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ASSESSMENT OF USE OF ANTIBIOTICS IN EARLY AND LATE-ONSET NEONATAL SEPSIS CASES ADMITTED IN A SICK NEWBORN CARE UNIT (SNCU) OF A MEDICAL COLLEGE AND HOSPITAL: A RECORD-BASED, CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Neonatal sepsis is a leading cause of morbidity and mortality in neonates, particularly in developing countries. Early-onset Sepsis (EOS) and Late-onset Sepsis (LOS) require prompt identification and appropriate antimicrobial therapy to optimize outcomes while minimizing antimicrobial resistance. This study aims to reveal the pattern of use of antibiotics in the management of EOS and LOS in the Sick Neonatal Care Unit (SNCU) of a tertiary care teaching hospital, with a focus on adherence to standard treatment guidelines. **Materials and Methods:** A descriptive, observational, record-based, cross-sectional study was conducted in the Sick Neonatal Care Unit (SNCU) of Calcutta National Medical College & Hospital, Kolkata, from December 15, 2023 to February 15, 2024. Data was extracted from Bed Head Tickets (BHTs) of 100 neonates diagnosed with EOS or LOS. The prescribed antibiotic regimens were assessed for appropriateness based on the Indian Academy of Pediatrics (IAP) Neonatal Sepsis Standard Treatment Guidelines 2022. Demographic characteristics, microbiological profiles, risk factors, antibiotic utilization patterns, and treatment outcomes were analyzed using descriptive statistics. **Result:** Among 100 neonates with sepsis, 66% had clinical sepsis, 20% probable sepsis, and 14% proven sepsis. Early-onset sepsis predominated (84%), with a male preponderance (68%). The mean gestational age of neonates was 33.58 ± 3.29 weeks. A significant relationship was observed between neonatal sepsis and the variables such as maternal/neonatal risk factors ($p < 0.001$), male sex ($p < 0.01$), and intrauterine growth retardation ($p < 0.00001$). The most common blood culture isolates were Acinetobacter baumannii and Klebsiella pneumoniae. Empirical antibiotics were initiated in all cases, with predominant use of 'Watch' group agents—piperacillin-tazobactam (51.7%), meropenem (27.6%), and vancomycin (12.6%); the mean number of antibiotics per encounter was 1.74. Overall, 74% neonates were discharged, 22% died, and 4% left against medical advice. **Conclusion:** Early-onset sepsis was prevalent, with male gender, prematurity, LBW, and IUGR as primary risk factors. Blood culture positivity was primarily due to multidrug-resistant A. baumannii and K. pneumoniae. The empiric treatment regimen included piperacillin-tazobactam, vancomycin, and meropenem as per IAP guidelines in view of the increasing trend of antimicrobial resistance (AMR). Mortality rate of 22% emphasizes the importance of appropriate antibiotics management, the need for ward-wise antibiogram, surveillance, and infection control practices for improved outcomes in neonates.

INTRODUCTION

Neonatal sepsis is defined as the presence of severe systemic features like altered hemodynamic function and multi-organ involvement associated with pure growth of bacteria from one or more sites.[1] Approximately 1.3 million cases of neonatal sepsis are reported globally. India has the highest rate of clinical sepsis, standing at 17,000 cases per 100,000 live births, while the case fatality rate ranges from 25% to 65%.[2-5] Sepsis is responsible for 5.7% of neonatal deaths in India during 2015-2017.[6] Risk factors associated with neonatal sepsis include prematurity, lower post-natal age, immunological immaturity, spontaneous preterm labor, chorioamnionitis, prolonged labor, unclean per vaginal examinations, perinatal asphyxia, foul-smelling liquor, maternal urinary tract infection, and prolonged rupture of membrane.[5] Depending on the time of presentation, neonatal sepsis is categorized as early and late onset neonatal sepsis (EOS and LOS). In early-onset neonatal sepsis, clinical symptoms typically start within 72 hours of life, whereas in late-onset sepsis, they usually begin after 72 hours of life.[2,3] The time of presentation, geographical location, and national economic status are determinants of clinical outcome in terms of mortality for neonatal sepsis. Neonates of Low and middle-income countries (LMICs) have high mortality rates in neonatal sepsis.[7] EOS is mostly caused by vertical transmission, where maternal–fetal transmission of the microorganism occurs.[8] LOS mainly affects newborns at risk, such as pre-term newborns hospitalized in the NICU, and happens through transmission via healthcare workers, healthcare environments, and other caregivers.[9] Different causative organisms are responsible for causing EOS and LOS in various regions of the world, which also depends on the country's economic status (HICs vs. LMICs). Group B Streptococcus (GBS) and E. coli are the dominant EOS pathogens, while Coagulase-negative staphylococci (CoNS) and Streptococci are the dominant pathogens in LOS of HICs.[3] The evidence from LMICs suggests that EOS is usually caused by both Gram-negative Enterobacteriaceae (i.e. Klebsiella) and Gram-positive dominant Staphylococcus aureus and CoNS whereas LOS is predominantly caused by Gram-negative organisms, of whom the most representative belong to the Enterobacteriaceae group (Klebsiella pneumoniae, E. coli, and Enterobacter species), followed by Pseudomonas aeruginosa.[10-16] Neonatal sepsis is again categorized as probable, clinical, and definitive sepsis based on clinical and laboratory findings. In probable or clinical sepsis cases, antibiotics are started empirically, which is confirmed by detection of a particular organism, and antibiotics are continued or changed depending on the sensitivity pattern of the particular organism to a particular antibiotic (IAP). The existing difficulties in the management of sepsis include the absence of epidemiological data, variations of microorganisms producing sepsis, as well as the unavailability of uniform, definite diagnostic criteria that could guide rational prescribing practices.[11] Significant variations have been observed in sepsis diagnostic protocol and guidelines on the use of antibiotics in sepsis, which have been proposed by different bodies such as the British National Institute for Health and Care Excellence (NICE) guidelines, American Academy of Pediatrics guidelines (AAP), and Indian Academy of Pediatrics (IAP) guidelines. For this, a single antibiotic policy may be recommended, but it may not be applicable for a particular newborn unit. The local culture and sensitivity data, and organism profile over the previous six to twelve months, should serve as its foundation for selection of antibiotics (IAP). Indiscriminate and overuse of antibiotics has led to the development of multidrug-resistant (MDR) organisms. The increase in incidence of Gram-negative MDR isolates, in particular, and high levels of resistance to first and second-line antibiotics currently being used in neonatal sepsis guidelines are being seen on a global scale.[17] MDR organisms are estimated to be responsible for 30% of deaths linked to neonatal sepsis globally in 2016.[19,20] Implementation of region, institution, unit-based antibiotic policy, strict adherence to sepsis diagnostic protocol and Standard Treatment Guidelines (STG), evaluation of changing patterns of use of antibiotics in different settings over different times, and other measures of antibiotic stewardship programs might help combat the present scenario.[21] The present study was undertaken on this background with the following objectives:

- To find out the antibiotic usage patterns in neonatal sepsis with a focus on adherence to Neonatal Sepsis Standard Treatment Guidelines (STG) 2022 of the Indian Academy of Pediatrics (IAP) in a Sick Neonatal Care Unit of a tertiary care teaching hospital.
- To detect the proportion of definitive or culture-proven cases of neonatal sepsis.
- To measure the outcome of neonatal sepsis cases in terms of recovery or death.

MATERIALS AND METHODS

This retrospective record-based, observational, cross-sectional study was conducted for a period of two months (from 15th December 2023 to 15th February 2024) in the Sick Neonatal Care Unit (SNCU) of the Department of Pediatrics, Calcutta National Medical College & Hospital in Kolkata, West Bengal. The study was a project under the ICMR Short Term Studentship (STS) Program conducted by the Department of Pharmacology of Calcutta National Medical College. Ethics clearance was obtained from the Institutional Ethics Committee (IEC) of the Medical College.

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Inclusion Criteria

Records of all newborn babies, admitted to SNCU of the Hospital, whose age was less than or equal to 28 days and were diagnosed with sepsis (either EOS or LOS), irrespective of whether they were born in the hospital or outside, were included in the study.

Exclusion Criteria:

Records of infants who were more than 28 days old or with major congenital anomalies and incomplete records were excluded from the study.

Study Procedure

Sample size: The sample size was calculated using the standard formula for prevalence studies, $n = Z^2pq/d^2$, where $Z = 1.96$ for 95% confidence, $p = 40\%$ (estimated prevalence of neonatal sepsis) [22], $q = 64.66\%$, and $d = 10\%$ margin of error, which made the sample size approximately 97. During the two-month study period, a total of 130 neonatal records were reviewed, of which 30 were excluded based on predefined criteria such as major congenital anomalies (Down syndrome, spina bifida, gastroschisis, and encephalocele) and incomplete records. Thus, 100 records of neonatal sepsis cases were finally analyzed.

Data collection: Data were extracted from Bed Head Tickets (BHTs) of SNCU records after completion of the record (finally preserved in the record section of the institute). Collected data were entered in a predesigned, structured data record form and transcribed to an Excel data sheet thereafter. The data that were recorded in the data record form included demographic details, perinatal history, relevant investigations, culture results, use of various classes and individual antibiotics, and use of the Access, Watch, and Reserve (AWaRE) group of antibiotics. Anonymity of the data was maintained throughout; patient interaction and interview of parents were not done as records, which were archived, were reviewed after discharge/death of the infants. Informed consent of the parents was not required as retrospective records were reviewed. After a detailed review of the case notes, sepsis was categorized as probable sepsis, clinical sepsis, culture-proven or definitive sepsis as per the Indian Academy of Pediatrics (IAP) Neonatal Sepsis Standard Treatment Guidelines (STG) 2022 criteria. In the case of culture-positive cases, the identified microorganisms were recorded to define causative microbial agents of sepsis. Antibiotic use was categorized as empirical or targeted based on the availability of culture results of appropriate material, either blood or CSF. Recommended fixed-dose combination of antibiotics such as amoxicillin-clavulanic acid, piperacillin-tazobactam, and cefoperazone-sulbactam was considered as a single agent.

Statistical Analysis: Descriptive statistics were calculated for all variables. Continuous variables were presented as mean ± standard deviation. Categorical variables were summarized and presented as frequencies and percentages, and comparisons between groups were done using Pearson's chi-square or Fisher's exact test where appropriate. A p-value of 0.05 (two- tailed) was deemed statistically significant.

RESULTS

A total of 100 diagnosed cases of sepsis were evaluated; among these, 20% of cases were identified as probable sepsis, 66% were diagnosed as clinical sepsis, and 14% were confirmed as definitive/proven sepsis. The mean gestational age of the neonates was 33.58 ± 3.29 weeks. Most affected neonates were male (n=68, 68%). EOS was more prevalent, accounting for 84% (n=84) of cases, while LOS accounted for 16% (n=16). [Table 1] Mean gestational age of neonates who were diagnosed as EOS was 32.9±6.36 weeks, and mean gestational age of neonates who were diagnosed with LOS was 35.5±3.53 weeks.

Risk factors (Maternal risk factors like chorioamnionitis, foul-smelling discharge, maternal urinary tract infection, hyperthermia; neonatal risk factors like birth asphyxia, RDS) for the development of sepsis were evaluated in 100 neonates [Figure 1]. A statistically significant relationship between neonatal sepsis and key risk factors was found when analyzed using Chi-square tests (Yates corrected $\chi^2 = 12.69$, $p < 0.00037$), indicating a statistically significant relationship ($p < 0.05$). Similarly, male neonates were found to have a significantly higher incidence of sepsis compared to females ($p < 0.002074$, Yates corrected $\chi^2 = 9.4833$). A statistically significant relationship between neonatal sepsis and IUGR was also established (Yates-corrected $\chi^2 = 73.37$, $p < 0.00001$). [Table 2] The pathogens which were isolated in blood culture were Acinetobacter baumannii (n=6), Klebsiella pneumoniae (n=4), Staphylococcus aureus (n=2), and Enterococcus spp. (n=2). Empirical antibiotic therapy was initiated in all cases.

The average number of antibiotics per encounter was 1.74. Piperacillin-tazobactam (51.7%) was the most commonly prescribed antibiotic, followed by meropenem (12.6%); gentamicin was used in 2.3% of cases, while amikacin, linezolid, azithromycin, and metronidazole were used in only 1.1% of cases. [Figure 2] Antifungal agent fluconazole was prescribed in 8% cases. Among the AWaRE classification of antibiotics, watch (94.3%) antibiotics were most frequently used. [Table 3]

Outcomes: Out of the 100 neonates, 74 were successfully discharged, 22 neonates died during treatment, and 4 patients left against medical advice (LAMA).

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Table 1: Demographic characteristics of the patients with features of neonatal sepsis

Variable	No. of Cases (n=100)	Percentage (%)
Type of Sepsis		
Early-Onset Sepsis (EOS)	84	84
Late-Onset Sepsis (LOS)	16	16
Sex Distribution		
Male	68	68
Female	32	32
Mode of Delivery		
Normal Vaginal Delivery (NVD)	64	64
Lower Segment Cesarean Section (LSCS)	36	36

Table 2: Clinical Risk Factors associated with Neonatal Sepsis

SL NO	Risk Factors	Total n=100	Chi-square Statistic with Yates correction	p-value
1.	Maternal risk factors and foetal risk factors complicating treatment outcomes	81 (81%)	12.68	0.0003
2.	Male sex	68 (68%)	9.48	0.0002
3.	IUGR	14 (14%)	73.37	<0.00001

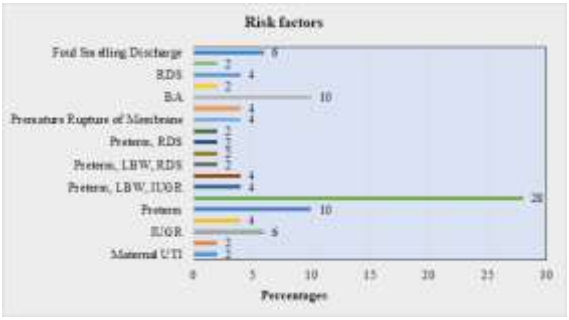

Figure 1: Clinical risk factors associated with Neonatal Sepsis (EONS and LONS)

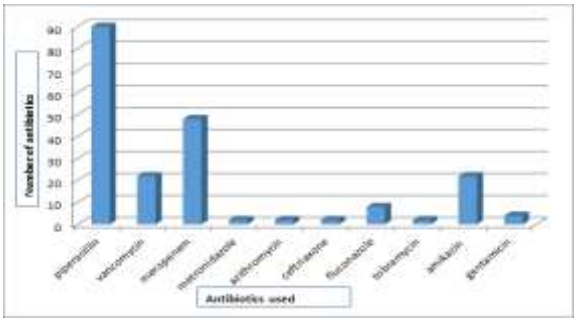

Figure 2: Different antibiotics used to treat neonatal sepsis.

Table 3: Distribution of antibiotics according to AWaRe category (n=174)

Sl no	Antibiotic	n/%	AWaRe category (n/%)
1.	Piperacillin-Tazobactam	90(51.7%)	Watch 164 (94.3%)
2.	Meropenem	48(27.6%)	
3.	Vancomycin	22(12.6%)	
4.	Azithromycin	2 (1.1%)	
5.	Ceftriaxone	2(1.1%)	
6.	Gentamicin	4(2.3%)	Access 8 (4.6%)
7.	Amikacin	2(1.1%)	
8.	Metronidazole	2(1.1%)	
9.	Linezolid	2(1.1%)	Reserve 2 (1.1%)

DISCUSSION

The present study highlights the clinical spectrum, microbiological etiology, and antibiotic utilization trends in neonatal sepsis in a tertiary NICU in Kolkata. EOS was predominant, accounting for 84% of cases, consistent with prior findings by others who reported 79.89% EOS among discharged neonates.[11] A notable male predominance (68%) was observed, corroborating earlier studies by Kartik et al., and is possibly explained by X-linked immunoregulatory genetic mechanisms that predispose males to infections.[5]

Prematurity (56%) and low birth weight (38%) were significant risk factors in our cohort. A high percentage of candidates with prematurity (30%) develop neonatal sepsis (15%).[5] These findings are aligned with studies that reported similar rates of prematurity and LBW.[22] However, maternal risk factors like Prolonged premature rupture of membranes (PPROM), Premature vaginal bleeding, Pregnancy Induced Hypertension (PIH), Gestational Diabetes mellitus (GDM), abnormal amniotic fluid, maternal infection like urinary tract infection (UTI) and respiratory-tract infection (RTI), and neonatal risk factors like birth asphyxia, IUGR, disseminated intravascular coagulation were found to be important contributors. In the present study, blood culture was positive in 14% of neonates. Almost similar (13.8%) blood culture positivity rate was reported by Srivastav et al.[23] In a study from North India, a higher (35.2%, Kurma et al., and 77%, Behera et al) blood culture positivity rate was reported by other studies in India.[24,25] The low rate of culture positivity may be attributed to the early initiation of empirical antibiotics, prior antibiotic exposure, inadequate blood sample volume, and delays in culture processing—factors well-documented in the literature on neonatal sepsis.[26] The most common isolated organism in our study was Acinetobacter

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baumannii (n=6, 42.8%), followed by Klebsiella pneumoniae (n=4, 28.6%), Staphylococcus aureus(n=2, 14.3%), and Enterococcus (n=2, 14.3%). Our study findings corroborate the results of studies of different regions of India, as studies in different regions of India have revealed varying rates of isolation of different gram-negative and gram-positive organisms from neonatal sepsis cases (Kurma et al, Behera et al, Panigrahi et al, Kumar et al).[24,25,27,28] In a study by Kurma et al in a government neonatal intensive care unit in South India, the isolation rate of gram-negative and gram-positive organisms was 68.3% and 31.7%, respectively, in which predominant organisms were K. pneumoniae (34.7%), Acinetobacter species (9.83%), and Staphylococcus aureus (21.8%).[24] In a population-based survey on neonatal sepsis in rural Odisha by Panigrahi P et al,[27] gram-negative organisms were identified on 58 (69%) blood cultures, gram-positives on 22 (26%); the most frequent pathogen was Klebsiella, which was found on 39 cultures (46%) as a single organism followed by S. aureus (26%). The predominance of gram-negative bacteria suggests maternal genital tract colonization as a likely source of infection.

The average number of antibiotics prescribed per encounter was 1.74 for both EONS and LONS. In both EONS and LONS, empirical therapy included either two, three, or four antibiotics per encounter. Antibiotic prescribing pattern in the study was analyzed in accordance with the Indian guidelines, the Indian Academy of Pediatrics Neonatal Sepsis Treatment Guidelines 2022.[1] In the present study, the important first-line antibiotic ampicillin (as per the Indian guidelines) was not prescribed to any neonates on admission; empirical second-line (piperacillin–tazobactam and meropenem) antibiotics were prescribed to 51.7% and 27.6% neonates, respectively. The most important first-line antibiotic gentamicin was prescribed to 2.3% of neonates, vancomycin and linezolid (not recommended in Indian Guidelines) were prescribed to 12.6% and 1.1% of neonates, respectively.[1] The preference of antibiotics reflects the predominance of gram-negative organisms in the SNCU settings, for which piperacillin–tazobactam provides effective coverage. Vancomycin was used in two cases of Staphylococcus aureus infection due to its gram-positive coverage, although not recommended in the Indian Guidelines. Similar practices of initial usage of second-line antibiotics in neonates have been observed in other studies in India (Srivastav et al., Behera et al) because of the high prevalence of MDR bacteria and long waiting times for culture results in SNCU units.[23,25]

In the present study, antibiotic use was also evaluated using the WHO AWaRe classification of antibiotics, as this classification aims to provide an easily interpretable framework for broad assessment of narrow-spectrum and broad-spectrum antibiotic use. Substantial variation in antibiotic use patterns for treatment of neonatal sepsis in different regions of the world was revealed by Hsia et al.[29] In their first Global Point Prevalence Survey (PPS), which included patients from 56 countries. In India, the overall use of Access antibiotics in neonatal sepsis was 30·7%. In the present study, gentamicin was the only access antibiotic that was prescribed in 4.6% of neonates, whereas most (94.3%) of the antibiotics prescribed belonged to the watch category. AWaRe classification may be incorporated in pediatric antibiotic stewardship programs, but treatment of neonatal sepsis is more complex due to the development of a frequently changing pattern of antimicrobial resistance. The development of multidrug resistance gram negative organisms has been observed in studies; high resistance to third-generation cephalosporins and aminoglycosides has also been revealed.[26] The rate of methicillin resistance was high in Gram-positive isolates, especially in Staphylococcus aureus and coagulase-negative staphylococci, but vancomycin and linezolid showed good sensitivity, as seen in previous studies in India.[26,28,30,31] Increasing use and strict adherence to prescribing access to antibiotics may not be appropriate in the tertiary setup newborn care units like the one under discussion, where more complicated neonatal sepsis cases are treated.

The utility of fluconazole becomes relevant in this high-risk population in the NICU, especially in preterm and VLBW infants exposed to broad-spectrum antibiotics, invasive lines, and prolonged hospital stay. Clinical research has confirmed the efficacious use of fluconazole in preventing invasive candidiasis with a significant reduction in morbidity and mortality due to candidemia without significant acute toxicity.[31]

CONCLUSION

This study reinforces that EOS, male gender, prematurity, and LBW are significant contributors to neonatal sepsis. The predominance of Klebsiella, Acinetobacter, and S. aureus, along with alarming MDR patterns, necessitates robust microbiological surveillance and rational antibiotic use. Despite alignment with standard empirical treatment guidelines, the threat of AMR underscores the urgent need for strengthened infection control practices and periodic NICU-specific antibiograms to guide therapeutic decisions.

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