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Original Article

Clinical Evaluation of Antibiotic Therapies for Neonatal Septicemia in NICU in a Tertiary Care Setting: A Prospective Observational Study

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ABSTRACT

Background: Neonatal septicemia is a major cause of neonatal mortality, often affecting infants from the first day of life. Due to the underdeveloped neonatal immune system, antibiotics must be prescribed judiciously, and timely, tailored care is essential for infants showing signs of inflammation and septicemia. In this context, evaluating the clinical response of neonates with septicemia to antibiotic treatment is important to enhance understanding and improve antimicrobial prescribing practices. This study therefore seeks to identify trends related to the causes, clinical course, and antibiotic treatment patterns associated with neonatal septicemia. **Materials and Methods:** A cross-sectional, prospective observational study with 58 pediatric patients diagnosed with neonatal septicemia was conducted at Dhiraj Hospital, Vadodara. Patients categorized as suspected or proven sepsis were included. Antibiotics were prescribed based on symptoms progression. CRP levels at diagnosis, post-treatment levels, and time to decrease levels were recorded. Statistical analysis included Excel, Social Science Statistics, and Chi-tests to calculate means, standard deviations, and derive results. **Results:** The study explored factors impacting the clinical course of neonatal septicemia, such as Early-Onset Sepsis (EOS) and Late-Onset Sepsis (LOS) risk factors, the prevalence of causative pathogens, and a comparative analysis of six antibiotic groups. Among them, Group 4 (Meropenem, Vancomycin, and Colistin) showed the highest ratio of average difference in C-reactive protein levels to average days to outcome compared to other groups. **Conclusion:** The findings of this research can elucidate the complex relationships among factors influencing the clinical advancement of neonatal septicemia. This information is valuable for establishing standardized protocols and enhancing antibiotic prescribing practices in neonatal care through initiatives such as antibiotic stewardship.

Keywords: Antibiotic therapy, C-reactive Protein (CRP), Early-Onset Sepsis (EOS), Late-Onset Sepsis (LOS), Neonatal Intensive Care Unit (NICU), Neonatal septicemia.

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INTRODUCTION

Neonatal septicemia, a global clinical issue, is a major cause of morbidity and mortality in infants. It is characterized by a blood stream infection in neonates caused by pathogenic microbes like bacteria, viruses, and fungi, resulting in systemic inflammatory responses (Lawn *et al.*, 2014). Neonatal sepsis is commonly categorized as early onset or late onset based on the age of onset (Shane *et al.*, 2017). The diagnosis of sepsis is not ruled out if a microbiological pathogen cannot be isolated (Singer *et al.*, 2016).

According to the 2016 Sepsis-3 consensus definition in adults, sepsis is characterized as a critical condition resulting from an uncontrolled immune response to infection leading to organ dysfunction (Schlapbach and Kissoon, 2018). A redefined concept of pediatric sepsis, encompassing a broader age range beyond the neonatal period similar to the Sepsis-3 definition, is under consideration (Schlapbach, 2017). There is a lack of consensus on a universal definition of neonatal sepsis in the scientific literature (Wynn *et al.*, 2014). Therefore, numerous newborns receive a diagnosis of probable or possible sepsis or presumed symptomatic infection but no bacterial etiology identified, commonly termed as suspected sepsis (National Institute for Health and Care Excellence (NICE), 2012). Low- and Middle-Income Countries (LMICs) exhibit a higher prevalence of neonatal sepsis, imposing a considerable burden on global healthcare systems. Annually, there are in excess of 3 million instances of neonatal sepsis, resulting in over 500,000 deaths (Fleischmann-Struzek *et al.*,

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2018). India significantly contributes to the global neonatal mortality rate, with neonatal sepsis accounting for nearly one-third of these deaths annually (Tzialla *et al.*, 2018). Most high-income countries neonatal sepsis publications typically focus on culture-confirmed cases, neglecting neonates treated with antibiotics for culture-negative sepsis. Consequently, data on culture-negative sepsis are limited, despite it contributing to the elevated antibiotic utilization in neonatal healthcare settings (Cantey *et al.*, 2016). Moreover, although there are no variations in infection-associated morbidity and mortality, there exists notable diversity in antibiotic utilization among NICUs and countries (Schulman *et al.*, 2015). These findings indicate potential antibiotic overutilization in specific NICUs, posing significant short- and long-term health risks for individual infants (Esaiassen *et al.*, 2017). Nevertheless, delaying antibiotic administration in neonates with confirmed infections can increase mortality and morbidity rates (Cordery *et al.*, 2008). Efficient sepsis management and antimicrobial stewardship efforts are challenged by culture-negative neonatal sepsis. Neonatal septicemia rates vary by region. Globally, incidence is around 15-20 per 1,000 live births, while in certain underserved areas of India, rates may escalate to 30-60 per 1,000 live births (Klingenberg *et al.*, 2018). Factors such as low birth weight, preterm deliveries, inadequate hygiene, and restricted healthcare access have been identified as contributory elements (Downie *et al.*, 2013). Neonatal sepsis is treated through supportive care, prompt initiation of empirical antibiotic therapy, and early detection. Early detection methods, such as Polymerase Chain Reaction (PCR) and biomarker analysis (e.g., procalcitonin and C-reactive protein), have enhanced diagnostic capabilities (Flannery and Puopolo, 2018). Despite this, professional judgment remains crucial for initiating treatment in resource-constrained settings (Zaidi *et al.*, 2009). The primary approach to treating neonatal sepsis involves the administration of antibiotics targeting common pathogens, including *Staphylococcus aureus, Klebsiella pneumoniae* for LOS, and *Escherichia coli* and Group B Streptococcus for EOS (Fouda *et al.*, 2021). The emergence of Multidrug-Resistant (MDR) infections, particularly bacteria producing Extended-Spectrum Beta-Lactamases (ESBLs), poses considerable therapeutic challenges (Mukhopadhyay and Puopolo, 2012). In NICUs, the implementation of antibiotic stewardship programs is necessary to mitigate the excessive and inappropriate use of antibiotics (Heath *et al.*, 2017). This study aims to evaluate the therapeutic efficacy of commonly prescribed antibiotic regimens and monitor resistance patterns in the treatment of neonatal septicemia. The research seeks to provide evidence-based guidelines for optimizing treatment protocols through the analysis of outcomes like antibiotic susceptibility, microbiological resistance trends, and alterations in pertinent biomarkers. The importance of this research lies in the association between early antibiotic exposure and the emergence of multidrug-resistant bacteria, difficult-to-treat infections, disturbance of microbiota development, and heightened susceptibility to chronic diseases later in life. Inappropriate antibiotic use in neonates and young children is linked to elevated mortality rates, increased acute and chronic morbidity, and a substantial escalation in healthcare costs. Excessive antibiotic usage in neonates and infants in NICUs primarily stems from the need to rule out sepsis. To enhance treatment outcomes, it is crucial to comprehend antibiotic utilization and resistance patterns in neonatal sepsis. These findings can bolster efforts at regional and global levels to combat Antimicrobial Resistance (AMR), which undermines the effectiveness of existing therapeutic strategies. Need for the Study: Neonates may present with nonspecific clinical signs of infection, potentially delaying the detection of late-onset infections. Empirical treatment often leads to unnecessary antibiotic administration due to the time required for microbiological culture to confirm pathogenic organisms in blood samples. The extensive use of broad-spectrum antibiotics increases selective pressure, fostering the development of drug resistance like extended-spectrum β-lactamases. Early antibiotic exposure in infancy can adversely affect the developing microbiome, a concern for vulnerable neonates, especially those who are sick or premature. Various biomarkers have been proposed to aid in diagnosing late-onset infections in neonatal infants, reducing stress on compromised organs like the gastrointestinal tract of preterm infants and addressing antimicrobial resistance. Combining biomarkers with blood culture can assist in assessing infection likelihood in suspected newborns. CRP levels in serum, an acute-phase reactant synthesized by hepatocytes in response to inflammatory cytokines from white blood cells reacting to microbial pyrogens, are commonly used. Evaluating the accuracy of serum CRP could make it a valuable late-onset infection indicator in neonates. However, the utilization of serum CRP in diagnostic algorithms for late-onset infections currently lacks solid supporting evidence for guideline formulation or protocol development. Research on CRP precision and other late-onset infection biomarkers has mostly been conducted at single centers due to small sample sizes. Neonatal sepsis remains a significant contributor to mortality and disability-adjusted life years (DALYs) in neonates, particularly in LMICs, despite advancements in neonatal care. This study aims to address the lack of reliable data on the efficacy of empirical antibiotic treatments in India. By focusing on practical clinical scenarios, this research can bridge the gap between theory and practice, enhancing neonatal outcomes and prompting policy enhancements.

MATERIALS AND METHODS

In a prospective observational study conducted in NICU of Dhiraj General Hospital, Vadodara, the efficacy of various antibiotic groups in treating neonatal septicemia was investigated in neonates aged 0-28 days. Ethical approval was obtained from the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC/ON/PHAR/BNPG22/DEC/23/13). A sample size of 58

was determined using Cochran's formula based on prevalence in the setting. Participants' parents or guardians were informed about the study, and informed consent was obtained. Excluded were patients with clinical sepsis or lacking laboratory evidence, with only those with suspected or proven sepsis included. Data collection included CRP levels, culture reports, identification of causative organisms, time to normalize CRP levels, and associated risk factors in early-onset and late-onset sepsis. Sepsis diagnosis relied on laboratory parameters and cultures. Data was entered using Epiinfo and analyzed in Microsoft Excel, presenting quantitative data as percentages and graphically. Assessment of antibiotic therapy efficacy was based on CRP level decline and time to normalization, providing insight into antibiotic impact on neonatal septicemia in NICU patients (Figure 1).

RESULTS

The research involved 58 neonates with neonatal septicemia admitted to the NICU at Dhiraj Hospital. Among them, 27 (47%) were female and 31 (53%) were male. 28 (48%) cases were classified as EOS, while 30 (52%) were classified as LOS according to Table 1. The population studied consisted of individuals with confirmed or suspected diagnoses excluding clinical sepsis. The research identified Low Birth Weight (<2.5 kg) and Severe Birth Asphyxia as the predominant risk factors associated with EOS, with 43 and 37 incidences, respectively. Conversely, factors like per vaginal leaking and history of multiple vaginal examinations, although significant risks in other contexts, were not associated with EOS in this study setting. For LOS, the most prevalent risk factors were previous invasive procedures (e.g., ventilation, catheterization, surgery), occurring in 29 cases, followed by preexisting intravenous fluid use (26 cases), history of prior hospitalization (24 cases), and ongoing Total Parenteral Nutrition (TPN) use (21 cases). Cord care practices did not contribute to LOS diagnosis in this study setting (Table 2). A total of 35 culture reports were conducted among 58 individuals during their hospitalization, with 28 showing growth of causative organisms. Among these, the primary causative agent for neonatal sepsis in our environment was identified as Acinetobacter Baumanii complex (14 cases), followed by Klebsiella Pneumonia (6 cases) (Figure 2). This study comprises 6 groups of antibiotic treatments administered to 58 neonates, as shown in Table 3. Following the administration of different antibiotic therapies, the patient's CRP level reduction was measured and compared to the initial CRP level at the time of diagnosis to calculate the difference. The average differences in CRP levels for each antibiotic group were then calculated. Group 3 demonstrated the highest CRP difference (53.48083), indicating its efficacy, while Group 1 showed the lowest difference (28.67364), suggesting relatively lower effectiveness (Table 4). Table 4 displays the mean number of days required to calculate the average difference mean of CRP for each antibiotic group. Group 3 had the longest duration to determine its CRP average difference mean, whereas Group 6 was the quickest. Ultimately, Group 4 exhibited the highest ratio of average difference mean of CRP to average days taken (5.2456), suggesting a more efficient decrease in total average CRP levels. This was followed by Group 6 (4.4208), Group 2 (3.9342), Group 3 (3.7886), Group 5 (3.3404), and Group 1, which showed the lowest ratio (3.2578).

DISCUSSION

The study had a balanced demographic distribution (53% male, 47% female), reducing sex-related bias. Low birth weight and severe birth asphyxia were identified as key risk factors for EOS, aligning with Liu *et al.*'s emphasis on perinatal stressors as significant contributors to EOS (Liu *et al.*, 2021). In a study by Shruti Murthy *et al.*, invasive procedures and extended intravenous therapy were identified as primary risk factors for nosocomial infections, with invasive ventilation and central line utilization playing key roles (Murthy *et al.*, 2020). *Acinetobacter baumannii* complex was identified as the predominant pathogen, with *Klebsiella pneumoniae* following as the second most common causative agent. Wen *et al.*, confirmed Klebsiella's prevalence in neonatal sepsis, especially in low- and middle-income nations (Wen *et al.*, 2021). The prevalence of *Acinetobacter baumannii* highlights regional diversity in pathogen profiles, possibly impacted by specific antibiotic usage and infection control strategies. The research results indicated that the combined use of meropenem, vancomycin, and colistin (Group 4) showed the best balance in reducing CRP levels and achieving a prompt clinical response. These findings align with previous research by David Carr *et al.*, emphasizing the significance of combination therapy in combating multi-drug resistant pathogens (Carr *et al.*, 2019). The dependence on empirical broad-spectrum treatments raises concerns regarding antimicrobial resistance, highlighting the necessity for therapy guided by culture results. This study employed a prospective observational approach to gather data on demographics, characteristics, risk factors, pathogen profiles, and the effectiveness of antibiotics based on CRP levels. In comparison to the retrospective study by Karacanoglu *et al.*, which had a larger cohort of 1735 neonates, the current study offers a more concentrated analysis but lacks the broad generalizability of the former (Karacanoğlu *et al.*, 2020). Karacanoglu *et al.* utilized a Tollner Scoring System for sepsis diagnosis, while this study used

Table 1: Distribution based on sex and diagnosis.

Variables	Count	Percentage
Sex		
Male	31	53%
Female	27	47%
Diagnosis		
EOS	28	48%
LOS	30	52%

EOS: Early Onset Sepsis, LOS: Late Onset Sepsis.

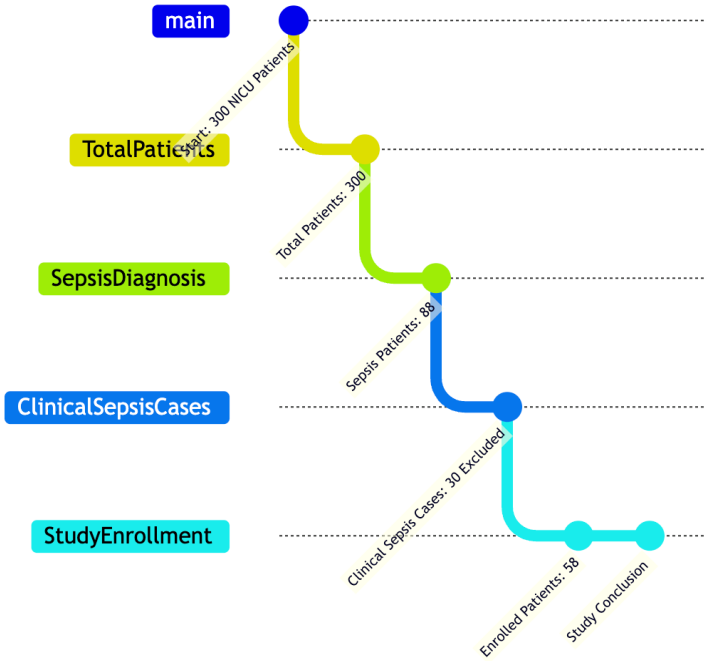

Figure 1: CONSORT flow chart.

Table 2: Distribution of Risk factors of EOS and LOS.

Risk factor for EOS							
	Low birth weight (<2.5 kg)	Maternal Febrile Illness	Meconium stained liquor foul smelling liquor	Leaking PV (>24 hr)	Multiple per vaginal examinations (>3) or single unclean examination	Prolonged and difficult delivery	Severe birth asphyxia
Sl. No.	43	11	21	0	0	15	37

Risk factor for LOS									
	Top Feeding	Bottle feeding /Unhygienic feeding practices	Use of animal milk / babulin /gripe water	Previous hospitalization	Cord care taken	Superficial Infections *	Invasive procedures**	On intravenous fluid at the time of diagnosis of sepsis	On TPN
Sl. No.	2	3	1	24	0	5	29	26	21

*(umbilical infection/pustules/conjunctivitis)

**(invasive ventilation/non-invasive ventilation/central venous line/ICD tube/catheterization/surgery).

Table 3: Antibiotic therapy under review.

Group No.	Antibiotics					
1.	Cefoperazone Salbactum	Amikacin	Meropenem			
2.	Meropenem	Colistin	Tigecycline	Vancomycin		
3.	Cefoperazone Salbactum	Meropenem	Amikacin	Colistin	Vancomycin	Tigecycline
4.	Meropenem	Vancomycin	Colistin			
5.	Meropenem	Amikacin	Linezolid	Vancomycin	Colistin	
6.	Cefoperazone Salbactum	Meropenem	Colistin			

Table 4: Average Difference Mean of CRP of each Antibiotic therapy group.

Antibiotics	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
Average Difference Mean of CRP	28.67364	43.42	53.48083	47.60143	33.55222	31.56091
Average Days taken by each Antibiotic therapy group to exhibit given CRP difference						
Antibiotics	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
Average Days Taken	8.272727	11.75	14.66667	9.142857	10.33333	7.090909

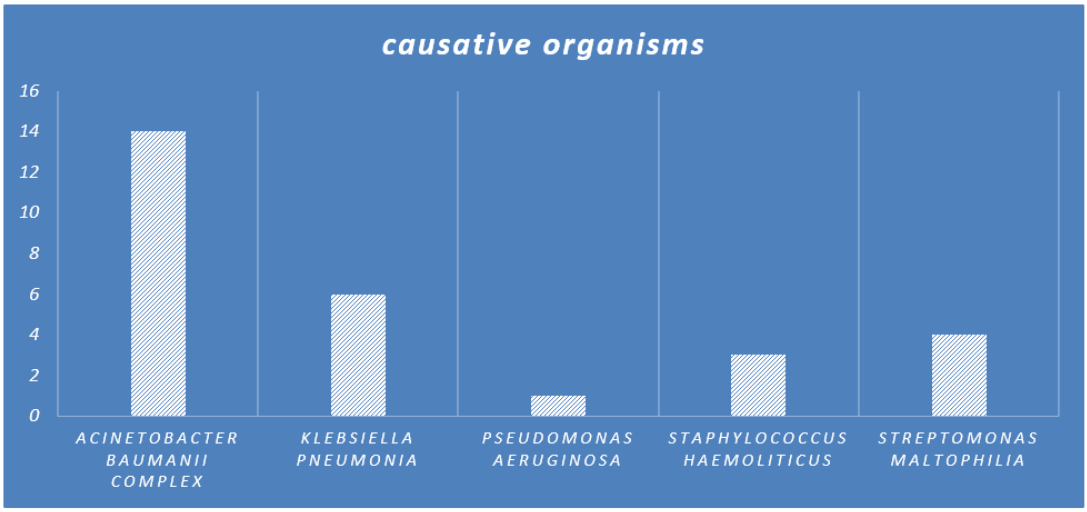

Figure 2: Distribution of Isolated organisms.

CRP levels, indicating a simpler diagnostic method. In contrast, Chaparro *et al.*, investigated antibiotic pharmacokinetics in neonates with advanced analytical techniques and a broader array of biomarkers (Chaparro *et al.*, 2020). The study was limited to using CRP as the only biomarker due to resource constraints. Although CRP is a widely recognized inflammatory marker, its specificity is limited compared to more advanced tools such as procalcitonin or molecular diagnostics, as demonstrated in studies by Rub *et al.*, and Klungenberg *et al.*, potentially affecting the strength of the results (Klungenberg *et al.*, 2020; Rub *et al.*, 2021). Fouzia Naeem and colleagues showed that an Antibiotic Stewardship Program (ASP) effectively decreased total antibiotic consumption and enhanced neonatal results (Naeem *et al.*, 2019). Although an Antimicrobial Stewardship Program (ASP) was not utilized in this study, the results implicitly endorse the necessity of stewardship initiatives. They emphasize the varying effectiveness of antibiotic treatments and the dangers linked to extended use of broad-spectrum antibiotics. The limited implementation of stewardship interventions in low-resource settings in this study mirrors the difficulties highlighted by Dhanya Dharmapalan *et al.*, who also pointed out the high levels of antibiotic resistance in these areas (Dharmapalan *et al.*, 2021). *Acinetobacter baumannii* was predominant in this study, differing from Jinchun Li *et al.*'s report where Staphylococcus epidermidis was noted as the most prevalent pathogen in a tertiary care environment (Li *et al.*, 2020). The variation could be attributed to differences in study cohorts, with Li *et al.*'s group comprising mainly preterm neonates with extended hospitalization. Moreover, this research noted elevated resistance levels to standard antibiotics, in line with global patterns highlighted by Russell *et al.*, underscoring the critical necessity for innovative empirical treatments due to escalating resistance (Russell *et al.*, 2017). This research emphasizes the importance of individualized antibiotic treatment and enhanced infection control measures in NICUs. The study supports the use of pathogen-specific strategies and advocates for the adoption of antimicrobial stewardship programs to address resistance issues. Future studies should explore the integration of advanced diagnostic tools and assess the effectiveness of targeted interventions in reducing neonatal sepsis rates. Limitations of this study, such as its single-center design and small sample size, constrain the generalizability of the results. Reliance solely on CRP as a biomarker and restricted access to culture data due to financial constraints may have underestimated pathogen diversity. Comparison with multicenter research and advanced diagnostic techniques underscores the necessity for larger, well-equipped studies to validate these results. This study adds to the existing literature on neonatal sepsis by identifying important risk factors, pathogen profiles, and antibiotic effectiveness. While the findings align with overall trends in neonatal sepsis management, they also underscore unique regional challenges, emphasizing the importance of globally standardized yet locally adaptable treatment protocols.

CONCLUSION

The study highlights the complex nature of neonatal septicemia in a resource-limited NICU. The findings emphasize the significant burden of sepsis, with an equal distribution of EOS and LOS among neonates. Risk factors such as severe birth asphyxia, low birth weight, and invasive procedures were identified as key contributors. Pathogen profiling revealed *Acinetobacter baumannii* and *Klebsiella pneumoniae*, indicating regional variability and a growing concern for multidrug-resistant infections. The study showed that a combination of meropenem, vancomycin, and colistin (Group 4) was the most effective in balancing reduction in CRP levels with time to clinical response. However, the study underscores the importance of culture-guided antibiotic therapy to prevent the overuse of broad-spectrum antibiotics and reduce the risk of antimicrobial resistance. It supports the urgent implementation of antibiotic stewardship programs in NICUs to optimize treatment regimens, address the increasing challenge of drug resistance, and minimize antibiotic misuse. While offering valuable insights into the management of neonatal sepsis in this clinical setting, the study is limited by sample size and reliance on CRP as the sole parameter for assessing the findings.

ABBREVIATIONS

AMR: Antimicrobial Resistance; **ASP:** Antibiotic Stewardship Program; **CRP:** C-reactive Protein; **DALYs:** Disability-Adjusted Life Years; **EOS:** Early-Onset Sepsis; **ESBLs:** Extended-Spectrum Beta-Lactamases; **ICD:** Intercostal Drainage; **LMICs:** Low- and Middle-Income Countries; **LOS:** Late-Onset Sepsis; **MDR:** Multidrug-Resistant; **NICU:** Neonatal Intensive Care Unit; **NICE:** National Institute for Health and Care Excellence; **PCR:** Polymerase Chain Reaction; **PV:** Per Vaginal; **SVIEC:** Sumandeep Vidyapeeth Institutional Ethics Committee; **TPN:** Total Parenteral Nutrition.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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