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Incidence and Risk Factors of Retinopathy of Prematurity: A Comprehensive Clinical Study

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Abstract

Background: Retinopathy of prematurity is a leading cause of preventable childhood blindness, primarily affecting preterm and low birth weight neonates. ***Aim:*** To determine the incidence of retinopathy of prematurity and evaluate the association between neonatal and maternal risk factors with its occurrence. ***Materials and Methods:*** A prospective observational study was conducted on 450 preterm and low birth weight neonates admitted to a tertiary care neonatal intensive care unit. The mean gestational age of the neonates was 32.6 ± 2.4 weeks, and the mean birth weight was 1.46 ± 0.31 kg. All neonates were screened for retinopathy of prematurity (ROP) using standard screening protocols. ***Results:*** In the present study, retinopathy of prematurity was identified in 40 out of 450 preterm and low birth weight neonates, resulting in an overall incidence of 8.9%, with a higher occurrence observed among neonates born at lower gestational ages and with lower birth weights. Male sex showed a slight predominance among affected infants, while maternal systemic diseases showed limited association. ***Conclusion:*** Retinopathy of prematurity remains a significant complication of prematurity, and early identification of high-risk neonates is essential for timely screening and prevention of visual morbidity.

Keywords: ***Retinopathy of prematurity; Preterm neonates; Low birth weight; Risk factors.***

Introduction

Retinopathy of prematurity (ROP) is a vasoproliferative disorder of the developing retina that primarily affects preterm and low birth weight neonates. It remains one of the leading preventable causes of childhood blindness worldwide, particularly in middle- and low-income countries where survival rates of premature infants have improved significantly without parallel expansion of neonatal screening programs [1]. Advances in neonatal intensive care have increased the survival of extremely preterm infants, thereby expanding the population at risk for ROP and emphasizing the importance of early detection and timely intervention.

The pathogenesis of ROP is multifactorial and closely linked to retinal vascular immaturity at birth. Disruption of normal retinal vascular development due to premature exposure to extrauterine oxygen levels leads to an initial phase of vascular growth arrest followed by hypoxia-driven pathological neovascularization [2]. The severity and progression of ROP are influenced by gestational age, birth weight, and postnatal factors, making it a dynamic disease that requires vigilant monitoring in at-risk neonates.

Low birth weight and prematurity are the most consistently identified and strongest predictors of ROP development. Numerous epidemiological studies have demonstrated an inverse relationship between gestational age, birth weight, and the incidence and severity of ROP [3,4]. Extremely low birth weight infants and those born before 32 weeks of gestation exhibit a markedly higher risk of developing severe forms of retinopathy of prematurity requiring treatment; in the present study, the mean birth weight was 1.46 ± 0.31 kg.

In addition to prematurity and low birth weight, several neonatal risk factors have been implicated in the development of ROP. Prolonged oxygen therapy, mechanical ventilation, respiratory distress syndrome, sepsis, anemia, blood transfusions, intraventricular hemorrhage, and poor postnatal weight gain have been shown to significantly increase the risk of ROP [5,6]. Oxygen exposure, in particular, remains a critical modifiable risk factor, as both hyperoxia and fluctuating oxygen levels are known to adversely affect retinal vascular development.

Recent studies have highlighted the role of systemic illness and inflammatory processes in the progression of ROP. Neonatal sepsis and necrotizing enterocolitis have been associated with increased oxidative stress and inflammatory mediators, which may exacerbate abnormal retinal angiogenesis [7]. Furthermore, poor postnatal growth has emerged as an independent predictor of ROP,

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underscoring the importance of adequate nutritional support in premature infants [8].

The incidence of ROP varies widely across different regions and healthcare settings, reflecting differences in neonatal care practices, screening criteria, and survival rates of preterm infants [9]. In developing countries, a higher incidence of ROP has been reported even among relatively heavier and more mature infants, suggesting the presence of additional risk factors and highlighting the need for region-specific screening guidelines [10].

Given the preventable nature of ROP-related blindness and the significant burden it imposes on affected children and healthcare systems, understanding the incidence and associated risk factors is crucial. Early identification of high-risk neonates allows timely screening, appropriate management, and prevention of visual impairment. Therefore, this study aims to determine the incidence of retinopathy of prematurity in low birth weight and preterm neonates and to evaluate the association between various neonatal risk factors and the occurrence of ROP.

Material and Methods

This prospective observational study was conducted in the Neonatal Intensive Care Unit (NICU) of Dr. M. K. Shah Medical College and Research Centre, Chandkheda Ahmedabad, Gujarat, India after obtaining approval from the Institutional Ethics Committee. The mean gestational age of the neonates admitted to the neonatal intensive care unit during the study period was 32.6 ± 2.4 weeks, and the mean birth weight was 1.46 ± 0.31 kg. Neonates with a birth weight of less than 2500 grams and/or gestational age of less than 37 weeks were included in the study. Neonates with major congenital anomalies, chromosomal abnormalities, congenital ocular defects, or those who expired or were discharged before the initial retinal screening could be completed were excluded. Written informed consent was obtained from parents or legal guardians prior to enrollment.

Detailed maternal and neonatal data were collected for all enrolled neonates using a structured proforma. Maternal variables included antenatal history and mode of delivery, while neonatal variables included gestational age, birth weight, sex, Apgar scores, duration of oxygen therapy, use of mechanical ventilation, occurrence of respiratory distress syndrome, sepsis, anemia, blood transfusions, intraventricular hemorrhage, and duration of NICU stay. Gestational age was assessed based on last menstrual period and early antenatal ultrasound findings or by clinical assessment using the New Ballard score when necessary.

All eligible neonates underwent retinal screening for retinopathy of prematurity as per standard screening guidelines. The first ophthalmologic examination was performed between 4 and 6 weeks of postnatal age or at 31 weeks postmenstrual age, whichever was later. Retinal examination was carried out by a trained ophthalmologist using indirect ophthalmoscopy after pharmacological pupillary dilation. The findings were documented according to the International Classification of Retinopathy of Prematurity, including stage, zone, extent of disease, and presence or absence of plus disease. The Study was Performed for the duration of one year from October 2024 to September 2025.

Neonates diagnosed with ROP were followed up at regular intervals based on the severity of disease until complete vascularization of the retina or regression of ROP was noted. Those with treatment-requiring ROP were managed as per standard treatment protocols. The incidence of retinopathy of prematurity was calculated as the proportion of neonates diagnosed with ROP out of the total number of preterm and low birth weight neonates screened during the study period, and the association between various neonatal risk factors and the development of ROP was analyzed.

All collected data were entered into a computerized database and analyzed using Statistical Package for the Social Sciences (SPSS) software version 25.0. Descriptive statistics were used to summarize the data. Associations between categorical variables, including risk factors and the incidence of retinopathy of prematurity, were assessed using the Chi-square test or Fisher's exact test, as appropriate based on expected cell frequencies. Multivariate analysis was performed to identify independent predictors of ROP. A p-value of less than 0.05 was considered statistically significant.

Results

The present study included a total of 450 preterm and low birth weight neonates screened for retinopathy of prematurity. Table 1 shows the distribution of study participants according to sex. Male neonates constituted a slightly higher proportion of the study population compared to female neonates.

Table 1: Distribution of patients according to sex (n = 450)

Sex	Number of patients	Percentage (%)
Male	238	52.9
Female	212	47.1
Total	450	100.0

Table 2 illustrates the incidence of retinopathy of prematurity among the study population of 450 preterm and low birth weight neonates admitted to the neonatal intensive care unit. A total of 40 neonates were diagnosed with ROP, accounting for an incidence of 8.9%, whereas the remaining 410 neonates (91.1%) did not develop ROP during the study period. This finding highlights that approximately one in eleven neonates in the study cohort was

Table 2: Incidence of retinopathy of prematurity among the study population (n = 450)

ROP status	Number of neonates	Percentage (%)
ROP present	40	8.9
ROP absent	410	91.1
Total	450	100.0

Table 3 presents the distribution of retinopathy of prematurity cases according to gestational age among the 40 affected neonates. The highest proportion of ROP cases was observed in neonates born at 28 weeks of gestation, accounting for 12 cases (30.0%), followed by those born at 30 weeks with 9 cases (22.5%). Neonates born at 29 weeks contributed 5 cases (12.5%), while 4 cases (10.0%) were observed at 31 weeks of gestation. Lower frequencies of ROP were noted at 27 weeks and 33 weeks, with 3 cases (7.5%) and 1 case (2.5%), respectively. These findings indicate that the majority of ROP cases occurred in neonates born before 31 weeks of gestation, highlighting the increased vulnerability of extremely and very preterm infants.

Table 3: Distribution of patients with ROP according to gestational age (n = 40)

Gestational age (weeks)	Cases of ROP	Percentage (%)
27	3	7.5
28	12	30.0
29	5	12.5
30	9	22.5
31	4	10.0
32	6	15.0

33	1	2.5
Total	40	100.0

Table 4 shows the distribution of ROP cases according to postmenstrual age at the time of screening. Most cases were detected between 30 and 35 weeks of postmenstrual age, comprising 18 cases (45.0%), followed by 14 cases (35.0%) identified between 35 and 40 weeks. A smaller proportion of cases, 8 neonates (20.0%), were diagnosed between 40 and 45 weeks of postmenstrual age. This distribution demonstrates that a substantial proportion of ROP cases were identified during the earlier postmenstrual screening window, emphasizing the importance of timely screening during this critical period.

Table 4: Distribution of patients with ROP according to postmenstrual age at screening (n = 40)

Postmenstrual age (weeks)	Cases of ROP	Percentage (%)
30–35	18	45.0
35–40	14	35.0
40–45	8	20.0
Total	40	100.0

Figure 1 depicts the distribution of patients with retinopathy of prematurity according to sex. Among the 40 neonates diagnosed with ROP, 23 were males, accounting for 57.5% of cases, while 17 were females, representing 42.5%. This indicates a slight male predominance in the occurrence of ROP in the study population.

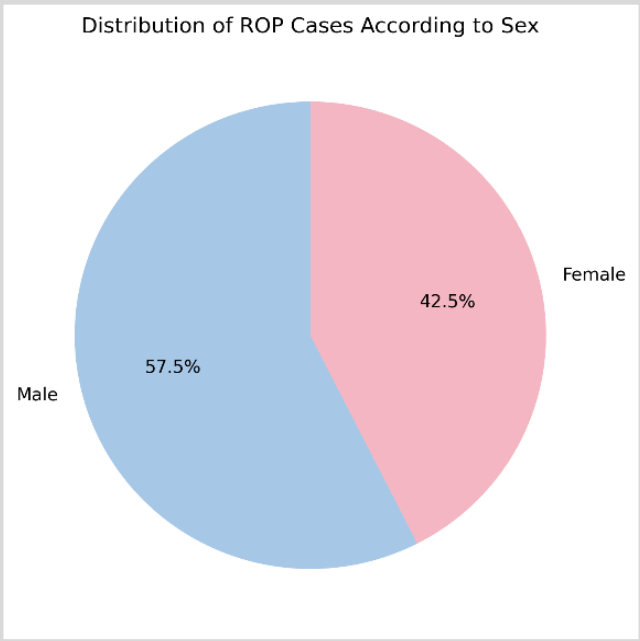

Figure 1: Distribution of patients with ROP according to sex

Table 5 describes the distribution of retinopathy of prematurity cases according to birth weight among the 40 affected neonates. The highest proportion of ROP cases was observed in neonates weighing between 1.5 and 1.9 kg, accounting for 12 cases (30.0%), followed by those weighing 2.0–2.49 kg with 11 cases (27.5%). Neonates with birth weight less than 1.0 kg contributed 7 cases (17.5%), while 6 cases (15.0%) were observed in the 1.0–1.49 kg category. A smaller proportion of ROP cases, 4 neonates (10.0%), had a birth weight of 2.5 kg or more. This distribution indicates that although ROP was more frequent among lower birth weight groups, cases were also observed in neonates with relatively higher birth weights.

Table 5: Distribution of patients with ROP according to birth weight

Birth weight (kg)	Cases of ROP
<1.0	7
1.0–1.49	6
1.5–1.9	12
2.0–2.49	11
≥2.5	4
Total	40

Table 6 presents the distribution of ROP cases according to the presence of maternal systemic diseases. Among the 40 neonates diagnosed with ROP, maternal systemic disease was present in 4 cases (10.0%), while the majority, 36 cases (90.0%), occurred in neonates born to mothers without any systemic illness. Pregnancy-induced hypertension was the most common maternal condition, accounting for 2 cases (5.0%), followed by gestational diabetes mellitus and maternal anemia, each contributing 1 case (2.5%). These findings suggest that most ROP cases in the present study occurred in the absence of identifiable maternal systemic disease.

Table 6: Distribution of patients with ROP according to maternal systemic diseases (n = 40)

Maternal systemic disease	Cases of ROP
Pregnancy-induced hypertension (PIH)	2
Gestational diabetes mellitus (GDM)	1
Maternal anemia	1
No maternal systemic disease	36
Total	40

Table 7 demonstrates the association between gestational age and the development of retinopathy of prematurity in the total study population of 450 neonates. Among neonates born at or before 30 weeks of gestation, 29 out of 125 (23.2%) developed ROP, compared to 11 out of 325 neonates (3.4%) born after 30 weeks. This difference was statistically significant ($p < 0.001$), indicating a strong association between lower gestational age and the occurrence of ROP.

Table 7: Association between gestational age and development of retinopathy of prematurity (n = 450)

Gestational age (weeks)	ROP present (n = 40)	ROP absent (n = 410)	Total	p-value
≤30	29	96	125	<0.001*
>30	11	314	325	
Total	40	410	450	

Table 8 shows the association between birth weight and the development of retinopathy of prematurity. Of the 75 neonates with birth weight less than 1.5 kg, 13 (17.3%) developed ROP, whereas among 375 neonates with birth weight equal to or greater than 1.5 kg, only 27 (7.2%) were affected. This association was statistically significant ($p < 0.001$), demon.

Table 8: Association between birth weight and development of retinopathy of prematurity (n = 450)

Birth weight (kg)	ROP present (n = 40)	ROP absent (n = 410)	Total	p-value
<1.5	13	62	75	<0.001*
≥1.5	27	348	375	
Total	40	410	450	

Discussion

The present clinical study assessed retinopathy of prematurity (ROP) among preterm and low birth weight neonates admitted to the neonatal intensive care unit during the study period. In this cohort of 450 neonates, 40 were diagnosed with ROP, yielding an incidence of 8.9%. The distribution of ROP cases was described across gestational age, postmenstrual age at screening, sex, birth weight, and maternal systemic diseases. In addition, statistical analysis demonstrated significant associations between lower gestational age (≤30 weeks) and the development of ROP ($p < 0.001$), as well as lower birth weight (<1.5 kg) and the development of ROP ($p < 0.001$). Maternal systemic diseases were infrequent among ROP cases, with 4 of 40 neonates (10.0%) having a documented maternal systemic condition, while most cases occurred in the absence of maternal systemic disease.

Recent large-scale neonatal studies have emphasized that decreasing gestational age and birth weight remain the most powerful predictors for the development of ROP [11]. Immaturity of the retinal vasculature at birth predisposes preterm neonates to dysregulated vascular growth, making them highly susceptible to both mild and severe forms of ROP. The clustering of cases in lower gestational age groups observed in the present study is consistent with contemporary epidemiological data.

Post-conceptional age at the time of screening also plays a crucial role in the detection and progression of ROP. Evidence from recent cohort studies indicates that the majority of ROP cases are detected between 30 and 35 weeks of post-conceptional age, corresponding to the critical window of retinal vascular development [12]. Timely screening during this period is therefore essential for early diagnosis and intervention, a finding supported by the distribution pattern observed in the present study.

Sex-based differences in the incidence of ROP have been inconsistently reported in the literature. However, recent analyses suggest a slightly higher predisposition among male neonates, potentially related to differences in lung maturity, oxygen requirement, and inflammatory response [13]. The male predominance observed among ROP cases in the present study aligns with these findings, although sex alone is unlikely to act as an independent risk factor.

Birth weight continues to be a strong determinant of ROP severity. Contemporary studies have demonstrated a higher incidence of ROP among neonates weighing less than 1500 grams, with risk declining progressively as birth weight increases [14]. The present study similarly observed a higher concentration of ROP cases in lower birth weight categories, underscoring the importance of targeted screening strategies for this vulnerable group.

Maternal systemic diseases have been explored as potential contributors to ROP through their impact on placental function and fetal oxygenation. Recent evidence suggests that while maternal systemic illnesses may contribute indirectly, neonatal factors play a more dominant role in ROP pathogenesis [15]. The relatively small proportion of ROP cases associated with maternal systemic disease in the present study supports the view that postnatal risk factors outweigh antenatal influences in determining ROP occurrence.

Overall, the findings of this study reinforce current understanding that ROP is a preventable yet persistent complication of prematurity. Identification of high-risk neonates based on gestational age, birth weight, and postnatal clinical course remains essential for effective screening and timely management.

Conclusion

Retinopathy of prematurity remains a significant morbidity among preterm and low birth weight neonates. Lower gestational age, reduced birth weight, and early post-conceptional age are strongly associated with increased incidence of ROP. Although maternal systemic diseases may contribute indirectly, neonatal risk factors play a predominant role in disease development. Early identification of at-risk infants through structured screening programs is crucial for preventing ROP-related visual impairment and childhood blindness.

Declarations

Conflict of interest

No! Conflict of interest is found elsewhere considering this work.

Source of Funding

There was no financial support concerning this work

Data Availability

All data available on corresponding author upon responsible request.

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