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TO STUDY THE PREVALENCE OF RETINOPATHY OF PREMATURITY IN PRETERM INFANTS: AN HOSPITAL BASED OBSERVATIONAL STUDY.

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Abstract

Background: Premature infants have avascular or incompletely vascularized retina at birth and ROP evolves over 4-5 weeks after birth. The aim of this study is to know the prevalence of retinopathy of prematurity in preterm infants, with birth weight ≤ 1500 grams and/or gestational age ≤32 weeks in a tertiary care center.

Material and methods: The study was conducted in a tertiary care center of Bihar region India The sample size is 145 babies. All preterm infants admitted with a birth weight of ≤1500 grams and/or ≤ 32 weeks of gestation and baby those at risk of ROP.

Results: 145 babies have enrolled during the study period of which 124 babies fulfilled the inclusion criteria and completed this prospective study.15 babies could not complete the follow-up protocol and 6 babies died before full vascularization of the retina. 124 babies who fulfilled the inclusion criteria were screened and 33 babies were found to have ROP. The prevalence of ROP in this study is 26.6%.

Conclusions: Among the preventable causes of blindness in children, ROP figures very high on the agenda. Low birth weight and gestational age were found to be the most important risk factors for the development of ROP.

Keywords: Low birth weight, Prematurity in preterm infant, Retinopathy, Oxygen therapy

Introduction

Retinopathy of Prematurity (ROP) is one of the most common eye disorders in premature infants, characterized by abnormal proliferation of retinal blood vessels.[1]. The survival rates of extremely premature infants have been increased with the improvement in the neonatal intensive care technologies and increased availability of healthcare services in recent years [2]. Infants with gestational age (GA) less than 28 weeks have particularly more risk for the development of ROP in developed countries [3, 4].

The first case of the epidemic was seen on St. Valentine's Day in 1941, when a premature baby in Boston was diagnosed. The first epidemic of ROP occurred during 1940s and 1950s, mainly in developed countries due to unmonitored use of oxygen in premature babies. With advances in neonatal intensive care more and lower Birth Weight (BW) and low Gestational Age (GA) infants surviving, 'Second Epidemic' of ROP began in 1970s and 1980s. From a global perspective, 'third epidemic' of ROP started mostly in the middle income countries [5].There are approximately 45 million blind people in the world today out of which, 30% are in Asia. Of the total blindness, childhood blindness accounts for 4%. India shares 20% of the world's childhood blind .ROP afflicts over 3,00,000 infants world.[6] In developing countries like India, the incidence of ROP has been reported at 24-47 % among high risk preterm infants. It is important not only in terms of economic burden, but in its severe social implication, which is very long in terms of blind years. These infants are more tending to develop severe ROP and require treatment [7]

In the present study was aimed to determine the incidence of ROP in Bihar region in India.

Material and methods:

The study was conducted Department of Pediatrics, Darbhanga Medical College and Hospital, Bihar. For one year. The sample size is 145 babies. All preterm infants admitted with a birth weight of ≤1500 grams and/or ≤ 32 weeks of gestation and baby those at risk of ROP.

Inclusion criteria

- Premature infants admitted with ≤32 week's gestation and/or birth weight ≤1500 g.
- Babies between 1501-2000 g and 33-35weeks that are at a higher risk of developing ROP like, respiratory distress syndrome, sepsis, multiple blood transfusions, multiple births, apneic episodes, intraventricular hemorrhage.

Exclusion criteria

- Babies from whom consent for the study could not be obtained.
- Babies who died before full vascularization of the retina.

A first screening examination was carried out at 32 weeks of gestation or 4 weeks of age, whichever was later. For this purpose, gestational age was calculated from the last menstrual period or with the help of the first-trimester sonography in cases where the last menstrual period date

was uncertain. Sometimes the babies were examined earlier in the case of extremely premature neonates.

Procedure

All preterm babies who satisfied any one of the inclusion criteria were taken up for the study. Demographic history and risk factors like respiratory distress syndrome, sepsis, multiple blood transfusions, multiple births, apneic episodes, and oxygen are given were documented using a study Proforma. Preparation of the child The pupils were dilated with a mixture of Phenylephrine 2.5% and Tropicamide 0.5% instilled 3 times at 10 minutes interval about 1 hour before the scheduled examination. Resistance to dilation was noted. Care was taken to wipe off any eye drops with sterile cotton that comes out of eyes to cheeks and not to feed the baby immediately before examination as the child might vomit or aspirate.

Method of examination

The examination was done under aseptic precautions in a temperature-controlled room by an ophthalmologist in the presence of a neonatologist. The indirect ophthalmoscopy examination was done. One drop of topical paracrine eye drops was used to anesthetize the cornea. A pediatric wire speculum was used to keep the eyelids apart. After decreasing the room illumination, the anterior segment was first visualized to look for tunica vasculosa lentils, pupillary dilatation and lens, and media clarity. Then the posterior pole was examined for any Plus disease. A scleral indenter was used to visualize the periphery. The periphery was examined in all clock hours to look for the extent of changes from nasal to the temporal retina. Care was taken not to put too much pressure on the globe. During the examination, untoward neonatal complications were looked for and managed appropriately. Follow up protocol if no ROP was detected at initial examination, the infants were re-evaluated once every two weeks until vascularization was complete. If ROP was detected, the examinations were performed weekly for stage 1-2 disease and more frequently for stage 3 diseases, till the disease started resolving or progressed to threshold stage. Babies showing evidence of regression were followed up till vascularization was complete. Babies progressing to threshold stage were advised treatment. The follow-up examinations were done at the Neonatal Intensive Care Unit itself if the baby had to stay there for some other reasons. The discharged babies were called up for follow up as advised by the ophthalmologist.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 20 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages, means and standard deviations were calculated

Results

Table 1: Prevalence of retinopathy of prematurity (any stage)

ROP	No.	%
Present	33	26.6
Absent	91	73.4
Total	124	100

124 babies who fulfilled the inclusion criteria were screened and 33 babies were found to have ROP. The prevalence of ROP in this study is 26.6%. Out of 33 babies with ROP, 14babies (42.4%) were in stage 1, 14 babies (42.4%) were in stage 2 and 5 babies (15.2%) were in stage 3 (Table1).

Table 2: Type of gestation and ROP

Type of Gestation	ROP		
	Present	Absent	Total
Single	18	55	73
Twin	11	40	51
Total	29	95	124

Out of 124 babies, 73 babies were singletons, 51 babies were twins. Out of 73 singletons, 18 babies developed ROP. Only 11 of the 51 twins developed ROP. (Table 2).

Table 3: Birth weight and ROP

Birth Weight	ROP		Total
	Present	Absent	
≤1000 g	17 (47.2%)	19 (52.8%)	36
1001-1500 g	7 (8.6%)	66 (90.4%)	73
>1500 g	0	15 (100%)	15
Total	24	100	124

The birth weight of the ROP babies ranged from 550- 1400 g (mean 882.31±219.55g), while that of non-ROP babies ranged from 800-2000 g (mean 1250.15±233.32g).

Lower birth weight was significantly associated with increased incidence of ROP. The incidence of ROP was 47.2% in extremely low birth weight babies weighing ≤1000g at birth, while in the very low birth weight group weighing 1001-1500g at birth was 8.6%. The only baby with Severe ROP had a birth weight of 640g (Table 3).

Table 4: Gestational age and ROP

Gestational Age	ROP		Total
	Present	Absent	
<28	14 (87.5%)	2 (13.7%)	16
28-32	8(8.1%)	90 (91.9%)	98
>32	0 (0%)	10 (100%)	10
Total	1522	63102	124

The gestational age of the ROP babies ranged from (26-32 weeks), while that of non-ROP babies ranged from 27-34 weeks significant risk factor for the development of ROP ($p < 0.001$). The only baby who had severe ROP was delivered at 27 weeks of gestation (Table4).

Table 5: Oxygen and ROP

Oxygen	ROP		Total
	Present	Absent	
Given	27 (30.7%)	61(69.3%)	88
Not Given	0	36 (100.0%)	36
Total	27	97	124

Out of 124 babies screened 88 were given oxygen and 27 (30.7%) babies developed ROP. None of the babies for whom oxygen was not given developed ROP. Oxygen administration was a significant risk factor or the development of ROP ($p < 0.001$) (Table 5)

Discussion

Retinopathy of prematurity (ROP) is a vaso-proliferative disorder affecting premature infants. It is one of the most common causes of visual loss in children and can lead to lifelong vision impairment and blindness.[8] Low birth weight and gestational age were found to be the most important risk factors for the development of ROP. With neonatal units equipped with the state-of-the-art technological background and highly qualified personnel providing optimum care of extremely premature newborns, ROP incidence is on a rise due to improved survival rates of premature neonates in many neonatal units.[9] Authors screened babies admitted to present neonatal intensive care unit with birth weight ≤1500g and gestation ≤32 weeks. Infants with birth weight >1500g and gestation more than 32 weeks were screened only if they had additional risk factors.[10] All India Institute of Medical Sciences, New Delhi in their recent protocol have suggested similar screening criteria. In India, large, relatively mature babies with BWs more than 1500g and Gestation more than 34 weeks or so have been reported to have high incidences of severe ROP since the early 1990s.[11] In a retrospective study of 138 patients with BWS more than 1250g referred for ROP examination, Darlow BA reported that 45% had a threshold or worse ROP, demonstrating that severe ROP occurs in bigger babies in India.

Present study included 124 neonates who were screened for ROP and 33 babies among them were found to have ROP.[12] The prevalence of ROP in the study is 26.6%. It is of current knowledge that, aggressive posterior ROP seems to occur especially among smaller and more immature neonates. However, in present study, authors did not have babies who developed APROP. None of the babies in present study had blindness due to ROP. The incidence of ROP from studies done in the Indian subcontinent was found to be 17.5%-46% whereas the incidence of ROP in different studies done outside India was found to be 9.4%-38%.[13] Among the Indian studies, Fortes Filho et.al reported overall incidence as 17.5 % and no severe ROP. It was comparable to present study. They had studied 40 babies with 1500 g had ROP.[16] Low birth weight was identified as a risk factor for ROP in several International and Indian studies. In India, large, relatively mature babies with BWs more than 1500 g and GAs more than 34 weeks or so have been reported to have high incidences of severe ROP since the early 1990s.[18] In 2012 an overall incidence of 47% ROP in their babies with BWs of 1700 g or less, with an incidence of 12.8% requiring treatment; this figure has changed little over the 15 years or so[19]. In a retrospective study of 138 patients with BWs, more than 1250g referred for ROP examination. Lower Gestational age was found to be a significant risk factor for the development of ROP ($p <$ 28 weeks of gestational age. Among babies born between 28-32 weeks of gestation, the prevalence of ROP was 8.3%. None of the babies delivered >32 weeks of gestation had ROP.[20]

Out of 124 babies screened 88 were given Oxygen and 27(30.7%) babies developed ROP. The causal link between ROP and supplemental oxygen has been confirmed by controlled trials and clinical studies.[21] Low birth weight survivors and found a significant association between, the more severe grade of disease and duration of oxygen therapy. Oxygen as a risk factor for ROP in different studies in India has been established.[22] In a recent study it has been found that exposure to unblended oxygen causes massive retinovascular vessel loss and that causes aggressive posterior ROP in large preterm babies. The regular screening, each neonatal unit should have a policy on oxygen administration. Pulse oximeters and blended oxygen should be used in delivery rooms and neonatal units to guide oxygen therapy. All babies who receive oxygen should be monitored closely to target oxygen saturation of 90-95% with appropriate use of oxygen blenders.

Conclusion

ROP screening programme should include neonates with birth weight 32weeks with other risk factors of ROP. Along with the regular screening, each neonatal unit should have a policy on oxygen administration. Pulse oximeters and blended oxygen should be used in delivery rooms and neonatal units to guide oxygen therapy. All babies who receive oxygen should be monitored closely to target oxygen saturation of 90-95% with appropriate use of oxygen blenders.

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