Print ISSN: 2321-6379
Online ISSN: 2321-595X
DOI: 10.17354/ijss/2018/92

Original Article

Study on Retinopathy of Prematurity and Its Risk Factors in Preterm Babies and Birth Weight <2 kg Admitted in a Rural Medical College

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Abstract

Background: Retinopathy of prematurity (ROP) is a potentially blinding condition commonly seen among premature infants. The most important aspect about ROP is that it is preventable and treatable by adequate and early screening. Hence, the present study has been designed to evaluate the incidence and risk factors of ROP in premature babies.

Objective: The objective of this study was to study ROP and its risk factors in preterm babies (<34 weeks and <2 kg).

Methods: This is a descriptive study conducted among all preterm babies <34 weeks and all preterm babies <2 kg admitted during the period of August 2016–July 2017. ROP screening was done in these babies on day 28 and complete history was recorded. Every week follow-up was done for babies with ROP and the risk factors were assessed.

Results: Among a total of 301 babies screened, 29 babies were diagnosed to have ROP. Our study showed normal vaginal delivery, birth weight, respiratory distress syndrome (RDS), surfactant, apnea, sepsis, and blood transfusion as the statistically significant risk factors ($P < 0.05$). The mode of oxygen delivery also played an important role. Statistically significant relationship was present between RDS and ROP.

Conclusion: With greater recognition of the risk factors of ROP and the understanding that timely treatment can save our vision, our community may be able to reduce the high burden of ROP, leading to morbidity.

Key words: Preterm babies, Respiratory distress syndrome, Retinopathy of prematurity

INTRODUCTION

Retinopathy of prematurity (ROP) is a potentially blinding condition. This mainly involves the developing retinal vasculature. This condition is commonly seen in premature and low birth weight infants. Terry explained this condition first in 1942 as retrolental fibroplasia.[1]

Improvements in neonatal care and increasing survival of very low birth weight infants in developing countries like India found to show rapid increase in the incidence of this condition. In India, according to the recent statistics, the incidence of ROP was found to be 47.2% by Dogra *et al.*[2] The incidence in various Western countries has been reported to range from 21% to 65.8%.[3-5] Variations in the incidence rates reported reflect differences in referral patterns, survival rates, the criteria used for examination, as well as levels of maternal and neonatal care.

Preliminary studies examining ROP from India reveal that ROP occupies an important area of public health. In spite of the variability in screening criteria in different regions of India, more recent studies have reported lower rates of ROP ranging from 20% to 30%.[6-8]

Several studies have shown that the incidence and severity of ROP rises with decreasing birth weight and gestational age (GA) and are attributed to the improved survival of low

Access this article online

www.ijss-sn.com

Month of Submission : 01-2018
Month of Peer Review : 02-2018
Month of Acceptance : 02-2018
Month of Publishing : 03-2018

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birth weight babies. The ROP incidence as demonstrated by Gopal *et al.*[6] was 45.5% in babies with birth weight <1500 g and 23.5% in babies with birth weight more than 1500 g and 42.9% in babies <32 weeks and 34.5% in more than 32 weeks GA.

Given that the possible disease burden for a child blind from ROP is high, dramatic vision loss may be prevented by the institution of appropriate treatment. Laser photocoagulation or cryotherapy of the avascular retina offers some promise in halting the progression of ROP to sight-threatening complications. Major improvements in the screening methods of susceptible infants play an important role in saving more vision in premature infants in India.

The mainstay of any ROP management program is an effective screening strategy. However, the screening guidelines used in the Western countries may not be applicable to Indian population. Hence, in addition to a different patient population, there is wide difference in the Indian neonatal intensive care units as they vary in the quality of care provided to patients. The factors include the use of oxygen therapy, comorbid conditions, and use of other medications.

In India, standardized screening system for neonates relies on three questions that must be answered. What babies need to be screened? When is the best time and duration for screening? What is the most practical and effective method for screening? The most important aspect about ROP is that it is preventable and treatable by adequate and early screening.

An increase in the number of survival rates among premature babies is seen due to advances in the neonatal care. Hence, the present study has been designed to examine the incidence and risk factors in premature birth babies in a two-tier city, in southern part of Tamil Nadu which caters to the people in the district of Theni equipped with a good pediatric care and referral system.

MATERIALS AND METHODS

Study Design
Descriptive study.

Study Area
SNCU Department of Pediatrics, Government Theni Medical College, Theni, Tamil Nadu, India.

Study Period
August 2016–July 2017.

Study Population
Babies admitted in SNCU Government Theni Medical College, Theni, Tamil Nadu, India.

Inclusion Criteria
1. All preterm babies (<34 weeks)
2. All preterm babies (weight <2 kg).

Methodology
ROP screening was done for all preterm babies with birth weight <2 kg and GA 34 weeks. Initial examination was carried out after the 28th day.

A complete history including birth weight, GA, weight for GA, and problems during NICU stay and their management were studied. Eye examination was done with an indirect ophthalmoscope by Ophthalmologist. An infant speculum and a Kreissig sclera depressor were used under topical anesthesia with 2% proparacaine drops, 0.5% cyclopentolate +2.5% phenylephrine eye drops 2 or 3 times, were used to dilate the pupils.

As per the international classification (ICROP), ROP was graded into zones and stages. Infants with normal vascularization were not examined again. Every week follow-up and screening was done for babies with ROP and the risk factors were assessed.

OBSERVATIONS AND RESULTS

This study was conducted between August 1, 2016 and July 31, 2017. It was a descriptive study. The follow-up data are based on assessment of babies done at the ophthalmology department of our medical college hospital.

The information collected was recorded in a master sheet. Frequencies, percentages, means, standard deviation, Chi-square, *P* value, and coefficient of correlation values were calculated for the available data. Chi-square test was used to test the significance of difference between quantitative variables. "*P*" value of <0.05 is considered to show statistically significant relationship.

A total of 301 babies were included in the study based on the inclusion and exclusion criteria.

The profile of the study participants was shown in Table 1. ROP screening was done for high-risk babies and 29 babies were diagnosed to have the disease. Development of the disease based on the individual risk factors has been discussed. Development of ROP is almost equal among male and female babies. From the above study, normal vaginal delivery, birth weight, respiratory distress syndrome (RDS), surfactant, apnea, sepsis, and blood transfusion are the statistically significant risk factors ($P < 0.05$).

The significant risk factors for the development of ROP were identified, of which mode of oxygen delivery for the

infants also played a statistically significant role ($P < 0.05$) as shown in Table 2.

Babies diagnosed of ROP were categorized mainly into 3 zones and 5 stages. More number of babies were in zone 3 (23) and zone 2 (6) with no babies in zone 1. Regarding the stages of ROP, many babies were in stage 1 (15) and stage 2 (10). Only four babies were in stage 3 and no babies were in stage 4 and stage 5 [Table 3].

Of the total 301 babies screened, around 6% (18 babies) did not complete full follow-up and were dropped out. 254 babies did not develop ROP [Table 4].

There is statistically significant relationship between babies with RDS and development of ROP as shown in Table 5.

There is a significant correlation between birth weight and ROP as shown in Table 6. Babies with birth weight <1.5 kg had more chance of developing ROP. Birth weight is an individual risk factor for ROP.

Table 1: Profile of study participants

Characteristic	*n* (%)		Chi-square	*P* value
	No ROP (*n*=272)	ROP (*n*=29)		
Sex				
Male	140 (51.5)	15 (51.7)	0.001	0.979
Female	132 (48.5)	14 (48.3)		
Mode of delivery				
Natural	158 (58.1)	11 (37.9)	4.324	0.038
LSCS	114 (41.9)	18 (62.1)		
Birth weight				
<1.25 kg	9 (3.3)	11 (37.9)	69.062	<0.0001
1.26–1.5 kg	57 (21)	13 (44.8)		
1.6–1.75 kg	68 (25)	5 (17.2)		
>1.75 kg	138 (50.7)	0		
RDS	79 (29)	25 (86.2)	37.867	<0.0001
Surfactant	30 (11)	21 (72.4)	70.168	<0.0001
Apnea	0	3 (10.3)	28.421	<0.0001
HIE	25 (9.2)	7 (24.1)	6.114	0.513
Multiple births	38 (14)	3 (10.3)	0.293	0.588
Jaundice requiring phototherapy	38 (14)	4 (13.8)	0.107	0.948
Blood transfusion	7 (2.6)	6 (20.7)	20.813	<0.0001
Sepsis	28 (10.7)	10 (34.5)	13.960	0.001
PDA	23 (8.5)	4 (13.8)	0.901	0.343
MSAF	8 (2.9)	0	0.876	0.349

ROP: Retinopathy of prematurity, RDS: Respiratory distress syndrome, LSCS: Lower segment cesarean section, MSAF: Meconium-stained amniotic fluid, PDA: Patent ductus arteriosus, HIE: Hypoxic-ischemic encephalopathy

Table 2: Risk factors for ROP

Risk factors for ROP	*n* (%), Mean±SD		Chi-square/ T statistic	*P* value
	ROP	No ROP		
Ventilator	0	5 (17.2%)	47.689	<0.0001
Hood oxygen	2.70±1.781	4.97±2.934	−6.050	<0.0001
CPAP	0.298±6339	6.172±3.576	−24.063	<0.0001

ROP: Retinopathy of prematurity, CPAP: Continuous positive airway pressure, SD: Standard deviation

DISCUSSION

Screening for ROP is essential in high-risk babies, which is almost not possible in developing countries like India with poor resources. However, early screening and treatment of ROP among high-risk babies is essential. Approximately 8.7% of 26 million annual live births in India are <2000 g in weight. This suggests that almost 2 million newborns are at risk for developing ROP.

Babies with birth weight <2000 g or with GA <34 weeks were screened. 301 babies were screened in our study. Of which, 29 babies were diagnosed as having ROP. Incidence

Table 3: Zone involved and stage in children with ROP

Characteristic	Number (%)
Zone	
1	0 (0)
2	6 (20.7)
3	23 (79.3)
Stage	
1	15 (51.7)
2	10 (34.5)
3	4 (13.8)

ROP: Retinopathy of prematurity

Table 4: Follow-up observation among all children

Characteristic	Number (%)
Drop out	18 (6.0)
Observation	23 (7.6)
Laser	6 (2.0)
No evidence of ROP	254 (84.4)

Table 5: RDS as a risk factor for ROP

RDS	ROP		Total
	No ROP	ROP	
No RDS	193 (98.0)	4 (2.0)	197 (100.0)
RDS	79 (76.0)	25 (24.0)	104 (100.0)
Total	272 (90.4)	29 (9.6)	301 (100.0)

ROP: Retinopathy of prematurity, RDS: Respiratory distress syndrome

Table 6: Birth weight and ROP

Birth weight	No ROP	ROP	Chi-square	*P* value
<1.25 kg	9 (3.3)	11 (37.9)	69.062	<0.0001
1.26–1.5 kg	57 (21)	13 (44.8)		
1.6–1.75 kg	68 (25)	5 (17.2)		
>1.75 kg	138 (50.7)	0		

of ROP is common in both male and female babies. Gestational diabetes and antepartum hemorrhage of the mothers of the screened babies were the major maternal risk factors.

Analysis showed that the following risk factors such as GA, birth weight, oxygen administration, and respiratory distress were involved in the development of ROP.

Of the 29 babies diagnosed as ROP, 15 babies (15/29 - 51.7%) had Stage I ROP, 10 babies (10/29 - 35.5%) had Stage II ROP, and 4 babies (4/29 - 13.8%) had Stage III ROP. Regarding the zone of ROP, no babies were in zone 1, 6 babies (20.7%) were in zone 2, and 23 (79.3%) babies were in zone 3. Among the diagnosed 29 babies, 23 babies had spontaneous regression of ROP and developed mature retina. Six babies needed laser therapy.

Babies with birth weight <1500 g and around 80% babies with respiratory distress went on for laser treatment. Chi-square test and *P* value were used as statistic tools to assess the correlation of incidence between birth weight/RDS and ROP.

Univariate analysis showed that the following risk factors were statistically significant: Birth weight, RDS, mode of delivery, post-conceptional age, oxygen administration, and sepsis.

Multivariate regression analysis of these univariately significant factors showed only the following remained significant: Birth weight, RDS, and oxygen administration.

Anandvinekar *et al.*[9] showed that ROP occurs at higher birth weights (>1250 g). In the Indian population, our study showed that 29% of the ROP occurred in 1.01–1.25 birth weight and 27% cases of ROP occurred in the 1.26–1.50 birth weight subgroup.

Shah *et al.*,[10] more specifically examined a south Indian population that may more closely resemble our population, but our results showed higher prevalence of ROP in GA <28 weeks, in lower (1–1.5 kg) birth weight subgroups and in oxygen therapy babies.

Anandvinekar *et al.*[11] reported outborn, RDS, and exchange transfusion as independent risk factors for severe ROP.

All the six babies who underwent laser therapy showed regression of ROP and had good visual results and are on long-term follow-up.

CONCLUSION

ROP is emerging as one of the major causes of preventable childhood blindness in India. Timely screening and early management is the key management of ROP. Most of the studies including ours show that not all cases of ROP need treatment, but those few which really do need should not be missed. With greater recognition of the devastating consequences of ROP and the understanding that timely treatment can save our vision, our community may be able to reduce the high burden of childhood illness. RDS, low birth weight, and oxygen administration are the significant risk factors for ROP. Laser photocoagulation is the best mode of management with better results.

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How to cite this article: Selvakumar R, Vasanthamalar C, Jeyaramapandian V. Study on Retinopathy of Prematurity and Its Risk Factors in Preterm Babies and Birth Weight <2 kg Admitted in a Rural Medical College. Int J Sci Stud 2018;5(12):96-99.

Source of Support: Nil, **Conflict of Interest:** None declared.