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Research Article

STUDY OF CLINICAL STAGING OF RETINOPATHY OF PREMATURITY IN A TERTIARY CARE HOSPITAL

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Abstract: Background: In India, with advancement in neonatal care units a large number of low birth weight premature babies are now surviving and also due to better screening protocols there is an apparent increase in the incidence of ROP. So this study was undertaken to clinically stage ROP, know the antenatal and postnatal risk factors in our setup, to provide an opportunity for effective treatment based on the clinical stage and also to increase the awareness about this condition. Objectives: 1. To determine the incidence and outcome of retinopathy of prematurity [ROP]**.** 2. To classify clinically staging of ROP**.** M**ethods:** A prospective clinical study was done from Feb 2024 to April 2025in 150 preterm babies less than 3 weeks of gestational age (GA) or less than 2000 gm of birth weight (BW) at KIMS Koppal. After having obtained an informed consent detailed history and risk factors were documented using a structured proforma. Baseline data was collected from each neonate. ROP screening was performed using wide-field digital imaging on a Retcam Shuttle (Clarity MSI, USA). The peripheral retina was looked for the extent of vascularization and if there was any immature retina.

Results: Among the total 150 babies 31(21.7%) had ROP. Of the total 300 eyes 51 were found to be positive. Of the babies who had ROP majority of the babies were between 30-32 weeks of gestation that being 61 eyes (40.5%). Of these babies between 30-32 weeks most had stage 2(82.2%) in zone 2(74%). Of the total 31 babies with ROP, majority weighed >1750gms that being 71 eyes (47%). In this range of birth weight majority had stage 2(78%) and zone 2(73%) disease.The study did not show any significant prenatal risk factor. However in the post natal period oxygen supplementation (p=<0.001), hyperbilirubinemia (p=0.003) and Patent Ductus Arteriosus (p=0.047) were found to be significant factors.Of the total 51 eyes, 10 eyes (20.8%) had stage I, 39(75%) had stage

II and 2 eyes (4%) had stage III. Among the total 51 eyes 2(4%) had zone I disease, 38 (72%) had zone II and 11 (22%) had zone 3 disease.

Conclusion: ROP screening programme is recommended to all babies ≤ 34 weeks gestation age and/or ≤1750 gm birth weight at 4 weeks after birth. Screening should be intensified in the presence of risk factors. Judicious use of oxygen in premature infants is important. Thorough screening, close monitoring and frequent follow ups are essential to prevent the blindness due to ROP.

Keywords: Retinopathy of Prematurity; ROP screening; Staging; Gestational Age; Birth Weight; Prenatal and Postnatal Risk Factors of ROP.

INTRODUCTION

Retinopathy of prematurity (ROP) is a multifactorial vaso-proliferative disease of premature retina affecting preterm neonates, that increases in incidence with decreasing gestational age and birth weight. It can range from mild, transient changes in the retina showing regression, to severe progressive vaso-proliferation, scarring, detachment of retina and blindness. [1] Its most severe form can lead to retinal detachment and subsequent blindness. Approximately 65% of infants with a birth weight of <1250 gm, and 80% of infants with a birth weight < 1000 gm, will develop some degree of ROP.

In view of ongoing trend for resuscitation of smaller infants with lower gestational age along with increased survival of very low birth weight (VLBW) & extremely low birth weight (ELBW) babies, an increase in incidence of ROP is expected. [2, 3]Out of 26 million annual live births in India, nearly 2 million are < 2000 g in weight and are at risk of developing retinopathy of prematurity (ROP). [4]In India, the incidence of ROP is between 38% and 51.9% in low-birth-weight babies. [5]Advances in neonatal care have improved survival of preterm babies. One of the foremost causes of blindness in preterm babies was found to be ROP. [6]Oxygen supplementation is identified to be an important risk factor for the development of ROP. [7]

Babies who have received oxygen need not necessarily develop ROP. ROP can develop without oxygen supplementation. [8]Early gestational age (GA), low- birth weight, hyperoxia, apnea, intraventricular hemorrhage, blood transfusions, and maternal bleeding are other risk factors associated with ROP. Large refractive error mainly myopia, strabismus, impaired vision, and blindness may occur following severe ROP. [9]

ROP is therefore now considered a major health problem and it has been included in the World Health Organization program for prevention of childhood blindness. The incidence of ROP and the population at risk of developing ROP are dependent on the availability, access to, and quality of neonatal care. Guidelines and screening programs that take into consideration the characteristics of local populations therefore have to be designed. [10]

ROP begins to develop between 32- and 34-weeks post conception, regardless of gestational age at delivery, and has two distinct phases. The first acute phase, is associated with vaso-obliteration and non-

vascularization of some areas of the anterior retina, as the normal vasculogenesis of the retina is disturbed by the relative hyperoxia of the extrauterine environment. [11] The second chronic phase, due to subsequent hypoxia is characterized by the proliferation of vascular and glial cells, arteriovenous shunt formation, occasionally leading to involution or permanent cicatricial changes and visual impairment. [12]

It is most commonly observed that ROP is not detected before 32 weeks of gestational age. The median age for detection of stage 1 ROP is 34 weeks. Pre- threshold ROP appears at 36 weeks of post-menstrual age and threshold disease at 37 weeks. Vascularization is completed by 40 weeks of gestation. Thus, the crucial period for detection of ROP is from 32 weeks to 40 weeks of post-menstrual period. The critical phase is from 34-35 weeks to 37-38 weeks age during which the progression of the disease takes place and treatment may have to be instituted. It may also be noted that ROP usually does not develop before 2 weeks of postnatal age. [13] International Classification of ROP (ICROP) is used to describe the vascularization of the retina and thereby classifies ROP by its position (zone), severity (stage), and extent (clock hours). [14] Retinal vascularization commences around the thirteenth week of gestation, proceeding centrifugally from the peripapillary region to the peripheral retina, which is fully vascularized by approximately term. The location of retinal vascularization provides an indication of infant maturity and risk of ROPdeveloping. [15]

Hence, the current study was undertaken to study the incidence and associated risk factors of ROP among all preterm infants (<1500gm and <32-week gestation) born in a tertiary care hospital. This study also examines short term outcome in preterm infants with ROP and evaluate the association between various risk factors and the outcome of ROP in preterm infants.

MATERIAL AND METHODS

This prospective study was conducted among Preterm neonates between 28-36 weeks and birth weight less than 2 kgs admitted in KIMS Koppal. Study Duration was Feb 2024 to April 2025 or till desired sample size is attained, whichever is earlier

Sample-size-150

Inclusion Criteria

- Parents giving consent for the study
- Preterm infants <36 weeks of gestation, and
- Preterm infants weighing<2000gm

Exclusion Criteria

- Parents not giving consent for ROP.
- Newborns with congenital anomalies, syndromes, congenital cataract and tumours of eyes.
- Term babies born with less than 2 kgs.

Outcome

The incidence of Retinopathy of Prematurity (ROP) and associated risk factors among all preterm infants (<2000gm and <36weeks gestation), born in a tertiary care hospital.

Short term outcome of our study will be interpreted as number of preterm infants requiring regular follow up, till 44 weeks of post menstrual age or until retina matured like that of term, or those requiring intervention either in the form of single modality or more than one modality of treatment.

Data Collection Method

- Informed parental consent will be taken from all cases.
- In all cases detailed history, physical examination and assessment of all risk factors will be done and recorded in study proforma.
- All the data will be compared and stored in form of excel sheet for further references.

METHOD

All Preterm infants who will be born in NICU of KIMS Koppal were screened for Retinopathy of Prematurity (ROP), after 3 weeks of post natal life, by an opthalmologist. Result of Retinopathy of Prematurity will be interpreted as those requiring regular follow up, until retina matured like that of term, or those requiring intervention. All the risk factors related to Retinopathy of Prematurity will be compared.

Retinopathy of Prematurity (ROP) screening will be done by an experienced ophthalmologist, with indirect ophthalmoscopy using 20 D or 28/30 D lens. After instilling a topical anesthetic drop like Proparacaine, a wire speculum is inserted to keep the eye-lids apart. First the anterior segment of the eye is examined to look for tunica vasculosalentis, pupillary dilation, and lens / media clarity; followed by the posterior pole to look for plus disease; followed by sequential examination of all clock hours of the peripheral retina. A scleral depressor is often used to indent the eye externally to examine areas of interest, rotate and stabilize the eye.

STATISTICAL METHODS

Linear variables will be summarized as mean and standard deviation whereas nominal/categorical variable will be expressed as proportion (%). Unpaired 't' test and one way ANOVA test will be used for analysis of linear variables while Chi square test and Fisher exact test will be used for analysis of nominal/categorical variables. Probability P value <0.05 will be considered statistically significant.

RESULTS

150 babies satisfying the inclusion criteria were enrolled in the study. Among the 150 babies, 31(21.7%) babies had ROP. Among the 31 babies most (20 babies) had the disease bilaterally. 11 babies however had ROP in one eye alone. So among the 300 eyes which were examined, 51 eyes were positive for the disease. Of the 51 eyes 27 were right eye and 24 were left eye. Of the 150 babies, 88 (58.6%) were males and 62(41.4%) were females. Among the 31 babies with ROP, 17 were male and 14 were female.

Table 1: Distribution of babies as per gestational age

GESTATIONAL AGE (weeks)	Number	Percentage
<30	12	8.0
30-32	61	40.5
33-34	49	32.8
34-36	28	18.5
Total	**150**	**100**

The gestational ages ranged from 28-36 weeks with 122(81%) of babies being less than 34 weeks. Of the babies who had ROP, majority were between 30-32 weeks of gestation.

Of the 31 babies with ROP majority were between 30-32 weeks and had **stage 2**.

Table 2: Gestational age of babies with ROP v/s Staging

Gestational age (weeks)	RE				LE			
	Stage 1	Stage 2	Stage 3	Total	Stage 1	Stage 2	Stage 3	Total
<30	0	3 (12%)	0	3 (12%)	0	2 (9%)	0	2 (9%)
30-32	1 (4%)	12 (48%)	0	13 (48%)	4 (17%)	8 (34%)	0	12 (52%)
32-34	3 (12%)	5 (20%)	1 (4%)	9 (36%)	2 (9%)	6 (26%)	1 (4%)	9 (39%)
34-36	0	2 (8%)	0	2 (8%)	0	1 (4%)	0	1 (4%)
Total	**4 (16%)**	**22 (80%)**	**1 (4%)**	**27 (100%)**	**6 (26%)**	**17 (70%)**	**1 (4%)**	**24 (100%)**

p value- 0.341 p value- 0.625

Of the 31 babies with ROP majority were between 30-32 weeks and had **zone 2**.

Table 3: Gestational age of babies with ROP v/s Zone of disease

Gestational age (weeks)	RE				LE			
	Zone 1	**Zone2**	**Zone 3**	**Total**	**Zone 1**	**Zone 2**	**Zone 3**	**Total**
<30	1 (4%)	2 (8%)	0	3 (12%)	1 (4%)	1 (4%)	0	2 (9%)
30-32	0	10 (40%)	3 (12%)	13 (52%)	0	8 (34%)	4 (17%)	12 (52%)
32-34	0	7 (28%)	2 (8%)	9 (36%)	0	7 (30%)	2 (9%)	9 (39%)
>34	0	2 (8%)	0	2 (8%)	0	1 (4%)	0	1 (4%)
Total	**1 (4%)**	**21 (76%)**	**5 (20%)**	**27 (100%)**	**1 (4%)**	**17 (70%)**	**6 (26%)**	**24 (100%)**

P value 0.087p value- 0.051

Among the total 150 babies, 75(50.0%) were examined within 4 weeks of life, 52(35%) between 4 and 8 weeks and the remaining 22(15%) were examined beyond 8 weeks of life. Among the 31 babies with ROP majority (17) were examined within 1st month.

Table 4: Age at first examination of babies with ROP

Age(weeks)	Number	Percent
1-4	17	55.1
4-8	10	31
>8	4	13.7
Total	**31**	**100**

p value- 0.855

Birth weight ranged from 900 to 2500gm in the study. Majority of the babies (65) weighed more than 1750grams. Of the total 31 babies with ROP, majority weighed between 1500 and 1750gms. In this range of birth weight majority had **stage 2** disease.

Of the total 31babies with ROP, majority weighed between 1500 and 1750 gms. In this range of

birth weight majority had **zone 2** disease.

Table 5: Risk factors

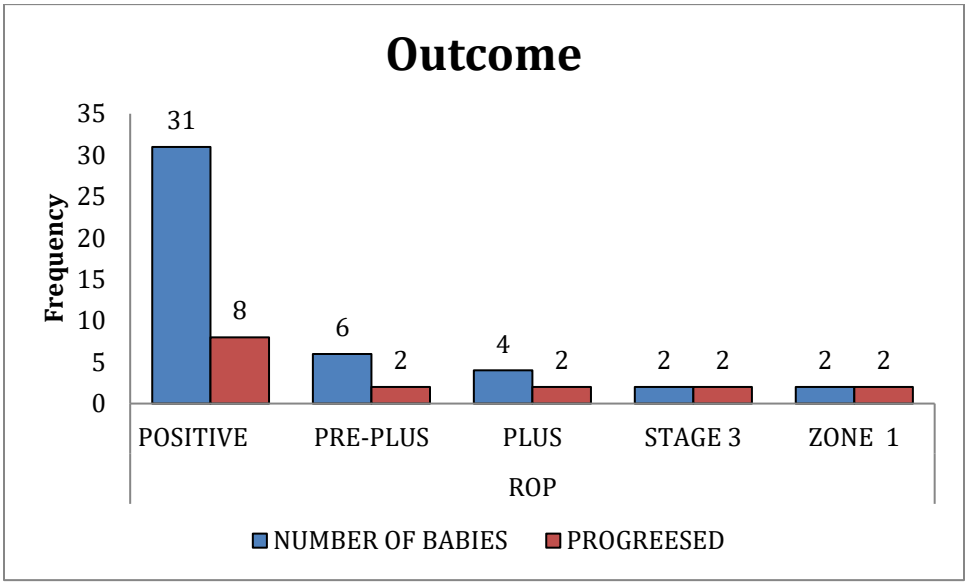
	Risk factors	No ROP		ROP present		p-value
		Number	%	Number	%	
Prenatal	PIH	8	7.2	5	17.2	0.097
	Multiple gestation	12	9.9	1	3.4	0.268
	APH	3	2.7	0	0	0.371
	Antenatal Steroid	6	5.4	0	0	0.201
	PROM	11	9.0	1	3.4	0.322
	GDM	3	2.7	0	0	0.371
Post natal	LSCS	24	19.8	4	13.8	0.457
	Asphyxia	9	8.1	1	3.4	0.386
	MAS	2	1.8	0	0	0.467
	HIE	7	6.3	0	0	0.165
	Hyaline Membrane Disease/ RDS	25	21.6	7	24.1	0.771
	Surfactant	2	1.8	1	3.4	0.586
	Oxygen	21	18	24	75.9	<0.001
	Ventilation	3	2.7	2	6.9	0.279
	Pneumonia	5	4.5	0	0	0.244
	Sepsis	4	3.6	3	10.3	0.138
	Polycythemia	0	0	0	0	
	Anemia	2	1.8	2	6.9	0.143
	Thrombocytopenia	2	1.8	0	0	0.467
	Transfusion	3	2.7	1	3.4	0.830
	Hypoglycemia	3	2.7	1	3.4	0.830
	Hyperbilirubinemia	16	13.5	12	37.9	0.003
	Phototherapy	15	12.6	3	10.3	0.739
	Ascites	1	0.9	0	0	0.608
	Shock	1	0.9	0	0	0.608
	PDA	1	0.9	2	6.9	0.047
	IVH	2	1.8	0	0	0.467
	DIC	1	0.9	0	0	0.608

Of the various risk factors that were observed, oxygen supplementation, hyperbilirubinemia and

PDA were found to be statistically significant. More number of babies was born to primigravida mothers. Among 27 right eyes with ROP, majority (22) had stage 2. Among the total 27 right eyes with ROP majority (21) had zone 2**.** Among the total 24 left eyes with ROP, majority (17) had stage 2. Among the total 24 left eyes with ROP majority (17) had zone 2.

PLUS DISEASE:

PRE-PLUS: 6 cases (20.7% of ROP)
PLUS disease: 4 cases (13.8% of ROP)



DISCUSSION

Many of the premature neonates are surviving now with improving neonatal care. Hence the incidence of ROP is also rising.[6] Reports show that the incidence of ROP is less in units where there is ongoing screening programme. So timely screening is important to detect ROP and intervene.

Among 150 babies, 31 had ROP. The proportion of ROP among premature neonates was found to be 21.7%. Various Indian studies show incidence ranging from 17.5% to 46%. 78, 79, 74, 41

A study by Gupta[16] et al reported an incidence of 21.7%. In the study 60 babies were included with gestational age ≤35 weeks or weight ≤1500gm. The incidences in these studies were in concordance with the present study since the proportion of babies with ROP was 21.7% in the present study.

It is evident from various studies that lower gestational age has higher incidence of ROP. In our study, majority of the babies screened were between 30-32 weeks i.e., 61 babies (40.5%).

Highest incidence of ROP was also found among the babies with the gestational age range between 30- 32 weeks that being 25 eyes (37.3%). Among the 25 eyes, 5 (20.0%) were in stage 1 and rest 20 (80.0%) had stage 2. Also, among the 25 eyes, 18 eyes (72%) had zone 2 and 7(28%) involved zone 3. The 2 cases of severe ROP that is stage 3 and beyond belonged to the gestational age between 32 and 34 weeks.

There were only 3 eyes (5.8%) with age >34weeks.

The American Academy of Pediatrics (AAP) guidelines [17] state that infants with a birth weight of less than 1500 g or gestational age of 30 weeks or less have to be mandatorily screened. However the infants >1500g or >30weeks are to be screened at the discretion of the attending neonatologist. If the present study had taken 30 weeks as the higher limit for inclusion then we would have missed 45 eyes (88.2%). Hence in developing countries like India wherein larger babies with higher gestational age and birth weight have also shown the disease, the guidelines might have to be modified.

A statistically significant number of babies (75 babies; 50.0%) were examined within 1st one month of birth. This was in accordance with standard NNF guidelines which suggest the examination to be done within 4 weeks of age or 30 days of birth.[18]In various studies including that by Vivek at al [35] and Vinekar et al [19] babies were examined at 4th week of age.

However 22 neonates (15.0%) first presented beyond 8 weeks of age. This may be due to the poor awareness of the disease and negligent attitude of the people especially of those from rural background.

ROP incidence and severity increases as birth weight decreases. The birth weight ranged between 900g and 2000g in our study. Many of the babies (71) weighed more than 1750g. But among the 51 eyes with ROP, 44(86.2%) were less than 1750g. This was in concordance with the CRYO-ROP [5] study.

RISK FACTORS

ROP is a multifactorial disease. Retinopathy is only one of the many devastating complications of premature birth.

Low birth weight and lower gestational age is associated with higher disease incidence as has been seen above.

The causal link between ROP and supplemental oxygen has been confirmed by controlled trials and clinical studies [17,22]. In our study oxygen administration was a significant risk factor for development of ROP (p=<0.001). Of 150 babies, 45 (30%) received supplemental oxygen. 24 of the 45 developed ROP i.e., nearly half of the babies who had received oxygen developed ROP. This correlates well with studies by Gupta et al [16] and Agarwal et al [20] who also showed that 50% of babies on oxygen developed ROP.

In our study, 75% of the babies with PDA had developed ROP suggesting it as a significant (p= 0.047) risk factor. Among the very few studies on associations of PDA and ROP the one conducted in New South Wales, Australia, ROP was seen in 79% of PDA babies. [21]

Hyperbilirubinemia

There was a significant (p=0.003) correlation between babies who had hyperbilirubinemia and ROP. Of the total 150 babies, 28 had hyperbilirubinemia. 12 babies (42.3%) among these developed ROP. Similar results were seen in Chaudhari[1] et al study.

A retrospective analysis on preterm babies showed that prolonged phototherapy and variations in serum bilirubin levels contributed to blindness attributable to ROP.[21]

Hence more research and multicentric trials are necessary to confirm these associations as important risk factors.

This was shown to have a protective effect against ROP according to study conducted by Rosemary et al. However our study did not show any significant correlation.

Hyaline membrane disease/ Respiratory Distress Syndrome

32 babies were found to have RDS in the present study, of which 7 had ROP. RDS was found to be a significant risk factor in studies by Vinekar et al [19] and Gupta [16] et al. However in the present study there was no statistically significant association.

STAGING OF ROP

Of the total 54 eyes, 10 eyes (19.6%) had stage I, 39(76.4%) had stage II and 2 eyes (4%) had stage III. This was in concordance with the study by Charanet al[12] and Vinekar et al [19] wherein more number of infants had stage II disease.

But according to Mantri et al more babies (45%) had stage I. Higher incidence of stage II ROP in our study can probably be attributed to admission of more sick infants in our center as a referral hospital

SEVERITY OF ROP

Most of the studies consider stage 3 and above as severe ROP. In our study only 1 case showed stage 3 (3.44%).

In the present study the proportion of patient with severe ROP was only 3.4%. This was similar to the above mentioned studies. This may be because of timely screening and following of protocol in our hospital.

There were 6 babies (20.7%) with preplus disease and 4 cases of Plus disease. These also indicate severity of ROP. Those with Plus disease especially in Zone 1 and 2 mandate treatment.

In our study there were no cases of APROP.

ZONE OF ROP

Among the total 51 eyes 2 (3.9%) had zone I disease, 38 (74.5%) had zone II and 11 (21.5%) had zone 3 disease.

This was similar to the study conducted by Dogra et al wherein majority for the babies (90%) had zone II disease.[22] Also in another South Indian study majority of the babies had zone 2.[76]

CONCLUSION

Among the post natal factors, supplemental oxygen still stands to be the major risk factor. This mandates judicious oxygen supplementation of utmost importance. Other post natal factors hyperbilirubinemia and patent ductus arteriosus were also found to be significant. Majority of the babies had milder stages of the disease at presentation. Hence frequent follow up is necessary to check for any progression. Despite increasing survival with improved neonatal intensive care, the incidence of ROP does not appear to be increasing.

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