

Original Research Article

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Incidence and risk factors of retinopathy of prematurity in Goa, India: a report from tertiary care centre

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ABSTRACT

Background: To report the incidence and risk factors leading to the development of retinopathy of prematurity (ROP) from a tertiary care center in the western Indian state of Goa, India.

Methods: This was a prospective observational study carried out in a level II neonatal intensive care unit (NICU) for a period of 18 months. Babies born at < 34 weeks' gestation and having a birth weight of <1500gm were screened for ROP and laser photocoagulation was done for those who developed threshold ROP. Group differences between any ROP and threshold ROP were analysed using the chi-square test.

Results: Out of the 244 preterm neonates screened, 37 developed ROP (15.16%), and 14 out of them (5.73%) developed threshold ROP requiring laser photocoagulation. Very low birth weight, prematurity, apnea, anemia, sepsis, respiratory distress syndrome, bronchopulmonary dysplasia, blood transfusions, exchange transfusions and days taken to reach full enteral feeds and regain birth weight were significantly associated with the development of ROP.

Conclusions: This is the first report of ROP from Goa where less than 1 in 5 babies developed ROP. This is similar to that reported across the rest of the country. Judicious oxygen use, ventilation strategies, transfusions guidelines, control of sepsis, early enteral feeds and adequate nutrition may help prevent the development of ROP in the future.

Keywords: NICU, Prematurity, ROP

INTRODUCTION

Retinopathy of prematurity (ROP) has emerged as an important cause of childhood blindness.^{1,2} Recent statistics show that there are about 1.5 million blind children globally with 75% residing in the developing world, many of which are due to untreated ROP.³ In view of the growing burden of ROP, the WHO vision 2020 program targets ROP for the prevention of childhood blindness.⁴ The cryotherapy for retinopathy of prematurity (CRYO-ROP) study established the benefit of treatment when ROP reaches the stage of threshold disease.⁵ Since then, screening of all premature babies for ROP has

become an important strategy in preventing ROP related childhood blindness.

The incidence of ROP has reduced considerably over the last few decades. The Cryo-ROP study reported an incidence of 66% and the early treatment of ROP study (ETROP) quoted an incidence of 68%.^{5,6} Since then, lower incidences have been reported from the west, ranging from 21-65%.^{7,8} The incidence and severity of the disease increase with decreasing birth weight and gestational age. The SUPPORT study enrolled very premature infants between 24-27 weeks' gestation and found an incidence of 28-32% of severe ROP requiring

either laser photocoagulation or intravitreal anti-VEGF injections.⁹

The incidence of ROP in India has been reported over the past 2 decades, with a reducing trend in the incidence across India. The reported incidence in India varies between 38%-51.9% among premature and low birth-weight babies.¹⁰⁻¹² In addition to low birth weight and gestational age, other risk factors implicated for the development of ROP include a high concentration of oxygen therapy, respiratory distress syndrome, apnea, sepsis, blood transfusions, and anemia.^{13,14}

This study was conducted at a level II NICU in a tertiary care center which is a part of a large multispecialty government general hospital. Here, all preterm babies are routinely screened for the presence of ROP. Although there are well-documented studies on the incidence of ROP from northern, eastern and southern India, there is scant data from western India. Specifically, there is no data on the incidence of ROP from Goa. In this study, authors present the incidence and risk factors associated with ROP over an 18-month period from a tertiary care hospital in Goa, India.

METHODS

The study was approved by the institutional review board and was conducted as per the tenets of the declaration of Helsinki. Informed consent was obtained from all the parents of the neonates enrolled in the study after explaining the nature of the study. This was a prospective observational study conducted for a period of 18 months in a level II NICU. All neonates weighing ≤ 1500 gm and/or with a gestation ≤ 34 weeks admitted to the NICU were included in the study. Infants with lethal congenital anomalies were excluded.

The initial examination was carried out at 4 weeks after birth or at 31 to 33 weeks' postconceptional age, whichever was later. Following the initial examination, the retina was examined weekly or every 2 weeks based on the course and severity of ROP, till complete vascularization of the retina. Those with ROP were examined every week till regression occurred or till they reached the threshold for laser treatment. The screening was done by an ophthalmologist using a binocular indirect ophthalmoscope. Babies were swaddled for pain control. Eyes were examined with an infant speculum and a Kreissig scleral depressor, under topical anesthesia using 2% proparacaine drops. The pupils were dilated by using 5% phenylephrine hydrochloride eye drops diluted in artificial tear drops in 1:3 dilution, 2 drops in each eye two or three times at an interval of 20 minutes till the pupils are fully dilated. Retinopathy was graded into stages and zones as per the international classification of retinopathy of prematurity (ICROP) classification. Laser photocoagulation was advised for infants who developed threshold disease as per ICROP classification.

Parameters recorded at the time of study enrollment were gestational age, gender, birth weight, maternal complications, APGAR score at birth, fetal distress, respiratory distress syndrome (RDS), and congenital malformations detected at birth. Oxygen administration was performed via hood, CPAP or intubation as required and continuous monitoring of oxygen saturation (SpO_2) was done by a pulse oximeter. Details of oxygen administration immediately after birth or anytime during the NICU stay were also recorded. Additionally, the partial pressure of oxygen (PaO_2) and partial pressure of carbon dioxide ($PaCO_2$) were also measured using arterial blood gas estimation.

Statistical analysis

Considering an incidence of 19.7% obtained from our prior pilot study, the total sample size required for the study was 240 babies. Data were analyzed with a computerized statistical package for social sciences 19 (SPSS 19). A database was created using the software and the frequency of variables was obtained. Univariate analysis was conducted using a chi-square test to study the association between the categorical variables and outcome.

RESULTS

A total of 244 babies fulfilled all the inclusion criteria and were screened for ROP as detailed above. Thirty-seven (74 eyes) of the 244 babies (15.16%) developed ROP of which 14 babies (28 eyes) (5.73%) developed threshold ROP requiring laser photocoagulation therapy. In the remaining 23 babies, the retinopathy regressed spontaneously with complete vascularization (Figure 1).

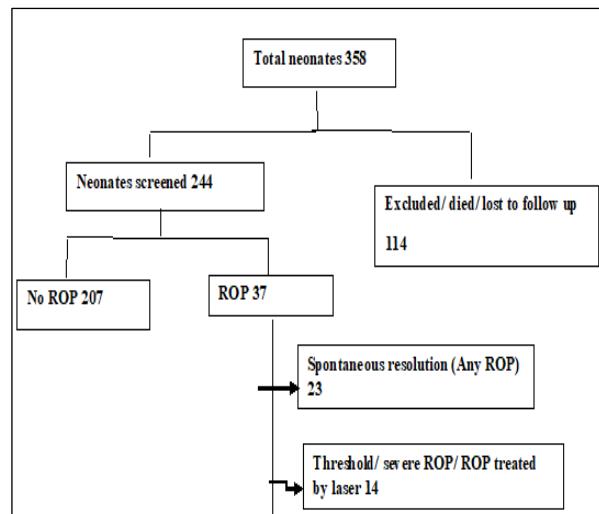


Figure 1: Incidence of ROP.

Mean gestational age of the study group was 32.05 ± 2.20 weeks and the mean birth weight was 1292.3 ± 240.2 gm. Neonates with threshold ROP had a significantly lower birth weight (1067.3 ± 185 gm) compared to those with

ROP which spontaneously regressed (1308.9±309 gm) and no ROP (1305.7±228 gm) (p=0.036).

Similarly, those with threshold ROP requiring laser photocoagulation had a significantly lower gestational age at birth (29.4±2 weeks) compared to those with ROP which spontaneously regressed (31.3±2 weeks) and no ROP (32.3±2 weeks) (p=0.001) (Table 1).

Shows differences in baseline demographics between all babies, those with any ROP (which includes all cases of ROP) and threshold ROP (which includes those cases of ROP which required laser photocoagulation).

The presence of maternal risk factors like pregnancy induced hypertension/ pre-eclampsia, premature rupture of membranes for more than 18 hours, symptoms suggestive of urinary tract infections and chorioamnionitis and placental abruption and their association with the occurrence of ROP were analyzed using univariate analysis by chi-square test. The P-values obtained for each were pregnancy induced hypertension/ pre-eclampsia (0.14), premature rupture of membranes for more than 18 hours (0.41), symptoms suggestive of urinary tract infections (0.83), chorioamnionitis (0.98) and placental abruption (0.02).

Table 1: Association between ROP and demographic risk factors (univariate analysis).

Characteristics -Demographic		Outcome			P value
		Total babies screened (n=244)	Any ROP (n=37)	Threshold ROP (n=14)	
Gender	Male	127 (52%)	21 (57%)	7 (50%)	0.671
	<28 weeks	7 (3%)	4 (11%)	2 (14%)	
Gestational age	28-32 weeks	138 (57%)	24 (65%)	11 (79%)	0.003*
	>32 weeks	99 (40%)	9 (24%)	1 (7%)	
Birth weight	<1000 gm	27 (11%)	8 (22%)	5 (36%)	0.001*
	1000-1500 gm	194 (80%)	23 (62%)	9 (64%)	
	>1500 gm	23 (9%)	6 (16%)	0	
Weight for gestational age	SGA (≤SD)	173 (77%)	24 (65%)	9 (64%)	0.804
	AGA	54 (22%)	11 (30%)	4 (29%)	
	LGA (≥2SD)	17 (1%)	2 (5%)	1 (7%)	

*Statistically significant (p<0.05), chi-square test

Table 2: Association between ROP and oxygen therapy.

Characteristics-oxygen therapy		Outcome			P value
		Total babies screened (n=244)	Any ROP (n=37)	Threshold ROP (n=14)	
O ₂	Yes	134 (55%)	32 (86%)	14 (100%)	0.001*
	No	110 (45%)	4 (11%)	0	
O ₂ duration	<3 days	43 (18%)	3 (8%)	0	0.001*
	4-7 days	42 (18%)	9 (24%)	5 (36%)	
Assisted ventilation	>7 days	49 (19%)	21 (57%)	9 (64%)	0.001*
	Yes	84 (34%)	26 (70%)	12 (86%)	
Ventilation duration (invasive/non-invasive ventilation)	No	160 (66%)	11 (30%)	2 (14%)	0.001*
	<3 days	160 (66%)	11 (30%)	2 (14%)	
	4-7 days	46 (19%)	10 (27%)	7 (50%)	0.001*
	>7 days	24 (10%)	9 (24%)	1 (7%)	
CPAP	>28 days	13 (5%)	7 (19%)	4 (29%)	0.001*
	Yes	138 (56%)	33 (89%)	14 (100%)	
CPAP duration	No	106 (44%)	4 (11%)	0	0.001*
	< 3 days	68 (28%)	10 (27%)	3 (21%)	
	4-7 days	48 (18%)	14 (38%)	4 (29%)	0.001*
	>7 days	22 (9%)	9 (24%)	7 (50%)	

Table 3: Comparison of arterial blood gas levels.

ABG levels		Outcome			P value
		Total babies screened (n=244)	Any ROP (n=37)	Threshold ROP (n=14)	
Highest FiO ₂	Not required	108 (44%)	4 (11%)	0	
	<0.4	38 (16%)	8 (22%)	2 (14%)	0.001*
	≥0.5	98 (40%)	25 (67%)	12 (86%)	
Max SO ₂ (%)	No	107 (44%)	5 (14%)	1 (7%)	
	≥95	136 (56%)	32 (86%)	13 (93%)	0.002*
	<95	1 (<1%)	0	0	
Min SO ₂ (%)	No	103 (42%)	4 (11%)	0	
	≥90	121 (50%)	23 (62%)	9 (64%)	0.001*
	<90	20 (8%)	10 (37%)	5 (36%)	
Max PO ₂ (mmHg)	No	105 (43%)	4 (11%)	0	
	<70	1	0	0	0.001*
	70-150	89 (36%)	11 (30%)	5 (36%)	
Min PO ₂ (mmHg)	>150	49 (20%)	22 (59%)	9 (64%)	
	N	109 (45%)	5 (14%)	1 (7%)	
	>50	122 (50%)	25 (68%)	10 (71%)	0.001*
Hyperoxia (PaO ₂ >70mmHg)	<50	13 (5%)	7 (18%)	3 (22%)	
	Yes	138 (57%)	33 (89%)	14 (100%)	0.001*
	No	106 (43%)	4 (11%)	0	
Hypoxia (PaO ₂ <50mmHg)	Yes	13 (5%)	7 (19%)	3 (21%)	0.001*
	No	231 (95%)	30 (81%)	11 (79%)	
Hypercapnia (>45mmHg)	Yes	38 (16%)	17 (46%)	8 (57%)	0.001*
	No	206 (84%)	20 (54%)	6 (43%)	

*Statistically significant (p<0.05), chi square test.

Table 4: Association between ROP and other co-morbidities of prematurity.

Co-morbidity	Outcome	Total number (n=244)	Any ROP (n=37)	Severe ROP (n=14)	P-value
Apnea	Yes	66 (27%)	21 (57%)	10 (59%)	0.001*
Anaemia	Yes	48 (20%)	16 (43%)	8	0.001*
Sepsis	Yes	131 (54%)	28 (75%)	10 (59%)	0.01*
Acidosis (ABG pH < 7.35)	Yes	119 (49%)	28 (75%)	11 (79%)	0.002*
Shock	Yes	138 (57%)	28 (75%)	11 (79%)	0.14
PDA	Yes	37 (15%)	9 (24%)	4 (29%)	0.206
IVH	Yes	21 (9%)	7 (19%)	3 (21%)	0.048
RDS	Yes	62 (25%)	21 (57%)	9 (64%)	0.001*
BPD	Yes	12 (5%)	5 (14%)	3 (21%)	0.001*
Days to regain birth weight	Not regained	41 (17%)	6 (16%)	0	
	<15	117 (48%)	17 (46%)	2 (14%)	0.001*
	> 15	86 (35%)	14 (38%)	12 (86%)	
Days to reach full enteral feeds	<7d	99 (40%)	3 (8%)	2 (15%)	
	7-15d	97 (40%)	13 (35%)	3 (21%)	0.001*
	>15d	48 (20%)	21 (57%)	9 (64%)	

*Statistically significant (p<0.05), chi square test.

This shows that those babies with threshold ROP had a significantly higher incidence of placental abruption compared to the other groups.

All neonates with threshold ROP required oxygen for a significantly longer duration required assisted ventilation

for longer periods and all of these neonates required CPAP at some point during their stay in the NICU (Table 2).

In terms of oxygen requirement, those with threshold ROP had higher FIO₂ requirements during their hospital stay, higher oxygen saturation levels SpO₂ on pulse-

oximetry and higher PaO_2 values on ABG. These neonates also had significantly higher incidences of hyperoxia, and hypercapnia noted on arterial blood gas (Table 3).

Additionally, those with ROP and threshold ROP had significantly higher proportions of other co-morbidities namely anemia, apnea, sepsis, acidosis, intraventricular hemorrhage, RDS and BPD (Table 4).

It is also worth noting that, these neonates took a significantly longer period to regain birth weight and to establish full enteral feeds. As far as the treatment received a significantly greater proportion of those with Any ROP and threshold ROP received blood transfusion ($P=0.001$) and exchange transfusion ($P=0.018$). Also, those neonates who received Caffeine ($P=0.001$) and Aminophylline ($P=0.002$) during the course of their NICU stay had a greater proportion of Any ROP and threshold ROP.

DISCUSSION

Authors found an incidence of ROP of 15% in our cohort of 244 preterm babies out of which 6% had threshold ROP requiring active intervention in the form of laser photocoagulation. Those with threshold ROP and any ROP had significantly lower birth weight and gestational age compared to the those without ROP. Authors also found a significant association between oxygen exposure through various modalities and PaO_2 levels on arterial blood gas with the occurrence of ROP. Finally, the other risk factors for ROP such as anemia, apnea, sepsis, RDS and BPD were also identified. Authors also found that receiving blood transfusion and exchange transfusions increased the risk of ROP development.

In present study, the incidence of ROP (15.16%) was found to be similar to some of the previous studies. Gupta VP et al, reported an incidence of ROP 21.7 % in Chaudhari S et al, reported an incidence of 22.3 % in Kumar P et al, reported the incidence to be 11.9 in 2011 and recently, Shetty SP et al.¹⁴⁻¹⁷ reported an incidence of ROP of 12.76% in 2014. A slightly lower incidence of ROP (10.2 %) was seen in a study conducted by Hungi B et al, in 2012 which was probably as a result of wider inclusion criteria of neonates with birth weight up to 2000gm.¹⁸

Earlier studies in India during the nineties showed a higher incidence of ROP. In 1995, a study by Gopal Let al, showed a ROP incidence of 38%, while in the studies conducted by Charan R et al, and Rekha S et al, incidence was 47% and 46 % respectively.^{10,11,19} Fourteen babies, of the 37 babies with ROP, developed threshold ROP requiring laser photocoagulation therapy, accounting for the incidence of 5.73%. These figures are similar to those reported by Chaudhari S et al, and Kumar P et al, in which the incidence of severe ROP requiring laser therapy was 7.4% and 4.7% respectively.^{14,16}

Oxygen therapy, its duration (>7 days) of administration and higher FiO_2 ($\text{FIO}_2 > 0.5$) had a significant association with ROP in present study. Present study has shown that hyperoxia ($\text{PaO}_2 > 70\text{mmHg}$), hypoxia ($\text{PaO}_2 < 50\text{mmHg}$) ($p < 0.001$) as well as hypercapnia ($\text{PaCO}_2 > 45\text{mmHg}$) ($p < 0.001$) has a significant association with development of ROP. Authors also found that a maximum SpO_2 greater than 95% had a strong association with the development of ROP. In a meta-analysis of ten studies, Chen ML et al, and colleagues showed that the need for oxygen is different at different developmental stages and phases of retinopathy of prematurity; low oxygen saturation (70-96%) in the first few postnatal weeks and high oxygen saturation (94-99%) at postmenstrual ages of 32 weeks or older were both associated with decreased risk for progression to severe retinopathy of prematurity.²⁰ In present study hypercapnia too had a significant association with the development of ROP, however, no previous studies have demonstrated such an association. In present study, it was observed that mechanical ventilation, duration of ventilation for more than 7days, CPAP and a duration of CPAP for more than 7 days were significantly associated with ROP. Murthy KB et al, found that mechanical ventilation and CPAP were non-significant risk factors for ROP.²¹ However, others observed that ventilator support and CPAP were significantly associated with the development of ROP.¹⁴

Sepsis was significantly associated with the development of ROP in present study ($p < 0.01$). This was in agreement with Gupta VP et al, and Vinekar A et al, which may be due to the effect of endotoxins on retinal blood vessels.^{15,22} Present study also showed that anemia and blood transfusion had a statistically significant association with ROP. This is explained by the fact that, adult RBCs are rich in 2,3 DPG whereas neonatal hemoglobin binds less firmly to oxygen, thus releasing excess oxygen to the retinal tissue and causing oxygen-related oxidative stress. Some attributed this effect to increased delivery of oxygen, iron, and free radicals of oxygen to the retina.¹⁸

In present study, it was observed that apneic spells ($p < 0.001$) and co-morbidities like respiratory distress syndrome (0.001), bronchopulmonary dysplasia ($p < 0.001$) had a significant association with ROP, while intraventricular hemorrhage, patent ductus arteriosus, phototherapy did not show a significant association. These findings were similar to study done by Taqui AM et al.²³ On the other hand, Owen LA et al, reported a significant relation between ROP development and patent ductus arteriosus, intraventricular hemorrhage and hypotension.²⁴ Chaudhari S et al, also observed a nonsignificant effect of phototherapy on ROP.¹⁴

It was observed in present study poor post-natal nutrition in the form of delay to regain birth weight (greater than 15 days) and delay in reaching full enteral feeds was significantly associated with ROP. The importance of post-natal weight gain in the development of retinopathy

of prematurity was shown in human infants in a clinical study in 2009.²⁵ Low serum IGF-1 after preterm birth is associated with poor postnatal growth and retinopathy of prematurity is also affected by immaturity, increased metabolic rate, insufficient nutrition, and concomitant illness, which could result in a vicious circle whereby nutrition is poorly assimilated and both general and vascular growth are impaired during the first few weeks of life.

CONCLUSION

In conclusion, the incidence of any stage of ROP in present study, in premature neonates born at gestation 34 weeks or less and/or birth weight 1500 gm or less was 15.16%. The incidence of threshold ROP requiring laser photocoagulation therapy was 5.73%. To the best of our knowledge, this is the first study in Goa, that has reported on the incidence and risk factors of ROP. The merits of the study were a relatively large sample size, reporting on many aspects of oxygen delivery including assisted ventilation, duration of oxygen delivered and associating ROP risk with arterial blood gas levels. The limitations of the study are the lack of photographic imaging of ROP due to lack of availability of a RetCam at our institution. Judicious use of oxygen, correct ventilation strategies, proper transfusions guidelines, control of sepsis, early initiation of enteral feeds and adequate nutrition may help prevent the development of ROP. All premature babies and those having predisposing risk factors should be regularly screened for ROP till complete vascularization of the retina. This will help in early diagnosis and timely treatment with laser photocoagulation and will contribute to preventing blindness.

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