

Research Article

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Retinopathy of prematurity in neonatal care unit

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ABSTRACT

Background: The objectives of the study were to find the incidence of retinopathy of prematurity and risk factors associated with its development.

Methods: Observational study was carried out at tertiary care hospital. Inclusion criteria: All hospitalized preterm infants with birth weight <1.5 Kg and gestational age ≤32 weeks. Selected preterm 1.5 to ≤2 Kg and gestational age >32 to ≤37 week, with additional risk factors (neonatal & maternal).

Results: The overall incidence of ROP in present study was 21.87%. Of these 14.28% had stage I, 64.28% had stage II ROP and 21.42% had plus disease. ROP was bilateral in all 14 neonates. The incidence was high in ELBW (100%), in the gestational age group 28-30 weeks (61.53%). Among the neonatal risk factors, oxygen therapy was a significant risk factor and chances of developing ROP were increased as duration of oxygen therapy increased (>72 hr) (p=0.0005). Episodes of hyperoxia, >3 episodes (p=0.0002) and hypoxia with 2-3 episodes, (p=0.008) were associated with development of ROP. Acidosis, (p=0.006), NEC (p=0.00002), proven sepsis (p=0.002), hyperbilirubinemia requiring intensive phototherapy (p=0.002), PDA (p=0.0007) and partial parenteral nutrition (p=0.02) were other risk factors associated. Mean NICU stay was longer in patients with ROP (p=0.001). Stage 1 and 2 ROP without plus disease showed spontaneous regression (100%) on follow up. Overall incidence of babies requiring laser treatment was 14.28%.

Conclusions: We should screen all preterm with birth weight <1500 g and gestational age ≤32 weeks, irrespective of risk factors and babies between 1.5 to 2 kg and between 32 and 37 weeks, having risk factors for ROP.

Keywords: ROP, Risk factors, Prematurity

INTRODUCTION

Retinopathy of prematurity (ROP) is a retinal disorder peculiar to premature infants potentially leading to blindness and severe visual impairment. It is an important cause of childhood blindness all over the world. With improved survival of very low birth weight (VLBW) infants, ROP is emerging as a significant problem even in developing countries like India.¹ The most important risk factor in the pathogenesis of ROP is prematurity. Other factors like problems with oxygenation, sepsis, HIE, NEC, apnea, jaundice, phototherapy and frequent blood

transfusions have also been implicated in causation of ROP.² Essentially asymptomatic in initial stages, a good screening program is essential for early detection and treatment of this condition.³ Clinical observations and comparative studies suggest that laser therapy is effective as in achieving favourable visual outcome.⁴ Most of the available data on ROP is from developed countries which cannot be extrapolated to less developed countries where the quality of care, genetic composition and incidence of growth retardation is different. There is a need to study the risk factors for severe ROP which can be taken care of and can be a step towards decreasing this disease.⁵

Keeping this in mind, this study was planned to find the incidence and risk factors contributing to ROP in our neonatal nursery. The aim was to determine incidence of ROP in preterm neonates, and various neonatal and maternal risk factors that can predispose to development of ROP.

METHODS

Study population

This prospective cohort study was conducted in neonatal intensive care unit of Pediatric department of a tertiary care hospital to study the incidence and the association of risk factors for development of ROP in preterm babies.

Inclusion criteria⁶

All babies admitted in our nursery who were 1) preterm infants with BW<1.5 Kg and Gestational Age \leq 32 weeks. 2) The selected preterm 1.5 to \leq 2 Kg and GA > 32 weeks up to \leq 37 week, only if they had additional risk factors (neonatal &/or maternal).

Neonatal risk factors

The following neonatal risk factors were considered: oxygen therapy, hypoxia, hyperoxia, acidosis, ventilatory support, CPAP support, apnea, birth asphyxia, hyaline membrane disease, HIE, sepsis, hypoglycemia, blood transfusion, hyper-bilirubinemia that require intensive phototherapy, NEC, anaemia, hypotension, surfactant therapy, undergone surgery, PDA, CHD other than PDA, intraventricular hemorrhage (IVH), partial parental nutrition and duration of hospital stay.

Maternal risk factors

The following maternal risk factors were also considered: APH, PROM (>12 hr), chorioamnionitis, gestational diabetes, maternal hypertension, multiple pregnancy and anaemia. Exclusion criteria: Infants with serious/lethal congenital malformations, babies who expired, did not come for follow-up or left against medical advice were excluded from the study.

Study design

Infants were enrolled into the study from March 2010 to September 2011 as per inclusion criteria. Eye examinations were performed on all infants who met the screening criteria. First screening was done at 4 week of post natal age or at 32-34 weeks of post conceptional age and subsequent examination was done according to stages of retinopathy of prematurity and it was decided by retinal surgeon according to the stage. The pupils were dilated using 2.5% phenylephrine eye drops and 0.4% tropicamide eye drops instilled in to each eye three times at interval of 15 minutes prior to examination.

Precaution

Babies were kept NBM half hour before examination to avoid vomiting. Examination was done under all aseptic precaution with an indirect ophthalmoscope. A pediatric wire speculum was used to keep eyelids apart. During examination babies were monitored using cardio-respiratory monitor and patients who required treatment were given laser therapy, during which they were monitored using cardio-respiratory monitor and looked for developing complications like apnea, cyanosis and hypothermia. Follow-up: All children who had laser therapy were asked to come for follow-up on 3rd day and 7th day after giving laser treatment for post-laser complications and to confirm regression of disease.

The study was approved by ethical committee of our university and informed written consent was taken from the parents of each participant before enrolment. Parents were counselled regarding the course of the disease and treatment modalities and prognosis after treatment.

RESULTS

Table 1: Epidemiological data.

Variable	Babies with ROP (n=14) (%)	Babies without ROP (n=50) (%)	p value
Sex			
Male	8 (57.14)	29 (58)	0.954
Female	6 (42.85)	21 (42)	-
Gestation at birth			
<28	0	0	-
28-30	8 (57.14)	5 (10)	0.001*
30-32	4 (28.57)	22 (44)	0.701
32-37	2 (14.28)	23 (46)	-
Mean Gestation age (weeks)			
	30.64 \pm 2.02	31.42 \pm 1.86	0.001*
Birth weight			
<1 kg	3 (21.42)	0	0.001*
1-1.5 kg	10 (71.42)	25 (50)	0.03
1.5-2 Kg	1 (7.1)	25 (50)	-
Mean Birth weight (gram)			
	1260 \pm 250	1450 \pm 159	0.000001*
Mean stay in NICU			
	31.85 \pm 7.20	24.7 \pm 7.1	0.001*

*statistically significant

A total number of 236 babies (both intramural and extramural) were eligible to enter in study. 172 babies were excluded from study. Out of 172; 80 babies expired, 87 babies left against medical advice and 5 babies could not be followed up. The total numbers of babies analysed during study period were 64 (17 extramural+47

intramural). The overall incidence of ROP in present study was 21.87%. The incidence of ROP was high in ELBW (100%) and VLBW (28.57%). Mean weight of babies with ROP was lesser than those without ROP 1260 ± 250 versus 1450 ± 159 . This was highly significant (0.0000001). Only 1 baby between 1.5 to 2 kg developed ROP. This baby had a stormy course in NICU with sepsis and oxygen exposure (3.8%).

Table 2: Supplemental oxygen and ROP.

Variable	Babies with ROP (n=14) (%)	Babies without ROP (n=50) (%)	p value
O2 support	12(85.71)	19(38)	0.04*
<24 hr	0	0	-
24-48 hr	0	4(8)	0.138
48-72 hr	1(7.14)	11(22)	0.01*
>72 hr	11(78.57)	4(8)	0.0005*
Hyperoxia (number of episodes)	12(85.71)	27(54)	0.06
0-1	0	7(14)	0.07
2-3	0	10(20)	0.01*
>3	12(85.71)	10(20)	0.0002*
Hypoxia (number of episodes)	4 (28.57)	0	0.001*
1	1(7.14)	0	0.218
2-3	3(21.42)	0	0.008*
CPAP support given	4 (28.57)	0	0.001*

*statistically significant

The incidence of ROP was highest in the gestational age group 28-30 weeks (61.53%) followed by 15.38% in gestational age group between 30-32 weeks. Mean gestational age of babies with ROP was 30.64 ± 2.02 and those without ROP were 31.42 ± 1.86 . This was statistically significant ($p=0.001$). Mean NICU stay of babies in days with ROP was 31.85 ± 7.20 as against those without ROP 24.7 ± 7.1 (p value 0.001), probably due to the complicated course of these babies (Table 1). On comparing babies based on gestational age, incidence of ROP was higher in younger gestational age of 28 – 30 weeks i.e. 57.14% Vs 28% in 30-32 weeks. Comparison based on birth weight showed that, amongst babies with ROP 92.8% were VLBW (<1.5 kg) against 7% babies between 1.5-2 kg.

Oxygen therapy was a high risk factor for development of ROP, 85.71% exposed to oxygen developed ROP. Longer duration of exposure to oxygen (>72 hours) was a significant risk factor. 78.57% of babies with prolonged exposure to oxygen developed ROP as against those who did not develop 8% (p value 0. 0005). Fluctuation in oxygen exposure resulting in hyperoxia (>3 episodes) and hypoxia (2-3 episodes) was also observed to be risk factors for development of ROP (p 0.0002 and 0.008

respectively). CPAP support was significant risk factor for ROP development (p value 0.001) (Table 2).

Table 3: Clinical risk factors in infants with ROP.

Variable	Total no of babies with ROP (n=14) (%)	Total no of babies without ROP (n=50) (%)	p value
NEC	9 (64.28)	4 (8)	0.00002*
Sepsis	13 (92.85)	21 (42)	0.002*
Probable	7(50)	20 (4)	0.274
Proven	6(42.85)	1 (2)	0.0001*
PDA	3 (21.42)	0	0.0007*
Hyperbilirubinemia requiring intensive phototherapy	10 (71.42)	12 (24)	0.002*
Partial parenteral nutrition	5 (35.71)	4 (8)	0.02 *
Birth Asphyxia	2 (14.28)	4 (8)	0.845
Mild	1 (7.1)	3 (6)	0.639
Moderate	0	1 (2)	-
Severe	1 (7.1)	0	0.21
HIE	1 (7.1)	0	0.218
Hypoglycemia	1 (7.14)	7 (14)	0.819
Apnea	3 (21.42)	3 (6)	0.217
CHD other than PDA	1 (7.14)	1 (2)	0.91
Anemia	1 (7.14)	2(4)	0.823
At birth	0	0	-
There after	1 (7.14)	2(4)	0.823
Blood transfusion	1(7.14)	2(4)	0.823
At birth	0	0	-
There after	1 (7.14)	2(4)	0.823
Antenatal steroid given	2 (14.28)	15 (3)	0.40

*statistically significant

Other neonatal risk factors like, Acidosis ($p=0.006$), NEC ($p=0.00002$), proven sepsis ($p=0.002$), hyperbilirubinemia requiring intensive phototherapy ($p=0.002$), PDA ($p=0.0007$) and partial parenteral nutrition ($p=0.02$) were associated with development of ROP. There were no patients in the screened population who underwent exchange transfusion, had HMD, received surfactant therapy, and had any surgical intervention and IVH. So, we could not comment on their association with development of ROP (Table 3).

We studied maternal risk factors like PIH, APH, PROM (>12 hr), chorioamnionitis, gestational diabetes, multiple birth and anaemia, but found none of the factors associated with development of ROP.

Table 4: Stages of ROP.

Stage of ROP (Bilateral)	Total numbers of babies (n=14)	Plus disease (%)
Stage 1	2 (14.28)	
Stage 2	9 (64.28)	2(14.28)
Stage 3	0	1(7.1)
Stage 4	0	
Stage 5	0	

All 14 babies had bilateral disease (Table 4). Maximum babies had stage 2 disease (64.28%) and 21.3% had plus disease. All babies with stage 1 and stage 2 ROP without plus disease regressed spontaneously (100%). Mean birth weight and mean gestational age was less in babies of ROP with plus disease as compared to babies with ROP without plus disease. Out of 3 babies with plus disease, 1 (33.33%) baby's ROP regressed spontaneously and two babies (66.66%) were given laser treatment and their ROP regressed after treatment. The overall incidence of babies requiring laser treatment was 14.28%. There was no infant with progression of ROP after laser therapy. All babies withstood the procedure well and there were no post laser complication other than reddening of conjunctiva, which disappeared in 2-3 days.

DISCUSSION

Incidence of ROP in various Indian studies ranged from 20 to 51.9%. Gopal et al had reported 38% incidence of ROP in 1995, Maheshwari et al had reported 20% incidence of ROP in 1996.^{7,8} International studies had reported incidence of ROP in preterm babies ranged from 10 to 45.5%. Schalij-Delfos et al had reported 27% incidence of ROP in 1996.⁹ Chye et al had also reported 27% incidence of ROP in 1999.¹⁰ Nair et al had reported 25.4% incidence of ROP in 2003.¹¹ However in most instances, it is not possible to compare studies, as the inclusion criteria are different. Some centre includes only smaller preterm babies while other has more liberal inclusion criteria.^{7,8,12-14} The overall incidence of ROP in present study is 21.87%, which was similar as reported in Chaudhari et al. study in 2008 (22.6%) and inclusion criteria for ROP screening was same as in our study⁴. In more recent studies, incidence of ROP reported is similar to our study.^{15,16}

Birth weight

- A. <1000 g: The incidence of ROP in babies with birth weight <1000 gm was 100% in our study and it was found statistically significant (p=0.001). Shah VA et al had reported 55.4% incidence in babies with birth weight <1000 g, Chaudhari et al reported 36.2% and the CRYO-ROP multi-centre study had showed 81.6% incidence of ROP in <1000 g.^{4,17,20}
- B. 1000-1500 g: The incidence of ROP in babies with birth weight of 1000 to 1500 g in our study was 28.5

% (p=0.03). Chaudhari et al had reported similar incidence (23.6%) in VLBW. Shah VA et al had reported 17.3% incidence in babies with birth weight 1000-1500 g.^{4,17}

- C. >1500 g: Incidence of ROP in babies with birth weight >1500 g in our study was 3.84 %. Chaudhari et al had reported 11.4% incidence in babies with birth weight of >1500 g and Gupta VP et al had reported 6% incidence in the same weight group. This is suggestive of the fact that as weight decreases the incidence of ROP increases proportionately.^{4,15}

Gestational age

Incidence of ROP in babies with gestational age 28-30 weeks in our study was 61.53%, those between 30-32 weeks 15.38% and between 32-37 weeks was 8%. Gupta VP et al had reported 30%, 27.3% and 13.8% incidence of ROP in gestational age 28-30 weeks, 30-32 weeks and 32-37 weeks respectively.¹⁶ Rekha et al had shown 88% incidence with 28-30 weeks and 60% between 30-32 weeks of gestational age.¹⁸ It is well recognized that incidence of ROP is inversely related to birth weight and gestational age.^{17,19}

Birth weight >1500 g and gestational age >32 weeks

In our study 2 (14.28%) babies >32 weeks gestation and 1 (7.1%) baby >1500 g developed ROP. They were sick and had a turbulent course in NICU. Pardeep et al had similarly 4 babies with birth weight of >1500 g and gestational age >32 weeks who developed severe ROP and also had a turbulent course in NICU.⁵ This highlights the importance of screening bigger infants with unstable neonatal course, using 'Third criteria'.⁵

Mean NICU stay

In our study, mean NICU stay was higher in babies with ROP as compared to babies without ROP. Almutuzah et al had shown similar results.¹⁴ Babies with ROP had longer duration of NICU stay because they had multiple risk factors.

Neonatal risk factors

Many other risk factors have been reported to predispose to the development of ROP.^{16,18,20} We studied various risk factors like oxygen therapy, NEC, sepsis, PDA, CHD other than PDA, Hyperbilirubinemia requiring intensive phototherapy, partial parenteral nutrition, birth asphyxia, HIE, apnea, blood transfusion, exchange transfusion, hypoglycemia, anaemia, HMD, surfactant therapy, IVH, surgery and antenatal steroid. Out of these risk factors oxygen therapy, NEC, sepsis, PDA, hyperbilirubinemia requiring intensive phototherapy and partial parenteral nutrition were found to be significant statistically in our study.

A. *Oxygen therapy*: The causal link between ROP and supplemental oxygen has been confirmed by controlled trials and clinical studies.^{8,21} Duration of oxygen: Hussain et al found duration of oxygen as factor predictive of ROP.²² Similarly our study had also found oxygen as a significant risk factor for ROP ($p=0.04$). Krishna and Rekha S et al had reported that duration of oxygen therapy of more than 72 hours was found to be statistically significant.^{18,23} Our study had shown that oxygen supplementation for >48 hrs ($p=0.01$) was significant risk factor for ROP and >72 hours ($p=0.0005$) was highly significant for ROP. This reveals that duration of oxygen therapy is directly proportional to the development of ROP. Shohat et al reported episodes of hypoxia as risk factors for ROP.²⁴ Other studies had also reported hyperoxia and acidosis as risk factors for ROP.^{2,25,26} In the present study ≥ 2 episodes of hypoxia ($p=0.008$) and hyperoxia ($p=0.0002$) and any episode of acidosis ($p=0.006$) were found to be significant risk factors for ROP. CPAP support: CPAP support was given in 4 babies and all four babies developed ROP. CPAP support was found to be highly significant risk factor for development of ROP ($p=0.001$). Pardeep et al had also shown significant correlation between CPAP support and ROP.⁵

B. *NEC*: Our study had found significant correlation between NEC and development of ROP ($p=0.00002$). Recent study by Pardeep K et al in 2010 had shown that NEC as significant risk factor for ROP.⁵

C. *Sepsis*: Many studies have reported sepsis as a significant risk factor for ROP.^{5,8,15} Probable cause behind that is endotoxin-induced retinitis with increased active leukocyte adhesion to the vascular endothelium of retinal blood vessels, leading to inflammation and leakage. Our study had shown sepsis as significant risk factor for ROP ($p=0.002$).

D. *PDA*: V.A. Shah et al and Pardeep K et al have reported PDA as highly significant risk factor for ROP.^{5,17} Our study had shown similar results ($p=0.0007$).

E. *Hyperbilirubinemia requiring intensive phototherapy*: We had analysed data of babies with neonatal jaundice who require intensive phototherapy and it was found statistically significant risk factor for development of ROP ($p=0.002$). V.A. Shah et al, Chaudhari et al and Gupta VP et al had not found neonatal jaundice as risk factor for ROP.^{4,15,17} Murthy KR et al had not reported any correlation between phototherapy and development of ROP.²³

F. *Partial parenteral nutrition*: Gupta VP et al and Al-Essa M et al had not reported any correlation between ROP and total parenteral nutrition.^{15,27} Our study had shown significant correlation between ROP ($p=0.02$) and partial parenteral nutrition.

Out of 14 babies with ROP; 14.28% had stage I ROP, 64.28% had stage II, 14.28% babies had stage 2 with plus disease, and 1 (7.1%) baby had stage 3 with plus disease. All babies with stage 1 and stage 2 ROP had regressed spontaneously. Of the babies with plus disease; 66.66% required laser treatment and 33.33% had shown spontaneous regression. Rekha et al had screened 100 babies.¹⁸ Out of the 100 babies, 21% had stage 1, 14% had stage 2, 8% had stage 3, 1% had stage 4. Sashidharan et al had also shown that most of infants with initial stages of ROP had spontaneous regression of disease.²⁸

CONCLUSION

With the survival of more number of preterm, ELBW, VLBW babies, their screening for long term morbidities becomes important aspect of their management. ROP being treatable condition, its screening needs to be stressed.

We should screen all preterm babies with birth weight <1500 g and gestational age ≤ 32 weeks, irrespective of risk factors and babies between 1.5 to 2 kg and between 32 and 37 weeks, with risk factors to diagnose and treat patients with ROP.

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