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Original article

Prevalence and Risk Factors Associated with Escherichia coli Sepsis in Neonates: A Cross-Sectional Study from Zawia Medical Center, Libya

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Abstract
This retrospective cohort study investigated the prevalence, risk factors, and outcomes of Escherichia coli (E. coli) sepsis among neonates admitted to the Neonatal Intensive Care Unit (NICU) at Zawia Medical Center, Libya, from 2018 to 2019. Analyzing 411 neonates, E. coli was identified in 2.7% of culture-confirmed sepsis cases, with significantly higher mortality in E. coli-positive neonates (45.5% vs. 15.8%, p=0.022). Preterm birth was a key risk factor (72.7% of E. coli cases, p=0.04), alongside elevated C-reactive protein (CRP) during clinical deterioration (p<0.0001) and blood transfusion history (72.7% vs. 17.3%, p<0.0001). No associations were observed with sex, birth weight, or maternal age. The study highlights E. coli's outsized impact on mortality despite its low prevalence, emphasizing the vulnerability of preterm infants in resource-limited settings. Challenges in diagnosis, rising antimicrobial resistance, and gaps in local surveillance underscore the need for improved infection control, context-specific empiric antibiotic protocols, and enhanced laboratory capacity. These findings advocate for targeted interventions to reduce neonatal sepsis burden in Libya, prioritizing preterm care and strengthening microbiological monitoring to guide clinical and public health strategies.
Keywords: Neonatal Sepsis, Escherichia Coli, Risk Factors, Libya, Mortality.

Introduction

Neonatal sepsis is a potentially fatal condition characterized by a systemic inflammatory response syndrome triggered by infection in newborns, typically within the first 28 days of life [1]. Globally, it remains a primary contributor to infant morbidity and mortality, accounting for a substantial proportion of the estimated neonatal deaths each year, with the burden falling disproportionately on low- and middle-income countries [2]. The clinical presentation can be non-specific, making early diagnosis challenging yet crucial for initiating timely treatment and improving survival rates [3].

Among the diverse pathogens responsible for neonatal sepsis, bacteria are the most common culprits. While Group B Streptococcus (GBS) remains significant, particularly in early-onset sepsis in high-income countries [4]. Gram-negative bacteria, especially Escherichia coli, are major and increasingly recognized pathogens worldwide, particularly in late-onset sepsis and in many developing regions [5]. E. coli sepsis is particularly concerning due to its association with rapid clinical deterioration, severe complications such as meningitis, and the alarming global trend of increasing antimicrobial resistance, including resistance to first-line empiric antibiotics like ampicillin and gentamicin [6]. Depending on the region and study population, E. coli is estimated to cause a significant percentage (e.g., 10-30%) of culture-confirmed neonatal sepsis cases [7].

Identifying infants at high risk is paramount for effective prevention and management strategies. Previous research has identified several maternal and neonatal risk factors associated with neonatal sepsis. Key maternal factors include prolonged rupture of membranes (>18 hours), maternal intrapartum fever, chorioamnionitis, maternal urinary tract infection near delivery, and colonization with relevant pathogens like GBS or specific E. coli strains [8]. Frequently cited neonatal risk factors encompass prematurity (gestational age < 37 weeks), low birth weight (< 2500g), male sex, birth asphyxia, congenital anomalies, and the requirement for invasive procedures like mechanical ventilation or central venous catheterization [8]. However, the relative importance and specific profile of these risk factors can vary depending on the geographic setting, healthcare practices, and the predominant causative organisms.

In Libya, while neonatal mortality remains a public health concern [9]. There is a paucity of recent, comprehensive data specifically addressing the current microbial causes of neonatal sepsis and their locally relevant risk factors. Much of the existing knowledge is extrapolated from international studies, which may not accurately reflect the specific etiological agents, resistance patterns, or risk factor distribution within the Libyan population [9]. This knowledge gap limits the ability of clinicians and public health policymakers in Libya to implement tailored, evidence-based preventive measures and optimize empiric antibiotic therapy protocols. Zawia Medical Center, serving as a key tertiary referral hospital in western Libya, manages a substantial number of high-risk neonatal admissions and provides a crucial setting for investigating neonatal infectious diseases in this under-researched context.

Therefore, this study was designed specifically to address the lack of local data by investigating the prevalence of Escherichia coli sepsis among neonates admitted to the Neonatal Intensive Care Unit (NICU) at Zawia Medical Center, Libya. Furthermore, this study aimed to explore and identify the associated maternal and neonatal risk factors that may contribute to E. coli sepsis susceptibility and adverse outcomes

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within this specific patient population. Understanding the local epidemiology is imperative for guiding clinical practice and public health interventions aimed at reducing the burden of neonatal sepsis in Libya.

Methods

Study design and setting

This retrospective cross-sectional study reviewed the medical records of neonates admitted to the Neonatal Intensive Care Unit (NICU) at Zawia Medical Center, located in Zawia, west of Libya. The study period encompassed two years, from January 2018 to December 2019, and included a total of 418 mother-neonate pairs.

Data collection

Data were extracted from patient files, focusing on maternal demographics (age, gestational age at delivery, mode of delivery), neonatal characteristics (sex, gestational age, birth weight), perinatal clinical variables (gestation, delivery details, pregnancy-related complications), microbiological findings (isolated organisms from blood cultures), and neonatal outcomes (survival, C-reactive protein (CRP) levels, and CRP trends).
Based on blood culture results, neonates were categorized into two groups: those with Escherichia coli (E. coli) sepsis and those with non-E. coli sepsis. Maternal characteristics, potential risk factors, and neonatal outcomes were compared between these two groups.

Eligibility criteria

Inclusion criteria for neonates were admission to the NICU during the study period and representation of both sexes. Neonates with major congenital anomalies or incomplete medical records were excluded from the study.

Statistical analysis

The collected data were coded and analyzed using SPSS statistical software (version 25). Descriptive statistics, including frequencies, percentages, means, and standard deviations, were employed to summarize the data and outcome variables. Where appropriate, categorical variables were compared using the Chi-square test or Fisher's exact test. The Mann-Whitney U test was used to compare continuous variables. A p-value of ≤0.05 was considered statistically significant for all analyses.

Ethical consideration

Ethical approval for this study was obtained from the relevant health authorities. Due to the retrospective nature of the study, informed consent from individual participants was not required; however, data were anonymized to ensure confidentiality.

Results

A total of 411 neonates admitted to the Intensive Care Unit (ICU) were included in this retrospective cohort study. The geographical distribution of the study population revealed that the majority of newborns (n = 350, 85.2%) resided in Zawya, while the fewest admissions were from Tripoli and Raqdalen (n = 2, 0.5% each; Table 1).

Table 1. Distribution of the Study Population by Residence

Address	Frequency	Percent
Zawia	350	85.2
Sobrata	23	5.6
Sorman	21	5.1
Algelat	13	3.2
Regdalin	2	0.5
Tripoli	2	0.5
Total	411	100.0

The temporal distribution of admissions indicated the highest frequency in December and the lowest in February and June (Figure 1).

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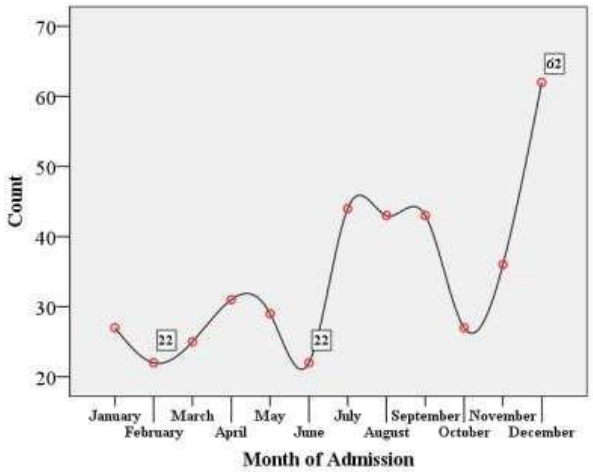

Figure 1. Monthly admission rates of the study population

The median maternal age was 31.0 years (mean 30.9 ± 5.6 years; Figure 2), and over half of the neonates (51.8%) were born preterm. Caesarean section was the predominant mode of delivery (Table 2). The sex distribution of the neonates was nearly balanced (54.7% male, 45.3% female; Table 2), with a mean birth weight of 2.5 ± 1.0 kg (median 2.5 kg; Table 2). At the time of NICU admission, 5.6% of neonates had elevated C-reactive protein (CRP) levels, which increased to 28.0% during any subsequent health deterioration (Figures 7 and 8). The majority of neonates (60.3%) did not experience deterioration during their admission; however, among those who did, most deteriorated within the first seven days. The overall mortality rate was 16.5%. Escherichia coli (E. coli) was identified in blood cultures of 2.7% of the neonates (Table 2).

Table 2. Baseline Characteristics of the Study Population

Characteristic		**n (%) or mean ± SD (Range, IQR)**
Maternal Age (years)		30.9 ± 5.6 (17-45)
Gestational Age	Preterm	213 (51.8)
	Full Term	198 (48.2)
Mode of Delivery	C/S	228 (55.6)
	NVD	182 (44.4)
Neonate Sex	Male	225 (54.7)
	Female	186 (45.3)
Birth Weight (kg)		2.5 ± 1.0 (0.5-6.0)
CRP at Admission	Positive	23 (5.6)
	Negative	388 (94.4)
Any Deterioration		163 (39.7)
Mortality		68 (16.5)
E. coli Positive		11 (2.7)
Blood Transfusion		77 (18.7)

A statistically significant association was observed between maternal gestational age and E. coli status (x 2 =4.21, df = 1, p=0.04), with a higher proportion of preterm neonates (3.8%) exhibiting E. coli infection compared to full-term neonates (1.5%; Table 3). No statistically significant differences in E. coli prevalence were found based on neonate sex (Fisher's exact test, p=0.555; Table 3), birth weight (Mann-Whitney U test, U=2107.5, p=0.160; Figure 12), mode of delivery (Fisher's exact test, p=0.228; Table 4), or maternal age (Mann-Whitney U test, U=2178.5, p=0.880; Table 3).

Table 3. Association of baseline characteristics with E. coli status

Characteristic	***E. coli* Negative**	***E. coli* Positive**	**p-value**
Gestational Age: Preterm n (%)	205 (51.2)	8 (72.7)	**0.04***
Neonate sex: Male n (%)	220 (55.0)	5 (45.5)	0.555
Birth Weight (kg) mean ± SD	2.5 ± 1.0	2.1 ± 0.9	0.160
Mode of Delivery: C/S n (%)	224 (56.0)	4 (36.4)	0.228
Maternal Age (years) mean ± SD	30.9 ± 5.6	32.0 ± 6.4	0.880
CRP at Admission: Positive n (%)	22 (5.5)	1 (9.1)	0.474

**Statistically significant.*

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Similarly, initial CRP status at admission was not significantly associated with E. coli infection (Fisher's exact test, p=0.474; Table 4). However, CRP status during health deterioration showed a highly significant association with E. coli infection (Fisher's exact test, p<0.0001; Table 4), with 9.2% of neonates with positive CRP on deterioration having E. coli infection, compared to 0% in the E. coli-negative group. The time to deterioration for E. coli-positive neonates varied, with most deteriorating within the first week of admission. Notably, the mortality rate was significantly higher among neonates with E. coli infection (7.4%) compared to those without (1.7%; Fisher's exact test, p=0.022; Table 4). Furthermore, a statistically significant association was found between E. coli status and blood transfusion history (Fisher's exact test, p<0.0001; Table 4), with a higher proportion of E. coli-positive neonates receiving blood or platelet transfusions (10.4%) compared to E. coli-negative neonates (0.9%).

Table 4. E. coli Status and Outcomes

Outcome	*E. coli* Negative	*E. coli* Positive (	p-value
CRP on Deterioration: Positive	108 (27.0)	11 (100.0)	< 0.0001*
Mortality	63 (15.8)	5 (45.5)	0.022*
Blood Transfusion	69 (17.3)	8 (72.7)	< 0.0001*

**Statistically significant.*

Discussion

Neonatal sepsis remains a leading cause of newborn mortality worldwide, with an estimated 6.31 million cases and 230,000 deaths in 2019 [10]. The burden is disproportionately borne by low- and middle-income countries (LMICs), which account for over 90% of cases and deaths [10]. In North Africa and the Middle East, Gram-negative bacteria predominate. For example, reviews of Arab countries report that 65–90% of neonatal sepsis isolates in Libya, Egypt, Jordan, and Iraq were Gram-negative (including Klebsiella, Serratia, Enterobacter, Escherichia coli, Pseudomonas) [11]. Our findings of E. coli as a notable pathogen (even if relatively infrequent) are consistent with such regional patterns of Gram-negative predominance. However, the exact ranking of pathogens can vary; a 2024 Libyan NICU study found Staphylococcus aureus and Klebsiella pneumoniae to be the most common [12].

Compared to high-income settings, differences are also seen in pathogen distribution. In the United States, group B streptococcus (GBS) and E. coli account for over half of early-onset sepsis, with E. coli especially dominant in preterm infants [13]. By contrast, in regions without routine GBS prophylaxis (as in Libya), other Gram-negatives may fill that role [12]. Nevertheless, our observed associations of E. coli with prematurity and severe disease align with global trends [14]. For instance, CDC surveillance shows E. coli is the leading cause of early-onset sepsis in preterm and very-low-birthweight infants [15]. Likewise, recent meta-analyses and systematic reviews in LMICs emphasize the importance of Gram-negative sepsis: Gram-negatives cause roughly 60% of neonatal sepsis in low-income hospitals, with Klebsiella and Escherichia coli among the most frequent [5,7,11]. Our results similarly highlight E. coli as a key Gram-negative pathogen in this setting, though our overall culture-proven rate was low. Key findings and risk factors. Our study identified prematurity (low gestational age and birthweight) as a strong risk factor for E. coli sepsis. This is biologically plausible because preterm neonates have immature immune systems and disrupted intestinal barriers. The association is supported by multiple studies: for example, in the U.S. it was found that 52% of infants with E. coli early-onset sepsis were preterm, and that E. coli was the most common cause of sepsis in neonates <37 weeks [15]. Similarly, a Serbian single-center study reported that deceased septic neonates were much more likely to be extremely preterm (74.5% in fatal cases vs 22.4% in survivors, p<0.001) [16]. That study also identified Gram-negative sepsis (like E. coli) as an independent predictor of death. In our cohort, E. coli cases indeed had very high case-fatality, reflecting this phenomenon. In fact, in that U.S. series, fully 29% of preterm infants with E. coli sepsis died (vs 0% of term infants), underscoring the vulnerability of this group [14].

We also observed that rising C-reactive protein (CRP) levels correlated with clinical deterioration. Serial CRP is widely used as an inflammation marker in neonates: although nonspecific, it can aid in monitoring response to sepsis therapy and in deciding antibiotic duration [17]. In resource-limited settings, CRP is often the only feasible lab indicator [18]. Our findings reaffirm that a persistent or rising CRP should prompt intensified care. However, like many studies have noted, CRP alone cannot definitively rule in or out infection [17,18]. Clinicians should therefore interpret CRP trajectories in the context of the clinical picture and other laboratory data when available. Another notable risk factor was receipt of blood (erythrocyte) transfusions in the first week of life.

Neonates requiring transfusion are, by definition, critically ill, and transfusion itself can modulate immunity. The Serbian study cited above found that early transfusion was a significant predictor of mortality in septic neonates [16]. This may reflect that transfused infants had more severe illness (e.g., severe anemia or hemorrhage) or that transfusions can exacerbate infection risk through immunologic mechanisms [19]. In any case, our data suggest that E. coli sepsis is clustering in the sickest neonates, including preterms and those needing transfusions.

Although the overall rate of culture-proven E. coli sepsis was low in our cohort, the cases that were confirmed

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proved to be highly severe. This pattern (few positives, but grave outcomes) underscores a key challenge in neonatal sepsis in low-resource settings: blood cultures often fail to detect many true infections. As noted by a recent review, "most neonates treated for suspected sepsis have negative blood cultures." [20]. Small blood volumes drawn, suboptimal culture techniques, prior antibiotic exposure, and laboratory constraints all contribute to low sensitivity [21]. In our hospital, limited microbiology capacity and occasional delays in specimen transport may have further reduced culture yield. Thus, the low prevalence of E. coli might partly reflect underdiagnosis. Importantly, even a low number of E. coli cases can be disproportionately lethal [22]. This means clinicians cannot be reassured by negative cultures alone; if E. coli is clinically suspected, empiric treatment must still be considered. Our findings echo other reports that a small fraction of neonatal sepsis may be E. coli, yet these cases have high mortality. In sum, the combination of low culture positivity and high severity highlights the need for better diagnostics and continued vigilance: protocols should account for E. coli coverage even when cultures are negative, and efforts to improve laboratory methods must be prioritized. Diagnostic and treatment challenges in resource-limited settings. The above findings must be interpreted in light of the systemic difficulties faced in Libya and similar contexts.

Clinically, neonatal sepsis can present subtly; signs like temperature instability or feeding intolerance are nonspecific in newborns. Effective risk stratification tools (like those used for GBS sepsis in high-income countries) are largely unavailable in low-resource NICUs [23]. Consequently, clinicians often err on the side of treating any sick neonate with broad-spectrum antibiotics. Without refined criteria, this leads to both possible over-treatment of uninfected infants and potential under-treatment of others. Laboratory confirmation is also problematic. Blood cultures are the cornerstone of diagnosis, but they suffer from reduced sensitivity in neonates due to small sample volumes and high contamination risks [24]. Additionally, in LMIC hospitals, the cost of culture bottles and reagents is often prohibitive, and transport from wards to labs (especially in extreme heat) can further degrade sample integrity. Advanced diagnostics such as PCR or multiplex panels remain largely inaccessible in our setting [25]. As a result, many cases of suspected sepsis must be managed empirically, sometimes for the full typical 7–10-day course, without microbiological confirmation [26]. This practice may mask the true etiology and delay recognition of unusual pathogens or emerging resistance. Therapeutic challenges compound the problem. The WHO and many guidelines recommend ampicillin (or penicillin) plus gentamicin as first-line empiric therapy for hospital-treated neonatal sepsis. Indeed, these "Access" antibiotics are included in the Essential Medicines List and are (in theory) affordable. In practice, however, maintaining a reliable supply can be difficult. Stock-outs or the use of substandard drugs can lead to treatment failures. Moreover, rising antimicrobial resistance undermines standard regimens: recent data show E. coli and Klebsiella in Africa often exhibit >80% resistance to ampicillin, gentamicin, or both [27].

Our local antibiograms suggest that gentamicin and cefotaxime retain good activity, but even these drugs are threatened by increasing resistance. Higher-tier antibiotics (like carbapenems) are scarce and expensive, and must be guarded [28]. On the other hand, to avoid further resistance. Altogether, balancing timely empiric coverage against stewardship is a constant struggle in our NICU. Another systemic barrier is infection control. It has been shown that lapses in hygiene can fuel Gram-negative outbreaks: "inadequate hand hygiene and lack of essential equipment and supplies" were major contributors to nosocomial Gram-negative infections [29]. It is noteworthy, we observed several E. coli cases in neonates with prolonged intensive care, suggesting a potential nosocomial component.

In summary, local resource constraints, from clinical decision tools through microbiology to infection prevention, create an environment where neonatal sepsis can flourish. Implications for surveillance and resistance monitoring. These challenges underscore the critical need for robust local microbiological surveillance. Our low culture yield means that we might be underestimating true sepsis incidence and missing shifts in pathogen prevalence.

Conclusion

Overall, our findings reinforce that neonatal E. coli sepsis, although infrequent in culture, poses an outsized threat in this Libyan NICU. The high mortality and association with prematurity underline the need for aggressive prevention and tailored management. Addressing this issue will require a multi-pronged approach: improve perinatal care, strengthen NICU infection control, refine empiric therapy based on local data, and continuously monitor pathogen trends. With these measures, we can hope to reduce the toll of sepsis on Libya's most vulnerable infants.

Conflicts of Interest

The authors declare no conflicts of interest.

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