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Original Research Article

CLINICO-BACTERIOLOGICAL PROFILE OF NEONATAL SEPSIS AND ANTI MICROBIAL SENSITIVITY PATTERN - A STUDY FROM A TERTIARY CARE CENTRE OF BUNDELKHAND REGION CENTRAL INDIA

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ABSTRACT

Background: Neonatal sepsis is a significant cause of morbidity and mortality, particularly in developing regions such as Bundelkhand, Central India. The emergence of multidrug-resistant organisms has complicated the management of sepsis, making the identification of prevalent bacterial pathogens and their antimicrobial sensitivity patterns crucial. This study aims to analyze the clinico-bacteriological profile of neonatal sepsis and assess the antimicrobial sensitivity patterns of the isolated pathogens in a tertiary care center in Bundelkhand.

Materials and Methods: An observational cross-sectional study was conducted, including 300 neonates with suspected sepsis admitted to the Neonatal Intensive Care Unit (NICU). Blood cultures were obtained, and the antimicrobial sensitivity patterns of the isolated pathogens were determined using standard laboratory methods. The neonates were categorized based on the onset of sepsis as early-onset (EOS) or late-onset (LOS).

Results: Out of 300 neonates with clinical sepsis, 52% were culture-positive. Among the culture-positive cases, 75.6% were classified as EOS and 24.4% as LOS. The most commonly isolated pathogens were Gram-negative bacteria, including Klebsiella pneumoniae and Acinetobacter spp. The study also identified significant resistance patterns, particularly against commonly used antibiotics such as ampicillin and cephalosporins. Vancomycin and carbapenems showed higher sensitivity among Gram-positive and Gram-negative isolates, respectively.

Conclusion: The high prevalence of multidrug-resistant organisms in neonatal sepsis underscores the need for continuous surveillance and tailored antimicrobial therapy in this region. The findings highlight the importance of region-specific studies to inform empirical treatment protocols and reduce neonatal mortality.

Keywords: Neonatal sepsis, Antimicrobial sensitivity, Bundelkhand Central India, Gram- negative bacteria, Multidrug -resistant organism.

INTRODUCTION

Neonatal sepsis (NS) is a systemic infection in newborns, caused by bacterial, viral, or fungal pathogens, and linked to hemodynamic abnormalities and other clinical signs.[1] One of the four main cause of neonatal mortality and morbidity in India is septicaemia, which is defined as generalized bacterial infection confirmed by a positive blood culture within the first four week of life. It is common in very low birth weight and in preterm neonate, and incidence rises in the presence of maternal and neonatal risk factors.[2] It remains a significant cause of neonatal morbidity , especially

in low-income countries like India, where septicaemia is a leading cause of death among newborns. In India, the incidence of neonatal sepsis ranges from 1 to 8 cases per 1000 live births.[3] Neverthless, in contrast to other cause of death like congenital abnormalities, heart abnormalities, sepsis is preventable, suggesting that if the right steps are taken, the death rate can be decreased.[4]

Neonatal sepsis is categorized into early-onset sepsis (EOS), occurring within the first 72 hours of life, and late-onset sepsis (LOS), which occurs after 72 hours to 28 days of life.[5] EOS is often acquired through maternal transmission during childbirth, while LOS is typically nosocomial or community-acquired. Risk factor for EOS are chorioamnionitis, preterm birth, GBS colonization and a prolonged rupture of membranes exceeding eighteen hours.[6] In developing nations, neonatal sepsis is commonly caused by Gram-negative bacteria such as Escherichia coli, Klebsiella, and Pseudomonas, while Gram-positive organisms like Staphylococcus aureus and Streptococcus pneumoniae are also prevalent. One metric used to asses a country's health is the newborn mortality rate. Newborn mortality may have multiple causes, however one of the leading causes of newborn mortality and morbidity globally is still septicaemia. While incidence varies by nation ,it is significantly higher in underdeveloped than in developed counntries.[7] The World Health Organization (WHO) estimates that 5 million neonates die annually, with developing nations accounting for 98% of these deaths.[8] Incidences of culture-positive sepsis were 6.2% and overall sepsis was 14.3% in India.[9] 28/1000 live births is the infant mortality rate (IMR), 20/1000 live births is the neonatal mortality rate (NMR), and 41/1000 live births is the infant mortality rate (IMR) in Uttar Pradesh.[10] Neonatal mortality is 20.8% due to sepsis.[11]

The clinical diagnosis of neonatal sepsis is challenging due to the nonspecific nature of its symptoms, often resembling other neonatal conditions. Blood culture remains the gold standard for diagnosis, although sensitivity is limited, especially when small sample volumes are used. The rising prevalence of multidrug-resistant (MDR) pathogens further complicates treatment, making antibiotic resistance a global issue. Empirical antibiotic therapy, tailored to local bacterial profiles and susceptibility patterns, is essential for effective management. Regular epidemiological surveillance of causative agents and their antimicrobial sensitivity is crucial for guiding empirical treatment and reducing neonatal mortality due to sepsis, especially in resource-limited settings where diagnostic tools are inadequate. Despite advances in care, both early and late-onset sepsis remain challenging due to varied causes and rising antibiotic resistance. The diversity in bacterial strains and their sensitivity to antibiotics across different regions highlights the need for localized studies to guide effective empirical treatment.

Aims and Objective

This study aims to investigate the clinical presentation of neonates with sepsis, identify the common bacterial pathogens, and assess their antibiotic sensitivity patterns to guide effective early treatment. The objectives include determining the rate of bacterial isolation through blood culture and evaluating the risk factors and clinical features associated with neonatal sepsis.

MATERIALS AND METHODS

Study Design and Setting

This observational cross-sectional study was conducted at the Neonatal Intensive Care Unit (NICU) of Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh, India, over a period of 12 months from May 2023 to August 2024. The study included 300 neonates with suspected sepsis admitted to the NICU. Ethical approval was obtained from the Institutional Ethics Committee, certificate no-2119/IEC/I/2022-2023 and informed consent was secured from the neonates' parents or guardians.

Sampling Population and Procedure

All neonate suspected of having neonatal sepsis and admitted in the NICU were included. Clinical sepsis was diagnosed based on presence of one or more clinical features .Clinical features considered were convulsions, lethargy , refusal to feed ,hypothermia(< 36.5℃) hyperthermia (>38.0℃), respiratory distress ,vomiting ,bulging fontanels ,and umbilical pus discharge .Fully informed and voluntary signed consent were obtained from the parents or attendants .All investigations and procedure were performed as per standard routine practice in the NICU and no additional interventions were advised as part of the study . A positive sepsis screen is defined as the presence of two or more aberrant values in the event of a strong clinical suspicion. The component of sepsis screen included a total leucocyte count of <5000/cumm, an absolute neutrophil count<1800/cumm, the immature: total neutrophil ratio (I:T ratio) of >0.2, C- reactive protein (CRP) > 1mg/dL, Micro ESR >15mm in 1st hour, Platelet Count of < 150000/cumm .[12]

Operational Definitions

Culture-positive/proven sepsis (CPS) refers when a neonate exhibits clinical signs of sepsis and has a positive blood culture indicating bacterial growth.

A positive sepsis screen is identified when two or more of the five sepsis screening parameters are positive, or in cases where one parameter is unavailable, two out of four parameters must be positive.

A negative sepsis screen is determined when all sepsis screening parameters are negative.

Sepsis screen positivity is defined when either the initial sepsis screen or both screens, conducted 12 to 24 hours apart, show positive results.

Sepsis screen negativity occurs when both sepsis screens, performed 12 to 24 hours apart, are negative.

Inclusion Criteria

- Preterm and term neonates with clinical signs of sepsis.
- Neonates with a maternal history of risk factors for early-onset sepsis.

Exclusion Criteria

- Neonates who had received antibiotic prior to blood culture sampling.
- Neonates who expired before the complete sepsis workup was conducted.

For each neonate, detailed clinical and maternal histories were recorded. Blood cultures were collected under sterile conditions and processed using standard microbiological techniques. All positive blood culture were considered a "gold standard" of diagnostic of neonatal sepsis.

Antibiotic susceptibility testing was performed using the disc diffusion method according to the Clinical Laboratory Standards Institute (CLSI) guidelines. Antimicrobial susceptibility was assessed based on CLSI standards, except for coagulase-negative staphylococci (CONS). Intermediate susceptibility was considered as resistant.

Statistical Analysis

Data were analysed using SPSS version 23.0 (IBM, USA). Categorical variables were presented as frequency and percentage, while continuous variables were expressed as mean and standard deviation (SD). The chi-square test was used for comparison between groups. A p-value < 0.05 was considered statistically significant.

RESULTS

Out of 300 neonatal sepsis cases, 156 (52%) were culture-positive, while 144 (48%) were sterile (Figure 1). Among culture-positive cases, Staphylococcus aureus was the most common organism (42.3%), followed by Streptococcus (16%), Acinetobacter (9%), E. coli (7.7%), and others (Table 1). Antibiotic sensitivity profiles revealed that Staphylococcus aureus was sensitive to vancomycin and linezolid but resistant to penicillin. Acinetobacter showed sensitivity to imipenem and piperacillin/tazobactam (Table 6).

Baseline demographic comparisons between clinical and culture-positive sepsis showed significant differences in place of delivery (p=0.032) and socio-economic status (p=0.022) (Table 2). Maternal factors like premature rupture of membranes (PROM) and foul-smelling liquor were significantly associated with culture-positive sepsis (p<0.05) (Table2). Neonatal characteristics, including preterm delivery and low birth weight, were significantly higher in culture-positive sepsis (p<0.05) (Table 4). However, clinical presentations like respiratory distress and seizures showed no significant difference between groups (Table 5).

STUDY METHOD/TOOLS

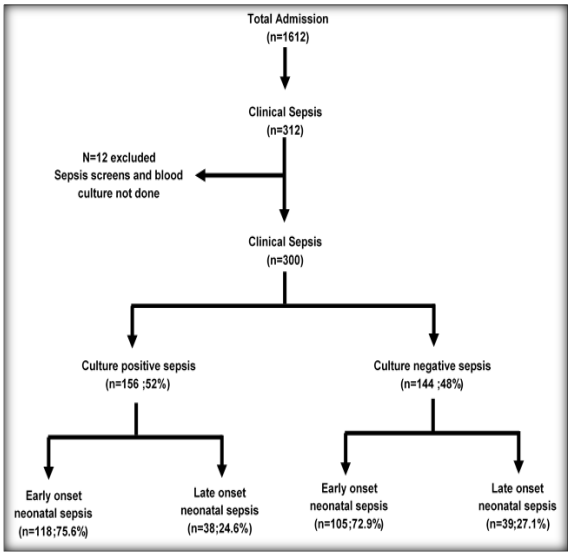

Table 1: Distribution of culture positive cases according to their microbiological profile

	Frequency	Percent
Staph Aureus	**66**	**42.3**
Streptococcus	**25**	**16.0**
Acinetobacter	**14**	**9.0**
E.Coli	**12**	**7.7**
Klebsiella	**11**	**7.1**
Pseudomonas	**10**	**6.4**
Citrobacter	**6**	**3.8**
Staph.Aureus (Cons)	**5**	**3.2**
Strept. Agalactiae	**4**	**2.6**
MRSA	**3**	**1.9**
Total	**156**	**100.0**

Abbreviations: MRSA, methicillin resistant staph aureus; Cons, coagulase negative staphylococcus.

Table 2: Description of baseline demographic characteristics between clinical sepsis and culture positive sepsis

Variables		Clinical sepsis (n=300)		Culture positive sepsis (n=156)		p-value
		Freq (n)	Perc (%)	Freq (n)	Perc (%)	
Place of delivery	**Outborn**	197	65.7	122	78.2	**0.032***
	Inborn	103	34.3	34	21.8	
Gender	**Male**	170	56.7	85	54.5	0.991
	Female	130	43.3	71	45.5	
Onset of sepsis	**EOS (<72hrs)**	222	74.0	118	75.6	0.809
	LOS (>72hrs)	78	26.0	38	24.4	
Mode of delivery	**LSCS**	86	28.7	32	20.5	0.078
	NVD	214	71.3	124	79.5	
Socio-economic status	**LUL**	261	87.0	142	91.0	**0.022***
	UM	27	9.0	10	6.4	
	MLM	7	2.3	2	1.3	
	UL	5	1.7	2	1.3	

Abbreviations: EOS, early onset neonatal sepsis; LOS, late onset neonatal sepsis; LSCS, lower segment caesarean section; NVD, normal vaginal delivery; LUL, lower upper lower; UM, upper middle; MLM, middle lower middle; UL, upper lower.

Table 3: Description of baseline maternal characteristics between clinical sepsis and culture positive sepsis

Variables		Clinical sepsis (n=300)		Culture positive sepsis (n=156)		p-value
		Freq (n)	Perc (%)	Freq (n)	Perc (%)	
PROM >18hrs	**No**	149	49.7	87	55.8	**0.021***
	Yes	76	25.3	31	19.9	
Foul Smelling Liquor	**No**	208	69.3	102	65.4	**0.028***
	Yes	17	5.7	16	10.3	
Multiple vaginal exam	**Yes**	175	58.3	88	56.4	0.066
	No	50	16.7	30	19.2	

Abbreviation: PROM, premature rupture of membrane

Table 4: Description of baseline neonatal characteristics between clinical sepsis and culture positive sepsis

Variables		Clinical sepsis (n=300)		Culture positive sepsis (n=156)		p-value
		Freq (n)	Perc (%)	Freq (n)	Perc (%)	
Gestational age	**Term**	170	56.7	64	41.0	**0.041***
	Preterm	130	43.3	92	59.0	
Birth weight	**NBW**	167	55.7	60	38.5	**0.039***
	LBW	77	25.7	50	32.1	
	VLBW	39	13.0	29	18.6	
	ELBW	17	5.7	17	10.9	
HIE	**No**	237	79.0	117	75.0	0.078
	Yes	63	21.0	39	25.0	
H/o of NICU admission	**No**	39	13.0	16	10.3	0.089

Abbreviations: NBW; normal birth weight; LBW; low birth weight; VLBW; very low birth weight; ELBW; extremely low birth weight; NICU; neonatal intensive care unit.

Table 5: Baseline distribution according to clinical presentation between clinical sepsis and culture positive sepsis

Variables	Clinical sepsis (n=300)		Culture positive sepsis (n=156)	
	Freq (n)	Perc (%)	Freq (n)	Perc (%)
RD	176	58.7	96	61.5
Seizure	53	17.6	28	17.9
MSL/RD	17	5.7	8	5.1
RTF	54	18	24	15.4
Total	300	100	156	100.0
p-value	0.058*			

Abbreviations: RD; respiratory distress; MSL/RD; meconium-stained liquor/respiratory distress; RTF; refusal to feed.

Table 6: Antibiotic susceptibility and resistance profile of isolated organisms

Antibiotics	S/R	Staph. Aureus (n=66)	Streptococcus (n=25)	Acinetobacter (n=14)	E. coli (n=12)	Klebsiella (n=11)	Pseudomonas (n=10)	Citrobacter (n=6)	Staph. Aureus (cons) (n=5)	Strep. Agalactiae (n=4)	MRSA (n=3)
		42.3 %	16%	9%	7.7 %	7.1%	6.4%	3.8%	3%	2.0 %	1.9 %
Ceftazidime	S	-	-	14	12	9	-	-	-	-	-
	R	-	-	-	-	2	10	-	-	-	-
Imipenem	S	-	-	14	12	11	10	6	-	-	3
	R	-	-	-	-	-	-	-	-	-	-
Piperacillin/ Tazobactam	S	-	-	14	12	11	-	6	-	-	3
	R	-	-	-	-	-	10	-	-	-	-
Levofloxacin	S	59	3	14	-	2	-	-	-	-	-
	R	2	22	-	-	-	10	-	-	-	-
Amikacin	S	-	-	5	12	9	-	6	-	-	-
	R	-	-	9	-	2	10	-	-	-	-
Ampicillin	S	-	-	5	-	-	-	-	-	-	-
	R	-	-	9	-	-	-	6	-	-	-
Gentamycin	S	-	-	-	-	-	10	6	-	-	-
	R	-	-	14	12	2	-	-	-	-	-
Ceftriaxone	S	-	-	-	12	2	-	-	-	-	-
	R	-	-	-	-	9	-	6	-	-	-
Colistin	S	-	-	-	-	2	-	-	-	-	3
	R	-	-	-	-	-	-	-	-	-	-
Vancomycin	S	66	25	-	-	-	-	-	-	-	-
	R	-	-	-	-	-	-	-		4	-
Cefoxitin	S	64	-	-	-	-	-	-	5	-	-
	R	2	-	-	-	-	-	-	-	-	-
Linezolid	S	66	25	-	-	-	-	-	5	4	-
	R	-	-	-	-	-	-	-	-	-	-
Teicoplanin	S	64	25	-	-	-	-	-	5	-	-
	R	2	-	-	-	-	-	-	-	-	-
Penicillin	S	6	18	-	-	-	-	-	-	-	-
	R	60	7	-	-	-	-	-	-	-	3
Ciprofloxacin	S	-	16	4	-	-	-	-	-	-	-
	R	-	9	10	-	-	-	-	-	4	-
Clindamycin	S	-	20	-	-	-	-	-	-	-	-
	R	-	5	-	-	-	-	-	-	4	3
Cefepime	S	-	-	-	-	-	-	-	-	-	-
	R	-	-	-	-	9	-	6	-	-	-
Amoxycillin	S	47	-	-	-	-	-	-	-	-	-
	R	19	-	-	-	-	-	-	-	-	-

S: Sensitive; R: Resistant

DISCUSSION

Neonatal septicaemia is a significant concern in NICUs worldwide, contributing to high infant mortality and morbidity. While neonatal mortality can result from various causes, septicaemia remains a leading contributor, with a markedly higher incidence in underdeveloped nations. Comprehensive laboratory investigations in affluent countries aid in diagnosing neonatal sepsis, often supported by pathogen isolation from blood cultures. The microorganisms responsible for neonatal sepsis vary by region. In underdeveloped nations, early-onset sepsis (EOS) is commonly associated with E. coli, GBS, and Enterobacter, while both EOS and late-onset sepsis (LOS) are frequently caused by Klebsiella, Acinetobacter, and Staphylococcus aureus. The emergence of multidrug-resistant (MDR) pathogens due to irregular antibiotic use further complicates sepsis management.

Microbiological Profile

Our study of 300 neonates admitted to NICU with suspected sepsis found that 52% were culture-positive. The predominant pathogen was Staphylococcus aureus (42.3%), followed by Streptococcus (16%) and Acinetobacter (9%). These findings align with other studies like those of Jyothi P et al,[13] where both Gram-positive and Gram-negative pathogens contributed significantly to sepsis cases. MDR pathogens like Klebsiella and Pseudomonas displayed high resistance to common antibiotics such as ampicillin and cephalosporins.

Demographic Characteristics

Among the clinical sepsis cases, 65.7% were outborn deliveries, with a male predominance

(56.7%). EOS accounted for 74% of the cases, and a significant proportion of neonates were born through normal vaginal deliveries (71.3%). Our findings corroborate those of Rashmi P et al,[14] who observed similar gender and onset distributions. Factors like prematurity and low socio-economic status were significantly associated with culture-positive sepsis.

Maternal Characteristics

Premature rupture of membranes (PROM) was observed in 25.3% of clinical sepsis cases and 19.9% of culture-positive cases. Foul-smelling liquor and multiple vaginal exams were more frequent in culture-positive cases. These maternal risk factors were statistically significant, consistent with findings from Jatsho J et al,[15]

Neonatal Characteristics

Preterm delivery (59%) and low birth weight were significant risk factors for culture-positive sepsis. Hypoxic-ischemic encephalopathy (HIE) was noted in 21% of clinical sepsis cases. Rashmi P et al. and Pokhrel B et al,[16] reported similar associations between low birth weight, prematurity, and neonatal sepsis.

Clinical Presentation

Common symptoms in culture-positive sepsis included respiratory distress and seizures, although these were not statistically significant. Similar presentations were reported by Pokhrel B et al., highlighting hypothermia and tachycardia as frequent symptoms.

Antibiotic Susceptibility

Gram-negative organisms, including E. coli, Klebsiella, and Pseudomonas, showed sensitivity to imipenem and piperacillin/tazobactam, but resistance to ceftazidime and amikacin was common. Gram-positive organisms like Staphylococcus aureus and Streptococcus were sensitive to vancomycin and linezolid, but resistant to penicillin. These findings align with studies by Kumhar GD et al,[17] and Pokhrel B et al., who reported high resistance to commonly used antibiotics like ampicillin.

The high resistance to empirical antibiotics emphasise the need for region-specific studies to guide treatment protocols. Broad-spectrum antibiotics should be used cautiously, with early adjustment based on culture and sensitivity reports.

CONCLUSION

Neonatal sepsis remains a significant challenge, particularly in regions like Bundelkhand, where the incidence of multidrug-resistant organisms is high. This study underscores the need for ongoing region-specific studies and the development of tailored antimicrobial policies. Early identification of sepsis and appropriate empirical antibiotic treatment based on local resistance patterns can significantly reduce neonatal mortality.

Declarations

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