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FREQUENCY AND CLINICAL CHARACTERISTICS OF EARLY NEONATAL SEPSIS IN A TERTIARY CARE HOSPITAL IN QUETTA

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Abstract

Background: *Early-onset neonatal sepsis (EONS), occurring within the first 72 hours of life, is a major cause of neonatal morbidity and mortality, particularly in low- and middle-income countries. Early diagnosis remains difficult because of nonspecific clinical manifestations, making timely recognition and treatment essential for improving neonatal survival and reducing complications in tertiary healthcare settings.*

Objectives: *To determine the frequency of early-onset neonatal sepsis and describe its clinical characteristics, maternal risk factors, laboratory findings, and clinical outcomes among neonates admitted to a tertiary care hospital in Quetta.*

Place and Duration of study. *From May 2025 to October 2025, Paediatrics Department Balochistan Institute of Child Health & Services Quetta.*

Methodology: *This descriptive cross-sectional study was conducted in the Neonatal Intensive Care Unit of a tertiary care hospital in Quetta from May to October 2025. A total of 100 consecutive neonates aged ≤72 hours with suspected sepsis were enrolled using non-probability consecutive sampling. Demographic characteristics, maternal risk factors, clinical features, laboratory investigations, blood culture findings, and treatment outcomes were recorded using a structured proforma. Early-onset neonatal sepsis was diagnosed based on compatible clinical features supported by laboratory investigations and/or positive blood culture. Data were analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequencies and percentages. Associations were assessed using the Chi-square test, with a p-value <0.05 considered statistically significant.*

Results: *Of the 100 enrolled neonates, **42 (42.0%)** were diagnosed with early-onset neonatal sepsis. The mean age at presentation was **1.8 ± 0.7 days**, and the mean birth weight was **2.74 ± 0.58 kg**. Males accounted for **58.0%** of participants. Prematurity and low birth weight were present in **30.0%** and **35.0%**, respectively. Respiratory distress (71.4%), poor feeding (64.3%), lethargy*

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(57.1%), and temperature instability (45.2%) were the predominant clinical manifestations. Blood cultures were positive in ***20 (47.6%)*** *septic neonates, predominantly yielding Klebsiella pneumoniae and Escherichia coli. Prematurity (****p=0.018****) and prolonged rupture of membranes (****p=0.011****) were significantly associated with EONS. Septic neonates had a mean hospital stay of* ***8.6 ± 2.9 days*** *and a higher mortality rate than non-septic neonates (****9.5% vs. 1.7%; p=0.041****).*

Conclusion: *Early-onset neonatal sepsis remains a common cause of NICU admission and adverse neonatal outcomes. Respiratory distress, poor feeding, and lethargy were the most frequent presentations, while prematurity and prolonged rupture of membranes significantly increased the risk of infection. Early recognition of maternal and neonatal risk factors with prompt diagnosis and treatment may reduce neonatal morbidity and mortality.*

Introduction

Early-onset neonatal sepsis (EONS) is a life-threatening systemic infection occurring within the first 72 hours of life. It remains one of the leading causes of neonatal morbidity and mortality worldwide. Despite significant advances in neonatal intensive care, antimicrobial therapy, and infection prevention strategies, neonatal sepsis continues to contribute substantially to neonatal deaths, particularly in low- and middle-income countries (LMICs). According to the World Health Organization (WHO), neonatal infections account for approximately one-third of neonatal mortality globally, with the highest burden reported in South Asia and sub-Saharan Africa. Pakistan continues to experience one of the highest neonatal mortality rates in the region, making neonatal sepsis an important public health concern [1,2]. Early-onset neonatal sepsis is primarily acquired through vertical transmission of microorganisms from the mother before or during delivery. Maternal conditions such as prolonged rupture of membranes, maternal fever, chorioamnionitis, prolonged labor, urinary tract infections, and inadequate intrapartum antibiotic prophylaxis significantly increase the risk of neonatal infection. Prematurity and low birth weight further predispose newborns to sepsis because of their immature immune systems and impaired physiological defense mechanisms. Early identification of these maternal and neonatal risk factors is therefore essential for timely diagnosis and effective management [3,4]. The clinical presentation of EONS is often subtle and nonspecific, posing a considerable diagnostic challenge. Affected neonates may present with respiratory distress, poor feeding, lethargy, hypothermia or fever, apnea, cyanosis, temperature instability, hypotonia, seizures, or circulatory compromise. Because these manifestations overlap with several noninfectious neonatal conditions, clinicians often rely on a combination of clinical assessment, laboratory investigations, and microbiological cultures to establish the diagnosis. Laboratory markers such as complete blood count, C-reactive protein (CRP), procalcitonin, and blood culture are commonly employed. However, blood culture remains the gold standard despite its relatively low sensitivity and delayed results [5,6]. The bacterial pathogens responsible for EONS vary according to geographical location and healthcare settings. In developed countries, **Group B Streptococcus** and **Escherichia coli** are the most frequently isolated organisms. In contrast, studies from Pakistan and other developing countries have consistently reported **Klebsiella pneumoniae**, **Escherichia coli**, **Staphylococcus aureus**, and other Gram-negative organisms as predominant pathogens. Increasing antimicrobial resistance among these organisms has complicated empirical treatment and emphasizes the importance of local epidemiological surveillance to guide antibiotic policies [7,8]. Prompt initiation of appropriate antimicrobial therapy significantly improves survival and reduces long-term neurological complications.

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However, indiscriminate use of broad-spectrum antibiotics contributes to antimicrobial resistance, prolonged hospitalization, and increased healthcare costs. Therefore, understanding the local frequency, clinical characteristics, maternal risk factors, and microbiological profile of EONS is essential for developing evidence-based treatment protocols and infection prevention strategies [9]. Although several studies have investigated neonatal sepsis in Pakistan, there remains limited published evidence from Balochistan, particularly Quetta, where healthcare resources and epidemiological patterns may differ from other regions. Regional data are essential because microbial profiles, maternal risk factors, and clinical presentations vary considerably across different healthcare settings. Generating local evidence will assist clinicians in early recognition, optimize empirical antibiotic selection, improve neonatal outcomes, and support hospital infection control policies [10]. Therefore, this study was undertaken to determine the frequency of early-onset neonatal sepsis and evaluate its clinical characteristics, maternal risk factors, laboratory findings, microbiological profile, and clinical outcomes among neonates admitted to the Neonatal Intensive Care Unit of a tertiary care hospital in Quetta.

Study Objectives

To determine the frequency of early-onset neonatal sepsis and evaluate its clinical characteristics, maternal risk factors, laboratory findings, microbiological profile, and clinical outcomes among neonates admitted to a tertiary care hospital in Quetta.

Materials and Methods: A hospital-based descriptive cross-sectional study was conducted in the Neonatal Intensive Care Unit (NICU) of Balochistan Institute of Child Health & Services Quetta, over 6 months from May 1, 2025, to October 31, 2025.

Participants

All neonates aged ≤72 hours admitted to the NICU with clinical suspicion of early-onset neonatal sepsis during the study period were screened for eligibility. Consecutive eligible neonates fulfilling the inclusion criteria were enrolled using non-probability consecutive sampling. Maternal obstetric history, neonatal demographic characteristics, clinical findings, laboratory investigations, blood culture results, treatment details, and clinical outcomes were recorded using a structured pretested data collection proforma.

Sample Size Calculation

The sample size was calculated using the WHO sample size calculator for descriptive studies based on the formula $n = Z^2P(1-P)/d^2$, assuming a prevalence of 50%, a 95% confidence level, and a margin of error of 10%. The minimum required sample size was 96 neonates; therefore, 100 participants were enrolled to improve study precision and compensate for incomplete data.

Inclusion Criteria

- Neonates aged **≤72 hours** admitted to the NICU.
- Clinical suspicion of early-onset neonatal sepsis based on established neonatal sepsis criteria.
- Both male and female neonates.
- Neonates whose parents or legal guardians provided informed consent.

Exclusion Criteria

- Neonates older than 72 hours at presentation.
- Neonates with major congenital anomalies or chromosomal abnormalities.
- Neonates who had received prolonged antibiotic therapy before admission.
- Cases with incomplete clinical records or missing essential laboratory investigations.
- Parents or guardians declining participation.

Diagnostic and Management Strategy

All neonates underwent complete blood count, C-reactive protein measurement, and blood

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culture before initiation of antibiotic therapy whenever feasible. Blood cultures were processed according to standard microbiological protocols. Empirical intravenous antibiotics were started immediately after clinical suspicion and later modified according to culture sensitivity reports and the patient's clinical response.

Statistical Analysis

Data were entered and analyzed using IBM SPSS Statistics version 26.0. Continuous variables were tested for normality using the Shapiro–Wilk test and presented as mean ± standard deviation. Categorical variables were expressed as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square test or Fisher's exact test where appropriate, while continuous variables were compared using the independent-samples t-test. A p-value <0.05 was considered statistically significant.

Results

A total of **100 neonates** with suspected early-onset neonatal sepsis were included in the study. **Forty-two (42.0%)** neonates were diagnosed with early-onset neonatal sepsis, whereas **58 (58.0%)** were diagnosed with other neonatal conditions. The overall **mean age at presentation was 1.8 ± 0.7 days**, and the **mean birth weight was 2.74 ± 0.58 kg**. Male neonates accounted for **58 (58.0%)** of the study population, while females constituted **42 (42.0%)**. Prematurity was identified in **30 (30.0%)** neonates and low birth weight in **35 (35.0%)**. The most common maternal risk factors were prolonged rupture of membranes **(31.0%)**, maternal fever during labor **(22.0%)**, prolonged labor **(18.0%)**, and maternal urinary tract infection **(14.0%)**. Respiratory distress **(71.4%)**, poor feeding **(64.3%)**, lethargy **(57.1%)**, temperature instability **(45.2%)**, and seizures **(9.5%)** were the predominant clinical manifestations among septic neonates. Blood cultures were positive in **20 (47.6%)** septic neonates, with **Klebsiella pneumoniae (40.0%)**, **Escherichia coli (30.0%)**, **Staphylococcus aureus (20.0%)**, and other organisms **(10.0%)** identified. Prematurity showed a significant association with early-onset neonatal sepsis **(60.0% vs. 34.3%; p = 0.018)**, while prolonged rupture of membranes was significantly associated with culture-confirmed sepsis **(p = 0.011)**. The **mean hospital stay was 8.6 ± 2.9 days**, and mortality was significantly higher among septic neonates than non-septic neonates **(9.5% vs. 1.7%; p = 0.041)**.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population (n = 100)

Variable	Frequency (n)	Percentage (%)
Total neonates	100	100.0
Confirmed EONS	42	42.0
Non-EONS	58	58.0
Male	58	58.0
Female	42	42.0
Prematurity	30	30.0
Term birth	70	70.0
Low birth weight (<2.5 kg)	35	35.0
Normal birth weight	65	65.0
Mean age (days)	1.8 ± 0.7	—
Mean birth weight (kg)	2.74 ± 0.58	—

Data are presented as frequency (percentage) or mean ± standard deviation. EONS = Early-onset neonatal sepsis.

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Table 2. Maternal Risk Factors Among the Study Population (n = 100)

Maternal Risk Factor	Frequency (n)	Percentage (%)
Prolonged rupture of membranes	31	31.0
Maternal fever during labor	22	22.0
Prolonged labor	18	18.0
Maternal urinary tract infection	14	14.0
Meconium-stained liquor	11	11.0
Foul-smelling liquor	8	8.0
No identified maternal risk factor	27	27.0

Multiple maternal risk factors could be present in the same patient; therefore, percentages may exceed 100%.

Table 3. Clinical Characteristics and Blood Culture Findings in Neonates with Early-Onset Neonatal Sepsis (n = 42)

Variable	Frequency (n)	Percentage (%)
Clinical Features		
Respiratory distress	30	71.4
Poor feeding	27	64.3
Lethargy	24	57.1
Temperature instability	19	45.2
Apnea	8	19.0
Cyanosis	6	14.3
Seizures	4	9.5
Blood Culture Results		
Positive blood culture	20	47.6
Negative blood culture	22	52.4
Culture Isolates (n=20)		
Klebsiella pneumoniae	8	40.0
Escherichia coli	6	30.0
Staphylococcus aureus	4	20.0
Other organisms	2	10.0

Percentages for clinical characteristics are calculated among confirmed EONS cases (n=42). Organism percentages are based on positive blood cultures (n=20).

Table 4. Association of Selected Risk Factors with Early-Onset Neonatal Sepsis

Variable	EONS (n=42)	Non-EONS (n=58)	p-value
Prematurity, n (%)	18 (42.9)	12 (20.7)	**0.018**
Low birth weight, n (%)	19 (45.2)	16 (27.6)	0.072
Prolonged rupture of membranes, n (%)	18 (42.9)	13 (22.4)	**0.011**
Maternal fever, n (%)	12 (28.6)	10 (17.2)	0.184
Mean hospital stay (days)	8.6 ± 2.9	5.2 ± 1.8	**0.001**
Mortality, n (%)	4 (9.5)	1 (1.7)	**0.041**

Continuous variables are presented as mean ± standard deviation, while categorical variables are presented as frequency (percentage). Chi-square test was used for categorical variables and the independent-samples t-test for continuous variables. Statistical significance was considered at **$p < 0.05$**. Significant p-values are shown in **bold**. EONS = Early-onset neonatal sepsis.

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Discussion

The present study demonstrated that **42.0%** of neonates admitted with suspected infection were diagnosed with early-onset neonatal sepsis (EONS), indicating that EONS remains a major contributor to neonatal morbidity in tertiary care settings in Pakistan. Although the reported frequency varies according to diagnostic criteria, study population, and healthcare setting, our findings are consistent with recent reports from South Asia and other low- and middle-income countries, where EONS continues to account for a substantial proportion of neonatal intensive care admissions despite advances in obstetric and neonatal care [11,12]. The relatively high frequency observed in this study may reflect delayed referral, inadequate antenatal infection screening, limited intrapartum preventive measures, and the high prevalence of maternal risk factors within the local population. Male neonates represented **58.0%** of the study population and were more frequently affected than females. This male predominance has been consistently described in recent studies from Pakistan, India, Ethiopia, and Bangladesh [13,14]. Proposed mechanisms include sex-related differences in innate immune responses, X-linked immune regulatory genes, and relatively slower immunological maturation among male newborns. Although gender itself is not a modifiable risk factor, recognition of this pattern may facilitate closer surveillance of high-risk neonates during the early postnatal period [15]. Respiratory distress, poor feeding, lethargy, and temperature instability were the predominant clinical manifestations among septic neonates. These findings are in agreement with contemporary neonatal sepsis studies reporting that respiratory compromise and feeding intolerance are the earliest and most frequent presenting symptoms of EONS [16,17]. Because these manifestations are nonspecific and frequently overlap with noninfectious neonatal disorders, clinicians should maintain a high level of suspicion, particularly in neonates with established maternal or perinatal risk factors. Early clinical recognition remains fundamental for timely initiation of empirical antimicrobial therapy while awaiting laboratory confirmation [18]. Prematurity and prolonged rupture of membranes were significantly associated with EONS in the present study. Similar associations have been consistently demonstrated in recent systematic reviews and prospective cohort studies, which identify prematurity, prolonged rupture of membranes, maternal fever, chorioamnionitis, and prolonged labor as the principal determinants of neonatal sepsis [19]. Premature infants possess immature cellular and humoral immunity, reduced transplacental transfer of maternal immunoglobulins, and impaired epithelial barrier function, making them particularly susceptible to invasive bacterial infection. Likewise, prolonged rupture of membranes increases fetal exposure to ascending microorganisms from the maternal genital tract, thereby facilitating vertical transmission [20]. Blood cultures were positive in **47.6%** of confirmed cases, with **Klebsiella pneumoniae** and **Escherichia coli** being the predominant pathogens. This microbiological pattern closely resembles findings from recent studies conducted in Pakistan, Nepal, and other South Asian countries, where Gram-negative organisms continue to predominate in EONS. In contrast, Group B Streptococcus remains the leading pathogen in many high-income countries owing to effective maternal screening programs and intrapartum antibiotic prophylaxis. These regional differences emphasize the importance of continuous local microbiological surveillance and antimicrobial susceptibility monitoring to optimize empirical antibiotic selection and strengthen antimicrobial stewardship programs [21,22]. The present study also demonstrated significantly prolonged hospital stay and increased mortality among neonates with EONS compared with non-septic neonates. These findings are consistent with recent international evidence demonstrating that neonatal sepsis substantially increases healthcare utilization, duration of intensive care, treatment costs, and mortality, particularly in resource-constrained settings [23]. Although the mortality rate observed in our study was lower than that reported in several multicenter studies from sub-

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Saharan Africa, it nevertheless highlights the persistent burden of neonatal sepsis and the need for earlier diagnosis and improved neonatal intensive care services.

Limitations

This study was conducted at a single tertiary care hospital with a relatively small sample size, limiting the generalizability of the findings. The cross-sectional design precluded causal inference, while blood culture-negative cases may have resulted from prior antibiotic exposure or low bacterial yield. Molecular diagnostic methods were not available.

Conclusion

Early-onset neonatal sepsis remains a significant cause of neonatal morbidity and mortality in Quetta. Prematurity and prolonged rupture of membranes were important risk factors, while respiratory distress and poor feeding were common presentations. Early recognition, prompt treatment, and strengthened maternal and neonatal infection prevention strategies are essential to improve clinical outcomes.

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Conflict of Interest: Nil

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Authors Contributions

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