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Incidence and Risk Factors for Rop Development in Babies Admitted In Nicu Outborn and Inborn In A Tertiary Care Center and Association of Anemia in Newborns with ROP

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ABSTRACT

Background:

Retinopathy of prematurity (ROP) is a leading cause of preventable childhood blindness, particularly in India, where high preterm birth rates and expanding neonatal intensive care services contribute to a growing disease burden.

Objectives:

To determine the incidence of ROP among neonates admitted to inborn and outborn NICUs of a tertiary care hospital in Assam, and to evaluate risk factors.

Methods:

A prospective observational study was conducted at Gauhati Medical College and Hospital from October 2022 to August 2023. Neonates with birth weight <2000 g, gestational age <34 weeks, or 34–36 weeks with additional risk factors were included. Ophthalmic screening with indirect ophthalmoscopy was performed at 3–4 weeks of age and classified according to the International Classification of ROP. Clinical data and neonatal morbidities were analyzed using Chi-square test and logistic regression.

Results:

Of 300 infants screened, 62 developed ROP, giving an incidence of 20.7%. Incidence was higher in males (56.7%) and inversely related to gestational age (80% at 31 weeks vs. 6.1% at \geq 37 weeks) and birth weight (77.7% <1000 g vs. 7.7% >2500 g) (p<0.001). Prolonged oxygen exposure (>3 days) markedly increased risk (63.9% vs. 4.1%, p<0.001). Independent predictors included phototherapy (OR 13.79), birth asphyxia (OR 11.28), sepsis (OR 4.80), multiple transfusions (OR 5.73), respiratory distress syndrome (OR 3.62), and multiple births (OR 3.32), while antenatal steroid use was protective (OR 0.19). Most cases (91.3%) regressed spontaneously; 6 infants (9.7%) required treatment.

Conclusion:

ROP incidence in this cohort was substantial, emphasizing the need for universal screening of high-risk neonates, stringent oxygen monitoring, and judicious transfusion practices to reduce preventable blindness.

INTRODUCTION

Retinopathy of prematurity (ROP) is a vasoproliferative disorder of the developing retina occurring almost exclusively in premature infants, characterized by abnormal retinal neovascularization due to halted normal vascular development, which leads to fragile, disorganized blood vessels that may leak, bleed, or exert traction on the retina. In its most severe form, this

process culminates in partial or total retinal detachment, making ROP a leading cause of permanent visual impairment and childhood blindness [1,2]. Globally, ROP is recognized as one of the most important preventable causes of childhood blindness, particularly in the context of rapidly advancing neonatal intensive care; improved survival rates of very preterm and low birth weight infants have coincided with rising ROP incidence [2].

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Retinopathy of prematurity (ROP) remains a major global cause of childhood blindness with marked regional disparities. In 2019, the Global Burden of Disease Study highlighted significant worldwide variation in ROP-related morbidity [3]. Earlier estimates suggested that in 2010, about 184,700 preterm infants developed ROP, with nearly 20,000 left severely visually impaired or blind [4]. The disease has been described in three "epidemics": the first in the 1940s–1950s in high-income countries due to unmonitored oxygen, the second in the 1970s–1980s with improved survival of very preterm infants, and the ongoing third in middle-income countries, where advances in neonatal care outpace consistent screening [5,6].

India bears one of the highest burdens of retinopathy of prematurity (ROP) globally, due to the combination of a large number of preterm births and expanding neonatal intensive care services. Approximately 3.5 million babies are born preterm annually in India, among whom nearly 200,000 may survive to be at risk of ROP, and an estimated 20,000 infants develop treatable ROP each year [4, 7]. Reported incidence of ROP varies widely across Indian studies—from 20% to nearly 50%—reflecting differences in inclusion criteria, NICU practices, and regional variations [8]. Unlike high-income countries where ROP is largely limited to extremely preterm and very low birth weight infants, in India and other LMICs, even more mature infants (32–34 weeks gestation and >1500 g birth weight) are at risk—underscoring important implications for screening policies, as many Western guidelines may not be directly applicable to the Indian context [4, 8].

Pathophysiologically, ROP results from disruption of the normal retinal vascularization process, which begins around 16 weeks of gestation and completes near term [9]. Premature delivery leaves the peripheral retina avascular. In the extrauterine environment, exposure to supplemental oxygen and fluctuating oxygen levels downregulates vascular endothelial growth factor (VEGF) and insulin-like growth factor-1 (IGF-1), halting vessel growth [10]. Subsequent hypoxia in the avascular retina triggers excess VEGF release, leading to abnormal, fragile neovascularization [3]. The resulting fibrovascular proliferation may cause vitreoretinal traction, culminating in retinal detachment and blindness if untreated [10,11].

The International Classification of Retinopathy of Prematurity (ICROP) provides a standardized framework for grading disease severity [12]. In stage 1, there is a faint demarcation line between vascular and avascular retina, which progresses in stage 2 to an elevated ridge. Stage 3 is characterized by extraretinal fibrovascular proliferation extending into the vitreous. More advanced disease presents as retinal detachment, which is partial (subtotal) in stage 4 and total in stage 5. In addition, the presence of plus disease, defined by venous dilatation and arteriolar tortuosity of the posterior pole vessels, denotes an aggressive form with a higher risk of progression. [12]

The development of retinopathy of prematurity (ROP) is influenced by multiple perinatal and neonatal risk factors. The strongest and most consistent predictors are low gestational age, low birth weight, and prolonged or poorly regulated oxygen exposure [10,11]. These factors reflect the immaturity of retinal vasculature and the effects of oxygen fluctuations on vascular growth. In addition, several neonatal morbidities have been shown to increase susceptibility, including sepsis, respiratory distress syndrome, apnea, the requirement for phototherapy, and multiple blood transfusions [13]. Anemia and transfusion practices are important modifiers of ROP risk; while early prolonged anemia independently increases susceptibility [14], transfusion frequency also correlates with severity [15]. Recent Indian data confirm a higher incidence of ROP among anemic preterm infants, underscoring its clinical relevance [16]. While prematurity and oxygen exposure are primary drivers of ROP, comorbidities like sepsis, anemia, and transfusion-related stress further modulate risk, making their identification and management vital in high-burden settings such as India.

The public health impact of ROP is considerable. Childhood blindness has lifelong consequences, including loss of education, productivity, and quality of life, with added socioeconomic burden on families and society [17]. Unlike many other causes of childhood blindness, ROP is largely preventable through timely screening and treatment [4]. However, barriers such as lack of awareness among pediatricians and parents, limited access to trained ophthalmologists, and the absence of national-level screening infrastructure hinder effective control [18]. In addition, regional variability in neonatal care practices means that India requires context-specific screening guidelines, rather than reliance on international criteria alone [19]. Identifying and targeting modifiable risk factors such as anemia, transfusion exposure, and oxygen therapy duration is therefore essential for prevention [13]. Despite the growing recognition of ROP as a public health priority in India, several gaps persist. Many neonatal centers still lack integrated ROP screening programs, resulting in missed diagnoses and delayed treatment [18]. The role of anemia and transfusion-related practices in ROP development remains inadequately studied in Indian cohorts, despite emerging evidence of their contribution [14, 16]. Moreover, data from tertiary care centers may not always reflect conditions in smaller district or rural facilities, where monitoring resources are limited [20]. Thus, more prospective, multicenter studies are required to establish locally relevant incidence rates and risk factor profiles, thereby guiding effective national policy and practice [19].

In this context, the present study was designed to determine the incidence of retinopathy of prematurity (ROP) among neonates admitted to both inborn and outborn NICUs of a

tertiary care hospital in Assam. A further objective was to identify the potential risk factors contributing to the development of ROP.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective observational study conducted in the Neonatal Intensive Care Unit (NICU), both inborn and outborn, at Gauhati Medical College and Hospital, Assam, between 1st October 2022 and 31st August 2023. Institutional ethical clearance was obtained prior to commencement of the study, and written informed consent was taken from the parents or guardians of all participating neonates.

Study Population

Neonates admitted to the NICU who fulfilled the inclusion criteria were enrolled. Inclusion criteria comprised neonates with birth weight <2000 g, gestational age <34 weeks, and those with gestational age 34–36 weeks with additional risk factors such as cardio-respiratory support, prolonged oxygen therapy, respiratory distress syndrome, chronic lung disease, intraventricular hemorrhage, blood transfusion, sepsis, exchange transfusion, apneas, fetal hemorrhage, or poor postnatal weight gain. Exclusion criteria included neonates >34 weeks and >2000 g without risk factors, those whose parents/guardians declined participation, and newborns at risk of cortical blindness due to structural brain lesions.

Data Collection and Clinical Assessment

All enrolled neonates underwent a detailed assessment. A structured history was recorded, including perinatal history (prematurity, sepsis, prolonged rupture of membranes >18 hours, maternal urinary tract infection, intrapartum fever >38°C, perinatal asphyxia) and presenting history (respiratory distress requiring oxygen therapy, neonatal sepsis, phototherapy, congenital heart disease, blood transfusion). Clinical examination included measurement of weight, length, head circumference, gestational age (assessed using the New Ballard score), vital signs, neonatal reflexes, and neurological, respiratory, and circulatory assessments.

Screening and Follow-Up for ROP

Initial ophthalmic screening was carried out using indirect ophthalmoscopy after pharmacological pupil dilation with tropicamide plus phenylephrine eye drops. Neonates <28 weeks of gestation or <1200 g birth weight were screened at 3 weeks of age, while all others underwent their first screening at 4 weeks of age. Retinal findings were documented, including presence of immature retina, zone and stage of ROP, presence or absence of plus disease, prethreshold or threshold disease, and anterior segment complications such as rubeosis iridis, corneal opacities, secondary glaucoma, or cataract. Classification was done according to the revised International Classification of Retinopathy of Prematurity (ICROP). Follow-up examinations were performed at intervals of 2-3 weeks, depending on retinal findings, until vascularization was complete or disease regression occurred.

Statistical Analysis

The collected data were compiled in Microsoft Excel and analyzed using SPSS software. Descriptive statistics were generated in the form of charts, tables, and graphs. Associations between risk factors and ROP were evaluated using the Chi-square test. Logistic regression was applied to assess independent predictors. A p-value <0.05 was considered statistically significant at the 5% level of significance.

RESULTS

A total of 300 neonates were screened for retinopathy of prematurity (ROP), comprising 170 males and 130 females. ROP was diagnosed in 62 infants, giving an overall incidence of 20.7%. The proportion of ROP was higher among males (38 cases, 56.7%) compared to females (24 cases, 22.3%). Immature vascularization was identified in 12 infants. With respect to staging, 27 cases were in stage 1, 19 in stage 2, and 4 in stage 3. Zone-wise distribution revealed that 5 cases involved zone I, 25 cases zone II, and 32 cases zone III. (Table 1)

Table 1: Distribution of Retinopathy of Prematurity (ROP) Cases by Sex, Stage, and Zone of Retinal Involvement (N = 300)

Total Sample (300)		STAGES		ZONE	
Males	Females	Immature Vasularization	12	Zone 1	5
170	130	Stage 1	27	Zone 2	25
38 ROP+	24 ROP +	Stage 2	19	Zone 3	32
56.7%	22.3%	Stage 3	4		
TOTAL ROP CASES - 62					
INCIDENCE 20.7%					

When stratified by gestational age, the risk of ROP demonstrated a clear inverse relationship with increasing maturity. The highest proportions were observed among extremely preterm infants: 75% of those born at ≤29 weeks and 80% at 31 weeks developed ROP. Between 32 and 34 weeks of gestation, the incidence remained considerable (17–55%), while beyond 35 weeks the risk decreased sharply. By 37 weeks or more, only 6.1% of infants were affected. Statistical testing confirmed a highly significant association

between lower gestational age and ROP ($\chi^2=37.838$, p <0.001). A parallel trend was evident with birth weight. The incidence was 77.7% among neonates <1000 g, 68% in those 1001–1250 g, and 47.6% in the 1251–1500 g category. Thereafter, the risk progressively fell, with only 7.7% of infants >2500 g affected. This relationship between low birth weight and ROP was also highly significant ($\chi^2=66.521, p<0.001$). (Table 2, 3,4; Figure 1)

Table 2: Association of Gestational Age with Retinopathy of Prematurity (ROP) in the Study Population (N = 300)

GESTATIONAL	TOTAL	ROP	ROP ABSENT	PERCENTAGE
AGE		PRESENT		(%)
≤29	8	6	2	75
30	6	4	2	66.7
31	10	8	2	80
32	20	11	9	55
33	23	8	15	34.7
34	47	8	39	17
35	40	4	36	10
36	65	8	57	12.3
≥37	81	5	76	6.1
TOTAL	300	62	238	20.7

Table 3: Association of Birth Weight with Retinopathy of Prematurity (ROP) in the Study Population (N = 300)

BIRTH	TOTAL	ROP	ROP	PERCENTAGE
WEIGHT		PRESENT	ABESENT	(%)
<1000	9	7	2	77.7
1001-1250	25	17	8	68
1251-1500	21	10	11	47.6
1501-1750	55	10	45	18.1
1751-2000	92	10	82	10.8
2001-2500	46	4	42	8.7
>2500	52	4	48	7.7
	300	62		

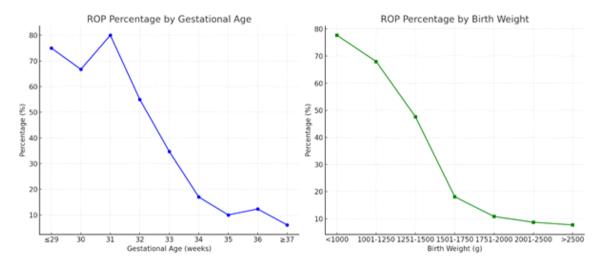


Figure 1. Percentage of retinopathy of prematurity (ROP) by gestational age and birth weight

ROP incidence decreased progressively with increasing gestational age and birth weight, with the highest risk seen in

Infants ≤31 weeks and <1250 g.

Table 4: Table X. Association of gestational age and birth weight with retinopathy of prematurity (ROP).

Group	ROP Present	ROP Absent	Total	Chi-square	P-value
GA ≤34	45	69	114	37.838	7.69E-10 (<0.001
) GA >34	17	169	186		
BW ≤1500	34	21	55	66.521	3.46E-16 (<0.001)
BW>1500	28	217	245		

Oxygen therapy duration showed a strong effect on ROP risk. Among infants who received oxygen for \leq 3 days, only 4.1% developed ROP, whereas 63.9% of those exposed for \geq 3 days

were affected. This difference was highly significant ($\chi^2 = 126.927$, p <0.001), underscoring prolonged oxygen exposure as a critical risk factor. (Table 5)

Table 5: Association of oxygen therapy duration with retinopathy of prematurity (ROP)

O ₂ Duration	ROP Present	ROP Absent	Total	Chi -square	P-value
≤3 days	9	208	217	126.927	1.93E -29 (<0.001
) >3 days	53	30	83		

Multivariate analysis revealed several independent risk factors. Phototherapy (OR 13.79, 95% CI 2.80–67.99), birth asphyxia (OR 11.28, 95% CI 4.33–29.40), sepsis (OR 4.80, 95% CI 1.84–12.55), multiple blood transfusions (OR 5.73, 95% CI 2.02–16.25), respiratory distress syndrome (OR 3.62, 95% CI 1.35–9.71), and multiple births (OR 3.32, 95%

CI 1.30–8.50) were all significantly associated with increased risk of ROP. In contrast, antenatal steroid use emerged as a significant protective factor (OR 0.19, 95% CI 0.07–0.51, p <0.001). Variables such as anemia, neonatal seizures, and apnea did not show a statistically significant association. (Table 6)

Table 6: Multivariate analysis of independent risk factors for retinopathy of prematurity (ROP).

Independent variables	P-value	Odds ratio	95.0% confidence interval for odds ratio	
Birth Asphyxia	<0.001	11.283	4.330	29.400
Sepsis	<0.001	4.799	1.835	12.547
Anemia	0.533	1.470	0.438	4.932
Neonatal seizure	0.479	0.655	0.203	2.116
Multiple blood transfusion	<0.001	5.734	2.024	16.245
Respiratory distress syndrome	<0.01	3.624	1.352	9.712
Multiple birth	<0.012	3.324	1.300	8.499
Antenatal steroid use	<0.001	0.194	0.073	0.514
Phototherapy	<0.001	13.792	2.798	67.992
Apnea	0.314	0.408	0.071	2.336

Among the 62 infants diagnosed with retinopathy of prematurity (ROP), the majority demonstrated spontaneous regression without the need for intervention. A total of 6 cases (9.7%) required active treatment, of which 4 infants (6.4%) underwent laser therapy alone, while 2 infants (3.2%) required a combination of laser therapy and intravitreal anti-VEGF injection. The remaining 58 infants (91.3%) showed spontaneous regression with conservative management and regular follow-up.

DISCUSSION

Retinopathy of prematurity (ROP) remains a major cause of avoidable childhood blindness globally, with the highest burden now seen in low- and middle-income countries (LMICs) [3,5]. The incidence and severity of ROP vary considerably across regions, largely influenced by neonatal care practices, oxygen monitoring, and survival of preterm infants [4,6]. While advances in neonatal intensive care have improved outcomes, they have also contributed to a rising number of infants at risk of ROP in countries like India [7,8]. Understanding these regional variations is essential to guide effective, context-specific prevention and management strategies. In this study, we evaluated the incidence and risk factors of ROP in a tertiary care center in Assam, with particular emphasis on the role of anemia.

In the present study, the overall incidence of ROP was 20.7%, which is comparable to some recent Indian reports but lower than earlier studies where incidence ranged from 32% to 47%. For instance, Charan et al. reported an incidence of 47.2% in a cohort from Chandigarh [21], Gopal et al. found 38% in a South Indian NICU [23], Rekha and Battu reported 46% from Tamil Nadu [22], and Aggarwal et al. documented 32% in New Delhi [24].

The relatively lower proportion in our cohort may partly reflect improvements in neonatal care practices, stricter oxygen monitoring, and the inclusion of infants beyond 34 weeks gestation and >1500 g, who are at comparatively lower risk. Nevertheless, the burden remains substantial, and our findings highlight the ongoing need for universal, systematic screening of all at-risk neonates admitted to NICUs to prevent missed diagnoses and delayed treatment [10]

A slightly higher proportion of males (56.7%) developed ROP compared with females (22.3%) in our study. Although sex is not consistently identified as an independent risk factor, a similar male preponderance has been reported in several Indian cohorts. Charan et al. observed that 59% of ROP cases were males in their Chandigarh series [21], while Rekha and Battu reported a male predominance of 62% among affected infants in Tamil Nadu [22]. Hungi et al., in a prospective study from rural Karnataka, also noted higher ROP incidence among males compared to females, though the difference was not statistically significant [20]. Biological plausibility for this trend has been proposed, including sex-related differences in angiogenic factors, hormonal influences, and greater systemic vulnerability of preterm male infants [10]. However, other studies such as those by Gopal et al. [23] and Aggarwal et al. [24] did not find a significant sex difference, underscoring the need for further large-scale prospective analyses to clarify this association in the Indian context.

A clear inverse association between gestational maturity and ROP was demonstrated in our study, with the highest incidence among infants \leq 31 weeks (75–80%) and the lowest (6.1%) in those \geq 37 weeks. This finding corroborates the established role of prematurity

as the strongest determinant of ROP [10,11]. Similar trends have been documented in Indian cohorts: Rekha and Battu reported that 82% of infants <32 weeks developed ROP compared to 17% beyond 34 weeks [22], while Hungi et al. observed a significantly higher incidence among those <32 weeks in a rural NICU [20]. Gopal et al. also noted that the majority of severe ROP cases occurred in neonates <32 weeks [23].

Similarly, low birth weight showed a strong correlation with disease risk in our study. Nearly 78% of infants <1000 g developed ROP, compared to only 7.7% of those >2500 g. These findings are consistent with global observations where the immaturity of retinal vasculature in very low birth weight infants predisposes them to severe disease [10,11]. Indian studies have reported comparable trends: Charan et al. found that over 80% of neonates <1000 g developed ROP [21], while Rekha and Battu reported an incidence of 73% in infants weighing <1250 g versus only 12% in those >1750 g [22]. Hungi et al., in a rural South Indian NICU, documented that 70% of neonates <1500 g were affected, reaffirming low birth weight as a critical determinant [20]. However, unlike in highincome countries where ROP is almost exclusively limited to extremely low birth weight infants, Indian cohorts have consistently shown that even babies weighing >1500 g remain at significant risk [8]. Vinekar et al. highlighted that such larger infants may develop ROP due to unregulated oxygen therapy, suboptimal monitoring, and comorbidities such as sepsis and anemia [18].

Prolonged oxygen exposure emerged as a powerful risk factor in our cohort. Only 4.1% of infants receiving oxygen ≤3 days developed ROP, whereas nearly 64% of those exposed for >3 days were affected, a highly significant difference (p<0.001). This strong association underscores the pivotal role of oxygen fluctuations and hyperoxia-hypoxia cycling in disrupting retinal angiogenesis, consistent with classical models of ROP pathophysiology [9–11]. Similar findings have been reported in other Indian studies: Rekha and Battu documented that the duration and concentration of oxygen supplementation were independent predictors of severe ROP [22], and Hungi et al. observed a markedly higher incidence of ROP among infants with prolonged oxygen requirement in a rural NICU [20]. Globally, early studies from the first epidemic in the 1940s–50s also demonstrated the role of unrestricted oxygen in driving high rates of blindness [5]. These findings highlight the need for strict oxygen monitoring in Indian NICUs, with adherence to target saturation, wider pulse oximetry use, and avoidance of unnecessary oxygen to reduce preventable ROP.

Multivariate logistic regression in our study identified several significant predictors of ROP. Phototherapy, birth asphyxia, sepsis, multiple blood transfusions, respiratory distress syndrome, and multiple births were all independently associated with disease occurrence. Among these, phototherapy showed the strongest odds ratio (OR 13.79), supporting the hypothesis that oxidative stress from hyperbilirubinemia management may contribute to retinal injury and disease progression [13]. Birth

asphyxia (OR 11.28) and sepsis (OR 4.80) also emerged as major contributors, consistent with previous Indian studies linking systemic hypoxia and inflammation to altered retinal angiogenesis [20,22]. Multiple blood transfusions (OR 5.73), cited in earlier reports by Maheshwari et al. further reinforce transfusion-related oxidative stress as a key modifiable risk [25]. Respiratory distress syndrome (OR 3.62) and multiple births (OR 3.32) also increased risk, likely reflecting the additive effects of prematurity and systemic instability. In contrast, antenatal steroid use (OR 0.19) demonstrated a clear protective effect, in line with studies showing that maternal steroids reduce the severity of neonatal respiratory morbidity and stabilize systemic physiology, thereby lowering susceptibility to ROP [13]. This finding underscores the importance of optimizing antenatal care as part of broader ROP prevention strategies.

Of the 62 infants diagnosed with ROP in our study, the vast majority (91.3%) regressed spontaneously with conservative management, while only 6 cases (9.7%) required intervention—4 with laser therapy and 2 with combined laser and intravitreal anti-VEGF therapy. This pattern is consistent with the natural history of ROP, where a significant proportion of early-stage disease undergoes spontaneous regression, and only a subset progresses to threshold or treatment-requiring stages [10,11]. Similar regression rates have been reported in Indian studies, with Vinekar et al. observing that over 85% of stage 1 and 2 cases resolved without intervention [18]. Nevertheless, the fact that nearly 1 in 10 infants required treatment underscores the critical importance of timely detection and follow-up, as delayed diagnosis in resourcelimited settings may lead to missed therapeutic windows and irreversible blindness [5].

The present study has certain limitations. The sample size was modest, and follow-up duration was relatively short. Being a single-center study from a tertiary NICU, results may not fully represent peripheral and rural facilities, where neonatal care and monitoring resources are limited. Nonetheless, the study provides valuable insight into incidence, risk factors, and treatment outcomes in a high-burden Indian state, reinforcing the call for locally tailored screening policies.

CONCLUSION

In conclusion, our study highlights that both the incidence and severity of ROP are inversely related to birth weight and gestational age, with an increasing trend of occurrence even among larger and more mature infants. In the Indian context, where neonatal care practices vary widely, it is essential that all infants <2000 g and <34 weeks undergo routine screening irrespective of additional risk factors. Early screening is particularly critical for low-birth-weight infants, as ROP is typically asymptomatic in its early stages but may progress rapidly if undetected. Preventive strategies such as judicious use of oxygen with strict monitoring, cautious administration of blood products, and

timely ophthalmic evaluation with appropriate intervention can significantly reduce the risk of progression to advanced stages. Strengthening screening programs, awareness, and resource allocation will therefore be pivotal in curbing the preventable burden of blindness due to ROP in India.

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