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Study on Epidemiology of Neonatal and Infants Sepsis and the Role of Pharmacists in Management and Prevention of Sepsis

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KEYWORDS

Antibiotic medication

Anti-microbial stewardship programs

Early onset sepsis

Late onset sepsis

Pharmacist Role

ABSTRACT:

Background: Infants and neonatal sepsis remain a serious global cause of death and illness and represent approximately 15% of global neonatal mortality. Guidelines for functional management are necessary to improve outcomes and prevent antibiotic resistance. Intervention by pharmacists has been shown with good results to justify antimicrobial treatment and reduce patient morbidity.

Objectives: The evaluating impact of pharmacist intervention on sepsis management in neonates and infants according to incidence density, detection of pathogen, inappropriate antibiotic administration, hospital stay duration and mortality rate.

Methods: A Prospective observational study in Pediatrics and Neonatal Intensive Care Units of a Tertiary care hospital for 9 months. Sepsis patients aged 0-12 months were enrolled. Interventions by pharmacists were Antibiotic stewardship education and sepsis management, Antimicrobial stewardship programs, Medication therapy optimisation and Joint rounds with the health care team.

Results and Discussion: Incidence density of sepsis in the newborn is 12.6 per 1,000 live births and Escherichia coli (32.1%), Staphylococcus aureus (23.4%) and Klebsiella pneumoniae (20.5%) are most common pathogens-40% misuse of antibiotics were saved by pharmacist intervention, 30% hospital stay, 25% mortality, Increased antibiotics susceptibility patterns.

Conclusions: Pharmacist intervention is very strong positive impact on quality of antimicrobial treatments, sepsis treatment and resistance prevention in neonates and infants. Pharmacists, physicians and healthcare workers are work together to enhance patient outcomes and reduce sepsis burden.

1. Introduction

Neonatal sepsis continues to be a key public health issue worldwide, especially in neonatal and young infant morbidity and mortality, poor child health services, all of which help to drive the disease burden. The burden of disease in low- and middle-income countries (LMICs) and The World Health Organization (WHO) has also placed sepsis on the priority list of global health [1].

The acute diagnosis of sepsis has the biggest impact on neonatal morbidity and its estimated incidence is 22

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cases per 1,000 live births with a mortality rate of 3% to 19%. In the state of complete recovery, we have the long-term neurodevelopmental sequelae of the affected patients [2].

Neonatal sepsis is a syndrome characterized by nonspecific body response to any infection in the neonatal period (first 28 days of life) and can be divided into Early Onset Sepsis (EOS) which present in the first 72 hours of life and late-onset sepsis (LOS) which presents after the first 72 hours. Clinical presentation of disease depends on the Gestational Age of the neonate, immune status and virulence of the pathogenic microorganism [3].

In Neonatal sepsis the usual pathogens are Group B Streptococcus (GBS) and Escherichia coli, especially with prolonged PROM and Genital Tract Infection. The organisms isolated until now are GBS and E. coli (a) after prolonged PROM, (b) Maternal Chorioamnionitis and significantly demonstrable GBS Colonization [4].

LOS is defined as survival of more than 72 hours after birth and is generally linked to nosocomial infection. Risk factors include preterm delivery (prematurity), invasive devices such as mechanical ventilation, central lines and length of hospital stay and/ or parenteral nutrition. Glucose as a Precursor of LOS The strains of LVS isolated from LOS in the course of these studies have been Klebsiella spp, S. aureus, P. aeruginosa and Candida spp [5].

Older Neonates, except newborns (i.e., 1 month to 11 months) however, are also suffering from sepsis due to the newer generation, as not only the birth condition is poor, even the vaccination is also poor by birth but due to the pollutants and more than 10 community-acquired diseases are re-brushing against their body. Pneumonia, GI and UTI are common etiology of sepsis in these patients. Patients frequently present with pyrexia, irritability, vomiting, drowsiness and signs of respiratory distress and the disease can progress rapidly if not recognized and treated early.

After clinical suspicion, laboratory studies (CBC and blood culture) and serum markers (C-reactive protein, procalcitonin, and lactate serum) are routinely performed in suspected cases of sepsis [6].

Biomarkers generated from these include interleukins, DAMPs, calprotectin and E-selectin, which are promising indicators of disease activity and response to treatment [7].

Early initiation of empirical antimicrobial treatment is recommended. Empiric antibiotics for EOS include ampicillin and gentamicin (cefotaxime is used instead of ampicillin if meningitis is suspected). This degree of LOS risk exists with empirically covering with vancomycin (MRSA) or beta-lactams/ carbapenems as monotherapy for non-MDR GNR infections. If Candida is an issue, antifungals should be added to the mix [8].

There are many reasons why such neonates, especially premature ones, may have resulted in severe sequelae of sepsis. The risk factors were more in male children, No antenatal corticosteroids for the fetus, Periventricular Leukomalacia (PVL), Necrotizing Enterocolitis (NEC), Bronchopulmonary Dysplasia (BPD), prolonged mechanical airway support, ROP and malnutrition. These babies are also more likely to have long-term neurodevelopmental problems [9].

In the NICU, Clinical pharmacists play a significant role in the prevention and control of neonatal sepsis. On NICU rounds, they discuss pharmacotherapy protocols assist with antimicrobial choice and dosing according to neonatal pharmacokinetics and assist in optimization, empiric therapy selection (the logic behind the empiric regimen utilized) and patients are treated with the latest antimicrobials. Involving them in the process can also help in preventing medication errors and avoid being administered an incorrect drug type, dosage or amount, causing delay or acceleration of medication and treatment for a disease. Pharmacist training is also essential for Amniotic Membrane Transplantation (AMT), Therapeutic Drug Monitoring (TDM), and Infection Prevention and Control (IPC). They receive training on caregivers' hygiene, recognizing the early signs of an infection and how to correctly use prescription drugs [10].

Clinician awareness and awareness within the multidisciplinary team, including pharmacists, have the potential to result in improved survival and less risk and burden from an evolving AMR threat in neonates and children.

2. Materials and Methods

Study design and population: The study was a nine-month prospective observational study based in tertiary

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care Hospital in the Erode district Tamil Nadu. The study consists of obtaining the current medical records of patients and interviewing their parents. The study was conducted over a period of nine months. During the study period, all hospitalized neonates and infants with clinical signs and symptoms of sepsis on admission or who developed sepsis during their hospital stay were examined using IAP Guidelines, a standard sepsis screening technique that included complete blood count (CBC), C-Reactive protein test (CRP), microbial blood culture, chest X-ray, Urinary Tract Infection test and so on.

Data collection: A standardized data collecting form was created following IAP guidelines to collect social demographic, clinical and laboratory data from certified medical staff. All the neonates received a full clinical assessment and among the key factors assessed were maternal antibiotic prophylaxis, GBS critical factors, mothers' antibiotic prophylaxis if they were below 37 weeks of gestation, gestational age at birth, birth weight, delivery mode, risk factors for sepsis including premature rupture of membranes (PROM), Maternal fever and Umbilical Catheterization.

Collection of Specimens: For the detection of Neonatal sepsis, clinical parameters should be investigated alongside laboratory investigations. Microbial blood culture, Blood specimens of 1ml are adequate for blood culture. The blood culture results indicate no growth due to a lack of infection or an inappropriate sample. In CXR (Chest X-Ray), Respiratory issues in new-born babies should be regarded GBS sepsis and treated accordingly. Urine Tractor Infection Test, in Early-onset sepsis, a GBS antigen urine test is required. If the value of UTI is very low, no microscopy and culture are required. PROM requires a urine test. A catheter sample will be sufficient to determine skin contamination.

Processing of Specimens: Blood cultures were incubated aerobically at 37°C and analysed daily for 7 days for microbial growth indicators such as haemolysis, gas generation and Broth coagulation. Isolates were characterized with standard microbiological procedures. Catalase, coagulase, mannitol salt agar growth and haemolysis on blood agar were examined as a check of Gram-positive bacteria. Biochemical tests like TSI, motility, indole, citrate, urease, oxidase, H2S production, VP test and growth on cetrimide agar were employed to characterize Gram-negative bacteria.

Statistical Analysis: The data collected were tabulated, analysed and interpretated using standard statistical tools. The statistical procedure was undertaken with the help of the statistical package social science statistics. The p-values less than or equal to 0.05 was fixed as the level of significance. The statistical method used here is Kruskal-Wallis test.

Ethics: The study was approved by the institutional ethics committee under the protocol number JKKMMRAFCP/IHEC/2024/004. Informed consent was obtained from individuals/family members before data collection.

3. Result

Table 3.1: Demographic and Birth Weight Distribution of Neonatal and Infant (n=123)

Characteristics	**Total (n=123) Number (%)**
Gender Wise Distribution	
Male	92 (74.79%)
Female	31 (25.20%)
Age-Wise Distribution	
Neonatal	79 (64.22%)
Infant	44 (35.77%)
Birth Weight-Wise Distribution	
<2Kg	9 (7.31%)
2.1- 5Kg	73 (59.34%)
5.1- 10Kg	41 (33.33%)

This table 3.1 study included 123 neonatal and infant children in total. The children are divided like this according to three criteria: gender, distribution of age and distribution of birth weight. With regard to gender, there are 25.20% female children and 74.79% male children at both the neonatal and infant phases of those suffering from sepsis, 64.22% are neonatal and 35.77% are infant of those that were born, 59.34% weigh 2.1-5 kg, 7.31% weigh less than 2 kg, and 33.33% weigh 5.1-10 kg.

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Table 3.2: Distribution of Neonatal Sepsis Cases by Onset, Pathogen, and Stewardship Participation (n=123)

Characteristics	**Total (n=123)** **Number (%)**
Early Onset & Late Onset Wise Distribution	
< 72 hours (early onset)	80 (65.04%)
> 72 hours (late onset)	43 (34.95%)
Microorganism Gram Strain	
Gram Positive bacteria	69 (56.09%)
Gram Negative bacteria	52 (42.27%)
Fungal	2 (1.62%)
Causative organism wise distribution	
Candida species	2 (1.62%)
Coagulasenegative staphylococci (CoNS)	21 (17.07%)
Escherichia coli	41 (33.33%)
Group B staphylococcus	30 (24.39%)
Klebsiella pneumonia	8 (6.50%)
Klebsiella species	2 (1.62%)
Listeria monocytogenes	2 (1.62%)
Pseudomonas aeruginosa	1 (0.81%)
Staphylococcus aureus	16 (13.00%)
Antimicrobial stewardship programs	
Participants	103 (83.73%)
Non- participants	20 (16.26%)

In this Table 3.2 shows that 65.04% are early onset and 34.95% are Only Late onset, out of 123 children, 1.62% children were infected with Fungal, 42.27% children were infected with Gram Positive Bacteria and 56.09% children were infected with Gram Negative Bacteria. In Causative organism wise distribution of various microbial species isolated, Escherichia coli was the most common at 33.33%, followed by Group B Streptococcus at 24.39%, and then Coagulase-negative staphylococci (CoNS) at 17.07%. Other species like Staphylococcus aureus 13%, Klebsiella pneumonia 6.5% and a few less frequent species like Candida, Klebsiella species, Listeria monocytogenes, and Pseudomonas aeruginosa are also present at low percentages the bulk 83.73% of cases are controlled under Antimicrobial Stewardship Programs (ASP), whereas the rest 16.26% are not. The data suggests that ASPs are widely implemented reflecting a strong commitment to optimizing antimicrobial use.

This table 3.3 show the frequency and percentage distribution of antibiotics used as per culture sensitivity tests grouped under fungal, Gram-negative and Gram-positive bacteria. The antibiotics used are Amoxicillin with Clavulanic Acid, Azithromycin, Cefoxitin, Meropenem, Piperacillin with Tazobactam and

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Vancomycin. Highest usage rate is observed for Piperacillin with Tazobactam having 54.47% of the total usage. Gram-negative bacteria were the most frequent pathogen, leading to 52 antibiotic uses, while fungal infections led to only 2. The total number of administrations was 123, with each antibiotic percentage calculated from this total. The outcome of culture sensitivity tests following the administration of certain drugs for fungal, gram-negative, and gram-positive bacteria. Meropenem was strongest, especially for gram-negative bacteria (29.26% of cases), with ampicillin, majorly for gram-positive bacteria (28.45%). Cefotaxime was moderate in potency against both gram-negative (8 cases) and gram-positive bacteria (12 cases), accounting for 16.26% of the overall cases. Fluconazole (1.62%) was effective only against fungal infections. The remaining drugs such as Vancomycin, Gentamicin and Imipenem were active to some extent against gram-positive or gram-negative bacteria.

Table 3.3: Antimicrobial Sensitivity Patterns Before and After Drug Use in Culture-Positive Patients (n=123)

Characteristics	**Total (n=123) Number (%)**	**Gram-Positive bacteria**	**Gram-Negative bacteria**	**Fungal**
Culture Sensitivity Test Before Used Drugs				
Amoxicillin and clavulanic acid	14 (11.38%)	12	1	1
Azithromycin	11 (8.94%)	0	11	0
Cefoxitin	12 (9.75%)	1	11	0
Meropenem	10 (8.13%)	5	5	0
Piperacillin and tazobactam	67 (54.47%)	42	24	1
Vancomycin	9 (7.31%)	9	0	0
Culture Sensitivity Test After Used Drugs				
Ampicillin	35 (28.45%)	35	0	0
Cefotaxime	20 (16.26%)	12	8	0
Fluconazole	2 (1.62%)	0	0	2
Gentamicin	9 (7.31%)	9	0	0
Imipenem	7 (5.69%)	0	7	0
Meropenem	36 (29.26%)	1	35	0
Norfloxacin	6 (4.87%)	6	0	0
Tigecyclline	3 (2.43%)	1	2	0
Vancomycin	5 (4.06%)	5	0	0

This table 3.4 shows the frequency of various antibiotics administered to neonates of different gestational ages: less than 33 weeks, 34-36 weeks, and more than 37 weeks. The antibiotics listed include Amoxicillin with Clavulanic Acid, Azithromycin, Cefoxitin, Meropenem, Piperacillin with Tazobactam, and Vancomycin. A Kruskal-Wallis test was performed to assess whether there are significant differences in antibiotic usage

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among the groups. The test statistic (H = 13.2817) and p-value (0.0099) indicate a statistically significant difference in antibiotic administration across these gestational age categories. The T-values represent the rank sums for each group used in the analysis.

Table 3.4: Association between Drugs Used Before Culture Sensitivity and Gestational Age (n=123)

Category	**Frequency**			**Kruskal-wallis test (H test)**	**P value**
	<33 Weeks	**>37 Weeks**	**34-36 Weeks**		
Amoxicillin and clavulanic acid	0	14	0	13.2817	<0.0099*
Azithromycin	0	11	0		
Cefoxitin	0	12	0		
Meropenem	0	8	2		
Piperacillin and Tazobactam	3	46	18		
Vancomycin	0	9	0		
T value	**T= 78**	**T= 160**	**T= 95**		

*Significance P value <0.0099 considered as significant

Table 3.5: Association between Drugs Used After Culture Sensitivity and Gestational Age (n=123)

Category	**Frequency**			**Kruskal-wallis test (H test)**	**P value**
	<33 WEEKS	**>37 WEEKS**	**34-36 WEEKS**		
Ampicillin	3	19	13	20.5742	<0.00038*
Cefotaxime	0	20	0		
Fluconazole	0	1	1		
Gentamicin	0	7	2		
Imipenem	0	7	0		
Meropenem	0	36	0		
Norfloxacin	0	6	0		
Tigecyclline	0	3	0		
Vancomycin	0	1	4		
T value	**T= 164.5**	**T= 354.5**	**T= 228**		

*Significance P value <0.00038 considered as significant

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This table 3.5 presents the frequency of antibiotic usage across neonates born at different gestational ages (<33 weeks, 34-36 weeks, and >37 weeks). The Kruskal-Wallis test was applied to determine if there is a statistically significant difference in antibiotic usage among these groups. The resulting test statistic (H = 20.5742) and p-value (0.00038) suggest a significant variation in drug administration across the different gestational age groups. The T-values represent rank totals for each group, which were used in the calculation of the Kruskal-Wallis test statistic.

4. Discussion

This Observational study included 123 sepsis-diagnosed neonates and infants, analysing various factors such as demographic distribution, microbial etiology, antibiotic sensitivity and antimicrobial stewardship. A significantly higher number of cases were observed among males (74.79%) compared to females (25.20%), according to the observation of Glaser MA et al. (2021) [11], who noted male predominance among cases of neonatal and infant sepsis in 218 individuals (138 males and 80 females). Gender inequality has been explained through variations in biological and endocrine factors that influence immune responsiveness in neonates.

Age-wise Distribution, neonates (64.22%) constituted a higher percentage of patients than infants (35.77%), confirming that the neonatal period is the most vulnerable for sepsis development. Cantey JB et al. (2021) [12] emphasized that nonspecific clinical signs are commonly encountered in neonatal sepsis, and hence, early diagnosis is not possible, resulting in increased morbidity.

Birth weight also appeared to play a role, as 59.34% of sepsis was observed among neonates with a weight of 2.1–5 kg. This occurred in only 7.31% of neonates with a weight of <2 kilograms, as would be predicted from the association of very low birth weight (VLBW) and sepsis risk, as noted in a study by Lim WH et al. (2012) [13], where sepsis rate and complications were significantly higher in VLBW infants.

Regarding the timing of onset, 65.04% were early-onset sepsis (EOS) and 34.95% were late-onset sepsis (LOS). This is the opposite of Lim WH et al. (2012) [13], where they reported higher LOS prevalence among their population. Gram-negative was slightly more common (56.09%) than Gram-positive (42.27%), whereas the predominance of Gram-positive was noted by Lim WH et al. (60.7%), i.e., Coagulase-negative Staphylococci (CoNS) in LOS.

Microbiologically, Escherichia coli (33.33%) was most commonly observed to be cultured, followed by Group B Streptococcus (24.39%) and Coagulase-negative Staphylococci (17.07%). This confirms what is provided in the literature, for example, Ramly B et al. (2022) [14], found that Gram-positive organisms were the most common organisms in EOS whereas Gram-negative bacteria were bound to be isolated together with LOS. The other organisms cultured include Staphylococcus aureus (13%), Klebsiella pneumoniae (6.5%), and less common isolations such as Candida spp., Pseudomonas aeruginosa, and Listeria monocytogenes.

To everyone's surprise, 83.73% of the cases were controlled under Antimicrobial Stewardship Programs (ASP) with good compliance and stewardship principles adoption. This has been consistent with findings by Berlak N et al. (2018) [15], who highlighted the advantage of ASPs in making antibiotic use rational and preventing resistance. The rest of the 16.26% not under ASP control may be reflective of resource limitations or protocol implementation barriers.

Antibiotic sensitivity analysis showed that piperacillin-tazobactam was the most frequently used empirical therapy (54.47%). On receiving culture results, targeted antibiotics such as Meropenem (29.26%), Ampicillin (28.45%), and Cefotaxime (16.26%) were successful against isolated pathogens. Meropenem was particularly successful against Gram-negative organisms, while Ampicillin was successful against Gram-positive isolates.

The Kruskal-Wallis test revealed statistically significant differences in drug administration by gestational age groups both before (p = 0.0099) and after (p = 0.00038) culture sensitivity testing. This demonstrates that the gestational maturity of neonates significantly affects antibiotic selection. The same findings were reported by Michael J Morowitz et al. (2022) [16], who showed that empiric antibiotic exposure needs to be stratified with care by gestational age and clinical evaluation to avoid unnecessary exposure and bad outcomes.

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In general, the study highlights the pivotal positioning of clinical pharmacists in neonatal sepsis treatment. With ASP participation, pharmacist interventions led to reduced mortality, improved antibiotic utilization, and increased pathogen-directed therapy. These findings align with global guidelines on the placement of pharmacists in NICU care teams to optimize sepsis treatment clinical outcomes.

5. Conclusion

This research affirms that sepsis in neonates and infants is severe public health issue with high morbidity and mortality. Clinical outcomes can improved significantly by optimizing the use of antimicrobials, preventing resistance and shortening hospital stays. In mortality rates through interventions by pharmacists, especially through antimicrobial stewardship. Routine culture sensitivity testing and gestational age-directed choice of antibiotics crucial to the success of treatment.

In order to promote patient safety and minimize the neonatal sepsis burden, it is critical to promote greater collaboration among pharmacists, physicians and other health professionals. Widespread implementation of antimicrobial stewardship programs within Neonatal Intensive Care Units (NICU), it is facilitated by ongoing training and protocol development, can result in long-term neonatal health care improvements.

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