

Retinopathy of Prematurity Screening in a Tertiary Care Centre

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Abstract

Background: To conduct an effective ROP screening program according to the Indian standard needs and to identify the infants who could benefit from treatment and make appropriate recommendations on the timing of future screening.

Aims and Objectives: To estimate the incidence of ROP among Premature infants. **Materials and Methods:** A Prospective Observational study of 2 years in which 170 patients were screened with following criteria: GA at birth of ≤ 35 weeks, BW < 1700 gms, exposed to oxygen > 30 days, other factors that can increase the risk of ROP and where screening should be considered are premature babies > 37 weeks and > 1700 gms but with the first screening was done within 4 weeks (30 days) of life in infants with age > 28 weeks of GA, 2-3 weeks after birth if GA < 28 weeks or BW is < 1200 gms. **Results:** Out of the 170 babies screened 35 babies had ROP. Incidence of ROP in our study was 20.59%. The sensitivity of AAP and UKRCPCH guidelines to ours were 77.14% and 60% respectively. **Conclusion:** ROP may be seen in heavier and larger babies in India that have consequently a shorter window period for development of ROP, Hence, a criteria screening even larger babies should be taken into consideration.

Keywords: Birth Weight, Gestational Age, Retinopathy of Prematurity, Screening

1. Introduction

Retinopathy of Prematurity (ROP), seen in the premature and low BW infant is a vaso proliferative disorder of the developing retinal vasculature and is a potentially blinding condition. Retinopathy of Prematurity was called as Retrorenal Fibroplasia (RLF) in 1940's. The term RLF was coined in the year 1942 by Terry¹. Term ROP was coined by Heath in 1951².

The retina is unique tissue in that it has no blood vessels until the fourth month of gestation. Normal retinal vascularization happens centrifugally from optic disc to ora. Vascularization up to nasal ora is completed by

8 months (36 weeks) and temporal ora by 10 months (39–41 weeks)³. The course of ROP may range from minimal sequelae to bilateral, irreversible and total blindness in more advanced cases. It is an avoidable cause of blindness.

Incidence of this condition is rising rapidly in developing countries who have just started to feel the burden of ROP with gradual improvement in neonatal care and awareness.

The World Health Organization's "Vision 2020 programme" has identified ROP as an important cause of blindness in both high and middle income countries. Approximately 2 million babies out of 26 million annual live births in India are born with BW < 2000 g and are at

risk of developing ROP³. WHO estimates that there are 15 million preterm births a year (born at <37 weeks) and India has the largest number of preterm births in the world⁴.

The incidence of ROP is increasing in India because of improved neonatal survival rate. In India the incidence of ROP is between 38 and 51.9% in low birth infants^{3,5}.

The most important determinant of any ROP management program is an effective screening strategy. The goal of an effective ROP screening program is to identify the infants who could benefit from treatment and make appropriate recommendations on the timing of future screening and treatment interventions.

Very few comprehensive review articles covering all the aspects of ROP are published. Hence the present study was undertaken to screen the premature infants for ROP which if untreated may cause severe visual disability. Knowing the relationship between the causative factor and ROP will help in prevention and reducing the incidence of ROP.

2. Aims and Objectives

1. To estimate the incidence of ROP among premature infants.
2. To classify or grade ROP based on ICROP Classification.

3. Materials and Methods

Study Type: Prospective observational study.

Study Settings: Department of Ophthalmology of Dr. Vasantarao Pawar Medical College and Research Centre.

Study Duration: August 2016 to September 2018.

Study Population: All the infants fitting into the Inclusion criteria admitted in our NICU and also those referred from outside attending OPD were screened from August 2016- September 2018.

Eligibility Criteria

Selection of Subjects

All neonates weighing <1700 gm and/or with a gestation ≤35 weeks admitted to NICU of our Tertiary Care Centre

and also those referred from outside attending our OPD were routinely screened for ROP between the year August 2016 - September 2018.

All relevant perinatal data including risk factors (exposure to oxygen, days of oxygen exposure, sepsis, anaemia and blood transfusion, phototherapy, apnea, congenital cardiac defect, Patent Ductus Arteriosus (PDA), intraventricular haemorrhage, ventilation, days on ventilation, history of RDS, multiple birth, pneumonitis.

Inclusion Criteria⁶

- Gestational Age (GA) at birth of <34-35 weeks
- Birth Weight (BW) <1700 g
- Exposed to oxygen >30 days
- Other factors that can increase the risk of ROP and where screening should be considered are premature babies >37 weeks and >1700 g but with
 3. Respiratory Distress Syndrome
 4. Sepsis
 5. Sickly survivors
 6. Pneumonitis
 7. Multiple blood transfusions
 8. Multiple births (twins/triplets)
 9. Apnoeic episodes
 10. Intraventricular haemorrhages

Exclusion Criteria

- Babies with Congenital anomalies of eye
- Babies with chorioretinitis
- Infants born after 36 weeks (excluding the above causes)
- BW >1700 g (excluding the above causes)

Methodology

- Informed consent was taken from the parents/guardian.
- IEC approval was taken.
- Patients were chosen according to the inclusion and exclusion criteria.
- Detailed maternal history and neonatal history was taken.
- All infants were screened by the same ophthalmologist.

Time of Screening

The first screening was done within 4 weeks (30 days) of life in infants with age >28 weeks of GA, 2-3 weeks after birth if GA is <28 weeks or BW is <1200g⁶.

Examination

- Screening was done under a radiant warmer in the NICU, under the guidance of the neonatologist. Discharged and stable babies were screened in the OPD. Parents/Guardians were informed before the examination about the procedure of screening and after their consents the infants were screened. Pupils were dilated using diluted Tropicacyl plus (0.5% tropicamide plus 2.5% phenylephrine) eye drops in 1:2 dilution using distilled water 2-3 times about 10-15 minutes apart or till full dilatation occurs. Care was taken to wipe off the excess drops to prevent systemic absorption though the cheek skin as over dosage carries the risk of tachycardia and hyperthermia.
- Topical anaesthesia 2% proparacaine drops was instilled. A pediatric wire speculum was used to keep the eyes apart. Gentle indentation with a pediatric scleral depressor was used to stabilize the globe.
- A detailed Anterior segment examination was done

Posterior Segment Evaluation

- Fundus evaluation: By Heine Indirect ophthalmoscopy with a VOLK condensing lens of +28D
- Follow up schedule for ROP Babies²:

Zone of Retinal Findings	Stage of Retinal Findings	Follow Up Interval
ZONE I	Immature vascularisation	1-2 weeks
	Stage I or II	1 week or less
	Regressing ROP	1-2 weeks
ZONE II	Immature vascularisation	2-3 weeks
	Stage I	2 weeks
	Stage II	1-2 weeks
	Stage III	1 week or less
ZONE III	Regressing ROP	1-2 weeks
	Stage I or II	2-3 weeks

Retinal examination was terminated based on postmenstrual age or retinal findings. Examination was terminated when

1. Full retinal vascularization was noted which was usually completed around 40-45 weeks.
2. Regression of ROP noted.

The babies were screened every 1-2 weeks at least until the infant is 38-40 weeks of postmenstrual age.

Statistical Analysis

A SPSS software was used for all statistics A P value <0.05 was considered as statistically significant.

4. Results

During the study period of 2 years from August 2016 - September 2018 the total number of babies screened were 177.

Out of the 177 babies that we screened 170 babies were included in our study. 116 males (68.24%) and 54 Females (31.76%). The birth mean BW of the babies in our study was 1590g ± 368.19g (Range: 898-3000g). Mean GA of the babies in our study was 33.38±2.8 weeks (Range: 25-41 weeks).

35 of the 170 babies had ROP. Thus, the incidence of ROP in our study was 20.59%.

ROP Data: Initial examination was done between 3 and 7 weeks with an average of 4 weeks. Late screening may be due to delayed referral of the baby from outside or late admission in our NICU and failure to screen outside.

Total males with ROP were 26 (74.28%), females with ROP 9 (25.71%) (p<0.05).

First Detection of ROP: 23(65.71%) babies had ROP in 1st screening. 1/25 baby had AP ROP and was lasered the same day. In 12(34.28%) babies the peripheral retinal was avascular which then developed ROP. 1/12 babies had later developed Plus disease. The mean BW at 1st detection of ROP was 1557.14 grams and average Post Conceptional Age was 37.08 weeks.

Incidence and Severity of ROP in Relation to BW: The mean BW of NON ROP babies was 1606.58±375.92 g. Mean BW of ROP babies was 1528.94±334.59 g (range: 898-2750 g) {p<0.05}. Incidence of ROP in BW ≤ 1250 g was 30.7%. Incidence of ROP in BW >1251g was 18.7% (p<0.05). Thus, ROP was significantly associated with BW (table 1).

Table 1. Distribution of ROP babies according to BW 8%)

BW	Total Babies	ROP Negative Eyes (N=270)	ROP Positive (Eyes)(N=70)
≤ 1000	5	8(2.9%)	2(2.8%)
1001-1250	21	28(10.3%)	14(20%)
1251-1500	57	90(33.33%)	24(34.2%)
1501-1750	46	74(27.4%)	18((25.57%)
1751-2000	27	46(17.03%)	8(11.42%)
>2001	14	24(8.8%)	4(5.7%)

Incidence of ROP in relation to GA at Birth: Mean GA at birth of NON ROP babies was 33.91 ± 2.81 week. Mean GA at birth of ROP babies was 32.31 ± 2.38 weeks, (range 26-39 weeks). ($p < 0.05$). Incidence of ROP ≤ 32 weeks was 33.92%. Incidence of ROP > 32 weeks was 13.91% ($p < 0.05$). Thus, ROP was found to be significantly associated with GA (table 2).

Table 2. Distribution of ROP according to GA at birth

GA in Weeks	Total Babies	ROP Negative Eyes (N=270)	ROP Positive(Eyes) (N=70)
≤ 28	13	20(7.4%)	6(8.5%)
29-30	10	12(4.44%)	8(11.4%)
31-32	33	42(15.5%)	24(34.28%)
33-34	61	96(35.5%)	26(37.14%)
35-36	27	50(18.51%)	4(5.71%)
37-38	21	42(15.5%)	0
39-40	4	6(2.2%)	2(2.8%)
> 40	1	2(0.7%)	0

4.1 Asymmetry

Out of 35 ROP babies (70 eyes), 3 babies (6 eyes) had asymmetrical disease. None of the babies in our study had unilateral presentation

4.2 Data according to the Stages

21 (30%) eyes had Stage I, 18 eyes (25.7%) had Stage II, 27 eyes (38.6%) had Stage III, 2 eyes (2.8%) had Aggressive Posterior ROP and 2 eyes (2.8%) had Plus disease. The BW and GA at birth were inversely proportion (table 3).

Table 3. Distribution of mean BW and GA according to the stages of ROP seen

	Stage I	Stage II	Stage III, Plus Disease and AP ROP
Mean BW(Grams)	1660 \pm 428	1567.5 \pm 238.8	1435.5 \pm 309.7
Mean GA (Weeks)	32.4 \pm 1.58	33.55 \pm 2.51	31.56 \pm 2.56

(in case of asymmetrical disease, the higher staging was considered).

4.3 Zone Distribution

4 eyes (5.71%) had ROP in Zone I, 14(20%) eyes had ROP in Zone II and 52(74.28%) eyes had ROP in Zone III. Maximum cases in our study was seen in Zone III.

4.4 Neonatal Risk Factors

Various neonatal risk factors were studied of which O₂ exposure, number of days of O₂ exposure, Ventilation, number of days on ventilation, RDS, Sepsis, Blood transfusion, Apnoea using Chi-Square test were significant indicating an increased association of ROP. (table4).

Table 4. Details of the risk factors

Neonatal Risk Factors	Non ROP Babies N=135	ROP Babies N=35	P Value	Significance
O ₂ Exposure	85	32	0.00119	Significant
Average No of Days of O ₂ Exposure	8.152	33.09	0	Significant
Ventilation	11	9	0.00404	Significant
Average No of Days of Mechanical Ventilation	2.18	8.44	0.009	Significant
Phototherapy	25	6	0.8510	Not Significant
Multiple Birth	28	5	0.389	Not Significant
RDS	57	26	0.00072	Significant
Sepsis	28	18	0.00021	Significant
Sickly Survivors	30	7	0.776477	Not Significant
Pneumonitis	33	8	0.844	Not Significant
Blood Transfusion	18	10	0.0303	Significant
IVH	1	1	0.3007	Not Significant
Apnea	12	11	0.00051	Significant

For Multivariate Analysis we applied Binary Logistic Regression analysis. We found that the number of days of O₂ exposure and Sepsis was a significant risk factor. Analysis showed that increasing day of O₂ exposure is associated with an increased likelihood of ROP. Also, it suggested that the odds of having ROP was 26.26 times greater for those having sepsis as opposed to those not having sepsis (table 5).

Table 5. Showing binary logistic regression

Risk Factors	P Value	95% Confidence Interval		Significance	Odd Ratio
		Upper	Lower		
Exposure to Oxygen	0.081	0	1.62	Not Significant	0.02
Days of O₂	0.002	1.192	2.186	Significant	1.614
Mechanical Ventilation	0.201	0	3.30E+01	Not Significant	0.001
Days on Mechanical Ventilation	0.406	0.22	41.996	Not Significant	3.041
Multiple Birth	0.292	0.356	30.918	Not Significant	3.317
Phototherapy	0.057	0.926	258.368	Not Significant	15.47
RDS	0.694	0.062	64.776	Not Significant	2.009
Sepsis	0.016	1.839	374.782	Significant	26.256
Sickly Survivor	0.873	0.035	17.183	Not Significant	0.777
Pneumonitis	0.198	0.001	4.338	Not Significant	0.061
Blood Transfusion	0.293	0.196	220.855	Not Significant	6.579
IVH	0.31	0.001	3.97E+09	Not Significant	1892.2
Apneic Episodes	0.685	0.033	182.589	Not Significant	2.44

Using the current American screening guidelines (≤ 1500 g BW or ≤ 32 weeks GA) 8 babies (22.85%) would have been missed.

So out of total 31 eyes of 16 babies (one baby had only one eyed lasered) that were lasered, 4 eyes of 2 babies (12.9%) would have been missed if AAP guidelines were used. Thus, the Sensitivity of AAP guidelines was 77.14%

If the UK Royal College of Paediatrician and Child Health (UKRCPCH) would have been used an additional 6 babies would have been missed.

So out of total 31 eyes of 16 babies (one baby had only one eyed lasered) that were lasered, 11 eyes of 6 babies (68.75%) would have been missed if BRITISH GUIDELINES were used.

Thus, the sensitivity of British Guidelines was 60%.

5. Discussion

The increasing incidence of prematurity and better survival of smaller babies has led to an increase in the incidence of ROP. Hence an attempt was made in current study to look at the incidence of ROP in a rural based Tertiary Care Centre.

In the present study, a total of 170 babies were screened in detail.

5.1 Screening

The first screening was done within 4 weeks (30 days) of life in infants with age >28 weeks of GA. Screening was

done earlier (2–3 weeks after birth) if GA was <28 weeks or BW is <1200 g.

The onset of serious ROP correlates better with Postmenstrual age (GA at birth plus chronologic age) than with Postnatal age.⁷ That is, the more preterm an infant is at birth, the longer the time to develop serious ROP. This knowledge has been used previously in developing a screening schedule^{8,9}.

According to the AAP¹⁰ Examination should be performed between 4 and 6 weeks’ postnatal age or between 31 and 33 weeks’ postconceptional age.

Jalali *et al.*⁵, also NNF 2010³ suggest that the screening in Indian babies especially the larger and heavier babies who have a shorter period of development of ROP should be screened earlier at least first screening should begin within 4 weeks of GA if >28 weeks and within 2-3 weeks if GA <28 weeks or BW <1200 grams.

5.2 Incidence

In our present study the incidence of ROP was 20.59%. Incidence of severe ROP (all which required treatment) was 9.41%. International studies suggest incidence of ROP ranges from 10-45%. In India, approximately, the incidence of ROP is reported between 24% and 47%¹¹.

The incidence in our study was on the lower side of the range found in India. This might probably be due to the fact that the neonatal care centre in our hospital provided controlled delivery of oxygen to the premature at-risk babies. Incidence in our study was similar to that

found in study done by Maheshwari *et al.*, Krishnarao *et al.*, Chaudhari *et al.*

5.3 Mean BW and GA

Mean BW of the babies in our study was $1590\text{g} \pm 368.19\text{g}$ (range 898-3000 g). The mean BW of NON ROP babies was $1606.58 \pm 375.92\text{g}$. Mean BW of ROP babies was $1528.94 \pm 334.59\text{g}$, (range: 898-2750 g).

Mean GA of the babies in our study was 33.38 ± 2.8 weeks (range 25-41 weeks). Mean GA of NON ROP babies was 33.91 ± 2.81 weeks. Mean GA of ROP babies was 32.31 ± 2.38 weeks, (range: 26-39).

This study suggested that the babies were heavier and older than the American screening cut-off

This was supported by a study done by Hungi *et al.*¹² in which the mean BWs and periods of gestation with and without ROP were 1555.9 vs. 1672.5 g and 32.2 vs. 34.6 weeks, respectively. Also, a study done by Sundar KC *et al.*¹³ also found that the mean BW of babies with and without ROP identified in their study was 1480 grams and 1620 grams respectively. The mean GA of babies with and without ROP was 32 weeks and 33 weeks respectively

However, many Indian studies as well as International studies have not supported the fact that ROP does occur in heavier and older babies¹⁴⁻¹⁶.

5.4 First Detection of ROP

23/35 (65.71%) babies had ROP in 1st screening. In 12/35 (34.28%) babies the peripheral retinal was avascular which then developed ROP. The average BW of all ROP babies at first detection was 1557.14 g. Average Post Conceptional Age at first detection of all ROP was 37.08 weeks.

Higgins *et al.*¹⁷ reported that most severe stage was reached at an average of 35.3 ± 2.7 weeks range 31-41 weeks. This was somewhat similar to our study. Rekha *et al.*¹⁸ stated that the maximum stage of ROP developed between 37-42 weeks post conceptional age.

5.5 Incidence and Severity of in Relation to BW and GA

In our study Incidence of ROP $\leq 1250\text{g}$ was 30.7% and those $> 1251\text{g}$ was 18.7%. Incidence of ROP ≤ 32 weeks was 33.92% and > 32 weeks was 13.91%.

Gupta *et al.*¹⁹ in their study found the incidence of ROP was 33.3% in babies ≤ 32 weeks gestation and 36.4% in babies weighing $\leq 1250\text{gm}$.

Parekh *et al.*²⁰ found the incidence of ROP in infants $\leq 1250\text{gm}$ was 55.1% and $> 1250\text{gm}$ was 16% and the incidence of GA out was (88.6%) in ≤ 32 weeks and (11.4%) in > 32 weeks. However, Wright *et al.* published a study that focused on the incidence of larger infants. In that study, no infant with a BW $\geq 1200\text{g}$ or with a PMA of ≥ 30 weeks developed Threshold ROP which is in complete contrast of our study.

5.6 Stage-wise Distribution of ROP

21(30%) eyes had Stage I, 18 eyes (25.7%) had Stage II, 27 eyes (38.6%) had Stage III, 2 eyes (2.8%) had Aggressive Posterior ROP and 2 eyes (2.8%) had Plus disease. The mean BW was $1660 \pm 428\text{g}$ for Stage I, $1567.5 \pm 238.8\text{g}$ for Stage II and $1435.5 \pm 309.7\text{g}$ for Stage III. The mean GA was 32.4 ± 1.58 weeks for Stage I, 33.55 ± 2.51 weeks for Stage II and 31.56 ± 2.56 weeks for Stage III.

We noticed as the Stage of ROP increased the average BW decreased. This was similarly notice by Charan, Dogra *et al.*²¹

5.7 Zone Distribution of 70 Eyes

2(2.8%) eyes had ROP in Zone I, 14(20%) eyes had ROP in Zone II and 54(77.1%) eyes had ROP in ZONE III. Few babies in Zone I may be due to regular screening and early identification of all severe ROP and also may be due to poor survival rate of very low BW infants.

Crystal Le *et al.*²² in their study found out patients with ROP most commonly in ZONE III (68%) and zone II was the second most common (26%) and only one case was noted in Zone I. Also, Alajbegovic-Halimic *et al.*²³ stated in their study that the babies with ROP was most commonly found to have ROP in Zone III (62.5%). 31.3% of babies had ROP in zone II and 6.3% of babies had ROP in Zone I.

5.8 Neonatal Risk Factors

We investigated role of O_2 , number of days of O_2 exposure, mechanical ventilation, number of days mechanical ventilation, RDS, sepsis, sickly survivors, phototherapy, IVH, pneumonitis, blood transfusion, apnoea and multiple birth in ROP.

Applying Chi Square test of significance on Univariate analysis O_2 exposure, number of days of O_2 , mechanical ventilation, number of days on mechanical ventilation, RDS, sepsis, blood transfusion and apnoea were found to be significant.

Applying **Binary Logistic Regression** multivariate analysis showed Number of days on O₂ and Sepsis were statistically significant. A detailed study of O₂ exposure in our study revealed that the average number of days on O₂ in ROP babies was 33.09 days and that in NON ROP babies was 8.152 days

Andrea Moraes *et al.*²⁴ in their study found on bivariate analysis found pulmonary disease, sepsis, APGAR score at 1 min and 5 mins, blood transfusion and average days on mechanical Ventilation was statistically significant. The average number of days on O₂ therapy in ROP babies was 27 days (range: 0-150 days) and NON ROP babies was 6 days (range: 0-150 days). In treated ROP it was 41 days (range: 2-150 days) and non-treated ROP was 8 days (range: 0-150 days). On Logistic regression analysis the found Pulmonary disease was a statistically significant risk factor.

Krishna A Rao *et al.*²⁵ found surfactant administration, apnoea, sepsis, Intermittent positive pressure ventilation and blood transfusion and for severe ROP RDS, surfactant administration, apnoea, hours of O₂ and Blood transfusion as risk factors on Univariate analysis and on multivariate only GA and BW were risk factors for ROP and IVH for severe ROP. They also investigated the O₂ exposure duration was in hours and they found that the ROP babies had an exposure of average 29 hours to that in NON ROP babies which was 23.5 hours. They did not find any statistical significance in the exposure of O₂ for development of ROP.

6. Conclusion

It is not uncommon that ROP in India does occur in larger and heavier babies. Moreover, these babies have a very short window period for development of ROP. An early identification of these heavy babies at risk for developing severe ROP would help to reduce the burden of blindness associated with Retinopathy of Prematurity.

We require a more definitive guideline rather than a discretionary one to include more and more babies so as to not miss out on any babies with ROP and to limit the burden of blindness caused by ROP.

For current scenario, the cut off for BW and GA need to be higher and a regionalisation of the screening criteria needs to evolve. Since our sample size was small a much larger study is required for confirming our findings.

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