

The association between risk factors and the occurrence of retinopathy of prematurity in premature infants: An exploratory study

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ABSTRACT

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Retinopathy of prematurity (ROP) remains a leading cause of preventable childhood blindness. Although gestational age and birth weight are well-established risk factors, the contribution of other clinical factors may vary across settings, particularly in low-and-middle-income countries such as Indonesia. The study aimed to evaluate risk factors associated with the incidence of retinopathy of prematurity, including gestational age, birth weight, duration of oxygen therapy, and infection, in a tertiary-care hospital in Indonesia. This retrospective study reviewed medical records of premature infants with and without ROP at Prof Dr. RD Kandou General Hospital, Manado, Indonesia. Eligible infants underwent initial ophthalmologic examination at or before 1 years old. Data collected included sex, gestational age, birth weight, duration of oxygen therapy, presence of infection or sepsis, and ROP status. Associations were evaluated using Chi-square tests and bivariate logistic regression to estimate crude odds ratios (ORs). Multivariable logistic regression analysis was performed to adjust for potential confounding, with adjusted odds ratios (aORs) and 95% confidence intervals (CIs) reported. Multivariable results were interpreted as exploratory due to the limited number of ROP cases. A total of 51 infants were included, of whom 14 (27.5%) developed ROP. Lower gestational age (≤ 34 weeks), lower birth weight (≤ 1500 grams), and oxygen therapy duration ≥ 1 weeks were significantly associated with ROP in bivariate analyses. After multivariable adjustment, none of the variables remained statistically significant, although the direction of association persisted for gestational age, birth weight, and oxygen therapy. Infection or sepsis was not significantly associated with ROP. In conclusion, lower gestational age, lower birth weight, and prolonged oxygen therapy are associated with an increased incidence of ROP in this cohort. These findings emphasize the importance of targeted screening and careful oxygen management in premature infants. Larger prospective multicenter studies are needed to clarify independent risk factors for ROP in Indonesia.

ABSTRAK

Retinopati prematuritas (ROP) merupakan salah satu penyebab utama kebutaan yang dapat dicegah pada anak. Meskipun usia kehamilan dan berat badan lahir telah dikenal sebagai faktor risiko utama, faktor klinis lain yang bervariasi antar daerah juga berkontribusi, khususnya di negara berpendapatan rendah dan menengah seperti Indonesia. Penelitian ini bertujuan mengkaji faktor risiko yang berhubungan dengan retinopati prematuritas, seperti usia kehamilan, berat badan lahir, durasi terapi oksigen, dan infeksi, di sebuah rumah sakit rujukan tersier di Indonesia. Penelitian retrospektif ini menggunakan data rekam medis bayi prematur dengan dan tanpa ROP yang menjalani pemeriksaan oftalmologis pertama pada usia ≤ 1 tahun di RSUD Prof Dr. RD Kandou, Manado, Indonesia. Data yang dikumpulkan meliputi jenis kelamin, usia kehamilan, berat badan lahir, durasi terapi oksigen, adanya infeksi atau sepsis, dan status ROP. Hubungan antarvariabel dianalisis menggunakan uji Chi-square dan regresi logistik bivariat untuk menghitung *odds ratio* (OR). Analisis regresi logistik multivariat dilakukan untuk menyesuaikan faktor perancu dengan nilai

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adjusted odds ratio (aOR) dan interval kepercayaan 95% (CI 95%). Hasil analisis multivariat diinterpretasikan secara eksploratif karena jumlah kasus ROP yang terbatas. Sebanyak 51 bayi diikutsertakan dalam penelitian ini, dengan 14 bayi (27,5%) mengalami ROP. Usia gestasi ≤ 34 minggu, berat badan lahir ≤ 1500 gram, dan durasi terapi oksigen ≥ 1 minggu berhubungan secara bermakna dengan kejadian ROP pada analisis bivariat. Setelah penyesuaian multivariat, tidak ada variabel yang tetap bermakna secara statistik, meskipun arah hubungan tetap konsisten untuk usia kehamilan, berat badan lahir, dan terapi oksigen. Infeksi atau sepsis tidak berhubungan secara signifikan dengan kejadian ROP. Secara kesimpulan, usia kehamilan lebih rendah, berat badan lahir yang lebih rendah, dan durasi terapi oksigen yang lebih lama berhubungan dengan peningkatan kejadian ROP. Temuan ini menegaskan pentingnya skrining yang tepat sasaran serta pemantauan terapi oksigen pada bayi prematur. Diperlukan penelitian prospektif multisenter dengan jumlah sampel yang lebih besar untuk memperjelas faktor risiko independen ROP di Indonesia.

INTRODUCTION

Retinopathy of prematurity (ROP) remains one of the major challenges in both pediatrics and ophthalmology, despite significant advances in neonatology over the past few decades. In the United States, the incidence of ROP requiring treatment has increased from 3.4% to 5.3% between 2009 and 2018 among neonates born at ≤ 30 weeks' gestation.¹ In Indonesia, the epidemiology of ROP in infants with gestational age < 32 weeks has been estimated to range between 18% and 30%.² ROP is a disorder of abnormal vasoproliferation of the immature retina of premature infants, particularly those who receive oxygen therapy. Screening guidelines for this leading cause of childhood blindness are based primarily on gestational age and birth weight, although several additional factors are known to influence disease incidence and severity. Early treatment with cryotherapy, laser photocoagulation, or anti-vascular endothelial growth factor (VEGF) therapy has greatly improved visual outcomes; however, early detection through timely screening remains crucial.³

Clinically, ROP is characterized by abnormal retinal vascular development.

The first phase involves cessation or delay of normal vascular growth immediately after birth, followed by a second phase characterized by reactivation of vascular proliferation. In mild cases, physiological vascular growth resumes, leading to gradual vascularization of avascular retinal areas.⁴ In severe cases, however, abnormal neovascularization occurs. In some infants—particularly those with higher gestational ages but excessive oxygen exposure—the disease may include regression of already formed vessels, sometimes referred to as “*big baby ROP*.”⁵

Most screening guidelines rely on birth weight (BW) and gestational age (GA) as primary risk indicators.^{6–8} The American Academy of Pediatrics, American Academy of Ophthalmology, and American Association for Pediatric Ophthalmology and Strabismus recommend screening all infants with GA ≤ 30 weeks or BW ≤ 1500 grams, as well as selected larger infants depending on their clinical condition.⁹

Studies from low- and middle-income countries have shown that affected infants tend to have higher birth weights and gestational ages compared with those in high-income countries, such as the United States.^{10,11} In Indonesia, screening criteria are based on the 2010 National

ROP and Premature Infant Working Group guidelines, which recommend screening all infants born with GA ≤ 34 weeks or BW ≤ 1500 grams.¹²

The aim of this study is to determine the potential risk factors influencing ROP incidence, including birth weight, gestational age, duration of oxygen therapy, and infection, which are essential for improving prevention and management strategies.

MATERIAL AND METHODS

Subjects and design

This retrospective study employed a consecutive sampling method, whereby eligible subjects were identified from medical records at Prof Dr. RD Kandou General Hospital, Manado, Indonesia. Subjects were then selected based on the documented diagnosis of ROP and the availability of relevant risk factor data. The study was conducted between December 2024 and February 2025. Prior to data collection, written informed consent was obtained from the parents or legal guardians of all participants. Ethical approval for this study was granted by the Research Ethics Committee of the Faculty of Medicine, Universitas Sam Ratulangi, on February 6, 2025 (Number: 026/EC/KEPK-KANDOU/II/2025).

Protocol

Eligible participants included premature infants with or without ROP whose initial ophthalmologic examination was performed at or before 1 year of age. Infants with incomplete or missing ROP-related data, as well as those who died prior to ROP screening, were excluded from the analysis. All included subjects had complete data for the analyzed variables; therefore, no imputation was performed.

Sample size estimation was performed using a formula for

comparing the means of two populations, incorporating the anticipated effect size and level of statistical significance. A type I error rate of 5% and a type II error rate of 10% were applied, with an assumed correlation coefficient of 0.40, yielding a minimum required sample size of 51 subjects.

Gestational age was categorized as ≤ 34 weeks and ≥ 34 weeks of gestation and was analyzed as a nominal variable. Birth weight was defined as the weight of the newborn measured immediately after birth, typically within the first hour of life, using a calibrated scale, and recorded in grams or kilograms. Birth weight was categorized as ≤ 1500 grams and >1500 grams.

Oxygen therapy was defined as the administration of supplemental oxygen to maintain arterial oxygen saturation within a safe range and to support respiratory function. Oxygen delivery methods included nasal cannula, simple face mask, endotracheal tube, continuous positive airway pressure (CPAP), or mechanical ventilation. In this study, oxygen therapy was considered a risk factor when administered for a duration of ≥ 1 weeks.^{13,14}

Infection or sepsis was defined as a systemic inflammatory response to infection, confirmed by clinical signs and laboratory findings in neonates, including preterm infants. The diagnosis was based on the presence of positive blood culture results or other microbiological evidence of infection, accompanied by clinical manifestations such as elevated body temperature, respiratory distress, and abnormal white blood cell counts within 28 days of life.¹⁵

Statistical analysis

Collected variables comprised of gender, gestational age, birth weight, duration of oxygen therapy, presence of infection or sepsis, and ROP status. Statistical analyses were conducted using

SPSS version 29.0. Descriptive univariate analyses were used to summarize demographic and clinical characteristics, which were presented as frequencies and percentages. Associations between potential risk factors and the occurrence of ROP were evaluated using the Chi-square test. Associations between individual risk factors and the occurrence of retinopathy of prematurity were initially evaluated using bivariate logistic regression, and crude odds ratios (ORs) with 95% confidence intervals (95%CI) were calculated.

To assess independent associations and adjust for potential confounding, multivariable logistic regression analysis was subsequently performed, including

gestational age, birth weight, duration of oxygen therapy, and presence of infection or sepsis in the model. Adjusted odds ratios (aORs) with 95% CIs were reported. Given the limited number of ROP cases, the multivariable analysis was considered exploratory, and results were interpreted with caution. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 51 subjects were included in this study, consisting of 28 males (54.9%) and 23 females (45.1%). The demographic and clinical characteristics of the study subjects are summarized in TABLE 1.

TABLE 1. Characteristics of infants included in the study (n = 51)

Characteristics	n (%)
Sex	
Male	28 (54.9)
Female	23 (45.1)
Gestational age (weeks)	
≤ 34	28 (54.9)
>34	23 (45.1)
Birth weight (gram)	
≤ 1500	27 (52.9)
>1500	24 (47.1)
Infection	
Yes	22 (43.1)
No	29 (56.9)
Oxygen therapy (weeks)	
< 1	30 (58.8)
≥ 1	21 (41.2)

TABLE 2 summarizes the associations between selected clinical factors and the incidence of retinopathy of prematurity (ROP). Gestational age ≤ 34 weeks and birth weight ≤ 1500 grams were both significantly associated with ROP occurrence, with a higher proportion of affected infants observed in these groups compared with their counterparts ($p = 0.007$ and $p = 0.004$, respectively). Prolonged oxygen therapy (≥ 1 week) was also significantly associated with ROP ($p = 0.039$). In contrast, no statistically significant association was found between infection or sepsis and the development of ROP ($p = 0.196$). Overall, lower gestational age, lower birth weight, and longer duration of oxygen therapy were associated with an increased incidence of ROP in this

study.

TABLE 3 presents the results of bivariate and multivariable logistic regression analyses examining factors associated with the occurrence of ROP. In bivariate analyses, gestational age ≤ 34 weeks, birth weight ≤ 1500 grams, and oxygen therapy duration ≥ 1 week were significantly associated with an increased odds of ROP ($p = 0.019$). Infants born at ≤ 34 weeks of gestation had more than a seven fold higher odds of developing ROP, while those with birth weight ≤ 1500 grams had nearly nine fold increased odds ($p = 0.009$). Prolonged oxygen therapy was also associated with higher odds of ROP ($p = 0.045$). In contrast, infection or sepsis was not significantly associated with ROP in the bivariate analysis ($p = 0.203$).

TABLE 2. Association between gestational age, birth weight, duration of oxygen therapy, and infection with the incidence of ROP

Factors	Incidence [n (%)]		Total [n (%)]	p
	ROP	Non-ROP		
Gestational age (week)				
≤ 34	12 (85.7)	16 (43.2)	28 (54.9)	0.007
>34	2 (14.3)	21 (56.8)	23 (45.1)	
Total	14 (27.5)	37 (72.5)	51 (100)	
Birth weight (gram)				
≤1500	12 (85.7)	15 (40.5)	27 (52.9)	0.004
>1500	2 (14.3)	22 (59.5)	24 (47.1)	
Total	14 (27.5)	37 (72.5)	51 (100)	
Duration of oxygen therapy (week)				
≥1	9 (64.3)	12 (32.4)	21 (41.2)	0.039
<1	5 (35.7)	25 (67.6)	30 (58.8)	
Total	14 (27.5)	37 (72.5)	51 (100)	
Infection				
Yes	4 (28.6)	18 (48.6)	22 (43.1)	0.196
No	10 (71.4)	19 (51.4)	29 (56.9)	
Total	14 (27.5)	37 (72.5)	51 (100)	

TABLE 3. Bivariate and multivariable logistic regression analysis of risk factors for ROP

Factors	Bivariate OR (95% CI)	p	Adjusted OR (95% CI)	p
Gestational age ≤ 34 week	7.06 (1.38–36.05)	0.019	3.10 (0.50–19.38)	0.226
Birth weight ≤ 1500 grams	8.80 (1.72–45.12)	0.009	4.37 (0.71–26.84)	0.112
Oxygen therapy ≥ 1 week	3.75 (1.03–13.65)	0.045	2.94 (0.25–34.00)	0.387
Infection	2.37 (0.63–8.93)	0.203	0.73 (0.06–9.20)	0.808

OR: odds ratio; 95%CI: 95% confidence interval

After adjustment for gestational age, birth weight, duration of oxygen therapy, and infection in the multivariable logistic regression model, none of the variables remained statistically significant. Although the direction of association for gestational age, birth weight, and oxygen therapy persisted, the confidence intervals were wide and crossed unity, indicating reduced precision of the estimates. Infection or sepsis showed no independent association with ROP after adjustment. The attenuation of statistical significance in the multivariable model is likely attributable to the limited number of ROP cases and the intercorrelation among key clinical variables.

DISCUSSION

The introduction of modern technology in neonatal intensive care units (NICUs) has resulted in remarkable improvements in the survival rates of extremely premature infants, including in Indonesia. However, many of these survivors present with complex medical challenges and are at high risk for developmental complications. One of the most severe complications of prematurity is ROP, which remains the most common cause of severe visual impairment or preventable blindness regardless of socioeconomic status.^{16,17}

In the present study, the incidence of ROP was 27.5% (14/51). This number

is considerably lower than that reported in several Indonesian studies conducted between 2005 and 2015, which found ROP incidences ranging from 18 to 30% among infants born before 32 weeks of gestation and/or weighing less than 1500 grams.²

Low gestational age and low birth weight are widely recognized as the most influential risk factors associated with the development of retinopathy of prematurity.¹⁸ This study demonstrated a significant correlation between birth weight with the occurrence of ROP. The incidence of ROP was higher among infants with gestational age < 34 week and birth weight < 1500 g, both showing a prevalence of 85.7% (12/14). This finding aligns with a study by Gilbert *et al.*,¹⁹ who reported that a greater proportion of infants born at < 38 weeks developed severe ROP in low- and middle-income countries compared with high-income nations. In this study, the proportions of ROP cases among infants with gestational age ≤ 34 weeks and birth weight ≤ 1500 grams were identical. This may be due to the close correlation between these two factors, as gestational age strongly influences birth weight. In standard clinical studies, it is nearly impossible to isolate the independent effects of gestational age and birth weight on ROP.⁸ However, a multivariate analysis in our study reported both gestational age ≤ 34 weeks and birth weight ≤ 1500 grams increase odds of ROP incidence.

However, not statistically significant and has wide range of confidence intervals. This is contradictory to the existing literature that reported gestational age and birth weight as a significant factor in contributing to ROP incidence.²⁰⁻²⁴

In several previous studies, duration of oxygen therapy had been reported to be associated with ROP incidence and progression.²⁵⁻²⁷ Our study reported that the duration of oxygen therapy of more than one week resulted in a non-significant risk factor for development of ROP. However, it is also important to highlight that among infants who received prolonged oxygen therapy, the majority being 64.3% (9/14) developed ROP. Other studies have also demonstrated a direct relationship between the duration of oxygen exposure and the severity of ROP. Furthermore, fluctuations in oxygen levels resulting in episodes of hyperoxia (>3 episodes) and hypoxia (2-3 episodes) have been identified as significant risk factors for ROP progression.²⁸ A multivariate analysis study by Ramirez *et al.*,²³ reported that duration of supplemental oxygen therapy exerted the greatest influence on disease progression, with the risk of ROP increasing in parallel with longer oxygen exposure. Among preterm infants requiring oxygen therapy for 2-48 days, the presence of late-onset sepsis was associated with a 28.9% increased risk of ROP progression. Furthermore, in preterm infants who required oxygen therapy for more than 99 days and had a body weight of ≤ 975 grams at 28 days of life, progression of ROP was consistently observed.²³ Despite the literature, oxygen therapy continues to be widely used, often without strict control or monitoring. Therefore, monitoring of oxygen therapy with ROP progression may aid in navigating therapies that best benefit the patient.²⁹

In this study, no significant association was found between infection or sepsis and the occurrence

of ROP [aOR = 0.73 (0.06-9.20); $p=0.808$]. However, a meta-analysis by Wang *et al.*,³⁰ reported eleven studies involving 5388 participants demonstrated that sepsis was significantly associated with an increased risk of ROP in premature infants (pooled OR = 1.57, 95% CI 1.31-1.89).⁸ The relationship between sepsis and ROP may be explained by inflammatory mediators and growth factors such as interleukin-1 β , which can markedly increase the activity of hypoxia-inducible factor 1-alpha (HIF-1 α), while transforming growth factor-beta (TGF- β) may inhibit HIF-1 α degradation through the SMAD signaling pathway. Consequently, the HIF-1 α pathway plays a key role in inducing and exacerbating ROP. Other inflammatory mediators, such as phospholipase-2 and prostaglandins, may further aggravate retinal neovascularization.³⁰

The strength of this study lies in providing specific single center incidence of ROP, specifically in Manado, North Sulawesi, Indonesia. The results of this study contribute to optimizing ROP screening by facilitating earlier diagnosis and appropriate treatment, while potentially reducing the number of unnecessary examinations. However, this study has several limitations. First, as a retrospective study based on medical records, the sample size was determined by the availability of eligible cases during the study period rather than by a prospective sample size calculation. Only infants who met the inclusion criteria and had complete clinical and ophthalmologic data were included in the analysis. Consequently, the relatively small sample size may have limited the statistical power of the study, particularly for multivariable regression analysis, and may have contributed to wide confidence intervals. Second, survivorship bias should be considered. Only infants who survived long enough to undergo ROP screening were included in this study. Infants who were critically

ill, died before screening, or were not examined may have had a higher risk of developing ROP. As a result, the true incidence of ROP in this population may be underestimated, and the observed associations should be interpreted with caution.

CONCLUSION

In this single-center retrospective study, lower gestational age, lower birth weight, and prolonged duration of oxygen therapy are associated with an increased incidence of ROP in premature infants. Bivariate analyses demonstrated significant associations between these factors and ROP occurrence. However, none remained independently significant after multivariable adjustment, likely due to the limited number of ROP cases and the intercorrelation among key clinical variables.

Despite these limitations, the findings highlight the continued importance of gestational age, birth weight, careful monitoring of oxygen therapy and infection in identifying infants at risk for ROP. These results may help inform screening strategies in similar clinical settings, although larger, multicenter prospective studies are needed to better define independent risk factors and optimize ROP prevention and management in Indonesia.

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