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Original article

Clinical Profile and Outcome of Neonates with Early Neonatal Sepsis at Benghazi Medical Center

Hanya Ali*, Najat Al-Gazal, Margwha Issa

Pediatric Department, Faculty of Medicine, University of Benghazi, Benghazi, Libya
Corresponding email. *Hanya.ali@uob.edu.ly*

Abstract
Neonatal sepsis (NS) is defined by the 2001 international pediatric consensus conference as a systemic inflammatory response syndrome resulting from suspected or proven infection in a neonate. Neonatal infections remain a major cause of mortality worldwide, accounting for nearly 4 million deaths annually, particularly in developing countries. This study aimed to assess the clinical profile and risk factors of early neonatal sepsis and its outcomes among newborns admitted to the neonatology department at Benghazi Medical Center (BMC), Libya, from March to August 2018. A descriptive cross-sectional study included 58 newborns selected by convenience sampling. Data were obtained from medical records and included demographic characteristics, maternal history, neonatal clinical parameters (gestational age, birth weight, Apgar score), invasive procedures, laboratory investigations, treatment, and outcomes. Data were analyzed using SPSS with descriptive statistics. The male-to-female ratio was 1.5:1. Low birth weight (<2000 g) was observed in 45% of cases, and 36.2% were preterm (<34 weeks) with a mean gestational age of 34.5 weeks. Respiratory conditions, including hyaline membrane disease (29.3%) and respiratory distress syndrome (22.4%), were common. Maternal risk factors included premature rupture of membranes (40%) and urinary tract infection (15.5%). Abnormal complete blood count was found in 65.5% of cases, and blood cultures predominantly showed Gram-negative organisms. Most neonates received ampicillin and gentamicin. Survival rate was 65.5%. Maternal infections, prematurity, low birth weight, and invasive procedures were key risk factors. Improved maternal and neonatal care is recommended to reduce neonatal sepsis.
Keywords. Early Neonatal Sepsis, Risk Factors, Infection.

Introduction

According to the international pediatric consensus conference of 2001, neonatal sepsis (NS) is defined as systemic inflammatory response syndrome in the presence of or because of suspected or proven infection in a neonate [1]. The normal fetus is sterile until shortly before birth, as the placenta and amniotic sac are highly effective barriers to infections. At birth, the newborn loses the protection afforded to it in the uterus and gets exposed to the microbial world [1,2]. Neonatal infections are a major cause of death worldwide. It is estimated that approximately 4 million deaths occur annually in developing countries in the neonatal period, attributable mostly to infection, birth asphyxia, and consequences of premature birth [3]. The incidence of neonatal sepsis varies from 1-4 / 1000 live births in developed countries to 10-50/1000 live births in developing countries [3]. The incidence of neonatal sepsis varies from nursery to nursery and within the same nursery at different times, and depends on conditions predisposing to infection [3].

Infants are exposed to a wide range of potential pathogens from the birth canal. The risk of infection is increased if there has been prolonged rupture of membranes, especially if chorioamnionitis has developed [4]. Risk factors are a complex interaction of maternal-fetal colonization, transplacental immunity, and physical and cellular defense mechanisms of the neonate [3]. The clinical symptoms of early sepsis, including fever, irritability, lethargy, and pneumonia, are nearly always accompanied by physical signs of tachypnoea, grunting [5].

The most reliable diagnostic of neonatal sepsis, often referred to as the gold standard, is a blood culture test for bacteria. While this test is the most reliable available, it can take 48 hours to obtain the results. As a result, treatment must often begin before the results are known. An additional complication is the fact that the blood culture test can be negative for one in five subjects with sepsis. Thus, it is of critical importance to identify new biomarkers that will enable fast and reliable hematological scoring systems for sepsis in its earliest stages [6]. Delays in the identification and treatment of neonatal sepsis are among the main contributors to the high mortality [7]. Therefore, the present study aimed to assess the clinical profile, risk factors of early sepsis, and its effect among newborns admitted to the neonatology department in Benghazi Medical Center (BMC) in Benghazi, from March to August 2018.

Methods

Study Design

A descriptive cross-sectional study was conducted. A convenience sample of 58 newborns was enrolled over a six-month period in 2018. Data were collected from medical records at the statistical department of Benghazi Medical Center (BMC), Benghazi, Libya.

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Data collection and analysis

Data were collected between March and August 2018. The dataset included neonatal demographic characteristics (age and gender), onset of diagnosis, and type of delivery (normal vaginal delivery or cesarean section), as well as maternal history of morbidity during pregnancy. Neonatal clinical data included gestational age, birth weight, Apgar score, and use of surfactant therapy.

Information on invasive procedures was also recorded, including peripheral intravenous lines, umbilical venous catheterization, mechanical ventilation, chest tube insertion, and urinary catheterization. A history of blood transfusion was documented. Baseline investigations at admission included complete blood count, C-reactive protein, chest X-ray, lumbar puncture, and blood culture. Details of antibiotic treatment were noted, along with the outcomes of the neonates.

The data were collected, entered, and analyzed using the Statistical Package for the Social Sciences (SPSS), version 17 (Chicago, Illinois). Descriptive statistics, including mean and standard deviation, were calculated for selected variables.

Results

Out of a total of 58 neonates with early-onset neonatal sepsis, the majority were males (60.3%, n = 35), while females accounted for 39.7% (n = 23) (Figure 1).

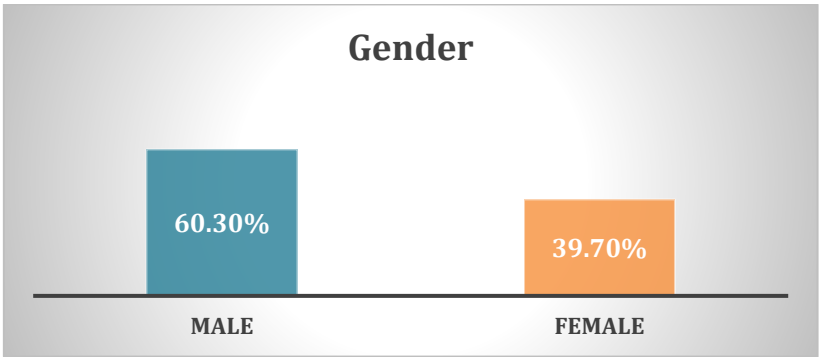

Figure 1. Gender distribution of neonates with early-onset neonatal sepsis at Benghazi Medical Centre, 2018

Table 1. Clinical characteristics, details of 58 cases of early neonatal sepsis at (BMC) 2018

Characteristics/Parameters	Details		Number	Percentage
Birth weight (grams)	< 1500 - 1999		26	44.8
	1500 – 2500		14	24.1
	>2500		18	31
Gestational age (weeks)	< 34 weeks		21	36. 2
	34 - 36 weeks		21	36. 2
	37 - 40 weeks		16	27. 5
Apgar Score	1 -minute	< 7	15	25.9
		> 7	43	74.1
	5 -minutes	< 7	5	8.6
		> 7	53	91.4
Invasive Procedure	Surfactant therapy		5	8.6
	Umbilical Venous catheter		6	10.5
	Mechanical ventilator +chest tube +peripheral line +umbilical venous catheter+ urine catheter		27	46.5
Co-Morbidities and Clinical Signs, Symptoms of EONNS	Respiratory distress		13	22.4
	HMD		17	29.3
	IDM		5	8.6
	HIE		5	8.6
	Congenital heart diseases		3	5.2
	Anomalies		2	3.4
	Septic shock		4	9.4
	Sclerma		4	9.6
	DIC		1	1.7
	Fever		2	3.4
	Hypothermia		1	1.7
	Lethargic and poor feeding		6	10.3

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Regarding birth weight, the largest proportion of neonates (44.8%) had a birth weight between 1500–1999 g, followed by 31.0% with birth weight below 2500 g, and 24.1% between 2000–2500 g, with a mean of 2272.41 ± 877.55 g, ranging from 1100 g to 4800 g.
In terms of gestational age, preterm neonates constituted the majority, with 36.2% born before 34 weeks and another 36.2% between 34–36 weeks, while only 27.5% were full-term (37–40 weeks), with a mean of 34.57 ± 2.79 weeks ranging from 28 to 39 weeks. Assessment of Apgar scores showed that most neonates (74.1%) had a score below 7 at 1 minute, whereas the majority (91.4%) improved scores above 7 at 5 minutes, suggesting initial perinatal compromise with subsequent stabilization.
Concerning invasive procedures, nearly half of the neonates (46.5%) required multiple interventions, including mechanical ventilation and catheterization, while smaller proportions received surfactant therapy (8.6%) or umbilical venous catheterization alone (10.5%). With respect to co-morbidities and clinical presentation, hyaline membrane disease (29.3%) and respiratory distress (22.4%) were the most common conditions. Other observed complications included septic shock (9.4%), sclerema (9.6%), hypoxic-ischemic encephalopathy (8.6%), and infants of diabetic mothers (8.6%). Less frequent findings included congenital heart diseases (5.2%), congenital anomalies (3.4%), fever (3.4%), hypothermia (1.7%), and disseminated intravascular coagulation (1.7%). Additionally, 10.3% of neonates presented with lethargy and poor feeding (Table 1).

Table 2. Mothers condition during pregnancy and delivery.

Maternal Condition		Cases	
		No.	%
Leaking (premature rupture of membrane, PROM)		23	39.6
Urinary infection (UTI)		9	15.5
Chorioamnionitis		2	3.4
Fever		7	12.9
Type of delivery	Normal Vaginal delivery	30	51.7
	Caesarean section	28	48.3

The most common maternal complaint was premature rupture of membranes (PROM), reported in 39.6% of cases, followed by urinary tract infection (15.5%) and maternal fever (12.9%). Chorioamnionitis was relatively uncommon, occurring in only 3.4% of cases. Regarding the mode of delivery, slightly more than half of the neonates (51.7%) were delivered by normal vaginal delivery, while 48.3% were delivered via caesarean section (Table 2).

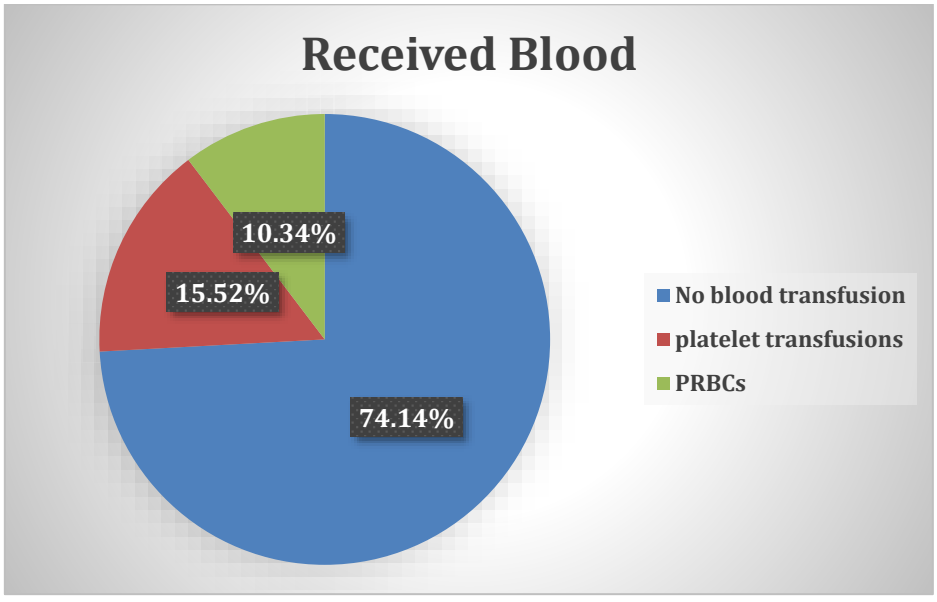

Figure 2. Distribution of blood transfusion among neonates with early-onset neonatal sepsis at Benghazi Medical Centre, 2018

Most neonates (74.14%) did not receive any blood transfusion. Among those who required transfusion, 15.52% received platelet transfusions, while 10.34% received packed red blood cells (PRBCs) (Figure 2).

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Table 3. Distribution of patients according to the investigation

Investigations	At admission				Not done	
	Normal		Abnormal			
	No.	%	No.	%	No.	%
Total leukocyte count	20	34.5	38	65.5	0	0
Platelet	26	44.8	32	55.1	0	0
C-reactive protein (CRP)	2	3.4	56	96.6	0	0
Chest X-ray	55	94.8	3	5.2	0	0
Lumbar puncture	1	1.7	1	1.7	56	96.6
Blood culture	8	13.8	14	24.1	15	25.9
Procalcitonin	2	3.4	4	6.8	52	89.7

At admission, abnormal total leukocyte count was observed in 65.5% of cases, predominantly due to leukopenia, while 34.5% had normal values. Thrombocytopenia was detected in 55.1% of neonates, whereas 44.8% had normal platelet counts. C-reactive protein (CRP) was elevated in the majority of cases (96.6%), indicating a high inflammatory response, with only 3.4% showing normal levels. In contrast, chest X-ray findings were normal in most cases (94.8%), with abnormalities detected in only 5.2%. Lumbar puncture was not performed in most neonates (96.6%), and only 1.7% showed abnormal or normal findings each. Blood culture was not done in 25.9% of cases, while 24.1% showed positive (abnormal) results, and 13.8% were negative. Procalcitonin was not performed in the majority of cases (89.7%), with only 6.8% showing elevated levels and 3.4% within normal range (Table 3).

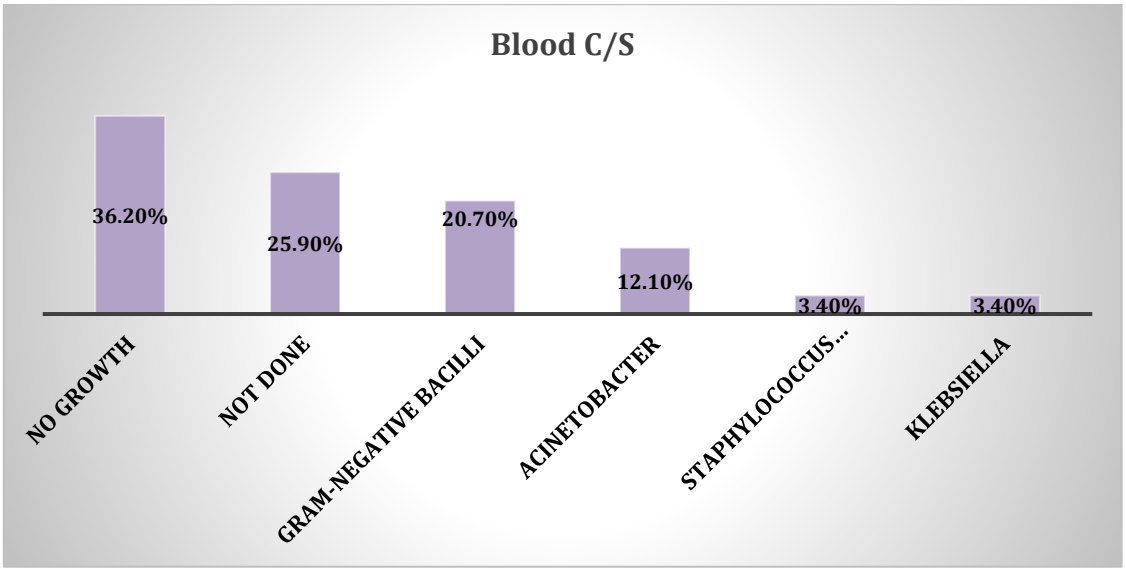

Figure 3. Distribution of blood culture results among neonates with early-onset neonatal sepsis at Benghazi Medical Centre, 2018

Blood culture and sensitivity (C/S) results were available for 58 cases. The most frequently reported finding was “not done” (25.9%), followed by “no result” (22.4%). Among positive cultures, Gram-negative bacilli were the most common isolates, identified in 20.7% of cases. *Acinetobacter* species accounted for 12.1%, while *Staphylococcus aureus* was detected in 3.4% and *Klebsiella* species in 1.7% of cases. Additionally, 13.8% of samples showed no bacterial growth (Figure 3).

Table 4. Distribution of Cases According to Treatment

Antibiotics	Cases	
	No.	%
First line (Ampicillin and gentamicin)	28	48.3
Second line (Meronium)	21	36.2
Third line (Ciproflocin)	15	26

The most commonly used regimen was the first-line therapy (ampicillin and gentamicin), administered in 48.3% of cases. Second-line treatment (meropenem) was used in 36.2% of patients, while third-line therapy (ciprofloxacin) was given in 26.0% of cases (Table 4). Among newborns diagnosed with sepsis, 65.52% survived while 34.48% died (Figure 4).

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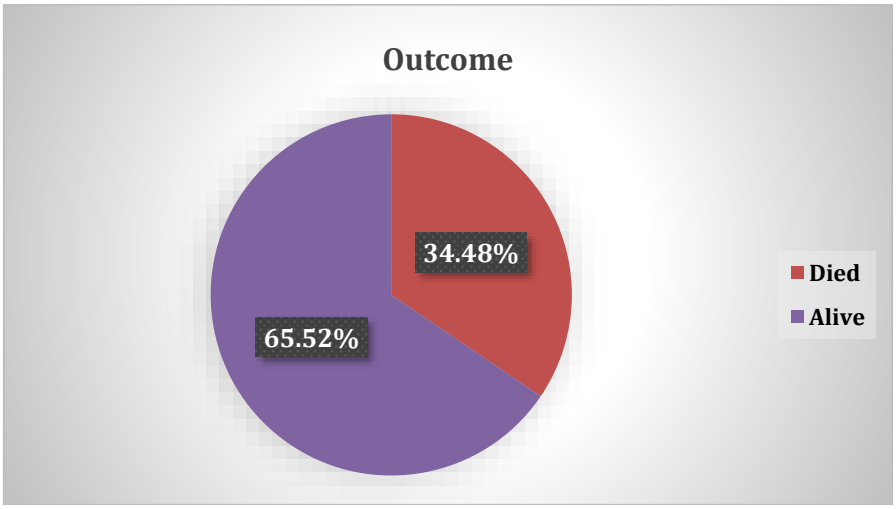

Figure 4. Outcome of the cases of newborn sepsis

Discussion

This study has also observed that the onset of neonatal sepsis was in the first week of the neonate's life. In this study, we recorded low birth weight (LBW<1500-1999g) in 44.8 % and gestational age <34 weeks in 36.2 % of newborn infants with sepsis. This is in agreement with other studies, which stated that newborn infants are especially vulnerable to nosocomial infections because of their intrinsic susceptibility to infection as well as the invasive procedures to which they are subjected [1]. This is particularly high for those born prematurely or of LBW. Similarly, different studies came up with the conclusion that LBW infants are at a high risk of developing sepsis compared with full-term infants [1]. Furthermore, Duha and Hassan study in Iraq, illustrated that low birth weight LBW, intra uterine growth retardation (IUGR) & prematurity were risk factors for death outcome in neonates with sepsis, a result similar to many previous studies carried in different countries whether developing and developed world a factor related to inherent immunological deficiency, or because these neonates need prolonged hospitalization which increases risk of nosocomial infection [3,7]. Ghotaslou et al. (2007) study stated that most infants, particularly those of very low birth weight, undergo one or more procedures that place them at risk of infection. A predominance of male infants is apparent in almost all studies of sepsis in newborns [8]. A similar observation of the neonatal profile of the Iyer et al study showed 60.5% males, 37.5% premature, 49.5% low birth weight babies [2]. From the literature, Lynn (2005) [9] revealed that early-onset sepsis (EOS)is a rare, but potentially lethal problem that affects neonates of low birth weight [9].

A study conducted in Tanzania (2016) showed preterm delivery as a significant factor for neonatal sepsis. This could be explained by the fact that premature neonates have poor host defenses and thus are more likely to suffer from neonatal sepsis [10]. In our study, we recorded that the majority of cases had an APGAR score at the 5th minute of more than 7%. Moreover, similar observations have been reported in the case-control study conducted in Derna, Libya (2009) [11], the Apgar scores at the first and fifth minutes were significantly lower in cases (3.4±2.3 and 5.7±0.8) than in the control group (6.3±1.1 and 8.1±2.3). This denotes a state of ante-and /or perinatal hypoxia among cases of neonatal sepsis. Apgar score was found to be negatively correlated with sepsis score (P <0.001). In fact, Tollner and Guerina et al. (1988 & 1991) reported that respiratory distress syndrome was the most common symptom occurring in up to 90% of infants with sepsis. Regarding hyaline membrane disease, it was reported to be very common among cases too [11]. Also, the results are in agreement with a study on neonatal sepsis at public hospitals in North Ethiopia that demonstrated the APGAR score at the 5th minute had a strongly significant effect on the development of neonatal sepsis [7].

Our finding where the vaginal delivery and cesarean section seemed to be equal, when compared to Magri et al study (2009) [11], which reported vaginal delivery was the most common mode of delivery. In addition, Roberton (1993), who reported instrumental intervention in delivery as one of the major sources of neonatal sepsis [11]. Furthermore, Camilla Runa (2016) [12] observed that vaginal spontaneous birth was found to be a significant protective factor for late onset sepsis (LOS), not early onset sepsis (EOS), and the highest rate of neonatal sepsis was identified among neonates with a gestational age of less than 32weeks [12].

On the other hand, in this study we reported that nearly half of neonates with sepsis born from mothers' with positive history of leaking also, history of urinary tract infection during pregnancy was common and history of intrapartum fever this results consistent with Minyahil and his colleagues study in Ethiopia (2014), recorded a significant number of neonates born from mothers' with UTI developed sepsis (p = 0.02) and this figure was almost 2.9-fold higher than the neonates born from mothers' with no UTI diagnosis. This is because the most common pathogens found in early onset neonatal sepsis are found across the vaginal

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wall and possibly increase the risk, whereas the child was born and passes through the vaginal wall [1]. Regarding maternal risk factors for neonatal sepsis, a recent study in Ethiopia (2015) [10] found that premature rupture of membranes [10]. Early membrane rupture exposes a newborn to ascending microorganisms from the vagina into the amniotic sac, and if not managed well, the neonate can develop sepsis after delivery. The other possible risk factors of neonatal sepsis were a history of maternal urinary tract infection or sexually transmitted infection, prolonged rupture of membrane, place of delivery, health facility delivery, intrapartum fever, Apgar score <7 at 5th minute, and not crying immediately at birth [10].
In this study regarding clinical signs and symptoms of early onset neonatal sepsis, poor feeding, lethargy, respiratory distress, signs of dehydration, hypothermia, pallor, cyanosis, apnea, & sclerma were reported significant association with the outcome of death in neonatal sepsis; similar observations were recorded from other studies [3,11].
Usually, early-onset neonatal sepsis is associated with prenatal background characteristics such as maternal prolonged or premature rupture of membranes. Late-onset is mainly related to the medical and surgical conditions or other procedures required by neonates, such as resuscitation at birth, and intravenous access after birth [10]. Regarding the investigation, almost the same results from our study as the literature, which showed that total leucocyte count and platelet count were lower in septic cases [1,11]. Total parenteral nutrition (TPN) administration (Central venous catheter (CVC), IV peripheral line) was found to be a significant risk factor for the development of late-onset sepsis in preterm infants [12].
Regarding blood culture, our results were Acinetobacter, followed by Gram-negative bacteria and Klebsiella. While another study [9] revealed that several differences were noted between cases of E coli– and group B Streptococcus-induced early-onset sepsis, which were related mostly to intrapartum events in the group B Streptococcus cases [9]. Mithal et al stated that the sensitive and specific diagnosis of sepsis is difficult in newborn infants. The diagnosis of sepsis is particularly challenging in preterm infants who are disproportionately affected by invasive infection in the first days of life. Early-onset sepsis (EOS) is commonly the result of an intrauterine infection. Laboratory tests such as white blood cell indices and C-reactive protein (CRP) have poor specificity. Thus, in the absence of reliable diagnostics for EOS, infants are frequently treated for presumed, culture-negative sepsis with antimicrobial agents. Diagnostic indecision leads to increased morbidity due to delayed treatment and overuse of empiric broad-spectrum antibiotics [13]. Blood culture, the current gold standard, is problematic: culture is slow, and the sensitivity is limited due to maternal antibiotics, small specimen volumes, and low pathogen density per sampled blood volume. Other postnatal laboratory tests, such as white blood cell indices and C-reactive protein (CRP), have poor specificity [13].
Lumbar puncture (LP) was not performed in 96.6% of cases, mainly due to contraindications in critically ill or ventilated neonates, where the procedure carries risks such as hypoxemia, bradycardia, and apnea. Similarly, procalcitonin (PCT) testing was not conducted in 89.7% of cases due to limited availability, cost constraints, and reliance on external private laboratories. These gaps may have reduced the depth of clinical profiling, particularly in identifying meningitis and assessing inflammatory response, potentially leading to underestimation of disease severity. Another study to determine the necessity of lumbar puncture (LP) in early neonatal sepsis, conducted by Saeedi [14] in Iran, reported that there was a significant relationship between blood culture and CSF culture results. However, regarding the low incidence of positive CSF, LP should be performed for each case, based on clinical manifestations and clinical opinion [14].
A study of umbilical cord blood culture in the diagnosis of early-onset sepsis among newborns with high-risk factors agrees that the umbilical cord is a less commonly used site for the collection of blood culture. They concluded that umbilical cord blood culture (UCBC) has good diagnostic validity for etiological diagnosis of bacterial sepsis in high-risk neonates. Organisms grown in umbilical cord blood samples are comparable with venous blood culture samples. UCBC could be a painless, kinder, gentle approach instead of the painful collection of blood by pricking the neonate [15].
Our findings for early treatment with antibiotics first line without waiting for the blood cultures results are consistent with the WHO guidelines for the integrated management of childhood strategy (IMCI), which recommends providing prophylactic intramuscular (IM) or intravenous (IV) ampicillin and gentamicin in neonates with documented risk factors for infection for at least 2 days and to reassess. Treatment should be continued only if there are signs of sepsis (or positive blood culture). IMCI recommends hospitalization and IM or IV antibiotic therapy with a combination of gentamicin and benzyl penicillin or Ampicillin for at least 7–10 days in infants aged < 2 months for infants fulfilling the case definition of serious bacterial infection. If infants are deemed at risk of staphylococcal infection, IV cloxacillin and gentamicin are recommended [16]. WHO sigs for neonatal sepsis report White blood cells (WBC) count: <4,000 x109 cells/L OR >20,000 x109 cells/L, Immature to total neutrophil ratio (I/T) greater than 0.2, Platelet count <100,000 x109 cells/L and C reactive protein > 15 mg/L, and again Duha and Hassan study which shows a statistically significant higher mortality was reported in neonates having thrombocytopenia, neutropenia and C -reactive protein ≥10 mg/dl. Regression analysis of different neonatal and maternal variables, hematological and microbiological tests [3]. Same results from our study, we recorded cases having abnormal total leucocyte count, thrombocytopenia, and neutropenia.

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Sepsis is traditionally suspected in neonates based on clinical features, maternal and neonatal risk factors, and is treated with empirical antibiotics. These risk factors and clinical features are variable depending on geographical, cultural, and socio-economic background. Implementation of quality care pathways for strict hand hygiene and proper blood sampling goes a long way to reduce blood contamination and better yield of positive blood cultures so that a definite diagnosis of neonatal sepsis can be made [9]. In this study regarding the outcome of cases of neonatal sepsis, most cases were alive, which is a positive indicator of successful treatment. The WHO reports recorded that a significantly higher percentage of deaths was reported among neonates with sepsis who had a history of previous hospitalization; these neonates were at a greater risk of acquiring nosocomial infection. An ill neonate who is subjected to various procedures gets a breach in their host defense mechanism, either mechanically or immunologically [16,17]. In addition, body weight, gestational age, thrombocytopenia, neutropenia, positive blood culture for Klebsiella spp., and signs of dehydration are predictive factors of the outcome of death in neonatal sepsis [3]. Outcome of admitted neonates in an Indian study by Iyer et al (2017) showed, third quarter of cases were discharged after improvement, death due to respiratory distress syndrome was common in preterm and male neonates [2].

Conclusion

They found that both maternal and neonatal factors had contributed to the risk of neonatal sepsis. The possible risk factors were a history of maternal UTI, leaking (premature rupture of membrane), prematurity, and low birth weight, which were found to be more frequent. The cases exposed to many invasive procedures, this could be one of the risk factors of neonatal sepsis. All these could have an association with the development of neonatal sepsis. Also, we concluded that only a few cases had a low APGAR score at the 5th minute, so the APGAR score at the 5th minute was not identified as a possible risk factor of neonatal sepsis.

Conflicts of Interest

The authors declare no conflicts of interest.

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