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Prevalence and Associated Risk Factors of Retinopathy of Prematurity in Preterm Infants: A Cross-Sectional Study

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ABSTRACT

Objective: To determine the prevalence of Retinopathy of Prematurity (ROP) and its associated risk factors in preterm infants at the National Institute of Child Health (NICH), Karachi, Pakistan.

Methods: This cross-sectional study was conducted in the neonatal intensive care unit (NICU) department of NICH, Karachi, Pakistan from October 2020 to March 2021. The study included preterm infants with a gestational age under 32 weeks, admitted to the NICU at the NICH, Karachi. ROP was diagnosed by indirect ophthalmoscopy following pupil dilation, performed by a trained ophthalmologist. Risk factors were assessed based on preterm infants' age, gestational age, residence, gender, maternal education, sepsis, respiratory distress syndrome (RDS), anemia, oxygen dependency duration, and mechanical ventilation.

Results: Of total 310 preterm infants, the mean age was 5.73 ±1.49 days. There were 184 (59.3%) males and 126 (40.6%) females. ROP was observed in 139 (44.8%) preterm infants. Binary logistic regression indicated significantly increased ROP risk in infants of illiterate mothers (aOR 3.31, 95% CI 1.08 to 10.17, p-value 0.036), those with family income ≤ 45,000 rupees (aOR 3.70, 95% CI 1.40 to 9.76, p-value 0.008), and reduced risk in female infants (aOR 0.12, 95% CI 0.04 to 0.31, p-value <0.001), infants on oxygen ≤ 4 days (aOR 0.04, 95% CI 0.01 to 0.12, p-value <0.001), and NICU stay ≤ 12 days (aOR 0.02, 95% CI 0.01 to 0.08, p-value <0.001).

Conclusion: Nearly half of the preterm neonates were affected by ROP, with contributing factors including maternal illiteracy, low family income, prolonged oxygen dependency, and extended NICU stays.

Keywords: Body Mass Index, Circuit Training, High Intensity Interval Training, Obesity, Overweight.

INTRODUCTION

Retinopathy of Prematurity (ROP) is a major contributor to preventable blindness among preterm infants worldwide. It is particularly prevalent in middle- and low-income countries, where the burden is exacerbated by the limited availability and accessibility of advanced neonatal care facilities.[1,2] The incidence of ROP in these regions remains alarmingly high due to factors such as inadequate monitoring of oxygen therapy, suboptimal preterm care, and insufficient screening programs.[1,2] It is a vascular proliferative disorder affecting the underdeveloped retina in preterm infants, particularly those with low birth weight or those requiring supplemental oxygen therapy. It arises due to disrupted vascularization of the retina, often exacerbated by the use of oxygen, leading to abnormal blood vessel growth and potential retinal detachment if left untreated.[3] Advances in neonatal care have led to the survival of increasingly younger and smaller infants, which, while improving survival rates, has also led to an increased incidence of ROP.[4] The World Health Organization and the International Agency for the Prevention of Blindness recognize ROP as a major public health issue, emphasizing the importance of early detection and timely intervention.[5]

Key risk factors for ROP include low gestational age, low birth weight, prolonged oxygen dependency, and comorbidities such as sepsis and respiratory distress syndrome (RDS). These factors significantly increase the susceptibility of preterm infants to developing this condition.[6-8] Additionally, the use of mechanical ventilation-a common intervention in neonatal intensive care units (NICUs) to manage respiratory complications in preterm infants-exposes the developing retina to higher oxygen levels, further increasing the risk of ROP.[9]

This study was conducted in the National Institute of Child Health (NICH), Karachi, one of the largest public sector pediatric hospitals in Sindh Province, Pakistan,

which serves a diverse population with limited access to specialized neonatal care. Given the high rates of preterm births and related complications in this setting, an in-depth understanding of ROP frequency and associated risk factors is essential for improving neonatal outcomes. This study aims to determine the frequency of ROP in preterm infants at NICH and to explore demographic, clinical, and socioeconomic risk factors contributing to its development.

METHODS

This cross-sectional study was conducted in the NICU department of NICH, Karachi, Pakistan from October 2020 to March 2021. Ethical approval was obtained from the Institutional Review Board of NICH (Reference Number: 26/2020). Signed informed consent was obtained from parents/guardians of preterm infants prior to the enrolment of participants in the study. Parents were informed of the study's purpose, procedures, and potential risks and benefits. Confidentiality of participants' information was strictly maintained.

By using OpenEPI sample size calculator taking prevalence of ROP 28%,[10] level of confidence 95%, 5% margin of error. The estimated sample size was 310. Eligible participants were selected using a consecutive sampling method. The inclusion criteria for this study required infants born preterm, specifically those with a gestational age of less than 32 weeks and admitted to the NICU at the NICH, Karachi. Exclusion criteria included preterm infants who expired before undergoing the initial ROP examination, those whose guardians declined consent for participation, infants without a history of oxygen therapy during their NICU stay, infants with major congenital anomalies, as these may complicate ROP screening and outcomes, and infants with severe systemic infections or conditions, which might interfere with ROP development or screening accuracy.

Data on demographics, including age, gestational age, birth weight, gender, and residential status, were collected from medical records and recorded on a structured proforma. ROP is defined as an abnormal development of retinal blood vessels in preterm infants. The presence of ROP was identified through ophthalmologic examination, characterized by abnormal vascular proliferation and development within the retina. The condition is classified into stages (1 to 5) based on the severity of retinal changes, in accordance with established international screening guidelines. ROP screening was performed under

mydriasis using 0.5% tropicamide and 2.5% phenylephrine eye drops, administered three times at 15-minute intervals. Binocular indirect ophthalmoscopy was conducted with a 20 D lens. Lid speculum and scleral depressors were utilized as standard practice to facilitate examination. Observations were documented, noting the presence or absence of ROP and the associated stages or findings.

Sepsis diagnosis was confirmed through positive blood culture results for bacterial pathogens or clinical diagnosis based on the combination of symptoms and laboratory findings. RDS was diagnosed by observing signs such as grunting, flaring, chest retractions, and increased respiratory rate, with confirmation by chest radiograph showing ground-glass appearance and air broncho-grams. Anemia is diagnosed through laboratory testing, with hemoglobin levels typically measuring below 10 g/dL in very preterm infants born at less than 32 weeks of gestation.

Data entry and analysis were performed using the Statistical Package for Social Sciences (SPSS) version 20.0. Mean ±SD was computed for quantitative variables like age, gestational age, and birth weight while frequency and percentages were computed for categorical variables like gender, residential status, mothers educational level, family income, oxygen dependency days, NICU stay, sepsis, anemia, RDS, and mechanical ventilation. Inferential statistics were explored using the Chi-square and Independent t-test test to compare ROP with baseline and clinical characteristics of infants. The p-value of ≤ 0.05 was considered statistically significant. Moreover, binary logistic regression was applied to all those variables found significant in the Chi-square/Fisher exact contingency table. Both univariable and multivariable logistic regression were applied. p-value of ≤ 0.05 was considered statistically significant. Moreover, binary logistic regression was applied to all those variables found significant in the Chi-square/Fisher exact contingency table. Both univariable and multivariable logistic regression were applied.

RESULTS

Of total 310 preterm infants, the mean age, gestational age, and birth weight were 5.73 ±1.49 days, 29.22 ±1.47 weeks, and 1.81 ±0.44 kg respectively. There were 184 (59.3%) males and 126 (40.6%) females. Most of the infants had family income 45,000 or above 183 (59.0%) and their mothers were illiterate 123 (39.7%). Oxygen dependency was ≤ 4 days in majority of the infants 160 (51.6%), however their NICU stay was more than 12 days

161 (51.9%). Sepsis, anemia, and RDS were observed in 75 (24.2%), 94 (30.3%), and 95 (30.6%) infants respectively. Mechanical ventilation was reported in 74 (23.9%) infants.

ROP was reported in 139 (44.8%) preterm infants. A significantly higher association of ROP found with female infants (p-value <0.001), gestational age ≤ 30 weeks (p-value <0.001), maternal illiteracy (p-value <0.001), birth weight ≤ 1.8 kg (p-value 0.014), family income ≤ 45,000 (p-value <0.001), oxygen dependency more than 4 days (p-value <0.001), and NICU stay more than 12 days (p-value <0.001). Furthermore, infants with sepsis (p-value 0.002) and mechanical ventilation (p-value <0.001) were also showed higher association of RDS (Table 1 and 2).

Table 3 reveals binary logistic regression analysis for predicting ROP in preterm infants. At the univariate level, all variables presented in Table 3 showed significant odds ratios. Furthermore, the findings of the multivariable analysis were presented after adjusting the variables that were significant in the univariable analysis. The risk of ROP was 3 times significantly higher in illiterate mothers (aOR 3.31, 95% CI 1.08 to 10.17, p-value 0.036), approximately 5 times significantly higher in mothers educated upto higher secondary (aOR 4.85, 95% CI 1.40 to 9.76, p-value 0.011), 3.7 times significantly higher among infants with ≤45,000 rupees of family income (aOR 3.70, 95% CI 1.40 to 9.76, p-value 0.008), while 88% significantly lower among female infants (aOR 0.12, 95% CI 0.04 to 0.31, p-value <0.001), 96% significantly lower among infants dependent on oxygen ≤4 days (aOR 0.04, 95% CI 0.01 to 0.12, p-value <0.001), and 98% significantly lower among infants stayed in NICU ≤ 12 days (aOR 0.02, 95% CI 0.01 to 0.08, p-value <0.001).

DISCUSSION

The frequency of ROP in our cohort of preterm infants was found to be high, aligning with recent studies reporting similar prevalence in preterm infants.[11,12] This high frequency underscores critical importance of ROP screening programs in NICUs, especially in settings like Karachi, where access to comprehensive neonatal care can vary.[13-15]

Table 1: Comparison of retinopathy of prematurity with baseline characteristics of preterm infants (n= 310)

Variables	Total	Retinopathy of Prematurity		p-value
		Yes (n =139)	No (n= 171)	
Age (days)	5.73 ±1.49	5.53 ±1.29	5.90 ±1.62	0.028[§*]
≤ 5	164	81 (49.4)	83 (50.6)	0.088[^]
> 5	146	58 (39.7)	88 (60.3)	
Gender				
Male	184	41 (22.3)	143 (77.7)	<0.001[^*]
Female	126	98 (77.8)	28 (22.2)	
Gestational Age (weeks)	29.22 ±1.47	28.95 ±1.30	29.4 ±1.57	0.004[§*]
≤ 30	241	120 (49.8)	121 (50.2)	<0.001[^*]
> 30	69	19 (27.5)	50 (72.5)	
Residential Status				
Urban	107	53 (49.5)	54 (50.5)	0.228[^]
Rural	203	86 (42.4)	117 (57.6)	
Maternal Education Status				
Illiterate	123	79 (64.2)	44 (35.8)	<0.001[^*]
Secondary or Higher Secondary	102	32 (31.4)	70 (68.6)	
Intermediate or above	85	28 (32.9)	57 (67.1)	
Birth Weight (kg)	1.81 ±0.44	1.75 ±0.47	1.85 ±0.41	0.037[§*]
≤ 1.8	168	86 (51.2)	82 (48.8)	0.014[^*]
> 1.8	142	53 (37.3)	89 (62.7)	
Family Income (PKR)				
≤ 45,000	127	72 (56.7)	55 (43.3)	<0.001[^*]
> 45,000	183	67 (36.6)	116 (63.4)	

-Quantitative variables described by mean ±SD, Categorical variables described by frequencies (percentages), PKR: Pakistani rupee

* p-value ≤ 0.05 (^Chi-Square test and $Independent t-test)

Table 2: Comparison of retinopathy of prematurity with clinical characteristics of preterm infants (n= 310)

Variables	Total	Retinopathy of Prematurity		p-value
		Yes (n =139)	No (n= 171)	
Oxygen Dependency (days)	4.85 ±1.60	5.87 ±1.38	4.02 ±1.27	<0.001[§*]
≤ 4	160	24 (15.0)	136 (85.0)	<0.001[^*]
> 4	150	115 (76.7)	35 (23.3)	
NICU Stay (days)	12.45 ±3.41	15.28 ±2.01	10.16 ±2.48	<0.001[§*]
≤ 12	149	14 (9.4)	135 (90.6)	<0.001[^*]
> 12	161	125 (77.6)	36 (22.4)	
Sepsis				
Yes	75	45 (60.0)	30 (40.0)	0.002[^*]
No	235	94 (40.0)	141 (60.0)	
Anemia				
Yes	94	43 (45.7)	51 (54.3)	0.832[^]
No	216	96 (44.4)	120 (55.6)	
Respiratory Distress Syndrome				
Yes	95	47 (49.5)	48 (50.5)	0.275[^]
No	215	92 (42.8)	123 (57.2)	
Mechanical Ventilation Applied				
Yes	74	49 (66.2)	25 (33.8)	<0.001[^*]
No	236	90 (38.1)	146 (61.9)	

-Quantitative variables described by mean ±SD, Categorical variables described by frequencies (percentages), NICU: Neonatal intensive care unit

* p-value ≤ 0.05 (^Chi-Square test and $Independent t-test)

Our findings highlight several significant risk factors associated with ROP, including female gender, low maternal education, sepsis, and the use of mechanical ventilation. Mechanical ventilation along with birth weight were also reported as significant risk factors in previous studies.[16,17] In this study, a higher prevalence of ROP was observed in female infants. A systematic review did not find a significant association between female gender and ROP prevalence. However, contrary to current study findings, they reported significant association of male gender with ROP.[18] However, it was reported that the association between male sex and severe ROP was primarily observed in cohorts from countries with high or high-middle sociodemographic indices.[18] Another study also reported a number of male infants who were treated for ROP were higher as compared to females.[19] The suspicion that more male infants are treated for ROP than female infants has been confirmed, potentially due to a known pathophysiological fragility of male neonates.[19]

Maternal education, particularly low or no formal education, was another significant risk factor in the current study. This could be due to the reason that mothers with limited education may have less access to healthcare resources, including antenatal care, potentially affecting prenatal and postnatal outcomes.[20,21]

These finding highlights the need for targeted health education and support for mothers in similar socio-demographic settings to improve neonatal health outcomes. Sepsis emerged as a key contributor to ROP in our study. Preterm infants with sepsis face an increased inflammatory response and oxidative stress, which are known to affect retinal vascular development.[22] This result is consistent with previous studies indicating a strong association between systemic infections and ROP.[12,23] Infection control measures and early treatment of sepsis are essential strategies to reduce this risk factor in vulnerable preterm populations.[24]

This study has several limitations. First, as a single-center study conducted in a public sector hospital, the findings may not be fully generalizable to other settings, especially private healthcare institutions where NICU resources and protocols might differ. Second, the cross-sectional design limits our ability to establish causal relationships between identified risk factors and ROP. Additionally, the sample size, though adequate for preliminary observations, may not capture the full spectrum of factors influencing ROP across a more diverse population. The study also relied on maternal recall for certain sociodemographic variables, such as educational level, which could

Table 3: Binary logistic regression analysis for predicting retinopathy of prematurity in preterm infants

Variables	Univariable analysis		Multivariable analysis	
	cOR (95% CI)	p-value	aOR (95% CI)	p-value
Gender				
Male	0.08 (0.04 to 0.14)	<0.001[*]	0.12 (0.04 to 0.31)	<0.001[*]
Female	1		1	
Gestational Age (weeks)				
≤ 30	2.61 (1.45 to 4.68)	<0.001[*]	2.31 (0.67 to 7.89)	0.181
> 30	1		1	
Maternal Education Status				
Illiterate	3.65 (2.03 to 6.55)	<0.001[*]	3.31 (1.08 to 10.17)	0.036[*]
Secondary or Higher Secondary	0.93 (0.50 to 1.72)	0.819	4.85 (1.40 to 9.76)	0.011[*]
Intermediate or above	1		1	
Birth Weight (kg)				
≤ 1.8	1.76 (1.11 to 2.77)	0.015[*]	2.63 (0.98 to 7.02)	0.054
> 1.8	1		1	
Family Income (pkr)				
≤ 45,000	2.26 (1.42 to 3.59)	<0.001[*]	3.70 (1.40 to 9.76)	0.008[*]
> 45,000	1		1	
Oxygen Dependency (days)				
≤ 4	0.05 (0.03 to 0.09)	<0.001[*]	0.04 (0.01 to 0.12)	<0.001[*]
> 4	1		1	
NICU Stay (days)				
≤ 12	0.03 (0.01 to 0.05)	<0.001[*]	0.02 (0.01 to 0.08)	<0.001[*]
> 12	1		1	
Sepsis				
Yes	2.25 (1.32 to 3.82)	0.003[*]	0.85 (0.20 to 3.50)	0.822
No	1		1	
Mechanical Ventilation Applied				
Yes	3.18 (1.83 to 5.50)	<0.001[*]	2.75 (0.63 to 11.98)	0.176
No	1		1	

-NICU: Neonatal Intensive Care Unit

cOR: Crude odds ratio, aOR: Adjusted odds ratio, CI: confidence interval, *p-value ≤ 0.05

introduce recall bias. Despite these limitations, our study has notable strengths. It provides valuable data on the prevalence and risk factors of ROP in a public sector setting in Karachi, addressing a significant gap in local neonatal research. The use of well-defined operational criteria for ROP, oxygen dependency, and other key variables strengthens the reliability of our findings. Future research should aim to validate our findings through multi-center studies that encompass both public and private hospitals, enhancing the generalizability of results. Prospective cohort studies would be particularly valuable in examining causality and temporal relationships between risk factors and ROP development. Additionally, larger sample sizes could help to identify less common risk factors and investigate any regional variations in ROP prevalence. Research on preventive strategies, including optimal oxygen therapy protocols and infection control in NICUs, could further aid in reducing ROP incidence. Lastly, exploring the psychosocial aspects, such as maternal support and access to health education, may provide comprehensive insights into modifiable risk factors, guiding more effective ROP prevention program.

CONCLUSION

This study identified ROP as a prevalent health concern, affecting nearly half of preterm infants, underscoring ROP as a major health concern in neonatal care. Key risk factors for ROP include maternal illiteracy, low family income, prolonged oxygen dependency, extended NICU stay. The findings emphasize the need for targeted interventions, such as improving maternal education, enhancing neonatal care practices, and

addressing socioeconomic disparities, to lower the prevalence of ROP and improve outcomes for preterm infants.

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