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Original Research Article

Incidence of Retinopathy of Prematurity in Early Onset Neonatal Sepsis

Dr. Tasnim Khanom[1], Dr. Rozina Akhter[2], Dr. Shahina Pervin[3], Prof. Dr. Md. Sanwar Hossain[4]

[1]Associate Professor, Department of Ophthalmology, Dr. Sirajul Islam Medical College and Hospital Ltd, Dhaka, Bangladesh
[2]Associate Professor, Department of Paediatrics, Dr. Sirajul Islam Medical College and Hospital, Dhaka, Bangladesh
[3]Associate Professor, Department of Paediatrics, Dr. Sirajul Islam Medical College and Hospital, Dhaka, Bangladesh
[4]Professor, Department of Ophthalmology, Dr. Sirajul Islam Medical College and Hospital Ltd, Dhaka, Bangladesh

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Abstract: ***Background:*** Retinopathy of prematurity (ROP) is a leading cause of visual impairment in premature neonates. Early-onset neonatal sepsis, has been identified as a potential contributing factor to the incidence of ROP. ***Aim of the study:*** The aim of this study was to assess the incidence of retinopathy of prematurity in early onset neonatal sepsis. ***Methods:*** This cross-sectional study was conducted in Department of Ophthamology and Neonatal Intensive Care Unit (NICU), Dr. Sirajul Islam Medical College & Hospital Ltd., Dhaka, Bangladesh from June 2022 to July 2024. Total 300 preterm neonates with ROP were included in this study. Then, they were divided into two groups- group A: 150 patients with early onset neonatal sepsis and group B: 150 patients with late onset neonatal sepsis. ***Result:*** The mean gestational age in Group A was significantly lower (28.9 ± 2.3 weeks) than Group B (30.1 ± 2.2 weeks) ($p < 0.01$). Maternal infections were higher in Group A (50%). Oxygen therapy duration was longer in Group A (14 ± 3 days) than in Group B (10 ± 2 days) ($p < 0.01$). Group A had more cases of ROP (70% vs. 57%, $p = 0.02$). Risk factors for ROP included gestational age <28 weeks (OR = 2.10), oxygen therapy (OR = 1.60), and mechanical ventilation (OR = 1.45). ***Conclusion:*** This study concludes that neonates with early-onset neonatal sepsis had higher incidence and severity of ROP, with key risk factors being low gestational age, prolonged oxygen therapy, mechanical ventilation, and maternal infections.

Keywords: Incidence, Retinopathy of Prematurity, and Early Onset Neonatal Sepsis.

INTRODUCTION

Retinopathy of Prematurity (ROP) is a leading cause of preventable childhood blindness globally, predominantly affecting preterm neonates with low birth weight. Defined as a disorder of the developing retinal vasculature, ROP occurs due to abnormal vascular proliferation following premature birth [1]. Among neonates born at less than 28 weeks of gestation, ROP affects approximately 60% [2]. Despite advancements in neonatal care in high-income countries that have reduced the incidence and severity of ROP, the condition remains a significant public health challenge in LMICs, where the growing survival rate of preterm neonates has inadvertently increased ROP cases [3]. Early Onset Neonatal Sepsis (EONS), defined as sepsis occurring within the first 72 hours of life, is a severe condition in neonates, typically associated with bacterial infections acquired during birth [4]. EONS is a major contributor to neonatal morbidity and mortality [5]. In Bangladesh, EONS is responsible for 15-20% of neonatal deaths, with an estimated incidence of 6.7 per 1,000 live births [6]. Factors such as prematurity, prolonged rupture of membranes, and maternal infections have been identified as major risk factors for the development of EONS [7]. While ROP is a well-recognized issue in preterm neonates, the role of EONS in increasing the risk and severity of ROP remains under investigation. Systemic inflammation induced by neonatal sepsis has been postulated as a potential mechanism that exacerbates retinal vascular damage, leading to worse outcomes in premature neonates [1]. Studies have shown that systemic inflammation can perturb retinal angiogenesis, resulting in abnormal vascular proliferation and an increased risk of severe ROP [8, 9]. Neonatal sepsis, particularly EONS, is believed to initiate inflammatory processes that disrupt normal retinal development, potentially accelerating the progression of ROP [10]. Preterm neonates in Bangladesh are often exposed to suboptimal neonatal care, including inadequate oxygen regulation and a high prevalence of maternal infections, both of which are known to increase the risk of neonatal sepsis and its complications [11]. Studies from South Asia have reported that 22-30% of premature neonates

***Corresponding Author:** Dr. Tasnim Khanom
Associate Professor, Department of Ophthalmology, Dr. Sirajul Islam Medical College and Hospital Ltd, Dhaka, Bangladesh

develop ROP, with neonatal infections contributing significantly to disease progression [2]. The pathophysiology of ROP involves two key phases: Phase I, characterized by retinal vaso-obliteration due to hyperoxia, and Phase II, marked by vasoproliferation in response to hypoxia [12]. Oxygen therapy, while essential for the survival of preterm neonates, can exacerbate these processes, leading to abnormal retinal vascular development [13]. Neonatal sepsis, particularly EONS, further complicates this dynamic by introducing systemic inflammation, which disrupts normal retinal angiogenesis and impairs vascular regulation [9]. In LMICs like Bangladesh, where the incidence of preterm births is high, neonatal sepsis remains a major challenge. Studies conducted in Bangladesh have shown that preterm neonates with sepsis are at an increased risk of developing ROP, with a 70% incidence rate of ROP in neonates with sepsis compared to 58% in those without sepsis [14]. These findings emphasize the need for improved neonatal care practices, including early screening for ROP and timely management of neonatal infections to reduce the incidence of severe ROP. Moreover, the high rates of EONS and ROP in Bangladesh call for further research to better understand the relationship between these two conditions and develop targeted interventions to mitigate their impact on neonatal health.

Objective

To assess the incidence of retinopathy of prematurity in early onset neonatal sepsis.

METHODOLOGY & MATERIALS

This cross-sectional study was conducted in Department of Ophthamology and Neonatal Intensive Care Unit (NICU), Dr. Sirajul Islam Medical College & Hospital Ltd., Dhaka, Bangladesh, during the period from June 2022 to July 2024. Total 300 preterm neonates with retinopathy of prematurity were included in this study. These study subjects were divided into two groups- group A: 150 patients with early onset neonatal sepsis (EONS) and group B: 150 patients with late onset neonatal sepsis (LONS). The inclusion criteria were preterm neonates admitted to the NICU within the first 72 hours of birth, diagnosed with retinopathy of prematurity based on clinical signs of sepsis and confirmed by positive blood cultures or elevated inflammatory markers. Neonates with major congenital anomalies or severe birth asphyxia were excluded from the study to eliminate confounding variables. Data collection began upon admission to the NICU, where clinical and demographic data, including gestational age, birth weight, Apgar scores, and maternal history (e.g., presence of infections or prolonged rupture of membranes), were recorded. Neonatal sepsis was diagnosed based on clinical criteria, such as respiratory distress, temperature instability, and feeding intolerance, along with microbiological evidence of infection within 72 hours of life. Additionally, inflammatory markers such as C-reactive protein (CRP) and white blood cell counts were measured. ROP screening was conducted by a qualified ophthalmologist using indirect ophthalmoscopy at 32 weeks postmenstrual age or 4 weeks after birth, whichever comes first. The screening followed the International Classification of ROP (ICROP) to assess the presence and severity of the condition. The primary outcome of interest was the incidence of ROP in neonates with confirmed EONS and with confirmed LONS. Secondary outcomes included the severity of ROP in relation to the severity of sepsis and other neonatal variables, such as the duration of oxygen therapy and mechanical ventilation. Ethical approval was obtained from the hospital review boards, and informed consent was sought from the parents or legal guardians of all participating neonates before enrollment in the study. After cleaning, the data were entered into computer and statistical analysis of the results being obtained by using windows-based computer software devised with Statistical Packages for Social Sciences version 22. P value of less than 0.05 was considered statistically significant.

RESULT

Table I demonstrates the demographic characteristics of the study groups (Group A and Group B). The mean gestational age in Group A is significantly lower at 28.9 ± 2.3 weeks compared to 30.1 ± 2.2 weeks in Group B (p-value <0.01), indicating that neonates in Group A are more premature. The gender distribution is similar in both groups, with 57% males in Group A and 53% in Group B, and this difference is not statistically significant (p-value = 0.2). The mean birth weight in Group A is significantly lower at 1280 ± 350 grams compared to 1420 ± 310 grams in Group B (p-value <0.01), highlighting that neonates in Group A have a lower birth weight. The Apgar score at 1 minute is lower in Group A (5.2 ± 1.8) compared to Group B (5.8 ± 1.2), with a marginally significant p-value of 0.05, suggesting that neonates in Group A may have had a more compromised condition immediately after birth. The Apgar score at 5 minutes, although higher in both groups, is still lower in Group A (6.8 ± 1.6) compared to Group B (7.3 ± 1.4), but this difference is not statistically significant (p-value = 0.08). Table II presents the clinical characteristics of the study groups. Maternal infections were significantly higher in Group A, with 50% of mothers experiencing infections compared to 40% in Group B (p-value = 0.02), suggesting a greater likelihood of neonatal complications in the EONS group. Prolonged rupture of membranes was also more common in Group A (42%) than in Group B (38%) with a statistically significant p-value of 0.03, indicating that this risk factor may contribute to sepsis. Cesarean deliveries were more frequent in Group A (40%) compared to Group B (30%) (p-value = 0.01). Neonates in Group A required oxygen therapy for a longer duration (14 ± 3 days) than those in Group B (10 ± 2 days) (p-value <0.01), suggesting more severe respiratory distress in the EONS group. Mechanical ventilation was also more common in Group A (30%) compared to Group B (20%) (p-value = 0.05),

further indicating that neonates with EONS had more severe respiratory complications. Table III shows the incidence of Retinopathy of Prematurity (ROP) between the two groups. A significantly higher proportion of neonates in Group A (70%) developed ROP compared to 57% in Group B (p-value = 0.02), highlighting the potential role of EONS in increasing the risk of ROP. Conversely, 43% of neonates in Group B did not develop ROP, compared to only 30% in Group A. Table IV compares the severity of ROP between the two groups. A higher proportion of neonates in Group B had no ROP (43%) compared to Group A (30%) (p-value = 0.01), while mild (Stage 1) ROP was more common in Group B (33%) than in Group A (27%) (p-value = 0.04). However, moderate (Stage 2) ROP was significantly more frequent in Group A (23%) than in Group B (13%) (p-value = 0.03), and severe (Stage 3) ROP occurred in 10% of neonates in Group A compared to 7% in Group B (p-value = 0.05). Stages 4 and 5 of ROP (very severe and retinal detachment) were more prevalent in Group A, although these differences were not statistically significant. Table V presents the univariate analysis of risk factors for ROP between the two groups. EONS was associated with an increased risk of ROP with an odds ratio of 1.85 (95% CI: 1.20-2.80) and a p-value of 0.02. Gestational age of less than 28 weeks was the strongest risk factor, with an odds ratio of 2.10 (95% CI: 1.30-3.00) and a highly significant p-value of <0.001. Birth weight below 1500 grams was also associated with an increased risk of ROP (OR = 1.95, p-value = 0.03). Oxygen therapy for more than 10 days (OR = 1.60, p-value = 0.04) and mechanical ventilation (OR = 1.45, p-value = 0.05) were additional significant risk factors. Maternal infections (OR = 1.70, p-value = 0.02) and prolonged rupture of membranes (OR = 1.50, p-value = 0.03) were also identified as significant risk factors for the development of ROP.

Table-I: Demographic characteristics of the study groups (N=300)

Characteristics	Group A (n=150)	Group B (n=150)	p-value
Gestational Age (weeks, mean ± SD)	28.9 ± 2.3	30.1 ± 2.2	<0.01
Gender (Male, %)	86 (57%)	80 (53%)	0.2
Birth Weight (grams, mean ± SD)	1280 ± 350	1420 ± 310	<0.01
Apgar Score at 1 minute (mean ± SD)	5.2 ± 1.8	5.8 ± 1.2	0.05
Apgar Score at 5 minutes (mean ± SD)	6.8 ± 1.6	7.3 ± 1.4	0.08

Statistical analysis was done by Chi-square test
p value < 0.05 indicates significant

Table-II: Clinical characteristics of the study groups (N=300)

Characteristics	Group A (n=150)	Group B (n=150)	p-value
Maternal Infections (%, n)	75(50%)	60 (40%)	0.02
Prolonged Rupture of Membranes (%)	63 (42%)	57 (38%)	0.03
Cesarean Delivery (%)	60 (40%)	45 (30%)	0.01
Oxygen Therapy (days, mean ± SD)	14 ± 3	10 ± 2	<0.01
Mechanical Ventilation (%, n)	45 (30%)	30 (20%)	0.05

Statistical analysis was done by Chi-square test
p value < 0.05 indicates significant

Table-III: Incidence of ROP between the study groups (N=300)

Group	ROP Cases (n, %)	No ROP Cases (n, %)	p-value
EONS (Group A)	105 (70%)	45 (30%)	0.02
LONS (Group B)	85 (57%)	65 (43%)	0.02

Statistical analysis was done by Chi-square test
p value < 0.05 indicates significant

Table-IV: Comparison of severity of ROP between the study groups (N=300)

ROP Severity	Group A (n=150)	Group B (n=150)	p-value
No ROP	45 (30%)	65 (43%)	0.01
Stage 1 (mild)	40 (27%)	50 (33%)	0.04
Stage 2 (moderate)	35 (23%)	20 (13%)	0.03
Stage 3 (severe)	15 (10%)	10 (7%)	0.05
Stage 4 (very severe)	10 (7%)	5 (3%)	0.08
Stage 5 (retinal detachment)	5 (3%)	0	0.1

Statistical analysis was done by Chi-square test
p value < 0.05 indicates significant

Table-V: Risk factors for ROP (Univariate Analysis) between the two groups (N=300)

Risk Factor	Odds Ratio (95% CI)	p-value
EONS	1.85 (1.20-2.80)	0.02
Gestational Age <28 weeks	2.10 (1.30-3.00)	<0.001
Birth Weight <1500 grams	1.95 (1.15-2.50)	0.03
Oxygen Therapy (≥10 days)	1.60 (1.10-2.20)	0.04
Mechanical Ventilation	1.45 (1.05-2.00)	0.05
Maternal Infections	1.70 (1.25-2.40)	0.02
Prolonged Rupture of Membranes	1.50 (1.10-2.10)	0.03

Statistical analysis was done by Chi-square test
p value < 0.05 indicates significant

DISCUSSION

This cross-sectional study was conducted in Department of Ophthamology, Dr. Sirajul Islam Medical College & Hospital Ltd., Dhaka, Bangladesh, during the period from June 2022 to July 2024. The current study aimed to evaluate the incidence of Retinopathy of Prematurity (ROP) in relation to Early Onset Neonatal Sepsis (EONS) among preterm neonates in Bangladesh. Total 300 preterm neonates with retinopathy of prematurity were included in this study. These study subjects were divided into two groups- group A: 150 patients with early onset neonatal sepsis (EONS) and group B: 150 patients with late onset neonatal sepsis (LONS). The gestational age and birth weight were significantly lower in neonates with EONS (28.9 ± 2.3 weeks and 1280 ± 350 grams) compared to neonates with LONS (30.1 ± 2.2 weeks and 1420 ± 310 grams). These differences suggest that neonates with EONS tend to be more premature and of lower birth weight, both of which are well-established risk factors for ROP. This is consistent with the findings from Hakeem *et al.*, [15], who also demonstrated that lower gestational age and birth weight are significant predictors of ROP. Furthermore, the Apgar scores at 1 and 5 minutes were lower in neonates with EONS, with scores of 5.2 ± 1.8 and 6.8 ± 1.6, respectively, compared to 5.8 ± 1.2 and 7.3 ± 1.4 in neonates with LONS. While these differences were not all statistically significant, they align with observations from studies such as that by Shreetal *et al.*, [16], which found that low Apgar scores were an important risk factor for adverse neonatal outcomes, including ROP. The clinical characteristics of the neonates in this study further emphasized the increased risk associated with EONS. Maternal infections were significantly higher in neonates with EONS (50% compared to 40% in neonates with LONS), and prolonged rupture of membranes (PROM) was more frequent in neonates with EONS (42% vs. 38%). These findings are consistent with those of Boskabadi *et al.*, [14], who demonstrated that maternal infections and PROM were significant contributors to neonatal complications, including sepsis and its sequelae such as ROP. The increased rate of cesarean deliveries in neonates with EONS (40% compared to 30% in neonates with LONS) further suggests that these neonates were at higher risk for neonatal complications. Prolonged oxygen therapy, required for a significantly longer duration in neonates with EONS (14 ± 3 days vs. 10 ± 2 days in neonates with LONS), further underscores the severity of respiratory complications in neonates with EONS. As demonstrated by Pinheiro *et al.*, [17], prolonged oxygen therapy is a well-established risk factor for ROP. In terms of ROP incidence, this study found that 70% of neonates with EONS developed ROP compared to 57% in neonates with LONS (p = 0.02), with a higher severity of ROP in neonates with EONS. Moderate ROP (Stage 2) occurred in 23% of neonates in neonates with EONS compared to 13% in neonates with LONS (p = 0.03), while severe ROP (Stage 3) was observed in 10% of neonates with EONS compared to 7% of neonates with LONS (p = 0.05). These findings strongly suggest that EONS not only increases the risk of developing ROP but also exacerbates its severity. This is in line with the findings from Kumar *et al.*, [18], who reported that sepsis was a significant risk factor for the progression to more severe stages of ROP. Similarly, the study by Bayat-Mokhtari *et al.*, [19] confirmed that neonates requiring prolonged oxygen therapy and mechanical ventilation are at increased risk for severe ROP. The univariate analysis of risk factors in this study found that EONS was associated with a significantly increased risk of ROP, with an odds ratio (OR) of 1.85 (95% CI: 1.20-2.80, p = 0.02). This is consistent with previous studies, such as those by Reyes *et al.*, [20], who also reported that neonatal sepsis, particularly late-onset sepsis, is a critical risk factor for ROP development. Gestational age of less than 28 weeks was the strongest predictor of ROP in this study, with an OR of 2.10 (95% CI: 1.30-3.00, p < 0.001), a finding echoed by Shreetal *et al.*, [16] and Pinheiro *et al.*, [17]. Birth weight below 1500 grams also significantly increased the risk of ROP (OR = 1.95, p = 0.03), further supporting the role of low birth weight as a critical factor in ROP development. Oxygen therapy for more than 10 days (OR = 1.60, p = 0.04) and mechanical ventilation (OR = 1.45, p = 0.05) were additional significant risk factors. These findings are corroborated by studies such as those by Kumar *et al.*, [18] and Pinheiro *et al.*, [17], which demonstrated similar associations between prolonged oxygen exposure and mechanical ventilation and the increased risk of ROP. Maternal infections (OR = 1.70, p = 0.02) and prolonged rupture of membranes (OR = 1.50, p = 0.03) were also identified as significant risk factors in this

study. These findings align with previous research by Boskabadi *et al.,* [14], who highlighted the role of maternal infections and PROM in increasing the risk of neonatal sepsis and subsequent complications, including ROP. In conclusion, this study provides robust evidence that EONS significantly increases the risk and severity of ROP in preterm neonates, with lower gestational age, low birth weight, prolonged oxygen therapy, and mechanical ventilation serving as additional risk factors.

Limitations of the study

In our study, there was small sample size and absence of control for comparison. Study population was selected from one center in Dhaka city, so may not represent wider population. The study was conducted at a short period of time.

CONCLUSION AND RECOMMENDATIONS

This study highlights that neonates with early onset neonatal sepsis showed a higher incidence and severity of retinopathy of prematurity, with key risk factors including low gestational age, prolonged oxygen therapy, mechanical ventilation, and maternal infections. The findings underscore the need for improved neonatal care and sepsis management to reduce ROP-related morbidity, particularly in low-resource settings like Bangladesh. Early intervention is crucial for better neonatal outcomes. Further research, particularly in low-resource settings like Bangladesh, is essential to develop targeted interventions to mitigate these risk factors and improve neonatal outcomes.

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