ORIGINAL ARTICLE

Incidence and outcome of retinopathy of prematurity in neonates and correlation with risk factors

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ABSTRACT

BACKGROUND: To study the incidence and risk factors predisposing to retinopathy of prematurity (ROP) in at-risk newborns at SNCU of a tertiary care hospital in Vadodara **METHODS:** Preterm infants with birth weight < 1500gm and gestation <=34 weeks were screened for ROP at 4 weeks after birth or 31-33 weeks post conceptional age, whichever was later. Infants with birth weight 1500 to 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 113 infants who were screened was 30.9%. No ROP was found in infants weighing >2000gm or with a gestational age more than 37weeks. Risk factors predisposing to ROP (P<0.05) were oxygen therapy, apnoea, ventilation, sepsis, anaemia, blood product transfusion, ventilation, shock requiring vasopressors and multiple gestation. Out of the 37 infants who developed ROP, 17 (48.5%) needed invasive management. **CONCLUSION:** Approximately half of the infants with ROP needed invasive management the outcome of which was good. Risk factors predisposing to ROP were Gestational Age and Birth weight alone and alongwith the various risk factors like oxygen therapy, apnoea, mechanical ventilation, sepsis, anaemia, blood transfusion, Shock and Multiple Gestation. The occurrence of ROP is trending towards a rise including newborns with higher birth weight and gestational Age in developing countries; hence necessitating the need to revise the guidelines for Screening Newborns for presence of ROP to include babies with higher Birth weight and Gestational Age.

Key Words: ROP, prematurity, gestational age, birth weight, Risk Factors

INTRODUCTION

Retinopathy of prematurity (ROP) is a complex disease of the developing retinal vasculature in premature newborns.[1] It generally occurs in those neonates who have received intensive care especially prolonged oxygen therapy and those having 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 is peripheral retinal neovascularisation which may result in scarring and retinal detachment. ROP can be mild and resolve spontaneously but may lead to blindness in its severe form. Incidence of ROP varies in different neonatal units. It has been reported between 21% and 66%[2,3] In Western studies and 34-60%[4,5] in Indian studies. ROP is a disease related to prematurity, low birth weight, oxygen administration and various other factors.[6-12] Out of the approximate 26 million annual live births in India, approximately 8.7% of newborns in India weigh < 2000 grams[13,14] at birth. This would imply that almost 2 million newborns are at risk for developing ROP.

The American Academy of Paediatrics (AAP) guidelines[15] state that the following newborns should be screened for the presence of ROP: Those having birth weight <1500 g, gestational age <=30 weeks and selected infants with a birth weight between 1500 and 2000g or gestational age of more than 30 weeks with risk factors.

The scenario differs slightly in India. The gestational age of newborns is not always known or accurate. The survival of extremely premature and very low birth weight babies has increased in recent times. Also there are reports showing the presence of ROP even in larger babies having birth weight between 1500 and

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2000 grams and gestational age >32 weeks. There is a paucity of population based data of ROP in these larger neonates. There is a concern that screening all neonates with a birth weight of < 2000 g will considerably increase the number of eligible babies; this is not feasible in the current scenario of limited access to trained ophthalmologists. The window of opportunity to conduct effective retinal examination and carry out timely intervention is limited: 2-6 weeks post-natal age depending on the gestational age of the baby. This warrants that no eligible neonate should be missed in this critical time period.

At our NICU, amongst the LBW babies, Small-for-date babies account for more Low birth weight babies rather than premature babies. It was not feasible to carry out ROP analysis for all these newborns. Therefore, in the group of 1500-2000 grams birth weight and 34 weeks to 36 weeks 6 days gestation age only newborns having risk factors have been screened for ROP.

METHODS & MATERIALS

Newborns admitted at the SNCU of Department of Pediatrics, SSG Hospital, Baroda and falling in the inclusion criteria during the period from March 2015 to February 2016 were screened for the presence of ROP.

Inclusion criteria:

1. Babies born at ≤ 34 weeks of gestational age.
2. Babies born with birth weight < 1500 gms.
3. Babies born with birth weight >=1500 gm or >34 weeks with presence of other risk factors like:

- oxygen therapy and duration >=48 hours
- sepsis
- anaemia
- blood transfusion
- ventilation
- shock
- apnea
- surfactant administration
- exchange transfusion
- PDA
- PPROM
- PIH
- Multiple Gestation

Exclusion criteria:

1. Babies born at > 34 weeks of gestational age and >=1500gms without risk factors.
2. Newborns having major congenital anomalies
3. Parents/ guardians not willing to enroll for study
4. Newborns at risk for developing cortical blindness (like those with structural brain lesions)

Sample Size and Design: 113 babies were enrolled in the study. It is a prospective observational study.

Method of Examination: The initial examination was carried out at 4 weeks after birth or 31 to 33 weeks post conceptional age, whichever was later. A detailed history including birth weight, gestational age at birth, weight for gestation, problems during NICU stay and its management were recorded in a prestructured proforma. The study population was screened for ROP at the Dept of Ophthalamology, SSG hospital, Vadodara WITH Indirect Ophthalamoscope after dilatation with Tropicamide plus Phenylephrine eye-drops. Those babies who were found to have peripheral vascularisation were not followed up. Those with ROP were followed up till regression occurred or till the threshold for laser photocoagulation developed. Those with the requirement of intervention were referred for further management.

According to Early Treatment for Retinopathy of Prematurity study (ETROP) [13] the indications for laser treatment of ROP i.e. high risk ROP (Type I ROP) are:

- Zone I, any stage ROP with plus disease
- Zone I, stage 3 ROP with or without plus disease
- Zone II, stage 2 or 3 ROP with plus disease.

Continued follow up till spontaneous regression of ROP was done for the babies with Type II ROP, which includes:

- Zone I, stage 1 or 2 ROP without plus disease

- Zone II, stage 3 ROP without plus disease.

If these babies reached any of the criterion for Type I ROP during their follow up, they were treated.

Statistical analysis: Results on Quantitative data were presented on Mean ± SD (Min-Max) and results on categorical measurements were presented in Number (%). Significance was assessed at 5% level of significance. Chi-square/Fisher Exact tests were used to find the significance of study parameters on categorical scale between two or more groups. Linear regression was performed to predict the ROP using various risk factors. The Statistical software namely MedCalc 12.5.0 was used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs and tables.

RESULTS

Out of the total admissions at our SNCU during the period of study, 1007 babies had weight less than <2000 grams. Amongst these, 207 babies died and 208 babies left against medical advice and were hence not available for screening. Of the remaining 592 babies, 113 babies had presence of one or more risk factors mentioned in this study; of these, 35 of them turned out to have ROP and 17 required to have intervention.

In our hospital setting, majority of LBW babies are Small-For-Dates rather than Pre-terms. These babies do not have risk factors and are generally discharged from SNCU within the first week of admission. Hence, they were not available at 4-6 weeks of post gestational age for screening. In an ideal setting, all babies <37 weeks and <2000 grams should be screened for the presence of ROP. However in our study because of problems of feasibility, only babies with additional risk factors (other than gestational age and birth weight) were enrolled for the study.

The results were analysed on the basis of these variables for the presence or absence of ROP.

Of the 113 enrolled subjects, 69 (61.1%) were <= 34 weeks and 44 (38.9%) were >34 weeks. 67 (59.3%) were males and 46 (40.7%) were females. 56 (49.5%) were <1500 grams and 57 (50.5%) were 1500-2000 grams (Table 1).

Table 1: Demographic Profile of Study Population

FACTORS	n = 113	PERCENTAGE
GESTATIONAL AGE		
<=34 WEEKS	69	61.1%
>34 WEEKS	44	38.9%
SEX		
MALE	67	59.3%
FEMALE	46	40.7%
BIRTH WEIGHT		
<1500 GRAMS	56	49.5%
1500-2000 GRAMS	57	50.5%

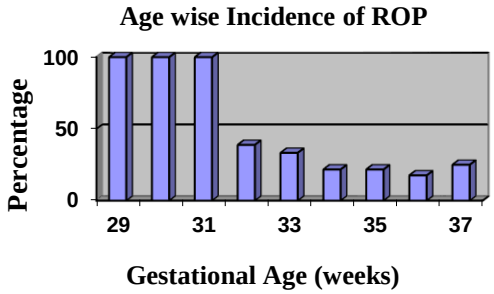
Out of the all patients, 35 developed ROP. Hence the incidence of occurrence of ROP in the study population is 309 per 1000 population (30.9%).

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. In our study, the gestational age ranged from 29-37 weeks with the incidence of ROP shown in table 2 and figure 1.

Table 2: Age-wise distribution of ROP

Gestational Age (Weeks)	Positive Cases	Negative Cases	Total Cases	Percentage
29	**2**	**0**	**2**	**100%**
30	**4**	**0**	**4**	**100%**
31	**1**	**0**	**1**	**100%**
32	**7**	**11**	**18**	**38.9%**
33	**7**	**14**	**21**	**33.3%**
34	**5**	**18**	**23**	**21.7%**
35	**5**	**18**	**23**	**21.7%**
36	**3**	**14**	**17**	**17.6%**
37	**1**	**3**	**4**	**25.0%**
Total	**35**	**78**	**113**	**30.9%**

Figure 1



(Positive cases in the table indicate the patients with ROP and Negative cases indicate patients without ROP). Mean age of the neonates who have ROP is 32.97 ± 2 weeks. Mean age of the neonates who do not have ROP is 34.24 ± 1.4 weeks. Out of the 113 babies under study, 26 of 69 (37.68%) who were <=34 weeks were found to have ROP and 9 of 44 (20.45%) who were >34 weeks were found to have ROP. By chi square test for gestational age

and occurrence of ROP, X^2 = 2.967 and p = 0.08. Therefore the difference in occurrence of ROP in neonates <=34 weeks and >34 weeks is not statistically significant at 95% confidence interval (Table 4).

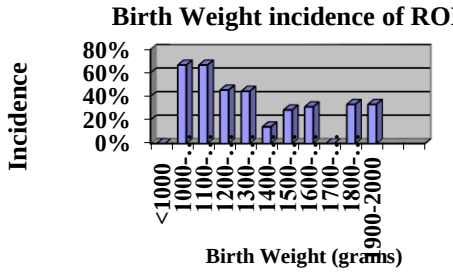
Amongst the study population of 113, 67 (59.3%) were males and 46 (40.7%) were females. 25 of 67 (37.3%) who were males were found to have ROP and 10 of 36 (21.7%) who were females were found to have ROP. By chi square test, X^2 = 2.409 and P =0.12. Hence the difference in occurrence of ROP in males and females is not statistically significant. Male: Female ratio in this study is 1.4 : 1. (Table 4) Of the total 35 patients with ROP, 25 (71.4%) were males and 10 (28.6%) were females.

In our study, the birth weight ranged from 900 to 2000 grams with the incidence of ROP shown in table 3 and figure 2.

Table 3: Comparison of incidence of ROP according to Birth weight

Birth Weight (grams)	Positive Cases	Negative Cases	Total Cases	Percentage
<1000	0	1	1	0%
1000 to <1100	2	1	3	66.7%
1100 to <1200	2	1	3	66.7%
1200 to <1300	5	6	11	45.5%
1300 to <1400	8	10	18	44.4%
1400 to <1500	3	18	21	14.3%
1500 to <1600	6	15	21	28.6%
1600 to <1700	5	11	16	31.3%
1700 to <1800	0	7	7	0%
1800 to <1900	2	4	6	33.3%
1900 to 2000	2	4	6	33.3%
Total	35	78	113	

Figure 2



Maximum incidence was found in the newborns with birth weight <1200 grams (66.7%). Mean weight of the neonates who had ROP was 1417.7 ± 230 grams and mean weight of the neonates who did not have ROP was 1501.3± 201 grams. On dividing the birth weights in 2 groups, <1500 and 1500-2000 grams, the result is in table 4.

Table 4: Correlation of gestational age, sex and birth weight with incidence of ROP

Parameter	ROP		X^2 VALUE	P VALUE
	Absent (n=78)	Present (n=35)		
Gestational Age				
<=34 weeks	43	26	2.967	0.08
>34 weeks	35	9		
Sex				
Male	42	25	2.409	0.12
Female	36	10		
Birth Weight				
<1500 grams	36	20	0.769	0.38
1500-2000 grams	42	15		

Out of the 113 babies under study, 20 of 56 (35.7%), who were <1500 grams, were found to have ROP and 15 of 57 (26.3%), who were 1500-2000 grams, were found to have ROP. By chi square test for birth weight and occurrence of ROP, X^2 = 0.769 and p = 0.3806. Therefore the difference in occurrence of ROP in neonates <1500 grams and 1500-2000 grams is not significant at 95% confidence interval (table 4).

Amongst the study population of 113, 65 (57.5%) were AFD babies and 48 (42.5%) were SFD babies. Out of the 65 AFD babies, 24 (36.9%) developed ROP; whereas out of 48 SFD babies (22.9%) developed ROP. By chi square test for AFD/SFD and occurrence of ROP, X^2 = 1.921 and p = 0.16. Therefore the difference in occurrence of ROP in these groups of neonates is statistically insignificant at 95% confidence interval.

Of the 73 enrolled patients who required oxygen, 30 (41.09%) developed ROP and 15 required treatment. By Fisher-Exact test for Oxygen requirement and occurrence of ROP, P=0.001493 suggesting that the difference in occurrence of ROP in these groups of neonates is HIGHLY significant. (Table 5)

Table 5: Correlation of risk factors with incidence of ROP (only statistically significant risk factors included for multivariate analysis)

Risk Factor	ROP Present	ROP Absent	P value	P value by multivariate analysis
Oxygen Given (n=73)	43	30	0.001	0.1007
Oxygen requirement >48 hours (n=30)	20	10	0.0045	0.0304
Sepsis (n=58)	29	29	<0.0001	0.0017

Anemia (n=8)	7	1	0.001	0.0221
BT (n=6)	5	1	0.01	0.1045
Ventilation (n=5)	5	0	0.003	0.0817
Apnea (n=5)	5	0	0.002	0.1879
Shock (n=3)	3	0	0.03	0.5736
Multiple Gestation (n=30)	26	4	0.02	0.0666
Asphyxia (n=8)	3	5	0.7	0.4579
Surfactant (n=1)	1	0	0.3	
Exchange Transfusion (n=1)	1	0	0.3	
PPROM (n=4)	3	1	0.08	
PDA (n=2)	0	2	1	
PIH (n=4)	2	2	0.5	
IVH (n=1)	1	0	0.3	

While studying the correlation of duration of oxygen administered and occurrence of ROP, the following results were found. By Chi square test, X^2 = 8.056 and P=0.0045, which was HIGHLY significant. Hence, longer duration of Oxygen therapy is also a risk factor for ROP. (Table 5)

Amongst 113, 58 had sepsis. Of these 58, 29 (50%) developed ROP and 15 required treatment. The Chi square value for sepsis and occurrence of ROP is 18.390 and P is <0.0001. This difference in occurrence of ROP in these groups of neonates is HIGHLY significant suggesting that sepsis is a risk factor for ROP. (Table 5)

Out of 113, 8 had anemia. Of these 8, 7 (87.5%) developed ROP and 3 required treatment. By Fisher-Exact test for Anemia and occurrence of ROP, P=0.001071; which is HIGHLY significant making it a risk factor for ROP. (Table 5)

Out of the 35 patients with ROP, 4 had Immature Vascularisation (IV), 10 had Stage 1 ROP, 12 had Stage 2 and 9 had Stage 3 ROP. Maximum Incidence is of Stage 2 ROP.

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/ Fisher Exact Test. By this, we can conclude that three risk factors namely duration of oxygen administration, Anemia and Sepsis were independent risk factors ($p<0.05$). Thus, these factors could have led to ROP even if they were the only risk factors. (Table 6)

DISCUSSION

Retinopathy of Prematurity is an important and preventable cause of Childhood Blindness. In recent Indian studies, its prevalence has been found to be significant in high-risk population. In recent Indian studies also there has been a trend to include neonates with higher gestational age and birth weight. In a study by Chaudhari S et al (2008),[14] all babies with < 1500 grams and <=32 weeks were screened and those with >=1500 grams and >32 weeks were screened for the presence for ROP. Maini B et al studied the risk factors and role of antenatal Betamethasone in Indian preterm newborns of <=34 weeks age.[17] In a study carried out at Safdarjung Hospital in 2011-2012 by Kapoor et al,[20] all babies of <=1800 grams were screened irrespective of their gestational age. Incidence of ROP in our study was found to be 30.9 %. The overall incidence in the study by Maini B S et al (2014) was 44.6%. This could have been attributed to a higher number of newborns with gestational age <34 weeks included in this study. In a study by Chaudhari S et al the incidence of ROP was 22.3 %. Our being a tertiary care centre would have increased number of sick newborns in comparison to this study. Kapoor et al (2012) reported the incidence of ROP in babies with ≤1800 g to be 13.67% (38/278). However it may be low as this study included all babies <=1800 grams irrespective of the risk factors.

All earlier studies and majority of western ones focused on neonates with <34 weeks especially <32 weeks. Our study found that there is not a statistically significant difference between incidence of ROP in neonates <=34 weeks (37.68%) and >34 weeks (20.45%). Also, it reiterates the importance of screening all neonates <32 weeks as the incidence of ROP in this group was very high (56%). A decreasing incidence of ROP was found as the gestational age increased.

29-32 weeks: 56%

33-34 weeks: 25%

>34 weeks: 20 %

Hence, Prematurity still remains the single most important risk factor for causation of retinopathy of prematurity.

Similar results were found in the recent Indian studies. Maini B et al (2014) found

that incidence of ROP in age group of 30-32 weeks is 59%. Kapoor R et al found maximum cases of ROP among the babies <32 weeks of gestation (32.76%).

The AIIMS protocol 2014 suggests to screen babies <32 weeks for the presence of ROP.[14] If this criterion alone was to be followed we would have missed 21 cases of ROP in the age group of >32 weeks. Hence, modification of the guidelines for screening of ROP in newborns should be considered especially in developing countries. Post conceptional age at first examination is also important, as early screening leads to detection of ROP at an early stage and prompt intervention.

In our study, the incidence of occurrence of ROP in males is 37.3% and 21.7% in females. This difference is not statistically significant ($p>0.05$) at 95% CI. This was also the case in other studies by Chaudhari S et al (2008), Maini B et al (2014) (in all $p>0.05$).

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[19] 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.[8] As a higher cutoff limit, they recommended screening babies born at <37 weeks and/or <2000 grams in the presence of high sickness score.

Also the birth weight of babies in our study did not necessarily correlate with the gestational age. A large number of babies (48) were SFD. This indicates that intra uterine hypoxia and ischemia might be a contributory factor for ROP development. The birth weight cut off criterion for ROP needs to be higher.

In this study, oxygen therapy as well as its duration have both been found to have a strong causal relationship with ROP ($p<0.01$ for both the variables). Chaudhari S et al (2008) and Vinekar et al found the similar result that oxygen therapy was a risk factor for occurrence of ROP. Kapoor R et al found the association of the prolonged oxygen exposure in babies weighing ≤1800 g on univariate analysis to be significant.

Also in our study, duration of oxygen therapy has proven to be an independent risk factor making it necessity to screen all the babies exposed to oxygen irrespective of the birth weight or maturity for the presence of ROP.

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. Hence the important message would be to do stringent screening of all newborns exposed to oxygen therapy.

In our study, sepsis was found to be a highly significant risk factor [p=<0.001]. It was also found by linear regression that septicemia alone is an independent risk factor in the causation of ROP. Vinekar et al, Aggarwal et al[5] and Chaudhari S et al (2008) also found that septicemia was a significant risk factor. 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. Hence Anaemia and Blood transfusion both are independent risk factors for the development of ROP. In the study by Maini et al, blood transfusion emerged as an independent risk factor for severe ROP. Three other Indian studies by Chaudhary *et al*, Dutta *et al*,[10] and Maheshwari *et al*,[18] also found blood transfusions as an independent risk factors. The same outcome was found in the study by Kapoor R et al. 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 our study, all these variables viz. Ventilation, apnoea, shock and multiple gestation were found to be significant risk factors [p=<0.001], so was it found in the studies by Kapoor R et al, Chaudhari S et al, Vinekar at al and Maheshwari et al. However, these risk factors are more likely to be concurrently present with other risk factors which were significant in the causation of ROP. Hence their independent effect on the occurrence of ROP needs to be studied in greater details. In our study, other variables like Surfactant therapy, PDA, Asphyxia, PPROM, PIH, IVH, Exchange Transfusion were found to have a non significant causal relation with the occurrence of ROP (>0.05).

Since the natural history of ROP tends to be asymptomatic in the early stages followed by a fulminant course if not taken care of, the standards of practice now demand carefully timed retinal examination of at risk infants for ROP. For this there must be a dedicated ophthalmologist experienced in the examination of the neonatal retina, so as to minimize the risks of childhood blindness and other ophthalmological morbidities.

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