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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON APPRAISAL OF INCIDENCE, PREDISPOSING FACTORS AND CLINICAL OUTCOMES IN NEONATAL SEPSIS

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Abstract:

Neonatal sepsis is a most common and frequent cause of morbidity and mortality in neonates. This study was conducted to appraise the incidence, predisposing factors and clinical outcomes of neonatal sepsis. A non experimental prospective cross sectional study was conducted for a period of 6 months in Neonatal Intensive Care Unit and Sick Newborn Care Unit of tertiary care teaching hospital located in Guntur. Study was ethically approved from Institutional ethical committee. A total of 197 neonates with age 0-28 days with clinical sepsis and culture proved sepsis were included into the study. Among 197 neonates, 78.7% with clinical sepsis and 21.3% neonates with culture positive sepsis. 68.5% neonates were diagnosed with early onset neonatal sepsis and 31.5% with late onset neonatal sepsis. Low birth weight (56.3%) was the predominant risk factor for neonatal sepsis and incidence rate was 20.6%. Klebsiella pneumonia (43.9%) was most isolated microorganism. Neonatal septicemia is one of the leading causes of infant morbidity and mortality. Our study found that sepsis was predominantly found in female patients and inpatients whose mode of delivery is vaginal. Most common isolated organism in culture positive cases is Klebsiella pneumonia. EOS is predominantly seen in culture where as LOS in clinical sepsis.

Keywords: sepsis, gasping, EOS, LOS, mortality

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INTRODUCTION:

Neonatal sepsis is a systemic infection in infants that occurs within 28 days of life and is an important cause of morbidity and mortality in newborns. Neonatal sepsis is a major cause of morbidity and mortality among neonates. In developed countries, it is responsible for 30-50 percent of the overall neonatal deaths. Up to 20% of neonates are expected to develop sepsis and about 1% dies from sepsis-related causes. An increased risk of neonatal infections has been related to several factors [1]. Sepsis involves multiple systemic infections of the new born such as septicemia, meningitis, pneumonia, arthritis, osteomyelitis and urinary tract infections. Both gram-positive and gram-negative bacteria cause neonatal sepsis. Different maternal, foetal and environmental factors lead to sepsis in neonates. Premature membrane rupture (PROM), one of the maternal factors is defined as spontaneous membrane rupture at any time after 37 weeks of pregnancy, but before the onset of labor. Fever, chorioamnionitis, persistent vaginal examination, amniotic fluid stained with meconium, dietary consumption of infected foods, cervix, place of birth, prematurity, low birth weight, difficult or instrumental delivery and low appearance pulse grimace activity respiration (APGAR) scores [2]. Invasive procedures during hospital admission can occur with late onset of sepsis acquiring nosocomial infections. Prematurity, low birth weight, asphyxia, congenital anomaly and long stay in the neonatal intensive care unit (NICU) are neonatal risk factors that have been shown to lead to neonatal sepsis. Signs and symptoms of neonatal infection are subtle and non-specific, can present with one or more signs of hyperglycemia, poor cry, absence of neonatal reflexes, poor perfusion, hypoglycemia, hypothermia or fever, failure to suck, lethargy, bulging fontanel, apnea and gasping breathing, bradycardia, tachycardia, respiratory distress, excessive capillary refill, hypotension, and metabolic acidosis [3]. Late-onset sepsis usually is caused by nosocomial pathogens. Organisms that have been implicated in causing late-onset sepsis include *Staphylococcus aureus*, *E.coli*, *Klebsiella*, *Pseudomonas*, *Acinoobacter* and *Candida* Species. Neonatal sepsis is a major cause of morbidity worldwide and one of the three primary causes of 2.7 million deaths every year [4]. The incidence of neonatal sepsis is 30 per 1000 live births, according to data from the National Neonatal Perinatal Database (NNPD), 2002-2003. Due to complications caused by sepsis, the mortality rate can remain high, such as severe sepsis and septic shock, end organ damage, such as respiratory, renal, cardiac and multiple organ dysfunction syndrome (MODS) or failure. Therefore the purpose of this study was to

assess the incidence, predisposing factors and clinical outcomes in neonatal sepsis [5].

METHODOLOGY:**Source of data**

The patients were screened based on inclusion and exclusion criteria. Patients who satisfy the inclusion criteria were included in the study. Data was collected from patient case record such as demographics, present clinical status, culture tests, antimicrobial regimen and other information that explains the clinical progression of the patient. Maternal data including gestational age at delivery based on last menstrual period, mode of delivery, any diseases or complications during pregnancy and medication used during gestation period etc were also collected.

Study site

The study was conducted after obtaining approval from Institutional Ethics Committee number

GMC/IEC/108/2018 and patient assent. The study was conducted in NICU and SNCU, Department of pediatrics, Government General Hospital, Guntur

Study design

A hospital based non-experimental prospective observational study

Sample size

197 neonates were included in our study based on inclusion and exclusion criteria

Study duration

The study was conducted over a period of 6 months, from September 2018 to February 2019.

Study Criteria**Inclusion Criteria**

Neonates with 0-28 days of age and of gender, all neonates with clinical sepsis and proven positive blood cultures, neonates with sepsis and its complications, guardians with language compatibility and both early onset and late onset (>72 hours) of sepsis are included.

Exclusion Criteria

Neonates without guardians, patients who are not willing to give assent, neonates whose case records contain inadequate information, neonates with suspected sepsis are excluded.

Data analysis

The obtained results were tabulated and arranged on Microsoft excel 2007.

RESULTS AND DISCUSSION:**Table 1: Age group (in days) Vs no of patients**

Age (days)	No. of patients		Total (n=197) (n)(%)
	Clinical sepsis (n)(%)	Culture positive sepsis (n)(%)	
1 to 7	111 (71.6)	24 (57.14)	135 (68.52)
8 to 14	13 (8.33)	11 (26.19)	24 (12.18)
15 to 21	17 (8.62)	5 (11.90)	22 (11.16)
22 to 28	14 (7.10)	2 (4.76)	16 (8.12)
Total	155	42	197

Based on the results obtained, our study revealed that the distribution of clinical sepsis 155 (78.68%) is more predominant which is dissimilar to the study done by Preeti M. Huggi *et. al* on A study of neonatal septicemia in a tertiary care hospital in kalaburagi which showed that 63 (31.5%) were found to be culture positive. Among the low birth weight 68.25%, the proportion of culture-positive cases was higher compared to normal birth weight 31.75% [7].

Table 2: Gender Vs no .of Patients

Gender	No. of patients		Total
	Clinical sepsis (n) %	Culture positive sepsis (n) %	
Male	73 (47.09)	15 (35.71)	88 (44.67)
Female	82 (52.91)	27 (64.29)	109 (54.33)
Total	155	42	197

In our study, males were 88 (44.67%) and females were 109 (54.33%) [6]. The percentage of culture positive cases was higher among females 27 (64.29%) compared to males 15 (35.71%), which is dissimilar to the study done by Fakadu G *et., al* on clinical treatment outcomes of Neonatal Sepsis in Neonatal Intensive Care Unit of Wollega University Teaching and Referral Hospital, Nekemte Town, Western Ethiopia which showed that males were 57.5% compared to females 42.5%.

Table 3: Birth Weight Vs no. of patients

Birth Weight	No .of patients		Total (n=197) (N) (%)
	Clinical Sepsis (n) %	Culture Positive Sepsis (n) %	
Low	86 (55.49)	25 (59.52)	111 (56.35)
Normal	69 (44.51)	17 (40.48)	86 (43.65)
Total	155	42	197

Based on the results obtained in our study, the proportion of culture positive cases was higher among the low birth weight 25 (59.52%) compared to normal birth weight 17 (40.48%), which is dissimilar to the study showed that the proportion of culture positive cases was higher among the low birth weight (68.25%) compared to normal birth weight (31.75%).

Table 4: Sepsis Distribution Vs No. of Patients

Types of Sepsis	No. of Patients (N=197) N (%)
Clinical Sepsis	155 (78.68)
Culture Positive Sepsis	42 (21.32)
Total	197 (100%)

The proportion of culture positive cases among Preterm neonates 28 (66.67 percent) was higher in our research compared to term neonates 11 (26.19 percent) and Post term neonates 3 (7.14 percent), which is different from the study, showed that culture positive cases among Preterm neonates were higher (61.9%) compared to term neonates (34.9%) and Post term neonates (61.9%), (3.2%) [8].

Table 5: Mode of Delivery Vs No. of Patients

Mode of Delivery	No. of Patients		Total (197)
	Clinical Sepsis (N) %	Culture Positive Sepsis (N) %	(N) %
Vaginal	106 (68.38)	26 (61.90)	132 (63%)
Caesarean	49 (36.62)	16 (38.10)	65 (37%)
Total(197)	155	42	197

Our study also revealed that culture positive cases were found to be delivered by spontaneous vaginal delivery 26 (61.90%) followed by Caesarean section 16 (38.10%) which is similar to the study showed that culture positive cases were found to be delivered by spontaneous vaginal delivery (76.2%) followed by Caesarean section (20.63%). Our research found that the percentage of culture-positive cases was higher in early onset septicemia cases 31 (73.80%) compared to late onset septicemia 11 (26.20%), which is close to the study, showed that culture-positive cases were higher in early onset septicemia cases (90.47%) compared to late onset septicemia cases (9.53%) [9].

Table 6: Clinical Outcome Vs No. of Patients

Outcome	Clinical Sepsis (N) (%)	Culture Positive Sepsis (N) (%)	Total (N) (%)
Discharge	98 (63.23)	33 (78.58)	131 (66.49)
Death	24 (15.48)	3 (7.14)	27 (13.72)
LAMA	33 (21.29)	6 (14.28)	39 (19.79)
Total	155	42	197

Based on the results obtained in our study it is found that the culture positive cases are higher in 0-7days 21 (81%) when compared to 8-14days 3(11%) 15-21days 2(8%). Based on our study it is found that in signs and symptoms the fever (P value of 0.0068) which is clinically significant and remaining signs and symptoms are clinically non significant. Our study found out that *Klebsiella pneumonia* 18 (43.90%), *E.coli* 7 (17.07%) are predominantly observed followed by *Staphylococcus* 6 (14.63%), *Acinetobacter* 5 (12.21%), *pseudomonas* 3 (7.32%), fungal 2 (4.87%) which is dissimilar to the study done by N.Muthukumaram et., al study on "Mortality profile of neonatal deaths and deaths due to neonatal sepsis in a tertiary care center in southern India : a retrospective study" which showed that *staphylococcus* (38.6%) and *Klebsiella pneumoniae* (32.7%) were the predominant organisms isolated [10].

Table 7: Incidence Rate in Months Vs No. of Patients

Month	No of Patients with Sepsis, (N)	No of Patients admitted in NICU, (N)	Incidence Rate (%)
September	78	315	24.76
October	61	287	21.25
November	53	274	19.34
December	49	236	20.76
January	57	295	19.32
February	44	249	17.67
Total (N)	342	1656	20.65

Our study found out that the various risk factors like birth asphyxia 44 (22.34), prematurity 37 (18.78%), maternal fever 22 (11.17%), abnormal in the level of amniotic fluid 20 (10.15%), foul smelling of liquor 19 (9.65%) are having a higher risk where clinical sepsis is more, membranes 16 (8.12%), maternal UTI 14 (7.11%), meconium aspiration 11 (5.58%) are having moderate risk and leaking PV >24hrs 5 (2.54%), antepartum hemorrhage 4 (2.03%), congenital abnormalities 3 (1.52%), antenatal steroids 2 (1.02%) are having minor risk where culture positive sepsis is less. Based on the results obtained our study revealed that out of 42 culture positive cases discharge cases were 33 (78.58%), LAMA 6 (14.28%) and death 3 (7.14%) [11]. Our study found out that 0 risk factors are observed in 29 cases (14.72%), 1 risk factor in 44 (22.34%), 2 risk factors in 65 (32.99%), 3 risk factors 27 (13.71%), 4 risk factors 23 (11.68%) and >4 risk factors 9 (4.57%). There was a significant relationship between the severity of sepsis and mortality. In our study we found the Incidence Rate during the study period i.e September 2018 to February 2019 and Incidence Rate is 20.65%.

CONCLUSION:

Neonatal septicemia is one of the leading causes of infant morbidity and mortality. Our study found that sepsis was predominantly found in female patients and inpatients whose mode of delivery is vaginal. Most common isolated organism in culture positive cases is *Klebsiella pneumoniae*. EOS is predominantly seen in culture where as LOS in clinical sepsis. Therefore preventive measures are to be taken to prevent the occurrence of sepsis. Further research on antibiotic sensitivity to sepsis antibiotics, empirical therapy and its efficacy are needed.

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