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Indian Journal of Clinical and Experimental Ophthalmology

Journal homepage: www.ijceo.org

Original Research Article

Retinopathy of prematurity: A revisit to the incidence, risk factors, and its response to laser therapy

Nikitha Ann Panakkal[1], Sooraj Singh Kubrey[1,*], Kavitha Kumar[1], Jyotsna Shrivastava[2]

[1]*Dept. of Ophthalmology, Gandhi Medical College, Bhopal, Madhya Pradesh, India*
[2]*Dept. of Pediatrics, Gandhi Medical College, Bhopal, Madhya Pradesh, India*

ARTICLE INFO

Article history:
Received 04-09-2021
Accepted 12-09-2021
Available online 31-03-2022

Keywords:
Retinopathy of prematurity
Incidence
Risk factors
Laser therapy

ABSTRACT

Background: The debilitating vasoproliferative retinal disorder retinopathy of prematurity (ROP), a prequel to neonatal blindness is known to be increasing in recent years with improved advances in neonatal care and survival. Aim of this study was to study the incidence of ROP, risk factors, and response to the gold standard treatment of laser has been explored in this study.

Materials and Methods: In this prospective observational study of all neonates referred to the retina clinic of a tertiary care centre, from both in-house referrals and peripheral centres. Demographic data, both maternal and neonatal data were recorded. Neonates complying to inclusion and exclusion criteria were examined under 28 diopter lens and all ROP were documented using RetCam®. Laser photocoagulation was performed and later followed up according to ETROP schedule.

Results: 699 neonates were screened in the study and ROP was detected in 13.73% (182/1398) of this population, with mean gestational age 31.82±2.44 weeks and mean birth weight 1425.36±287.73 grams. Neonatal risk factors of gestational age <34 weeks, low birth weight, ventilatory support, RDS, oxygen supplementation, sepsis, birth asphyxia, blood transfusion, and phototherapy were found to have significant association for incidence of ROP and those requiring treatment. When 67.58% regressed spontaneously, all 59 eyes requiring treatment underwent laser therapy. 46 out of these 59 eyes (77.97%) showed regression and remaining seven eyes required further intervention.

Conclusion: Better premature neonates survival rates has shown an increased incidence of ROP over the past decades. Red flag signs like low gestational age, low birth weight, RDS, oxygen supplementation, sepsis, blood transfusion, AGA and twin pregnancy are confirmed to have significant association with the development of ROP. Laser therapy still remains effective in controlling progression of the disease.

1. Introduction

Abnormal development of immature retinal blood vessels in premature newborns is capable of progressing to the vasoproliferative retinal disorder called retinopathy of prematurity (ROP). It can result in severe visual impairment and therefore neonatal blindness.[1] ROP is a disease with lifelong ocular sequelae and adults with history of prematurity have increased prevalence of amblyopia, myopia, strabismus, early nuclear sclerotic cataract and glaucoma.[2]

With the dawn of new technologies and improved care for premature newborns, survival rates of very low BW (<1500g) and extremely low BW (<1000g) neonates have jumped from 35% to 90% and 5% to 65% respectively, during the recent years.[3,4] ROP is being increasingly

* *Corresponding author*.
E-mail address: dr_kubrey@rediffmail.com (S. S. Kubrey).

https://doi.org/10.18231/j.ijceo.2022.007

diagnosed in these infants. India and other middle-income countries are facing the third epidemic of ROP due to various factors, such as increased survival of preterm babies, inadequate quality of neonatal care, and low coverage of screening and treatment services for ROP.[5,6] Although, with proper care most neonates develop mild degrees of ROP, but in some babies the condition is progressive and needs treatment.

The development of ROP depends on the interaction of multiple factors, the most important among which are low gestational age (GA), low birth weight (BW) and prolonged exposure to supplementary oxygen therapy. Premature infants are exposed to higher oxygen tension after birth compared to that in-utero. This leads to a down-regulation of the major hypoxia-triggered VEGF, resulting in vasoobliteration of the developing retinal capillaries.[7,8] Other risk factors include respiratory distress syndrome, sepsis, frequent blood transfusions, asphyxia, etc.[3,5]

India has the highest number of preterm births in the world, meaning ROP is a considerable risk.[9] The Indian Retinopathy of Prematurity Society was established in July 2016 with the aim of increasing awareness of ROP among the people of India and supporting work to detect and treat ROP.[10] Premature births are primarily institutional deliveries rather than home deliveries. Recent studies from India report an incidence ranging from 20% to 46%.[11] However, institutional incidence of ROP are inadequately reported or updated and so are regional/community attributes of indicative and predictive factors of progression of ROP. This study was conducted to bridge gaps in knowledge of incidence of ROP in central India and to analyse causative risk factors, predictive and indicative markers of risk for progression of ROP requiring intervention.

2. Materials and Methods

A prospective observational clinical study was conducted in preterm, low BW neonates and infants attending eye OPD, ROP clinic, and infants referred for ROP screening from peripheral centres at a tertiary care referral centre, during the period from November 2018 to August 2020. Demographic data, BW, multiplicity of birth, gender, and treatment details were recorded. All preterm neonates of ≤37 weeks of GA and/or ≤2000g BW were included. Neonates with congenital hydrocephalus, anterior segment pathology and posterior segment pathologies other than ROP, and whose parents denied consent for the study were excluded from the study.

Parents were initially explained about the procedure and written consent was taken. Initial ocular examination including examination of anterior segment was carried out to assess any pathology. Pupils were dilated with topical 2.5% phenylephrine and 0.5% tropicamide. Ophthalmoscopy was performed using a binocular indirect ophthalmoscope, a lid speculum, a scleral indenter, and a 28-diopter lens. The zone of vascularization (from I to III), presence or absence of plus or pre-plus disease, and the stage of ROP (stages 1–5) were evaluated as per International Classification of ROP. Plus disease, pre-plus disease, aggressive posterior retinopathy of prematurity (AP-ROP), prethreshold disease, threshold disease were carefully documented. In cases where ROP is detected fundus photo-documentation is done using RetCam® for future reference and to detect progression or regression of the disease.

Once a baby is detected with ROP requiring laser therapy, the baby was admitted for blood investigations. After paediatric fitness, laser treatment was performed in operation theatre with required precautions under sedation in the presence of a paediatrician. Cases that required intravitreal anti-VEGF or vitrectomy were performed accordingly. The parents were counselled regarding the importance of timely follow up for early detection of ROP and intervention if required in order to prevent lifelong ocular sequelae. The data were then analysed and results were obtained after Chi-square tests. P value less than 0.05 was considered to be significant.

3. Results

The study period saw a total of 699 preterm low BW neonates for ROP screening. Their mean GA was 33.22±2.18 weeks. Among them, ROP was detected in 182 eyes of 96 neonates (10 neonates had unilateral involvement). The incidence of ROP was observed to be 13.73% of the screened neonates, the mean GA of which was 31.82±2.44 weeks and mean BW was 1425.36±287.73 grams. The study saw 56.2% of the affected neonates were male, though not statistically significant (p value >0.05). The association of ROP in neonates of multiple pregnancy was highly significant with twin pregnancy noted in 22.5% (p value 0.001), whereas, no such association was found between retinopathy and other maternal risk factors (p value >0.05). (Table 1)

Incidence of ROP was higher in neonates of less than 34 weeks of gestation as compared to >34 weeks of gestation (p value <0.01). Similarly, very low BW was a significant risk factor (p value <0.01). Ventilatory support, RDS, birth asphyxia, neonatal sepsis, oxygen supplementation (both less than and more than 7 days), blood transfusion, and phototherapy were significantly associated with higher incidence of ROP (p value <0.05). Also of mention, mean hemoglobin levels in neonates with ROP was significantly lower (12.45±2.39gm/dl) as compared to neonates with no retinopathy (p value <0.01). Other described risk factors such as apnea, surfactant use, hyperbilirubinemia, PDA and total leucocyte count were found to be not statistically significant in this study population (p value >0.05). (Table 2)

Table 1: Association of maternal risk factors with ROP

Maternal risk factors	ROP		P value
	Present (n=182)	Absent (n=1216)	
Pregnancy induced hypertension	2.2	2	0.840
Eclampsia/preeclampsia	3.3	5.3	0.257
Premature rupture of membrane	2.2	3.1	0.494
Twin pregnancy	22.5	12.6	0.001
History of premature birth	1.1	1.8	0.491

Table 2: Association of neonatal risk factors with ROP

Neonatal risk factors		ROP				P value
		Present (n=182)		Absent (n=1216)		
			%		%	
Gender	Male	102	56	634	52.1	0.325
	Female	80	44	582	47.9	
Gestational age (weeks)	≤27	2	1.1	4	0.3	0.001
	28-30	61	33.5	130	10.7	
	31-33	61	33.5	350	28.8	
	≥34	58	31.9	732	60.2	
Birth weight (in kg)	<1	18	9.9	56	4.6	0.001
	1-1.5	98	53.8	504	41.4	
	1.5-2	66	36.3	656	53.9	
Ventilatory support		39	21.4	137	11.3	0.001
RDS		115	63.2	651	53.5	0.015
Surfactant		0	0	2	0.2	0.584
Apnoea		6	3.3	22	1.8	0.182
Asphyxia		2	1.1	72	5.9	0.007
Sepsis		66	36.3	236	19.4	0.001
PDA		5	2.7	17	1.4	0.173
Oxygen supplementation		110	60.4	604	49.7	0.007
Oxygen >7 days		91	50	269	22.1	0.001
Oxygen <7 days		34	18.7	330	27.1	0.015
Blood transfusion		29	15.9	67	5.5	0.001
Hyperbilirubinemia		52	28.6	350	28.8	0.953
Phototherapy		24	13.2	60	4.9	0.001
Hemoglobin (mean±SD)		12.45±2.39		13.14±1.71		0.001
TLC (mean±SD)		7462.1±2543.1		7415.38±2344.1		0.804

Although there was no statistically significant association of maternal factors with ROP requiring treatment (p value >0.05), several neonatal factors were found to be closely related. (Table 3) Treatment for ROP was required in maximum neonates belonging to less than 32 weeks of gestation as compared to those of beyond 32 weeks of gestation (p value <0.01). Also very low and extremely low BW neonates required treatment for ROP in higher proportions as compared to neonates with low BW (p value <0.01). Similarly treatment for ROP was required in higher proportions of neonates with sepsis (p value <0.05). (Table 4)

By initial examination or first follow-up, it was noted that 59/182 eyes required treatment. All 59 of them underwent LASER therapy in the first sitting. 46/59 eyes (23 out of 29 neonates) showed significant regression of ROP, while the remaining showed progression in spite of LASER. (Table 5) These seven patients (22.03% eyes) underwent either anti-VEGF therapy, vitrectomy or retinal detachment surgery. ROP regressed in 91.7% neonates in present study with 67.6% showing spontaneous regression. Vitreous hemorrhage was the only complication observed, and found in 6.52% eyes that underwent LASER therapy.

4. Discussion

An increasing number of preterm neonates are surviving in India due to improved access to facility-based neonatal care. As a result, ROP is emerging as a major cause of childhood blindness which needs timely detection and prompt treatment.

Recent literature from India and similar countries depict incidence of ROP ranging from 2.3 to 19.9%.[3,11–13] Similarly this study showed an institutional incidence of 13.73% (96 out of 699 infants). In a study conducted by

Table 3: Indicative markers of ROP requiring treatment (maternal risk factors)

Maternal factors	Treatment		P value
	Yes (n=59)	No (n=123)	
PIH	3.4	1.6	0.447
Eclampsia/preeclampsia	0	4.9	0.084
PROM	0	3.3	0.161
Twin pregnancy	25.4	21.1	0.517
Previous h/o premature birth	0	1.6	0.325

Table 4: Indicative markers of ROP requiring treatment (neonatal risk factors)

Neonatal factors		Treatment				P value
		Yes (n=59)		No (n=123)		
			%		%	
Gender	Male	36	61	66	53.7	0.35
	Female	23	39	57	46.3	
Gestational age (weeks)	≤27	9	15.3	16	13	0.044
	28-30	35	59.3	50	40.7	
	31-33	12	20.3	39	31.7	
	≥34	3	5.1	18	14.6	
Birth weight (in kg)	<1	9	15.3	9	7.3	0.013
	1-1.5	37	62.7	61	49.6	
	1.5-2	13	22	53	43.1	
Ventilatory support		16	27.1	23	18.7	0.195
RDS		41	69.5	74	60.2	0.222
Apnoea		2	3.4	4	3.3	0.961
Asphyxia		1	1.7	1	0.8	0.593
Sepsis		28	47.5	38	30.9	0.030
PDA		0	0	5	4.1	0.116
Oxygen supplementation		40	67.8	70	56.9	0.160
Oxygen >7 days		35	59.3	56	45.5	0.082
Oxygen <7 days		11	18.6	23	18.7	0.993
BT		13	22	16	13	0.12
Hyperbilirubinemia		16	27.1	36	29.3	0.764
Phototherapy		6	10.2	18	14.6	0.405
Hemoglobin (mean±SD)		12.03±2.56		12.64±2.28		0.12
TLC (mean±SD)		7894.9±2660.7		7254.5±2468.9		0.11

Table 5: Distribution of outcomes of ROP

Outcomes	Number	Percentage
Regressed spontaneously	123	67.58%
Regressed after LASER	46	25.27%
Secondary procedure	13	7.14%

Vasavada D et al.[14] in 2017, no association was found between gender and ROP in 280 infants at the Regional Institute of Ophthalmology in Gujarat (p value 0.21). Still again in 2019, Warad C et al.[15] reported ROP in 55.8% male and 44.2% female babies (p value 0.32). In accordance with these studies, the current study showed no significant association between gender and ROP, with ROP being observed in 56% males and 44% females (p value 0.325). The higher percentage of males affected with ROP could probably be due to a higher male:female ratio in central India. Freitas AM et al.[16] conducted a study in 602 newborns, showed that of the 520 neonates with GA below 32 weeks or with BW below 1500 g, 196 (37.6%) developed ROP, citing a significant association between development of ROP and GA and BW. Thakre S et al.[17] reported 26 out of 33 neonates (78.7%) with ROP had ≤32 weeks of gestation and 60.6% of infants with ROP had BW ≤1500g. In the current study, 110 out of 182 infants (60.4%) with ROP had GA ≤32 weeks and 116 out of 182 infants (63.7%) had BW ≤1500g showed a statistically significant relationship between ROP, and BW and GA with p values of 0.001 for both.

In a study conducted by Patel SS et al.[18] in Vadodara enrolling 286 neonates, 69 neonates were detected with

ROP. Multiple gestation was found to be significantly associated with ROP (p value <0.001) in this study . The study conducted by Raj et al.[19] in Kannur, stated that maternal factors like pregnancy-induced hypertension (p value 0.005) and premature rupture of membranes (p value <0.001) have significant association with ROP. The current study showed a statistically significant association between ROP and twin pregnancy (22.5%, p value 0.001). No significant association was found between ROP and other maternal factors like pregnancy-induced hypertension, premature rupture of membranes, pre-eclampsia, eclampsia and history of premature birth.

RDS and asphyxia are conditions that necessitate oxygen supplementation and as oxygen supplementation during neonatal period plays an important role in the pathogenesis of ROP, they are considered to be independent neonatal risk factors of ROP. Of the 2910 neonates studied by Le C et al.[13] in Hyderabad, 58% with ROP had respiratory distress syndrome and 32% required respiratory support via ventilation for an average of 3.5 days. The association between ROP and, RDS and mechanical ventilation was found to be statistically significant. Whereas Thakre S et al.[17] reported 26 out of 33 neonates detected with ROP had RDS (78.7%) and ten required mechanical ventilation (30.3%) with p values of both being <0.001. Patel SS et al.[18] in Vadodara reported birth asphyxia was found to be a significant risk factor of ROP with p value 0.046 in 286 neonates. A statistically significant association was seen between ROP and, RDS (63.2%) and mechanical ventilation (21.4%) in the current study as well with p values of 0.001 and 0.015 respectively.

Out of 78 babies screened by Nikhil R et al.[20] in 2016, 15 out of 51 babies (29.41%) developed ROP in those who were given oxygen therapy. None of the babies for whom oxygen was not given developed ROP, citing that oxygen administration was a significant risk factor for the development of ROP. In a study conducted in 65 preterm neonates by Anudeep K et al.[21] the mean duration of oxygen therapy in babies with ROP was 11 days, and in babies without ROP was 3.37 days. The present study showed a significant association between oxygen supplementation and ROP (60.4% of infants with ROP received oxygen supplementation) with a p value of 0.007. Oxygen supplementation for both >7 days (50%) and < 7 days (18.7%) was found to have an association with ROP. The association with oxygen supplementation irrespective of the duration could be due to the variation in percentage of oxygen given to the neonates in NICU, where percentage of oxygen given for more than 7 days triggers obliteration of vessels and development of ROP.

Studying 100 neonates, Rekha S and Battu RR[22] stated that anaemia (Hb <10g/dl) was found to be a significant risk factor of ROP (p value 0.005). Another study conducted in London by Banerjee J et al.[23] in 890 infants showed a hemoglobin level of <12g/dl at birth to be significantly associated with ROP (p value <0.01). In a study conducted by Patel SS et al.[18] in Vadodara enrolling 286 neonates, both anemia and blood transfusion were found to be highly significant risk factors of ROP (p value <0.001). While in Shimla, Kumar N et al.[24] reported three out of nine neonates who received blood transfusion developed ROP . Whereas in Sudan, 22 out of 26 neonates who received transfusion developed ROP (p value <0.005).[25] Similarly a significant association was found between ROP and, low haemoglobin levels and blood transfusion with p value being 0.001 in the present study. Though the exact role of anemia in the development of ROP is not clear, blood transfusion results in increased formation of reactive oxygen species due to increased iron loads which in turn leads to the development of ROP. This advocates blood transfusion in a restricted manner in preterm infants. Though only 12 out of 53 infants (22.6%) with proven sepsis developed ROP (p value 0.084) in a study conducted by Kothuri M et al.,[12] whereas Raj R et al.[19] demonstrated sepsis to have significant association with ROP with p value 0.042. The current study shows a significant association between sepsis and ROP (36.3%, p value 0.001) as preterm neonates with sepsis requires higher dose of oxygen supplementation, which in turn triggers the development of ROP.

In Japan, a study conducted by Uchida A et al.[7] in 182 infants with GA <33 weeks, 84 infants (46%) developed any stage of ROP, of which 45 (25%) required laser treatment. GA <33 weeks was found to be an indicative marker of ROP requiring treatment in this study. In close accordance, this study showed GA <32 weeks (p value <0.01) to be an indicative marker of ROP requiring treatment. In addition to this, neonates with BW <1500g (p value <0.01), and sepsis (p value <0.05) are found to require treatment for ROP at a higher proportion than those without these risk factors. In 2019, in 347 eyes of 182 infants undergoing treatment for ROP with 532 nm green laser, complications encountered were vitreous haemorrhage in 36 eyes (11.2%), anterior segment ischemia in two eyes (0.006%) and cataract in one eye (0.003%).[26] In the current study, vitreous haemorrhage (6.52%) was noted in three eyes out of 49 treated with LASER. Follow up period of one or two years might have demonstrated complications like cataract following laser therapy.

The importance of indicative and predictive markers come into play in the current scenario of COVID-19 pandemic, where the number of patients in the OPDs and ROP clinics are to be limited. These markers help us to recognize newborns who have to undergo mandatory ROP screening and follow up as they are likely to develop sight threatening complications if not treated promptly. Tele-screening by use of digital photographic retinal images is a developing approach to ROP screening. A well-organized screening strategy and timely intervention can prevent

blindness due to ROP to a large extent.

5. Conclusion

Better survival rates of premature neonates has brought about an increased incidence of ROP over the past few decades. Red flag signs like low GA, very low BW, RDS, oxygen supplementation, sepsis, blood transfusion, AGA and twin pregnancy are confirmed to have significant association with the development of ROP. This study further emphases the need of restricted oxygen supplementation and blood transfusion to reduce the risk of ROP, and validates that laser therapy still remains effective in controlling progression of the disease. Regular screening is unlikely in unprecedented times like the ongoing pandemic and the post-COVID era, however neonates with established red flag signs need mandatory screening and regular follow-up.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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Author biography

Nikitha Ann Panakkal, Junior Resident

Sooraj Singh Kubrey, Associate Professor

Kavitha Kumar, Professor

Jyotsna Shrivastava, Professor

Cite this article: Panakkal NA, Kubrey SS, Kumar K, Shrivastava J. Retinopathy of prematurity: A revisit to the incidence, risk factors, and its response to laser therapy. *Indian J Clin Exp Ophthalmol* 2022;8(1):30-35.