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TRENDS IN THE INCIDENCE OF RETINOPATHY OF PREMATURITY: IMPACT OF IMPROVED NEONATAL CARE.

Neonatal care

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ABSTRACT

Background: Retinopathy of prematurity (ROP) is a retinal vasoproliferative disorder affecting preterm and low-birth-weight infants. Although advances in neonatal care have improved survival, ROP remains an important cause of preventable childhood blindness. Early screening and timely identification of at-risk infants are crucial to prevent disease progression. **Objective:** To determine the incidence, stages, and neonatal risk factors associated with ROP among preterm infants admitted to a tertiary care NICU and to assess the impact of improved neonatal care on disease trends. **Methods:** This retrospective observational study was conducted at a tertiary care charitable hospital in Maharashtra, India, from October 2023 to October 2025. A total of 200 eyes from 100 preterm infants with gestational age <34 weeks or birth weight <2000 g were screened for ROP using indirect ophthalmoscopy at 3–4 weeks postnatal age. Infants ≥34 weeks or ≥2000 g were screened only if additional risk factors were present. Neonatal variables—including oxygen therapy, CPAP, sepsis, anemia, apnea, surfactant use, phototherapy, and blood transfusion—were recorded. ROP was classified according to the International Classification of Retinopathy of Prematurity (ICROP, 3rd revision). Statistical analysis was performed using Chi-square testing. **Results:** ROP was diagnosed in **8%** of screened infants, with **5%** exhibiting Stage 1 and **3%** Stage 2 disease; no cases of Stage 3 or higher were observed. Plus disease was documented in **2%** of eyes. The majority (92%) showed Stage 0 with vascularization mainly in Zones II and III. Significant associations were identified between ROP and **blood transfusion, neonatal sepsis, anemia, necrotizing enterocolitis (NEC), and apnea** ($p < 0.001$). Phototherapy and surfactant therapy demonstrated borderline significance ($p = 0.05$), whereas oxygen therapy, CPAP, respiratory distress syndrome (RDS), prematurity, and low birth weight did not show statistically significant associations. No infant in the cohort required treatment, as all cases were mild and regressed spontaneously. **Conclusion:** The incidence of ROP in this cohort was low and limited to early stages, with no progression to severe disease. Systemic complications—especially sepsis, anemia, NEC, apnea, and the need for blood transfusion—were strongly associated with ROP development, emphasizing the role of postnatal systemic instability. Although prematurity and low birth weight were not statistically significant, they remain important baseline risk factors. Strengthened neonatal care practices, rigorous monitoring of systemic morbidities, optimized oxygen management, and structured ROP screening protocols are essential to prevent disease progression and long-term visual impairment.

KEYWORDS

Retinopathy of prematurity, preterm infants, neonatal risk factors, sepsis, blood transfusion, laser photocoagulation, anti-VEGF, ICROP

INTRODUCTION

Retinopathy of prematurity (ROP) is a multifactorial retinal vasoproliferative disorder characterized by abnormal neovascularization in the incompletely vascularized retina of preterm infants. The pathogenesis of ROP occurs in two distinct phases: an initial suppression of normal vascular maturation due to premature birth and relative hyperoxia, followed by a compensatory phase of hypoxia-driven excessive angiogenic response leading to proliferative vasculopathy [1]. Clinically, ROP is classified into five stages based on disease severity. Stage 1 presents as a thin demarcation line separating the vascularized and avascular retina, Stage 2 involves a ridge at the junction, Stage 3 is characterized by extraretinal fibrovascular proliferation, Stage 4 denotes partial retinal detachment, and Stage 5 represents total retinal detachment resulting in blindness.

Globally, ROP continues to be a leading cause of potentially preventable childhood blindness. The condition primarily affects premature infants born before 37 weeks of gestation, especially those with low birth weight (<1500 g) and low gestational age (<32 weeks) [6,7]. Prematurity itself remains the most significant determinant for ROP development [1]. Other recognized risk factors include low gestational age, low birth weight, exposure to supplemental oxygen, multiple births, and male gender. In addition to the concentration of oxygen administered, the duration of exposure and fluctuations in oxygen saturation are strongly associated with disease progression [2]. Over recent decades, with remarkable advancements in neonatal intensive care, survival of extremely preterm infants has increased substantially [3]. Although this has improved overall neonatal outcomes, it has also expanded the population at highest risk for developing ROP. This has led to periodic "epidemics" of ROP: the first in the 1940s–50s associated with unregulated oxygen use, the second in the 1970s–80s linked to improved preterm survival, and the third—currently ongoing—in middle-income countries, attributed to developing neonatal services with inconsistent oxygen monitoring and inadequate screening [4].

Preventing irreversible blindness due to ROP relies on timely ophthalmologic screening and early intervention [2]. Regular retinal screenings of high-risk preterm infants allows for early identification of sight-threatening stages and prompt treatment, such as laser photocoagulation or intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy, thereby reducing visual morbidity [5].

Therefore, the present study was designed to analyze the current trends in the incidence and stages of retinopathy of prematurity (ROP) among preterm infants and to evaluate the impact of improved neonatal care practices and associated risk factors on disease occurrence and outcomes.

MATERIALS AND METHODS

Study Design And Setting

This retrospective observational study was carried out in the Neonatal Intensive Care Unit (NICU) and Ophthalmology Department of a tertiary care charitable hospital in Maharashtra, India, from October 2023 to October 2025. The primary objective was to evaluate the incidence and risk factors associated with retinopathy of prematurity (ROP) among preterm infants receiving intensive neonatal care. Ethical clearance for the study was obtained from the institutional ethics committee prior to data collection, and all infant records were anonymized to ensure confidentiality.

Study Population

All preterm infants admitted to the NICU with a gestational age less than 34 weeks and/or birth weight below 2000 grams were included in the study as per the National Neonatal Forum (NNF) of India screening guidelines. Infants with a gestational age ≥34 weeks or birth weight ≥2000 grams were screened only if additional risk factors such as oxygen therapy, sepsis, anemia, or mechanical ventilation were present. Exclusion criteria included infants with congenital ocular anomalies, systemic malformations, or incomplete medical records. A total of 100 preterm infants meeting the inclusion criteria were screened for ROP at 3–4 weeks of postnatal age or at 31–33 weeks of post-conceptional age, whichever occurred later.

Data Collection

Demographic and clinical details were obtained from NICU records using a predesigned structured data sheet. Information collected included gestational age, birth weight, gender, and perinatal variables such as Apgar score, mode of delivery, and antenatal corticosteroid administration. Neonatal factors like duration and type of oxygen therapy (humidified oxygen or CPAP), surfactant administration, ventilation support, respiratory distress syndrome (RDS), sepsis, anemia, apnea, necrotizing enterocolitis (NEC), phototherapy exposure, and history of blood transfusion were also recorded. All data entries were cross-verified with the NICU registry to maintain accuracy and completeness.

Ophthalmic Examination And ROP Screening

ROP screening was performed by an experienced ophthalmologist using an indirect ophthalmoscope with a +20 diopter condensing lens. Prior to examination, the pupils were dilated with a 0.5% tropicamide eye drops – single drop is administered. Repeat after 10–15 mins only if inadequate dilation observed. Topical anesthesia was provided using 0.5% proparacaine hydrochloride eye drops to ensure infant comfort during the procedure. Each examination was conducted under aseptic precautions using a sterile infant speculum and scleral depressor to visualize the retina up to the ora serrata.

Each eye was systematically examined and graded according to the International Classification of Retinopathy of Prematurity (ICROP, 3rd revision). The disease was classified based on three parameters: zone, stage, and the presence or absence of plus disease. The zones were categorized as Zone I, II, or III, depending on the proximity of the retinal vessels to the optic disc. The stages ranged from Stage 1, characterized by a demarcation line separating vascularized from avascular retina, to Stage 5, representing total retinal detachment. Plus disease was defined by venous dilatation and arteriolar tortuosity of the posterior pole vessels, indicating active disease progression.

Infants diagnosed with ROP were monitored closely with follow-up examinations scheduled at intervals of one to two weeks, depending on the severity and progression of the disease. Screening continued until complete retinal vascularization was documented or until spontaneous regression occurred. This systematic follow-up approach ensured timely detection of disease progression and initiation of treatment when indicated.

Treatment Protocol

Infants meeting treatment criteria were managed according to the Early Treatment for Retinopathy of Prematurity (ETROP) guidelines. Laser photocoagulation was performed for threshold ROP involving the peripheral avascular retina, aiming to ablate the ischemic areas and reduce angiogenic drive. Intravitreal anti–vascular endothelial growth factor (anti-VEGF) injections were administered in cases presenting with posterior or aggressive ROP, particularly when laser therapy was not feasible or when rapid disease progression was observed.

Following treatment, all infants underwent a re-examination within one week to assess regression of neovascularization and resolution of plus disease. Subsequent follow-ups were conducted at regular intervals until complete regression of ROP or stable peripheral retinal vascularization was achieved. Infants who recovered were advised long-term ophthalmic surveillance to monitor for potential sequelae such as myopia, strabismus, or late-onset retinal complications.

Statistical Analysis

All data were compiled and analyzed using IBM SPSS Statistics, Version 25.0 (Armonk, NY, USA). Descriptive statistics were used to summarize baseline characteristics. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean ± standard deviation (SD). Associations between neonatal risk factors and ROP development were assessed using the Chi-square test or Fisher's exact test, as appropriate. A p-value less than 0.05 was considered statistically significant.

Outcome Measures

The primary outcome of the study was to determine the incidence and severity distribution of ROP among screened infants. The secondary outcomes included identifying significant neonatal risk factors contributing to ROP and documenting the treatment outcomes following laser photocoagulation or intravitreal anti-VEGF therapy.

RESULTS

Table 1: Demographic and Clinical Characteristics of Study Population (n = 100)

Parameter	Category / Variable	Frequency (n)	Percentage (%)
Gender	Male	63	63
	Female	37	37
Number of eyes	Male	126	63
	Female	74	37
Gestational Age (weeks)	< 28 weeks	5	5
	28–32 weeks	35	35
	32–34 weeks	24	24
	34–37 weeks	28	28
	> 37 weeks	8	8
Birth Weight Category	< 1000 g (Extremely Low Birth Weight)	11	11
	1000–1500 g (Very Low Birth Weight)	51	51
	1500–2500 g (Low Birth Weight)	29	29
	> 2500 g (Normal Birth Weight)	9	9
Preterm Infants ≤ 34 Weeks	—	64	64
Low Birth Weight ≤ 1500 g		62	62

The study population consisted of 100 infants, of whom 63% were male and 37% were female, contributing 126 and 74 eyes respectively. Most infants were born preterm, with 64% delivered at ≤34 weeks; specifically, 35% were born between 28–32 weeks, 24% between 32–34 weeks, 28% between 34–37 weeks, and 5% at <28 weeks, while 8% were born after 37 weeks. Birth weight distribution showed that over half of the infants (51%) fell within the very low birth weight range of 1000–1500 g, followed by 29% with low birth weight (1500–2500 g), 11% with extremely low birth weight (<1000 g), and 9% with normal birth weight (>2500 g), resulting in 62% of the cohort weighing ≤1500 g. Overall, the demographic profile reflects a predominantly preterm, low-birth-weight population at increased risk for developing retinopathy of prematurity.

Table 2: Distribution Of Neonatal And NICU-Related Risk Factors among Study Population (n = 100)

Risk Factor	Number of Infants (n)	Percentage (%)
Oxygen therapy (humidified)	90	90
Bubble CPAP	88	88
Phototherapy	67	67
Blood transfusion	27	27
Respiratory distress syndrome (RDS)	86	86
Neonatal sepsis	32	32
Anemia	46	46
Necrotizing enterocolitis (NEC)	3	3
Apnea	31	31
Surfactant administration	70	70

Among the 100 preterm infants evaluated, the most common neonatal or NICU-related risk factors were oxygen therapy (90%) and bubble CPAP use (88%), followed by respiratory distress syndrome (RDS) in 86% of infants and surfactant administration in 70%. Phototherapy was administered in 67% of cases, while anemia (46%) and neonatal sepsis (32%) were also frequent comorbidities. Less frequent but clinically important complications included apnea (31%), blood

transfusion (27%), and necrotizing enterocolitis (NEC) in 3% of the study population. These findings indicate that respiratory complications and oxygen-related interventions were the predominant risk factors among preterm infants in this cohort.

Table 3: Distribution Of Eyes Based On Stage And Zone Of Retinopathy Of Prematurity (n = 200 eyes)

Stage / Zone	No. of Eyes
STAGE 0	184
Zone 1	4
Zone 2	62
Zone 3	118
STAGE 1	10
Zone 1	0
Zone 2	8
Zone 3	2
STAGE 2	6
Zone 1	0
Zone 2	6
Zone 3	0
STAGE 3	0
STAGE 4	0
PLUS DISEASE	4

Based on the evaluation of **200 eyes from preterm infants**, the majority (92%) were classified as **Stage 0 ROP**, indicating no retinopathy. Within this group, retinal vascularization was distributed across **Zone 1 (4 eyes)**, **Zone 2 (62 eyes)**, and **Zone 3 (118 eyes)**. **Stage 1 ROP** accounted for **10 eyes (5%)**, predominantly occurring in **Zone 2 (8 eyes)** and less frequently in **Zone 3 (2 eyes)**. **Stage 2 ROP** was identified in **6 eyes (3%)**, all localized to **Zone 2**, with no involvement of Zones 1 or 3. Importantly, **no eyes demonstrated Stage 3 or Stage 4 disease**, indicating the absence of more advanced ROP in this cohort. **Plus disease** was detected in **4 eyes (2%)**.

Overall, the distribution pattern indicates that most eyes exhibited either normal vascularization or early-stage ROP, with only a small proportion showing signs of progression. The absence of advanced stages and minimal presence of plus disease suggest effective screening and possibly improved neonatal care, limiting the progression to clinically significant ROP..

Table 4: Association Of ROP With Different Risk Factors

Risk factors	ROP -nt (n=92)	ROP +nt (n=8)	P value
Oxygen therapy (humidified oxygen)	82(89.1%)	8 (100%)	0.32
Bubble CPAP	80(87.0%)	8 (100%)	0.59
Phototherapy	59(64.1%)	8 (100%)	0.05
Blood transfusion	19(20.7%)	8 (100%)	<0.001
RDS	78(84.8%)	8 (100%)	0.59
Neonatal Sepsis	24(26.1%)	8 (100%)	<0.001
Anaemia	38(41.3%)	8 (100%)	<0.001
NEC	0(0.0%)	3 (37.5%)	<0.001
Apnoea	23(25.0%)	8 (100%)	<0.001
Surfactant	60(65.2%)	8 (100%)	0.05
Preterm ≤ 34 weeks	62(67.4%)	3 (37.5%)	0.12
Low-birth-weight ≤ 1500 grams	60(65.2%)	3 (37.5%)	0.14

In the present study, several neonatal risk factors showed a significant association with the development of retinopathy of prematurity (ROP). Blood transfusion, neonatal sepsis, anaemia, necrotizing enterocolitis (NEC), and apnoea were significantly associated with ROP ($p < 0.001$), indicating that these comorbidities markedly increase the risk of retinal vascular injury in preterm infants. Phototherapy and surfactant administration also showed borderline significance ($p = 0.05$), suggesting a possible contributory role. In contrast, oxygen therapy, bubble CPAP, respiratory distress syndrome (RDS), prematurity (≤ 34 weeks), and low birth weight (≤ 1500 g) did not demonstrate statistically significant associations ($p > 0.05$) in this study, though their clinical importance as background risk factors cannot be excluded. These findings suggested that while prematurity and low birth weight remain essential predisposing factors, the development of ROP is more likely when additional postnatal complications such as sepsis, anemia or recurrent apneic episodes are present, reflecting the multifactorial etiology of the disease.

Table 4: Association Of ROP With Different Risk Factors At Eye Level (n = 200 Eyes)

Risk factors	Eyes without ROP (n = 184) n (%)	Eyes with ROP (n = 16) n (%)	P value
Oxygen therapy (humidified oxygen)	164 (89.1)	16 (100.0)	1.00
Bubble CPAP	160 (87.0)	16 (100.0)	0.59
Phototherapy	118 (64.1)	16 (100.0)	0.050
Blood transfusion	38 (20.7)	16 (100.0)	<0.001
RDS	156 (84.8)	16 (100.0)	0.60
Neonatal sepsis	48 (26.1)	16 (100.0)	<0.001
Anaemia	76 (41.3)	16 (100.0)	0.001
NEC	0 (0.0)	6 (37.5)	<0.001
Apnoea	46 (25.0)	16 (100.0)	<0.001
Surfactant administration	120 (65.2)	16 (100.0)	0.052
Preterm ≤ 34 weeks	124 (67.4)	6 (37.5)	0.124
Low-birth-weight ≤ 1500 grams	120 (65.2)	6 (37.5)	0.142

Analysis of risk factors at the eye level demonstrates significant associations between several neonatal conditions and the development of ROP. All eyes with ROP had received oxygen therapy, bubble CPAP, phototherapy, blood transfusion, and surfactant, though statistically significant associations were observed primarily with blood transfusion ($P < 0.001$), neonatal sepsis ($P < 0.001$), anaemia ($P = 0.001$), necrotizing enterocolitis (NEC) ($P < 0.001$), and apnoea ($P < 0.001$). Notably, NEC and apnoea were present in 37.5% and 100% of ROP-affected eyes respectively, while these conditions were rare or absent among non-ROP eyes. Phototherapy ($P = 0.050$) and surfactant use ($P = 0.052$) approached statistical significance but did not meet the conventional threshold. Gestational age ≤34 weeks and low birth weight ≤1500 g were more common in eyes without ROP, and their associations were not statistically significant. Overall, conditions indicating systemic instability-such as sepsis, anaemia, NEC, and apnoea-showed the strongest relationships with ROP development in this cohort.

DISCUSSION

The present study evaluated the incidence, stages, and associated neonatal risk factors of retinopathy of prematurity (ROP) among preterm infants admitted to a tertiary care NICU. Out of 100 screened infants (200 eyes), only **8%** were diagnosed with ROP, and all cases were confined to **Stage 1 and Stage 2**, with no infants demonstrating advanced stages such as Stage 3 or 4. Plus disease was documented in a small subset. The absence of severe ROP and the predominance of Stage 0 findings (92% of eyes) reflect effective early screening, strict oxygen regulation, and improved neonatal care practices within the study setting. The low incidence observed is notably reduced compared with earlier reports from India and Europe, where ROP prevalence ranges from **20% to 40%**, influenced by gestational age and birth weight variations [6,7]. Studies by Larsen et al. in Germany [6] and Hellström et al. in Sweden [6] reported incidences between 23–32% and 31.9%, respectively, while several Indian studies have documented substantially higher rates, particularly in resource-limited settings [8]. The comparatively low ROP rate in the present cohort likely reflects standardized monitoring protocols and adherence to oxygen saturation guidelines.

Analysis of neonatal and NICU-related risk factors demonstrated that **blood transfusion, neonatal sepsis, anemia, necrotizing enterocolitis (NEC), and apnea** were significantly associated with ROP development ($p < 0.001$). These findings are consistent with existing evidence that systemic morbidities contribute to retinal ischemia, oxidative stress, and vascular dysregulation in preterm infants. Fortes Filho et al. identified anemia and sepsis as independent predictors of ROP severity, while Seiberth and Linderkamp highlighted the oxidative load imposed by repeated transfusions [9]. The significant relationship of NEC and apnea with ROP in our cohort corresponds with Hartnett's observations [10], noting that hypoxia and inflammation disrupt retinal vascular maturation. Phototherapy and surfactant administration showed borderline significance ($p = 0.05$), suggesting a possible indirect role mediated by oxygen fluctuations, which aligns with the findings of Walz et al. [11] and Hakeem et al. [12].

In contrast to expectations from earlier studies, **oxygen therapy,**

CPAP, respiratory distress syndrome (RDS), prematurity (≤34 weeks), and low birth weight (≤1500 g) did not show statistically significant associations with ROP in this cohort. Although these remain well-established background risk factors in the literature [7,12-13], their lack of statistical significance here may reflect improved oxygen targeting, advanced ventilation strategies, and better overall neonatal stabilization. Historically, unregulated oxygen exposure was one of the most important drivers of ROP [14,15], but advances in neonatal protocols have markedly reduced its contribution to disease development. Thus, while prematurity and low birth weight remain key predisposing factors, our findings suggest that additional postnatal complications-particularly sepsis, apnea, NEC, and anemia-play a more decisive role in ROP progression.

Regarding disease distribution, all ROP cases in this study were limited to **Zone II**, with no involvement of Zone I or progression to advanced disease stages. This pattern is comparable to observations by Larsen et al. [6] and Walz et al. [11], who reported that a majority of ROP cases in similar cohorts occurred in Zone II. Advanced stages (Stage 4 and 5) are now increasingly rare in tertiary care centers in middle- and high-income regions, contrasting with persistent reports of advanced ROP in low-resource settings where delays in screening and inconsistent neonatal care remain challenges [8]. The absence of advanced disease in our study underscores the importance of structured screening protocols and timely neonatal interventions, consistent with recent trends reported across Europe and North America [16,17].

Although many international studies report that 2–6% of infants undergoing screening may require intervention [7,16,18], **none of the infants in the present study required treatment**, given the absence of threshold or Type 1 ROP. Laser photocoagulation remains the gold standard for treating threshold disease, as described by Tiryaki [19] and Walz et al. [11], while anti-VEGF therapy has gained increasing importance for posterior or aggressive forms of ROP. Evidence from the BEAT-ROP [20] and RAINBOW [21] trials demonstrates the efficacy of bevacizumab and ranibizumab, especially in Zone I disease. Although treatment was not indicated in our cohort, ongoing vigilance is essential, as recurrence rates may differ depending on treatment modality. Mintz-Hittner et al. [22] reported lower recurrence after anti-VEGF treatment, whereas Hwang et al. [14] and Walz et al. [11] highlighted higher reactivation rates compared with laser therapy, emphasizing the importance of individualized decision-making and long-term follow-up where treatment is administered.

Overall, the findings from this study reinforce that ROP is a multifactorial disease influenced by perinatal immaturity and postnatal systemic disturbances. The significant associations of sepsis, anemia, NEC, apnea, and transfusion with ROP highlight the central role of systemic instability, oxidative stress, and inflammation in disease pathogenesis. The low incidence of ROP and absence of advanced stages observed in this cohort emphasize the beneficial impact of improved neonatal care, stringent oxygen monitoring, and structured screening protocols. Collectively, these results reaffirm that early detection, prevention of systemic complications, and meticulous neonatal management remain critical for reducing the burden of ROP and preventing avoidable childhood blindness.

CONCLUSION

In conclusion, this study demonstrated a **low incidence of ROP (8%)**, with all cases restricted to **early stages (Stage 1 and Stage 2)** and no progression to severe forms such as Stage 3 or Stage 4. The absence of advanced disease reflects effective neonatal care practices, timely screening, and appropriate oxygen monitoring in the study setting. Significant associations were observed between ROP and **neonatal sepsis, anemia, apnea, necrotizing enterocolitis (NEC), and blood transfusion**, emphasizing the critical role of postnatal systemic instability and inflammatory events in the pathogenesis of ROP. Phototherapy and surfactant administration showed borderline significance, indicating the need for further evaluation of their contributory roles. Although prematurity and low birth weight did not reach statistical significance in this cohort, they continue to be clinically recognized predisposing factors. Overall, the findings underscore the importance of **strengthened neonatal care, stringent monitoring of systemic morbidities, optimized oxygen management, and early, structured ROP screening protocols** to prevent disease progression and safeguard long-term visual outcomes in preterm infants.

Data Availability Statement:
The data supporting the findings of this study are available from the corresponding author upon reasonable request

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