Pediatr Infect Vaccine. 2023 Apr;30(1):12-19
https://doi.org/10.14776/piv.2023.30.e6
pISSN 2384-1079·eISSN 2384-1087

PIV PEDIATRIC INFECTION & VACCINE

Original Article

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Prognostic Factors of Neonatal Sepsis Mortality in Developing Country

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OPEN ACCESS

Received: Apr 12, 2022
Revised: Dec 24, 2022
Accepted: Jun 2, 2023
Published online: Jun 3, 2023

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

Author Contributions
Conceptualization: Rasyida IA, Pratama DC, Chamida FM; Data curation: Rasyida IA, Pratama DC, Chamida FM; Formal analysis: Rasyida IA, Pratama DC, Chamida FM; Investigation: Rasyida IA, Pratama DC, Chamida FM; Methodology: Rasyida

ABSTRACT

Purpose: Sepsis is the most common cause of neonatal death accounting for 30–50% of mortality annually in developing countries. This study was to determine the prognostic factors of neonatal sepsis mortality.
Methods: A retrospective cohort was conducted in Dr. R. Sosodoro Djatikoesoemo Governor Hospital from April 2021 to September 2021 on 121 neonates in the neonatal intensive care unit (NICU) diagnosed with sepsis. The inclusion criteria were neonates aged 0–28 days, admitted to the NICU, and diagnosed with sepsis. The exclusion criteria were incomplete data and the presence of congenital abnormalities. A χ^2 test was performed on the sex, gestational age, mode of delivery, birth weight, APGAR score, birthplace, and blood culture. A normality test was performed on leukocytes, lymphocytes, neutrophils, platelets, C-reactive protein (CRP), and length of stay. Then performed a Mann-Whitney test.
Results: Birth weight (P=0.038), gestational age (P=0.009), and blood culture (P=0.014) showed a significant relationship with the neonatal sepsis outcome while Mann-Whitney test showed significant differences in the platelets (P=0.018), CRP (P=0.002), and length of stay (P<0.001). Multivariate analysis showed that 3 prognostic factors associated with neonatal sepsis mortality were prematurity (odds ratio [OR], 3.906; 95% confidence interval [CI], 1.344–11.356; P=0.012), low birth weight (LBW, OR, 2.833; 95% CI, 1.030–7.790; P=0.044), and gram-negative bacteria (OR, 4.821; 95% CI, 1.018–22.842; P=0.047).
Conclusions: Prematurity, LBW, and gram-negative bacteria were associated with the prognostic factors of neonatal sepsis.

Keywords: Neonates; Sepsis; Prognostic factors; Mortality

INTRODUCTION

Neonatal sepsis is still a serious global health concern and contributes to the high mortality rate in the first 28 days of life, when is the most critical period of child survival.[1)]

According to the novel World Health Organization data, there were approximately 3.9 million annually cases of neonatal sepsis (2,824 per 100,000 live births) and 689,922 mortalities around the world between January 1979 and May 2019.[2)] In developing countries, sepsis is the most common cause of neonatal death accounting for 30–50% mortality annually.[3)]

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IA, Pratama DC, Chamida FM; Project administration: Rasyida IA, Pratama DC, Chamida FM; Resources: Rasyida IA, Pratama DC, Chamida FM; Software: Rasyida IA, Pratama DC, Chamida FM; Supervision: Rasyida IA; Validation: Rasyida IA; Visualization: Rasyida IA, Pratama DC, Chamida FM; Writing - original draft: Rasyida IA, Pratama DC, Chamida FM; Writing - review & editing: Rasyida IA, Pratama DC, Chamida FM.

Indonesia sits in fifth place of the highest neonatal mortality rate in Southeast Asia. There are 13.5/1,000 live births with a mortality rate due to sepsis of 2.9/1,000 live births.[4] A report from the Ministry of Health in 2010 showed that sepsis was the third leading cause of early neonatal death at 12% and the first leading cause of late neonatal death (7–28 days) at 20.5%.[5]

The high mortality rate in neonatal sepsis is caused by a delay in recognizing risk factors that increase mortality, increasing the infant mortality rate by up to 50%.[6] The aim of this study was to determine the prognostic factors associated with mortality in neonatal sepsis so that these risk factors can be recognized earlier and preventive measures can be taken as early as possible.

MATERIALS AND METHODS

The study was conducted in Dr. R. Sosodoro Djatikoesoemo Governor Hospital. This is a retrospective cohort with a total sampling method on medical records of neonates from 2020 to July 2021 diagnosed with sepsis and treated in the neonatal intensive care unit (NICU). This study was held from April 2021 to September 2021 and has received ethical approval from the Ethical Committee of Dr. R. Sosodoro Djatikoesoemo Governor Hospital (No. 893.3/011/412.202.1/Diklat/2021).

The inclusion criteria were neonates aged 0–28 days, admitted to the NICU, and diagnosed with sepsis, while the exclusion criteria were incomplete medical record data and the presence of congenital abnormalities.

The variables analyzed in this study were sex, mode of delivery, gestational age, birth weight, APGAR score, location of delivery, and length of stay. The mode of delivery was grouped into spontaneous delivery and cesarean section or other methods. Gestational age was grouped into term and premature, birth weight was grouped into normal (≥2,500 g) and low birth weight (LBW, <2,500 g). The APGAR score is grouped into normal (≥7) and low (<7) APGAR score. Birth place is grouped into birth in the hospital and birth outside the hospital. Neonatal outcome is grouped into alive and deceased.

Laboratory data analyzed in this study were leukocytes, platelets, neutrophils, lymphocytes, C-reactive protein (CRP), and blood culture. The laboratory reference values used according to Indonesia Pediatric Society sepsis consensus and Schmutz et al.[7] based on age are as follows[7,8]:

- Leukocytes
  - 0 day–1 week: >34,000/mm^3
  - 1 week–1 month: >19,500 or <5,000/mm^3
  - 1 month–1 year: >17,500 or <5,000/mm^3
  - 2–5 years: >15,500 or <6,000/mm^3
  - 6–12 years: >13,500 or <4,500/mm^3
  - 13–18 years: >11,000 or <4,500/mm^3
- Neutrophils[9]
  - <28 weeks: 1,300–15,300/mm^3
  - 28–36 weeks: 1,000–12,500/mm^3
  - >36 weeks: 2,700–13,000/mm^3
- Lymphocytes ≥4,000 or <1,300
- Platelets <150,000

https://doi.org/10.14776/piv.2023.30.e6

- CRP ≥0.5
- Positive blood culture: the blood culture result was recorded based on the findings on the microscope and then grouped based on neonatal outcomes to determine the most common pathogens causing death in neonatal sepsis.

The minimum sample size in this study is according to previous research held by Putra; namely, 96 samples with α=5%, β=10%, and the proportion of risk factors are 28%.[9] Data were analyzed using IBM SPSS Statistics Version 23 (IBM Corp., Armonk, NY, USA). Categorical data scale (sex, gestational age, mode of delivery, birth weight, APGAR score, birthplace, and blood culture) were analyzed using χ^2 test. The *P*-value < 0.05 with a 95% confidence interval (CI) showed statistical significance, then multivariate analysis with logistic regression was performed on the variables to determine which risk factors had the most influence on the outcome of neonatal sepsis. A comparative test was conducted on numerical data scale (leukocytes, lymphocytes, neutrophils, platelets, CRP, and length of stay in the NICU). The Kolmogorov-Smirnov test was conducted to determine the data distribution. The data is normally distributed if the significance value is >0.05 and followed by an independent t-test. If the significance value is <0.05, the Mann-Whitney test is performed.

RESULTS

Neonates treated in the NICU from 2020 to July 2021 were 2,895, with 129 neonatal sepsis cases consisting of 86 males and 43 females. A total of 8 cases were excluded due to congenital heart disease (3), congenital talipes equinovarus (2), congenital hypothyroidism (1), Down syndrome (1), atresia ani (1), bringing the total sample to 121 cases. The subject enrolment can be found in **Fig. 1**.

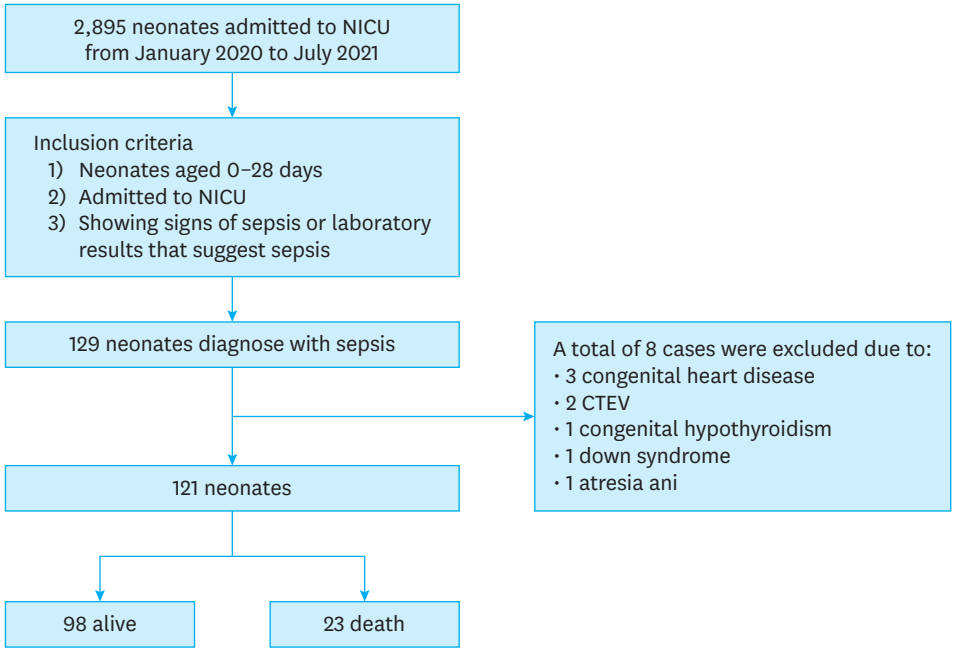

Fig. 1. Subjects' enrollment.
Abbreviations: NICU, neonatal intensive care unit; CTEV, congenital talipes equinovarus.

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Chi-square test results on sex, mode of delivery, APGAR score, and birthplace on the outcomes of neonates treated in the NICU did not show significant results. Birth weight showed a significant relationship (P=0.038) where the highest mortality rate was found in infants born with LBW, which was 73.9% of deaths. LBW neonates in this study had a risk of 2.8 times to die compared to normal birth weight neonates (odds ratio [OR], 2.833; 95% CI, 1.030–7.790; P=0.044). There was also a significant relationship in gestational age (P=0.009), where 78.3% of deaths were experienced by premature neonates. The premature neonates with sepsis had a 3.9 times greater risk of dying when compared to term neonates (OR, 3.906; 95% CI, 1.344–11.356; P=0.012). This is described in **Table 1** and the results of multivariate analysis in **Table 4**. The bacterial culture results in **Table 2** obtained significant results (P=0.011) on neonatal outcomes. Gram-negative culture results provided a 4.8 times greater risk of dying than gram-positive (OR, 4.821; 95% CI, 1.018–22.842; P=0.047). Sepsis due to *Klebsiella pneumoniae* in this study had the highest mortality in the gram-negative group. The map of bacteria can be found in **Table 3**.

Mann-Whitney test was performed to compare the laboratory results (leukocytes, platelets, neutrophils, lymphocytes, and CRP) and the length of stay between the alive and deceased

Table 1. Subjects characteristics

Variables	Outcome		Total	*P*-value
	Alive	Deceased		
Sex				0.845‡
Male	66 (67.3)	15 (65.2)	81 (66.9)	
Female	32 (32.7)	8 (34.8)	40 (33.1)	
Gestational age				0.009*‡
Aterm	51 (52.0)	5 (21.7)	56 (46.3)	
Preterm	47 (48.0)	18 (78.3)	65 (53.7)	
Birth weight				0.038*‡
Normal (≥2,500 g)	49 (50.0)	6 (26.1)	55 (45.5)	
LBW (<2,500 g)	49 (50.0)	17 (73.9)	66 (54.5)	
Mode of delivery				0.451‡
Spontaneous	69 (70.4)	18 (78.3)	87 (71.9)	
CS or others	29 (29.6)	5 (21.7)	34 (28.1)	
APGAR score				0.200‡
Normal (≥7)	35 (35.7)	5 (21.7)	40 (33.1)	
Low (<7)	63 (64.3)	18 (78.3)	81 (66.9)	
Birth place				0.472‡
Hospital	55 (56.1)	11 (47.8)	66 (54.5)	
Outside hospital	43 (43.9)	12 (52.2)	55 (45.5)	
Length of stay	11 (6.8–15.0)	4.0 (1.0–7.0)	9.0 (4.0–14.0)	<0.001*†

Values are presented as number (%) or median (interquartile range).
Abbreviations: LBW, low birth weight; CS, Caesarean section.
*Significance <0.05; †Mann-Whitney U test; ‡Chi-square test.

Table 2. Laboratory results

Laboratory tests	Outcome		Total	*P*-value
	Alive	Deceased		
Leukocyte count (/mm^3)	12,150 (8,975–16,600)	12,700 (6,800–19,400)	12,200 (8,700–16,700)	0.739†
Platelet count (/mm^3)	235,000 (170,500–324,250)	138,000 (99,500–258,500)	226,000 (133,000–314,500)	0.018*†
Neutrophil count (/mm^3)	6,950 (4,350–11,500)	7,000 (4,000–14,000)	7,000 (4,300–11,550)	0.840†
Lymphocyte count (/mm^3)	3,150 (2,200–4,500)	2,100 (1,400–5,500)	3,000 (2,050–4,600)	0.150†
CRP	30.75 (10.7–82.1)	90.00 (40.0–172.1)	38.20 (13.7–105.7)	0.002*†
Blood culture				0.014*‡
Gram-positive	26 (76.5)	3 (33.3)	29 (67.4)	
Gram-negative	8 (23.5)	6 (66.7)	14 (32.6)	

Values are presented as number (%) or median (interquartile range).
Abbreviation: CRP, C-reactive protein.
*Significance <0.05; †Mann-Whitney U test; ‡Chi-square test.

https://doi.org/10.14776/piv.2023.30.e6

Table 3. Map of bacterial culture

Bacteria	Alive	Deceased
Gram positive		
Staphylococcus aureus	6	2
Staphylococcus gallinarum	1	
Staphylococcus haemolyticus	11	1
Staphylococcus hominis	2	
Staphylococcus epidermidis	5	
Gram negative		
Eschericia coli	1	
Enterobacter cloacae	1	
Enterococcus faecalis	2	1
Klebsiella pneumoniae		2
Sphingomonas paucimobilis	2	
Acinetobacter lwofii	1	
Acinetobacter baumannii	1	
Pseudomonas aeruginosa		1
Pseudomonas luteola		1
Serratia marcescens	1	1

Table 4. Multivariate analysis on risk factors that have a significant effect

Variable	OR	95% CI	*P*
LBW (<2,500 g)	2.833	1.030–7.790	0.044
Premature (<37 weeks)	3.906	1.344–11.356	0.012
Gram negative bacteria	4.821	1.018–22.842	0.047

Abbreviations: OR, odds ratio; CI, confidence interval; LBW, low birth weight.

neonates. Significant differences were shown in the platelets (*P*=0.024), CRP (*P*=0.003), and length of stay (*P*=0.001). The median thrombocyte in the deceased neonates was lower than alive neonates, while the CRP value in the deceased neonates had a higher median than the alive neonates which is described in **Table 2**. The length of stay on the outcomes of alive neonates has a lower median than deceased neonates described in **Table 1**.

DISCUSSION

The significant results in this study were gestational age, birth weight, CRP, length of stay, blood culture, and platelets. Sex, number of leukocyte count, lymphocyte, neutrophil, mode of delivery, birthplace were not associated with mortality of neonatal sepsis, this was consistent with previous studies. Despite APGAR being the significant factor in previous studies, but not in this study. This may be due to the variability in interpreting some components such as tone, skin color, and reflex.

This study found that prematurity was 4 times greater to die due to sepsis. The study conducted by Kardana[10] showed that prematurity has the potential to be 3 times more likely (relative risk [RR], 3.39; CI, 1.043–11.035; *P*=0.042) to die if they have sepsis. The relationship between preterm birth and neonatal mortality in sepsis is due to humoral and cellular immunity deficiency. This condition is caused by the immature immune system and the non-optimal transfer of transplacental immunoglobulin in preterm neonates so that the immunoglobulin is lower than term neonates.[10] Organ immaturity also makes it difficult for the preterm neonates to adapt extra-uterine, making it easier to deteriorate and death.[11] Efforts to prevent premature labor could reduce neonatal sepsis mortality.

https://doi.org/10.14776/piv.2023.30.e6

LBW contributes the risk of death in neonatal sepsis by 3 times in this study. This finding is in line with a study conducted by Kardana[10] that LBW neonates are 8 times more likely (RR, 8.41; CI, 2.4 to 29.0; *P*=0.001) to die if they have sepsis. The high mortality rate in the LBW neonates might be due to either inherent immune deficiency or the need of prolonged hospitalization, which raises the risk of nosocomial infection.[12,13]

The results of CRP in this study were higher in the deceased neonates. This is because CRP is associated with the immune system and triggers inflammation in the body.[14] The increase in CRP is associated with organ damage and mortality.[15] To date, no studies have been conducted to examine CRP as a prognostic factor associated with mortality in neonatal sepsis, so further research is needed.

In this study, the number of neonates who lived had a length of stay 2 times longer than the number of neonates who died. These results are in line with the findings by Meshram et al.[12] that is, the mean length of stay for the surviving neonates was 9.67±4.50 days while that of the deceased neonates was 4.68±3.86 (OR, 0.69; CI, 0.63–0.74; *P*<0.001).

Neonates who died in this study were dominated by gram-negative bacteria, which had a 5 times greater risk of causing death. This is in line with the study conducted by Kermorvant-Duchemin et al.,[16] which showed that 63% of neonates died from infection with gram-negative bacteria where the number of deaths was ten times (OR, 10.1; 95% CI, 1.5–65.7; *P*=0.015) greater than gram-positive bacteria. In this study, the gram-negative bacteria that caused the most deaths was *K. pneumoniae*. The study conducted by Jumah et al.[6] obtained the same results where the most cases of death were caused by *K. pneumoniae* as many as 38 cases (36.6%), followed by *Escherichia coli* as many as 33 (27.5%), and *Pseudomonas aeruginosa* as many as 27 (22,5%). In addition, the study results by Saleem et al.[17] showed that *K. pneumoniae* was highly resistant to antibiotics and resulted in poor neonatal outcomes. Our findings contradict the findings of Turhan et al.,[18] which found that Gram-positive bacteria dominated neonates who died, and most deaths were caused by *Staphylococcus* spp. with a total of 25 cases (48.3%). This difference in findings was due to differences in the map of bacteria between regions.

The platelet count in deceased neonates in this study was less than 150,000, indicating thrombocytopenia in this group. This is in line with a cohort study conducted by Ree et al.,[19] which showed as many as 55% of neonates with sepsis had thrombocytopenia and 20% of neonates had severe thrombocytopenia, which was 3.7 times (OR, 3.77; 95% CI, 1.33–10.64; *P*=0.012) risk of increased mortality. The mechanism of thrombocytopenia is still unknown. It is thought that thrombocytopenia occurs due to impairment platelets production, increased platelets consumption, increased platelets destruction, or increased platelets sequestration in the spleen.[20] Production of platelets that cannot meet and replace damaged platelets causes thrombocytopenia in neonatal sepsis.[20]

This study has some limitations. First, the incomplete data is an inevitable problem due to retrospective cohort such as maternal profiles (pregnancy history, illnesses during pregnancy) in this study. Second, vital signs were not included because they were written in a range, making it difficult to know the exact value. Third, the diagnosis were made by different clinicians.

In conclusions, there is a correlation between prematurity, LBW and gram-negative infection with mortality in neonatal sepsis. Prematurity had a 4 times greater risk of death than infants

https://doi.org/10.14776/piv.2023.30.e6

born at term, infants with LBW had 3 times greater risk than infants with normal birth weight, and infants with gram-negative blood cultures had a 5 times greater risk of dying.

ACKNOWLEDGEMENTS

The authors are grateful and thanks to Pediatric Department and Medical Record Center of Dr. R. Sosodoro Djatikoesoemo General Hospital which provide facility for the author.

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요약

목적: 패혈증은 개발도상국에서 연간 사망률의 30–50%를 차지하는 신생아 사망의 가장 흔한 원인이다. 본 연구는 신생아 패혈증 사망률의 예후인자를 알아보고자 하였다.
방법: 2021년 4월부터 2021년 9월까지 R. Sosodoro Djatikoesoemo 주지사 병원 신생아 중환자실에서 패혈증을 진단받은 121명의 신생아를 대상으로 후향적 코호트 연구로 진행되었다. 연구대상자 선정기준은 신생아 중환자실에 입원하고 패혈증을 진단받은 생후 0–28일된 신생아였다. 임상 기록이 불완전한 경우와 선천적 기형을 가진 경우는 제외하였다. 성별, 재태주령, 분만방식, 출생체중, APGAR 점수, 출생지, 혈액배양에 대해 카이제곱 검정을 시행하였고 백혈구, 림프구, 호중구, 혈소판, C반응단백 (C-reactive protein, CRP) 및 체류 기간에 대하여서는 정규성 검정을 한 후 Mann-Whitney 테스트로 분석하였다.
결과: 출생체중 (P=0.038), 임신주수 (P=0.009), 혈액배양 (P=0.014)은 신생아 패혈증 결과에 유의한 상관관계를 보였고, Mann-Whitney 검사는 혈소판 (P=0.018), CRP (P=0.002) 및 재원 기간 (P<0.001)에서 유의한 차이를 보였다. 다변량 분석에서 신생아 패혈증 사망률과 관련된 세 가지 예후 인자는 미숙아 (오즈비 [odds ratio, OR], 3.906; 95% 신뢰구간 [confidence interval, CI], 1.344–11.356; P=0.012), 저체중 출생 (OR, 2.833; 95% CI, 1.030–7.790; P=0.044), 그람 음성 박테리아 (OR, 4.821; 95% CI, 1.018–22.842; P=0.047)인 것으로 나타났다.
결론: 미숙아, 저체중아, 그람 음성균 감염이 신생아 패혈증의 예후와 관련이 있었다.