ORIGINAL RESEARCH

Prevalence and factors associated with early neonatal sepsis in a neonatal intensive care unit in Medellín, Colombia

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ABSTRACT

Background: Early neonatal sepsis poses a significant public health challenge worldwide, especially in Colombia and Latin America. It remains a leading cause of morbidity and mortality among newborns, particularly affecting those born prematurely or with low birth weights. Despite advancements in care and preventive strategies, the prevalence of sepsis continues to be alarming.

Methods: A descriptive study employing retrospective data was conducted in the PROCAREN Neonatal Intensive Care Unit (NICU) from May 2015 to January 2018. The study aimed to assess the prevalence and identify factors associated with early neonatal sepsis. A total of 88 medical records of neonates diagnosed with sepsis, either clinically or microbiologically, were reviewed, excluding those with incomplete records.

Results: Of the neonates studied, 55% were male, and 56% resided outside the metropolitan area. Maternal risk factors identified included chorioamnionitis (85.7%) and nearly half (46%) of women did not receive full prenatal care. Neonatal risk factors included pre-term birth (52.3%), low birth weight (49%), and a 5.7% mortality rate due to sepsis. Additionally, 37 neonates exhibited factors associated with early sepsis, with higher prevalence rates of hypoglycemia (29.7%), pneumonia (24.3%), and urinary tract infections (13.5%).

Conclusions: Our findings corroborate those in the literature, emphasizing socio-demographic and neonatal risk factors for early neonatal sepsis. Notable maternal factors identified included chorioamnionitis and prolonged rupture of membranes, while the main neonatal factors were pre-term birth and low birth weight. Despite preventive measures, high incidence and mortality rates due to sepsis persist, underscoring the importance of addressing these factors to improve neonatal outcomes.

KEYWORDS
Neonatal sepsis, intensive care, neonatal, pediatric

INTRODUCTION

Early neonatal sepsis (ENS) constitutes a critical medical emergency within the first 72 hours of a newborn's life. It is defined by a systemic inflammatory response to microbial infections acquired during or shortly after birth. Neonates, particularly those born prematurely or with a low birth weight, are at an elevated risk due to their underdeveloped immune systems. This increases their susceptibility to this condition (Odabasi & Bulbul, 2020). The clinical manifestations of ENS include respiratory distress, lethargy, feeding difficulties, hypothermia, hypotension, and other signs of clinical instability (Celik *et al.*, 2022; Odabasi & Bulbul, 2020). Timely diagnosis and intervention are paramount to preventing severe complications such as organ failure and neurological damage, which greatly impact morbidity and mortality rates among this vulnerable demographic (Odabasi & Bulbul, 2020). The early detection of ENS often relies on clinical suspicion, underscored by the presence of known risk factors (Celik *et al.*, 2022; Odabasi & Bulbul, 2020).

The principal risk factors for ENS are intrinsically linked to the immaturity of the newborn's immune system, a condition that is particularly pronounced in pre-term infants and those with low birth weight. Contributing biological factors include the premature rupture of membranes, maternal fever during delivery, inadequate prenatal care, and maternal infections such as Group B *Streptococcus* (*S. agalactiae*) (Ospino-Muñoz *et al.*, 2019; Zelellw *et al.*, 2021). These elements collectively heighten the risk of ENS, highlighting the critical need for vigilant monitoring and preventive strategies in high-risk neonates.

Recent studies have highlighted the global incidence and mortality rates associated with neonatal sepsis, noting significant geographical disparities. The Global Burden of Disease study

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estimated approximately 1.3 million annual cases of neonatal sepsis and related infections, equating to about 937 cases per 100,000 births (Fleischmann *et al.*, 2021). Developed countries such as the United States and Canada have seen a decrease in the incidence of neonatal sepsis, thanks to intrapartum antibiotic prophylaxis against Group B streptococcal infections, with reported incidences at 980 cases per 100,000 births (Sgro *et al.*, 2019). In contrast, the estimated incidence in developing countries stands at 3,930 per 100,000 live births over the past decade (Fleischmann *et al.*, 2021; Pérez *et al.*, 2015). Further studies involving premature and very low birth weight neonates have demonstrated significant susceptibility, with regional variations in incidence and mortality rates estimated at 27.4%, while morbidity rates soar to 89.3% (Fleischmann *et al.*, 2021).

In Latin America, the combination of prematurity and socio-demographic, cultural, and economic barriers, compounded by limitations in health systems affecting women's access to prenatal care, creates significant challenges. These factors collectively exacerbate the incidence of neonatal sepsis (Burga-Montoya *et al.*, 2017; Pérez *et al.*, 2015). Consequently, the region reports a relatively high rate of neonatal sepsis, with estimates ranging from 200 to 8,000 cases per 100,000 live births (Pérez *et al.*, 2015). This situation underscores the critical need for the effective design and implementation of prevention and early management strategies against neonatal sepsis in Latin America (Noah *et al.*, 2022; World Health Organization (WHO), 2022).

In Colombia, the precise incidence of neonatal sepsis is yet to be clearly defined. However, data from the National Administrative Department of Statistics (DANE) reveal that neonatal sepsis is a leading cause of infant mortality in the country. It accounts for 15.82% of neonatal deaths, with 5,507 reported cases, making it the second most common cause of death after respiratory conditions (Departamento Administrativo Nacional de Estadística (DANE), 2023). Despite the preventive measures by the Ministry of Health, the incidence of sepsis continues to rise. This lack of comprehensive data highlights an urgent need for further epidemiological research to guide the development of effective interventions to reduce the incidence and mortality rates of neonatal sepsis. Thus, the aim of this study is to describe the occurrence of neonatal sepsis in an intensive care unit and to characterize the associated risk factors.

METHODS

Study design and participants

This study was observational, descriptive, and retrospective, conducted at the PROCAREN Neonatal Intensive Care Unit (NICU) of San Vicente de Paul Hospital in, Caldas Department of Antioquia, Colombia between May 2015 and January 2018. A total of 1,044 medical records of neonates were evaluated. Of these, 940 were excluded for failing to meet the eligibility criteria for sepsis, and 16 were excluded due to incomplete records, 88 records of neonatal sepsis (8.4%) were retained (Figure 1).

The study population was primarily drawn from southwest Antioquia, with a minority originating from the Metropolitan area. Included in the sample were neonates with complete clinical histories and a confirmed clinical and/or microbiological diagnosis of early neonatal sepsis. Exclusions were made for cases with incomplete clinical histories or those that did not meet the diagnostic criteria for early neonatal sepsis.

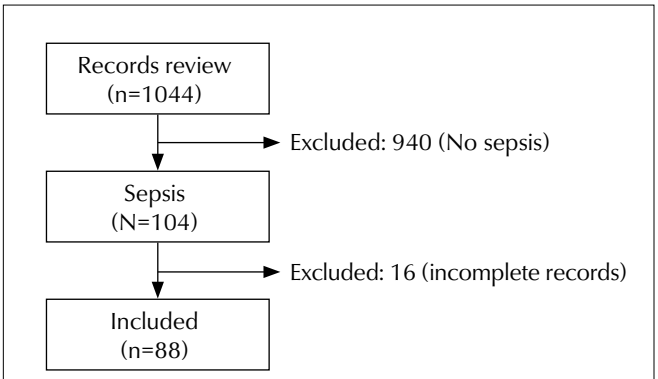

Figure 1: Flowchart of record screening.

Instruments

The investigated variables were categorized into three primary groups: sociodemographic, maternal and delivery-related, and neonatal-specific. Sociodemographic factors included the neonate's place of origin and sex. Maternal and delivery-related variables included high obstetric risk factors (OHR), the number of prenatal controls, screening, and prophylaxis for Group B *Streptococcus* (GBS), prolonged rupture of membranes, serology (VDRL, HIV, HBV, and toxoplasma), the presence of infections during delivery, and the mode of delivery (caesarean or vaginal). Neonatal variables encompassed gestational age, birth weight, the reason for the initial consultation, the need for resuscitation manoeuvres, admission temperature, birth-related events, premature classification by extreme pre-term (less than 28 weeks), very pre-term (28 to 32 weeks), and late pre-term (32 to 37 weeks), and results of paraclinical examinations and microbiological cultures (cerebrospinal fluid [CSF], blood, urine). Variables were selected based on existing literature and clinical guidelines identifying factors common to neonatal sepsis.

Procedure and statistical analysis

Data collection was carried out by reviewing and extracting information from the medical records using a structured survey designed specifically for this purpose. The collected data were recorded in a Microsoft Excel spreadsheet for subsequent organization and analysis. Data extraction was performed by a nurse trained in the use of electronic medical records and the institution's software. The principal investigator oversaw data extraction and quality control. He performed periodic reviews of the data extraction and conducted double entry for randomly selected records. If inconsistencies were found, the entire medical record was re-extracted. Data analysis used a univariate approach, where qualitative variables were analyzed by determining absolute and relative frequencies. Quantitative variables were categorized according to predefined cut-off points for analysis as qualitative variables, thereby facilitating their interpretation.

Ethical approval

The study was conducted in accordance with rigorous ethical regulations. It was approved by the Ethics and Research Committee of the Fundación Universitaria San Martín under act 012 of 2021, and endorsed by the UCIN PROCAREN at the hospital of the present study. The investigators signed an agreement for data extraction. The extraction was performed by a nurse at the health institution, who anonymized the information in the Excel file, ensuring data confidentiality. The analysis relied on secondary sources, and there were no additional risks for the participants. Furthermore, it was confirmed that there were no conflicts of interest among the researchers involved.

RESULTS

The study analyzed a cohort of 88 neonates, with 55% (n=48) identified as male. Regarding geographic origin, 44% (n=39) were from the Metropolitan Area, which includes municipalities such as Medellín, Itagüí, La Estrella, and Caldas. In contrast, 43% (n=38) were from municipalities in southwestern Antioquia, while the remaining 13% (n=11) came from various regions across Antioquia, including Occidente, Oriente, Norte, Magdalena Medio, and Bajo Cauca Antioqueño.

Microbiological variables

Prenatal screening for infectious diseases revealed that 73%, 71%, and 60% of the patients were tested for Venereal Disease Research Laboratory (VDRL), Human Immunodeficiency Virus (HIV), and Hepatitis B Virus (HBV), respectively. However, only 25% underwent testing for Toxoplasmosis. Among the patients screened, two were positive for VDRL, one for HIV, 17 for HBV, and five for Toxoplasma. Additionally, screening for Group B *Streptococcus* (GBS) during prenatal care was conducted in only 20% of cases, yielding five positive results from 17 tests.

Cultures from normally sterile sites in neonates yielded significant findings. In the cerebrospinal fluid (CSF) of a neonate from Caldas, born to a mother with diabetes, oxacillin-resistant but vancomycin-sensitive *Staphylococcus aureus* was identified. This neonate also exhibited bacteremia caused by coagulase-negative *Staphylococcus spp.*, resistant to erythromycin but sensitive to clindamycin.

Five urine cultures returned positive. One neonate, diagnosed with congenital heart disease, had a urine culture positive for *Klebsiella sp.* , sensitive to amikacin and amphotericin B, with a blood culture revealing Enterococcus sp. sensitive to ampicillin. Another neonate, suffering from enterocolitis, showed *Escherichia coli* in the urine culture, which was sensitive to amikacin but resistant to cefepime. The third case involved ampicillin-sensitive *Escherichia coli*, with no noted additional risk factors. *Staphylococcus haemolyticus*, sensitive to trimethoprim-sulfamethoxazole and vancomycin, was detected in a fourth case, while *Enterobacter sp.*, sensitive to amikacin, was identified in a fifth patient.

Furthermore, eight neonates exhibited positive blood cultures without corresponding positive cultures from other sites. Two of these cases were attributed to *Staphylococcus aureus*, with one linked to a skin infection. One isolate demonstrated sensitivity to amikacin, oxacillin, and cefepime; this patient also harbored a cefepime-sensitive *Enterobacter* infection. Three neonates presented with *Escherichia coli* in their blood, all of which were sensitive to cefepime. Two instances involved coagulase-negative Staphylococcus, albeit without further details. Lastly, a patient diagnosed with pneumonia displayed a positive blood culture, but specific information regarding the microorganism or its antibiotic sensitivity profile was not disclosed.

Table 1: Clinical variables of the neonate

Variable		Percentage
Temperature (31)*		
Normothermia	19	61.3
Temperature alterations (n=12)		
Hypothermia	8	66.7
Hyperthermia	4	33.3
Lactate (73)*		
<2.5 mmol/L	49	67.0
>2.5mmol/L	24	33.0
Resuscitation manoeuvres (86)*		
Basic	32	37.2
Advanced	14	16.3
Not performed	40	46.5
Factors associated with early neonatal sepsis (37)		
Hypoglycemia	11	29.7
Pneumonia	9	24.3
Congenital heart disease	3	8.1
Necrotizing enterocolitis	3	8.1
Convulsive state	2	5.4
Meningitis	2	5.4
Skin Infection	2	5.4
Urinary tract infection	5	13.5
Sepsis-associated death (88)	**5**	**5.7**

Note: *Missing record: Temperature 57, Lactate 15, resuscitation 2

Table 1 provides a comprehensive overview of the clinical characteristics observed in the study's neonatal subjects. Temperature alterations were noted in 14% of cases (n=12), with hypothermia representing 66.7% and hyperthermia 33.3% of these instances. Additionally, 33% of neonates exhibited serum lactate concentrations equal to or greater than 2.5 mmol/L. Thirty-seven clinical events associated with early neonatal sepsis were documented, with hypoglycemia (29.7%) being the most prevalent, followed by pneumonia (24.3%) and urinary tract infections (13.5%). Five fatal events were reported, representing 5.7% of all cases analyzed with neonatal sepsis. These fatalities occurred in patients from both rural and urban settings, specifically in La Pintada, Támesis, Amagá, Caldas, and Medellín, with none of these cases presenting positive cultures.

Table 2: Maternal factors		
Variable		**Percentage**
High-risk obstetric (88)		
Yes	37	42.0
No	51	58.0
Factor associated with HRO (n=37)		
Under 18 years old	16	43.2
Over 40 years old	1	2.7
Multigestant	16	43.2
Maternal Infection	13	35.1
Urinary tract infection	8	21.6
Gestational diabetes	6	16.2
Drug dependence	6	16.2
Smoking	2	5.4
Thyroid disorders	1	2.7
Malnutrition	1	2.7
Preeclampsia	1	2.7
Prenatal care (87)*		
Complete	47	54.0
Incomplete	38	43.7
Not performed	2	2.3
GBS prophylaxis (84)*		
Received	83	98.8
Did not receive	1	1.2
Maternal Infection		
Yes	28	31.8
No	60	68.2
Type of maternal infection (n=28)		
Chorioamnionitis	24	85.7
SGB	4	14.3
Bacterial vaginosis	3	10.7
Syphilis	1	3.6
HIV	1	3.6
Prolonged rupture of ovarian membranes (77)*		
Over 18h	32	41.6
Under 18h	45	58.4

Note: *Missing: Prenatal care 1, GBS prophylaxis 4, Prolonged rupture of ovarian membranes 11.

HRO: High-risk obstetric. h: hours. HIV: Human Immunodeficiency Virus. GBS: Group B *Streptococcus*

Concerning initial interventions, 52% (n=46) of neonates underwent some form of resuscitation maneuver at birth, with basic resuscitation procedures making up 37.2% and advanced resuscitation 16.3%. These findings highlight the critical role of early interventions and the need for vigilant monitoring and management of complications associated with early neonatal sepsis to enhance outcomes in this vulnerable group.

Table 2 highlights the relevance of high obstetric risk factors in the incidence of early neonatal sepsis. It was noted that 42% of the patients exhibited high obstetric risk, with a higher prevalence observed among young under 18 years old, accounting 43.2% of cases. Urinary tract infection was identified in 21.6% of pregnant women, while diabetes and drug dependence were reported in 16.2% of cases.

Prenatal follow-up was incomplete in 43.7% of the patients. Intrapartum prophylaxis against Group B *Streptococcus* (GBS) was administered to 98.8% of the mothers. Prolonged rupture of membranes was documented in 36.3% (n=32) of cases, and among these patients, 37.5% (n=12) developed maternal infection. In contrast, 28% of patients without prolonged rupture of membranes also developed infections. Chorioamnionitis was observed in 24 cases, accounting 85.7% of all maternal infections reported, with a higher incidence noted in patients with prolonged rupture of membranes.

Finally, the prevalence of risk factors for neonates during labour and birth revealed a high incidence of very premature gestational age (14.8%) and late premature (31.8%). Additionally, more than 48% of neonates had a birth weight under 2,500 grams (table 3).

Table 3: Neonatal factors during labour and birth		
Variable	**n (88)**	**Percentage**
Gestational age		
Extreme prematurity	5	5.7
Very premature	13	14.8
Late premature	28	31.8
Thermal newborn	42	47.7
Birth weight (grams)		
< 1,000	5	5.7
< 2,500	38	43.2
2,500 – 4,000	43	48.9
> 4,000	2	2.3
Delivery route (87)*		
Caesarean section	30	34.1
Vaginal	57	64.8

Note: *Missing: Delivery route 1.

DISCUSSION

This study characterized maternal risk factors for early neonatal sepsis, including chorioamnionitis and prolonged rupture of membranes. Neonatal characteristics typically involved pre-term birth and low birth weight. The study reported a 5.7% mortality rate due to sepsis. Conducted in a neonatal intensive care unit serving municipalities in southwestern Antioquia, the research highlighted that a significant portion of patients hailed from non-metropolitan areas. Notably, in these peripheral regions and similar areas across Colombia, first-level hospitals are tasked with providing health services, yet they often lack access to critical tests

such as VDRL, HIV, HBV, toxoplasma, and rectal-vaginal screening for GBS that is essential for comprehensive prenatal care (Yepes & Marin, 2018). Hence, geographic, and socioeconomic barriers pose significant challenges to accessing fundamental health services during prenatal care, impacting the early detection of maternal infections, and increasing the risk of neonatal sepsis.

One of the study's most alarming findings was that 46% of pregnant women did not receive a complete prenatal check-up. This aspect is crucial as prenatal care offers a unique opportunity to provide pregnant women care, support, and information. In this context, humanized prenatal care refers to best practices aimed at improving care by emphasizing quality through good practices, respectful support, and a focus on minimizing harm while ensuring the best quality of care for both the mother and child (Cáceres-Manrique *et al.*, 2015). Additionally, approximately 42% of the sample exhibited high obstetric risk factors, with urinary tract colonization during gestation identified as the primary infectious cause associated with neonatal sepsis. This underscores the importance of early detection and prophylaxis in situations of clinical suspicion of this infection as key strategies in preventing neonatal sepsis (Ospino-Muñoz *et al.*, 2019).

Urinary tract infections (UTIs) are prevalent in pregnant women, possibly due to anatomical changes like increased kidney size and uterine pressure on the ureters (Ifeanyi *et al.*, 2023). Blanco *et al.*'s retrospective cohort study found a lower UTI prevalence 2% for cystitis and 0.5% for pyelonephritis (Blanco *et al.*, 2015; Jaramillo-Jaramillo *et al.*, 2021). Conversely, our study showed a notably higher prevalence of 21.6%, stressing the need for heightened surveillance during pregnancy to safeguard neonatal health. Research indicates an increased UTI risk in women with pregestational diabetes mellitus (Bakiavathy & Lakshmi, 2023). Surprisingly, we found no UTI episodes in women with gestational or pregestational diabetes, with the highest incidence observed in patients with drug dependence and those under 18, including one case of chorioamnionitis. Only two high-risk pregnancies adhered to complete prenatal care. Various microorganisms, including cefepime-resistant *E. coli*, were identified as UTI causes, differing from prior studies (Jacobo-Gallardo *et al.*, 2023). Nonetheless, our study observed a higher prevalence of pre-term delivery among pregnant women with UTIs.

Amniotic membranes serve as protective barriers for the fetus, but prolonged rupture increases the risk of chorioamnionitis by allowing microbes to ascend (Al-Lawama *et al.*, 2019; Guío *et al.*, 2015; Jain *et al.*, 2022). Chorioamnionitis complicates about 10% of pregnancies (Guío *et al.*, 2015; Jain *et al.*, 2022) and untreated prolonged rupture leads to infection in 20-25% of cases (Bierstone *et al.*, 2018; Guío *et al.*, 2015; Sahu *et al.*, 2020). In our study, chorioamnionitis and prolonged rupture rates were higher than reported, with 85.7% and 36% of cases, respectively. Xie *et al.* found varying rates of histologic chorioamnionitis by gestational age (Xie *et al.*, 2015). Larger studies are needed to confirm these trends and their consequences, including pre-term delivery, neonatal infection, and fetal death. Additionally, our study found that 52% of neonates needing resuscitation had been exposed to chorioamnionitis, a significant risk factor for respiratory distress syndrome and ventilation needs (Metcalfe *et al.*, 2017).

From the 1990s to the present, a significant decrease in neonatal deaths attributable to sepsis has been observed, largely due to the implementation of prophylaxis strategies that reduce exposure to *Streptococcus agalactiae* or Group B streptococcus (GBS) (Rosa-Fraile & Alos, 2022). In Colombia, screening for GBS at 35 weeks of gestation has been made mandatory (Minsalud & Colciencias, 2013). However, this study revealed that only 20% of pregnant women were screened for GBS during their prenatal care, showing a considerable gap in the early identification of this infection. Despite this deficit in screening, it is noteworthy that 98% of pregnant women received at least one dose of GBS prophylaxis, which is a positive compensatory measure.

In addition, factors associated with neonatal sepsis of non-infectious origin were identified in the mothers who participated in the current study such as low birth weight, pre-term delivery, and vaginal delivery. Interestingly, three cases of sepsis were documented in neonates born by caesarean section, without the presence of conventional risk factors. These cases suggest the possible involvement of microorganisms in the amniotic fluid, derived either from the maternal microbiome or from pathogens present in the amniotic fluid during gestation, supported by previous research findings that have reported genetic material from a wide range of microorganisms in this fluid (Tapiainen *et al.*, 2018). This link requires further examination through future research.

While most pregnancies benefitted from GBS prophylaxis, no positive blood cultures for this pathogen were detected; instead, *Escherichia coli* was the most frequently isolated microorganism. These data could serve as a starting point to investigate a potential relationship between these observations. In contrast, a study at the Prado Clinic in Medellín, Colombia, reported a lower proportion of pregnant women receiving GBS prophylaxis and a prevalence of early neonatal sepsis of 0.14% associated with this microorganism (Ceballos *et al.*, 2014).

Mothers completing prenatal care avoided neonatal sepsis in 53% of cases, underscoring the im-portance of optimal adherence to prenatal care; however, reasons for lack of follow-up were not explored in this study. Critical neonatal factors increasing susceptibility to infections and potentially triggering sepsis include prematurity and low birth weight. Premature and low birth weight neonates have up to 10 times the incidence of infections compared to normal weight term neonates, primarily due to the immaturity of their immune system, lack of transplacentally transferred antibodies, and exposure to invasive procedures during their NICU stay (Shane *et al.*, 2017). The literature indicates an inverse relationship between the rate of sepsis and birth weight, reporting rates of 10.96 per 1000 live births for neonates weighing 401-1,500 g, 1.38 for those weighing 1,501-2,500 g, and 0.57 for those above 2,500 g (Shane *et al.*, 2017). This study highlighted the prevalence of prematurity and low birth weight in 52% and 49% of cases, respectively, although these conditions did not always occur concurrently.

In our study, the mortality rate was 5.7%, lower than the 9% observed in a similar investigation in Cali, Colombia, where low

birth weight (≤1500 g) was the most common factor among cases, accounting for 12.5% of these (Betancur *et al.*, 2008; Pérez-Camacho *et al.*, 2017). Notably, 60% of the deaths oc-curred in neonates with this characteristic. *Escherichia coli* was the most frequently isolated microorganism in early neonatal sepsis cases, consistent with our findings. Coagulase-negative Staphylococ-cus spp. was also identified, aligning with results reported by Betancur *et al.* in Medellín, Colombia (Betancur *et al.*, 2008). Among neonates with pneumonia in our study, 43% of cases were associated with mothers with chorioamnionitis, and mortality among pre-term infants with pneumonia reached 29%. The proportion of deaths in patients with sepsis associated with pneumonia was 33%. According to the WHO, the main direct causes of global neonatal mortality include asphyxia, pneumonia, tetanus, congenital malformations, prematurity, and sepsis, with 98% of neonatal deaths occurring in developing countries. A high proportion of the deceased cases (60%) in the current study presented with pneumonia and prematurity. There were no cases of tetanus, congenital malformations, or asphyxia among those who died of early neonatal sepsis.

The main limitation of the study is its observational design and the focus on a specific neonatal intensive care unit population which may potentially limit the generalizability of the study findings. The study is also limited by the lack of a controlled group to assess risk as well as the lack of long-term follow-up to assess persistent intervention effects and neonatal development. The incomplete data on prenatal care and socioeconomic characteristics may obscure additional factors for neonatal sepsis. Reliance on clinical registries and potential diagnostic accuracy variability among health professionals could introduce biases in identifying cases.

Despite these limitations, the study demonstrates that sociodemographic and neonatal risk factors for early neonatal sepsis are prevalent in the study population. Chorioamnionitis, prolonged rupture of membranes, and vaginal delivery were primary maternal risk factors, while prematurity and low birth weight were prevalent neonatal conditions. Despite preventive strategies, persistently high incidence and mortality rates associated with sepsis emphasize the ongoing need to strengthen and continually assess preventive measures.

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