



## Changing Trends in Retinopathy of Prematurity Profile in A Tertiary Care Centre in India

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### Abstract

**Background:** To conduct an effective ROP screening program according to the National Neonatology Forum (NNF) 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.

**Material and Methods:** A Prospective Observational study of 2 year in which 170 patients were screened with following criteria: GA at birth of  $\leq 35$  weeks, BW < 1700 gms, exposed to oxygen > 30days, other factors that can increase the risk of ROP and where screening should be considered are premature babies >37 weeks and >1700gms. 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 <1200gms

**Results:** Out of the 170 babies screened 35 babies had ROP. Incidence of ROP in our study was 20.59%. Mean BW of ROP babies was  $1528.94 \pm 334.59$  g. Mean GA at birth of ROP babies was  $32.31 \pm 2.38$  weeks, (range 26-39 weeks). Using the current AAP screening guidelines ( $\leq 1500$ g BW or  $\leq 32$  weeks GA) 8 babies (16 eyes) i.e 22.85% would have been missed. 11 eyes of 6 babies (68.75%) would have been missed if UKRCPH were used.

**Conclusion:** ROP may be seen in heavier and larger babies in India that have consequently a shorter window period for development of ROP.

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

### Introduction

Retinopathy of Prematurity (ROP), seen in the premature and low Birth Weight (BW) infant is a vasoproliferative disorder of the developing retinal vasculature and is a potentially blinding condition.

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 ROP.<sup>[1]</sup>

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 world.<sup>[2]</sup> 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.<sup>[1,3]</sup>

Very few comprehensive review articles covering all the aspects of ROP are published. Also, due absence of large epidemiological studies and mapping of nationwide ROP data, the present study was undertaken with a wider screening criteria to screen the premature infants for ROP which if left untreated would have resulted in severe visual disability.

### Material 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  $\leq$  35 weeks admitted to Neonatal ICU(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 was undertaken

**(Inclusion Criteria according to National Neonatology Forum (NNF) Guidelines<sup>[1]</sup>**

- Gestational Age (GA) at birth of  $\leq$ 35 weeks
- Birth Weight(BW) < 1700 g
- Exposed to oxygen > 30days
- Other factors that can increase the risk of ROP and where screening was done are premature babies >37 weeks and >1700g but with

1. Respiratory Distress Syndrome
2. Sepsis
3. Sickly survivors
4. Pneumonitis
5. Multiple blood transfusions
6. Multiple births(twins/triplets)
7. Apnoeic episodes
8. Intraventricular haemorrhages

### Exclusion Criteria

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

### Methodology

Informed consent was taken from the parents/guardian.

Institutional Ethical Committee approval was taken. (IEC- 42/2016-2107)

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 <1200g.<sup>[5]</sup>

### 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 outpatient department (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 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 through the cheek skin.

- 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 and Posterior Segment Evaluation:
- Follow up schedule for ROP Babies was done accordingly.<sup>[4]</sup>
- Retinal examination was terminated based on post conceptional 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 postconceptional age.

**Statistical Analysis**

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

**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 mean BW of the babies in our study was 1590 g± 368.19 g(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}

**Incidence and Severity of ROP in Relation to BW**

The mean BW of NON ROP babies was 1606.58±375.92g. Mean BW of ROP babies was 1528.94±334.59 g (range: 898-2750 g){p<0.05}. [Table 1]

**Table 1** Distribution of ROP Babies According. to BW

| 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). [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                          |

**First Detection of ROP:** 23(65.71%) babies had ROP in 1<sup>st</sup> 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 1<sup>st</sup> detection of ROP was 1557.14 grams and average Post Conceptional Age was 37.08 weeks.

**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

**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 (APROP) and 2 eyes(2.8%) had Plus disease. The BW and GA at birth were inversely proportional. [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±428  | 1567.5±238.8 | 1435.5±309.7                       |
| MEAN GA (WEEKS) | 32.4±1.58 | 33.55±2.51   | 31.56±2.56                         |

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

**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.

**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.[Table 4]

**Table 4** Details of the Risk Factors

| NEONATAL RISK FACTORS                        | NON ROP BABIES<br>N=135 | ROP BABIES<br>N=35 | P VALUE  | SIGNIFICANCE    |
|--|-------------------------|--------------------|----------|-----------------|
| O2 EXPOSURE                                  | 85                      | 32                 | 0.00119  | SIGNIFICANT     |
| AVERAGE NO OF DAYS OF O2 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. [Table5]

**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 Association of Paediatrics (AAP) guidelines ( $\leq 1500g$  BW or  $\leq 32$  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 UKRCPH guidelines were used.

Thus, the sensitivity of UKRCPH guidelines was 60%.

### 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.

### 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%.<sup>[5]</sup>

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.

### Mean BW and GA

Mean BW of ROP vs Non ROP babies was 1528.94±334.59 g vs 1606.58±375.92 g respectively and mean GA of ROP vs Non ROP babies was 32.31 ± 2.38 vs 33.91±2.81 weeks(range: 26-39).

A study done by HUNGI et al<sup>[6]</sup> 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 K.C et al<sup>[7]</sup> also found that the mean BW and GA of babies with and without ROP was 1480 grams vs 1620 grams and 32 vs 33 weeks respectively.

### First Detection of ROP

23/35 (65.71%) babies had ROP in 1<sup>st</sup> 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<sup>[8]</sup> Rekha et al<sup>[9]</sup> reported that most severe stage was reached at a range 31-41 weeks and 37-42 weeks PCA respectively

### Stage Wise Distribution of ROP

In our study we noticed as the Stage of ROP increased the average BW decreased. This was similarly noticed by Rohit Charan, M R Dogra et al.<sup>[10]</sup>

### 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<sup>[11]</sup> 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, Jasmina Alajbegovic-Halimic et al<sup>[12]</sup> stated in their study that the babies with ROP was most commonly found to have ROP in Zone III (62.5%).

### Neonatal Risk Factors

We investigated role of various risk factors listed. Applying Chi Square test of significance on Univariate analysis O<sub>2</sub> exposure, number of days of O<sub>2</sub>, 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 O<sub>2</sub> and Sepsis were statistically significant. A detailed study of O<sub>2</sub> exposure in our study revealed that the average number of days on O<sub>2</sub> in ROP babies was 33.09 days and that in NON ROP babies was 8.152 days

This was similar to studies conducted by Andrea Moraes et al<sup>[13]</sup> and Krishna A Rao et al<sup>[14]</sup>

Using the current AAP screening guidelines ( $\leq$  1500g BW or  $\leq$  32 weeks GA) 8 babies (16 eyes) i.e 22.85% would have been missed. 11 eyes of 6

babies (68.75%) would have been missed if UKRCPH were used. Studies from India have shown that children with BW of 2000 g can develop ROP.<sup>[15,16,17]</sup> About 6.7% and 13.3% of severe ROP would have been missed using the UKRCPH or AAP screening criteria, respectively<sup>[16]</sup> Another study from South India noted that 17.7% and 22.6% of children with threshold ROP or worse would have been missed if they were to use the AAP or RCO screening criteria, respectively.<sup>[17]</sup>

### Conclusion

As seen in this study and many studies conducted in India ROP 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 ROP.

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.

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**Declaration of patients consent:** The authors certify that they have obtained all appropriate patient's parent(s)/guardian consent forms. In the form the patient's parent(s)/ guardian has/ have given his/her/their consent for his /her/their data and other clinical information to be reported to the journal. The patient's parent(s)/ guardian understands that their names and initial will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

**Declaration of Ethics Committee:** The authors certify that they have obtained ethical clearance

from the Institutional Ethical Committee (IEC-42/2016-2107).

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**Author's Contribution:**

Dr.Miloni Shah: Conception, Design of the work, Analysis, Interpretation of data

Dr. Kalpana Gadsingh: Conception, Acquisition of data

Dr. Mrunall Borrse: Analysis, Interpretation of data

Dr. Pranjali Pawar: Analysis, Design of work

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#### Abbreviations

ROP- Retinopathy Of Prematurity

BW- Birth Weight

GA- Gestational Age

NICU- Neonatal Intensive Care Unit

NNF- National Neonatology Forum

APROP- Aggressive Posterior Retinopathy of Prematurity

UKRCPH- UK Royal College of Paediatrician and Child Health

OPD- Out Patient Department