





Unmet Need for ROP Screening in Peripheral Rural Areas

Seema Meena , Kavita Bhatnagar , Abhishek Sheemar, Neeraj Gupta , Manjari Tandon, Nikhil Agrawal 

Department of Ophthalmology, AIIMS, Jodhpur, Rajasthan, India

Correspondence: Seema Meena, Department of Ophthalmology, AIIMS, Jodhpur, Rajasthan, India, Tel +91 9953572984, Email doc.seema15@gmail.com

Aim: To study the incidence and risk factors associated with retinopathy of prematurity (ROP) at a tertiary care centre in Western India.

Methods: A retrospective review of records of both referred and babies born in our hospital who were screened for ROP within the last 21 months at a tertiary care centre was done. The newborns were screened as per National Neonatology Forum of India guidelines. ROP was classified according to the International Classification for Retinopathy of Prematurity criteria.

Results: A total of 167 neonates were screened with an incidence of ROP of 26.9%. The mean gestational age (GA) and mean birth weight (BW) were 31.89 ± 2.824 weeks and 1538.11 ± 530.84 gm. The mean BW of neonates having any ROP was significantly lower (1296.98gm , $p < 0.001$), and the mean GA was also significantly lower in ROP babies (30.67 weeks, $p < 0.001$). O₂ supplementation, RDS, IVH, and NEC were the systemic risk factors that significantly correlated with ROP p -value < 0.001 . On analysis of the correlation of stage of ROP with BW and GA, a significant correlation of -0.307 ($p < 0.001$) and -0.283 ($p < 0.001$) was found.

Conclusion: The incidence of ROP in this study is similar to that reported in the literature from other regions. Other than LBW and GA, oxygen supplementation, RDS, IVH, and NEC were significant risk factors associated with ROP.

Keywords: retinal neovascularization, screening, risk factors of ROP, patterns of ROP

Introduction

Retinopathy of prematurity (ROP) is a vascular proliferative disorder of the retina first described in premature infants by T.L. Terry in 1942.^{1,2} Since then, it has been increasingly diagnosed in premature babies and identified as a significant cause of blindness in children. In India, the reported incidence is 20% to 30%, which is high.³⁻⁵ Initially, high supplemental oxygen saturation was considered to be the sole reason for ROP. Still, now other factors including low birth weight, prematurity, respiratory distress syndrome (RDS), anaemia, sepsis, and blood transfusion were also found to have a significant association with ROP.⁶ Timely fundus screening of a neonate is the most important intervention to prevent ROP. However, its incidence is still quite high in developing countries like India mostly because of unawareness and lack of speciality care services at a rural level.

Many studies identify the incidence and risk factors of ROP from different regions of the world. However, there are very scarce data on the profile of ROP patients in western India. A lot of research is currently undergoing in this field to understand various risk factors. Here, our main goal was to evaluate the risk factors, incidence and profile of ROP patients in western India.

Methods

A retrospective review of records of babies screened for at neonatal intensive care unit and ophthalmology OPD of a tertiary care institute AIIMS, Jodhpur, Rajasthan, was done from January 2020 to September 2021. The study adhered to the declaration of Helsinki, and Institutional Ethics Committee approval was obtained from the All India Institute of Medical Sciences, Jodhpur (Reference no. AIIMS/IEC/2021/3903). As the study was retrospective, parental consent was

not required for reviewing the medical records as per the ethics committee, and personal details of patients were not revealed. The inclusion criteria consisted of ROP screening guidelines followed in India.⁷ All babies born in our hospital admitted to the neonatal intensive care unit and referred babies from other health-care centres with the following criteria were examined by binocular indirect ophthalmoscopy and 28D lens: all infants born at 34 weeks or less gestational age; all infants weighing <2000 g or less at birth; all infants born at more than 34 weeks gestational age with associated risk factors (cardiorespiratory support; prolonged oxygen requirement; respiratory distress syndrome; chronic lung disease; fetal hemorrhage; blood transfusion; sepsis; exchange transfusion; intraventricular hemorrhage; apnea; poor postnatal weight gain); other preterm infants based on the discretion of the paediatrician or neonatologist.

ROP screening was done by a vitreoretinal consultant, and the data was entered in a designated form. ROP was classified according to the International Classification of Retinopathy of Prematurity (ICROP) criteria and managed and followed up as per the Early Treatment of Retinopathy of Prematurity (ETROP) study.^{8,9} Aggressive Posterior ROP (APROP), plus, and pre-plus diseases were diagnosed according to revised ICROP criteria.⁹ The screening was terminated when either full retinal vascularization was complete or regression of ROP was noted. The data was entered in the Microsoft Excel sheet and analysed using SPSS software version 23 (IBM Corp, Armonk, NY, USA). The zone, stage, plus, pre-plus and APROP were calculated using the basic frequency table. The bivariate analysis of the association of ROP with birth weight (BW), gestational age (GA), and other systemic risk factors was done using independent t and chi-square tests. The correlation of the stage of ROP with BW and GA was analysed by using Spearman's rho test. In the case of small sample size, Fisher's Exact Test was used. A p-value of <0.05 was considered significant.

Results

A total of 167 neonates were screened for ROP from January 2020 to September 2021 including both inborn and outborn out of which 80 were females and 87 were males. The mean gestational age (GA) of infants was 31.89 ± 2.824 weeks with 18.7% >34 weeks and 81.3% <34 weeks. The mean birth weight (BW) was 1538.11 ± 530.84 ranging from 580 to 3500gm (Table 1). Any form of ROP was present in 45 neonates with incidence of 26.9% (Table 2). The ROP stage and zones were distributed as follows (Table 3): 20% stage 1 (n = 9), 33.3% stage 2 (n = 15), 28.9% stage 3 (n = 13), 2.2% stage 4 (n = 1), 8.9% stage 5 (n = 4), 8.9% zone 1 (n = 4), 40% zone 2 (n = 18), and 53.3% zone 3 (n = 24). APROP was present in 20% (n = 9) whereas 11.11% (n = 5) and 15.6% (n = 7) had plus and pre-plus.

The mean BW of neonates having any ROP was significantly lower, 1296.98gm ($p < 0.001$), as compared to other babies screened for ROP (1626.35 gm). Similarly, the mean GA was also significantly lower in ROP babies, 30.67 weeks ($p < 0.001$), compared to other babies without ROP with a mean GA of 32.33 weeks.

In a bivariate analysis for correlation of ROP with other risk factors, which included mode of delivery (vaginal or caesarean), O₂ supplementation, respiratory distress syndrome (RDS), sepsis, blood transfusion, multiple births, necrotising enterocolitis (NEC), intraventricular haemorrhage (IVH), apnoea, anaemia, thrombocytopenia, patent ductus arteriosus, cardiovascular defects other than PDA and maternal risk factors (HTN, anaemia, assisted conception/premature rupture of membranes), only O₂ supplementation, RDS, IVH and NEC were significantly correlated with ROP, p-value <0.001 (Table 4). On analysis of the correlation of stage of ROP with BW and GA, a significant correlation of -0.307 (p

Table 1 Demographic Data of Screened Babies

		N% or Mean \pm SD
Sex	Female	47.9%
	Male	52.1%
BW (gram)		1538.11 \pm 530.84
GA (weeks)		31.89 \pm 2.824

Table 2 Comparison of Mean Gestational Age and Mean Birth Weight Between ROP Positive and Negative Cases by *t*-Test

	ROP	N	Mean	Std. Deviation	Std. Error Mean	p-value
GA (weeks)	Absent	122	32.33	2.754	0.177	
	Present	45	30.67	2.644	0.279	<0.001
Birth Weight	Absent	122	1626.35	541.352	34.728	
	Present	45	1296.98	420.333	44.307	<0.001

Table 3 Pattern of ROP

Parameter	Percentage
Zone	
1	8.9
2	40
3	53.3
Stage	
1	20
2	33.3
3	28.9
4	2.2
5	8.9
APROP	20
Plus	11.1
Pre-plus	15.6

< 0.001) and -0.283 ($p < 0.001$) was found. The laser was done for stage 3 babies (31.4%), surgery for stages 4a and 4b (11.1%). Regression of ROP was noted in 34.7%, and 31.4% did not follow up.

Discussion

A total of 167 neonates were screened at our centre for 21 months, with ROP present in 45 babies. The incidence of ROP in our study was 26.9%, comparable with other studies. In a study by Thakre et al, the incidence of ROP was 27.73%, with a mean birth weight of (1390 ± 310 g; $P = 0.012$) and the mean gestational age (31.12 ± 2.67 wk; $P = 0.0000$).¹⁰ In another study by Paranjpe et al from Maharashtra, the reported incidence of ROP was 35.62%.¹¹ A similar incidence with a slightly higher incidence has been reported in other studies (Table 5).^{12–19} The mean BW of screened babies was 1538.11 gm range (580–3500), and the mean GA was 31.89 weeks range (26–39) weeks. So very premature babies with very low birth weight (LBW) were part of this retrospective cohort, mostly inborn and screened in a neonatal intensive care unit (NICU).

On the other hand, the mean GA of ROP babies at 30.67 weeks was significantly lower than the mean GA of screened babies without ROP at 32.33 weeks, $p < 0.001$. Similarly, the mean BW of ROP babies (1296.98 gm) was significantly less than non-ROP babies (1626.35 gm, $p < 0.001$). So, both these parameters suggest that LBW and prematurity are significant risk factors for ROP development. In a premature delivery, these factors are unavoidable, so a mandatory ROP screening assumes utmost importance in these babies. This collaborates with other studies.^{12–19}

Table 4 Correlation of ROP with Risk Factors by Bivariate Analysis

Parameter	Chi-Square Test	P value
Delivery	0.295	0.863
O2 supplementation	16.815	0.001
Sepsis	0.619	0.734
Blood transfusion	4.901	0.086
NEC	9.618	0.008
Apnoea	0.857	0.652
RDS	11.448	0.003
Anaemia	1.906	0.386
Thrombocytopenia	0.913	0.633
Intraventricular haemorrhage	6.784	0.034
PDA	14.742	0.001
CVS defect other than PDA	1.099	0.577
Maternal (HTN, anaemia, assisted conception/PROM)	3.860	0.145

Table 5 Incidence of ROP in Recent Studies from India

Study	Year	Region	Sample Size	Incidence (%)	Mean BW (gm)	Mean GA (wks)
Present study	2021	Western Rajasthan	167	26.9	1297	30.67
Manjunathaswamy ³⁷	2021	Karnataka	591	10.2	1316	30.5
Kulkarni et al ¹⁷	2020	Maharashtra	2465	11.1	–	–
Padhi et al ¹⁸	2020	Odisha	3058	33.8	–	–
Dwivedi et al ¹⁴	2019	Madhya Pradesh	763	30.0	1340	31.05
Anudeep et al ¹³	2019	Puducherry	65	36.9	1630	30.8
Patel et al ¹⁵	2019	Gujarat	286	24.1	1622	33.23
Sathar et al ¹⁶	2019	Kerala	812	25.0	–	–
Agarwal et al ¹⁹	2019	South India	11088	25.4	–	–
Paranjpe et al ¹¹	2019	Maharashtra	233	35.62	–	–
Thakre et al ¹⁰	2017	Central Maharashtra	119	27.7	1390	31.1

In a bivariate analysis of risk factors for ROP, oxygen supplementation, RDS, IVH, and NEC were the systemic factors significantly associated with ROP with a p-value <0.001. Several studies have evaluated the role of supplemental oxygen in ROP; the prominent ones being STOP-ROP (Supplemental Therapy with Oxygen to Prevent ROP), ELGAN (Extremely Low Gestational Age Newborn), SUPPORT (Surfactant, Positive Airway Pressure, Pulse Oximetry Randomized Trial), and BOOST (Benefits of Oxygen Saturation Targeting Study).^{20–23} The STOP-ROP showed no difference in the incidence of ROP between 96–99% SaO₂ and 89–94% SaO₂ groups; the SUPPORT and BOOST studies showed higher mortality in lower oxygen saturation group though with lower incidence of ROP. Some of the authors

have found that lower oxygen saturation targets at young post-gestational ages with higher targets at older post gestational ages reduced the incidence of severe ROP.^{24–26} So, supplemental oxygen must be carefully titrated against its disadvantages. Similarly, RDS leads to hypoxia requiring assisted ventilation and supplemental oxygen, which can independently lead to ROP. The role of RDS in ROP has been evaluated, and very few studies have shown it to be a risk factor for ROP.²⁷ NEC was significantly associated with ROP in our study. Tomlinson et al have reported NEC to be an independent risk factor for ROP.²⁸ ROP were noted in 79% of infants with NEC in their study, with early NEC more strongly correlated with ROP than late NEC. Ford et al also reported that NEC might increase the risk of more advanced disease and the risk of laser treatment for ROP.²⁹ IVH was another factor in our study which was significantly associated with ROP. In a study of 324 eyes, a similar significant association of ROP with INH was noted by Chang et al.³⁰ The incidence of IVH in premature infants with a BW less than 1500gm is around 20% to 40%.³¹ A similarity in pathogenesis between IVH and ROP has been proposed, with immature vasculature as the underlying cause.^{32,33}

The other factors that were evaluated but were insignificant were the mode of delivery, sepsis, blood transfusion, multiple births, apnoea, anaemia, thrombocytopenia, patent ductus arteriosus, cardiovascular defects other than PDA and maternal risk factors, though individually they have been found associated with ROP in other studies.²⁷

Correlation of Stages of ROP with BW and GA by a bivariate analysis shows a significantly negative correlation of -0.371 ($p < 0.0001$) and -0.283 ($p < 0.0001$), suggesting an increase in the stage of ROP with lowering of BW and GA. This is a significant correlation that signifies the need for early screening for very premature and very low birth weight babies and their early referral to specialized centres for ROP management in case of stage progression. On quantitative analysis of ROP parameters, stage 3 was present in 28.9%. In contrast, stages 4 and 5 were noted in 2.2% and 8.9%, respectively, which required treatment. The babies having stages 4 and 5 were referred babies, suggesting an unmet need for ROP screening in peripheral rural areas. This is primarily due to a lack of awareness and non-availability of specific treatment in rural regions. These cases can be managed at the earliest, thereby reducing severe morbidity.

The incidence of type 1 ROP is variable in different studies. The presence of APROP was noted in 21.1% of ROP babies in zone 1 and 2 in our study, which is quite high and indicates the severity of ROP. A similar incidence of APROP of 28% was noted by Anamika et al in eastern Madhya Pradesh.¹⁴ However, other authors have reported a lower incidence of APROP, ranging from 9% to 13%.^{34,35} In our study, treatment was required in 42.5% of ROP babies; these patients required laser therapy/surgery or both. The spontaneous regression of ROP was noted in 22.8% of babies. In contrast, it has been around 90% in the CRYO-ROP study. More evaluation needs to be done to see an actual rate of regression in the eastern part of the world.³⁶ About 31.4% of patients did not come for follow-up as was advised. This is significant as ROP can progress rapidly and is difficult to treat later.

Initially, for ROP screening, babies less than 1750gm birth weight and 34 weeks gestational age were examined, but this has been modified to cover at-risk infants. The criteria of $<1500\text{gm}$ and <30 weeks as followed in the USA were found to be inadequate to cover all babies in developing countries like India.³⁸ On comparing ROP screening criteria with other countries worldwide, the birth weight limit in India is now higher at 2000gm, and the gestational age limit is also increased to 34–36 weeks.

The barriers to regular follow-up in a peripheral area need to be addressed, and regular counselling of parents is required in this regard. This can be achieved with proper planning and involving different welfare departments at the state and national levels through IEC (information, education and communication) activities.

Conclusion

The incidence of ROP in our study was similar to that reported in the literature from other regions. In addition to LBW and GA, RDS, IVH, and NEC were significant risk factors associated with ROP. The babies having stages 4 and 5 were referred babies suggesting an unmet need for ROP screening in peripheral rural areas.

Disclosure

The authors report no conflicts of interest in this work.

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