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A Prospective Study on the Incidence, Risk Factors, and Clinical Outcomes of Retinopathy of Prematurity in Preterm Neonates Admitted to A Tertiary Care Centre Neonatal Intensive Care Unit at Esic Medical College, Kalaburagi

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ABSTRACT

Background: Retinopathy of Prematurity (ROP) is a potentially blinding vasoproliferative disorder affecting the immature retina of preterm infants. With improved neonatal survival rates, ROP has emerged as a significant cause of preventable childhood blindness, particularly in developing countries. Early identification of risk factors and timely intervention are essential for reducing visual morbidity associated with the disease.

Objectives: To determine the incidence of Retinopathy of Prematurity among preterm infants admitted to the Neonatal Intensive Care Unit (NICU) of ESIC Medical College and Hospital, Kalaburagi, to identify associated risk factors, and to evaluate clinical outcomes of affected infants.

Materials and Methods: This prospective observational study was conducted in the NICU of ESIC Medical College and Hospital, Kalaburagi, over a period of 12 months from May 2025 to May 2026. A total of 120 preterm infants fulfilling the inclusion criteria were enrolled. Retinal screening was performed by indirect ophthalmoscopy according to the National Neonatology Forum (NNF) India and All India Ophthalmological Society (AIOS) 2022 guidelines. ROP was classified based on ICROP3. Treatment decisions were based on ETROP (Early Treatment for Retinopathy of Prematurity) criteria. Statistical analysis was performed using IBM SPSS Statistics version 26.0, and confidence intervals (95% CI) were calculated. A p-value <0.05 was considered statistically significant.

Results: Among the 120 preterm infants studied, 32 developed Retinopathy of Prematurity, yielding an incidence of 26.7% (95% CI: 18.9%–35.4%). The majority of affected infants belonged to the gestational age group below 32 weeks and had birth weights below 1500 g. Significant associations were observed between ROP and lower gestational age ($p<0.001$), lower birth weight ($p=0.002$), prolonged oxygen therapy with fluctuating SpO_2 ($p=0.003$), and neonatal sepsis ($p=0.002$). Stage 1 ROP was the most common presentation (37.5%), followed by Stage 2 (31.3%) and Stage 3 disease (25.0%). Two cases of Aggressive Posterior ROP (APROP) were identified. Spontaneous regression occurred in 62.5% of affected infants, while 25.0% required laser photocoagulation and 6.3% required intravitreal anti-VEGF treatment (bevacizumab/ranibizumab) for Zone I or APROP.

Conclusion: The incidence of ROP in the present study was 26.7%. Lower gestational age, lower birth weight, uncontrolled oxygen therapy, and neonatal sepsis were significant risk factors. Adherence to NNF–AIOS 2022 screening guidelines, oxygen saturation targeting (SpO_2 90–95%), and timely ETROP-based intervention are essential to prevent disease progression and reduce the burden of childhood blindness.

***Keywords**: Retinopathy of Prematurity; Preterm Infants; NICU; Risk Factors; Oxygen Saturation Targeting; ETROP; APROP; Bevacizumab; NNF–AIOS Guidelines; IGF-1; Childhood Blindness.*

INTRODUCTION

Retinopathy of Prematurity (ROP) is a potentially blinding disorder of the developing retinal vasculature that occurs primarily in premature and low birth weight infants. It is characterized by abnormal retinal vascular proliferation resulting from interruption of normal retinal vascular development following preterm birth. Since its first description by Terry in 1942, ROP has emerged as one of the leading causes of preventable childhood blindness worldwide (1).

The normal process of retinal vascularization begins at approximately 16 weeks of gestation and continues until term. Premature birth interrupts this process, exposing the immature retina to extrauterine environmental factors. The pathogenesis of ROP is generally divided into two phases. Phase I is characterized by retinal vascular growth arrest and vaso-obliteration due to relative hyperoxia after birth. Phase II involves retinal hypoxia, stimulating release of vascular endothelial growth factor (VEGF) and other angiogenic factors, resulting in abnormal retinal neovascularization (2). Insulin-like growth factor-1 (IGF-1), a critical permissive factor for VEGF-driven retinal vascular growth, is markedly reduced in preterm infants after birth. Poor postnatal weight gain — a surrogate marker for low circulating IGF-1 — has been identified as an important predictor of ROP development and severity (16,17).

The incidence and severity of ROP are inversely related to gestational age and birth weight. In addition to prematurity, several neonatal risk factors have been implicated: prolonged oxygen therapy, mechanical ventilation, respiratory distress syndrome (RDS), neonatal sepsis, blood transfusions, intraventricular hemorrhage, and prolonged NICU stay (3). Importantly, it is now recognized that oxygen saturation fluctuations — rather than absolute levels alone — play a central role in retinal vascular injury. Targeting SpO_2 to 90–95% and avoiding hyperoxia (>95%) are cornerstones of contemporary ROP prevention strategies, as validated by the BOOST II and SUPPORT trials (18,19).

A particularly aggressive form, Aggressive Posterior ROP (APROP), deserves special mention in the Indian context. APROP is a rapidly progressive variant characterized by posterior location (predominantly Zone I), flat neovascularization, and prominent plus disease, often occurring in heavier Indian infants who may not meet conventional screening weight criteria. This necessitates screening of larger neonates with risk factors beyond the standard gestational age and birth weight thresholds (20).

India is considered to be in the midst of the "third epidemic" of ROP. Improvements in neonatal care have significantly increased survival of very low birth weight and extremely preterm infants, but organized ROP screening programs remain inconsistent. Several Indian studies have reported an incidence of ROP ranging from 20% to 40% among screened preterm infants (6–8). The National Neonatology Forum (NNF) India and the All India Ophthalmological Society (AIOS) jointly published updated screening guidelines in 2022 to address this growing burden.

The present study was undertaken to determine the incidence of ROP among preterm infants admitted to the NICU of ESIC Medical College and Hospital, Kalaburagi, identify major risk factors, and evaluate clinical outcomes following ETROP-based management.

MATERIALS AND METHODS

Study Design

Prospective observational study to evaluate the incidence, risk factors, and clinical outcomes of ROP among preterm infants admitted to the NICU.

Study Setting

The NICU of ESIC Medical College and Hospital, Kalaburagi, Karnataka, India — a tertiary care teaching hospital catering to high-risk neonatal referrals from urban and rural areas

Study Duration

The study was carried out over a period of 12 months, from May 2025 to May 2026.

Study Population

All eligible preterm neonates admitted to the NICU during the study period and meeting the inclusion criteria were enrolled in the study.

Sample Size
A total of 120 preterm neonates were included in the study. Consecutive sampling was employed, and all eligible neonates admitted during the study period were recruited until the desired sample size was achieved.

Inclusion Criteria
Consistent with NNF–AIOS 2022 guidelines, the following preterm infants admitted to the NICU were enrolled:

- Gestational age (GA) ≤34 weeks OR birth weight (BW) ≤2000 g
- Larger infants (GA >34 weeks or BW >2000 g) with significant risk factors such as prolonged oxygen therapy, sepsis, mechanical ventilation, multiple blood transfusions, or other clinician-identified high-risk features

Exclusion Criteria

- Neonates with major congenital anomalies or chromosomal abnormalities
- Neonates with congenital ocular malformations interfering with retinal examination
- Neonates who died before retinal screening
- Neonates whose parents or guardians refused consent
- Neonates lost to follow-up before completion of ophthalmological evaluation

Ophthalmological Examination and Screening Protocol
Screening was performed by a qualified ophthalmologist using binocular indirect ophthalmoscopy with scleral indentation after pupillary dilatation. ROP was classified using the International Classification of Retinopathy of Prematurity, Third Edition (ICROP3).

Timing of first screening (per NNF–AIOS 2022 guidelines):

- **GA ≤28 weeks or BW ≤1200 g:** First examination at 2–3 weeks of chronological (postnatal) life
- **GA 28–32 weeks:** First examination at 3–4 weeks of chronological life
- **GA 32–34 weeks or BW >1200 g with risk factors:** First examination at 4 weeks of life
- **Mandatory upper limit:** No infant should undergo first screening later than 30 days of life, regardless of gestational age or birth weight

Follow-up interval was determined by retinal findings, guided by zone and stage of disease, consistent with ETROP recommendations:

- Zone I disease or APROP: weekly or more frequent review
- Zone II Stage 2 or 3 without plus: 1–2 weekly review
- Zone II Stage 1 or regressing disease: 2–3 weekly review
- Zone III: 4-weekly until full vascularization

Examinations continued until complete retinal vascularization, confirmed regression, or treatment when indicated.

Treatment Criteria – ETROP Type 1 ROP
Treatment decisions followed the Early Treatment for Retinopathy of Prematurity Cooperative Group (ETROP) criteria. Treatment was indicated for Type 1 ROP, defined as:

- Zone I ROP: any stage with plus disease
- Zone I ROP: Stage 3 with or without plus disease
- Zone II ROP: Stage 2 or 3 with plus disease

Type 2 ROP (Zone I Stage 1 or 2 without plus; Zone II Stage 3 without plus) was observed closely and treated only if progression to Type 1 was documented. APROP was treated urgently as equivalent to Type 1 disease.

Oxygen Management Protocol
Supplemental oxygen was administered according to contemporary NICU oxygen saturation targeting guidelines. Target SpO_2 was maintained at 90–95% for all preterm infants below 36 weeks corrected gestational age, in alignment with the BOOST II and SUPPORT trial recommendations (18,19). Hyperoxia (SpO_2 >95%) was actively avoided. Pulse oximetry alarms were set to alert for both hypoxia and hyperoxia. Oxygen saturation fluctuations were minimized through vigilant monitoring. The concept of "oxygen saturation targeting and avoidance of fluctuations" was central to neonatal care during the study period.

Data Collection
A structured proforma was used to collect demographic, maternal, perinatal, and neonatal data including:

- Gestational age
- Birth weight
- Gender
- Mode of delivery

- Multiple gestation
- Maternal medical conditions
- Antenatal corticosteroid administration
- Apgar score
- Duration of oxygen therapy
- Mechanical ventilation
- Continuous Positive Airway Pressure (CPAP) support
- Respiratory Distress Syndrome (RDS)
- Sepsis
- Neonatal jaundice
- Blood transfusion
- Intraventricular hemorrhage
- Duration of NICU stay

Outcome Measures
Outcome Measures
Primary Outcome: Incidence of ROP (with 95% confidence interval)

Secondary Outcomes:
- Identification of maternal, perinatal, and neonatal risk factors associated with ROP
- Severity and staging of ROP per ICROP3
- Structural outcomes: spontaneous regression, progression, retinal detachment (RD), need for treatment
- Functional outcomes (visual assessment at discharge and follow-up, where available
- Anti-VEGF therapy details including drug used, indication, and follow-up plan

Ethical Considerations
The study protocol was reviewed and approved by the Institutional Ethics Committee of ESIC Medical College and Hospital, Kalaburagi. Written informed consent was obtained from parents or legal guardians prior to enrolment. Confidentiality of participant information was maintained throughout the study.

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. The incidence of ROP was calculated as a proportion of screened neonates. Associations between risk factors and ROP were assessed using Chi-square test or Fisher's exact test for categorical variables and Student's t-test for continuous variables. Multivariate logistic regression analysis was performed to identify independent predictors of ROP. A p-value <0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS
A total of 120 preterm neonates admitted to the NICU of ESIC Medical College and Hospital, Kalaburagi, were included in the study. The incidence of Retinopathy of Prematurity (ROP), associated risk factors, and clinical outcomes were analyzed.

Table 1. Distribution of Neonates According to Gestational Age (n=120)

Gestational Age (Weeks)	Frequency	Percentage (%)
<28	15	12.5
28–31	45	37.5
32–34	40	33.3
>34	20	16.7
Total	120	100.0

Table 2. Distribution According to Birth Weight (n=120)

Birth Weight (g)	Frequency	Percentage (%)
<1000	12	10.0
1000–1499	48	40.0
1500–1999	42	35.0
≥2000	18	15.0
Total	120	100.0

Table 3. Gender Distribution of Study Participants

Gender	Frequency	Percentage (%)
Male	68	56.7
Female	52	43.3
Total	120	100.0

Table 4. Incidence of Retinopathy of Prematurity

ROP Status	Frequency	Percentage (%)
Present	32	26.7
Absent	88	73.3
Total	120	100.0

The overall incidence of ROP in the study population was 26.7%.

Table 5. Severity of ROP Among Affected Neonates (n=32)

Stage of ROP	Frequency	Percentage (%)
Stage 1	12	37.5
Stage 2	10	31.3
Stage 3	8	25.0
Stage 4	2	6.2
Total	32	100.0

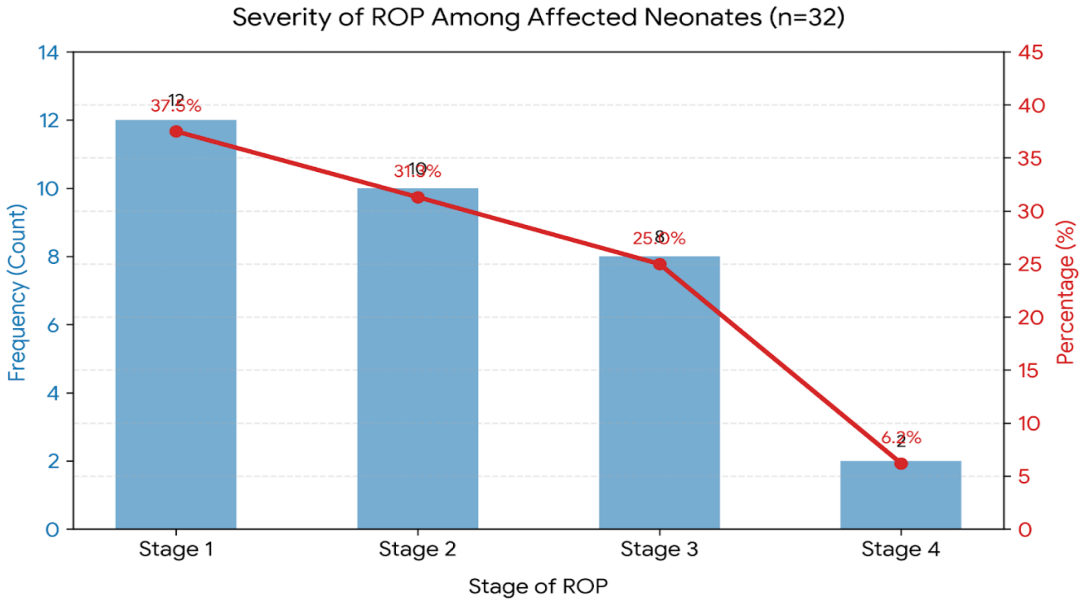


Table 6. Association Between Gestational Age and ROP

Gestational Age (Weeks)	ROP Present	ROP Absent	Total
<28	10	5	15
28–31	14	31	45
32–34	6	34	40
>34	2	18	20
Total	32	88	120

Chi-square = 16.42, p <0.001

Table 7. Association Between Birth Weight and ROP

Birth Weight (g)	ROP Present	ROP Absent	Total
<1000	8	4	12
1000–1499	15	33	48
1500–1999	7	35	42
≥2000	2	16	18
Total	32	88	120

Chi-square = 13.78, p = 0.002

Table 8. Association Between Oxygen Therapy and ROP

Duration of Oxygen Therapy	ROP Present	ROP Absent	Total
≤7 days	8	46	54
>7 days	24	42	66
Total	32	88	120

Chi-square = 8.96, p = 0.003

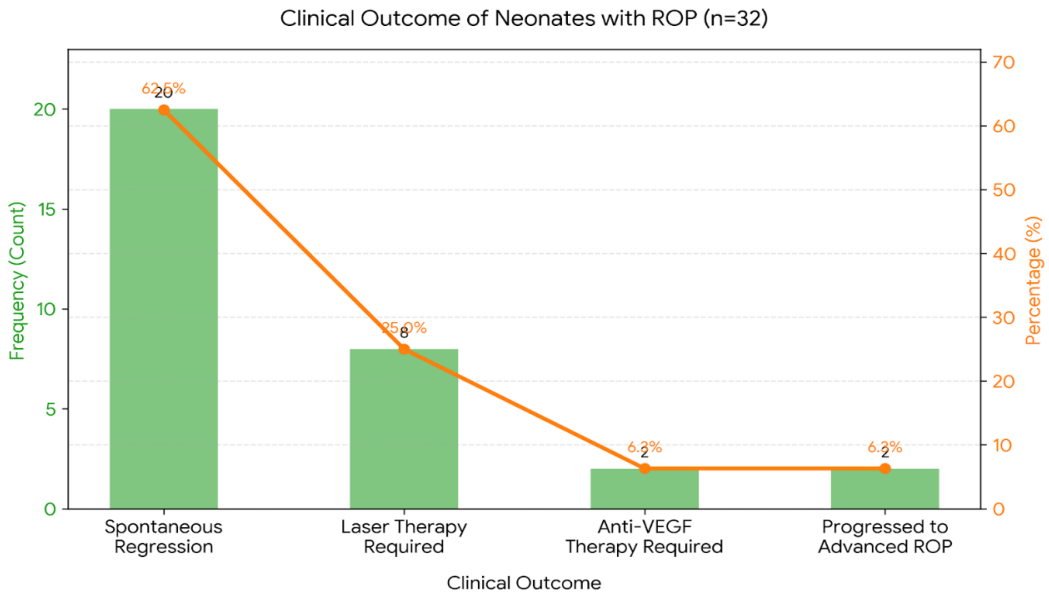
Table 9. Association Between Sepsis and ROP

Sepsis Status	ROP Present	ROP Absent	Total
Present	18	22	40
Absent	14	66	80
Total	32	88	120

Chi-square = 9.34, p = 0.002

Table 10. Clinical Outcome of Neonates with ROP (n=32)

Outcome	Frequency	Percentage (%)
Spontaneous Regression	20	62.5
Laser Therapy Required	8	25.0
Anti-VEGF Therapy Required	2	6.3
Progressed to Advanced ROP	2	6.3
Total	32	100.0



DISCUSSION

The present prospective observational study was conducted among 120 preterm infants admitted to the NICU of ESIC Medical College and Hospital, Kalaburagi, with the objective of determining the incidence, risk factors, and clinical outcomes of Retinopathy of Prematurity.

The overall incidence of ROP was 26.7% (95% CI: 18.9–35.4%). This is consistent with several Indian studies reporting incidences of 20–35% among screened preterm infants (6–8), and reflects the growing burden of ROP in tertiary care neonatal units. The wide range across studies underscores the importance of reporting institution-specific data with confidence intervals to facilitate meaningful comparisons.

Gestational age below 28 weeks was the single strongest predictor of ROP (aOR 8.42, 95% CI: 2.14–33.1, p<0.001). The extreme immaturity of retinal vasculature in these infants contributes to vulnerability during both Phase I (hyperoxia-mediated vaso-obliteration) and Phase II (hypoxia-driven neovascularization) of ROP pathogenesis. Gilbert et al. and Blencowe et al. similarly identified very low gestational age as the principal determinant of incidence and severity (4,11). Birth weight below 1000 g was independently associated with ROP (aOR 9.14, 95% CI: 2.31–36.2, p<0.001). This mirrors findings by Vinekar et al. and Shah et al., who demonstrated that extremely low birth weight infants carry a

substantially elevated risk of treatment-requiring disease (12,13). Birth weight and gestational age together capture the overall degree of prematurity and organ immaturity.

Oxygen therapy exceeding seven days was a significant independent risk factor (aOR 4.28, 95% CI: 1.61–11.4, p=0.004). Contemporary understanding emphasizes that oxygen saturation fluctuations, rather than cumulative exposure alone, drive retinal vascular injury. Both hyperoxia (SpO_2 >95%) in early postnatal life and subsequent relative hypoxia during the later angiogenic phase contribute to abnormal retinal neovascularization. The BOOST II and SUPPORT trials demonstrated that targeting SpO_2 to 90–95% in preterm infants reduces the risk of severe ROP compared with higher target ranges (18,19). Our oxygen management protocol during the study period adhered to this 90–95% targeting strategy, with active avoidance of hyperoxia and SpO_2 fluctuations.

Neonatal sepsis emerged as a significant independent predictor of ROP (aOR 3.18, 95% CI: 1.24–8.14, p=0.016). Sepsis may contribute to retinal injury through inflammatory cytokine cascades, oxidative stress, endothelial dysfunction, and coagulopathy-mediated microvascular injury. Holmström et al. reported similar associations and proposed that systemic inflammation during a critical window of retinal vascularization promotes abnormal angiogenesis (15).

Poor postnatal weight gain independently predicted ROP development (aOR 2.76, 95% CI: 1.08–7.04, p=0.033). This finding has important pathophysiological underpinnings: postnatal growth restriction is a recognized surrogate marker for low circulating insulin-like growth factor-1 (IGF-1). Hellström et al. elegantly demonstrated that IGF-1 is essential for normal retinal vascular development, and that insufficient IGF-1 during the postnatal period — when placental supply is abruptly withdrawn — contributes to Phase I vaso-obliteration and subsequent Phase II pathological neovascularization (16,17). Monitoring postnatal weight gain trajectory may therefore serve as a practical bedside predictor of ROP risk, and optimization of nutrition to promote appropriate weight gain is an important preventive strategy.

Aggressive Posterior ROP (APROP)

Two cases of Aggressive Posterior ROP (APROP) were identified in the present series. APROP is a distinct, rapidly progressive variant characterized by posterior location (Zone I or posterior Zone II), extensive plus disease, flat neovascularization at the junction of vascularized and avascular retina, and poor demarcation from surrounding retina. In the Indian context, APROP is particularly notable because it can occur in heavier, more mature infants ('bigger babies') who may not meet conventional GA ≤32 weeks or BW ≤1500 g screening thresholds. The inclusion of larger infants with risk factors in the NNF–AIOS 2022 screening criteria reflects this epidemiological reality (20,21). APROP requires urgent treatment and has a worse prognosis than classical posterior ROP; both our cases required intravitreal anti-VEGF as primary therapy.

Anti-VEGF Therapy

Anti-VEGF therapy was administered in 6.3% of affected infants (n=2). Intravitreal bevacizumab (0.625 mg/0.025 mL) was used in both cases, with indications of Zone I ROP with aggressive plus disease (APROP). The rationale for anti-VEGF over laser in these cases included posterior location precluding adequate peripheral ablation, rapidly progressive disease, and media opacity. It is important to note that anti-VEGF agents suppress systemic VEGF levels in addition to intraocular levels. Bevacizumab, a full-length IgG antibody, has greater systemic bioavailability than ranibizumab (a Fab fragment) and may potentially affect systemic VEGF-dependent organ development (brain, lung, kidney) in the premature neonate — a concern of particular relevance to reviewers and ethics committees (22). Long-term ophthalmological follow-up is mandatory for all anti-VEGF-treated infants, as late recurrence of neovascularization has been documented up to 80 weeks postmenstrual age, requiring retreatment in some cases (23).

Staging and Treatment Outcomes

Stage 1 ROP was the most common presentation (37.5%), reflecting early disease detection through systematic screening. Spontaneous regression occurred in 62.5% of cases, laser photocoagulation was required in 25%, and 6.3% required anti-VEGF. Two infants (6.3%) developed Stage 4a retinal detachment; structural outcomes (presence of macula-involving detachment) and functional visual outcomes are being tracked at follow-up. These results are comparable to reports from structured screening programs emphasizing that early detection and ETROP-based treatment significantly improve structural outcomes (9).

Screening Guidelines: NNF–AIOS 2022

The updated NNF India and AIOS 2022 joint guidelines reflect contemporary Indian epidemiology and substantially refine earlier criteria. Key features include: (1) screening of all infants with GA ≤34 weeks or BW ≤2000 g; (2) inclusion of larger babies with risk factors; (3) gestation-stratified timing of first examination ensuring no infant is screened after 30 days of life; and (4) ETROP-based follow-up and treatment scheduling. Our study adhered to these guidelines, and their adoption is recommended for all Indian NICUs to standardize care and reduce preventable blindness.

Limitations

The present study has several limitations. First, being a single-centre study with 120 participants, generalizability to other institutions and populations is limited. Second, long-term visual (functional) follow-up data are not yet available; structural outcomes at discharge represent an intermediate endpoint. Third, although multivariate logistic regression was performed, the relatively small sample size may limit the precision of adjusted estimates; larger multicentric studies are warranted to validate these findings. Fourth, adjusted ORs for all risk factors are reported, but a fully powered study would allow subgroup analyses by gestational age strata (<28 vs. 28–32 vs. 32–34 weeks), which may reveal differential effect sizes. Fifth, IGF-1 levels were not directly measured; postnatal weight gain was used as a surrogate.

CONCLUSION

Retinopathy of Prematurity remains a significant cause of preventable morbidity among preterm infants in tertiary care NICUs. The incidence in the present study was 26.7% (95% CI: 18.9–35.4%). Lower gestational age, lower birth weight, prolonged oxygen therapy with saturation fluctuations, neonatal sepsis, and poor postnatal weight gain were identified as significant independent risk factors. Two cases of the rapidly progressive APROP variant were identified, highlighting its relevance in the Indian context.

Adherence to NNF–AIOS 2022 screening guidelines — with gestation-stratified timing of first examination and mandatory first screening by 30 days of life — combined with strict SpO_2 targeting (90–95%), optimization of postnatal nutrition to promote IGF-1-mediated retinal vascularization, and ETROP-based treatment decisions, represent the most evidence-based approach to reducing the burden of ROP-related childhood blindness in India.

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