Section: Miscellaneous

Original Research Article

RISK FACTORS AND MICROBIOLOGICAL PROFILE OF NEONATAL SEPSIS IN A TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY

Neha M Kaila[1], Ajaykumar A. Kaila[2], Hardik M. Thakkar[3], Adityasinh G. Dabhi[4]

[1]*Junior resident, Ophthalmology Department, GMERS Medical college and hospital, Morbi, Gujarat, India.*
[2]*Second year resident of Diploma in Child Health, Paediatric Department, Sir Mansinhji Hospital, Palitana, Gujarat, India.*
[3]*Assistant professor, Paediatric Department, GMERS Medical college, Dharpur, Patan, Gujarat, India.*
[4]*Indian Medical Graduate, Smt. B.K. Shah Medical Institute and Research Centre, Vadodara, Gujarat, India.*

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Corresponding Author:
Dr. Neha M Kaila,
Junior resident, Ophthalmology department, GMERS Medical college and hospital, Morbi, Gujarat, India.
Email: kailaneha111@gmail.com

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ABSTRACT

Background: Neonatal sepsis remains a major cause of morbidity and mortality, especially in developing countries like India, due to its nonspecific presentation and rising antimicrobial resistance. This study aimed to identify risk factors and the microbiological profile of neonatal sepsis in a tertiary care hospital in Gujarat.

Materials and Methods: A hospital-based cross-sectional study was conducted among 97 neonates with blood culture-positive sepsis. Relevant maternal and neonatal clinical data were collected using a predesigned proforma. Blood cultures were processed using standard microbiological techniques, and antimicrobial susceptibility testing was done as per CLSI guidelines. Data were analyzed using SPSS v21.

Results: Among the 97 neonates, 59.8% had early-onset sepsis and 40.2% had late-onset sepsis. Key maternal risk factors were prolonged rupture of membranes (21.6%) and maternal fever (17.5%), while neonatal risk factors included low birth weight, prematurity, and birth asphyxia. Gram-positive organisms (48.5%) were most common, notably Coagulase-negative Staphylococci (20.6%) and Staphylococcus aureus (10.3%). Gram-negative bacteria (46.4%) included Klebsiella pneumoniae (22.7%) and Escherichia coli (9.3%). Candida species were isolated in 5.1% of cases.

Conclusion: Neonatal sepsis is influenced by multiple risk factors such as prolonged rupture of membranes, maternal fever, low birth weight, prematurity, and birth asphyxia. The predominance of Gram-positive organisms, particularly CoNS, underscores the need for local antibiogram-based empirical therapy. Early identification of risk factors, timely diagnosis, and antibiotic stewardship are critical to improving neonatal outcomes.

Keywords: Coagulase-negative staphylococci, Klebsiella pneumoniae, Neonatal sepsis, Prematurity, Risk factors.

INTRODUCTION

Neonatal sepsis remains a significant cause of morbidity and mortality among newborns, particularly in developing countries like India. It is a systemic infection occurring in infants within the first 28 days of life, often resulting from bacterial, viral, or fungal pathogens. Despite advancements in neonatal care, sepsis continues to pose a major challenge due to its nonspecific clinical presentation, diagnostic limitations, and increasing antimicrobial resistance. Understanding the risk factors and microbiological profile of neonatal sepsis is crucial for improving early detection, treatment strategies, and overall neonatal outcomes. According to World Health Organisation, infections contribute to nearly one-quarter of the 2.8 million global neonatal deaths annually.[1] In India, the National Neonatal Perinatal Database (NNPD) reports an incidence of 8.5 per 1,000 live births, largely due to inadequate infection control, poor maternal health, and limited neonatal care access.[2]

Several maternal and neonatal factors have been recognized as significant contributors to the development of neonatal sepsis. Maternal risk factors such as urinary tract infection during pregnancy, prolonged labor, and perinatal complications further elevate the risk. Among neonatal factors, male sex, prematurity and low birth weight are particularly associated with increased susceptibility to sepsis due to immature immune function and compromised physiological barriers.[2,3]

The causative organisms of neonatal sepsis vary by region, hospital environment, and antibiotic practices. In India, Gram-negative bacteria such as Klebsiella pneumoniae, Escherichia coli, and Pseudomonas aeruginosa are most common. Among Gram-positive pathogens, Staphylococcus aureus and Coagulase-negative Staphylococci are frequently seen, particularly in late-onset sepsis. Candida species have also emerged as important pathogens, especially in neonates with prolonged antibiotic use and invasive interventions.[4]

Diagnosing neonatal sepsis is difficult due to its nonspecific symptoms such as lethargy, poor feeding, and respiratory distress. Although blood culture is the diagnostic gold standard, its sensitivity is limited. Emerging tools like PCR and biomarkers (e.g., procalcitonin, CRP) may improve diagnostic accuracy.[6]

Treatment relies on empirical antibiotics based on local resistance patterns, but rising antimicrobial resistance poses major challenges. Effective management requires robust antibiotic stewardship and preventive measures such as improved maternal care, infection control, and timely prophylactic interventions.[5]

Early recognition and timely management of neonatal sepsis are vital for improving outcomes. As the microbial profile and risk factors vary by region, understanding local epidemiology is essential for effective prevention and treatment. This study aimed to identify the risk factors and microbiological profile of neonatal sepsis in our institute.

MATERIALS AND METHODS

Study Design and Setting: This hospital-based cross-sectional study was conducted in the Neonatal Intensive Care Unit (NICU) of a tertiary care hospital in Gujarat, India, over a period of one year, from January 2024 to December 2024.

Study Population: A total of 97 neonates diagnosed with neonatal sepsis during the study period were enrolled in the study using a convenient sampling technique.

Inclusion Criteria

- Neonates aged ≤28 days admitted to the NICU with clinical features suggestive of sepsis.
- Blood culture-positive cases.
- Informed written consent obtained from parents or legal guardians.

Exclusion Criteria

- Neonates with major congenital anomalies.
- Neonates whose blood samples for culture were collected after initiation of antibiotic therapy.
- Cases with incomplete medical records or where consent was not provided.

Data Collection: Data were collected using a predesigned structured proforma. Relevant demographic and clinical information was retrieved from hospital records, including maternal risk factors (e.g., prolonged rupture of membranes, maternal fever, gestational diabetes), neonatal clinical presentations, and laboratory findings. Neonatal sepsis was classified as early-onset sepsis (EOS), occurring within the first 72 hours of life, or late-onset sepsis (LOS), occurring after 72 hours of life.

Microbiological Investigations: Blood samples were collected aseptically before the administration of antibiotics and processed in the microbiology laboratory using standard protocols. Identification of organisms was performed through culture, Gram staining, and biochemical tests. Antimicrobial susceptibility testing was carried out using the Kirby-Bauer disk diffusion method, and the results were interpreted in accordance with Clinical and Laboratory Standards Institute (CLSI) guidelines.[6]

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using the SPSS, version 21. Continuous variables were summarized as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. The Chi-square (χ^2) test was used to examine associations between categorical variables. A p-value of <0.05 was considered statistically significant

RESULTS

Out of the total 97 neonates with sepsis included in the study, Early-Onset Sepsis (EOS) accounted for 58 cases (59.8%) and Late-Onset Sepsis (LOS) for 39 cases (40.2%).

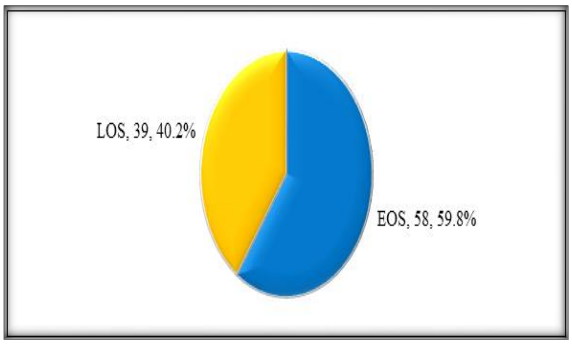

Figure 1: Distribution of EOS and LOS

Table 1: Characteristics of neonates with sepsis (N=97)

Characteristics	Total (N=97)	EOS (N=58)	LOS (N=39)	X^2 & p-value
Gender				
Male	56 (57.7%)	34 (58.6%)	22 (56.4%)	$X^2 = 0.001$, p-value = 0.994
Female	41 (42.3%)	24 (41.4%)	17 (43.6%)	
Gestational Age				
Preterm (<37 weeks)	62 (63.9%)	40 (69.0%)	22 (56.4%)	$X^2 = 1.096$, p-value = 0.295
Term (≥37 weeks)	35 (36.1%)	18 (31.0%)	17 (43.6%)	
Birth Weight				
ELBW (<1000 gm)	9 (9.3%)	6 (10.3%)	3 (7.7%)	
VLBW (1000-1499 gm)	17 (17.5%)	10 (17.2%)	7 (17.9%)	$X^2 = 0.216$, p-value = 0.975
LBW (1500-2499 gm)	35 (36.1%)	21 (36.2%)	14 (35.9%)	
NBW (>2500 gm)	36 (37.1%)	21 (36.2%)	15 (38.5%)	
Mode of Delivery				
Vaginal	50 (51.5%)	32 (55.2%)	18 (46.2%)	$X^2 = 0.441$, p-value = 0.506
LSCS	47 (48.5%)	26 (44.8%)	21 (53.8%)	

In this study, total 97 neonates diagnosed with sepsis during study period were included. There was a male predominance with 56 (57.7%) males and 41 (42.3%) females. Preterm births (<37 weeks gestation) were significantly higher, accounting for 62 (63.9%) cases, while only 35 (36.1%) were term neonates (≥37 weeks gestation). Birth weight distribution revealed that a substantial proportion of neonates had low birth weight (<2500 g). Specifically, 9 (9.3%) were extremely low birth weight (ELBW <1000 g), 17 (17.5%) were very low birth weight (VLBW 1000–1499 g), and 35 (36.1%) were low birth weight (LBW 1500–2499 g). Only 36 (37.1%) neonates had a normal birth weight (>2500 g). The mode of delivery was nearly evenly distributed, with 50 (51.5%) of neonates delivered vaginally and 47 (48.5%) via lower segment cesarean section (LSCS). There was no significant difference between EOS and LOS in terms of gender, gestational age, birth weight, or mode of delivery ($p > 0.05$ for all).

Table 2: Laboratory findings in neonates with sepsis (N=97)

Investigation	Total (N=97)	EOS (N=58)	LOS (N=39)	X^2 & p-value
Platelet Count				
<150000	39 (40.2%)	23 (39.7%)	16 (41.0%)	$X^2 = 0.01$, p = 1.0
>150000	58 (59.8%)	35 (60.3%)	23 (59.0%)	
CRP				
Positive	61 (62.9%)	36 (62.1%)	25 (64.1%)	$X^2 = 0.01$, p = 1.0
Negative	36 (37.1%)	22 (37.9%)	14 (35.9%)	
Sepsis Screen				
Positive	54 (55.7%)	32 (55.2%)	22 (56.4%)	$X^2 = 0.01$, p = 1.0
Negative	43 (44.3%)	26 (44.8%)	17 (43.6%)	
CSF				
Positive	12 (12.4%)	8 (13.8%)	4 (10.3%)	$X^2 = 0.405$, p = 0.817
Negative	81 (83.5%)	48 (82.8%)	33 (84.6%)	
Not done	4 (4.1%)	2 (3.4%)	2 (5.1%)	

Among 97 neonates, thrombocytopenia (40.2%) was a common finding, indicating its role as a hematological marker of infection. CRP was positive in 62.9% of cases, reinforcing its association with sepsis, though 37.1% had a negative CRP, suggesting possible early or low-grade infection. Sepsis screening was positive in 55.7% of neonates, highlighting its diagnostic utility but also the need for microbiological confirmation. CSF analysis, performed in 93 neonates, was positive in 12.4%, indicating meningitis in a subset of cases, while 83.5% had negative results. These findings underscore the significance of CRP, sepsis screening, and platelet count in neonatal sepsis diagnosis, while also emphasizing the need for CSF analysis in suspected cases of meningitis. Among the 97 neonates, no statistically significant differences were observed between EOS and LOS in terms of laboratory parameters.

Table 3: Clinical presentation among neonates with sepsis (N=97)

Clinical presentation	Total (N=97)	EOS (N=58)	LOS (N=39)	X^2 & p-value
Respiratory distress	29 (29.9%)	21 (36.2%)	8 (20.5%)	$X^2 = 2.04$, p = 0.15
Birth asphyxia	19 (19.6%)	15 (25.9%)	4 (10.3%)	$X^2 = 2.683$, p = 0.104
Neonatal jaundice	16 (16.5%)	9 (15.5%)	7 (17.9%)	$X^2 = 0.001$, p = 0.970
Hypoglycaemia	14 (14.4%)	9 (15.5%)	5 (12.8%)	$X^2 = 0.005$, p = 0.939
Seizures	12 (12.4%)	8 (13.8%)	4 (10.3%)	$X^2 = 0.041$, p = 0.838
Poor suckling/Poor cry	10 (10.3%)	7 (12.1%)	3 (7.7%)	$X^2 = 0.126$, p = 0.723
Lethargy	9 (9.3%)	6 (10.3%)	3 (7.7%)	$X^2 = 0.007$, p = 0.933

Among the 97 neonates with sepsis, respiratory distress (29.9%) was the most common symptom followed by birth asphyxia (19.6%) and neonatal jaundice (16.5%). Hypoglycaemia (14.4%), seizures (12.4%), poor suckling/weak cry (10.3%), and lethargy (9.3%) were also noted. Clinical manifestations were comparable between EOS and LOS groups, with no statistically significant differences ($p > 0.05$) in any symptom.

Table 4: Maternal risk factors among neonates with sepsis (N=97)

Risk Factor	Total (N=97)	EOS (N=58)	LOS (N=39)	X^2 & p-value
Prolonged Rupture of Membranes (>18 hrs)	21 (21.6%)	18 (31.0%)	3 (7.7%)	**$X^2 = 6.18$, p = 0.01**
Maternal Fever	17 (17.5%)	12 (20.7%)	5 (12.8%)	$X^2 = 0.52$, p = 0.46
Gestational Diabetes	7 (7.2%)	3 (5.2%)	4 (10.3%)	$X^2 = 0.30$, p = 0.58
Meconium Stained Liquor (MSL)	14 (14.4%)	9 (15.5%)	5 (12.8%)	$X^2 = 0.01$, p = 0.93
Pregnancy Induced Hypertension (PIH)	8 (8.2%)	4 (6.9%)	4 (10.3%)	$X^2 = 0.04$, p = 0.83
Oligohydroamnios	6 (6.2%)	4 (6.9%)	2 (5.1%)	$X^2 = 0.12$, p = 0.72
Leaking Per-Vaginal	6 (6.2%)	4 (6.9%)	2 (5.1%)	$X^2 = 0.12$, p = 0.72
Young Primi Mother	5 (5.1%)	3 (5.2%)	2 (5.1%)	$X^2 = 0.01$, p = 0.99
Pre-eclampsia	5 (5.1%)	3 (5.2%)	2 (5.1%)	$X^2 = 0.01$, p = 0.99
Severe Anemia	4 (4.1%)	3 (5.2%)	1 (2.6%)	$X^2 = 0.01$, p = 0.91
Non-Progression of Labour (NPL)	3 (3.1%)	2 (3.4%)	1 (2.6%)	$X^2 = 0.06$, p = 0.81
Placenta Previa	2 (2.1%)	1 (1.7%)	1 (2.6%)	$X^2 = 0.08$, p = 0.77
Neonates with No Maternal Risk Factor	35 (36.1%)	15 (25.9%)	20 (51.3%)	**$X^2 = 5.48$, p = 0.01**

Among 97 neonates with sepsis, prolonged rupture of membranes (21.6%) was the most common maternal risk factor, followed by maternal fever (17.5%) and meconium-stained liquor (14.4%). Other contributing factors included gestational diabetes (7.2%), pregnancy-induced hypertension (8.2%), oligohydramnios (6.2%), leaking per vaginum (6.2%), and pre-eclampsia (5.1%). Notably, 36.1% of neonates had no identifiable maternal risk factors, emphasizing that sepsis can occur even in the absence of maternal complications. Among maternal risk factors, prolonged rupture of membranes (PROM >18 hrs) was significantly more associated with EOS (31.0%) compared to LOS (7.7%) ($p = 0.01$). Additionally, absence of maternal risk factors was significantly higher in LOS cases (51.3%) than EOS (25.9%) ($p = 0.01$), suggesting perinatal factors played a larger role in EOS. Other risk factors like maternal fever, gestational diabetes, meconium-stained liquor, PIH, and anemia were observed with no statistically significant differences between the two groups ($p > 0.05$).

Table 5: Microbiological profile of neonatal sepsis (N=97)

Organisms	Total (N=97)	EOS (N=58)	LOS (N=39)	X^2 & p-value
Gram-Positive Bacteria	**47 (48.5%)**	**20 (34.5%)**	**27 (69.2)**	$X^2 = 8.89$, p = 0.63
Coagulase-Negative Staphylococci (CONS)	20 (20.6%)	8 (13.8%)	12 (30.8%)	
Staphylococcus aureus	10 (10.3%)	4 (6.9%)	6 (15.4%)	
Enterococcus faecalis	6 (6.2%)	3 (5.2%)	3 (7.7%)	
Staph hemolyticus	5 (5.1%)	2 (3.4%)	3 (7.7%)	
Staph epidermidis	3 (3.1%)	2 (3.4%)	1 (2.6%)	
Methicillin-Resistant Staphylococcus Aureus (MRSA)	3 (3.1%)	1 (1.7%)	2 (5.1%)	
Gram-Negative Bacteria	**45 (46.4%)**	**31 (53.4%)**	**14 (35.9%)**	
Klebsiella pneumoniae	22 (22.7%)	15 (25.9%)	7 (17.9%)	
Escherichia coli	9 (9.3%)	7 (12.1%)	2 (5.1%)	
Acinetobacter baumannii	7 (7.2%)	5 (8.6%)	2 (5.1%)	
Pseudomonas	5 (5.1%)	3 (5.2%)	2 (5.1%)	
Citrobacter freundii	2 (2.1%)	1 (1.7%)	1 (2.6%)	
Fungal Infections				
Candida spp.	5 (5.1%)	2 (3.4%)	3 (7.7%)	

Among the 97 neonates with sepsis, Gram-positive bacteria were isolated in 47 (48.5%) cases, with Coagulase-Negative Staphylococci (CONS) (20.6%) being the most common, followed by Staphylococcus aureus (10.3%) and Enterococcus faecalis (6.2%). Other Gram-positive isolates included Staph hemolyticus (5.1%), Staph epidermidis (3.1%), and Methicillin-Resistant Staphylococcus Aureus (MRSA) (3.1%). Gram-negative bacteria were identified in 45 (46.4%) cases, with Klebsiella pneumoniae (22.7%) being the predominant pathogen, followed by Escherichia coli (9.3%), Acinetobacter baumannii (7.2%), Pseudomonas (5.1%), and Citrobacter freundii

(2.1%). Fungal infections were detected in 5 (5.1%) cases, all caused by Candida spp. Gram-negative bacteria were more commonly isolated in EOS (53.4%) compared to LOS (35.9%), while Gram-positive organisms were predominant in LOS (69.2%) versus EOS (34.5%), though the overall difference was not statistically significant (p = 0.63). Among Gram-positive organisms, Coagulase-Negative Staphylococci (CONS) and Staphylococcus aureus were more frequent in LOS. In contrast, Klebsiella pneumoniae and Escherichia coli were the most common Gram-negative isolates in EOS. Fungal infections (Candida spp.) were relatively uncommon, slightly more observed in LOS (7.7%) than EOS (3.4%).

DISCUSSION

Proportion of EOS and LOS

In the present study, EOS accounted for 59.8% of cases, while LOS constituted 40.2%. This pattern is consistent with findings from Sharma et al,[7] (67.7% EOS) and Das et al,[6] (61.0% EOS), where EOS predominated. In contrast, Vimal K et al,[8] reported a higher proportion of LOS (53.9%). Studies by Kamalakannan S et al,[9] and Chauhan H et al,[10] showed a more balanced distribution, with LOS rates of 26.1% and 48.1%, respectively. These differences likely reflect regional variations, population characteristics, and healthcare practices. The predominance of EOS in the present study may be attributed to maternal and perinatal risk factors such as prolonged rupture of membranes, maternal fever, and birth asphyxia.

Characteristics of neonates with neonatal sepsis

In the present study, male neonates comprised 57.7% of sepsis cases, aligning closely with findings from Kamalakannan S et al.9 (54.1%) and Chauhan H et al,[10] (54.7%), though Das et al,[6] reported a higher male preponderance (73.2%). Regarding gestational age, 63.9% of neonates were preterm in the current study, comparable to Chauhan H et al,[10] (60.4%) and lower than in Das et al,[6] (71.7%), where a larger proportion were near-term or term. This emphasizes the role of prematurity as a significant risk factor for neonatal sepsis due to immature immune function and barrier systems. In terms of birth weight, LBW neonates accounted for the majority in the current study (62.9%), consistent with Chauhan H et al,[10] (58.6%) and Kamalakannan S et al,[9] (57.0%). These findings reinforce the well-established association between lower birth weight and increased vulnerability to sepsis. Furthermore, the mode of delivery in the present study showed nearly equal distribution between vaginal delivery (51.5%) and LSCS (48.5%), similar to the pattern observed in Chauhan H et al,[10] indicating no clear association between mode of delivery and sepsis risk in this setting.

Clinical presentation

In the present study, respiratory distress (29.9%) was the most common clinical presentation, followed by birth asphyxia (19.6%), neonatal jaundice (16.5%), hypoglycemia (14.4%), seizures (12.4%), poor suckling/cry (10.3%), and lethargy (9.3%). Sharma et al,[7] reported higher rates of respiratory distress (68.8%) and lethargy (27.1%), while Das et al,[6] observed respiratory distress (26.8%), hypoglycemia (19.5%), seizures and poor suckling/cry (17.1% each), lethargy (14.6%), and birth asphyxia (7.3%).

Maternal risk factors

In the present study, the most common maternal risk factor associated with neonatal sepsis was prolonged rupture of membranes (>18 hours), seen in 21.6% of cases, followed by maternal fever (17.5%), meconium-stained liquor (14.4%), pregnancy-induced hypertension (8.2%), gestational diabetes (7.2%), oligohydroamnios and leaking per-vaginal (6.2% each), young primi mother and pre-eclampsia (2.1%). Notably, 36.1% of neonates in the present study had no identifiable maternal risk factor. In comparison, Chauhan H et al,[10] reported meconium-stained liquor as the most common risk factor (15.5%), followed by pregnancy-induced hypertension and oligohydroamnios (5.8% each), young primi mother and leaking per-vaginal (3.9% each), pre-eclampsia (3.9%), severe anemia and non-progression of labour (2.9% each), COVID-19 positivity (1.94%), and placenta previa (0.97%). Interestingly, a larger proportion (53.7%) of neonates in their study had no associated maternal risk factor.

Organism causing neonatal sepsis

In the present study, Gram-positive organisms accounted for 48.5% of isolates, with coagulase-negative Staphylococci (CONS) being the most common (20.6%), followed by Staphylococcus aureus (10.3%), Enterococcus faecalis (6.2%), Staph hemolyticus (5.1%), Staph epidermidis (3.1%), and MRSA (3.1%). Gram-negative organisms constituted 46.4%, with Klebsiella pneumoniae (22.7%) and Escherichia coli (9.3%) being predominant, followed by Acinetobacter baumannii (7.2%), Pseudomonas spp. (5.1%), and Citrobacter freundii (2.1%). Fungal pathogens, mainly Candida spp., were isolated in 5.1% of cases. In contrast, Sharma et al,[7] reported a higher prevalence of Gram-negative organisms (61.6%), while Vimal K et al.8 found a similar trend (59.8% Gram-negative). However, Das et al.6 noted a predominance of Gram-positive pathogens (51.2%), particularly CONS (43.9%) and Staphylococcus aureus (17.1%). Chauhan H et al,[10] reported Klebsiella pneumoniae (30.18%) and Acinetobacter baumannii (17.92%) as the leading isolates, followed by MRCONS (13.2%) and Enterococcus faecalis (12.26%). Fungal infections were also noted in Das et al,[6] (9.8%), including Candida peliculosa and Candida glabrata.

The predominance of Gram-positive organisms in the present study, particularly Coagulase-Negative

Staphylococci (CONS) and Staphylococcus aureus, likely reflects nosocomial infections related to invasive procedures in preterm or low birth weight neonates. The presence of MRSA and MRCONS further indicates antibiotic resistance and hospital-acquired infections. The significant proportion of Gram-negative bacteria such as Klebsiella pneumoniae and Escherichia coli suggests both vertical transmission and environmental contamination. Fungal infections, mainly Candida spp., are associated with prolonged antibiotic use and prematurity. Variations across studies may be due to differences in hospital settings, infection control practices, and regional microbial profiles.

CONCLUSION

This study highlights the multifactorial nature of neonatal sepsis, with both maternal and neonatal risk factors significantly contributing to its occurrence. Common risk factors identified included prolonged rupture of membranes, maternal fever, low birth weight, prematurity, and birth asphyxia. The microbiological profile revealed a predominance of Gram-positive organisms, particularly Coagulase-negative Staphylococci, followed by Gram-negative bacteria such as Klebsiella pneumoniae and Escherichia coli. These findings underscore the importance of early identification of risk factors and region-specific pathogen surveillance to guide empirical therapy. Strengthening infection control practices, improving maternal care, and promoting rational antibiotic use are essential to reduce the burden of neonatal sepsis and improve neonatal outcomes.

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