

Retinopathy of Prematurity: Correlating Neonatal Risk Factors with Disease Severity in a Tertiary Referral Center in Shiraz, Iran

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ABSTRACT

Background: Retinopathy of prematurity (ROP) is a preventable cause of blindness in children. This study evaluated the risk factors for ROP in preterm and at-risk neonates.

Methods: This descriptive, analytical, cross-sectional study was conducted at Namazi and Hafez hospitals from April 2020 to March 2021. A sample size of 183 neonates was calculated based on previous studies. Data on demographic and clinical factors, including gestational age, birth weight, sepsis, respiratory support, packed cell transfusion, hypotension, Apgar score, and hypoglycemia, were collected from hospital records. Statistical analyses were performed using SPSS, employing chi-square and logistic regression tests, with a significance level set at $P < 0.05$.

Results: The mean birth weight was 1444.9 ± 335.59 grams, and the mean gestational age was 31.01 ± 2.36 weeks. Lower gestational age and birth weight were significantly associated with ROP ($P < 0.001$). Among infants with a gestational age of less than 34 weeks, ROP severity was significantly associated with blood transfusion ($P < 0.001$), sepsis ($P = 0.003$ for zone, $P = 0.03$ for stage), and severe hypoglycemia ($P < 0.001$ for zone, $P = 0.03$ for stage). In infants born at or after 34 weeks, blood transfusion was the primary factor associated with ROP severity ($P = 0.018$ for zone).

Conclusion: Our study identified lower gestational age, birth weight, blood transfusion, sepsis, and hypoglycemia as significant risk factors for ROP severity in neonates under 34 weeks of gestation. The findings underscore the importance of vigilant monitoring and management of these risk factors to prevent the progression of ROP.

Keywords: Blood transfusion, Premature birth, Retinopathy of prematurity, Sepsis

Introduction

Retinopathy of prematurity (ROP), the second leading cause of blindness in children (1), is a condition characterized by the growth of abnormal blood vessels in the retina. These vessels are fragile, prone to leaking or bleeding, and can cause scarring in the retina, which may

lead to retinal detachment—the primary cause of vision loss and blindness in patients with ROP (2).

Over the past decades, following improved preterm survival rates, the incidence of ROP has increased (3). The incidence of ROP varies widely across different regions of Iran, with rates ranging

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Please cite this paper as:

Rouhafshari M, Barzegar H, Hashemi Z, Oboodi R, Khazaei M, Ziyae F. Retinopathy of Prematurity: Correlating Neonatal Risk Factors with Disease Severity in a Tertiary Referral Center in Shiraz, Iran. Iranian Journal of Neonatology. 2026 Apr; 17(2). DOI: [10.22038/ijn.2026.85247.2636](https://doi.org/10.22038/ijn.2026.85247.2636)

from 1% to 70% (4–11).

In addition to lower gestational age and birth weight, which are the major risk factors for ROP, other significant risk factors include sepsis, bronchopulmonary dysplasia, and a high number of blood transfusions (12). Prompt screening examinations and timely treatment are crucial aspects of effective ROP management (13).

Given the varying incidence of ROP in Iran, it is essential to screen at-risk infants and ensure careful monitoring by experienced ophthalmologists. This is crucial for the timely diagnosis and treatment of ROP, a common complication of prematurity and a preventable cause of visual impairment. This study aims to investigate the incidence of ROP in premature infants admitted to NICUs in Shiraz, the main referral center in southern Iran. Additionally, the study seeks to identify the risk factors associated with ROP in our region and to examine their relationship with the severity and incidence of the condition. Despite several studies on ROP across different parts of Iran, considerable variability remains in reported incidence rates and associated risk factors, likely due to differences in screening criteria, neonatal care quality, and regional healthcare practices. Few studies have comprehensively evaluated these factors in the southern region of Iran, particularly in high-volume tertiary centers like Shiraz. Understanding the local epidemiology and contributing factors is essential to develop region-specific screening guidelines and improve outcomes. Therefore, this study fills an important gap by providing updated, region-specific data that can inform clinical practice and health policy.

Methods

This descriptive-analytical, cross-sectional study was conducted on premature, low-birth-weight, and at-risk infants admitted to the NICUs of Hafez and Namazi Hospitals in Shiraz, the main referral centers in southern Iran, from April 2020 to March 2021. The sample size was estimated at 200 using the formula based on the study by Azami et al., with $\alpha = 0.05$, $p = 0.05$, $\beta = 0.80$, and $d = 0.01$, accounting for a 10% dropout rate (8).

A random census sampling method was used. Inclusion criteria included: (1) All premature infants with a GA of ≤ 34 weeks and/or a birth weight of ≤ 1500 grams, regardless of clinical condition; (2) Infants with a GA between 34 and 37 weeks or a birth weight between 1500 and 2000 grams were also included if they had an unstable clinical condition, as determined by the

attending physician.

Exclusion criteria included incomplete medical files, infant death before the first eye examination, congenital abnormalities, and metabolic diseases.

Demographic information of the eligible infants was collected using a checklist, which included several sections: demographic information, such as gestational age, birth weight, number of infants, method of delivery, and five-minute Apgar score. Additionally, details of the infant's clinical condition from birth to the first eye examination or discharge, including the need for respiratory support, sepsis, blood transfusion or exchange, severe hypoglycemia, and severe hypotension, were collected.

Severe hypotension was defined as blood pressure measurements below the 5th percentile for the infant's gestational and postnatal age.

The third section of the questionnaire included information regarding eye examinations during the first screening and subsequent visits, such as the infant's age on the first ophthalmology visit, the location of the first eye examination, results, and the timing of subsequent examinations.

ROP is classified based on the location and severity of the disease. Zone I is the smallest and most posterior area centered around the optic disc. Zone II surrounds Zone I and extends outward. Zone III is the crescent-shaped temporal area outside Zone II, covering the peripheral retina. For severity, stages are used. Stage 1 is a defined line of demarcation between normal and abnormal retina. Stage 2 is an elevated ridge along the line of demarcation. Stage 3 is a ridge with newly formed blood vessels (vascularized ridge). Stage 4 is defined as partial retinal detachment, and Stage 5 is complete retinal detachment (14).

The first examination was conducted by an expert ophthalmologist at the hospital for neonates still admitted to the NICU at either 28 days of age or 31 weeks of corrected gestational age, whichever was later, following national guidelines (15). The results of this initial examination were used to schedule the follow-up exams. We followed the patients for up to 6 months.

After obtaining the necessary permissions, these checklists were completed based on the medical files, and sometimes through interviews with the infant's treating physician. The collected data were analyzed using descriptive statistics, mean \pm SD, frequency and percentages, Chi-Square test, and logistic regression test in SPSS ver. 19. A P-value of < 0.05 was considered statistically significant.

Ethical approval

The study protocol was approved by the ethics committee of Shiraz University of Medical Sciences (IR.SUMS.MED.REC.1399.397).

Results

The study population included 200 premature and low-weight infants admitted to the NICUs of Namazi and Hafez hospitals in Shiraz between April 2020 and March 2021. Seventeen infants were excluded due to death before the first examination and incomplete questionnaires, leaving 183 infants for statistical analysis. Among the infants, 88 (48.08%) were female and 95 (51.9%) were male. The mean birth weight was 1444.9 ± 335.59 grams, and the mean gestational age was 31.01 ± 2.36 weeks.

Among these, 161 infants (88%) had some degree of ROP, while 22 infants (12%) had normal eye examinations. The majority of participants ($n = 157$, 85.8%) were in Stage I, 1 (0.55%) in Stage II, and 3 (1.63%) in Stage III. One hundred twenty (65.57%) were in Zone II, 1 (0.55%) in Zone I, and 40 (21.86%) in Zone III.

Of the infants studied, 80 (84.2%) male infants and 81 (92%) female infants had some degree of ROP. Although the ROP incidence rate was higher in girls than in boys, this difference was not statistically significant ($P = 0.103$). The incidence of ROP based on birth weight and GA is shown in Table 1 with a statistically significant difference in

different GA and birth weights ($P < 0.001$ for both).

The relationship between ROP incidence and severity with the studied variables was investigated, and the results showed a significant relationship only between ROP incidence with sepsis ($p = 0.01$) and blood transfusion ($p < 0.001$) in the group aged greater than 34 weeks. In the group aged less than 34 weeks, a significant relationship was observed between ROP severity (based on zone) and sepsis ($p = 0.03$), blood transfusion ($p = 0.001$), and severe hypoglycemia ($p < 0.001$). Regarding ROP severity based on stage, the results generally indicated a significant relationship between ROP severity and sepsis ($p = 0.03$), blood transfusion ($p < 0.001$), and hypoglycemia requiring treatment ($p = 0.03$) in the group aged less than 34 weeks (Table 2). These correlations for birth weight are shown in Table 3.

The logistic regression model revealed a significant association between ROP incidence and two specific risk factors: sepsis ($p = 0.005$) and blood transfusion ($p = 0.001$). These findings indicate that both sepsis and blood transfusion are significant predictors of ROP incidence.

During long-term follow-up, 136 infants (74%) had normal eye examinations, 14 infants (7.6%) received laser therapy, and 33 infants (18%) were lost to follow-up due to death, failure to attend clinic visits, or incorrect contact information.

Table 1. The incidence of ROP in different GA and BW.

Demographic information	ROP N (%)	No ROP N (%)	P-value*
Gestational age(week)			
<28	24 (14.9%)	0 (0)	<0.001
28-30	50 (31%)	2 (9.1%)	
30-32	54 (33.54%)	6 (27.3%)	
32-34	25 (15.5%)	10 (45.4%)	
>34	8(4.97%)	4(18.2%)	
Weight (grams)			
<1000	18(11.2)	0 (0)	<0.001
1000-1500	90(55.9)	5 (22.7%)	
1500-2000	53 (33)	17 (77.3%)	

*Assessed by the Chi-square test

P-value <0.05 is considered statistically significant.

Discussion

Our study, involving 183 premature and low-birth-weight infants, found that 88% of the cohort were diagnosed with some degree of ROP. The analysis revealed a significant association between ROP incidence and both birth weight ($P < 0.001$) and gestational age ($P < 0.001$), underscoring these factors as critical risk

determinants. Logistic regression further identified sepsis ($P = 0.005$) and blood transfusion ($P < 0.001$) as significant predictors of ROP incidence, emphasizing their substantial impact on the development of ROP. Additionally, in infants with a gestational age of less than 34 weeks, ROP severity was significantly linked to blood transfusion ($P < 0.001$), sepsis ($P = 0.03$),

Table 2. Correlation between the incidence of retinopathy, stage, and zone, and the studied variables among the gestational age groups

		<34 weeks									>34 weeks										
		ROP			Zone			Stage			ROP			Zone			Stage				
		Yes	No	NI	1	2	3	NI	1	2	3	Yes	No	NI	1	2	3	NL	I	II	III
Sepsis	Yes	89	5	5	1	74	14	5	85	1	3	6	1	1	0	2	4	1	6	0	0
	No	64	13	13	0	42	22	13	64	0	0	2	3	3	0	2	0	3	2	0	0
	P*	0.01			0.003			0.03			0.09			0.09			0.09				
Apgar	≤6	30	1	1	1	23	6	1	29	0	1	1	0	0	1	0	0	0	1	0	0
	>6	123	17	17	0	93	30	17	120	1	2	7	4	4	0	3	4	4	7	0	0
	P	0.14			0.08			0.42			0.46			0.33			0.46				
Respiratory support	Yes	150	18	18	1	115	34	18	146	1	3	8	0	4	0	4	4	4	8	0	0
	No	3	0	0	0	1	2	0	3	0	0	4	0	0	0	0	0	0	0	0	0
	P	0.54			0.27			0.93			**										
Packed Cell	Yes	85	1	1	1	65	19	1	82	0	3	3	0	0	3	0	0	0	3	0	0
	No	68	17	17	0	51	17	17	67	1	0	5	4	4	0	1	4	4	5	0	0
	P	<0.001			<0.001			<0.001			0.15			0.018			0.15				
Hypotension	Yes	8	0	0	0	7	1	0	7	0	1	0	0	0	0	0	0	0	0	0	0
	No	145	18	18	1	139	35	18	142	1	2	8	4	4	0	4	4	4	8	0	0
	P	0.32			0.63			0.09													
Hypoglycemia	Yes	5	1	1	1	3	1	1	4	0	1	0	0	0	0	0	0	0	0	0	0
	No	148	17	17	0	113	35	17	145	1	2	8	4	4	0	4	4	4	8	0	0
	P	0.61			<0.001			0.03													

P-value <0.05 is considered statistically significant.

*Assessed by Chi-Square test.

**Due to the lack of variability in the data and the absence of statistical calculations, no p-value is available for reporting.

Table 3. Correlation between the incidence of retinopathy, stage, and zone, and the studied variables among the birth weight groups

		≤1500										1501-2000									
		ROP		NI	Zone			NI	stage			ROP		NI	Zone			Stage			
		Yes	No		1	2	3		1	2	3	Yes	No		1	2	3	NL	I	II	III
Sepsis	Yes	79	2	2	1	67	11	2	75	1	3	16	4	4	0	9	7	4	16	0	0
	No	29	3	3	0	21	8	3	29	0	0	37	13	13	0	23	14	13	37	0	0
	P*	0.1			0.13				0.25			0.59			0.79			0.59			
Apgar	≤6	22	1	1	1	17	4	1	21	0	1	9	0	4	0	71	15	0	9	0	0
	>6	86	4	0	0	7	2	4	83	1	2	44	17	17	0	25	19	17	44	0	0
	P	0.98			0.26				0.9			0.06			0.08			0.06			
Respiratory support	Yes	105	5	5	1	87	17	5	101	1	3	53	17	17	0	32	21	17	53	0	0
	No	3	0	0	0	1	2	0	3	0	0	0	0	0	0	0	0	0	0	0	0
	P	0.7			0.13				0.96			**									
Packed Cell	Yes	67	0	0	1	54	12	0	64	0	3	21	1	1	0	14	7	1	21	0	0
	No	41	5	5	0	34	7	5	40	1	0	32	16	16	0	18	14	16	32	0	0
	P	0.006			0.04				0.012			0.009			0.02			0.009			
Hypotension	Yes	7	0	0	0	6	1	0	6	0	1	1	0	0	0	1	0	0	1	0	0
	No	101	5	5	1	82	18	5	98	1	2	52	17	17	0	31	21	17	52	0	0
	P	0.55			0.92				0.23			0.56			0.54			0.56			
Hypoglycemia	Yes	5	0	0	1	3	1	0	4	0	1	0	1	1	0	0	0	1	0	0	0
	No	103	5	5	0	85	18	5	100	1	2	53	16	16	0	32	21	16	53	0	0
	P	0.62			<0.001				0.09			0.07			0.2			0.07			

P-value <0.05 is considered statistically significant.

*Assessed by Chi-Square test.

**Due to the lack of variability in the data and the absence of statistical calculations, no p-value is available for reporting.

and severe hypoglycemia ($P = 0.01$). While for infants born at or after 34 weeks, the significant associations were primarily with blood transfusion ($P = 0.02$). These findings highlight the complex nature of ROP and the importance of targeted interventions tailored to gestational age and specific clinical conditions to manage and potentially mitigate the risk of ROP effectively.

Our study underscores the critical relationship between gestational age and the incidence of retinopathy of prematurity (ROP). We observed that a substantial majority of neonates in our cohort exhibited some degree of ROP, with all neonates below 28 weeks, 96% of those born at 28–30 weeks, 90% of those born at 30–32 weeks, and 71% of those born at 32–34 weeks affected. These findings are consistent with the well-established link between earlier gestational age and increased risk of ROP (16). Despite national guidelines recommending screening for neonates born before 30 weeks of gestation or with a birth weight less than 1500 grams (17), in Iran we screen all preterm neonates below 34 weeks. Given the high prevalence of ROP in neonates just below the 34-week threshold, screening all infants born before 34 weeks appears to be a reasonable and prudent approach to identifying and managing ROP effectively in our society. This adjustment in screening practice could potentially enhance early detection and intervention, thereby improving outcomes for at-risk premature infants.

Our study identified sepsis as a significant predictor of ROP incidence and severity, particularly in neonates born before 34 weeks of gestation. This finding aligns with a meta-analysis of 29 studies, which reported that early-onset sepsis is associated with a higher incidence and greater severity of ROP (18). Additionally, late-onset sepsis has also been linked to an increased risk of ROP (19, 20). Given that sepsis is a preventable risk factor, our results underscore the importance of implementing effective strategies to minimize sepsis in premature infants.

Blood transfusion was another risk factor identified in our study. Despite varying results across different studies (21–24), a systematic review and meta-analysis comprising 13 cohort and five case-control studies, which included 15,072 preterm infants and 5,620 cases of ROP, examined the relationship between RBC transfusion and ROP. This analysis found that RBC transfusion significantly increased the risk of ROP in preterm infants, with a pooled odds ratio of 1.50 (95% CI: 1.27–1.76) (25).

ROP is a retinal vascular disease that affects

premature infants and can lead to a broad range of vision disorders, from minor correctable defects in visual acuity to more severe outcomes such as retinal detachment and blindness. Importantly, ROP is often preventable and treatable if diagnosed early; however, if left undetected, it can progress rapidly, leading to blindness (31, 32).

Another factor contributing to the severity of ROP in neonates under 34 weeks was hypoglycemia, although it was not linked to the occurrence of ROP. Fernandez Martinez and colleagues, in their study of 60 preterm neonates, also found no association between hypoglycemia and ROP (26). Similarly, Esmail and colleagues studied 235 infants and found that while 49% were hypoglycemic at admission and 73% developed iatrogenic hyperglycemia within the first 72 hours of life, hypoglycemia itself was not associated with ROP. However, the incidence of ROP and severe ROP was higher in infants with hyperglycemia (27). Jagła and colleagues, in a case-control study, demonstrated a relationship between glycemic variability and the occurrence of severe ROP (28). Kermorvant-Duchemin and colleagues also identified hyperglycemia as an independent risk factor for severe ROP (29). Most studies have focused on hyperglycemia, highlighting the importance of carefully managing both hypoglycemia and iatrogenic hyperglycemia when treating hypoglycemia.

Hypotension was not identified as a risk factor for ROP in our study, consistent with the findings of other research (30). However, some studies, including a meta-analysis, have reported an association between hypotension and the development of ROP in preterm neonates (31, 32). This highlights the need for further research to better understand and identify the risk factors contributing to ROP. We also evaluated the Apgar score in our study. Although a majority of neonates with a low Apgar score developed ROP, there was no statistically significant association observed. However, some studies have identified asphyxia and low Apgar scores as risk factors for ROP (33–35), suggesting that further investigation is needed to clarify the role of these factors in ROP development.

One of the strengths of our study is the comprehensive assessment of multiple neonatal risk factors in a substantial cohort, using a rigorous screening protocol that extended screening to infants up to 34 weeks of gestation, beyond the standard WHO guidelines, thereby capturing a broader at-risk population. However, several limitations warrant consideration. First,

the cross-sectional design precludes causal inference, and 18% loss to follow-up may introduce bias despite our best efforts to track patients. Second, we treated sepsis as a single category and did not distinguish between early- and late-onset cases, nor did we evaluate hyperglycemia or glycemic variability; as such, these factors were not discussed in the manuscript. Third, potential confounding variables—such as maternal health status and quality of prenatal care—were not collected and thus could not be adjusted for in our analyses. We recommend that future longitudinal studies in larger cohorts incorporate detailed sepsis timing, comprehensive glycemic monitoring, maternal and prenatal data, and robust follow-up strategies to better elucidate the temporal and causal relationships underlying ROP development.

Conclusion

In conclusion, our study highlights the critical role of multiple risk factors, including birth weight, gestational age, sepsis, and blood transfusion, in the development and severity of ROP in premature infants. The comprehensive approach we employed, screening neonates up to 34 weeks of gestational age, provides valuable insights into ROP incidence beyond the standard guidelines. Future research should focus on these areas to further refine our understanding and improve outcomes for premature infants at risk of ROP.

Acknowledgments

The authors would like to thank Shiraz University of Medical Sciences for this project. This paper was relevant to MR's thesis, project no. 21384.

Conflicts of interest

The authors declare that they have no competing interests.

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