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Original Research Article

Retinopathy of prematurity: a study of incidence and risk factors

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ABSTRACT

Background: A historic cohort observational study was conducted between 2009-2014 in NICU of a tertiary care hospital to study the incidence and risk factors predisposing to retinopathy of prematurity (ROP) using wide field digital fundus camera.
Methods: Preterm babies with birth weight < 2000 g and gestation ≤ 34 weeks were screened for ROP at 2-3 weeks after birth. Babies with gestation > 34 weeks were screened only if they had additional risk factors. Those meeting early treatment for ROP study guidelines (ETROP) were treated by laser.
Results: The incidence of ROP in the 154 babies who were screened using wide field digital fundus camera was 28.57% (44 babies) and incidence of severe ROP was 4.5% (7 babies). All babies with severe ROP were treated with laser photocoagulation. The mean gestational age of ROP babies was 30.1(±1.9) weeks; 39 (88.6%) were ≤ 32 weeks and 5 (11.4%) were >32 weeks. As the gestational age decreased, the incidence of ROP increased (P = 0.001). Birth weight of ROP babies ranged from 628 gm to 1650 g with a mean of 1160 (±230) g. The incidence of ROP in infants ≤1250 gm was 55.1% and >1250 was 16%. On multivariate analysis the higher incidence of risk factors such as RDS, blood transfusion, apnea, low birth weight and low gestational age (prematurity) were independent and significant determinants of ROP (P-value < 0.05 for all) while anaemia requiring blood transfusion and apnea were significant risk factors for severe ROP.
Conclusions: ROP screening can be effectively done by using RETCAM. Risk factors predisposing to ROP were apnea, respiratory distress syndrome, anemia requiring blood transfusion, low birth weight and low gestational age (prematurity) while anemia requiring blood transfusion and apnea were significant risk factors for severe ROP.

Keywords: Laser photocoagulation, Retinopathyof prematurity, Risk factors, Telemedicine

INTRODUCTION

Retinopathy of prematurity (ROP) is a vasoproliferative disease that affects the developing retinal vessels of premature infants. ROP is treatable disorder, but its severe form can lead to traction retinal detachment and blindness.[1] If identified early, it can be treated successfully.

The aim of this retro-prospective study was to find out the incidence and to identify the risk factors which predispose to ROP in a neonatal intensive care unit (NICU) babies.

METHODS

The study was historic cohort observational study conducted from 2011 to 2014 in NICU of tertiary care hospital. Our study was carried out after approval by the ethical committee of the institute. Informed consents were obtained from the parents of the subjects.

Preterm babies with birthweight < 2000 g and gestation ≤ 34 weeks were screened for ROP at 2-3 weeks after birth. Babies with gestation > 34 weeks were screened only if they had additional risk factors.

Antenatal history regarding maternal risk factors, maternal sepsis, perinatal asphyxia, multiple pregnancy, pregnancy induced hypertension, use of antenatal steroids were recorded.

As per our NICU protocol on admission of the newborn weight, length, skull circumference, gestational age using last menstrual period or new Ballard score were recorded. Cardiorespiratory monitoring and neurological manifestations were also recorded. The variables were studied like respiratory distress syndrome, use of surfactant, oxygen therapy, ventilation therapy, phototherapy for jaundice, anemia requiring blood transfusions, sepsis (by clinical diagnosis, with either leucocytosis/leucopenia with C-reactive protein greater than 6.0 mg/dl, or blood culture positive cases), hypotension (as identified by the standard mean for age and weight), intraventricular hemorrhage (as identified by cranial ultrasound done on day 3, 7, 21 and before discharge), apnea (identified as temporary cessation of breathing for more than 20 sec or associated with bradycardia and cyanosis) and patent ductus arteriosus (as identified by echocardiography, done if significant murmur present).

Local eye examination

The screening was done by wide field digital fundus camera, by the same ophthalmologist. Eyes were examined with wide field digital fundus camera, pupils were dilated by using 0.4% tropicamide +1.25% phenylepherine eye drops. Retinopathy was graded into stages and zones as per the ICROP classification.1The initial examination was carried out at 2nd to 3rd week after birth and were repeated weekly or biweekly, using the schedule for follow-up recommended by NNFI until full vascularization of the retina reached zone 3 (the most peripheral temporal retinal zone) or until regression of ROP after treatment.[2] Severe ROP was defined as those having ETROP disease Type 1.[3]

Statistical analysis

Descriptive statistics included the mean and standard deviation for numerical variables, and the percentage of different categories for categorical variables. Students "t" test was performed for continuous variables. Chi-squared (χ^2) test was used for categorical variables. A probability (P) of less than 0.05 was considered significant. Univariate analysis was performed to determine significant risk factors for development of ROP. Multiple logistic regression analysis was performed using variables which were significant on univariate analysis.

RESULTS

The study population included 154 neonates from January 2011 to December 2014. The incidence of any ROP and severe ROP was 28.57% (44 infants) and 4.5% (7 infants) respectively. Laser photocoagulation was done in all babies with severe ROP. More than one laser photocoagulation was needed in 3 infants. ROP regressed in all 7 babies following treatment.

Out of the 44 infants with ROP; 22 (50%) were males and 22 (50%) were females. There was no difference in the incidence of ROP between appropriate for gestational age (AGA) and small for gestational age (SGA) low birth weight infants (p value = 0.74).

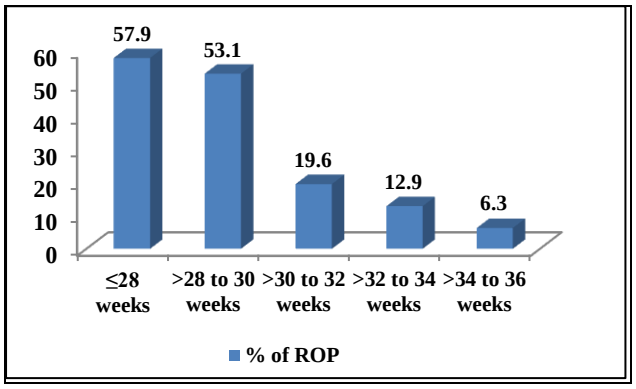

Figure 1: Incidence of ROP according to gestational age.

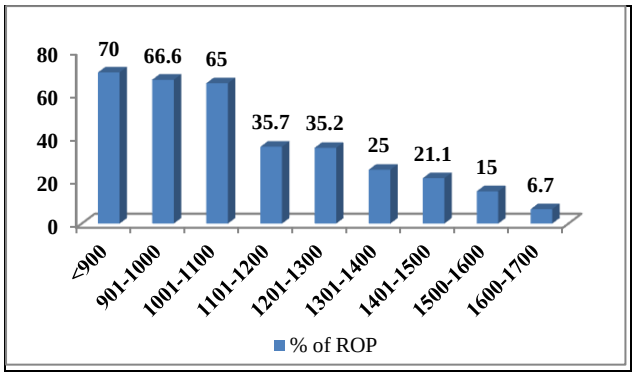

Figure 2: Incidence of ROP according to birth weight.

Table 1: Distribution of stages of ROP.

Stage of disease	Right eye n (%)	Left eye n (%)
Stage 1	9 (21.4%)	7 (18.4%)
Stage 2	21 (50%)	18 (47.4%)
Stage 3	6 (14.3%)	7 (18.4%)
PLUS disease	3(7.2%)	3 (7.9%)
PREPLUS	3 (7.2%)	3 (7.9%)
Total	**42**	**38**

The mean gestational age of ROP babies was 30.1(± 2.0) weeks (p <0.001), significantly less than non ROP babies

32.4 (±1.9) weeks. Out of which 39 (88.6%) were ≤ 32 weeks and 5 (11.4%) were >32 weeks. As the gestational age decreased, the incidence of ROP increased (P = 0.001). The incidence of ROP according to gestational age is shown in Figure 1.

Birth weight of ROP babies ranged from 628 gm to 1650 gm with a mean of 1160 (±230) gm (p <0.001), significantly less than non ROP babies 2.4 (±0.7) gm. The incidence of ROP in infants ≤1250gm was 55.1% and >1250 gm was 16%. The incidence of ROP according to birth weight is shown in Figure 2. Frequency distribution of stages of ROP is shown in Table1.

In Table 2 a) on Univariate analysis the higher incidence of risk factors such as oxygen therapy, ventilation, RDS, blood transfusion, apnea, surfactant were significant determinants of ROP (P-value <0.05 for all).

Table 2 (a): The univariate and multivariate determinants of ROP (n = 154).

Risk factors	ROP (n = 44)	Non ROP (n = 110)	Univariate odds (95% CI)	P-value	Multivariate odds (95% CI)	P-value
Oxygen therapy	35	56	3.75 (1.65-8.54)	0.001***	1.48 (0.39-2.12)	0.278NS
Ventilation	23	26	3.54 (1.69-7.39)	0.001***	1.13 (0.40-2.01)	0.477NS
RDS	25	22	5.26 (2.47-11.2)	0.001***	4.09 (2.00-8.79)	0.001***
Anemia requiring blood transfusion	20	17	4.56 (2.08-10.02)	0.001***	3.94 (1.68-7.54)	0.001***
Sepsis	13	23	1.59 (0.72-3.51)	0.293NS	1.63 (0.70-2.21)	0.343NS
Apnea	19	17	4.16 (1.89-9.16)	0.001***	3.08 (1.57-6.94)	0.001***
IVH	1	2	1.26 (0.11-14.21)	0.999NS	1.19 (0.43-1.97)	0.787NS
Surfactant	18	22	2.77 (1.29-5.93)	0.014*	1.74 (0.77-2.01)	0.097NS
PDA	3	7	1.08 (0.27-4.37)	0.999NS	1.03 (0.31-1.87)	0.447NS
Seizures	4	3	3.57 (0.76-16.64)	0.103NS	1.57 (0.68-1.94)	0.123NS
Jaundice	35	72	2.05 (0.89-4.71)	0.121NS	1.41 (0.49-1.97)	0.246NS
Birth weight (<=1250 g)	27	22	6.35 (2.95-13.66)	0.001***	4.88 (2.01-9.59)	0.001***
Gestational age (<=32 weeks)	39	68	4.82 (1.76-13.19)	0.001***	3.22 (1.37-8.06)	0.001***

Univariate p-values by chi-square test; multivariate P-values by multiple logistic regression analysis; P-value <0.05 is considered to be statistically significant; *p-value <0.05; **p-value <0.01; ***p-value <0.001.

Table 2 (b): The comparison of some selected quantitative variables between cases with ROP and without ROP (n = 154).

Variables	ROP (n = 44)	Non ROP (n = 110)	T-value	P-value
Duration of oxygen therapy (days)	3.5±3.7	1.2±2.9	16.13	0.001***
Duration of ventilation (days)	3.4±1.9	3.2±2.9	0.17	0.698NS
Duration of hospitalization (days)	45.6±13.1	29.4±13.3	49.73	0.001***
Birth weight (kg)	1.2±0.2	2.4±0.7	137.20	0.001***
Gestational age (wks)	30.1±2.0	32.4±1.9	42.65	0.001***

Values are Mean ± Standard deviation; P-values by unpaired t test; P-value<0.05 is considered to be statistically significant; *p-value <0.05; **p-value <0.01; ***p-value <0.00; T-value is calculated value of unpaired t test.

Also the incidence of low birth weight and low gestational age were significant determinants of ROP (P-value <0.05 for both). But on Multivariate analysis the only the higher incidence of RDS, anemia requiring blood transfusion, apnea, low birth weight and low gestational age (prematurity) were independent and significant determinants of ROP (P-value <0.05 for all).

On comparing some quantitative variables we found that the average duration of oxygen therapy, average duration hospital stay, low average birth weight, low average gestational age were significantly higher for the group of cases with ROP compared to the Non-ROP group of cases (P-value <0.001) (Table 2b).

In case of severe ROP on univariate analysis we found that the higher incidence of risk factors such as ventilation, anemia requiring blood transfusion, apnea and seizures were significant determinants of severe ROP (P-value<0.05 for all). But on multivariate analysis only the higher incidence of anemia requiring blood transfusion and apnea were independent and significant determinants of severe ROP (P-value <0.05 for both) (Table 3 a). On comparing some quantitative variables

the average duration of ventilation, average duration of hospital stay and low average gestational age is significantly higher for the group of cases with severe ROP compared to the Non-severe ROP + No ROP group of cases (P-value<0.01) Table 3 b.

Table 3 (a): The univariate and multivariate determinants of severe ROP (n = 154).

Risk factors	Severe ROP (n = 7)	Non severe ROP + No ROP (n=147)	Univariate odds (95% CI)	P-value	Multivariate odds (95% CI)	P-value
Oxygen therapy	6	85	4.38 (0.51-37.28)	0.241^{NS}	1.24 (0.69-1.97)	0.398^{NS}
Ventilation	5	44	5.85 (1.09-31.32)	0.034*	1.43 (0.57-1.89)	0.307^{NS}
RDS	4	39	3.69 (0.79-17.24)	0.096^{NS}	1.78 (0.86-4.42)	0.128^{NS}
Anemia requiring blood transfusion	5	32	8.98 (1.66-48.49)	0.009**	2.47 (1.14-5.59)	0.019*
Sepsis	2	34	1.33 (0.25-7.16)	0.666^{NS}	1.47 (0.41-1.74)	0.443^{NS}
Apnea	5	31	9.36 (1.73-50.55)	0.008**	3.16 (1.67-6.03)	0.012*
IVH	0	3	-	0.999^{NS}	-	-
Surfactant	4	36	4.11 (0.88-19.24)	0.075^{NS}	1.51 (0.52-2.23)	0.143^{NS}
PDA	1	9	2.56 (0.28-23.57)	0.381^{NS}	1.16 (0.39-1.61)	0.596^{NS}
Seizures	2	5	11.36 (1.76-73.46)	0.033*	1.74 (0.53-1.97)	0.134^{NS}
Jaundice	7	100	-	0.101^{NS}	-	-
Birth weight (<=1250 g)	3	45	1.70 (0.37-7.91)	0.678^{NS}	1.63 (0.58-1.78)	0.549^{NS}
Gestational age (≤32 weeks)	6	101	2.73 (0.32-23.36)	0.676^{NS}	1.73 (0.51-1.99)	0.553^{NS}

Univariate p-values by Chi-Square test; multivariate P-values by multiple logistic regression analysis; P-value<0.05 is considered to be statistically significant; *p-value <0.05; **p-value <0.01; ***p-value <0.001.

Table 3 (b): The comparison of some selected quantitative variables between cases with severe ROP and without severe ROP (n = 154).

Variables	Severe ROP (n = 7)	Non severe ROP + No ROP (n = 147)	T-value	P-value
Duration of oxygen therapy (days)	3.1±2.3	2.4±3.3	0.627	0.531^{NS}
Duration of ventilation (days)	3.4±2.0	0.9±1.9	3.240	0.001***
Duration of hospitalization (days)	51.3±20.2	33.0±14.5	3.207	0.002**
Birth weight (kg)	1.2±0.4	1.3±0.3	1.533	0.127^{NS}
Gestational age (weeks)	29.6±2.4	31.9±2.1	2.710	0.007**

Values are Mean±Standard deviation; P-values by unpaired t test; P-value<0.05 is considered to be statistically significant; *p-value <0.05; **p-value <0.01; ***p-value <0.001; T-value is calculated value of unpaired t test.

DISCUSSION

We screened babies with birth weight <2000 g and gestation ≤34 weeks and babies with gestation more than 34 weeks were screened only if they had additional risk factors using wide field digital fundus camera. In present study, there were screened babies as per NNFI recommendations.[2] The AAP criteria were followed by Chaudhari et al and Chawla et al.[4-6] In India, larger and more mature babies are at risk of developing sight threatening ROP, hence Vinekar et al, Jalali et al.[7-8] Shah et al recommended screening babies born at <37 weeks gestation and/or birthweight <2000 g in the presence of a high sickness score, in order to prevent missing any infant with threshold ROP.[9] Gupta et al and Maheshwari et al screened all babies ≤1500 g and/or gestational age ≤35 weeks.[10,11] In present study, there was screened babies as per NNFI recommendations.[2]

Multiple community-based studies reported positively on the potential for telemedicine screening in remote areas to detect disease that will eventually require treatment.[12-14] In a retrospective analysis of the first four years of its telemedicine initiative to screen for retinopathy of prematurity, the Stanford University Network for diagnosis of retinopathy of prematurity reported that none of the infants who needed treatment were missed.[12] Jackson and colleagues found that telemedicine was more cost-effective than standard binocular indirect ophthalmoscopy.[15] In India, KIDROP tele-ROP model

demonstrates that ROP services can be delivered to the outreach despite lack of specialists and may be useful in other middle-income countries with similar demographics. Since its inception 7.9% have been diagnosed with ETROP grade disease and treated in this remote centers itself, obviating travel for these underprivileged rural babies who would not otherwise have had access to ROP care.[16]

In Germany, Lorenz and colleagues showed 100% detection of suspected treatment warranted cases.[17] A further real world program in Auckland, New Zealand reported 100% sensitivity and 90% specificity in detecting treatment warranted ROP.[18]

The incidence of ROP was 28.57% in present study. Incidence of 22.6% reported by Chaudhari S et al and 21.6% by Rao et al was less to ours.[5,19] The incidence of ROP requiring laser treatment in present study was 4.5%which was less than some studies in which incidence was 6.7% and 7.8% respectively.[19,20] The ETROP incidence study 3 reported severe pre threshold ROP in 36.9% and 27% incidence of threshold disease was reported in the CRYO ROP study underlining the continued occurrence of this sight-threatening stage of ROP.[21] Some studies have reported incidence less than 5%.[22,23] Chow et al reported zero incidence of severe ROP needing treatment and attributed it to a protocol of improved management of oxygen administration.[24]

It was found that higher incidence of risk factors such as oxygen therapy, ventilation, RDS, blood transfusion, apnea, surfactant were significant determinants of ROP (P-value <0.05 for all). Also incidence of low birth weight and low gestational age were significant determinants of ROP (P-value <0.05 for both). But on Multivariate analysis only the higher incidence of RDS, blood transfusion, apnea, low birth weight and low gestational age (prematurity) are independent and significant determinants of ROP (P-value <0.05 for all).

In case of severe ROP on multivariate analysis only the higher incidence of blood transfusion and apnea are independent and significant determinants of severe ROP (P-value <0.05 for both).

The average duration of oxygen therapy, average duration hospital stay, low average birth weight, low average gestational age is significantly higher for the group of cases with ROP compared to the Non-ROP group of cases (P-value <0.001) and in case of severe ROP the average duration of ventilation, average duration of hospital stay, and low average gestational age is significantly higher (P-value <0.01).

Some studies identified oxygen therapy, anemia, double volume exchange, packed cell volume transfusion, septicemia, apnea and clinical sepsis as important risk factors.[6,9,25] Chaudhari et al, found oxygen administration, septicemia and apnea as significant risk factors.[5] Multiple gestations have been described as an independent risk factor for ROP by Sood et al.[26] Intraventricular hemorrhage independent risk factor for severe ROP in a study by Watts et al.[27] Aggarwal et al found apnea, clinical sepsis and male sex to be significant risk factors.[28] Seiberth et al found surfactant a significant risk factor, but surfactant was not found to be significant by Chaudhari et al.[29,5]

On the other hand in present study, there was no significant relationship between the occurrence of ROP and multiple gestation, sex, SGA, patent ductus arteriosus, use of surfactant, intraventricular hemorrhage, seizures, sepsis, phototherapy.

CONCLUSION

The study highlights the use of wide field digital fundus camera for screening of ROP. RDS, blood transfusion, apnea, low gestational age and birth weight were risk factors for any ROP. Anemia requiring blood transfusion and apnea were risk factors for severe ROP. Limitation of our study is its historic nature, less number of cases, lack of data on concentration of O_2 required. A more efficient strategy, which includes, increasing awareness among ophthalmologists and neonatologists regarding the magnitude of the problem is essential.

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