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Original Research Article

Comparison of complete IV antibiotic course versus partial IV with oral antibiotics in probable and proven early-onset sepsis in a tertiary care centre; a step toward antimicrobial stewardship in the neonatal intensive care unit: a prospective observational study

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ABSTRACT

Background: Neonatal sepsis, particularly early onset sepsis (EOS), remains a leading cause of neonatal morbidity and mortality. The standard treatment involves intravenous (IV) antibiotics; however, prolonged IV antibiotic use increases hospital stay, healthcare costs, and the risk of antimicrobial resistance. Transitioning from IV to oral antibiotics in stable neonates may be a viable alternative. Aim and objectives were to compare the clinical outcomes of neonates with EOS receiving a complete course of IV antibiotics versus those transitioning from IV to oral antibiotics following initial stabilization.

Methods: A prospective observational study was conducted at the neonatal intensive care unit (NICU) of L.L.R.M Medical College, Meerut, from April 2023 to April 2024. Neonates diagnosed with EOS were categorized into two groups: group A (complete IV antibiotic course) and group B (IV-to-oral transition). Data on neonatal demographics, clinical parameters, duration of hospital stay, readmission rates, mortality, and weight gain were analysed. Statistical comparisons were performed using Chi-square and independent t-tests, with a p value <0.05 considered significant.

Results: A total of 100 neonates were included (50 per group). The mean hospital stay was significantly shorter in group B (7.2±1.4 days) compared to group A (10.1±2.1 days; p<0.01). No significant difference in mortality was observed between the groups (group A: 4%, group B: 3%; p=0.68). Readmission rates were comparable (group A: 6%, group B: 5%; p=0.74). Weight gain was significantly higher in group B at follow-up (p=0.03). The incidence of hospital-acquired infections was lower in group B, suggesting potential benefits of early transition to oral therapy.

Conclusions: Early transition from IV to oral antibiotics in stable neonates with EOS is a safe and effective strategy that reduces hospital stay without increasing mortality or readmission rates. This approach may contribute to antimicrobial stewardship by minimizing unnecessary IV antibiotic exposure. Further large-scale studies are needed to establish standardized protocols.

Keywords: Neonatal sepsis, Early onset sepsis, Intravenous antibiotics, Oral antibiotics, Antimicrobial stewardship, Hospital stay, Neonatal outcomes, Oral step-down therapy

INTRODUCTION

Neonatal sepsis remains a leading cause of morbidity and mortality among newborns, particularly in low- and middle-income countries.[1] Early onset sepsis (EOS), occurring within the first 72 hours of life, is primarily transmitted vertically from the mother and poses significant health risks, including systemic infections, prolonged hospitalization, and increased neonatal mortality.[2,3] Despite advancements in neonatal care, EOS continues to be a major contributor to neonatal deaths globally, with a particularly high burden in countries like India.[1-5]

The management of neonatal sepsis relies heavily on intravenous (IV) antibiotic therapy, which is the standard treatment approach. However, prolonged IV antibiotic use is associated with multiple drawbacks, including increased hospital stays, higher healthcare costs, mother-infant separation, and potential antimicrobial resistance.[4,5]

Additionally, extended hospitalization exposes neonates to hospital-acquired infections and disrupts early breastfeeding practices, potentially affecting long-term health outcomes.[6]

Antimicrobial stewardship has emerged as a crucial strategy to optimize antibiotic use in neonatal care. The concept of transitioning from IV antibiotics to oral therapy in neonates showing clinical improvement is gaining attention as a means to reduce the duration of hospitalization without compromising treatment efficacy.[7]

Studies have indicated that oral antibiotics can be a safe and effective alternative for neonates who have stabilized after initial IV therapy, thus reducing the burden on healthcare facilities and minimizing the risks associated with prolonged IV antibiotic administration.[7,8]

This study aims to compare the outcomes of neonates with EOS who received a complete course of IV antibiotics versus those who received a partial course of IV antibiotics followed by oral antibiotics. By evaluating mortality, hospital stay duration, readmission rates, and physical growth parameters, this study seeks to provide evidence on the feasibility and safety of early transition to oral antibiotic therapy in neonatal sepsis management.

The findings of this research will contribute to the ongoing efforts in antimicrobial stewardship and potentially guide future protocols for neonatal sepsis treatment in resource-limited settings.

METHODS

Study design and setting

This study was a prospective observational study conducted in the NICU at L.L.R.M Medical College, Meerut, from April 2023 to April 2024. The study aimed to compare the outcomes of neonates diagnosed with EOS who received a complete course of IV antibiotics versus those who transitioned to oral antibiotics after an initial IV course.

Study population

Neonates admitted to the NICU with a clinical diagnosis of probable or proven early-onset sepsis were considered for inclusion in the study. EOS was defined as sepsis occurring within the first 72 hours of life. The diagnosis was based on clinical signs, sepsis screen results, and blood culture findings.

Inclusion criteria

Neonates diagnosed with probable or proven EOS, gestational age ≥32 weeks, hemodynamically stable neonates showing clinical improvement after 48-72 hours of IV antibiotic therapy, and patients who provided parental consent for participation in the study and follow-up were included.

Exclusion criteria

Neonates with severe congenital malformations or genetic syndromes, neonates requiring prolonged respiratory or inotropic support, neonates diagnosed with meningitis, necrotizing enterocolitis (NEC), or other conditions requiring extended IV antibiotic therapy, and parents unwilling to provide consent or comply with follow-up visits were excluded.

Study groups

The neonates were categorized into two groups: group A (n=50): received a complete course of IV antibiotics for EOS as per standard NICU protocol, and group B (n=50): received an initial IV antibiotic course (minimum 48-72 hours) followed by oral antibiotics for the remaining duration of treatment, upon showing clinical improvement.

Data collection

Data were collected on the following parameters: neonatal demographic and clinical details (gestational age, birth weight, mode of delivery, and place of delivery); maternal risk factors associated with EOS (prolonged rupture of membranes, maternal fever, and meconium-stained amniotic fluid); laboratory investigations, including complete blood count, C-reactive protein (CRP), blood culture, and sepsis screen parameters; duration of hospital stay and need for readmission; and neonatal outcomes, including mortality, weight gain, feeding difficulties, and exclusive breastfeeding rates.

Follow-up

Neonates were followed up at 7, 14, and 28 days post-discharge through hospital visits and telephonic assessments. Parents were asked about any signs of infection, feeding issues, weight gain, and need for readmission.

Statistical analysis

Data analysis was performed using statistical package for the social sciences (SPSS) software. Continuous variables were expressed as mean±standard deviation (SD), and categorical variables were expressed as percentages. Comparisons between the two groups were performed using the chi-square test for categorical variables and the independent t-test for continuous variables. A p value of <0.05 was considered statistically significant.

RESULTS

Sociodemographic characteristics

A total of 100 neonates were included in the study, with 50 in group A (complete IV antibiotics) and 50 in group B (IV to oral transition). The mean gestational age was 35.2±2.1 weeks, and the mean birth weight was 2.5±0.4 kg. The majority (60%) of neonates were male, and 55% were born via cesarean section. Table 1 presents the detailed sociodemographic characteristics of the study population.

Table 1: Sociodemographic parameters of neonates with EOS.

Parameters	Group A (n=50)	Group B (n=50)	P value
Gestational age (weeks)	35.1±2.0	35.3±2.2	0.67
Birth weight (kg)	2.4±0.3	2.5±0.5	0.52
Male (%)	58	62	0.45
LSCS delivery (%)	54	56	0.81

Demographic characteristics of neonates with early onset sepsis in both treatment groups (Table 1).

Clinical outcomes

There was no significant difference in mortality between the two groups (group A: 4%, group B: 3%, p=0.68). The mean duration of hospital stay was significantly lower in group B (7.2±1.4 days) compared to group A (10.1±2.1 days, p<0.01). Readmission rates within 28 days were comparable between the groups (group A: 6%, group B: 5%, p=0.74).

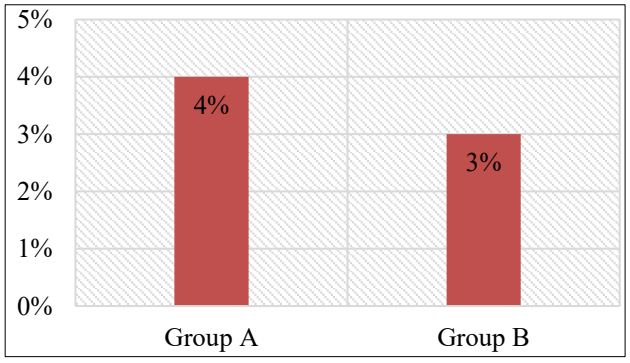

Figure 1: Percentage of mortality between groups.

Mortality was comparable between group A (4%) and group B (3%), with no significant difference (p=0.68) (Figure 1).

Correlation and associations

A significant correlation was found between prolonged hospital stay and increased risk of hospital-acquired infections (p<0.05). Weight gain was significantly higher in group B at follow-up (p=0.03). Table 2 presents the association between hospital stay duration and key outcomes.

Longer hospital stays (≥8 days) were associated with a higher incidence of hospital-acquired infections and lower weight gain. Weight gain was significantly greater in neonates with shorter hospital stays (p<0.05).

Table 2: Association between hospital stay and outcomes.

Hospital stay duration (days)	Infecti-ons (%)	Weight gain (g)	Readmiss-ion (%)
<8	10	450±50	4
≥8	25	380±40	7

DISCUSSION

Our study highlights the effectiveness and safety of transitioning stable neonates from IV to oral antibiotics in cases of EOS. The results demonstrate that early transition to oral therapy does not negatively impact neonatal mortality or readmission rates, supporting findings from Mukhopadhyay et al.[9] This approach is particularly beneficial in reducing the duration of hospitalization, which aligns with previous research showing that prolonged hospital stays increase the risk of nosocomial infections and hospital-acquired complications.[10]

Additionally, our study observed a notable improvement in weight gain among neonates who transitioned to oral antibiotics earlier. A recent meta-analysis indicated that antibiotic exposure before 24 months of age, compared to no exposure, was linked to a higher risk of overweight and obesity in later childhood, with a higher mean BMI z score of 0.07 (95% confidence interval [CI] 0.05 to 0.09).[11] However, the results of various studies have been inconsistent, likely due to differences in study populations and methodologies for defining exposures and outcomes.[12,13] Additionally, antimicrobial resistance remains a significant concern in neonatal intensive care, and our findings contribute to the growing body of evidence suggesting that shorter courses of IV antibiotics, followed by oral therapy, could help mitigate this issue.[14]

Despite the benefits observed in our study, larger multicenter randomized controlled trials are needed to confirm these findings and establish standardized protocols for neonatal sepsis treatment.[15,16] Future research should also focus on long-term neurodevelopmental outcomes in neonates receiving early oral antibiotic therapy to ensure its safety beyond immediate clinical parameters.

Limitations

While this study provides valuable insights, it has certain limitations. Firstly, the sample size was limited to a single tertiary care center, potentially affecting the

generalizability of the findings. Secondly, the follow-up period was relatively short, and long-term neurodevelopmental outcomes were not assessed. Additionally, potential confounding factors such as variations in maternal health, neonatal nutrition, and home care practices could have influenced outcomes. Finally, the reliance on telephonic follow-ups may have introduced recall bias in assessing post-discharge morbidity and readmissions. Future research should address these limitations by incorporating larger, multi-institutional studies with extended follow-up periods to establish comprehensive guidelines for EOS management.

CONCLUSION

This study demonstrates that transitioning stable neonates from IV to oral antibiotics in cases of EOS is a safe and effective approach, leading to reduced hospital stays without increasing mortality or readmission rates. The findings support the growing emphasis on antimicrobial stewardship by minimizing unnecessary IV antibiotic exposure, thereby reducing the risk of hospital-acquired infections and antimicrobial resistance. Early transition to oral therapy was associated with better weight gain and improved breastfeeding rates, reinforcing its potential benefits for neonatal health. However, to implement this approach widely, further large-scale, multicenter randomized controlled trials are necessary to validate these findings and develop standardized protocols for neonatal sepsis management.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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