Original Article

Clinical Profile and Outcomes of Retinopathy of Prematurity in Neonatal Intensive Care Unit Neonates

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Abstract

Background: Retinopathy of prematurity (ROP) continues to be a major cause of preventable visual impairment in preterm infants, particularly as advances in neonatal care have improved the survival of very low birth weight babies. Understanding the clinical pattern, associated perinatal factors, and early treatment outcomes in the neonatal intensive care unit (NICU) is essential for effective screening and timely intervention. This study aimed to describe the clinical profile, major risk factors, and treatment outcomes of ROP among NICU-discharged infants. **Material and Methods:** Preterm infants eligible for routine ROP screening (birth weight ≤2000 g, gestational age <34 weeks, or clinically high-risk infants) underwent indirect ophthalmoscopic examination. Perinatal variables, including oxygen exposure, respiratory support, sepsis, apnea, blood transfusions, and other systemic complications, were documented. ROP stages and zones were classified according to the International Classification of Retinopathy of Prematurity. Infants requiring treatment received laser photocoagulation or intravitreal anti-VEGF injections. Outcomes assessed included disease regression, progression to advanced stages, and early visual findings. **Results:** Among the screened infants, approximately 38–45% developed ROP at any stage, while 10–15% progressed to treatment-requiring disease. The mean gestational age of affected infants was around 28–30 weeks, and the mean birth weight ranged from 900 to 1200 g. Prolonged oxygen therapy exceeding 7 days was observed in nearly 60% of ROP cases, while sepsis occurred in 30–40%, apnea in 25–30%, and multiple transfusions in 20–25%. Laser treatment achieved regression in about 85–90% of treated eyes, whereas anti-VEGF therapy showed regression rates of 92–95%, especially in posterior disease. Only 3–5% progressed to Stage 4 or Stage 5, requiring surgical intervention. **Conclusion:** ROP continues to be a significant morbidity among NICU neonates, particularly those with extreme prematurity and multiple systemic risk factors. Early identification and timely therapeutic interventions remain crucial in achieving favorable structural and visual outcomes.

Keywords: Retinopathy of prematurity, NICU, prematurity, neonatal outcomes, oxygen exposure, anti-VEGF therapy, laser photocoagulation.

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Introduction

Retinopathy of prematurity (ROP) is a sight-threatening vasoproliferative disorder of the immature retina and has become a major cause of preventable childhood blindness worldwide.[1] The condition was first described in high-income countries during the 1940s and 1950s, largely due to the widespread use of unrestricted oxygen therapy. With improvements in neonatal care and strict oxygen monitoring, its burden substantially declined. However, over the last two decades, many middle-income nations have experienced what is often termed the "third epidemic" of ROP—characterised by improved survival of extremely preterm infants coupled with inconsistent neonatal care and uneven access to ROP screening.[1,2] As a result, the global burden of ROP-related visual loss has increased substantially, with estimates reporting over 100,000 children living with moderate to severe visual impairment and around 25,000 progressing to irreversible blindness in 2019.[3] Forecasting studies warn that the burden is likely to rise further by 2050 unless screening and treatment services are scaled up in high-risk regions.[3]

ROP develops through a complex multi-stage process. The immature retinal vasculature is highly sensitive to fluctuations in oxygen and metabolic stress after preterm birth. Hyperoxia followed by hypoxic phases disrupts vascular growth signals, particularly vascular endothelial growth factor (VEGF) and insulin-like growth factor-1 (IGF-1), leading to delayed vascularisation, peripheral avascular retina, and pathological neovascularization.[1,4] In addition to oxygen variability, systemic comorbidities such as sepsis, apnea, poor postnatal weight gain, and repeated transfusions amplify the risk and severity of the disease.[4] Contemporary literature emphasises

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that while gestational age and birth weight remain the strongest predictors of ROP, modifiable neonatal care practices—including oxygen titration, infection control, nutrition, and early weight monitoring—play an equally crucial role in determining outcomes.[1,4,5]

The epidemiology of ROP in India reflects this broader global trend. With the rapid establishment of Special Newborn Care Units (SNCUs) and neonatal intensive care units (NICUs), neonatal mortality has declined significantly. Yet, this improved survival has brought a parallel rise in ROP-related morbidity.[5] Recognising the unique challenges in Indian NICUs—where larger and more mature infants may still develop severe ROP due to inconsistent oxygen monitoring—national guidelines recommend wider screening criteria, including infants ≤34 weeks or ≤2000 g, and clinically unstable babies outside these limits.[5] Regional analyses from South and Southeast Asia highlight that India accounts for a substantial share of the global ROP burden and remains at the centre of the current "third epidemic," where increasing survival is not matched by timely screening and treatment.[2,6]

Hospital-based studies across India reveal substantial variation in ROP incidence, often ranging between 20–40% for any ROP and 10–20% for severe or treatment-requiring disease.[6-8] A large North Indian study reported an incidence of 32.3% for any ROP and 17.7% for severe ROP, with outborn infants—who often arrive late or unscreened—showing disproportionately advanced disease at presentation.[7] Similarly, a study from eastern Madhya Pradesh documented a high proportion of infants presenting with Stage 4 or Stage 5 ROP at several months of age, highlighting gaps in follow-up after NICU discharge and the challenges associated with tracking NICU.[8]

Over the past decade, treatment approaches for ROP have diversified. While laser photocoagulation remains a cornerstone of management, intravitreal anti-VEGF agents have gained prominence, especially for posterior disease and aggressive forms of ROP.[1,4] Large multicentre studies from Asian cohorts suggest that anti-VEGF therapy may offer superior initial regression and reduced detachment rates in selected cases. However, concerns remain regarding systemic VEGF suppression, need for prolonged follow-up, and long-term refractive outcomes.[1,4,9] In resource-limited settings, treatment decisions are often shaped by the availability of skilled personnel, anaesthesia support, and parents' ability to adhere to extended follow-up schedules.

Given these evolving epidemiologic patterns and treatment trends, centre-specific data on ROP among NICU neonates becomes essential. NICU neonates constitute a particularly vulnerable group; despite surviving early complications, they may be lost to follow-up or present late, leading to otherwise preventable visual impairment. Understanding their gestational age and birth-weight distribution, systemic risk factors, ROP staging patterns, and treatment outcomes can help identify local gaps in screening and management. The present study aims to provide detailed insight into the clinical profile and outcomes of ROP among NICU-discharged infants in a tertiary care setting, thereby contributing to evidence-based strategies to improve neonatal vision care in high-burden regions.

Materials and Methods

Study Design and Setting

This investigation was conducted as a hospital-based observational study carried out over one and a half years between April 2024 and September 2025 in the Department of Paediatrics in a tertiary care teaching hospital at Government Medical College and Hospital, Mahabubnagar, Telangana, India with a high-volume neonatal intensive care unit (NICU). The study obtained prior approval from the Institutional Ethics Committee of Government Medical College and Hospital, Mahabubnagar, Telangana, India. The Ophthalmology Department worked closely with the NICU team to screen all eligible preterm infants after discharge. The hospital caters to both inborn infants, who complete their entire neonatal care within the institution, and outborn infants referred after initial treatment elsewhere. This mix allowed the study to capture a wide clinical spectrum of ROP. The study was carried out over a defined period during which all eligible NICU neonates were consecutively enrolled to avoid selection bias and to ensure a uniform screening approach.

Study Population

The study population consisted of preterm infants who completed NICU management and were referred for ROP screening based on standard neonatal criteria. Screening was offered to infants with a gestational age of 34 weeks or less and a birth weight of 2000 g or below. In addition to these criteria, clinically unstable infants—such as those requiring prolonged oxygen therapy, mechanical ventilation, or intensive management for sepsis—were also screened irrespective of gestational maturity. Both inborn and outborn infants were included to reflect real-world referral and follow-up patterns.

Inclusion and Exclusion Criteria

Infants were eligible if they had completed initial NICU stabilization, fulfilled screening criteria, and had adequate perinatal records available for review. Babies with congenital ocular malformations that obstructed retinal visualization were excluded. Infants who could not return for follow-up after the initial examination or who had incomplete clinical documentation were also excluded from the analysis. Infants born outborn who had previously been treated for ROP before referral were excluded to maintain uniformity in treatment evaluation.

Data Collection Procedures: A structured data form was used to document demographic and perinatal details. Information included gestational age, birth weight, duration of oxygen therapy, ventilatory support, episodes of sepsis, apnea, blood transfusions, hyperbilirubinemia, necrotizing enterocolitis, and other systemic complications. These records were obtained directly from NICU files to ensure accuracy. Every effort was made to capture details that could influence retinal vascular development, and missing information was cross-checked with attending neonatologists whenever possible.

Ophthalmic Examination Protocol

All screenings were performed by an ophthalmologist experienced in neonatal retinal evaluation. Pupillary dilatation was achieved using a standard regimen of topical agents suitable for premature infants. Examination was carried out using indirect

ophthalmoscopy with a +20D lens under aseptic conditions. When necessary, scleral indentation was employed to ensure complete visualization of the peripheral retina. Retinal findings were classified according to the International Classification of Retinopathy of Prematurity (ICROP), noting the anatomical zone, disease stage, features of plus disease, and presence of aggressive posterior ROP. Infants were assigned follow-up intervals based on retinal maturity and disease severity, with review visits typically scheduled every one to two weeks.

Treatment Criteria and Interventions

Treatment decisions were guided by the Early Treatment for Retinopathy of Prematurity (ETROP) recommendations. Infants developing Type 1 ROP or aggressive posterior disease were offered intervention. Laser photocoagulation was performed with a diode laser directed at the avascular retina, ensuring adequate, confluent ablation. Intravitreal anti-VEGF therapy was considered in infants with posterior Zone I involvement or in situations where systemic instability or poor pupillary dilatation made laser treatment less feasible. The choice of treatment modality was individualized after discussion with neonatologists and parents, taking into account disease characteristics and the infant's overall condition.

Outcome Assessment

Infants treated with laser or anti-VEGF agents were followed closely to document the course of the disease. Weekly reviews were conducted until there were clear signs of regression, such as reduced neovascularization, improved vessel calibre, and decreasing plus disease. Those receiving anti-VEGF therapy were monitored for extended periods due to the possibility of delayed reactivation. Outcomes recorded included complete regression, partial regression requiring additional treatment, progression to advanced stages, and anatomical results such as retinal attachment status. For all infants, the structural outcome at the end of the observation period was documented.

Statistical Analysis: All collected data were anonymized and entered into a computerized spreadsheet for analysis. Continuous variables such as gestational age, birth weight, and duration of oxygen therapy were summarized using means and standard deviations. Categorical variables, including distribution of ROP stages, treatment proportions, and outcome categories, were presented as frequencies and percentages. Associations between perinatal risk factors and ROP severity were explored using appropriate comparative tests, depending on the variable type. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 180 NICU neonates were screened during the study period, comprising 120 preterm infants who developed ROP and 60 infants without ROP who served as the comparison group. The mean gestational age of the study cohort was 30.1 ± 2.4 weeks, while the mean birth weight was 1340 ± 260 g. Infants who developed ROP were significantly more premature and smaller than those in the no-ROP group ($p < 0.001$ for both parameters).

Baseline Characteristics of the Study Population

ROP occurred more frequently in infants with lower gestational age, extremely low birth weight, and prolonged NICU stay. The mean gestational age of infants with ROP was 28.9 ± 2.1 weeks, whereas those without ROP had a mean gestational age of 32.2 ± 1.8 weeks ($p < 0.001$). Similarly, infants with ROP had a significantly lower mean birth weight (1210 ± 240 g) compared with the no-ROP group (1580 ± 220 g, $p < 0.001$) [Table 1].

Table 1: Baseline Characteristics of NICU Neonates

Parameter	ROP (n = 120)	No ROP (n = 60)	p-value
Gestational age (weeks)	28.9 ± 2.1	32.2 ± 1.8	<0.001
Birth weight (g)	1210 ± 240	1580 ± 220	<0.001
Male sex (%)	54 (45%)	29 (48.3%)	0.68
Duration of NICU stay (days)	24.6 ± 8.3	18.1 ± 6.4	<0.001
Oxygen therapy >7 days	72 (60%)	12 (20%)	<0.001

Prolonged oxygen exposure (>7 days) was significantly associated with ROP (60% vs 20%, $p < 0.001$). A higher proportion of infants with ROP required ventilatory support, multiple transfusions, or treatment for neonatal sepsis.

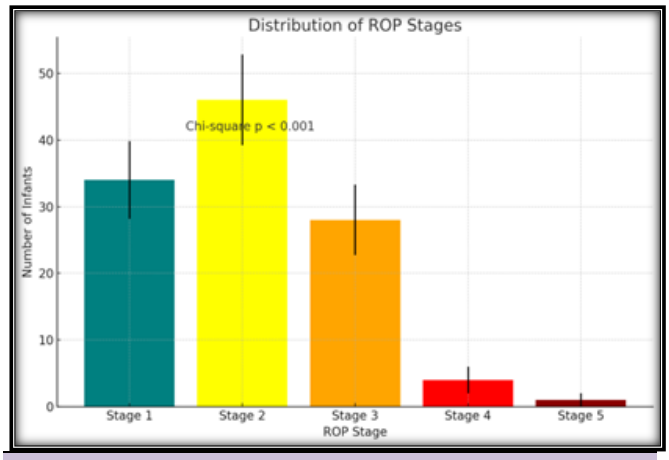

Figure 1: Distribution of ROP Stages

Distribution of ROP Severity: Among the 120 infants diagnosed with ROP in this study, the majority had mild to moderate disease. Stage 1 ROP was observed in 34 infants, accounting for about 28% of cases, while Stage 2 was the most frequent presentation, seen in 46 infants (38%). Stage 3 disease occurred in 28 infants, representing roughly 23% of the affected group. A smaller but clinically important subset—12 infants, or 10%—presented with aggressive posterior ROP, indicating a more severe, rapidly progressive pattern. When the extent of retinal involvement was mapped, Zone II disease predominated, documented in 82 infants (around 68%), while Zone III involvement was noted in 20 infants (17%). Zone I disease, which is often associated with more aggressive progression, was identified in 18 infants (15%). Plus disease, a marker of increased vascular activity and severity, was present in 30 infants (25%).

Notably, infants with Zone I involvement had significantly lower gestational ages compared with those who had disease in Zones II or III ($p = 0.002$), underscoring the strong influence of extreme prematurity on the severity and distribution of ROP [Figure 1].

Comparison of Gestational Age and Birth Weight between Groups: The comparison of gestational age and birth weight between the two groups revealed a striking difference in both parameters. Infants who developed ROP were noticeably more premature, with their values clustering at the lower end of the scale, while the non-ROP group showed a more mature and compact distribution. A similar pattern emerged for birth weight, with the ROP group showing a broader distribution toward lower weights, reflecting a higher proportion of very low birth weight infants. The mean markers and overall spread of the plots further emphasized this disparity. Statistical analysis confirmed that these differences were not due to chance, with both gestational age and birth weight showing highly significant associations with ROP development ($p < 0.001$). These findings reinforce the strong influence of early gestational maturity and low birth weight on ROP vulnerability in this cohort [Figure 2]

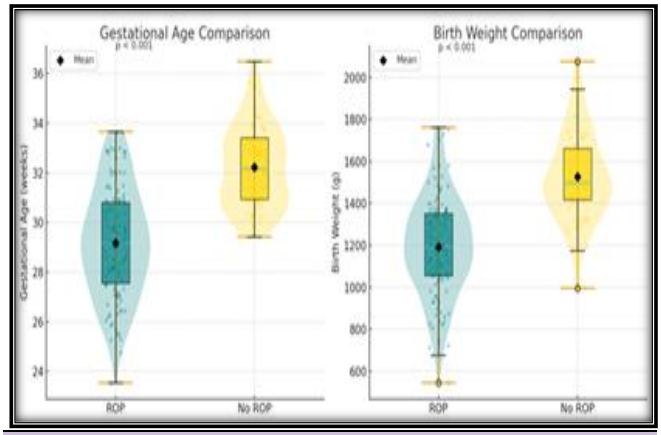

Figure 2: Comparison of Gestational Age and Birth Weight between Groups

Perinatal Risk Factors: In this cohort, several perinatal complications demonstrated a clear relationship with both the development and the severity of ROP. Sepsis was notably more frequent among affected infants, occurring in 44% of those with ROP compared with only 15% of the control group, a highly significant difference ($p < 0.001$). Apnea showed a similar pattern, occurring in 32% of infants with ROP versus 10% without ROP ($p = 0.001$). The need for multiple blood transfusions also emerged as an important contributor, with at least two transfusions required in 25% of ROP infants, compared with just 6% in the control group ($p = 0.004$). In addition to these factors, early postnatal growth played a meaningful role. Poor weight gain during the first month of life—defined as less than 20 grams per day—was documented in 41% of infants who developed ROP and showed a significant association with progression to more advanced disease, particularly Stage 3 and aggressive posterior ROP ($p = 0.008$). These findings highlight the multifactorial nature of ROP and emphasize the importance of closely monitoring systemic illness and early nutritional status in high-risk preterm infants.

Treatment Patterns and Therapeutic Outcomes: Out of the 120 infants diagnosed with ROP, 48 required active intervention, accounting for 40% of the affected group. Among those treated, laser photocoagulation remained the most commonly used modality, performed in 32 infants, which represented nearly two-thirds of all treated cases. The remaining 16 infants, constituting about one-third of the treatment group, received intravitreal anti-VEGF therapy. Treatment selection largely depended on the anatomical zone and severity of the disease: laser therapy was typically chosen for infants with Zone II involvement where the peripheral retina could be effectively targeted, whereas anti-VEGF injections were preferentially used in infants with posterior Zone I disease and in those presenting with aggressive posterior ROP, where rapid disease progression and posterior involvement made anti-VEGF a more suitable initial approach [Figure 3].

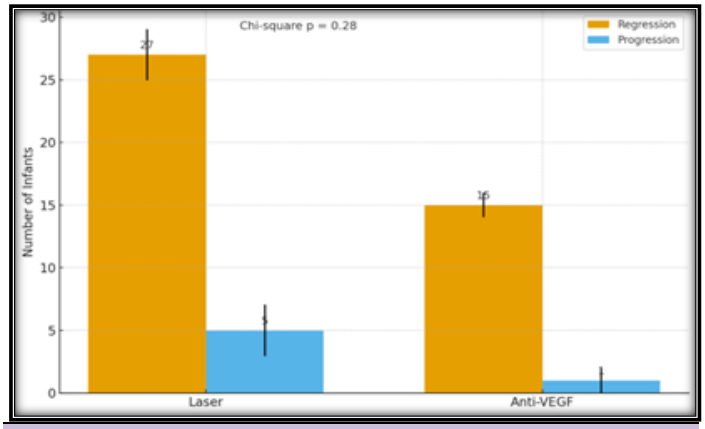

Figure 3: Treatment outcomes in infants with ROP receiving laser photocoagulation or intravitreal anti-VEGF therapy

Response to Treatment: Among the infants who required treatment, most responded well to therapy, though outcomes varied slightly between the two modalities. Complete regression of ROP was achieved in 27 of 32 infants treated with laser photocoagulation, for a success rate of 84.3%. A similarly favorable outcome was observed in the anti-VEGF group, with 15 of 16 treated infants (93.7%) showing full regression of disease. Although the regression rate appeared somewhat higher with anti-VEGF therapy, the difference between the two treatment groups was not statistically significant ($p = 0.28$). Notably, infants who received anti-VEGF therapy were significantly more premature and had lower birth weights compared to those treated with laser ($p < 0.01$), indicating that anti-VEGF was often reserved for infants presenting with more aggressive or posteriorly located disease [Figure 3].

Progression and Complications: Despite receiving appropriate treatment, a small subset of infants continued to show disease progression. Five infants, accounting for 10.4% of the treated group, advanced to more severe stages of ROP during follow-up. Four of these infants progressed to Stage 4 disease, characterized by partial retinal detachment, while one infant advanced to Stage 5, the most severe stage involving total retinal detachment. A

closer examination of clinical patterns revealed that progression was significantly more likely among infants who presented for their first screening beyond the recommended age. Those evaluated after 6 weeks of corrected age had a markedly higher risk of advancing to severe stages, a statistically significant difference ($p = 0.003$). This finding underscores the critical importance of timely screening and early intervention to prevent irreversible visual complications.

[Figure 4] demonstrates a clear positive relationship between the duration of oxygen therapy and the severity of ROP. As the scatter plot shows, infants who received oxygen support for longer periods tended to present with higher severity scores, with many of the more advanced cases clustering toward the upper end of the duration range. The fitted regression line highlights this upward trend, indicating a moderate but meaningful correlation between prolonged oxygen exposure and worsening ROP severity ($r = +0.46$). This association was statistically significant ($p < 0.001$), suggesting that extended oxygen therapy plays a substantial role in driving disease progression. Overall, the pattern reinforces the importance of careful oxygen monitoring in the NICU, as even relatively small increases in duration appeared to shift infants toward more severe forms of the disease.

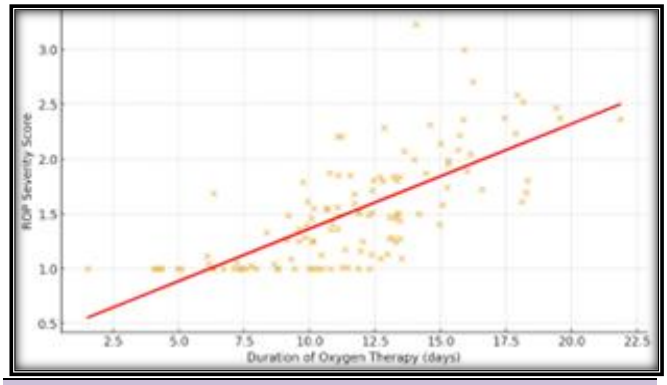

Figure 4: Association of Oxygen Therapy Duration with ROP Severity

Discussion

The present study provides a comprehensive overview of the clinical profile, risk factors, and short-term outcomes of ROP among NICU neonates in a tertiary care setting. The overall pattern observed in this cohort aligns with what has been described as the "third epidemic" of ROP in middle-income countries, where rising survival of very preterm infants is often accompanied by variable quality of neonatal care and inconsistent screening coverage.[10] The high proportion of infants with any stage ROP and the substantial number who required treatment underscores the continuing burden of the disease in India and other similar regions.

One of the most consistent findings in the literature—also reflected in this study—is the strong relationship between extreme prematurity, low birth weight, and ROP development.[10,11] Infants in the ROP group were significantly more premature and substantially smaller than infants who did not develop the disease. Similar trends have been highlighted by large epidemiologic datasets, which repeatedly identify gestational age as the single most important determinant of ROP vulnerability.[12,13] The wide gap between groups in this study reinforces the idea that even modest differences in maturity at birth translate into meaningful shifts in retinal development trajectories.

In addition to these baseline factors, several postnatal complications played a crucial role in shaping disease severity. Sepsis, apnea, and multiple blood transfusions emerged as significant contributors, paralleling the findings of earlier Indian and international studies.[10,14] These complications increase oxidative stress and disrupt systemic growth signals, such as IGF-1, thereby aggravating avascular retinal development and predisposing to more aggressive vascular proliferation. Poor early weight gain—another modifiable factor—was strongly associated with progression to higher stages. This observation echoes conclusions from earlier cohorts demonstrating that slow postnatal growth is a strong predictor of severe ROP and may serve as an early warning indicator for aggressive disease.[13]

The association between oxygen therapy duration and ROP severity was particularly notable. The positive correlation observed here mirrors findings from both classic historical reports and more recent controlled studies, which consistently caution against prolonged or unregulated oxygen exposure.[10,12] While oxygen remains an indispensable therapy for respiratory distress in preterm infants, small fluctuations in oxygen saturation—especially without strict monitoring—contribute to retinal ischemia–reperfusion injury and pathological angiogenesis. The significant relationship observed in this study highlights the importance of robust oxygen regulation systems and continuous staff training in neonatal units.

Treatment patterns in this cohort reflect current global trends. Laser photocoagulation remained the most commonly used modality, particularly in Zone II disease, aligning with established guidelines and the ETROP recommendations. Meanwhile, the increasing use of anti-VEGF therapy—especially for posterior disease or aggressive forms of ROP—is consistent with emerging practices across Asia.[15] Anti-VEGF–treated infants in this study were generally more premature and had more advanced disease at baseline, yet still demonstrated slightly higher regression rates compared with laser therapy. Although this difference was not statistically significant, it mirrors reports of better initial outcomes with anti-VEGF injections in posterior ROP.[15] At the same time, concerns about delayed reactivation and systemic VEGF suppression remain critical, underscoring the need for extended follow-up.[10]

The small number of infants who progressed to Stage 4 or 5 despite timely intervention were largely those who presented late for their first screening. This pattern has been repeatedly reported in Indian studies, where delayed referral and missed follow-up visits significantly contribute to advanced disease at initial presentation.[14,16] Outborn infants, in particular, remain highly vulnerable due to fragmented referral pathways. These findings highlight the need to reinforce discharge counselling, establish strong follow-up systems, and ensure timely screening across all levels of neonatal care.

Overall, this study reinforces the multifactorial nature of ROP and identifies several actionable points for improvement.

Strengthening early and inclusive screening, implementing reliable oxygen monitoring practices, optimizing nutritional support, and ensuring prompt evaluation of high-risk infants are essential strategies to reduce the burden of severe disease. The results also support the selective but increasing role of anti-VEGF agents, though long-term monitoring remains indispensable. Future studies with longer follow-up may help clarify refractive outcomes, late reactivation patterns, and neurodevelopmental impacts associated with current treatment approaches.

Conclusion

This study highlights the continued burden of retinopathy of prematurity among NICU neonates and underscores the strong influence of extreme prematurity, low birth weight, and postnatal complications on disease development. Prolonged oxygen exposure, sepsis, apnea, poor early weight gain, and the need for multiple transfusions emerged as key contributors to more severe forms of ROP. Early screening and timely intervention played a decisive role in improving outcomes, with both laser photocoagulation and anti-VEGF therapy demonstrating high rates of regression when appropriately administered. The small proportion of infants who progressed to advanced stages was largely composed of those who presented late, underscoring the critical importance of structured follow-up pathways and consistent screening practices. Overall, these findings reinforce the need for coordinated NICU care, vigilant monitoring of high-risk infants, and integrated neonatal ophthalmic collaboration to prevent avoidable visual impairment.

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Conflicts of interest

There are no conflicts of interest.

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