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Association Between Prematurity and Neonatal Sepsis: A Case–Control Study at a Tertiary Referral Hospital in Indonesia

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ABSTRACT

Background: *Neonatal sepsis remains a leading cause of morbidity and mortality in newborns, particularly among preterm infants whose immature organ systems and immune defenses increase their vulnerability to infection. Evidence on the association between prematurity and neonatal sepsis remains variable across settings, highlighting the need for context-specific research.* ***Objective:*** *To examine the association between prematurity and the occurrence of neonatal sepsis at a tertiary referral hospital in Indonesia.* ***Methods:*** *A hospital-based analytic observational study with an unmatched case–control design was conducted at Margono Soekarjo Regional Hospital, Central Java, Indonesia, from June to November 2024. Medical records of neonates admitted in 2023 were reviewed. Cases were neonates diagnosed with sepsis, while controls had no sepsis diagnosis. A total of 136 neonates were selected using simple random sampling, with 68 cases and 68 controls. Data were analyzed using Chi-square tests and odds ratios (OR) with 95% confidence intervals (CI).* ***Results:*** *Preterm birth was more frequent among cases (64.7%) compared to controls (32.4%). The majority of sepsis cases were moderate-to-late preterm (41.2%) and predominantly late-onset (86.8%). Bivariable analysis demonstrated a significant association between prematurity and neonatal sepsis ($\chi^2 = 14.248$, $p < 0.001$), with an OR of 3.833 (95% CI: 1.883–7.805), indicating that preterm neonates had nearly four times higher risk of developing sepsis than term neonates.* ***Conclusion:*** *Prematurity is a significant risk factor for neonatal sepsis, particularly late-onset cases, in this tertiary care setting. These findings highlight the urgent need for targeted infection prevention strategies and enhanced clinical monitoring for preterm infants in neonatal intensive care units.*

1. INTRODUCTION

Neonatal sepsis remains one of the leading causes of morbidity and mortality during the neonatal period worldwide. This condition, a multifactorial systemic infection, ranks as the third most common cause of neonatal death in Indonesia. Neonatal sepsis frequently results in multi-organ dysfunction, often culminating in fatal outcomes, thus posing a significant threat to the survival of newborns. A comprehensive understanding of the contributing factors to neonatal sepsis is therefore essential for effective prevention and early intervention strategies (Ministry of Health of the Republic of Indonesia, 2017; Martua, 2021).

According to the United Nations International Children's Emergency Fund (UNICEF), the global neonatal mortality rate (NMR) in 2021 reached 17.6 per 1,000 live births, with an estimated 6,400 neonatal deaths occurring daily. In Indonesia, the NMR in 2020 was reported at 11.3 per 1,000 live births, placing the country fifth among ASEAN nations in terms of neonatal mortality. In Banyumas Regency, the NMR in 2023 was recorded at 9.0 per 1,000 live births (Banyumas District Health Office, 2024; UNICEF, 2023). These variations reflect regional disparities in risk

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factors, underscoring the need for locally based research to identify specific determinants influencing the incidence of neonatal sepsis.

Risk factors for neonatal sepsis include male sex, low birth weight (LBW), severe asphyxia, use of invasive devices, and prematurity. A study conducted in Bandung identified prematurity as the most prominent risk factor, accounting for 74% of neonatal sepsis cases. Based on the 2018 National Basic Health Survey (Riskesdas), the prevalence of preterm births in Indonesia was 29.5 per 1,000 live births, positioning the country fifth globally in terms of prematurity incidence (Prawesti et al., 2018).

Despite numerous studies exploring the association between prematurity and neonatal sepsis, the findings remain inconsistent. For instance, Nurrosyida et al. (2022) in East Java reported no significant association between prematurity and neonatal sepsis, whereas Ningsih et al. (2016) in Kolaka found a significant relationship. Similar discrepancies are observed in international literature; Flannery et al. (2021) in Philadelphia concluded that preterm infants are more susceptible to infections, including neonatal sepsis, while Baheru et al. (2024) found that prematurity was not an independent risk factor after multivariable analysis. These contradictory results highlight a knowledge gap, necessitating further research with robust methodological design to draw more valid conclusions.

This study employs an analytical observational approach with a case-control design, which is considered more appropriate for identifying causal relationships compared to cross-sectional designs (Sastroasmoro & Ismael, 2011). Through this methodological choice, the study aims to yield higher validity outcomes, offering valuable insights for future research and informing health policy development.

Margono Soekarjo General Hospital was selected as the study site due to its status as a type-A referral hospital in western Central Java, equipped with a Neonatal Intensive Care Unit (NICU) capable of managing cases of prematurity and neonatal sepsis. As a regional referral center, the hospital receives patients from various districts, representing a heterogeneous population. This characteristic makes it a strategically significant location for generating findings that are not only locally relevant but also have broader implications at national and global levels in improving the quality of neonatal healthcare services.

2. METHOD

This study employed an analytical observational design using an unmatched case–control approach. This design was selected due to its efficiency in terms of time and cost, its suitability for investigating conditions with relatively low incidence such as neonatal sepsis, and its ability to assess multiple risk factors within a single study. The study was conducted retrospectively by reviewing medical records, with no direct intervention applied to the study subjects. The research site was Margono Soekarjo General Hospital, a type-A referral hospital in Central Java equipped with Neonatal Intensive Care Unit (NICU) facilities, which receives referrals from various regions and thus provides a diverse patient population suitable for research purposes.

The target population of this study comprised all neonates aged ≤ 28 days, while the accessible population included all neonates recorded at Margono Soekarjo Hospital during the year 2023. The study subjects were divided into two groups: cases and controls. The case group consisted of neonates born at Margono Soekarjo Hospital in 2023 who were diagnosed with neonatal sepsis based on clinical and laboratory findings, including blood culture results, leukocyte count, immature-to-total neutrophil (I/T) ratio, C-reactive protein (CRP) levels, and procalcitonin levels. The control group included neonates born in the same hospital and during the same year without a diagnosis of neonatal sepsis. Neonates with major congenital anomalies such as anencephaly, tetralogy of Fallot, or esophageal atresia were excluded from the study.

Sample size was calculated using the OpenEpi software for unmatched case–control studies, applying the following parameters: 95% confidence level, 80% power, 1:1 ratio of controls to cases, 40% exposure rate among controls, 65.28% exposure rate among cases, and an odds ratio of 2.82 derived from previous studies. Calculation using the Fleiss method with continuity correction (CC) yielded a minimum required sample of 68 subjects per group, resulting

in a total minimum sample size of 136 subjects. The sampling technique used was simple random sampling based on a list of patients meeting the inclusion criteria.

The independent variable in this study was prematurity, defined as birth before 37 completed weeks of gestation, further classified into extremely preterm (<28 weeks), very preterm (<32 weeks), and moderate-to-late preterm (32–<37 weeks). The dependent variable was the incidence of neonatal sepsis, classified into early-onset (0–72 hours) and late-onset (3–28 days). Data were extracted from hospital medical records and underwent several processing stages including editing (to ensure completeness), coding (to categorize variables), data entry using IBM SPSS Statistics software, and data cleaning (to remove duplicates or invalid entries).

Data analysis was conducted in two stages. Univariate analysis was used to describe the frequency distribution and percentage of each variable. Bivariate analysis was conducted using the Chi-square test with a significance level of $p < 0.05$ and a 95% confidence interval to assess the association between prematurity and neonatal sepsis. Odds ratios (ORs) and confidence intervals (CIs) were calculated to quantify the strength of association, where OR > 1 indicates a risk factor, OR < 1 indicates a protective factor, and OR = 1 suggests no association.

This study received ethical approval from the Research Ethics Committee of Margono Soekarjo General Hospital. Since secondary anonymized data were used, individual informed consent was not required, in accordance with applicable regulations and the principles of the Declaration of Helsinki.

3. RESULT AND DISCUSSION

Result

A total of 136 neonates met the inclusion criteria, comprising 68 cases (neonatal sepsis) and 68 controls (no sepsis). The ratio of controls to cases was 1:1. Cases were defined as neonates diagnosed with neonatal sepsis in 2023 at Margono Soekarjo Regional Hospital, while controls were neonates without such a diagnosis during the same period. The mean gestational profile showed that preterm birth was more prevalent in the case group compared to the control group.

Table 1 presents the baseline characteristics of the study population. Low birth weight (<2500 g) was found in 73.5% of cases compared with 29.4% of controls. APGAR scores at 1, 5, and 10 minutes were consistently lower in the case group, with the largest difference observed at 1 minute (normal score ≥7: 66.2% in cases vs. 85.3% in controls). Mortality was higher among cases (23.5%) compared to controls (4.4%). In the case group, blood culture results revealed *Coagulase-Negative Staphylococci* (CoNS) as the most frequently isolated pathogen (30.8%), followed by *Escherichia coli* (23.1%), *Klebsiella pneumoniae* (18.5%), *Staphylococcus aureus* (15.4%), and *Pseudomonas aeruginosa* (12.3%). Laboratory profiles in cases showed leukopenia (<5000/mm^3) in 17.6%, leukocytosis (>15000/mm^3) in 26.5%, elevated C-reactive protein (CRP >5 mg/L) in 41.2%, and thrombocytopenia (<150000/mm^3) in 29.4%.

Table 1. Baseline characteristics of neonates with and without sepsis

Characteristic	Category	Cases (n=68) %	Controls (n=68) %	Total %
Birth weight	<2500 g	50 (73.5)	20 (29.4)	70 (51.5)
	≥2500 g	18 (26.5)	48 (70.6)	66 (48.5)
APGAR score (1 min)	Normal (≥7)	45 (66.2)	58 (85.3)	103 (75.7)
	Low (<7)	23 (33.8)	10 (14.7)	33 (24.3)
APGAR score (5 min)	Normal (≥7)	48 (70.6)	60 (88.2)	108 (79.4)
	Low (<7)	20 (29.4)	8 (11.8)	28 (20.6)
APGAR score (10 min)	Normal (≥7)	52 (76.5)	63 (92.6)	115 (84.6)
	Low (<7)	16 (23.5)	5 (7.4)	21 (15.4)
Neonatal status	Alive	52 (76.5)	65 (95.6)	117 (86.0)
	Deceased	16 (23.5)	3 (4.4)	19 (14.0)
Blood culture	*S. aureus*	10 (15.4)	–	10 (15.4)
	CoNS	20 (30.8)	–	20 (30.8)
	E. coli	15 (23.1)	–	15 (23.1)

	K. pneumoniae	12 (18.5)	–	12 (18.5)
	P. aeruginosa	8 (12.3)	–	8 (12.3)
Leukocyte count	<5000/mm^3	12 (17.6)	–	12 (17.6)
	5000–15000/mm^3	38 (55.9)	–	38 (55.9)
	>15000/mm^3	18 (26.5)	–	18 (26.5)
CRP	Normal (<5 mg/L)	40 (58.8)	–	40 (58.8)
	Elevated (>5 mg/L)	28 (41.2)	–	28 (41.2)
Platelets	<150000/mm^3	20 (29.4)	–	20 (29.4)
	≥150000/mm^3	48 (70.6)	–	48 (70.6)

Analysis of prematurity distribution showed that 44 cases (64.7%) were preterm, compared with 22 controls (32.4%). The majority of preterm cases were in the *moderate-to-late preterm* category (41.2%), followed by *very preterm* (23.5%). In contrast, the control group was dominated by term births (69.1%). Regarding sepsis onset, late-onset sepsis was predominant in the case group (86.8%), while early-onset sepsis accounted for only 13.2% of cases. Bivariate analysis demonstrated a statistically significant association between prematurity and neonatal sepsis ($\chi^2 = 14.248$, $p < 0.001$). The odds ratio was 3.833 (95% CI: 1.883–7.805), indicating that preterm neonates had a 3.83-fold higher risk of developing neonatal sepsis compared with term neonates.

Table 2. Univariable and bivariable analysis of prematurity and neonatal sepsis

Variable	Category	Cases n (%)	Controls n (%)	Total n (%)	χ^2 (p-value)	OR	95% CI
Prematurity	Preterm	44 (32.4)	22 (16.2)	66 (48.5)	14.248 (<0.001)	3.833	1.883–7.805
	Term	24 (17.6)	46 (33.8)	70 (51.5)	–	–	–
Prematurity classification	Very preterm (<32 wks)	16 (23.5)	1 (1.5)	–	–	–	–
	Moderate-to-late preterm (32–<37 wks)	28 (41.2)	20 (29.4)	–	–	–	–
	Term (≥37 wks)	24 (35.3)	47 (69.1)	–	–	–	–
Sepsis classification	Early-onset (0–72 hrs)	9 (13.2)	–	–	–	–	–
	Late-onset (3–28 days)	59 (86.8)	–	–	–	–	–

Among the 68 neonates with sepsis, 44 (64.7%) were preterm, compared to 22 (32.4%) in the control group. Conversely, term neonates accounted for 46 (67.6%) of the control group, compared with 24 (35.3%) in the case group. This distribution indicates a markedly higher proportion of preterm births among sepsis cases. When stratified by gestational age category, the most common subgroup among cases was *moderate-to-late preterm* (28/68; 41.2%), followed by *very preterm* (16/68; 23.5%). In contrast, the control group was predominantly term (47/68; 69.1%), with only one neonate classified as *very preterm* (1.5%).

Regarding sepsis onset, late-onset sepsis (3–28 days) was substantially more common (59/68; 86.8%) than early-onset sepsis (0–72 hours) (9/68; 13.2%). Bivariable analysis demonstrated a statistically significant association between prematurity and neonatal sepsis ($\chi^2 = 14.248$, $p < 0.001$). The odds ratio was 3.833 (95% CI: 1.883–7.805), indicating that preterm neonates had a 3.83-fold higher risk of developing neonatal sepsis compared with term neonates.

Discussion

This study demonstrated a significant association between prematurity and the occurrence of neonatal sepsis, with preterm neonates exhibiting a 3.83-fold higher risk compared to term neonates. The majority of sepsis cases occurred in the moderate-to-late preterm category,

while the predominant form of sepsis observed was late-onset. These findings align with the current understanding that preterm infants are more vulnerable to severe infections due to multiple physiological and clinical factors.

Preterm neonates have underdeveloped organ systems, including an immature immune system, which limits their ability to mount effective responses against invading pathogens. This immaturity affects both the innate and adaptive immune responses. Neutrophils in preterm infants demonstrate reduced chemotaxis and phagocytic activity, coupled with a limited production capacity, thereby impairing bacterial clearance. Furthermore, adaptive immunity is compromised by a reduced transplacental transfer of maternal immunoglobulin G (IgG), leaving preterm neonates deficient in passive humoral protection during early life (Palić et al., 2024). These immunological deficits are compounded by frequent exposure to invasive procedures such as mechanical ventilation and central venous catheterization, which can disrupt mucocutaneous barriers and serve as entry points for pathogens (Stoll et al., 2010).

The predominance of moderate-to-late preterm infants among sepsis cases highlights that susceptibility is not confined to extremely preterm infants. While moderate-to-late preterm infants may exhibit more mature physiology than their extremely preterm counterparts, they still face higher sepsis risk compared to term neonates. This elevated risk is attributed to incomplete maturation of host defenses, frequent hospitalization, and the need for supportive medical interventions that increase nosocomial exposure (Perin et al., 2022). In contrast, the control group in this study, dominated by term infants, benefited from fully matured organ systems, robust immune defenses, and minimal exposure to invasive interventions, resulting in significantly lower sepsis incidence (Escobar et al., 2014).

Late-onset sepsis (LOS) accounted for the majority of sepsis cases in this study. LOS, typically occurring after 72 hours of life, is frequently associated with nosocomial infections acquired during prolonged neonatal intensive care unit (NICU) stays. Preterm infants are particularly susceptible to LOS due to prolonged hospitalization, frequent handling, and repeated use of invasive devices. Common causative pathogens include Coagulase-Negative Staphylococci (CoNS), Escherichia coli, Klebsiella pneumoniae, and Staphylococcus aureus, organisms well-documented in NICU outbreaks (Ramasethu, 2017; Schrag et al., 2016). In this study, CoNS was the most frequently isolated organism, consistent with previous literature noting its role as both a frequent contaminant and a true pathogen in immunocompromised neonates.

The significant odds ratio observed in this study is in line with previous findings from Martua (2021), who reported an OR of 2.823 for the association between prematurity and neonatal sepsis in an Indonesian cohort. This consistency across studies underscores the need for enhanced infection prevention protocols in preterm populations, particularly during extended NICU admissions. Preventive strategies could include minimizing invasive procedures where possible, strengthening aseptic techniques, and implementing targeted antimicrobial stewardship to prevent the emergence of resistant pathogens.

This study has several limitations that should be considered when interpreting its findings. First, the analysis focused solely on prematurity as a risk factor for neonatal sepsis, while other potential contributors—such as low birth weight, maternal infection, and invasive procedures—were not assessed. Second, the retrospective design relied entirely on the completeness and accuracy of medical record documentation, which may introduce information bias. Third, the study was conducted at a single tertiary referral hospital, which may limit the generalizability of the results to other settings or populations. Despite these limitations, the findings provide valuable evidence to inform future research on prematurity and neonatal sepsis.

4. CONCLUSION

This study identified a significant association between prematurity and the occurrence of neonatal sepsis. Univariable analysis showed that preterm neonates constituted the majority of sepsis cases, whereas term neonates predominated in the control group. Late-onset sepsis was more common than early-onset sepsis among affected neonates. Bivariable analysis confirmed that prematurity was a strong risk factor, with an odds ratio of 3.833 (95% CI: 1.883–7.805),

indicating that preterm neonates were nearly four times more likely to develop neonatal sepsis compared to their term counterparts. These findings underscore the critical need for targeted infection prevention and management strategies in preterm populations, particularly within neonatal intensive care settings.

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