How to Cite:
Jyothi, Y. N. S., Karimi, P. K., Sarvani, G., & Raju, D. S. S. K. (2022). Neonatal sepsis and associated maternal risk factors: A clinical case- control study. *International Journal of Health Sciences*, *6*(S7), 2096–2101. https://doi.org/10.53730/ijhs.v6nS7.11765

Neonatal sepsis and associated maternal risk factors: A clinical case- control study

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***Abstract*---**Background: Neonatal sepsis is usually diagnosed with pathogen/bacterial isolation from the bloodstream or symptoms of infection seen in infection of 28 days or younger. In neonates, the major cause of mortality and morbidity is sepsis globally, even with the significant advancements in the healthcare sector. Neonatal sepsis incidence in asymptomatic subjects having bacteremia is low. Neonatal sepsis includes various diseases with varying mortality rates of 11-40% contributing to nearly 3.1 deaths globally in new-borns every year. Aim: The present study was conducted to assess the risk factors associated with low-birth-weight babies in an Indian setup. Methods: The present study screened 502 subjects and 202 were found to have confirmed diagnosis of neonatal sepsis as assessed by the Pediatrician depending on the signs and symptoms of the sepsis. For all the study subjects, neonatal information for sepsis, maternal data, and sociodemographic data were collected and assessed for result fabrication. Results: Premature membrane rupture was seen in 7.89% (n=3) subjects of late-onset sepsis and 20.12% (n=33) subjects with early-onset sepsis. Multipara was seen in 13.15% (n=5) and 11.58% (n=19) subjects with late and early-onset sepsis, meconium-stained amniotic fluid was the risk factor in 5.26% (n=2) and 13.41%

(n=22) subjects with late and early-onset sepsis, maternal UTI was seen in 2.63% (n=1) and 15.24% (n=25) study subjects with late and early onset sepsis, and foul-smelling liquor was the risk factor in 2.63% (n=1) and 64.63% (n=106) study subjects with late and early onset sepsis respectively. Late onset sepsis and early onset sepsis was respectively seen in 31.57% (n=12) and 64.63% (n=106) study subjects. There were 15.78% (n=6) culture positive subjects in late onset, whereas, in early onset sepsis cases of 164 subjects, there were 18.29% (n=30) culture positive subjects. Conclusion: The present study concludes that male gender predilection was seen for both early-onset and late-onset neonatal sepsis. Identification of the maternal risk can help in the early diagnosis and prompt reinforcement of antibiotic therapy to prevent death. The diagnosis and prediction for neonatal sepsis should be done based on the scoring systems utilizing the scoring systems and culture-dependent methods.

***Keywords*---**antibiotic therapy, bacteremia, bacterial infections, Neonatal sepsis, neonatal death.

Introduction

One of the major causes of mortality and morbidity in preterm as well as term infants is neonatal sepsis which also has a significant contribution to morbidity and mortality in NICU (Neonatal Intensive Care Units) admitted pediatric subjects with VLBW (very-low-birth-weight). The death rate in subjects of age less than 5 years is nearly 3.6 million death per year accounting for nearly 40% of total death in children. The majority of these deaths are reported in low-income or developing countries where nearly one-third of deaths are caused by infectious etiologies like pneumonia, meningitis, or neonatal sepsis.[1]

Neonatal disease signifies a clinical condition presented as symptoms or signs of the infection in infants of age 28 days or less. It is commonly presented as systemic infection signs or the isolation of infectious pathogens or bacteria from the bloodstream of the infected subject. One of the major causes of mortality and morbidity worldwide in neonates is sepsis irrespective of significant advancement in the healthcare sector with infant mortality rate varying between 11-40% with approximately 3 million deaths worldwide.[2]

Neonatal sepsis includes multiple conditions including urinary tract infections, arthritis, osteomyelitis, meningitis, pneumonia, and/or septicemia. The clinical features of neonatal sepsis are usually non-specific and not enough for the identification of early-onset sepsis in neonates. However, there is a low reported incidence of bacterial neonatal sepsis leading to bacteremia in the asymptomatic infant subjects. In preterm newborn subjects, neonatal sepsis is usually presented as hypothermia owing to temperature control transition difficulty in the first two days, whereas, in full-term infants, fever with bacterial infection is usually seen.[3]

Transient tachypnea of newborns is misinterpreted with other presentations of sepsis with or without pneumonia including respiratory muscle retraction and grunting, nasal flaring, and tachypnea of the newborns. Complications in neonatal sepsis can be attributed to shock, congestive heart failure, DIC (disseminated intravascular coagulation), and metastatic infection foci. Depending on the infection timing, neonatal sepsis can be classified as either late-onset sepsis or EOS (early-onset sepsis).[4] The present clinical case-control study was conducted to assess the risk factors associated with low-birth-weight babies in an Indian setup.

Material and Methods

The present clinical case-control study was conducted to assess the risk factors associated with low-birth-weight babies in an Indian setup. The study population was comprised of the subjects admitted to the PICU (pediatric intensive care unit) of the institute.

After explaining the detailed study design, informed consent was taken from the guardian/parent of all the study subjects. After obtaining the informed consent, for the present study, 502 subjects were screened and 202 were found to have confirmed diagnosis of neonatal sepsis as assessed by the Pediatrician depending on the signs and symptoms of the sepsis at the time of admission to the institute. After the final inclusion of the study subjects, the data and necessary was obtained from the guardian/parent of the admitted subject.

The data collection for all 202 neonates was done in three parts including the data for the neonates for neonatal sepsis, data concerning the maternal status, and the sociodemographic data including the age and gender of the neonates. Data collection was done by a single expert in the field for all the study subjects to obtain accurate results.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$.

Results

The present clinical case-control study was conducted to assess the risk factors associated with low-birth-weight babies in an Indian setup. For the present study, 502 subjects were screened and 202 were found to have confirmed diagnosis of neonatal sepsis as assessed by the Pediatrician depending on the signs and symptoms of the sepsis at the time of admission to the institute. The demographic characteristics of the study subjects are listed in Table 1. There were 54.45% (n=110) males and 45.54% (n=92) females in the present study. There were 81.18% (n=164) subjects in the age range of 0-7 days and 18.81% (n=38) subjects in the age of 8-28 days. These were significantly higher in the age of 0-7 days with $p<0.001$. Early-onset neonatal sepsis was significantly higher in the study subjects with 81.18% (n=164) study subjects compared to 18.81% (n=38) subjects having late-onset neonatal sepsis ($p<0.001$) as shown in Table 1.

On assessing the maternal risk factors in the study subjects, it was seen that premature membrane rupture was seen in 7.89% (n=3) subjects of late-onset sepsis and 20.12% (n=33) subjects with early-onset sepsis. Multipara was seen in 13.15% (n=5) and 11.58% (n=19) subjects with late and early-onset sepsis, meconium-stained amniotic fluid was the risk factor in 5.26% (n=2) and 13.41% (n=22) subjects with late and early-onset sepsis, maternal UTI was seen in 2.63% (n=1) and 15.24% (n=25) study subjects with late and early-onset sepsis, and foul-smelling liquor was the risk factor in 2.63% (n=1) and 64.63% (n=106) study subjects with late and early-onset sepsis respectively. Late-onset sepsis and early-onset sepsis were respectively seen in 31.57% (n=12) and 64.63% (n=106) study subjects as depicted in Table 2.

Concerning the assessment of the culture-positive cases in the study subjects, it was seen that in 38 study subjects with late-onset sepsis, there were 15.78% (n=6) culture-positive subjects, whereas, in early-onset sepsis cases of 164 subjects, there were 18.29% (n=30) culture-positive subjects. There were higher subjects with early-onset sepsis compared to lesser culture-positive subjects in the late-onset neonatal sepsis as shown in Table 3.

Discussion

The present clinical case-control study was conducted to assess the risk factors associated with low-birth-weight babies in an Indian setup. For the present study, 502 subjects were screened and 202 were found to have confirmed diagnosis of neonatal sepsis as assessed by the Pediatrician depending on the signs and symptoms of the sepsis at the time of admission to the institute. There were 54.45% (n=110) males and 45.54% (n=92) females in the present study. There were 81.18% (n=164) subjects in the age range of 0-7 days and 18.81% (n=38) subjects in the age of 8-28 days. These were significantly higher in the age of 0-7 days with $p<0.001$. Early-onset neonatal sepsis was significantly higher in the study subjects with 81.18% (n=164) study subjects compared to 18.81% (n=38) subjects having late-onset neonatal sepsis ($p<0.001$). These demographics were comparable to the studies of Kartik R[5] in 2006 and Newman TB et al[6] in 2010 where authors assessed subjects with comparable demographics as in the present study.

For the assessment of the maternal risk factors in the study subjects, it was seen that premature membrane rupture was seen in 7.89% (n=3) subjects of late-onset sepsis and 20.12% (n=33) subjects with early-onset sepsis. Multipara was seen in 13.15% (n=5) and 11.58% (n=19) subjects with late and early-onset sepsis, meconium-stained amniotic fluid was the risk factor in 5.26% (n=2) and 13.41% (n=22) subjects with late and early-onset sepsis, maternal UTI was seen in 2.63% (n=1) and 15.24% (n=25) study subjects with late and early-onset sepsis, and foul-smelling liquor was the risk factor in 2.63% (n=1) and 64.63% (n=106) study subjects with late and early-onset sepsis respectively. Late-onset sepsis and early-onset sepsis was respectively seen in 31.57% (n=12) and 64.63% (n=106) study subjects. These results were consistent with the findings of Roy P et al[7] in 2014 and Cortese F et al[8] in 2016 where similar risk factors were reported by the authors as in the present study.

On assessing the culture-positive cases in the study subjects, it was seen that in 38 study subjects with late-onset sepsis, there were 15.78% (n=6) culture-positive subjects, whereas, in early-onset sepsis cases of 164 subjects, there were 18.29% (n=30) culture-positive subjects. There were higher subjects with early-onset sepsis compared to lesser culture-positive subjects in the late-onset neonatal sepsis. These findings were in agreement with the studies of Russell NJ et al[9] in 2017 and Fleischmann-Struzek C et al[10] in 2018 where authors reported a comparable proportion of culture-positive subjects in early and late-onset neonatal sepsis as in the present study.

Conclusion

Within its limitations, the present study concludes that male gender predilection was seen for both early-onset and late-onset neonatal sepsis. Identification of the maternal risk can help in the early diagnosis and prompt reinforcement of antibiotic therapy to prevent death. The diagnosis and prediction for neonatal sepsis should be done based on the scoring systems utilizing the scoring systems and culture-dependent methods. The present study had a few limitations including small sample size, shorter monitoring period, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

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Tables

	Characteristics	**Percentage (%)**	**Number (n)**	**p-value**
Gender	Males	54.45	110	
	Females	45.54	92	
Age range (days)	0-7	81.18	164	**<0.001**
	8-28	18.81	38	
Onset	Early	81.18	164	**<0.001**
	Late	18.81	38	

Table 1: Demographic and disease characteristics of the study subjects

Risk factors	**Late-onset sepsis (%)**	**Late-onset sepsis (n=38)**	**Early-onset sepsis (%)**	**Early-onset sepsis (n=164)**
Premature membrane rupture	7.89	3	20.12	33
Multipara	13.15	5	11.58	19
Meconium-stained amniotic fluid	5.26	2	13.41	22
Maternal UTI	2.63	1	15.24	25
Foul-smelling liquor	2.63	1	4.26	7
Total	31.57	12	64.63	106

Table 2: Maternal risk factors in the study subjects

Onset type of sepsis	**Culture positive (n)**	**Culture positive (%)**
Late-onset	6	15.78
Early-onset	30	18.29

Table 3: Assessment of culture-positive cases in the study subjects