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Incidence and risk factors of retinopathy of prematurity in Medina city, Saudi Arabia

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ABSTRACT

Retinopathy of prematurity (ROP) is the most common cause of childhood blindness. It is a proliferative retinopathy of premature, low birth weight (BW) infants. This study aimed to report the incidence and risk factors of ROP in premature infants in Medina, Saudi Arabia. The data of premature infants recorded between January 2019 and December 2022 were reviewed. Gender, gestational age, birth weight, Apgar score, length of hospital stays, existence of systemic disorders, congenital anomalies, quantity and duration of oxygen therapy, presence of ROP, severity and location were all gathered and examined. *Results:* Among 101 premature infants, 25.74% had ROP and 65.4% had bilateral presentation. Patients who developed retinopathy had a lower gestational age and BW ($p < 0.001$*) than those who did not develop retinopathy. Moreover, they had statistically lower Apgar scores at 1 min and were exposed to longer duration of oxygen therapy ($p < 0.05$*) than patients who did not develop retinopathy. *Conclusions:* The incidence of ROP was 25.74% and low BW and low gestational age were independent main risk-factors for ROP development.

Keywords: Retinopathy of prematurity, Gestational age, Oxygen therapy

1. INTRODUCTION

Retinopathy of prematurity (ROP) was first described in 1942 by Terry and it was previously known as Terry's syndrome (Chen et al., 2011). It is a proliferative vascular disorder that affects the growing retinal vessels of infants who are born with a gestational age of <32 weeks or weighing <1500 g (Sen et al., 2020). The main avoidable cause of childhood blindness is ROP (Shah et al., 2016). The retina generally shows a physiological hypoxic condition during pregnancy. By producing large amounts of vascular endothelial growth factor (VEGF), this promotes retinal angiogenesis. The nasal retina takes 36 weeks and the temporal retina 40 weeks to fully vascularize from the optic disc to the periphery. Therefore, following birth exposure to high level of oxygen concentrations generally halts vascular development, leaving the areas of retina without blood supply (Brown and Nwanyanwu, 2022).

Neovascularization develops off the surface of the retina and continued

growth and contraction of the fibro vascular tissue may cause retinal detachment (Hakeem et al., 2012). ROP is categorized according to zones and stages. A circle with a radius equal to twice the disc fovea distance is used to define Zone I, Zone II is a circle of the retina from zone I end to the nasal ora serrata while, Zone III represents the remaining temporal crescent. There are five stages of ROP. A thin but distinct white line distinguishes the vascularized retina from the avascular retina in stage 1.

A ridge that emerges from the demarcation line makes up Stage 2. While in stage 3, there is fibrovascular proliferation at the ridge, which extends into the vitreous. Partial retinal detachment occurs in stage 4, which is divided into 4A (extrafoveal) and 4B (foveal). Tractional retinal detachment represents the final stage (stage 5). Worldwide, 43.1% of premature infants who undergo eye examination are diagnosed with ROP and 6.9% of them undergo treatment (Alajbegovic-Halimic et al., 2015). In Saudi Arabia, the incidence rate of ROP in Riyadh was reported to be 56% (Marinov et al., 2017).

Different studies have been done in Tabuk and Jeddah, detecting a similar incidence of 33% (Badeeb et al., 2021). The most significant and effective causal factors for ROP development include low birth weight (BW), gestational age and Apgar score at 5 min, in addition to hypoxia and prolonged duration of oxygen supplementation (Alajbegovic-Halimic et al., 2015; Marinov et al., 2017). In our clinical practice, we have observed a significant number of ROP cases in Medina, Saudi Arabia, which is one of the largest cities in the west of the kingdom. However, during our literature review, we found no studies that investigated the incidence rate of ROP in our region. Therefore, we designed this retrospective study to report the incidence of ROP in premature infants and investigate its common risk factors in Medina, Saudi Arabia.

2. MATERIAL AND METHODS

This retrospective cross-sectional study was done at the Maternity and Children's Hospital in Medina and aimed at measuring the incidence rate of ROP and predicting the related risk factors among the premature infants from January 2019 to December 2022. Data were obtained from medical records after reviewing to meet the inclusion criteria. Premature infants with a gestational age of <34 weeks or a BW of not >1500 g were included in the study after ensuring their parents of the confidentiality of the collected information and that it was used only for the aim of this study.

A structured questionnaire was prepared with two sections. The first section consisted of questions concerning the demographic characteristics of the newborn infants, such as gender, gestational BW and age, oxygen therapy duration, A-P-G-A-R score at one and five mins and family history of prematurity and ROP. The second section was related to the clinical characteristics of the newborn infants, such as the presence of systemic diseases, respiratory distress syndrome, hypoglycemia, intraventricular hemorrhage, neonatal jaundice, pneumothorax and blood diseases, including leukopenia and infection (sepsis).

Ophthalmic examinations were conducted to detect the presence of ROP, location and severity, which were performed by expert retinal consultants. The questionnaire was tested for reliability and validity through a pilot study, including 10% of the sample, which was excluded from the results of the study after revising the questionnaire by two retinal consultant experts. Version 26 of the Statistical Packge for Social Science (SPSS) was used for data collection and analysis. For quantitative data, mean and standard deviation (SD) were employed and percentages were used to represent qualitative data.

2 different groups of normally distributed data were compared using independent t-tests and two groups of non-normally distributed variables were compared using the Mann-Whitney test. Logistic regression was used to examine a number of risk factors. P values under 0.05 were considered significant. Official permission was obtained from the Research Ethics Committee. Informed written consent was obtained from all the caregivers of the participants after describing the aim of this study. Privacy and confidentiality were assured.

3. RESULTS

This retrospective study included 101 premature infants with a median (IQR) age of 5 (4–12.5) months and BW of 1400 (1061–1865) g. The mean gestational age of the study group was 31.44 ± 3.27 weeks. The median duration of oxygen therapy was 11 (3–30) days. The mean Apgar scores were 6.43 ± 2.02 and 7.80 ± 1.45 at 1 and 5 min, respectively (Table 1).

As in Table 2, 63.4% of the study group comprised boys. Approximately 80.2% of the infants received oxygen therapy, 75.2% of them had systemic diseases, 11.9% had a positive history of prematurity and 53.5% suffered from respiratory distress syndrome. A total of 26 infants (25.74%) were found to have ROP of different degrees.

Table 1 Clinical characteristics of the study group (n = 101)

Variables	Study group (n = 101)
Age (months)	
Mean ± SD	11.02 ± 12.12
Median (IQR)	5 (4–12.5)
Gestational age (weeks)	
Mean ± SD	31.44 ± 3.27
Median (IQR)	32 (29–34)
Gestational weight at birth (g)	
Mean ± SD	1481.71 ± 525.85
Median (IQR)	1400 (1061–1865)
Oxygen therapy duration (days)	
Mean ± SD	20.61 ± 23.34
Median (IQR)	11 (3–30)
APGAR score at 1 min	
Mean ± SD	6.43 ± 2.02
Median (IQR)	6 (5–8)
APGAR score at 5 min	
Mean ± SD	7.80 ± 1.45
Median (IQR)	8 (7–9)

Table 2 Distribution of different demographic and clinical characteristics of the study group

Variables	No	%
Gender		
Male	64	63.4
Female	37	36.6
Multiple birth		
Twins	7	6.9
Triplets	3	3
Family history		
Prematurity	12	11.9
ROP	2	2
Oxygen therapy	81	80.2
Presence of Systemic diseases	76	75.2
Respiratory distress syndrome	54	53.5
Hypoglycemia	4	4
Intraventricular hemorrhage	2	2
Neonatal jaundice	12	11.9
Pneumothorax	2	2
Leukopenia	2	2
Sepsis	15	14.9
Presence of ROP by examination		
Yes	26	25.7
No	75	74.3

ROP: Retinopathy of prematurity.

As in Figure 1, 15.8% of the neonates had congenital anomalies, with congenital heart diseases being found in 24.8% of them. According to Figure 2, 65.4% of ROP cases were bilateral, 61.5% of cases were in stage 1 and 73.15% were in Zone III. Only 4 cases (15.4%) required intervention.

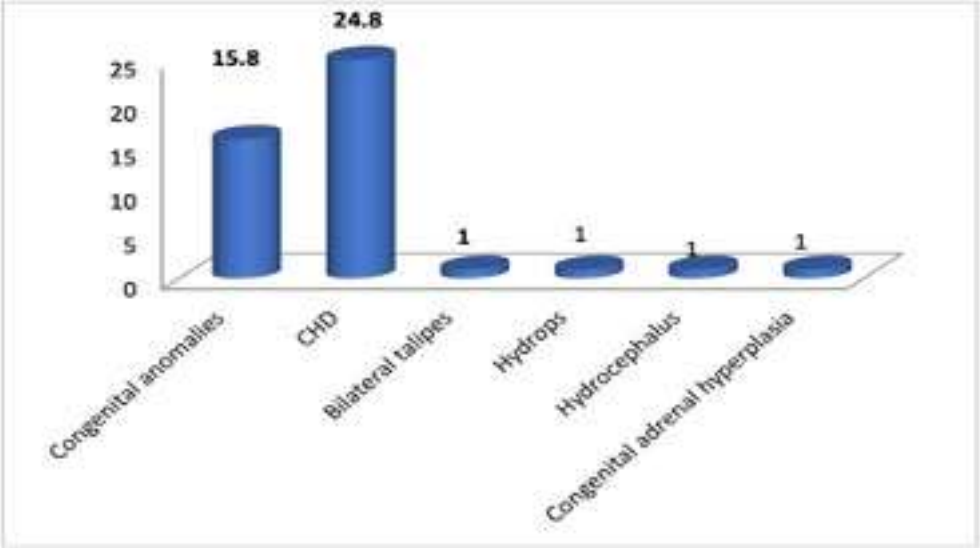

Figure 1 Distribution of congenital anomalies among the study group

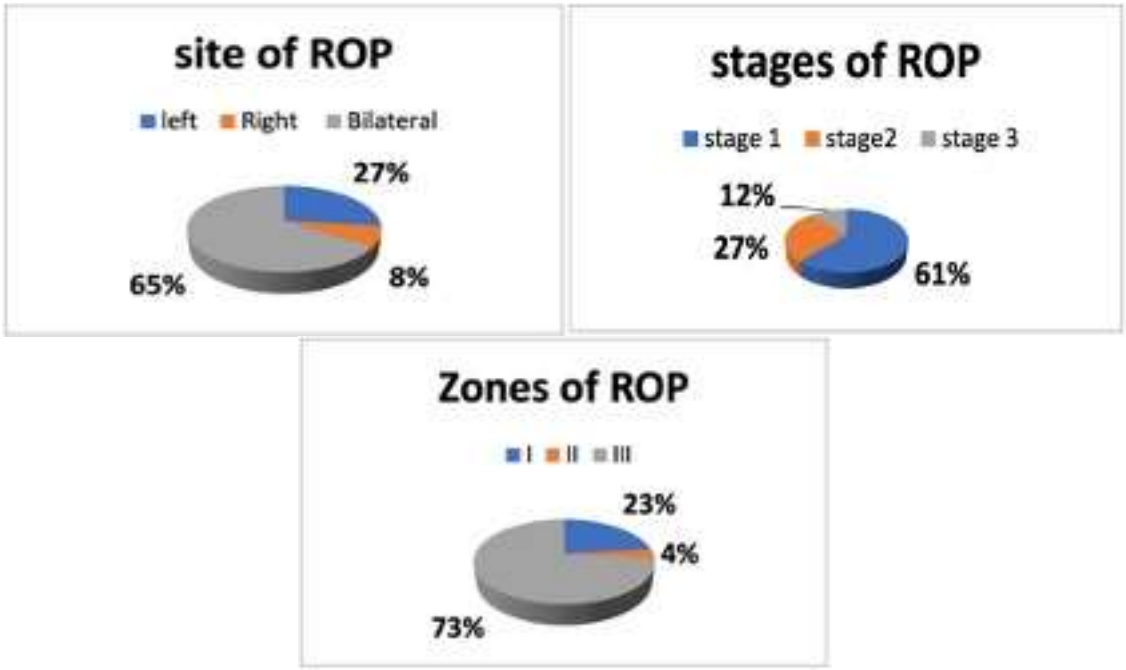

Figure 2 Clinical characteristics of the group with retinopathy of prematurity

Regarding the possible risk factors for ROP, we detected a highly statistically significant difference between patients who developed retinopathy and those who did not regarding gestational age and BW. We observed that patients who developed retinopathy had lower gestational age and BW ($p < 0.001$*) than those who did not develop retinopathy. Furthermore, patients who developed retinopathy had statistically lower Apgar scores at 1 min and were exposed to longer duration of oxygen therapy ($p < 0.05$*) than those who did not develop retinopathy (Table 3).

Table 3 Different possible risk factors between patients with ROP and those without ROP

Variables	With retinopathy (n = 26)	Without retinopathy (n = 75)	Test	P value
Gestational age (weeks)				
Mean ± SD	28.53 ± 2.87	32.45 ± 2.77	6.140	<0.001*
Gestational weight at birth (g)				
Mean ± SD	1135.26 ± 312.40	1601.81 ± 532.83	4.212	<0.001*
A-P-G-A-R score at 1 min				
Mean ± SD	5.40 ± 2.23	6.77 ± 1.848	2.734	0.008*
A-P-G-A-R score at 5 min				
Mean ± SD	7.57 ± 1.12	7.88 ± 1.55	0.783	0.436
Duration of oxygen therapy				
Mean ± SD	31.05 ± 22.39	16.11 ± 14.6	−2.1	0.04*
Median (IQR)	28 (4–31)	7 (3–28)		

[a]Independent *t*-test [b]Mann–Whitney test

The need for oxygen therapy, low BW and the need for resuscitation were the significant risk factors associated with increased ROP development (Table 4). No association was detected between congenital anomalies and ROP development, as in (Table 5).

Table 4 Possible risk factors for the increase development of retinopathy of prematurity

Variables	With retinopathy (n = 26)		Without retinopathy (n = 75)		CI	P value
	N	%	N	%		
Gender						
Male	16	25	48	75	(0.443–2.78)	0.822
Female	10	27	27	73		
Oxygen therapy	25	30.9	56	69.1	(1.016–63.562)	0.022*
Birth weight (g)						
<1000	9	56.2	7	43.7	----------	<0.001*
1000–1500	16	32	34	68		
>1500	1	2.8	34	97.14		
Resuscitation	20	37	34	63	(1.229–9.584)	0.015*
Family history of prematurity	2	16.7	10	83.3	(0.405–4.345)	0.812
Family history of ROP	1	50	1	50	(0.178–49.09)	0.438
Systemic disease	22	28.9	54	71.1	(6.951–0.658)	0.199
Feeding imbalance	1	100	0	0	(0.351–0.178)	0.088
Respiratory distress syndrome	18	33.3	36	66.7	(6.290–0.945)	0.061
Hypoglycemia	0	0	4	100	(0.826–0.649)	0.230
Interventricular hemorrhage	2	100	0	0	(0.343–0.171)	0.015*
Candida infection	1	100	0	0	(0.178–0.351)	0.088
Neonatal jaundice	3	25	9	75	(0.238–3.841)	0.950
Pneumothorax	1	50	1	50	(0.178–49.09)	0.428
Leukopenia	1	50	1	50	(0.178–49.09)	0.428
Sepsis	4	26.7	11	73.3	(0.305–3.665)	0.929
Twins	2	28.6	5	71.4	(0.212–6.413)	0.859
Triplets	1	33.3	2	66.7	(0.127–16.802)	0.760
Fetal distress	0	0	1	100	(0.659–0.831)	0.554

Chi-squared test (χ^2)

Table 5 Comparison of congenital anomalies between patients with ROP and those without ROP

Variables	With retinopathy (n = 26)		Without retinopathy (n = 75)		CI	P value
	N	%	N	%		
Congenital anomalies	6	37.5	10	62.5	(0.630–6.033)	0.241
CHD	5	41.7	7	58.3	(0.664–8.054)	0.179
PDA	3	50	3	50	(0.591–16.592)	0.161
ASD	2	50	2	50	(0.406–22.780)	0.258
TR	0	0	1	100	(0.659–0.831)	0.554
VSD	0	0	1	100	(0.659–0.831)	0.554
TGA	0	0	1	100	(0.659–0.831)	0.554
Bilateral talipes	1	100	0	0	(0.178–0.351)	0.088
Hydrops	0	0	1	100	(0.659–0.831)	0.554
Hydrocephalus	1	100	0	0	(0.178–0.351)	0.088
Congenital adrenal hyperplasia	1	100	0	0	(0.178–0.351)	0.088

Congenital heart disease = CHD; Patent ductus arteriosus = PDA; Atrial septal defect = ASD; Tricuspid regurgitation = TR; Ventricular septal defect = VSD; Transposition of the great arteries =TGA.

Logistic regression analysis was used to assess the association between ROP and risk factors, which identified gestational age and BW as the in-dependent risk factors for development of ROP (Table 6).

Table 6 Logistic regression analysis for different variables

		B	SE	Wald	df	Sig.	Exp (B)	95% CI for EXP (B)	
								Lower	Upper
Step 1[a]		1.233	.921	1.791	1	.181	3.430	.564	20.858
	Gestational age	−.471	.257	3.371	1	.046*	.624	.377	1.032
	Birth weight	−1.739	1.025	2.877	1	.050*	.176	.024	1.310
	A-P-G-A-R score at 1 min	.062	.251	.060	1	.806	1.064	.650	1.741
	Resuscitation	1.162	1.290	.812	1	.368	3.197	.255	40.072
	Duration of oxygen therapy	−.039	.026	2.197	1	.138	.962	.914	1.013
	Systemic diseases	.178	1.197	.022	1	.882	1.194	.114	12.483
	Congenital anomalies	−2.336	1.439	2.635	1	.105	.097	.006	1.624
	Constant	15.192	7.405	4.209	1	.040	3962057.933		

A: Variable(s) entered in step 1: Gestational age, birth weight, APGAR score at 1 min, resuscitation, duration of oxygen therapy, systemic diseases, congenital anomalies

4. DISCUSSION

ROP is a Vaso proliferative disorder and one of the main causes of preventable blindness worldwide in premature neonates (<32 weeks of gestational age). Approximately 20%–50% of infants weighing <1500 g develop ROP and up to 19% of them present with a severe form. In this study, the incidence rate of ROP among premature infants was 25.74% (n = 26) and approximately 61.5% of them were in stage I. This result was found to be an acceptable percentage compared with other developmental indexes, indicating the advances in neonatal care in Saudi Arabia. However, these percentages are less than those that reported by Badeeb et al., (2021) (31.9% and 56%, respectively, in Riyadh).

The disparities in ROP incidence rates in Saudi Arabia are due to different national screening programs that are applied in different institutes (Marinov et al., 2017; Mgharbil et al., 2020). Akkawi et al., (2019), reported a low incidence rate of ROP (23.5%) in Palestinian infants, whereas Oman and Jordan reported incidence rates of 46.4% and 28.6%, respectively, which are high values. The prevalence rates in Pakistan, Singapore and India were 32.3%, 29.2% and 24%, respectively. The increase in the prevalence of ROP in most of developing countries has been suggested to be due to the high survival rate of extremely premature infants (Ballot et al., 2010).

Several interventions have been evaluated to reduce the incidence rate of ROP among premature infants; however, this evaluation differs from one country to another. Low oxygen saturation in the United States has led to a reduction in the stage of ROP, whereas in other countries, this is a risk for an increasing mortality rate before discharge from the hospital. A reduction in infections and vitamin A supplementation has been reported to decrease the stage of ROP by 30% and vitamin E supplements may also reduce the risk (Fang et al., 2016).

In this study, the mean gestational age for neonates who developed ROP was 28.53 ± 2.87 weeks and it was significantly different compared with neonates who did not develop ROP ($p < 0.001$). This finding is consistent with that observed by Akkawi et al., (2019), who reported a statistically significant difference between the two groups (29.4 ± 1.3 weeks, with a p value of <0.001) and that observed by Nassar, (2016) who also reported a significant difference ($p = 0.012$) with a significant inverse correlation between gestational age and the severity and stage of ROP. However, another study reported ROP development in more mature infants in developed countries (Akkawi et al., 2019; Gilbert et al., 2005).

The American Academy of Pediatrics and Association for Pediatric Ophthalmology recommend retinal screening for those infants who have a BW of ≤1500 g and for those with a BW between 1500 & 2000 grams with an un-stable clinical condition as they may be susceptible to ROP development (Fierson, 2013). In one study, the mean value of the BW of infants with ROP was 1135.26 ± 312.4 g with a statistically significant difference when compared with non-ROP infants ($p < 0.001$). In contrast, Sahin et al., (2014) reported no significant difference regarding BW and Akkawi et al., (2019), showed no significant difference between the two groups in the multivariate analysis, whereas Lermann et al., (2006) and Bassiouny et al., (2017) demonstrated that BW and gestational age were less among the infants with ROP in their multivariate logistic analysis.

Binkhathlan et al., (2008) reported that gestational age was the most significant independent factor. This difference among studies may reveal differences in the level of neonatal and prenatal care, in addition to variations among ethnicities and countries (Liu et al., 2014). Supplementary oxygen therapy used in cases of respiratory distress among premature infants was found to be linked with an increase in the risk of getting ROP. In our study, 66.7% of premature infants had respiratory distress without ROP development due to good oxygen regulation and early screening for ROP. The use of high oxygen saturation (PaO_2 ≥80 mmHg) in preterm infants may cause damage to the capillaries in the retina and result in retinal vasoproliferation and hypoxia (Hartnett and Lane, 2013).

In our multivariate logistic analysis performed for various risk factors such as GA, BW, Apgar score, resuscitation, duration of oxygen therapy, systemic disease and congenital anomalies, we identified two factors (GA and BW) as the independent risk factors for getting ROP. Badeeb et al., (2021) evaluated neonatal and antenatal risk factors for getting of ROP and identified GA, BW, interventricular hemorrhage and long hospital stay as significant risk factors, whereas maternal factors were non-significant. A literature review of 26 studies from different countries identified BW, GA, sepsis, mechanical ventilation and blood transfusion as the most statistically significant risk factors present in ROP cases (Souza et al., 2018). A limitation of our study was its retrospective design with a small sample size.

5. CONCLUSION

The incidence rate of ROP was 25.74%. Multivariate logistic regression analysis identified low BW and low gestational age as independent statistically significant risk factors for getting ROP.

Authors' Contributions

Conceptualization: Majed Tale'a Alharbi
Methodology: Majed Tale'a Alharbi, Haneen Omar Alhujaili
Formal Analysis: Abeer Habeeb Almutairi, Mohammed Ghazi Alsaedi.
Data curation: Abeer Habeeb Almutairi, Mohammed Ghazi Alsaedi
Writing and preparation of the first draft: Haneen Omar Alhujaili
Writing-review and editing: All authors
All authors have read and agreed to the published version of the manuscript.

Informed consent

Written informed consent was obtained from all caregivers of the participants included in the study and informed about the aim of the study.

Ethics Approval and Consent to Participate

Ethics approval was taken from the Research Ethics Committee in Tibah University, Madinah, Saudi Arabia with ethical approval code: TU-20-003.

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Conflict of interest

The authors declare that there is no conflict of interests.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

Appendix

Abbreviations

Abbreviations	Full form
ROP	Retinopathy of prematurity
VEGF	Vascular endothelial growth factor
BW	Birth weight
G	Gram

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