INTRODUCTION: Neonatal sepsis is a systemic inflammatory response syndrome leading to multiorgan dysfunction, which may be caused by infection or non-infectious factors. Neonatal sepsis is the most important cause of morbidity and mortality in developing countries. Neonatal sepsis is diagnosed when generalized systemic features are associated with bacterial growth from one or more sites. It is a major public health problem in developing countries. Every year, millions of newborns die due to neonatal sepsis. Sepsis is the leading cause of death in neonates. The incidence of neonatal sepsis is high in developing countries due to underdeveloped medical facilities and a lack of awareness among the public. The Global Assessment of Neonatal Sepsis in 2007 estimated that 1 in 100 newborns died of septicaemia in low-income countries 

BACKGROUND: Neonatal sepsis is the most important cause of morbidity and mortality in developing countries. Neonatal sepsis is diagnosed when generalized systemic features are associated with bacterial growth from one or more sites. In developing countries like ours, neonatal mortality (death in the first 28 days of life per 1000 live births) due to all causes is about 34 per 1000 live births, most of these deaths occur in the first week of life. In developing countries, sepsis is the commonest cause of mortality responsible for 30% to 50% of 5 million neonatal deaths every year. Detailed studies on the clinical manifestations and laboratory profile of neonatal sepsis in rural India are uncommon.

OBJECTIVES AND METHODS
- It is an observational cross-sectional study conducted in NICU, Mahatma Gandhi Memorial Hospital from November 2013 to October 2014.
- To study the incidence of neonatal septicaemia among the cases admitted in our NICU, Mahatma Gandhi Memorial Hospital, Warangal.
- To compare the results of clinical diagnosis statistically with that of the confirmed cases of septicaemia (by blood culture reports) taking different demographic patterns into consideration.

RESULTS
Out of 2992 NICU admissions in the study period from November 2013 to October 2014, the incidence of proven septicaemia was 6.58%. Lethargy, respiratory distress and feeding difficulties were common clinical manifestations. Hypothermia, abdominal distension, vomiting, apnoea, depressed neonatal reflexes were more frequently seen in preterm neonates than term. Mortality was more in males, EOS, preterm and in very low birth weight neonates.

CONCLUSION
In the present study taking the different demographic patterns into consideration, the accuracy with which the clinical diagnosis and the blood culture reports can diagnose immediately and the progression of the disease can be halted is shown.

KEYWORDS
Neonatal Sepsis, Laboratory, Clinical.


INTRODUCTION: Neonatal sepsis is defined as generalised systemic infection of newborn, associated with pure growth of bacteria from one or more sites. Neonatal sepsis can be broadly classified into early onset (<72 hours) and late onset sepsis (>72 hours). National Neonatology Forum of India defines neonatal sepsis as follows:

Proven Sepsis: The baby presents with clinical picture of sepsis and isolation of pathogens from blood, CSF, urine or other body fluids or autopsy evidence of sepsis.

Probable Sepsis: Newborn with clinical picture suggestive of sepsis with one or more of the following criteria:
- Evidence of predisposing factors, e.g. maternal fever, foul smelling liquid or prolonged rupture of the membrane (>12 hours) or gastric polymorphs more than 6/high power field.
- Positive septic screen (two of the four parameters to be present).
- Total leukocytes count <5000/mm³, immature to total neutrophil count ratio >0.2, C-reactive protein positive and micro ESR >15/1 hour or >age in days +3.
- Radiological evidence of pneumonia.
Sepsis syndrome: When septicaemia is associated with altered organ perfusion (hypoxia, increased blood lactate, oliguria and altered mental state), it is termed as sepsis syndrome.²

Neonatal Sepsis is the most important cause of morbidity and mortality in developing countries. Neonatal sepsis is diagnosed when generalized systemic features are associated with pure growth of bacteria from one or more sites.¹ In developing countries, neonatal mortality (death in the first 28 days of life per 1000 live births) due to all causes is about 34 per 1000 live births, most of these deaths occur in the first week of life.³,⁴ In developing countries, sepsis is the commonest cause of mortality responsible for 30% to 50% of 5 million neonatal deaths every year.³ It is important to remember that bacterial flora is dynamic, different from one place as compared to the other and it changes in the same place over a period of time. It is essential to closely monitor the bacterial flora of the NICU and the antibiotic sensitivity pattern of pathogens to evolve rational antibiotic policy, which is most suitable and specific for a particular NICU.¹ Detailed studies on the clinical manifestations and laboratory profile of neonatal sepsis in rural India are uncommon. Good laboratory facilities, especially blood culture, are frequently unavailable in the rural healthcare setting, resulting in the non-availability of relevant data on culture-proven neonatal sepsis.⁵ Although a number of studies have been made in the past to understand the demographic pattern of the disease, a sincere effort has been made in this present study to understand the disease and its clinical manifestations and also to understand the demographic patterns of the disease. This study is intended to help the practising paediatrician to understand and also help him to identify before any crisis occurs.

AIMS AND OBJECTIVES:
- To study the incidence of neonatal septicaemia among the cases admitted in our NICU, Mahatma Gandhi Memorial Hospital, Warangal.
- To compare the results of clinical diagnosis statistically with that of the confirmed cases of septicaemia (by blood culture reports) taking different demographic patterns into consideration.

MATERIALS AND METHODS:
Design: It is an observational cross-sectional study.

Source: NICU, Mahatma Gandhi Memorial Hospital.

Period of Study: November 2013 to October 2014.

Inclusion Criteria: Neonates were included when at least three of the following risk factors were present¹:
1. Febrile illness in the mother during or within two weeks of delivery (More than 38°C oral temperature).
2. More than 3 vaginal examinations during labour.
3. Prolonged rupture of membranes (More than 12 hours).
4. Foul smelling or meconium stained liquid.
5. Preterm baby or LBW baby.
7. Pathological evidences of funisitis.

In addition, neonates who presented with symptoms of septicaemia like refusal of feeds, decreased activity, lethargy, respiratory distress, fever, hypothermia, sclerema, abdominal distension, seizures and shock were all included.

Exclusion Criteria:
1. Neonates with lethal congenital anomalies.
2. Neonates whose parents didn’t give consent.

All cases of suspected septicaemia considering inclusion and exclusion criteria admitted in the NICU, Mahatma Gandhi Memorial Hospital, from November 2013 to October 2014 was taken up for study.

After admission, detailed history and thorough clinical examination was done. Required data was entered in a pre-set proforma and statistical analysis was done. Blood culture was sent.

The confirmed cases (i.e., blood culture positive cases) were statistically compared with that of the clinically diagnosed cases to find out the significance of the clinical diagnosis and also to find out the importance of early clinical diagnosis to avert the tragedy of the progression of the disease. The comparison was done taking different demographic patterns like sex, gestation age, birth weight, clinical signs and symptoms.

RESULTS: Out of 2992 NICU admissions in the study period from November 2013 to October 2014, 419(14%) cases were taken up for the study considering inclusion and exclusion criteria. Out of 419 cases, blood culture was positive in 197 (47.016%) cases.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Clinical sepsis</th>
<th>Blood culture positive sepsis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>242(57.75%)</td>
<td>104(52.79%)</td>
</tr>
<tr>
<td>Female</td>
<td>177(42.24%)</td>
<td>93(47.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>419</td>
<td>197</td>
</tr>
</tbody>
</table>

Table 1: Sex Distribution Among Clinical and Blood Culture Positive Sepsis

Out of 419 cases of clinical sepsis, 242(57.75%) were male neonates, 177(42.24%) were female neonates. Male neonates with clinical sepsis were admitted more frequently than female neonates which is statistically significant. (p-value 0.01).

Among 197 cases of proven sepsis, 104(52.79%) were male neonates and 93(47.2%) were female neonates. There was no sex difference in blood culture positive sepsis (p-value 0.42).
In the cohort of neonates with clinical sepsis, term neonates were more than (231(55.13%)) preterm neonates 188(44.86%) which is statistically significant (0.03). However, blood culture positivity was comparable in both preterm 92(46.70%) and term (53.29%) neonates (p-value 0.35).

In the present study, mean birth weight in clinical sepsis group was 2167±801 g. Among 419 cases of clinical sepsis, 105(25.05%) were <1500 g, 139(33.17%) were between 1500-2500 g and 175(41.76%) were >2500 g. Among 197 cases of proven sepsis, 53 (26.9%) were <1500 g, 69(35.02%) were between 1500-2500 g and 100(50.76%) were >2500 g. Among 139 neonates between 1500-2500 g, 83 were preterm and 56 were term neonates and small for dates.
respiratory distress, lethargy, feeding difficulties, abdominal distension, convulsions, sclerema, hypothermia, hyperthermia, apnoea, jaundice, depressed neonatal reflexes were present in equal proportions in both clinical and blood culture positive sepsis.

Fig. 4: Clinical Manifestations among Clinical and Blood Culture Positive Sepsis

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Preterm</th>
<th>Term</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory distress</td>
<td>90(44.68%)</td>
<td>54(41.12%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>84(44.68%)</td>
<td>17(7.35%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Hyperthermia</td>
<td>6(3.19%)</td>
<td>31(13.41%)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Feeding difficulties</td>
<td>75(39.89%)</td>
<td>113(48.91%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Jaundice</td>
<td>49(26.06%)</td>
<td>59(25.54%)</td>
<td>0.93</td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>23(12.23%)</td>
<td>6(2.59%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Sclerema</td>
<td>32(17.02%)</td>
<td>18(7.79%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Vomiting</td>
<td>37(19.68%)</td>
<td>24(10.38%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Lethargy</td>
<td>136(72.34%)</td>
<td>129(55.84%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Convulsions</td>
<td>11(5.85%)</td>
<td>46(19.91%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Apnoea</td>
<td>49(26.06%)</td>
<td>2(0.86%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Depressed neonatal reflexes</td>
<td>132(70.21%)</td>
<td>56(24.24%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Umbilical erythema</td>
<td>2(1.06%)</td>
<td>1(0.43%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 5: Clinical Manifestations in Relation to Gestational Age in Clinical Sepsis

Hypothermia, abdominal distension, sclerema, vomiting, lethargy, apnoea, depressed neonatal reflexes were more frequently seen in preterm neonates than term neonates.

Fever/hyperthermia and convulsions were more frequently seen in term neonates than preterm neonates (p-value 0.0002, 0.000 respectively).

Respiratory distress, feeding difficulties and jaundice were seen with equal proportions in both term and preterm neonates (p-value 0.16, 0.06, 0.93 respectively).

Fig. 5: Clinical Manifestations in Relation to Gestational Age in Clinical Sepsis

DISCUSSION: Present study was undertaken to analyse the clinical features and bacteriological profile in neonatal septicemia.

Total admissions in NICU, Mahatma Gandhi Memorial Hospital during the study period from November 2013 to October 2014 were 2992. Among these, 419 cases were suspected of septicemia and 197 cases were of proven septicemia. So, the incidence of clinical septicaemia among the cases admitted in NICU, Mahatma Gandhi Memorial Hospital was 14% and the incidence of proven septicemia was 6.58%.

According to NNPD (2002 - 2003) reports, the incidence varying from 0.1% to 4.5% from 18 hospitals across India. The reported incidence of neonatal sepsis varies from 7.1 to 38 per 1000 live births.

Sex: Among 419 cases of clinical sepsis, 242(57.75%) were male neonates, 177(42.24%) were female neonates, ratio being 1.3:1. Male neonates were admitted with clinical sepsis more frequently than female neonates. The ratio was similar in study done by Muhammad Z et al (2010). In the study done by Waheed M et al (2003), male to female ratio was 2.1:1.

Gestational Age: In the present study, in clinical sepsis term 231(55.13%) neonates were more than preterm 92(46.7%) neonates. This was comparable to study conducted by Bhat Y R et al (2011). However, blood culture positivity was comparable in both preterm 92 (46.7%) and term (53.29%) neonates. In the study done by Shitaye D et al (2010), preterms were 60%.

Birth Weight: In this study, mean birth weight was 2167±801 g. In the study done by Bhat Y R et al(2011) mean birth weight was 2344.5 g. Among 419 cases of clinical sepsis, 105 were <1500 g (25.05%), 139 were between 1500-2500 (33.17%) g, 175 (41.76%)were >2500 g. In the study done by Manzoni P et al (2009), VLBW neonates were 38.3%.
**Clinical Manifestations:** In this study, lethargy (63.24%), respiratory distress (44.15%), feeding difficulties (44.86%) and depressed neonatal reflexes (44.86%) were observed to be common manifestations. Shitaye D et al (2010) observed hypothermia (84.8%), respiratory distress (72.8%), failure to feed (71.5%) and lethargy (30.1%) in their study. In the study done by Viswanathan R et al (2012), poor feeding and lethargy had the sensitivity of more than 85%.

Respiratory distress, feeding difficulties were found to be common manifestations in both term and preterm babies. Hypothermia, abdominal distension, sclerema, vomiting, lethargy, apnoea, depressed neonatal reflexes were more frequently seen in preterm neonates than term. This was comparable to study done by Mancilla Ramirez et al (1990).

**CONCLUSION:** Out of 2992 NICU admissions in the study period from November 2013 to October 2014, the incidence of proven septicemia was 6.58%. Lethargy, respiratory distress and feeding difficulties were common clinical manifestations. Hypothermia, abdominal distension, sclerema, vomiting, apnoea, depressed neonatal reflexes were more frequently seen in preterm neonates than term. Mortality was more in males, EOS, preterm and in very low birth weight neonates.

**REFERENCES:**