ORIGINAL ARTICLE

Clinico-epidemiological Profile of Retinopathy of Prematurity in Preterm and Low Birth Weight Neonates in a Peripheral Tertiary Care Hospital

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ABSTRACT

Background and objectives: The survival rate of premature low-birth-weight newborns is increasing globally as a result of the swiftly growing number of neonatal intensive care units with cutting-edge infrastructure. The preterm low-birth-weight babies face several complications. One notable complication is retinopathy of prematurity (ROP), which can lead to blindness and visual impairment. It is the outcome of the interplay of multiple risk factors. However, there is a dearth of information regarding the exact magnitude of ROP and the identification of risk factors, especially in lower- and middle-income nations like India. Therefore, the purpose of this study is to identify risk variables among enrolled newborns and to estimate the incidence of ROP. **Methods:** This hospital-based prospective observational study included 179 newborns who met the inclusion criteria over 1.5 years. All research participants were screened at the District Early Intervention Centre by an authorised ophthalmologist. The enrolled neonates' data, including ROP reports, were entered into the pre-made proforma and analysed with SPSS-22 software. **Results:** Of the neonates who were enrolled, 55.3% were boys, and the remaining 44.7% were girls; the incidence of ROP was 11.17%. The multivariate logistic regression model determined the independent risk factors for ROP to be blood transfusion (AOR: 14.93, 95% CI: 3.16-70.47, P value = 0.0006), ionotropic use (AOR: 4.89, 95% CI: 1.29-18.6, P value = 0.0199), and apnoea of prematurity (AOR: 7.93, 95% CI: 1.54-40.8, P value = 0.0132). **Conclusion:** We found that, in addition to well-known risk factors, including oxygen therapy and a preterm low birth weight baby, apnoea of prematurity, ionotropic usage, and blood transfusions were independent risk factors for ROP. Hence, these risk variables are to be addressed meticulously at all levels of newborn care facilities.

KEY WORDS: Low birth weight, Neonates, Preterm, Retinopathy of prematurity, Risk factors

Introduction

An estimated 15 million premature newborns are born each year, representing an 11% global preterm birth rate[1]. A third of the morbidity among children under five is caused by complications that premature neonates encounter. Retinopathy of prematurity (ROP) is one such retinal problem. It may be insignificant with no visual impairments, or it may become aggressive with the formation of new vessels (neovascularization) and lead to blindness, scarring, and retinal detachment. ROP, which fortunately regresses on its own in most affected infants, may be present in about one-third of neonates undergoing screening to some degree; in a few instances, it advances to the stage of retinal detachment and blindness[2, 3]. Heath coined the term "retinopathy of prematurity" in 1951, whereas Terry originally referred to the initial changes in the eyes of surviving premature babies in 1942 as "retrolental fibroplasia"[4]. Although the occurrence of ROP is typically associated with preterm delivery, the risk for its occurrence is a result of the interaction of multiple factors[5]. Low birth weight (BW) < 1500 g and early gestational age (GA) ≤ 30 weeks are without a doubt the most significant risk factors for the development of ROP. Other factors that contribute to the development of ROP include the proportion of oxygen in the air that is inhaled, hypoxia, respiratory distress syndrome, twin pregnancy, anaemia, blood transfusions, fungal infections, sepsis, and intraventricular haemorrhage[6-9]. According to the International Classification of Retinopathy of Prematurity (ICROP), ROP should be monitored by three

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zones and five phases. Other risk factors for the progression of ROP are referred to as "plus disease" and the emergence of aggressive ROP, also known as AP-ROP[10]. According to the world's updated standards, it is crucial to begin ROP screening in premature newborns at risk as soon as possible due to serious vision impairment and potential blindness. Depending on the maturation of retinal blood vessels, an ophthalmologist may recommend additional monitoring.[11] According to CRYO-ROP and Etrop research, cryotherapy, laser photocoagulation, cerclage, pars plana vitrectomy (VPP), and the use of drugs that block vascular endothelial growth factor (VEGF) are all effective treatments for retinopathy of prematurity[11, 12].

Rationale of this study: The rapid expansion of neonatal intensive care units (NICUs) has resulted in a rise in the survival rate of preterm and low birth weight babies globally, which has increased the burden of ROP. Many studies on ROP were conducted in high-income countries; however, there is a dearth of information regarding it in low- and middle-income (LMIC) countries, such as India. Therefore, our goal in doing this research was to estimate the incidence of ROP by promptly screening newborns at risk and attempting to identify risk variables in a peripheral tertiary care hospital located in the eastern part of India. Concerned stakeholders may find it useful to plan for cutting-edge infrastructure to solve the ROP by understanding the precise burden and risk factors. Additionally, it will bridge the knowledge gap among the carers of the tiny newborn and provide baseline data for further research.

Aims and Objectives: To determine the prevalence and stages of ROP among preterm and low birth weight neonates, and to identify the neonatal risk factors associated with the development of ROP.

Methodology

Study area: Special Newborn Care Unit (SNCU) and District Early Interventional Centre (DEIC) of Bankura Sammilani Medical College and Hospital (BSMCH).

Study design: Hospital-based prospective observational study. Study period: December 2022 to May 2024.

Study Population: Neonates admitted to the SNCU during the study period.

Study subjects: Inclusion criteria – i. All newborns born at 34 weeks or less gestational age. ii. Late preterm (>34 weeks - <37 weeks of gestational age) with the presence of one or more risk factors, i.e., respiratory distress, perinatal asphyxia (PNA), apnea, sepsis, shock, exchange transfusion, blood transfusion, intraventricular hemorrhage, poor postnatal weight gain, and prolonged oxygen therapy, iii. All Low-birth-weight neonates weighing <2000 grams admitted to SNCU and gestational age not known, iv. were allowed to go home following successful treatment and returned for ROP screening, and v. Those parents have given consent. Exclusion criteria –i. Term neonates, ii. Neonates with congenital anomaly, iii. Neonates lost to follow-up, and iii. Those parents did not give consent.

Calculation of sample size: We applied Cochran's formula ($n = Z^2 \times P \times (1-P)/d^2$) to calculate the sample size. Where n = sample size, normal standard variate at 95% confidence interval, and it is 1.96, P = percentages of event of interest, which is 30% as per previous study,[13] and d = precision error, which is 7. Putting all these values $n= (1.96)^2 \times 30 \times 70/ (7)^2 = 164.64$. Adding 10% non-respondents to the calculated value, the final sample size was n=164.64+16 ≈181.

Selection of study subjects: All the neonates fulfilling the inclusion criteria were enrolled consecutively until the final sample size was achieved and were subjected to screening for retinopathy of prematurity (ROP) at DEIC at the specific postnatal age, i.e., 4 weeks. ROP screening was performed either before discharge, or the caregiver of the enrolled baby was asked to come for ROP at the prescribed date if the baby was discharged before 4 weeks of postnatal age. All enrolled neonates were screened by an Ophthalmologist designated for the same at DEIC. Data about basic demography, treatment modalities, complications, if any, during hospital stay, and ROP reports were collected in the pre-designed proforma.

Statistical analysis: Two enrolled neonates were lost to follow-up to DIEC within a specific period. Hence, we collected data from 179 neonates. Data was put into the Microsoft Excel Sheet and was analyzed with the help of SPSS 22 software. The continuous variables were expressed in terms of mean and standard deviation, whereas categorical variables were measured as rates and ratios. Chi-square tests, univariate logistic regression, and multivariate logistic regression were done to find out any association between ROP and risk factors. The P value <0.05 was set as statistically significant.

Ethical approval: The Institutional Ethics Committee approved this study.

Results

[Table. 1] shows the basic characteristics of the 179 enrolled newborns we studied in this hospital-based prospective observational analysis. According to the present study, there were more boys than girls (55.3% vs. 44.7%). The majority of the newborns (96.5%) were delivered normally (74.3%) and at the health care facility. Seventy-two percent of neonates were inborn, and 28.5% were outborn. The contributions of late preterm and low birth weight neonates were 36.31% and 59.22%, respectively, when gestational age and birth weight were considered. The incidence of ROP among the study participants was 11.17% (n=20).

Table 1: Basic characteristics of study subjects (n=179)

Variables	Subgroup	Number	Percentages
Gender	Male	99	55.3
	Female	80	44.7
Residence	Rural	165	92.18
	Urban	14	7.82
Place of delivery	Institutional	173	96.5
	Home	6	3.5
Mode of delivery	NVD	133	74.3
	AVD	12	6.7
	LUCS	34	19.0
Type of pregnancy	Single	144	80.4
	Multiple	35	19.6
Type of admission	Inborn	128	71.5
	Out born	51	28.5
Maturity status	Extremely preterm	2	1.12
	Severe preterm	35	19.55
	Moderate preterm	52	29.05
	Late preterm	55	30.73
	Not known	35	19.55
Birth weight	ELBW	9	5.03
	VLBW	64	35.75
	LBW	106	59.22
ROP	Present	20	11.17
	Absent	159	88.83

The different stages of ROP found at the time of screening are shown in [Table. 2]. The largest contribution was made by Stage 2 ROP without Plus Disease (35%). However, the lowest contributions (5% each) came from Stage 4 ROP without Plus Disease and Stage 2 ROP with Plus Disease.

Table 2: Different stages of ROP at the time of screening (n=20)

Stages of ROP	Number	Percentages
A-ROP	3	15
Stage 1 ROP without Plus Disease	4	20
Stage 2 ROP without Plus Disease	7	35
Stage 2 ROP with Plus Disease	1	5
Stage 3 ROP without Plus Disease	2	10
Stage 3 ROP with Plus Disease	2	10
Stage 4 ROP without Plus Disease	1	5

We did univariate logistic regression analysis of all documented risk factors of ROP, which is illustrated in [Table. 3] and found that gestational age ≤34 weeks (COR; 10.60, 95% CI: 2.38-47.22, P -value = 0.0019), VLBW (COR:10.42, 95% CI: 2.32-37.10, P-value = 0.0002), PNA (COR:3.36, 95% CI: 1.17-9.69, P-value = 0.025), oxygen therapy (COR: 9.5, 95%CI: 1.24-72.89, P-value = 0.03), artificial ventilation (COR: 7.02, 95% CI: 2.63-18.76, P-value = 0.0001), apnea of prematurity(COR: 7.6, 95% CI: 2.61-22.14, P-value = 0.0002), ionotropic support (COR:6.72, 95%CI:2.42-18.63, P - value = 0.0025), neonatal sepsis (COR: 4.15, 95%CI:1.33-12.97, P-value = 0.014), and blood transfusion(COR: 7.42, 95%CI: 2.67-20.68, P-value = 0.0001) were associated with statistically significant increased risk of ROP. However, multiple pregnancies (COR: 1.84, 95% CI: 0.65-5.19, P-value = 0.247) and female neonates (COR: 1.04, 95% CI: 0.41-2.65, P-value = 0.93) weren't associated with an increased risk of ROP.

Table 3: The univariate logistic regression shows an association between risk factors and ROP

Variables	X^2 value	95% CI	COR	P value
Female neonates	0.007	0.41-2.65	1.04	0.93
≤34 weeks gestation	15.74	2.38-47.22	10.60	0.0019
VLBW	18.80	2.32-37.10	10.42	0.0002
Multiple pregenancy	1.25	0.65-5.19	1.84	0.247
PNA	5.64	1.17-9.69	3.36	0.025
Oxygen therapy	8.84	1.24-72.89	9.5	0.03
Artificial ventilation	15.26	2.63-18.76	7.02	0.0001
Apnea of prematurity	16.38	2.61-22.14	7.6	0.0002
Ionotropics supports	14.89	2.42-18.63	6.72	0.00025
Sepsis	7.31	1.33-12.97	4.15	0.014
Blood transfusion	16.42	2.67-20.68	7.42	0.0001

Table 4: The multivariate logistic regression shows an association between risk factors and ROP

Variables	Coeffi-cients	S.E	AOR	95% CI	P value
GA <34 weeks	1.530	0.978	4.62	0.68 -31.41	0.118
VLBW	0.939	0.796	2.56	0.54 -12.16	0.238
PNA	0.483	0.815	1.62	0.33 -8.01	0.554
Oxygen therapy	0.604	1.364	1.83	0.13 -26.5	0.658
Artificial ventilation	0.240	0.960	1.27	0.19 -8.35	0.802
Apnea of prematurity	2.071	0.836	7.93	1.54 -40.8	0.0132
Ionotropic supports	1.588	0.682	4.89	1.29 -18.62	0.0199
Neonatal sepsis	1.103	1.093	3.01	0.35 -25.69	0.3129
Blood transfusion	2.70	0.792	14.93	3.16 -70.47	0.0006

Chi Square (X^2) value: 62.2

Furthermore, we carried out multivariate logistic regression analysis [Table. 4] of all risk factors that the univariate analysis had found to be significant. We observed that only three risk variables were statistically significant and independently associated with increased

risk of ROP: blood transfusion (AOR: 14.93, 95% CI: 3.16-70.47, P value = 0.0006), ionotropic support (AOR: 4.89, 95% CI: 1.29-18.6, P value = 0.0199), and apnoea of prematurity (AOR: 7.93, 95% CI: 1.54-40.8, P value = 0.0132). Despite being considered risk factors, other variables such as neonatal sepsis, VLBW, PNA, oxygen therapy, artificial ventilation, and gestational age <34 weeks didn't show independent significance in this model (P value > 0.05).

Discussion

A potentially blinding disease known as retinopathy of prematurity could affect prematurely born babies who have received extensive neonatal care[14, 15]. Apnoea of prematurity, neonatal sepsis, mechanical ventilation, blood transfusions, ionotropic usage, inadequate weight growth after birth, and incorrect oxygen therapy are all risks associated with ROP. Therefore, avoiding risk factors and being well-informed about them are important to lowering ROP. The vision of infants can also be effectively preserved with early identification and prompt laser treatment[16].

Of the 179 participants in the present study, 11.17% (n=20) of the newborns experienced ROP. Alajbegovic-Halimic J *et al.*[17] and Thomas K *et al.*[18] observed ROPs of 12.7% and 11.94%, respectively, among their cohorts, which is comparable to the present study. In contrast, a number of authors from around the world have reported 23.2%, 38%, and 48.5% of ROP in their study patients, respectively. These authors include Chang JW (48.5%), Dani C *et al.* (38%), and Yau GSK *et al.* (23.2%)[19-21]. The difference in the study subjects may be the cause of this discrepancy in the incidence of ROP. While they selected neonates with gestational ages 24 – ≤ 32 weeks, we enrolled neonates with gestational ages 24 – ≤ 37 weeks.

According to Dani C *et al.*,[20] the ROP in stages 1, 2, and 3 was 18%, 61%, and 21%, respectively. The present study is similar in that we discovered 20%, 40%, and 20% of ROP in stages 1, 2, and 3, respectively. However, Dani C *et al.* did not identify A-ROP (15%) or stage 4 (5%), although the present study did find both. Their enrolled neonates may have variable risk factors, which could explain this discrepancy.

The following risk factors were associated with a statistically significant increased risk of ROP in a univariate logistic regression model: gestational age ≤34 weeks (P-value = 0.0019), VLBW (P-value = 0.0002), PNA (P-value = 0.025), oxygen therapy (P-value = 0.03), artificial ventilation (P-value = 0.0001), apnoea of prematurity (P-value = 0.0002), ionotropic support (P-value = 0.0025), neonatal sepsis (P-value = 0.014), and blood transfusion (P-value = 0.0001). On the other hand, multiple pregnancies (P-value = 0.247) and female neonates (P-value = 0.93) were not associated with a higher risk of ROP. However, there was a 1.04-fold increase in the odds of ROP in female newborns (OR = 1.04) and a 1.84-fold increase in the odds of ROP in multiple pregnancies (OR = 1.84).

In the present study, only the use of ionotropics (AOR: 4.89, 95% CI: 1.29-18.62, P-value = 0.0199), blood transfusions (AOR: 14.93, 95% CI: 3.16-70.47, P-value = 0.0006), and apnoea of prematurity (AOR: 7.93, 95% CI: 1.54-40.8, P-value = 0.0132) were all independently related to an increased risk of ROP in the multivariate logistic regression model. However, factors such as gestational age <34 weeks, VLBW, PNA, oxygen therapy, artificial ventilation, and neonatal sepsis that were statistically significant in the univariate logistic regression model lost their significance (P value > 0.05) in this model, probably as a result of overlapping effects or a small sample size.

Similar to the current investigation, Yau GS *et al.*[19] discovered that, on univariate analysis, low birth weight, preterm neonates, and inotropic use are independent risk factors for ROP, while on multivariate analysis, preterm babies and mechanical ventilation are. In a Turkish study, Kavurt S *et al.* found that small for gestational age and sepsis were independent risk factors for ROP[22]. In line with research by Dani C *et al.*,[20] Slidsborg C *et al.*,[23] and Bas AY *et al.*,[24] our investigation showed that blood transfusion is a risk factor for ROP on its own.The association between blood transfusions and ROP has been explained by the pro-oxidant effect of transfusions, which is in turn due to the increase in oxygen delivery to the retina secondary to lower oxygen affinity of adult haemoglobin in packed red cells and iron overload[25].

The study's key observation was that apnoea of prematurity (AOR: 7.93, 95% CI: 1.54-40.8, P-value = 0.0132) is an independent risk factor for ROP. 85% of newborns delivered at or before 34 weeks gestation have apnoea of prematurity, one of the most prevalent problems[26]. It frequently requires breathing assistance for survival, which raises the risk of ROP[2, 27]. Variations in arterial oxygen saturation brought on by apnoea of prematurity result in intermittent hypoxia, which raises superoxide levels and inhibits superoxide dismutase[28]. Superoxide plays a role in abnormal neovascularisation, inflammation, and retinal blood vessel disruption[29].

Limitations of the present study:

The following are some of the study's limitations: (i) Follow-up of neonates after discharge may be incomplete, leading to possible underestimation of late-onset ROP cases. (ii) Certain confounding factors, such as

duration of oxygen therapy, type of ionotropics used and their dose and duration, may not be uniformly documented. (iii) Resource limitations in peripheral centres may affect the frequency and accuracy of ophthalmologic screening. (iv) We only screened our cohort and did not treat and follow up with the neonates who had ROP.

Conclusion

Despite limitations, we identified that apnoea of prematurity, use of ionotropics, and blood transfusions were the independent risk factors for ROP, aside from well-known risk factors including oxygen therapy and a preterm low birth weight baby. Therefore, per current guidelines, oxygen therapy should be dealt with in combination with the prevention of premature delivery, timely management of apnoea of prematurity, careful administration of ionotropics, and blood transfusions. To stop childhood blindness, the ROP programmes must be intensified immediately. Three main programmes currently offer a range of services to prevent blindness from ROP. They are the National Programme for Control of Blindness and Visual Impairment (NPCB and VI), Rashtriya Bal Swasth Karyakram (RBSK), Ministry of Health and Family Welfare, and Child Health.

Declaration

Conflict of interest: The authors declare no conflict of interest among them.

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Ethical approval: The Institutional Ethics Committee approved this research work (Vide memo no. BSMC/IEC/3389, dated 29.09.2022).

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