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Original Article

A Prospective Observational Study on Retinopathy of Prematurity in Low Birth Weight Babies at a Tertiary Care Centre of West Bengal

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Abstract

Aims: The aim of the study was to know the prevalence, severity, and progression of retinopathy of prematurity (ROP) among the screened low birth weight (LBW) and preterm babies and to determine how many of these babies require treatment.

Methods: Prospective, observational study was done between August 2018 and March 2019. Screening for the presence of ROP and its severity in 588 eyes of 294 infants below 2000 g birth weight and/or period of gestation <34 weeks in Special Newborn Care Units. The retinal findings were documented and staging of ROP was determined, based on the International Classification of ROP guidelines. Further follow-up and treatment were done accordingly.

Results: In our study, 14.28% of the total numbers of babies screened were found to have different stages of ROP and 6.5% of the total number needed treatment. Among babies with birth weight above 1250 g, screening of 418 eyes of 209 babies was done, of which 28 eyes of 14 babies were diagnosed as ROP (6.7%). Of which 12 babies received oxygen and 4 babies (8 eyes) required treatment. Among babies with ≤1250 g body weight, screening of 170 eyes of 85 babies was done, of which 56 eyes of 29 babies developed ROP (33%), of which 25 babies received oxygen and 15 babies (30 eyes) required treatment such as laser photocoagulation and intravitreal ranibizumab.

Conclusion: ROP is emerging as one of the leading causes of irreversible childhood blindness, if not diagnosed and treated early. As very LBW babies are increasingly surviving because of the ever-improving perinatal care, the prevalence of ROP is also increasing. That's why regular ocular screening and timely intervention of those babies are to be done to prevent permanent blindness. Moreover, the magnitude of the problem in this part of our country will enable us to prepare our infrastructure to tackle it.

Key words: Childhood blindness, low birth weight, retinopathy of prematurity

INTRODUCTION

Retinopathy of prematurity (ROP) is emerging as one of the leading causes of preventable childhood blindness in India. Incidence of ROP varies between 38 and 51.9% in low birth weight (LBW) infants.[1,2] It is an ischemic retinopathy of premature and LBW infants. Normal retinal vascularization proceeds from the optic disc to the periphery and is complete in the nasal quadrants at approximately 36 weeks of gestation and on the temporal side at 40 weeks. Although an important contributing factor, oxygen is no longer considered the sole factor in the pathogenesis of ROP. Other factors, such as genetic predisposition, LBW, and a short gestational period, also increase the risk of developing the disease. Clinically, vascularized retina in the premature infant without ROP normally blends almost imperceptibly into the anterior, grey, non-vascularized retina. With ROP, however, the juncture between the two becomes more distinct due to variable glial hyperplasia, shunts, and neovascularization leading to vitreous hemorrhage, tractional retinal detachment, and loss of vision.

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Prematurity is the single most important risk factor responsible for ROP. ROP begins to develop between 32 and 34 weeks after conception, regardless of gestational

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age at delivery.[3] Incidence of ROP in India varies between 38% and 51.9% in LBW infants, but more recent studies showed lower incidence ranging from 20% to 30%.[4]

Aims and Objectives

General objective

To screen all LBW and preterm infants admitted at Special Newborn Care Units (SNCU) and NICU and who were referred for ROP screening within August 2018–March 2019 (approximately 6 months) at R. G. Kar Medical College of Kolkata.

Specific objective

The specific objective of the study was:

1. To know the prevalence of ROP among the LBW babies in a tertiary care center of Kolkata, who are screened for it (criteria suggested by National Programme for Control of Blindness,[5] National Neonatology Forum and Neonatal Intensive Care Unit (NICU), and AIIMS, New Delhi)[6]
2. To determine the severity and progression of ROP among these babies
3. To know the distribution of the disease varying with the birth weight of these babies
4. To know the prevalence of the disease among those babies who received oxygen supplementation by any means
5. To determine how many of these babies require treatment (laser, intravitreal injection of anti-vascular endothelial growth factor (VEGF), or vitreoretinal surgery).

METHODOLOGY

Study Design/Experimental Design

This was a prospective observational study.

Place of Study

This study was conducted at SNCU and NICU of R. G. Kar Medical College of Kolkata.

Period of Study

The study was from August 2018 to March 2019 (8 months).

Study Population

Infants below 2000 g birth weight and/or period of gestation (POG) <34 weeks and infants with unstable postnatal clinical course, attended for ROP screening in SNCU of a tertiary care center of Kolkata.

Sample Size

A total of 588 eyes of 294 babies, who attended for ROP screening in SNCU, of a tertiary care center of Kolkata, from September 2018 to February 2019.

Inclusion and Exclusion Criteria

Inclusion criteria

The following criteria were included in the study:

1. Birth weight <2000 g
2. Gestational age <34 weeks
3. Gestational age between 34 and 36 weeks but with risk factors such as cardiorespiratory support, prolonged oxygen therapy, respiratory distress syndrome, chronic lung disease, fetal hemorrhage, blood transfusion, neonatal sepsis, exchange transfusion, intraventricular hemorrhage, apnea, and poor postnatal weight gain
4. Infants with an unstable clinical course who are at high risk (as determined by the neonatologist).

Exclusion criteria

Fulfilling inclusion criteria but babies severely sick to examine were excluded from the study.

Study Variables

Babies with ROP, without ROP, stages of ROP, gender, birth weight, POG, postnatal exposure to oxygen supplementation, and requirement of treatment for ROP.

Procedure

Ocular examination and investigation

1. Consent form and case record form
2. Indirect ophthalmoscope with +20 D lens
3. Alfonso eye speculum for newborn and wire vectis
4. 50% dilution of a combination of 5% phenylephrine and 0.8% tropicamide eye drop
5. Proparacaine eye drops 0.5%, normal saline eye drops, and moxifloxacin eye drops
6. Gauge soaked with 25% dextrose as pacifier.

Outcome Definition and Parameters

The retinal findings should be documented and stage of the ROP to be determined based on the International Classification of ROP guidelines.[7]

Follow-up based on retinal findings, according to AIIMS-NICU protocols (2010).

Findings that suggest further examinations are not needed include:

- Zone III retinal vascularization attained without previous Zone I or II ROP
- Full retinal vascularization Postmenstrual age of 45 weeks and no pre-threshold disease (defined as Stage 3 ROP in
- Zone II, any ROP in Zone I) or worse ROP is present
- Regression of ROP.

Treatment

1. All eyes with plus disease
2. Eyes without plus disease having new extraretinal

vessels (Stage 3), especially if the condition has worsened since the previous visit

3. Aggressive posterior ROP (APROP) eyes urgently and aggressively (involves Zone I and posterior Zone II).

No treatment

All eyes with ROP in Zone III; Eyes with Zone II with no new vessels and no plus. They should be followed closely, every 7–10 days, to watch for regression or progression of disease and if any treatment is needed.[8]

Treatment options including intravitreal anti-VEGF, laser photocoagulation.[9]

Data Collection and Interpretation

After taking clearance from the Ethical Committee the study was performed. The consent form was signed by one or both of the parents of the infant. Case record sheet was filled up after examination. A thorough ophthalmological evaluation was done under neonatal monitoring. The data collected were studied, analyzed and compared by suitable statistical method.

Statistical Analysis

The data were tabulated in Microsoft Excel sheet and presented as tables and bar charts and interpreted by SPSS Version 20 and excel (by student *t*-test, Chi-square tests, and Mann-Whitney U test).

RESULTS

Babies fulfilling criteria for screening of ROP were examined, followed up, and treated as per schedule under proper aseptic condition and neonatal care.

Prevalence of ROP among Different POG Group

We divided our study population in three group based on POG, i.e.: <32 weeks, 32–<34 weeks, and 34–<40 weeks, and there were 109 babies in the first group, 120 in second, and 65 in last one. Prevalence of ROP was 27% in <32 weeks of POG, 7.9% in 32–<34 weeks of POG, and 4.6% in 34–<40 weeks of POG. Table 1 shows most of the ROP are found in less than 32 weeks of POG.

Prevalence of ROP among Different Birth Weight Group

According to birth weight, we divide our study population into four group:

There were 30 babies in the first group, 55 in Group 2, 149 in Group 3, and 60 babies in last group. The prevalence of ROP was 53% in first group, 22.2% in second, 6.7% in third, and 6.5% in last group. Table 2 shows most of the ROP occurred in less than 1kg weight babies.

Of total 294 babies, 149 babies were female and 145 were male.

Moreover, findings of 4 babies were APROP.

Of total 294 babies, 160 babies received oxygen by any means (face mask, continuous positive airway pressure, ventilation, etc.) and 134 babies not received oxygen irrespective of birth weight and POG. Table 3 confirms that exposure to oxygen is a risk factor for ROP.

Hence, the risk ratio is 5.1646 for developing ROP in babies with history of postnatal oxygen therapy.

A number of babies defaulted during the study period:

- A total of 48 babies were lost to follow-up of 294 babies within the study period (16.3%), of which, findings of 4 babies with Stage 2 Zone II or III and 6 babies with large temporal avascular retina and rest were no ROP.
- A total of 20 babies died of different postnatal complications.
- In this study, 38 eyes of 19 babies of 588 eyes of 294 babies required treatment for ROP.

Table 1: Distribution of ROP in different POG group

POG (in week)	Eyes examined	Eyes with ROP	Frequency (%)
<32	218	59	27
32–<34	240	19	7.9
34–<40	130	6	4.6
Total	588	84	14.28

ROP: Retinopathy of prematurity, POG: Period of gestation

Table 2: Distribution of ROP in different birth weight group

Birth weight	Eyes examined	Eyes with ROP	Frequency (%)
≤1000	60	32	53
1001– ≤1250	110	24	22.2
1250–≤1500	298	20	6.7
>1500	120	8	6.5
Total	588	84	14.28

ROP: Retinopathy of prematurity

Table 3: Comparison between development of ROP with postnatal oxygen therapy

Exposure to oxygen	ROP	No ROP
Yes	37	123
No	6	128

ROP: Retinopathy of prematurity

Table 4: Number of babies required treatment

Birth weight	No of babies required treatment
≤1250 g	15 (30 eyes)
>1250 g	4 (8 eyes)

Table 4 shows most of the eyes requiring treatment are below 1250 gm in birth weight. Hence, 44.2% babies with ROP needed treatment irrespective of birth weight and POG.

DISCUSSION

Within the 8 months of the study period, over 294 babies were screened for ROP. A total of 48 babies were lost for follow-up and 20 were died after first examination. Hence, all babies were included in the study population and statistical calculation.

Of all LBW babies, 204 babies were very LBW (1001 to ≤1500 g), and 30 were extremely LBW baby (≤1000 g).

According to POG, 13 babies were extremely preterm (<28 weeks), 96 babies were very preterm (<32 weeks), 120 babies were late preterm (<34 weeks), and remaining 65 babies were term.

The prevalence of ROP among our study population was 14.28% (84 eyes of 588 eyes). Whereas a study was done on "incidence and severity of ROP in China"[10] by Xu *et al.* in 2010–2012, they found incidence of ROP in China was 17.8%.[11] It is also noted that the prevalence of ROP in Saudi Arabia was 33.7% in 2016 (mean POG - 26.7 and mean birth weight 843 g).[12] In Egypt, 36.5% in 2016 (mean POG - 31.3 week and mean birth weight - 1234.6 g).[13] In Pakistan, 11.5% in 2014 in infants meeting the current screening criteria of Pakistan.[14] In India recent studies reported that the prevalence of ROP ranging from 20% to 30%.[4,10]

Incidence of ROP in this study, among extremely LBW babies were 53.3% (32 eyes of 60 eyes) and very LBW babies 10.8% (44 eyes of 408 eyes). In a study on "prevalence of ROP" done by Ali *et al*, they found much higher prevalence of ROP in extremely LBW babies (86.7%) than very LBW babies (27.8%).[15]

It was also noted that the prevalence of ROP in Hong Kong – 16.9% (mean birth weight – 1285 g) and 70.6% (in babies whose birth weight were <1000 g).[16]

Incidence of ROP in our study was 32.9%, among those birth weight ≤1250 g (56 eyes of 170 eyes) and 6.7% among those birth weight >1250 g (28 eyes of 418 eyes).

In the Indian scenario, more than 50% of preterm infants weighing <1250 g at birth show evidence of ROP.[17]

Oxygen therapy, by any means, is a risk factor for the development of ROP, (ROP is 5.16 times more associated with oxygen therapy).

Chaudhari *et al.* done a study on ROP in 2009 where the incidence of ROP was 22.3% among babies gestational age ≤32 weeks or birth weight <1500 g or babies with significant perinatal illness and they also found that postnatal oxygen therapy is a significant risk factor for development of ROP.[4]

In our study, 44.2% babies with ROP needed treatment whereas, 39.3% babies with ROP needed treatment in a study done by P. Sharma in 2009 among infants with birth weight ≤1500 g or gestational age ≤32week.

As a significant portion of study population defaulted (16.3%), we have to improve our peripheral infrastructure and awareness of the people by IEC (Information, Education, Communication) activities so that we can screen all the babies where it is needed.

CONCLUSION

In our study, though in a small study population, 14.28% of the total numbers of babies screened were found to have different stages of ROP and 6.5% of the total number needed treatment. Timely screening of those babies averted permanent blindness in them. That's why regular ocular screening and timely intervention is required, especially for severely LBW babies to prevent permanent blindness. The infrastructure in the peripheral regions of our country is needed to be improved to tackle this significant and emerging cause of childhood blindness. Moreover, we should be concerned among the significant number of the defaulter group (16.3%) and should try to increase the awareness of the disease and importance of regular screening among the mothers and other family members.

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