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ORIGINAL ARTICLE

Neonatal sepsis markers used at Portoviejo General Hospital

Marcadores de sepsis neonatal empleados en el Hospital General Portoviejo

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Abstract Neonatal sepsis is an invasive infectious disease that affects children under 28 days of age and is characterized by potentially fatal organ dysfunction due to the dysregulation of the neonate's response to invasive microorganisms. It is classified into early sepsis, manifested within the first 72 hours of life, and late sepsis, occurring after this period, representing a significant cause of morbidity and mortality in this population. The objective was to evaluate the sepsis markers used at the General Hospital of Portoviejo. The qualitative-quantitative, descriptive, cross-sectional, and retrospective observational study included 42 reports of neonatal sepsis markers obtained from anonymized medical records of newborns diagnosed with sepsis between July and December 2022. Descriptive statistics and the Pearson coefficient were applied to analyze the correlation between variables. Most cases involved male neonates, full-term births, children of mothers aged 26 to 35 years, and those from rural areas. Late sepsis predominated, and procalcitonin was the most sensitive marker, with elevated levels in all cases. A significant relationship was found between procalcitonin and the diagnosis of sepsis, the medical history or risk factors, and respiratory distress as a clinical manifestation.

Keywords sepsis markers, procalcitonin, C-reactive protein, neonatal sepsis.

Resumen La sepsis neonatal es una enfermedad infecciosa invasiva que afecta a niños menores de 28 días de nacidos, caracterizada por una disfunción orgánica potencialmente mortal debido a la desregulación de la respuesta del neonato frente a microorganismos invasores. Se clasificó en sepsis precoz, manifestada en las primeras 72 horas de vida, y sepsis tardía, después de este período, representando una causa importante de morbilidad y mortalidad en esta población. El objetivo fue evaluar los marcadores de sepsis utilizados en el Hospital General de Portoviejo. El estudio, de tipo cualicuantitativo, observacional descriptivo, transversal y retrospectivo, incluyó 42 reportes de marcadores de sepsis neonatal obtenidos de historias clínicas anonimizadas de recién nacidos diagnosticados con sepsis entre julio y diciembre de 2022. Se aplicó estadística descriptiva y el coeficiente de Pearson para analizar la correlación entre variables. La mayoría de los casos correspondieron a neonatos masculinos, nacidos a término, hijos de madres de entre 26 y 35 años, y provenientes de zonas rurales. Predominó la sepsis tardía, y la procalcitonina destacó como el marcador más sensible, con niveles elevados en todos los casos. Se identificó una relación significativa entre la procalcitonina y el diagnóstico de sepsis, los antecedentes o factores de riesgo y el distress respiratorio como manifestación clínica.

Palabras clave marcadores de sepsis, procalcitonina, proteína C reactiva, sepsis neonatal.

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PUBLIS EDITORIAL

Introduction

Neonatal sepsis is an invasive infectious disease that affects children under 28 days of life, characterized by potentially fatal organ dysfunction caused by the dysregulation of the neonate's immune response to the invasion of a microorganism (Attia et al., 2023). This condition constitutes a medical emergency due to its rapid progression and high lethality, making it one of the leading causes of admission to neonatal intensive care units (NICU) worldwide. It can present as early neonatal sepsis, when it occurs within the first 72 hours of life, or as late sepsis, when it develops after this period. Both forms represent a significant cause of morbidity and mortality in this age group (Eichberger et al., 2022).

Early identification of neonatal sepsis is a clinical challenge, as symptoms are often nonspecific and can be confused with other neonatal conditions. Therefore, diagnostic markers have become an essential tool to improve prognosis and guide therapeutic management. Commonly used markers include hematological indices such as leukocyte count and the neutrophil/lymphocyte ratio; acute phase reactants such as C-reactive protein (CRP) and procalcitonin (PCT); inflammatory cytokines like tumor necrosis factor-alpha (TNF-α) and interleukins; and more recent biomarkers such as presepsin and endocan, which have shown promising potential in recent studies (Boscarino et al., 2023).

In Ecuador, specifically in Manabí, neonatology services have begun integrating some of these markers into their clinical practice. However, access to advanced technologies and diagnostic tests may vary across regions, highlighting the importance of conducting local research to assess the utility and availability of these biomarkers in specific contexts. Therefore, this study aimed to evaluate the neonatal sepsis markers used in the Neonatology Service of the General Hospital of Portoviejo to provide evidence that may contribute to the improvement of diagnostic and therapeutic protocols in the region.

Methodology

The research was developed using a qualitative-quantitative approach, with a descriptive observational design, cross-sectional, and retrospective design. The study was conducted at the General Hospital of Portoviejo, evaluating the results of the sepsis markers used in the neonatology service and the sociodemographic characteristics and risk factors associated with neonatal sepsis. Data was collected by reviewing medical records of mothers and neonates diagnosed with sepsis from July to December 2022. The correlation between the results of the sepsis markers and the study variables was determined.

The population included the medical records of mothers and neonates diagnosed with neonatal sepsis, both early and late, during the mentioned period. The final sample consisted of 42 selected medical records based on inclusion criteria, which required complete data for the study. Those with incomplete information or without serum values for CRP, procalcitonin, and blood cultures were excluded.

The information was obtained directly from anonymized medical records, and data collection was carried out using a specifically designed form for the study. The form included sociodemographic data, maternal history, neonatal clinical manifestations, and sepsis marker results.

The data was processed in Microsoft Excel and analyzed using SPSS version 26 (IBM). The results were presented through tables and graphs, employing descriptive statistics, frequencies, percentages, and cross-tabulations. The Pearson coefficient was used to analyze the specific objective related to variable correlation, with a significance level set at $\alpha = 0.05$. Prior to the development of the research, approval was obtained from the Human Research Ethics Committee of the Technical University of Manabí, with the code CEISH-UTM-INT_23-06-28_NTS.

Results and discussion

The maternal age and gestational age of the neonates diagnosed with neonatal sepsis during the study period were recorded. The age of half of the mothers was in the range between 26 and 35 years (50.0%), followed by those between 19 and 25 years (26.19%). These figures coincide with the optimal reproductive age, which explains the higher frequency of sepsis cases in neonates born to mothers in these age ranges. Adolescent mothers under 18 years represented 7.14% of the cases despite the high incidence of teenage pregnancies in the region. This finding could suggest a lower risk associated with this age group in the studied population or a possible underrepresentation of these cases.

Full-term neonates (37-42 weeks) had a higher prevalence of neonatal sepsis (50%), possibly related to the fact that most births worldwide occur within this gestational range, which could be linked to greater exposure to perinatal risk factors associated with sepsis. Late preterm neonates (34-36 weeks and 6 days) represented 26.19% of the cases, while extremely preterm neonates (less than 30 weeks) showed a lower incidence (2.38%).

Ezinmegnon et al. (2022) documented that most cases involved neonates born between 33 and 37 weeks of gestation, while the incidence was significantly lower in those born at

less than 28 weeks. The most common maternal ages in that study were between 32 and 37 years.

Table 1. Sociodemographic characteristics of mothers and neonates diagnosed with sepsis

Indicator	Frequency	Percentage
Mother's age (years)		
< 18	3	7.14
19-25	11	26.19
26-35	21	50.0
>35	7	16.66
Gestational age (weeks)		
< 30	1	2.38
31-33	0	0
34-36	11	26.19
37-42	30	71.42
Total	42	100
Sex of neonates diagnosed with sepsis		
Female	19	45.24
Male	23	54.76
Origin		
Rural	25	59.52
Urban	17	40.48

The majority (54.76%) of the neonates diagnosed with sepsis were male, while 19 (45.24%) were female. In a study by Ezinmegnon et al. (2022), of 172 neonates diagnosed with sepsis, 55% were male, and the remaining 45% were female. The 59.52% of the neonates diagnosed with sepsis were from rural areas, and 40.48% from urban areas. It was reported that 99.42% of sepsis cases were from urban areas (Ezinmegnon et al., 2022), which contrasts with the results of the present study.

Figure 1 shows the monthly incidence of diagnosed sepsis cases during a six-month period (July-December 2022). The highest number of neonates with sepsis occurred in November, with 10 cases (23.88%).

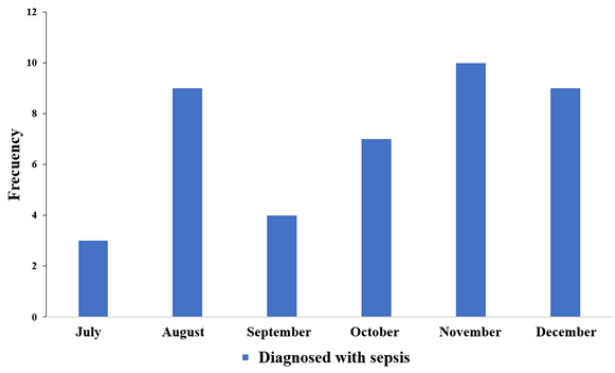

Figure 1. Patients diagnosed with sepsis.

In July, only three patients were diagnosed with sepsis (7.14%), but in August and December, there was an increase, with 9 cases (21.42%) recorded in each month. Ospino-Muñoz et al. (2022) conducted a similar study but did not report the specific frequency of sepsis cases for each month of the study.

Urinary sepsis stood out as the most frequent antecedent or risk factor in mothers, affecting 29 (69.04%). Other factors included vaginosis (35.71%), chorioamnionitis, prolonged rupture of membranes (more than 18 hours), and fever, with one case each (2.38%). Some mothers had more than one risk factor at the same time. Table 2 shows the risk factors for mothers and the clinical manifestations of neonates diagnosed with sepsis.

Table 2. Risk factors of the mother and clinical manifestations of the neonate diagnosed with sepsis

Indicator	Frequency	Percentage
Maternal risk factors		
Urinary sepsis	29	69.04
Vaginosis	15	35.71
Chorioamnionitis	1	2.38
PROM >18h	1	2.38
Fever	1	2.38
Clinical manifestations of the neonate		
Food intolerance	8	19.05
Respiratory distress	23	54.76
Thermal instability	3	7.14
Color changes	18	42.86

Respiratory distress was observed in 23 neonates diagnosed with sepsis, constituting 54.76% of the sample. Other clinical manifestations were identified in the neonates, and several manifestations were present in the same neonate. Skin and mucosal color changes were a clinical manifestation of early sepsis, and these signs were recorded in 18 children (42.86%). Feeding intolerance was also observed in 8 cases (19.05%) and thermal instability (7.14%).

Aydemir et al. (2018) identified thrombocytopenia as the most frequent risk factor (34.8%), in addition to prolonged membrane rupture (11.81%) and chorioamnionitis (10.33%). The clinical manifestations reported by Roble et al. (2022) were fever (38%) and respiratory distress (14.71%).

Table 3 shows the types of sepsis, C-reactive protein (CRP) levels, and procalcitonin. The diagnosis of early and late sepsis provided information on the timing of detection and diagnosis of this serious medical condition. The results

reveal an apparent disparity in the phase in which sepsis occurred.

Table 3. Distribution of clinical indicators and biomarkers in patients diagnosed with sepsis

Indicator	Frequency	Percentage
Patients diagnosed with sepsis		
Early sepsis	3	7.15
Late sepsis	39	92.85
C-reactive protein (CRP)		
Normal value	38	90.48
Altered value	4	9.52
Procalcitonin		
> 0.5	24	57.1
0.047 – 0.5	18	42.9

Early sepsis was presented in 7.15%, while the majority (92.85%) was diagnosed with late sepsis. These results matched Aydemir et al. (2018), who reported that late sepsis predominated at 51.96%. The C-reactive protein (CRP) test results in neonates with sepsis, indicating the probability of sepsis, revealed that only 9.52% of neonates had elevated values. In comparison, 90.48% had results within the normal range.

The study by Cortés et al. (2019) reported a sensitivity and specificity of CRP of 72.2% and 82.4%, respectively. In the work by Khan et al. (2019), 63.8% had negative CRP test results, while 36.4% were positive. In contrast to CRP, 100% of the cases had elevated procalcitonin levels, with no results in the normal range. 43% showed values between 0.047 and 0.5 ng/mL, while 57% had values greater than 0.5 ng/mL, confirming its high predictive capacity for neonatal sepsis diagnosis. Kordek et al. (2017) evaluated the usefulness of procalcitonin, CRP, and white blood cell (WBC) count in 57 infected neonates and 72 uninfected neonates, finding significant differences in the levels of these biomarkers. A rapid decrease in procalcitonin was observed after two days of antibiotic treatment.

On the other hand, Robledo-Restrepo et al. (2015) confirmed the diagnosis of sepsis in 39 of the 65 neonates studied, with elevated procalcitonin levels in all cases. This result highlighted the superiority of acute phase reactants (procalcitonin and CRP) as indicators of neonatal sepsis. Likewise, Tang et al. (2022) reported 100% positivity in procalcitonin tests, corroborating its diagnostic accuracy.

The use of procalcitonin as a highly sensitive and specific biomarker to identify bacterial infections in neonates has been supported. Compared to CRP, its rapid elevation and return to normal levels make it a valuable tool in managing neonatal sepsis, especially with a threshold value of 0.05 ng/mL that practically rules out the presence of infection.

Determining blood cultures in neonates revealed that only one case (2.38%) had a positive result, with Enterobacter cloacae identified as the etiological agent. The frequency of microorganism detection in blood cultures was low, suggesting possible limitations in the method's sensitivity and highlighting the need to review sample collection procedures and culturing techniques.

The low positivity rate emphasized the importance of complementing blood cultures with other biomarkers and diagnostic tests to diagnose neonatal sepsis accurately. Biomarkers such as C-reactive protein (CRP) and procalcitonin have proven valuable tools to improve diagnostic sensitivity and specificity, especially in cases where blood cultures yield negative results.

The blood culture results indicated that 49% were positive and 51% were negative. The predominant microorganisms were E. coli and Enterobacter cloacae, both pathogens commonly associated with neonatal sepsis. The variability between studies indicates that optimizing diagnostic techniques and clinical approaches for neonatal sepsis detection is necessary (Aydemir et al., 2018).

Table 4 shows the relationship between procalcitonin and gestational age. The correlation between the gestational age of neonates with sepsis and procalcitonin levels as a marker of the disease was determined. Using Pearson's correlation coefficient, a significant positive relationship of 0.045 ($p \leq 0.05$) was identified, indicating that procalcitonin levels tended to be more positive as gestational age increased.

Hahn et al. (2015) determined the reference levels of serum procalcitonin (PCT) in newborns based on gestational age (GA) and postnatal age (PNA). The results showed that serum PCT levels were negatively correlated with GA and birth weight, higher in neonates with GA ≤ 32 weeks and PNA of 7 to 30 days. The reference levels of PCT in infants with GA ≤ 32 weeks are influenced by PNA.

Preterm newborns showed an earlier, more intense, and prolonged PCT response compared to term neonates, indicating an inverse relationship between GA and the magnitude of the PCT response. There are reference values for PCT according to GA and days of life to establish specific cutoff values for the diagnosis of early-onset neonatal sepsis. Its utility is limited by the influence of non-infectious factors, such as intraventricular hemorrhage, perinatal asphyxia, and respiratory distress, which can also elevate serum PCT le-

Table 4. Correlation between procalcitonin and gestational age

Variable	Parameter	Procalcitonin	Gestational age
Gestational age	Pearson correlation	0.081	1
	Sig. (two-tailed)	0.045	
	N	42	42
Procalcitonin	Pearson correlation	1	0.081
	Sig. (two-tailed)		0.045
	N	42	42

Statistical significance level 0.05.

vels, complicating or hindering accurate diagnostic evaluation (Ospino-Muñoz et al., 2022).

In this study, most newborns (71.42%) were full term, while 26.19% were late preterm, and only one case was preterm with GA less than 30 weeks. Therefore, the correlation between these variables differed from that reported by other studies.

Table 5 shows the correlation between procalcitonin and the history of urinary sepsis. A significant correlation was observed between the history of maternal urinary sepsis and procalcitonin levels as a marker of neonatal sepsis, using Pearson's correlation coefficient, with a result of 0.045 (p

Table 5. Correlation between procalcitonin and history of urinary sepsis

Variable	Parameter	Procalcitonin	Urinary sepsis
History of urinary sepsis	Pearson correlation	0.125	1
	Sig. (two-tailed)	0.043	
	N	42	42
Procalcitonin	Pearson correlation	1	0.125
	Sig. (two-tailed)		0.043
	N	42	42

Statistical significance level ≤ 0.05.

≤ 0.05).

Mohsen & Kamel (2015) demonstrated that procalcitonin (PCT) was 80% sensitive for diagnosing neonatal sepsis and 85.7% specific. A correlation was identified between the maternal history of urinary tract infection and higher procalcitonin levels as a marker of sepsis in 35 neonates with early-onset sepsis (Tang et al., 2022). Table 6 shows the correlation between procalcitonin and respiratory distress.

No studies have established a specific correlation between this clinical manifestation, which is common in newborns and has varied etiology, and sepsis markers. In neonatal sepsis, the early signs are often nonspecific and subtle, making it difficult to differentiate between microorganisms, including viruses.

Table 6. Correlation between procalcitonin and respiratory distress

Variable	Parameter	Procalcitonin	Respiratory distress
Respiratory distress	Pearson correlation	0.023	1
	Sig. (two-tailed)	0.008	
	N	42	42
Procalcitonin	Pearson correlation	1	0.023
	Sig. (two-tailed)		0.008
	N	42	42

Statistical significance level p ≤ 0.05.

The most common early signs include decreased spontaneous activity, weak sucking, anorexia, apnea, bradycardia, and thermal instability (hypothermia or hyperthermia). Fever is observed in only 10-15% of affected newborns. Other common signs and symptoms include respiratory distress, neurological manifestations, and jaundice (Sharma et al., 2018).

The usefulness of procalcitonin lies in its ability to relate to the first clinical manifestations, facilitating the early diagnosis of early-onset neonatal sepsis in newborns with risk factors. This marker has the advantage of rising ahead of C-reactive protein (CRP) within a range of 4 to 6 hours, in addition to being useful as an indicator of infection severity, response to treatment, and prediction of clinical evolution (Boscarino et al., 2023).

Conclusions

This study provided an overview of the sociodemographic and clinical characteristics of mothers and newborns affected by sepsis. It was identified that the majority of mothers were between 26 and 35 years old, while most affected newborns were born between 37 and 42 weeks of gestation, predominantly male, from rural areas, and with late-onset sepsis. Portoviejo General Hospital's markers used for diagnosis included C-reactive protein, procalcitonin, and blood cultures. Procalcitonin stood out as the most effective marker, with high diagnostic accuracy and prognostic value, being positive in all cases and showing a significant relationship with the neonate's gestational age, maternal urinary tract infection history, and the most common clinical manifestation, respiratory distress.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Author contributions

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Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Statement on the use of AI

The authors acknowledge the use of generative AI and AI-assisted technologies to improve the readability and clarity of the article.

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