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Original Research Article

Incidence and risk factors for retinopathy of prematurity at a medical college hospital in rural Tamil Nadu, India

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ABSTRACT

Background: The objective of the research was to evaluate the incidence of retinopathy of prematurity (ROP), association of prenatal and postnatal risk factors, pattern of ROP and treatment outcomes among infants admitted to neonatal intensive care unit (NICU) of tertiary care center located in Thiruvannamalai, Tamil Nadu.
Methods: A retrospective study done in all infants admitted between April 2019 and March 2020 who met the criteria for ROP screening with gestational age (GA) less than or equal to 36 weeks or birth weight less than 2000 grams or with GA more than 36 weeks and birth weight more than 2000 gram with significant risk factors like intrauterine growth restriction, respiratory distress syndrome, sepsis, long term oxygen use, phototherapy, blood transfusion and maternal anemia. Treatment was offered to infants with stage 3 ROP and stage 2 in zone 2 with or without plus disease. Qualified infants were treated with argon laser photocoagulation within 72 hours of diagnosis. They were followed until the disease was successfully treated.
Results: Out of total 3121 neonates, 717 neonates met the screening criteria. Incidence of ROP was found to be 33% (n=237). 46.4% (n=110) of ROP belongs to 32-36 weeks GA. 42.6% (n=101) of ROP belongs to 1500-2000 gm birth weight.
Conclusions: Incidence of ROP is quite high in high risk neonates in our unit. Significant risk factors are long term oxygen use, blood transfusion and sepsis.

Keywords: Prematurity, Retinopathy, Oxygen use, Sepsis

INTRODUCTION

Prevalence of childhood blindness in the world is approximately 1.4 million, of which three quarters live in the poorest region of Africa and Asia where the prevalence is reported to be as high as 1.5 per 1000 children. In middle income countries, retinopathy of prematurity (ROP) is one of the leading causes of childhood blindness. The incidence of which can be reduced through availability and affordability of screening and curative services. In low-middle income countries, the prevalence is reported to be as high as 1.5 per 1000 children, In contrast to high income countries where the prevalence is 0.3 per 1000.[1,2]

Current prevalence of childhood blindness in India is around 0.8 per 1000 children.[3,4] In developing countries, 30-72% of pediatric blindness is preventable.[3,5,6]

Advances in neonatal care have improved survival of preterm babies. ROP is emerging as one of the foremost causes of blindness in preterm babies.[7,8] This emerging epidemic of ROP blindness is the result of high birth rate, high rate of preterm births and its survival is due to the advancement in medical care.[9] Short gestation and low birth weight (LBW) are the most important risk factors responsible for ROP. Other risk factors that contribute to ROP are recognized to be sepsis, intra ventricular

hemorrhage (IVH), mechanical ventilation, oxygen therapy, inotrope support, blood transfusion, exposure to ultraviolet (UV) light.[10] Growing interest in pediatric ophthalmology and vitreoretinal subspecialty has led to increased detection of ROP.

Screening guidelines published by the national neonatology forum recommends first screening between 2 and 3 weeks for infants born before 28 weeks gestational age (GA) or with birth weight (BW) <1200 gm and not later than 4 weeks after birth for infants born between GA of 28 and 34 weeks or BW ≤2000 gm.[11] The latest ROP guidelines (published by a collaborated of neonatal care and ROP experts in India, London school of hygiene and tropical medicine, led by the Indian institute of public health – public health foundation of India, supported by the Queen Elizabeth diamond jubilee trust) are an attempt to standardize the screening and management of ROP in India and integrate it with the public health delivery system.[12] It proposes screening of all children born ≤34 weeks and those >34 weeks with risk factors if the GA is known or all infants ≤2000 gm BW if GA is unknown. Screening is performed at neonatal intensive care unit (NICU) before discharge or by 30 days of life, whichever is sooner.

This study is to analyze the incidence and severity of ROP in neonates of any GA i.e. preterm as well as term infants and also to analyze the maternal and neonatal risk factors related to its incidence.

METHODS

This is a retrospective observational study done in NICU of Government Thiruvannamalai medical college and hospital (a tertiary referral centre), Thiruvannamalai district, Tamil Nadu, south India. All neonates admitted in NICU for the period of April 2019 to March 2020 were taken into study. Screening was done for babies with GA ≤36 weeks or BW ≤2000 gm and BW >2000 gm or GA >36 weeks if they were on oxygen therapy for more than 7 days.[13] Also infants of any GA if they had a course of instability (like sepsis, asphyxia or ventilation). Infants with congenital anomalies, chromosomal abnormalities and inborn error of metabolism were excluded from the study (N=156). Infants who had oxygen therapy but died during the course of follow up were also excluded (N=170). Neonates considered for study were 717.

Screening examination was carried out at 32 weeks of gestation or 2 weeks of age whichever was later.

Preparation and method of examination

All infants were examined regularly by the same ophthalmologist at 1-2 weeks interval from the 2nd postnatal week onwards. 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.

Indirect ophthalmoscopic examination was done with a 28 dioptre lens, speculum and scleral indenter. One drop of topical paracrine eye drops was used to anesthetize the cornea. Retinal examination was performed by ophthalmologist with retinal drawing and ret cam 2 fundus imaging was done when indicated.

If no ROP was detected at initial examination, infants were re-evaluated once every 2 weeks until vascularization was complete. If ROP was detected, 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 with regression were followed up till complete vascularization. Babies progressing to threshold stage were advised treatment with laser photocoagulation. Treatment with laser was performed within 72 hours of detecting this finding after family consent.

In this study we considered pre and postnatal risk factors for ROP to identify association between independent risk factors with the development of mild and severe forms of disease. The prenatal variables were maternal anemia, pregnancy induced hypertension, gestational diabetes, GA, birth weight and sex. The peri- and postnatal variables were respiratory distress syndrome, oxygen therapy (through nasal catheter, hood, continuous positive airway pressure i.e. CPAP or mechanical ventilation), Hypoxic-ischemic encephalopathy (HIE) stage 1, 2 or 3, requiring cardiopulmonary resuscitation (CPR) within first 10 minutes of life, sepsis (requiring IV antibiotic ≥5 days, C-reactive protein >6.0 mg/dl or positive blood culture), phototherapy for jaundice, blood transfusion and hypotension requiring inotropic support.

Statistical analysis

Data about the occurrence of ROP collected in 717 high risk neonates along with details about perinatal and maternal risk factors. Assuming an ROP incidence of 20% in our population with 3% precision on either side at type I error of 5%, the calculated sample size was around 700. Continuous variables were subjected to parametric tests after ensuring normality. Categorical variables were analyzed by non-parametric tests. Statistical tests were done in the R programming language (R version 3.6.3 (2020-02-29) - "Holding the Windsock") with basic R stats package. Descriptive analysis and plotting was done in the ggplot package (version 3.3.2) of R language.

RESULTS

237 neonates were found to have ROP resulting in 33% of ROP in our population. Their severest form of ROP in their entire follow-up period is tabulated. Among affected neonates 19 had plus disease. 53 neonates needed intervention in the form of laser therapy.

ROP has no predilection for particular sex. Immaturity and low birth weight are significantly associated with

increased incidence of ROP. Respiratory distress, sepsis and transfusion history are other factors that are significantly associated with ROP.

Probability of ROP decreases as maturity advances. Odds of developing ROP decreases by 10% for every one week increment in gestation (odds ratio=0.8966497, p value ≤0.001).

Table 1: Frequency, severity and extent of ROP in our study population.

	No ROP	Stage I	Stage II
No ROP	480	-	-
Zone 1	-	11	1
Zone 2	-	117	35
Zone 3	-	72	1

Table 2: Association of ROP with maturity and other clinical parameters.

Parameter		No ROP	ROP	P value
Sex	Female	219	115	0.5142
	Male	261	122	
Maturity (weeks)	≤28	2	5	0.001327 (Fisher's exact)
	28-32	50	35	
	32-36	188	110	
	>36	240	87	
Birth weight	≤1000	3	9	0.0001128 (Fisher's exact)
	1000-1500	52	47	
	1500-2000	228	101	
	2000-2500	101	49	
	>2500	96	31	
Nutritional status	Normal	176	89	0.8816
	IUGR	304	148	
Birth asphyxia	No asphyxia	226	133	0.04035 (Fisher's exact)
	HIE 1	181	71	
	HIE 2	69	28	
	HIE 3	4	5	
Respiratory distress	Absent	377	162	0.004
	Present	103	75	
Sepsis	Absent	278	117	0.03704
	Present	202	120	
Transfusion history	Absent	450	201	0.0001714
	Present	30	36	
Maternal anemia	Absent	322	172	0.1591
	Present	158	65	

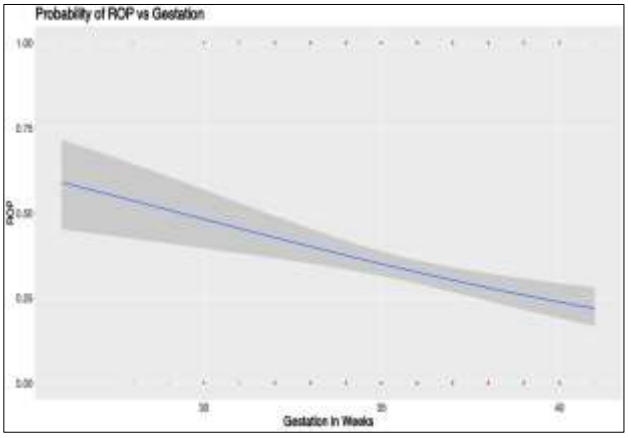

Figure 1: Probability of ROP decreases as gestational age advances.

Chances of developing ROP increases as time spent under continuous positive airway pressure (CPAP) increases. Odds increase by 20% as duration increases by one day (odds ratio=1.20441, p value <0.001).

Odds of developing ROP increase by 12% for every single day spent under oxygen therapy (odds ratio=1.12, p value=0.00935).

Increase in odds of developing ROP, when increase in duration of mechanical ventilation is not statistically significant (odds ratio=1.12129, p value=0.143).

Duration of antibiotic therapy has significant correlation with development of ROP. Each day of antibiotic therapy increases the odds of ROP by 5% (odds ratio=1.051492, p value=0.000251).

Duration of phototherapy correlates well with development of ROP. Each day of phototherapy increases the odds by 17% (odds ratio=1.171119, p value=0.0105).

DISCUSSION

ROP is characterized by abnormal neo vascularization in the retina of premature infants. These blood vessels are fragile and can bleed, scarring the retina. This causes tractional retinal detachment leading to visual impairment and blindness.[14] This neo vascularization process evolves over 4-5 weeks after birth.[15] This relatively slow evolution gives a small window of opportunity to effectively conduct retinal examinations and timely intervention to improve visual outcome and avoid irreversible blindness due to retinal detachment from progressive untreated ROP.[16]

The 2019 American academy of pediatrics (AAP) guidelines recommends screening of all infants with BW ≤1500 gm or GA ≤30 weeks and selected infants with BW between 1500 and 2000 gm or GA >30 weeks (if required inotrope support; oxygen supplementation for more than a few days.[17] United Kingdom guidelines developed by the Royal college of ophthalmology (RCO), pediatrics and child health included babies <32 weeks GA or <1501 gm BW should be screened for ROP.[18]

Clinical profile of ROP is very much different in developed and developing countries. There is variation even in urban and rural parts of India.[19] Due to improvement in maternal and neonatal health care facilities and with increased survival, prevalence of ROP is expected to rise. ROP can develop in bigger and mature babies in India which is due to the various risk factors and variable treatment protocols of Neonatal care in different centers.[20-22] Studies from India have shown that children with BW of >2000 gm can develop ROP who experience an unstable course requiring cardio respiratory support.[20-22]

A prospective study from south India confirmed that ROP does occur in babies who lie outside the conventional American or British screening criteria.[21] About 13.3% and 6.7% of severe ROP would have been missed if they were to use the AAP or RCO screening criteria respectively.[21] They suggested that broader screening criteria of GA <34 weeks and BW <1750 gm would be ideal. Another study from south India noted that 17.7% and 22.6% of neonates with threshold or severe type ROP would have been missed if they were to use the AAP or RCO screening criteria respectively.[22] A study from India found the mean BW in the group with severe ROP was 1554 gm (range 850-2290 gm) and the mean GA was 31.75 weeks (range 28-34 weeks).[23]

The Vermont Oxford network database, collected data from more than 1000 NICUs worldwide and estimated in 2010 an incidence of 33.2% of ROP in neonates with BW <1500 gm.[24] In another study done by Freitas et al, which is a retrospective 10 year study had ROP incidence of 33.9% and their selection criteria included infants with BW >1500 gm or GA >32 weeks with determined risk factors.[25] ROP incidence ranges between 15.6% and 47.3% as reported from previous studies in India.[26-30] In our study the incidence of ROP is 33% and screening is done for babies with GA ≤36 weeks or BW ≤2000 gm and BW >2000 gm or GA >36 weeks who are at high risk of developing ROP like respiratory distress syndrome, hypoxic ischemic encephalopathy (HIE), oxygen therapy, sepsis, inotrope support, blood transfusion, and phototherapy. Babies with congenital anomalies, incomplete prenatal and perinatal details and dropout from follow up were excluded from the study. These variations in the incidence of ROP may reflect the differences in type of study, study population, screening criteria, variable risk factors involvement, mortality rates and the characteristics of neonatal care in each institution, corroborating the need to do research further in this topic.

The duration of oxygen therapy and mechanical ventilation is an independent risk factor for ROP development.[31,32] In our study odds of developing ROP increases by 12% for every single day spent with oxygen therapy. But duration of mechanical ventilation is not statistically significant with development of ROP.

Slidsborg et al identified blood transfusion as an independent risk factor for ROP.[33] Our study also supports its significance in the development of ROP. Adult hemoglobin has lower affinity for oxygen than fetal hemoglobin. Increased oxygen transport by adult hemoglobin increases oxygen delivery to developing retina, which induces angiogenesis. Also, elevated iron loads can induce free radicals. Both these contribute to ROP development or progression.[34]

Studies showed that sepsis increases the risk of development of any stage of ROP.[35] Our study also strongly supports sepsis as the independent risk factor for ROP. But it is difficult to adjust the impact of the use of oxygen and mechanical ventilation on the development of ROP and so the bias exist.[36-42]

The limitation of the study is that it is a single centre study. Since the study is of retrospective nature it does not include expired babies which require cardiorespiratory support and also it limits the control over the quality of measurements. However the advantages of this study are its clinical utility by including a broader screening criteria and assessment of the disease done by a single trained examiner.

CONCLUSION

Incidence of ROP among high risk neonates is 33% and this incidence is quite high in our institution. ROP is an emerging epidemic and is with variable risk factors, so broader screening criteria need to be practiced. So that careful timed retinal examination of all at risk infants will minimize the development of ROP and subsequent vision

loss. It should be a comprehensive eye care approach in which the health promotion, disease prevention, diagnosis, treatment and rehabilitation are coordinated to tackle with the current cause of ocular morbidities related to retinal abnormalities. The preventable and potentially blinding diseases like ROP should be emphasized timely to prevent these children from becoming blind in future years.

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