

Original Research Article

Retinopathy of prematurity in India: incidence, risk factors, outcome and the applicability of current screening criteria

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ABSTRACT

Background: To study the incidence, risk factors and outcome of retinopathy of prematurity (ROP) in at-risk newborns at tertiary care hospital in Vadodara.

Methods: Preterm infants with birth weight ≤ 2000 gm and gestation ≤ 34 weeks were screened for ROP at 4 weeks of birth for first screening or if < 28 week or < 1200 grams then at 3 weeks after delivery. Infants with birth weight > 2000 gm and gestation > 34 weeks were screened only if they had additional risk factors. Those found to have high risk ROP were treated.

Results: The incidence of ROP in 286 infants who were screened was 24.1%, 12 ROP positive cases were having birth weight > 2000 gm. On multivariate analysis risk factors predisposing to ROP ($P < 0.05$) were birth asphyxia, Sepsis, multiple blood transfusion, respiratory distress syndrome, multiple birth, antenatal steroid use and Phototherapy. Out of 69 infants who developed ROP, 6(8.7%) needed invasive management.

Conclusions: Risk factors predisposing to ROP were gestational age and birth weight alone and along with the various risk factors like birth asphyxia, sepsis, multiple blood transfusion, respiratory distress syndrome, multiple birth, antenatal steroid use and phototherapy. The occurrence of ROP is trending towards a rise including newborns with higher birth weight and gestational age in developing countries; hence necessitating to use different guideline for Screening of Newborns in these developing countries.

Keywords: Incidence, Gestational age, Low birth weight, Retinopathy of prematurity, Risk factors, Screening Criteria

INTRODUCTION

Retinopathy of prematurity (ROP) is a complex disease of the developing retinal vasculature in premature infants. It generally occurs in those infants who have received intensive neonatal care especially prolonged oxygen therapy and several other risk factors. It is thought to be caused by disorganized growth of retinal blood vessels which may result in scarring and retinal detachment. The key pathological change in ROP is peripheral retinal neovascularization. ROP can be mild and resolve

spontaneously but may lead to blindness in its severe form.

Over one-fourth of the world's blind children live in India. Childhood blindness in India accounts for a serious health problem. Over 22% of childhood blindness in India is attributable to Retinal aetiologies and "Retinopathy of Prematurity - ROP" is the commonest, and more preventable of these causes. In fact the WHO now suggests that India and other middle-income

countries are suffering from the 'third epidemic' of this disease.¹

Incidence of ROP varies in different neonatal units. It has been reported to vary from 21% to 65.8% in Western studies.²⁻⁴ Studies from India have reported ROP in 20% to 52% of screened neonates. More recent studies reporting lower rates of ROP ranging from 20% to 30%.⁵⁻⁷

The American Academy of Pediatrics (AAP) guidelines state that infants with a birth weight of less than 1500 g or gestational age of 30 weeks or less and selected infants with a birth weight between 1500 and 2000g or gestational age of more than 30 weeks with an unstable clinical course should have retinal screening examinations.⁸ In India, the gestational age of infants is not always known or accurate; in addition, ROP has been reported in larger babies with a birth weight between 1500 and 2000 grams.⁹⁻¹¹ There have been several anecdotal reports from ophthalmologists of babies between 1750 and 2000 grams being diagnosed with ROP. However, there is a paucity of population based data of ROP in these larger neonates.

Earlier studies had been done only on babies <1500 grams and <32 weeks. So, present study has been taken to find the incidence of ROP in babies >1500 grams and >32 weeks.

METHODS

A hospital based prospective study carried out at Neonatal intensive care unit of KGP Children Hospital, Vadodara between 20th November-2017 to 30th November-2018 and 286 neonates who fulfilled the inclusion criteria were screened for the presence of ROP after the approval from the Ethics committee and scientific committee.

*Inclusion criteria*⁷

- Birth weight less than 2000 grams
- Gestational age less than 34 weeks
- Gestational age between 34 to 36 weeks but with risk factors such as:
 - Cardio-respiratory support, Prolonged oxygen therapy, Respiratory distress syndrome, Chronic lung disease, Fetal haemorrhage, Blood transfusion, Neonatal sepsis, Exchange transfusion, Intraventricular haemorrhage, Apnea.

Exclusion criteria

- Babies born at >34 weeks of gestational age and >2000 grams without risk factors.
- Patients/Guardians not willing to enrol for study.
- Newborns at risk for developing cortical blindness (like those with structural brain lesions)

An informed consent obtained from the parents of neonates who included in the study. A detailed history including birth weight, gestational age at birth, expected date of delivery (EDD), problems during NICU stay and its management were recorded in a prestructured performa.

Method of examination

The neonates were followed up at 4 weeks of birth for First screening or if <28 week or <1200 grams then at 3 weeks after delivery. The study population was screened for ROP with Indirect Ophthalmoscope after dilatation with Tropicamide plus Phenylephrine eye-drops.

Information like Presence of immature retina, zone and worst stage of ROP, presence or absence of plus, pre threshold or threshold disease, Anterior segment complications like rubeosisiris, corneal abnormalities, secondary glaucoma and cataractous lens were noted and ROP was classified according to revised international classification of retinopathy of prematurity.¹² After that follow up examination of those neonates done at interval of 2 to 3 weeks based upon retinal findings.

Screening was continued regularly until retina was completely vascularised, ROP was fully regressed, there are no signs of risk for visual loss and ROP was progressed to a level of severity where treatment is indicated.

Indication of the treatment was based on results of Early Treatment for Retinopathy of Prematurity Randomized Trial (ETROP).¹³

Statistical methods

Results on Quantitative data were presented on Mean \pm SD (Min-Max) and results on categorical measurements were presented in Number (%). Pearson's chi-square test was used to check association between qualitative variables. Independent T-test was used to compare mean of two groups. Significance was assessed at 5% level of significance. Linear regression was performed to predict the ROP using various risk factors. The statistical analysis was performed using statistical package for social science (SPSS) 16.0 software.

RESULTS

In present study 286 neonates screened over a period of one year who fulfilled the screening criteria for ROP. Out of total 286 cases, 69 cases were positive for Retinopathy of prematurity (ROP). Hence incidence of ROP was 24.1% in present study. Out of total 286 cases, 161 were males (56.3%) and 125 were females (43.7%). From 161 males, 38 (23.6%) were have ROP and from 125 females, 31(24.8%) were have ROP. There was no statistically significant association between males and females for occurrence of ROP. (P value 0.814, X²: 0.055).

Out of 69 neonates who developed Retinopathy of prematurity, 13(18.8%) were having immature vascularization, 30(43.5%) were in stage 1, 21(30.4%) were in stage 2 and 5(7.3%) were in stage 3. Stage 1 was most common out of all stages. Preplus disease was noted in 6 cases. No plus or APROP cases were noted. While in zone wise distribution, out of 69 cases of ROP, 6 (8.7%) cases were in zone 1, 27(39.1%) cases were in zone 2, 36(52.2%) cases were in zone 3. Maximum incidence was in zone 3.

Table 1: Gestational age wise distribution of ROP.

GA	Total	ROP Present	ROP Absent	Percentage
≤29	10	7	3	70%
30	6	5	1	83.3%
31	9	8	1	88.9%
32	21	12	9	57.1%
33	19	7	12	36.8%
34	44	8	36	18.2%
35	39	3	36	7.7%
36	61	7	54	11.5%
≥37	77	12	65	15.5%
Total	286	69	217	

Gestational Age was recorded by the dates evident from the history as well as physical and neurological assessment of the newborn by New Ballard Score. Incidence of ROP in different gestational age group shown in Table 1. Maximum incidence of ROP was in 31

weeks and as gestational age increases incidence of ROP was decreased.

Birth weight usually correlates with maturity of the newborn. Incidence of ROP with various birth weight groups shown in Table 2. Incidence of ROP decreased as birth weight increases. Maximum incidence was in ≤1000 grams group.

Table 2: Birth weight wise distribution of ROP.

Birth Weight	Total	ROP Present	ROP Absent	Percentage
≤1000	10	8	2	80%
1001-1250	24	16	8	66.7%
1251-1500	20	11	9	55%
1501-1750	54	11	43	20.4%
1751-2000	91	11	80	12.1%
2001-2500	45	4	41	8.9%
>2500	42	8	34	19%
Total	286	69	217	

ROP positive cases in ≤34 weeks were 47(43.1%) out of 109 and in >34 weeks were 22(12.4%) out of 177. Therefore the difference in occurrence of ROP in neonates ≤34 weeks and >34 weeks was statistically significant at 95% confidence interval. (P value <0.001, X²: 34.709). While ROP positive cases in ≤1500 grams were 35(64.8%) out of 54 and in >1500 grams 34 (14.7%) out of 232 and this was also statistically significant at 95% confidence interval (P value <0.001, X²: 60.207) (Table 3).

Table 3: Comparison of ROP positive cases between ≤34 weeks and >34 weeks and ≤1500 grams and >1500 grams.

		Retinopathy of prematurity		Total	X ² value	p-value
		Present	Absent			
Gestational age (Weeks)	≤34	47	62	109	34.709	<0.001
	>34	22	155	177		
Birth weight (Gms)	≤ 1500	35	19	54	60.207	<0.001
	>1500	34	198	232		

Mean gestational age of ROP positive cases was 33.23±3.38 weeks and for ROP negative cases was 35.73±2.25 weeks, mean birth weight of ROP positive cases was 1622.38±612.89 and for ROP negative cases was 2032.98±496.23 and the difference of mean gestational age and mean birth weight between ROP positive and negative cases were statistically significant (p value <0.001) (Table 4). Out of 135 cases which had oxygen duration ≤3 days, 11 cases were Positive for ROP, while 91 cases which had oxygen duration for >3 days, 58 cases were Positive for ROP. So, there was statistically significant association between O2 duration

>3 days and ROP occurrence. (p value <0.001, X²: 79.195) (Table 5).

On univariate analysis done by Pearson chi-square test the risk factors significantly associated with ROP were Birth Asphyxia (P value 0.046), Apnea (p value <0.001), Sepsis (P value <0.001), Anemia (p value <0.001), Neonatal Seizure (p value 0.039), Multiple Blood Transfusion (p value <0.001), Respiratory distress syndrome (p value <0.001), Phototherapy (p value <0.001), Antenatal Steroid Use (p value <0.001) and Multiple Birth (p value <0.001).

Table 4: Comparison of mean age and mean birth weight between ROP positive and negative cases by T-test.

	Retinopathy of prematurity	N	Mean Age and birth weight	Std. deviation	T-value	p-value
Gestational age	Present	69	33.23	3.38	-7.046	<0.001
	Absent	217	35.73	2.25		
Birth weight	Present	69	1622.38	612.89	-5.643	<0.001
	Absent	217	2032.98	496.23		

Table 5: Comparison of ROP occurrence between ≤3 days and >3days oxygen duration groups.

		Retinopathy of prematurity		Total	X ² value	p-value
		Present	Absent			
O ₂ Duration	≤3 Days	11	124	135	79.195	<0.001
	>3 Days	58	33	91		

Table 6: Correlations of ROP with risk factors by multivariate logistic regression model.

Independent variables	p-value	Odds ratio	95.0% Confidence interval for odds ratio	
			Lower	Upper
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
Constant	<0.001	.014		

A Linear Regression test was performed on the dependent variable (presence of ROP) and various independent variables which were found to be significant by Chi square Test and on multivariate analysis the risk factors significantly associated with ROP were Birth Asphyxia (P value <0.001), Sepsis (P value <0.001), Multiple Blood Transfusion (P value <0.001), Respiratory Distress Syndrome (P value <0.01), Multiple Birth (P value <0.012), Antenatal Steroid Use (P value <0.001) and Phototherapy (P value <0.001). R² for this model was 0.72 and Predictability for ROP occurrence by this model was 90.9% (Table 6). Out of 69 ROP cases, 6 cases required treatment. 4 (5.8%) cases required laser treatment, 2 (2.9%) cases required both laser and VEGF and 63 (91.3%) cases regressed on their own.

DISCUSSION

With improving neonatal care and increasing survival of low and very low-birth weight children, the incidence of ROP expected to increase exponentially in the near future. In India, the gestational age of infants is not always known or accurate; in addition, ROP has been reported in larger babies with a birth weight between 1500 and 2000 grams.

In recent Indian studies also there has been a trend to include neonates with higher gestational age and birth weight. A study done by Charan R et al had screened all babies <1700 gm for ROP.¹⁴ Le c et al, retrospectively analysed data of 2910 infants admitted to the NICU between March 2008 and December 2013 and include neonates with ≤1750 g of birth weight.¹⁵ A study carried out at Safdarjung Hospital by Kapoor et al, all babies of <1800 grams were screened irrespective of their gestational age.¹⁶ The present study was an attempt to find incidence for ROP by newer guidelines from Government of India, published under the Rashtriya Bal Swasthya Karyakram (RBSK) which include screening of all newborns <2 kg and in present study it had shown the significant incidence of ROP in >1.5 kg newborns.⁷

In present study incidence of ROP was 24.1% which was similar like in Maheshwari R et al, (20%), Chaudhari S et al, (22.3%) and Goyal A et al, (25.4%).¹⁷⁻¹⁹

In other studies high incidence of ROP were noted, they were Charan R et al (47.2%), Gopal L et al (38%), Rekha S et al (46%), Aggarwal R et al, (32%), Hungi B et al, (41.5%), Padhi TR et al (33.2%) and Maini B et al, (44.6%).^{6,10,11,14,20-22} High incidence in this studies can be attributed to low sample size and mainly inclusion of <1500 grams and <34 weeks babies.

Birth weight usually correlates with maturity of the newborn. Hence in most of the previous studied, incidence of ROP was highest in babies weighing <1500

grams. However recent studies show a slightly different pattern. Vinekar et al, suggested that the scenario in developing countries is quite different. Larger and gestationally 'older' infants are more likely to develop ROP compared to their counterparts in Western countries. Hence, the application of Western screening guidelines for developing countries had been questioned by Jalali et al.^{23,24}

Mean birth weight (1622.38±612.89) in present study was higher than mean birth weight of other studies like 1285 grams in Charan R et al, 1355 grams in Gopal L et al, 1282 grams in Aggarwal R et al, 1113 grams in Kumar P et al, 1555 grams in Hungi B et al, and 1315 grams in Padhi TR et al.^{5,6,10,11,14} Most of these study screened neonates by following AAP screening guidelines (<1500 grams) or NNF screening guidelines (<1750 grams).⁸

By following AAP screening guidelines in present study, 34 ROP cases could be missed and by following NNF screening guidelines 23 ROP cases could be missed. Hence present study shows that ROP has been reported in larger babies with a birth weight between 1500 to 2000 grams, and mean birth weight of ROP positive cases was increased which was also seen in study of Hungi B et al, Padhi TR et al and Shah PK et al.^{10,11,15}

Prematurity is single most important risk factor for ROP. Both the incidence and severity of ROP are inversely related to gestational age. Mean gestational age (33.23±3.38 weeks) in present study was higher than mean gestational age of other studies like, 30.3 weeks in Aggarwal R et al, 29 weeks in Kumar P et al, 32 weeks Hungi B et al, 31 weeks in Le c et al, 30.7 weeks in Padhi TR et al and 31.6 weeks in Maini B et al.^{5,6,10,11,15,22}

In present study, stage 1 was more common out of all stages. Similar results like in present study were seen in Rekha S et al, Chaudhari S et al and Le c et al.^{15,18,21} While stage 2 was more common in Charan R et al and Goyal A et al.^{14,19} Stage IV and V were absent in present study as well as in recent studies. Due to increased awareness of ROP screening and early screening of ROP, end stage of ROP were in decreasing trend.

Over the years, the causal link between ROP, supplemental oxygen and its duration has been confirmed by various controlled trials and clinical studies. However, a safe level of oxygen usage has not been found. Complete elimination or restriction of oxygen from intensive management of neonate is not feasible. In present study result shows that maximum numbers (42%) of ROP cases was in 4-7 days group and maximum chances (73.3%) of ROP was in >14 days oxygen supplementation. In multivariate analysis Rekha S et al, Gupta VP et al, Kumar P et al, Chaudhari S et al and Maini B et al, were found similar result that oxygen therapy was a risk factor for ROP occurrence.^{5,18,21,22,25} Hence the important message would be to do stringent

screening of all newborns exposed to oxygen therapy and especially to those who exposed for >72 hours.

In present study, Sepsis was found to be a highly significant risk factor (p<0.001). It was also found by linear regression that septicemia alone was an independent risk factor in the causation of ROP. Maheshwari R et al, Aggarwal R et al, Gupta VP et al and Chaudhari S et al also found septicemia a significant risk factor in multivariate analysis.^{6,17,18,25} Measures to prevent and adequately treat sepsis would go a long way in lowering the incidence of ROP.

In our study, Anemia and Blood Transfusion, both were found to be highly significant risk factors (p<0.001) for the development of ROP. While on multivariate analysis multiple Blood Transfusions found to be significant independent risk factor. In the study conducted by Maheshwari R et al and Maini B et al blood transfusion emerged as an independent risk factor for severe ROP.^{17,22} Two other Indian studies by Rekha S et al and Chaudhari S et al also found blood transfusions as significant risk factor on univariate analysis.^{18,21} Although, the exact role of blood transfusion in ROP is not clear in Indian and western literature, with an apparent trend of more ROP with the association of blood transfusion, the nurseries all over the world are now using blood in a restricted manner. Exposure to blood of adult type, in preterm babies, itself may be causative of ROP in a dose independent manner.

In present study, Respiratory Distress Syndrome (RDS) (p <0.01) and Antenatal Steroid Use (p <0.001) both were found to be a highly significant risk factor on univariate and multivariate analysis. Kumar P et al and Kapoor R et al both found Respiratory Distress Syndrome (RDS) as a significant independent risk factor for ROP in multivariate analysis.^{5,16} While Maini B et al and Le c et al, on univariate analysis found that by giving complete dose of antenatal steroid, risk of developing ROP were decreased.^{15,22} Hence by giving complete dose of antenatal steroid we can prevent occurrence of ROP directly and indirectly by decreasing incidence of Respiratory Distress Syndrome (RDS).

Multiple birth (p <0.012) was also found as significant independent risk factor on multivariate analysis in present study. The same was also found by Kapoor R et al on multivariate analysis and by Le c et al on univariate analysis.^{15,16} High incidence of prematurity and low birth weight in multiple births may be causative factor for ROP.

Birth asphyxia (p <0.001) and Phototherapy (p <0.001) emerged as independent significant risk factor on multivariate analysis in present study. Chaudhari S et al found phototherapy as significant risk factor.¹⁸

In our study, Apnea and neonatal seizures were found as significant risk factor on univariate analysis. This was

also found by Aggarwal R et al, Gupta VP et al and Chaudhari S et al.^{6,18,25} While other risk factor like Hypoglycemia, Cardiac Defects, Transient Tachypnea Of New Born, Intraventricular Hemorrhage, Shock, Exchange Transfusion, PIH (pregnancy induced hypertension), Anemia In Pregnancy, PROM (Premature Rupture of Membrane) and Assisted Conception were found to have a non-significant causal relation with occurrence of ROP. (p >0.05)

In present study, out of 69 ROP cases, 6 cases were required treatment. 4(5.8%) cases were required laser treatment, 2(2.9%) cases required both laser and VEGF and 63(91.3%) cases regressed on their own. While in other studies like 46% required cryotherapy in Maheshwari R et al, 21% required laser and 5% required cryotherapy in Gopal L et al, 19.5% required cryotherapy in Rekha S et al, 8% required cryotherapy in Aggarwal R et al, 33% required laser in Chaudhari S et al, 26.4% required laser in Hungi B et al, 12 % required laser in Le c et al, and 9.8% required laser in Goyal A et al.^{6,15,17-21}

CONCLUSION

There is an increasing trend of occurrence of ROP in newborns with high birth weight and gestational age. Both the incidence and severity of ROP were inversely related to birth weight and gestational age. In developing countries like India, all newborns <2000 grams and <34 weeks should be screened irrespective of risk factors. Early screening is advised in VLBW and ELBW newborns because ROP tends to be asymptomatic in the early stages followed by a fulminant course later in these newborns. Oxygen should be used judiciously in newborns and try to limit duration as less as possible. Blood products should be used very carefully in newborns. Effective screening and timely intervention halted the progression of ROP to end stages.

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