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A PROSPECTIVE OBSERVATIONAL STUDY OF THE CLINICAL PREVALENCE OF RETINOPATHY OF PREMATURITY IN PRETERM INFANTS AT A HOSPITAL IN ODISHA.

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Abstract

Background

Retinopathy of prematurity (ROP), the scar tissue behind the neonate lens associated with retinal detachment, has been responsible for the two largest 'epidemics' of blindness in neonates in modern times. There is a rise in such cases reported around the world. However, ROP is preventable with advanced techniques. This study is carried out to determine the epidemiological profile of ROP

Method

This was a prospective observational study carried out at the Department of Ophthalmology and Neonatal Intensive Care Unit Veer Surendra Sai Institute of Medical Sciences and Research Centre, Burla, Sambalpur, Odisha for a period of two. Infants with lesser birth weight and preterm were considered for the study. The demography of the infants, along with oxygen therapy and the other required treatments were recorded. The eyes of the infants were examined with RetCam. Retinopathy was graded into Zone and Stages as per ICROP classification. Those infants with retinopathy were further examined and those with proper vascularization were not examined.

Results

Overall 268 infants were included in this study. The occurrence of ROP was 45.9%. The infants with less than 1000 grams, gestational age between 26-30 weeks, had sepsis, had RDS, were IVH, had anemia, and received supplemental oxygen were prone to ROP. Zone II was the most affected zone and the ROP was at stage I and II IN most of the infants.

Conclusion

The risk factors associated with the occurrence of ROP include gestational age, birth weight, RDS, anemia, sepsis, IVH, RDS, and supplemental oxygen. Proper screening is required for diagnosis of occurrence ROP.

Recommendation

The risk factors discussed in the study should be considered for preterm babies and necessary screening should be done. Early diagnosis can prevent blindness in infants

Keywords*: *Retinopathy of Prematurity, Preterm Infants, Blindness
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Introduction

Retinopathy of prematurity is a risk associated with preterm babies which can lead to loss of visual acuity and even lead to blindness. It is a disorder of the vascularization of the retina. During pregnancy, the retina is in hypoxia and the retina is not completely formed until the complete term of pregnancy [1]. It has many endothelial growth factors that lead to angiogenesis of the blood vessels in the retina. If the baby is born prematurely before completing the term, they are generally kept under supplemental oxygen. While the retina is still developing, there are many endothelial growth factors present but the hypoxia is completely

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reversed and the retina comes under a hyperoxia state. This causes abnormal development of the blood vessels in the retina which can lead to retinal detachment and blindness later on [2].

Retinopathy of prematurity has been studied in various instances, the risk factors associated with the occurrence of such a condition in infants and young children are low birth weights, younger gestational age, and supply of supplemental oxygen. The worst prognosis of retinopathy is preventable with earlier detection and treatment. During the 1950s there was an epidemic of retinopathy which caused visual impairment in various infants [3]. This has drawn the attention of the doctors treating infants in the neonatal intensive care unit. Infants with a birth weight of less than 1200 gms and gestational age below 33 weeks have to be monitored closely to prevent any such occurrence [4].

A study stated that with each 100 grams decrease in weight the chances of occurrence of retinopathy increase by 27% and with each week lesser than the full-term gestation the chances of occurrence of retinopathy increase by 15% [5]. However, it was reported that certain full-term infants with no supplemental oxygen developed retinopathy. Thus the odds of developing retinopathy cannot be predicted [6]. Epidemiological data with regards to retinopathy can help clinicians in predicting retinopathy and so necessary steps for prevention of retinopathy can be taken. This study aims to collect data regarding the prevalence of retinopathy among infants in a hospital in Odisha.

Method

Study design

This was a prospective observational study.

Study setting

The study was carried out at the Department of Ophthalmology and Neonatal Intensive Care Unit Veer Surendra Sai Institute of Medical Sciences And Research Centre, Burla, Sambalpur, Odisha, India, from September 2019 to October 2021.

Participants

Infants with less than 1750 grams and with less than 34 weeks of gestation were considered for the study. Irrespective of the other associated complications such as respiratory distress, requirement of supplemental oxygen, and sepsis, preterm infants were included in this study. Except for the infants who had intrauterine growth restriction full-term infants were not included in this study.

The maternal details and details of the infants such as a gestational week, requirement of blood transfusion, requirement of oxygen, and any other complications associated with preterm birth. The information was recorded and arranged in a tabular format. The infants underwent eye screening pupil dilators such as tropicamide and phenylephrine were given for complete dilation of the pupil. A topical anesthetic was also instilled in the eyes. With the help of RetCam indirect ophthalmoscopy and +20D lens, the retina was examined. Those infants who had abnormal vascularization were taken further for the treatment whereas those who did not have any abnormal vascularization were not followed up again.

Sample size

To calculate the sample size for this study, the following formula was used for estimating a proportion of a population:

$$n = \frac{Z2 \times p \times (1-p)}{E2}$$

Where:

- n = sample size
- Z = Z-score corresponding to the desired level of confidence
- p = estimated proportion in the population
- E = margin of error

Bias: There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

Ethical consideration

The Ethics committee of the institute approved this study. Informed consent was taken from the mothers for the participation of the infants.

Statistical analysis

The data obtained was arranged in a tabular format on an Excel sheet. Then the data was subjected to statistical analysis.

Result

Initially, 274 infants were considered based on criteria like birth weight and gestational age, with full-term infants excluded. Six infants were excluded, due to intrauterine growth restriction. The study then focused on recording maternal and infant details and conducting eye screenings. Infants with abnormal vascularization were treated, while others were not followed up.

In all 268 infants participated in this study out of which 49.52% had developed retinopathy of prematurity. The occurrence of ROP was correlated with gender, weight, gestational age, presence of sepsis, presence of respiratory

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distress syndrome, zone of ROP, stage of ROP, singleton or multiple pregnancies, the requirement of oxygen supplementation, presence of intraventricular hemorrhage, and anemia. Table no.1 shows the frequency of infants in our study as per the above-stated parameters.

Table no.1: Frequency of infants as per the stated parameters

Sr no.	Parameters	Frequency
1	*Gender*	
	Male	154
	female	114
2	*Gestational age*	
	26 to 30 weeks	126
	Gestational age more than 30 weeks	142
3	*Birth weight*	
	Less than 1000 gms	61
	Between 1000 to 1500 gms	165
	More than 1500 gms	42
4	*Zones*	
	Zone I	31
	Zone II	52
	Zone III	185
5	*Stages*	
	1	38
	2	38
	3	32
	4A	1
	APROP	13
	TRD	1
6	*Oxygen supplementation*	
	Oxygen given	177
	Oxygen not given	91
7	*Sepsis*	
	Present	190
	Absent	78
8	*Respiratory distress syndrome*	
	Present	196
	Absent	72
9	*Intraventricular Haemorrhage*	
	Present	77
	Absent	191
10	Multiple pregnancies	43
	Single pregnancy	225
11	*Mode of delivery*	
	Vaginal delivery	196
	LSCS	72
12	*Anemia*	
	Present	13
	Absent	255

After recording the information regarding the above characteristics, it was correlated with the occurrence of Retinopathy of prematurity. Table no.2 gives the percentage of infants with retinopathy and without retinopathy in each of the above characteristics. It also gives the significance of the correlation between occurrences of retinopathy.

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Table no.2 (a): Correlation of infant's characteristics with the occurrence of retinopathy

Sr no.	Parameters	Positive retinopathy	Negative retinopathy	Correlation
1	*Gender*			
	Male	76	78	Not significant
	Female	47	67	
2	*Gestational age*			
	26 to 30 weeks	73	53	Significant
	More than 30 weeks	50	92	
3	*Birth weight*			
	Less than 1000 gm	33	28	Significant
	Between 1000 to 1500 gm	76	89	
	More than 1500 gm	14	28	
4	*Immature retina zones*			
	Zone I	24	7	Significant
	Zone II	39	13	
	Zone III	60	125	
5	*Stages*			
	1	38	-	Significant
	2	38	-	
	3	32	-	
	4A	1	-	
	APROP	13	-	
	TRD	1	-	

Table no.2 (b): Correlation of infant's characteristics with the occurrence of retinopathy

Sr no.	Parameters	Positive retinopathy	Negative retinopathy	Correlation
6	*Oxygen supplementation*			
	Oxygen given	102	75	Significant
	Oxygen not given	21	70	
7	*Sepsis*			
	Present	101	89	Significant
	Absent	22	56	
8	*Respiratory distress syndrome*			
	Present	107	89	Significant
	Absent	16	56	
9	*Intraventricular Haemorrhage*			
	Present	44	31	Significant
	Absent	77	114	
10	Multiple pregnancies	21	22	Significant
	Single pregnancy	102	123	
11	*Mode of delivery*			
	Vaginal delivery	95	101	Not significant
	LSCS	28	44	

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12	*Anemia* Present Absent	 8 115	 5 140	Significant

Male infants showed a slightly greater but not substantially higher risk of ROP than female babies. In gestational age groups 26-30 weeks, 58% of neonates developed ROP, and >30 to 34 weeks, 35%. Which correlates with newborn prematurity. 53% of newborns under 1000 grams had ROP, but only 33% of those above 1500 grams did. Lower birth weight increased ROP risk. Zone I was the least damaged and Zone III the worst. 62% were in stages 1 or 2, 26% in stage 3, and 12% in stage 4 or APROP or Total retinal detachment.

Supplemental oxygen caused ROP in 57.6% of newborns and 23% of those without. Supplemental oxygen strongly correlates with ROP. 53% of sepsis infants and 28% of non-sepsis neonates experienced ROP. ROP development is strongly linked to sepsis. 54.6% of RDS newborns and 22.2% of non-RDS infants developed ROP. A strong association exists between RDS and ROP. ROP occurred in 49% of multiple-pregnant newborns and 45% of single-preg No significant relationship existed between multiple pregnancies and ROP. 60% of IVH and 40% of non-IVH neonates developed ROP. Intraventricular hemorrhage is linked to ROP. Infants delivered via NVD 48% and LSCS 39% experienced ROP. ROP was unaffected by the delivery mode. 61.5% of anemic newborns and 45% of non-anemic neonates had ROP. Infants with anemia were more likely to develop ROP.

Discussion

There were 268 infants born with birth weight <1750 gm and/or gestational age <34 weeks. ROP occurred in 123 of 268 tested babies. The total ROP rate was 45.9%, highlighting the significant risk of ROP in this specific population of premature babies. A study with identical screening parameters found 46% ROP [7]. Studies in India report ROP rates from 20% to 60.2%. Of 268 tested newborns, 154 were male and 114 females. ROP affected 76 men (49%) and 47 girls (41%) of 154. Gender does not affect ROP development [5,6].

Of the 126 neonates in the 26-30 weeks of GA group, 73 (58%) developed ROP, whereas 50 (35%) of the 142 in the >30-34 weeks group did. This demonstrated that the lower GA group had more neonates with ROP while the higher GA group had the majority without ROP, highlighting the inverse relationship between gestational age and ROP occurrence in this study. A study found that Indian newborns with higher birth weight and gestational age were more likely to develop ROP [7]. The development of ROP by birth weight class in our research was: Out of 61 newborns under 1000g, 33 (54%), 165 (1500g+) 76 (46%), and 42 >1500 gram 14.33% developed ROP. This reveals a strong association between birth weight and ROP. Lower birth weight increases ROP risk.

It was found an inadequate retina in zone I in 31 newborns, 24 of whom (77.4%) had ROP. Zone II included 39 out of 53 (75%), and Zone III had 60 out of 185 (32.5%) newborns with ROP. It shows that zone I is dangerous while zone III is safe. Of the 123 babies with ROP, 38 (31%) were in stage 1, 38 (31%) in stage 2, 32 (26%) in stage 3, 1 (0.8%) in stage 4A, 13 (10.5%) in APROP, and 1 (0.8%) had complete retinal detachment. 62% of newborns were stage 1 and 2, 26% were stage 3, and 12% were stage 4 or greater and APROP, illustrating the severity distribution among ROP cases. Retinopathy of prematurity (ROP) primarily affects zone I and II of the retina, with higher severity in zone I, while zone III has a lower incidence. Most cases are in stages 1 and 2, with a smaller percentage progressing to stage 3 or higher, indicating a significant risk for vision impairment in premature infants. Studies found 4.7% of severe ROP and 3.5% of severe ROP needing therapy [8,9,10].

102 (57.6%) of 177 newborns who received supplementary oxygen developed ROP, whereas 21 (23%) did not. Oxygen supplements strongly correlate with ROP, emphasizing the significant impact of oxygen supplementation on ROP incidence. Similar results are seen in other investigations [11,12,13]. 101 of 190 sepsis newborns (53%) developed ROP, whereas 22 of 78 (28%) did. A strong association exists between sepsis and ROP. 107 (54.6%) of the 196 babies with respiratory distress syndrome (RDS) had ROP, whereas 16 (22.2%) of the 72 without RDS got ROP. Our research found a strong link between RDS and ROP, as did others [14,15]. 46 (60%) of 77 babies with intraventricular hemorrhage (IVH) developed ROP, whereas 77 (40%) of 191 without IVH did. IVH is strongly linked to ROP. 102 (45%) of the 225 single-pregnancy babies and 21 (49%) of the 43 multiple-pregnancy newborns had ROP. Our research found no link between multiple and single pregnancies and the development of ROP. Of 196 children delivered by normal vaginal delivery (NVD), 95 (48.5%) had ROP, whereas 28 (39%) of 72 born with LSCS did not. The relationship between NVD and LSCS newborns was insignificant. However, ROP is somewhat greater in the NVD group, maybe because some NVDs took place at home and are prone to sepsis or other problems. Out of 13 babies

with anemia, 8 (61.5%) had ROP, whereas 115 (45%) of 255 without anemia did. ROP was strongly linked to anemia.

Generalizability

The study provides valuable insights into retinopathy of prematurity (ROP) risk factors, informing screening guidelines for preterm infants to enable early intervention, optimize care protocols, educate stakeholders, and guide further research and policy development, ultimately aiming to reduce ROP-related visual impairment and blindness on a broader scale.

Conclusion

The risk factors associated with the occurrence of ROP include gestational age, birth weight, RDS, anemia, sepsis, IVH, RDS, and supplemental oxygen. Proper screening is required for diagnosis of occurrence ROP.

Limitation

The cohort taken for this study is smaller in comparison to the epidemiology studied for the occurrence of Retinopathy of prematurity. Studies with larger sample sizes are required to confirm the findings.

Recommendation

The risk factors discussed in the study should be considered for preterm babies and necessary screening should be done. Early diagnosis can prevent blindness in infants.

Acknowledgment

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List of abbreviation

ROP - Retinopathy of Prematurity
NICU - Neonatal Intensive Care Unit
gms - grams
IVH - Intraventricular Hemorrhage
RDS - Respiratory Distress Syndrome
APROP - Aggressive Posterior Retinopathy of Prematurity
LSCS - Lower Segment Cesarean Section
NVD - Normal Vaginal Delivery

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Conflict of interest

The authors declare no conflict of interest.

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