Research Article

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Screening based on incidence of severe retinopathy of prematurity in a tertiary care center in India: are Indian infants different?

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ABSTRACT

Background: Incidence of retinopathy of prematurity (ROP) and screening criteria among the preterm infants varies widely. The incidence of ROP and severe ROP in different Birth Weight (BW) and Gestational Age (GA) groups were studied. The aim of the study was to review the existing screening criteria for ROP based on the highest birth weight and or gestational age of infants who developed severe ROP.

Methods: This is a retrospective descriptive study of neonates with GA of \leq 34 weeks and/or BW of \leq 1750 gm screened for ROP by experienced ophthalmologist from January, 2011 to December, 2015. End point was either complete vascularisation or need for laser therapy as per ETROP guidelines. Severe ROP was defined as ROP needing treatment. Highest BW and or GA of infants who developed severe ROP were taken as cut off points for revising the existing screening criteria for ROP.

Results: Among 1366 infants included in this study, 252 (18.4%) and 86 (6.2%) developed ROP and severe ROP, respectively. Mean GA was 29.2 ± 1.4 weeks and 28.7 ± 2.3 among infants with ROP and severe ROP, respectively. Stratified analysis showed a significant increase in the incidence of ROP with decreasing BW and GA (p <0.001). A threshold of BW \leq 1750 gm and or GA \leq 34 weeks would not miss any infant with severe ROP. Applying screening criteria of developed nations would miss 9.3 to 11.6% of infants with severe ROP.

Conclusions: We suggest screening for ROP in all premature infants born with GA of \leq 32 weeks and or BW of \leq 1750 gm, as this screening criteria has detected all infants with severe ROP.

Keywords: Retinopathy of prematurity, Screening criteria, Incidence, India, Severe retinopathy of prematurity

INTRODUCTION

Retinopathy of prematurity (ROP) is one of the leading causes of preventable blindness in children. There has been a growing concern about blindness due to ROP in middle and low income countries and this surge has been described as the third epidemic of ROP. With the advancement of neonatal care, the survival of premature infants has improved in India but parallel development of

human resources in terms of trained ophthalmologist and infrastructure in terms of availability of advanced equipment for treatment, remains a challenge. The targets of vision 2020 include screening for ROP in India and Latin America. Incidence of ROP varies widely depending on the population screened for ROP and ranges from 29% to 68% in developed country and 38-51% in India. 4-8

Based on population studies, developed nations have established guidelines for screening ROP. 9,10 These criteria have been constantly revisited and revised as the need for screening population varies from time to time. 11,12 Screening criteria needs to be safe as well as efficient so that none of the infants needing ROP treatment are missed and too many infants are not Availability screened unnecessarily. of trained ophthalmologist and the nature of procedure being painful and distressing to infants warrant efficient screening criteria. As severe ROP has been reported in bigger and more mature infants in developing countries the same screening criteria cannot be applied to India. 13-15 National neonatology forum (NNF), India recommends performance of screening in all preterm infants born <34 weeks gestation and or <1750 grams birth weight and screening infants between 34 and 36+6 weeks gestation or 1750 and 2000 birth weight with risk factors for ROP. 16 Screening criteria was largely based on studies from ophthalmological referral institutes which may not represent general population.

The incidence of ROP and ROP needing treatment (severe ROP) in different birth weight and gestational age groups were studied. Based on the results, the study aimed to review the existing screening criteria for ROP based on the highest birth weight and or gestational age of infants who developed ROP needing treatment (severe ROP).

METHODS

This is a retrospective descriptive study of infants with gestational age \leq 34 weeks and/ or birth weight ≤1750 gm admitted in NICU of a tertiary care hospital from January, 2011 to December, 2015. The neonatal unit is a 60 bedded level III-B accredited unit with average annual admission of 1000 premature infants. Institutional ethics committee approval (IEC- NI/14/DEC/44/84) was obtained for conducting the study. Neonates with birth weight ≤ 34 weeks and/or ≤ 1750 gm admitted within 24 hours of birth and survived till the initial ROP screening were included. The infants who did not undergo the ophthalmological examination till complete vascularisation of retina or infants with major congenital ophthalmologic malformations, chorioretinitis or cataract were excluded from the study. Data were retrieved from medical records department using inpatient database classified according to international code of diseases-10 (ICD -10) using the ICD code "P-07.3" (code for preterm). It was cross checked with neonatal admission register maintained in the neonatal unit. Data pertaining to ROP including the LASER therapy was obtained from prospectively entered ROP registry maintained in the Ophthalmology department of our institute. The end point was either complete vascularization or need for laser therapy. The parameters including gestational age, birth weight and sex were collected. Gestational age was assigned by treating neonatologist according to the dating scan done between 6 and 8 weeks from last menstrual

period (LMP) or if not available, from LMP. Infants were stratified into birth weight groups (<750 gm, 750-999 gm, 1000-1249 gm, 1250-1499 gm, 1500-1750 gm, >1750) and gestational age (GA) groups (≤ 28 weeks, 29-30 weeks, 31-32 weeks, 33-34 weeks, >34 weeks) which were based on the results of previous studies. This was done to enable ease of comparison with other national and international data.

In the neonatal unit, saturation limits of all preterm neonates requiring oxygen therapy or those on respiratory therapy were maintained strictly according to the protocol. During the study period of January 2011 to May 2013 and June 2013 to December 2015, oxygen targets were maintained between 88% and 92% and 91% and 95%, respectively. The change in oxygen targets were based on the results of BOOST trial. All the staff nurses were trained to adjust FiO₂ to maintain the target oxygen saturation. In addition, there were ongoing training sessions to reinforce the importance of maintaining target oxygen saturation.

In the present study, all the eligible infants were screened on day 21 of life, irrespective of the gestational age. Screening was performed by two senior ophthalmologists with more than 10 years of experience in ROP. Informed verbal consent was obtained from parents for ROP screening. The pupils were dilated using phenylephrine (0.5%) and tropicamide (1%) eye drops, 30 minutes prior to the procedure. During the procedure, procedural pain protocol was followed and vitals were monitored. The eve examination was undertaken with strict aseptic precautions using a binocular indirect ophthalmoscope with the use of eyelid specula and scleral depressors as necessary, under topical anesthesia (2% proparacaine drops). The International Classification of ROP (ICROP) was used to document the ROP status of the baby, including stage, zone and extent of disease and presence or absence of plus disease. 18 Subsequent follow-up eye examinations were done based on the zone and severity of ROP as per AAP recommendation.9 Infants who developed threshold disease as per ICROP classification, APROP in zone 1 and those who had pre-threshold disease as per ET-ROP guidelines were treated with LASER photocoagulation using 532 nm double frequency yag laser (green) with laser indirect ophthalmoscope. 4,18 The avascular retina beyond the ridge was ablated using confluent medium intensity burns in one or more sessions. Laser therapy was done as early as possible within 3 days of identification of the eligible infants for therapy.

Data including stage and zone of ROP and details regarding therapy including laser photocoagulation were collected. The highest stage of ROP in either eye for an individual was recorded as the stage of ROP. In this study, severe ROP was defined as any stage of ROP needing treatment.

Outcome measures

The outcome measures were the proportion of infants who developed ROP and severe ROP among the eligible infants. The incidence of ROP in various birth weight groups and gestational age were calculated. The largest birth weight and or the highest gestational age of infants who developed severe ROP were ascertained and taken as cut off points for revising the existing screening criteria for ROP. Screening criteria for ROP used in USA and UK were applied on the existing data, to compare the applicability of other national criteria with present study group.

Sample size

A sample size of 1250 was needed to calculate the incidence in our study population assuming a known incidence of 11.8% of any ROP and expected incidence of 15% with power of 80% and alpha error of 1%.²⁴ The expected incidence of any ROP of 15% was from previous one year data (unpublished) of our institute.

Data analysis

The collected data was subjected to statistical analysis using Statistical Package for social sciences (SPSS 17.0; SPSS Inc, Chicago, IL). Scatter plot was used to represent the distribution of ROP and severe ROP and to decide the cut off for ROP screening for GA and birth weight. Chi-square test was performed to compare categorical data. The 'p' value of less than 0.05 was considered as statistically significant.

RESULTS

During the study period, there were a total of 1458 infants who were \leq 34 weeks and/or \leq 1750 gm. Figure 1 depicts the flow chart of the study population. Among 1366 infants included in this study, 53 % were males. The mean gestational age (GA) was 31.2 \pm 2.2 weeks. The mean birth weight (BW) was 1431 \pm 386.5 gm.

ROP was seen in 252 infants which accounts for an overall incidence of 18.4%. Mean BW and GA of infants with ROP is depicted in Table 1. The frequency distribution among infants with stage I, II and III ROP were 34%, 36% and 30%, respectively. One infant progressed to stage IV in spite of treatment. The progression of ROP from stage I directly to stage III occurred in 7% of the infants.

The incidence of ROP and the distribution of stages of ROP according to birth weight groups are depicted in Table 2. Stratified analysis showed a significant increase in the incidence of ROP with decreasing birth weight (Chi-square test p <0.001). The incidence of ROP among 272 extremely low birth weight (ELBW) infants in the study cohort was 52.4% and among 893 very low birth

weight (VLBW) infants was 28.5%. Stage III occurred more frequently in lower birth weight group infants.

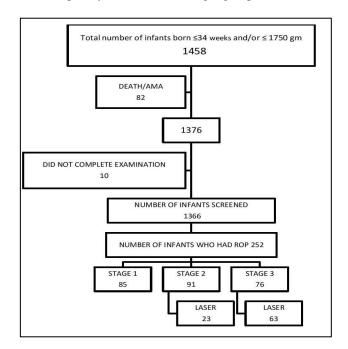


Figure 1: Flow chart of the study.

Table 1: Baseline characteristics of study group.

GA and BW	Total infants screened	Infants with ROP	Infants with severe ROP
Mean GA (in weeks)	31.2±2.2	29.2±1.4	28.7±2.3
GA in weeks(range)	24-36	24-36	24-35
Mean BW (in gram)	1431±386.5	1120±233	1022±287
BW in grams (range)	430-3315	430-2250	430-1800

GA-gestational age; BW-birth weight

The incidence of ROP and the distribution of the various stages of ROP according to GA groups are shown in Table 3. Stratified analysis showed a significant increase in the occurrence of ROP with lower GA (chi square test p< 0.001). Incidence of ROP in infants with gestational age ≤ 28 weeks was 60.8% and in infants with GA $\leq \!\! 32$ weeks was 23.8%. None of the infants of GA greater than 36 weeks developed ROP.

The overall incidence of severe ROP (needing laser therapy) in present study was 6.2%. In the entire cohort, laser treatment was done in 86 infants, of whom 63 infants had stage 3 ROP and 23 infants had stage 2 ROP. APROP was noted in two infants and 6 had plus disease. The frequency distribution of infants needing laser according to birth weight and GA are shown in Table 2 and Table 3, respectively.

One fourth of infants less than 28 weeks who developed ROP required treatment. More than 40% of infants of birth weight less than 750 gm with ROP needed therapy.

There were no laser related adverse effects in the study group.

Table 2: Distribution of ROP in different birth weight groups.

Birth weight in gram	Total number screened	ROP (n %)	Stage 1 (n %)	Stage 2 (n %)	Stage 3 (n %)	Laser (n %)
<750	27	18 (66.7)	1 (3.7)	8 (29.6)	9 (33.3)	12 (44.4)
750-999	145	79 (54.4)	25 (17.2)	25 (17.2)	29 (20)	30 (20.7)
1000-1249	285	79 (27.7)	27 (9.4)	30 (10.5)	22 (7.7)	23 (8.1)
1250-1499	303	41 (13.5)	17 (5.6)	16 (5.2)	8 (2.6)	13 (4.3)
1500-1750	349	23 (6.6)	9 (2.3)	8 (2.4)	6 (1.7)	6 (1.7)
>1750	257	12 (4.7)	6 (2.3)	4 (1.5)	2 (0.7)	2 (0.7)

The distribution of infants with ROP and severe ROP with GA plotted on x-axis and birth weight plotted on y-axis is depicted in the Figure 2. If screening criteria practiced in USA (GA < 30 weeks and BW <1500 grams) is followed, 10.7% of infants with ROP and 11.6% with severe ROP would have been missed. If screening criteria of UK (GA <32 weeks and BW <1500 grams) is followed, 8.3% of infants with ROP and 9.3% with

severe ROP would have been missed. A threshold of BW \leq 1750gm and or \leq 32 weeks would not miss any infant with severe ROP and would miss only 3 (1.1%) infants with ROP (not needing treatment). All the 3 infants were of GA 33 weeks, 2 with birth weight 1900 grams and one with 2250 grams. There are 133 infants above this cut off who were screened and did not develop severe ROP.

Table 3: Distribution of ROP in different gestational age groups.

GA weeks	Total number screened	ROP+ (n %)	Stage 1 (n %)	Stage 2 (n %)	Stage ≥ 3 (n %)	Laser (n %)
≤28 weeks	171	104 (60.8)	20(11.6)	45(26.3)	39(22.8)	44(25.7)
29-30 weeks	283	75(26.5)	33(11.6)	24(8.4)	18(6.4)	21(7.4)
31-32 weeks	506	50(9.8)	22(4.3)	15(2.9)	13(2.6)	16(3.1)
33-34 weeks	342	18(5.2)	8(2.3)	6(1.7)	4(1.2)	3(0.9)
>34 weeks	64	5(7.6)	2(3.0)	1(1.5)	2(3.1)	2(3.1)

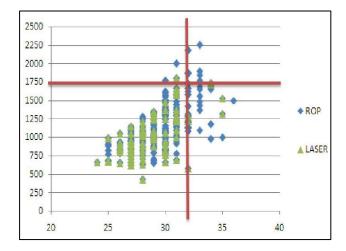


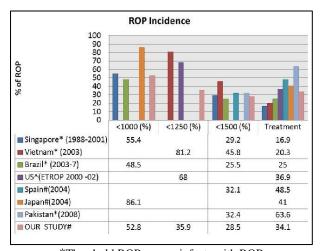
Figure 2: Scatter plot of distribution of infants with ROP and severe ROP with GA plotted on X-axis and birth weight plotted on Y- axis.

DISCUSSION

With increasing survival of extreme preterm infants, ROP has become an emerging global problem and hence screening is important to prevent blindness. Aggressive posterior ROP (APROP) can occur early in very low birth weight (VLBW) infants and has poor visual outcome which is relatively common in Indian infants. 19,20 Therefore in the present study, initial screening of eligible infants admitted in neonatal unit was undertaken at 3 weeks of life irrespective of gestational age. Incidence in ROP in our study was 18.3%. Incidences of ROP in various studies in India have been reported to be 51% from Delhi (79 patients), 47% in a study from Chandigarh (165 patients), 44% from north east (50 patients), 38% from Chennai (50 patients), 22% from Bangalore (7106 images), 22.3% from Pune (552 infants) and 11.8% from AIIMS, Delhi (704 patients). 6-8,21-24 Among the various studies done in India, the present

study involved the highest number of infants screened for ROP. The incidences of ROP in other parts of the world are 12.7% in China (472 patients), 34% in Egypt (152 patients) and 56% in Saudi Arabia (174 patients). ²⁵⁻²⁷ Our study has concurred with other national and international studies in showing an independent association of GA and BW with ROP. ^{5,13,21,23-27}

The incidence of ROP among VLBW infants was 28.5%, and among ELBW infants was 52.4% which are comparable to the incidence reported from various studies done internationally (Figure 3). 4,5,28-32 Maintaining a strict protocol for oxygenation in our unit could be the reason for the comparable incidence of ROP in VLBW and ELBW infants to that of international data. The incidence of severe ROP (treated with laser) in the present study was 6.2% among the infants screened. Among those who developed ROP, severe ROP occurred in 34.1% and in literature the incidence varied from 16.9 to 63.6% (Figure 3). 4,5,28-32 However, compared to developed nations, we had bigger infants with the highest BW being 2250 in ROP group and 1800 in severe ROP group and more mature infants with highest GA of 36 weeks in ROP group and 35 weeks in severe ROP group.



*Threshold ROP among infants with ROP
^Prethreshold needing treatment among infants with ROP
#Threshold/prethreshold needing treatment among infants with
ROP

Figure 3: Comparison of the incidence of ROP and severe ROP in present study with international data in various birth weight groups.

There are wide variation in proportion and incidence of severe ROP. More mature infants develop ROP in low and middle income countries. ^{1,14} This could be due to difference in the management protocol in neonatal units or ethnicity or genetic polymorphism. ³³ With ultimate aim to prevent childhood blindness due to ROP, the focus should be not to miss any infant with severe ROP. With the existing resources and the expertise, it is also equally important not to over burden the system. As the study group varies with time, revising the screening protocol

from time to time is a good practice. The other methods like the WINROP algorithm has not yet been proven to sensitively pick up infants needing treatment.³⁴ BW and GA remain the standard risk factors.^{5,13,21,23-27}

Screening criteria with BW \leq 1750 gms and or GA \leq 32 weeks would detect all the infants needing treatment (severe ROP) and would miss only 3 (1.1%) infants with ROP who did not need treatment. This cut off would avoid unnecessary examination of 133 infants. In the presence of additional risk factors and at the discretion of treating neonatologists, infants with GA \geq 32 weeks and BW \geq 1750 grams should continue to be screened. Screening criteria of USA and UK cannot be applied to Indian population as it would have missed a significant proportion of infants with severe ROP.

The study involved large sample, with distribution across varied GA and BW which is more representative of the general population. This is a single institutional study with standardized protocol being practiced in the neonatal unit. Birth weight and GA was ascertained accurately. The limitations are the retrospective study design and that risk factors were not analysed. Further research is needed to find out if combining the risk factors with GA and BW for more mature infants would bring down the cut off for screening. Those infants with BW above 1750 and GA >34 weeks with a turbulent course though screened were not included in the study. There is a need for further larger population based study or multi-institutional study to refine the screening criteria for Indian infants.

CONCLUSION

In the present study, incidence of ROP and severe ROP were 18.4% and 6.2%, respectively among premature infants with GA <34 weeks and or BW \leq 1750 gm. Applying screening criteria of developed nations for the present study cohort, would miss 9.3 to 11.6% of infants with severe ROP. We suggest infants born premature with GA of \leq 32 and or BW of \leq 1750 gm weeks should undergo screening for ROP, as this screening criteria has detected all infants with severe ROP.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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