make them fail to fight early life infections cause of the higher risk of infections [24].

About 51.5% of preterm infants and 19.8% of term infants had anemia resulting in four times increased risk in preterm infants (OR = 4.28, 95% CI; 2.79–6.60). The incidence of 58.2% and 21.0% for preterm and term infants, respectively, were also reported elsewhere [25,26]. Compared to term infants, typically preterm infants have a lower number of red blood cells which also have a short life span, thus exposing them to an increased risk of anemia that may require blood transfusion [27]. NEC, on the other hand, was not as common as other complications. However, the risk was five times higher for preterm infants. Likewise, four times increased risk among preterm infants was observed in a retrospective study conducted in late preterm infants, although only 0.4% of preterm and 0.1% term infants had NEC [28]. Despite the low prevalence reported in different studies, NEC is among the most detrimental neonatal outcomes. It is associated with a high mortality rate among victims, particularly preterm infants and it is the leading cause of death among infants admitted in NICUs [29].

The overall odds of morbidity were seven times higher among preterm infants compared to term infants. Similar odds of morbidity among preterm infants were reported in a study conducted in Switzerland [17]. The proportion of infants with adverse outcomes increased with decreased gestational age. Various studies have documented that the longer the baby stays in the womb, the lower the risk of adverse neonatal outcomes [11,28,30].

This study is not without limitations. Firstly , the assessment of adverse neonatal outcomes

in this study was done between birth and discharge. Adverse outcomes that occurred after discharge were not traced. However, with an adequate number of enrolled participants, we could still establish significant findings that align with similar studies from different parts of the world. Secondly, this assessment addressed only some adverse outcomes but the range of outcomes is wide. Some events such as the need for resuscitation at birth, admission temperature, feeding type were not included in the assessment. We recommend addressing of this shortcoming in other researches. Lastly, this study did not analyze the impact of confounders such as infant age and maternal factors thus interpretation of the findings presented here should be treated with caution.

## CONCLUSION AND RECOMMENDATIONS

Preterm infants have an increased risk of mortality, apnea, RDS, NEC, anemia, pneumonia and sepsis in the first month of life compared to term infants. No increased risk was observed for IVH, PDA and jaundice. Following the observed high mortality risk in preterm infants, this research recommends researchers and health workers to continue working to find ways to prevent preterm birth, stop delivery as a result of preterm labor and understand health challenges of preterm infants for the aim of establishing treatment strategies. Pregnant women should also receive adequate prenatal care and education so as to ensure the risk of preterm birth as a result of preventable factors is reduced.

## ACRONYMS

| | |
|---|---|
| IVH | Intraventricular Hemmorhage |
| MNH | Muhimbili National Hospital |
| NatHREC | National Health Research Ethics Committee |
| NEC | Necrotizing Enterocolitis |
| NICU | Neonatal Intensive Care Unit |
| NIMR | National Institute for Medical Research |
| PDA | Patent Ductus Arteriosus |
| RDS | Respiratory Distress Syndrome |

## DECLARATIONS

**Author's contribution:** All authors have equal contribution.

**Competing interest:** The authors decares no conflict of interest.

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