An Observational Descriptive Study on the Clinical and Bacteriological Profile   of Neonatal Septicemia

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Abstract
Background: The Neonatal Sepsis Occupies The Major Cause Of Neonatal Mortality In Developing Countries Like India, The Present Study Was Chosen To Evaluate And Understand The Clinical, Bacterial And Antimicrobial Susceptibility Profile Of These Cases To Control And Reduce The Total Neonatal Mortality. Research Question: What Are The Common Bacterial Microorganisms And Their Antimicrobial Susceptibility Pattern Associated With Neonatal Sepsis In Our Setup? The Setting Of The Study Was At NICU (Neonatal Intensive Care Unit), Department Of Pediatrics, Government Medical College, Ongole, Andhra Pradesh. A One Year Observational Study Was Conducted During The Period From January 2022 To December 2022 On About 200 Neonatal Septicemia Patients Admitted In NICU By Studying Their Socio-Demographic Profiles, Parity By The Mother, Preterm Delivery, Birth Weight, Clinical Features, Bacteriological Profile And Its Antimicrobial Susceptibility Pattern Etc. Results: There Was Significant Difference Between EOS & LOS Neonatal Septicemia With Reference To Total Number Of Cases, Mean Birth Weight, Preterm, Positive Blood Culture And Mortality Rate Etc. And Among All The Cases 29% Were Blood Culture Positive, 20% Was Mortality Rate, 25.5% Were Preterm Babies' And 2.16 Kg Was The Mean Birth Weight. Predominant Common Clinical Feature Was Lethargy (66%) Followed By Respiratory Distress (50%), Refusal To Feed (45%), Jaundice (40%), Hypothermia (25%), Abdominal Distension (20%) And Convulsions (20%) Etc. About 35% Gram - Ve Organisms Were Isolated And 14% Gram + Ve Organisms Were Isolated. Klebsiella Pneumoniae Was The Predominant Pathogen Among Gram - Ve Organisms And Staphylococcus Aureus Was The Predominant Pathogen Among Gram +Ve Organisms . Vancomycin (100%) And Meropenem (80%), Drugs Showed Highest Antimicrobial Sensitivity Whereas Ampicillin (70-80%), Cefotaxime (50-80%), Amikacin (30-50%) And Gentamycin (45-70%) Showed Highest Antimicrobial Resistance. And Also Maximum 64% Of The Study Group Belongs To Male Sex And 82% Of The Cases Are LBW Babies.
Keywords: *EOS & LOS (Early Onset Septicemia & Late Onset Septicemia), NICU (Neonatal Intensive Care Unit), LBW (Low Birth Weight) And Bacteriological Profile & Antimicrobial Susceptibility Etc*

I.   INTRODUCTION:

Sepsis in newborn is a serious medical emergency that occurs when a baby younger than 28 days old has a life threatening response to an infection and bacterial infections are the most common cause for this[1] and also it is documented by positive blood culture in first four weeks of life[2]. This Neonatal Septicemia continues to be a major cause of neonatal morbidity and mortality world wide[3]. According to World Health Organization (WHO) estimates there are about 5 million deaths a year, with 98% occurring in developing countries[4]. Neonatal mortality rate is one of the indicators for measuring the health status of the nation[3]. Neonatal Sepsis accounts for 30-50% of neonatal deaths each year in developing countries [(5,6)] and this neonatal sepsis and related mortality is largely preventable with proper antenatal and intranatal care and use of rational antimicrobial therapy along with aggressive supportive care.

In India according to data from "National Neonatal Perinatal Database" (NNPD) 2000, the incidence of Neonatal Sepsis has been reported to be 38/1000 live births in tertiary care institutions[7].Basing on the factor of

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age of onset the neonatal septicemia is broadly divided into two types: Early onset sepsis (<72 hrs) and late onset sepsis (>72 hrs – 28days) [8]. And it is caused by a veriety of Gram negative as well as Gram positive bacteria and sometimes yeasts[9]. The spectrum of organisms that causes Neonatal sepsis changes overtimes and varies from region to region which is due associated with many factors like therapeutic, life style, social and cultural etc.[10]

So the present study was carried out to determine the clinical bacteriological profile along with antimicrobial susceptibility pattern isolated from the blood of septicemic neonates' admitted in NICU in order to provide appropriate management of the cases.

II.   MATERIAL & METHODOLOGY:

The setting of the study was at NICU, Department of Pediatrics, Government Medical College, Ongole, Andhra Pradesh, India. The study was conducted during the period from January 2022 to December 20202 According to the hospital census the prevalence of the neonatal cases admitting to NICU was found to be 52% and the sample size was calculated by using the formula $N=4P/L^2$ where $P=35.5\%$, $Q=100\text{-}P$ that is 64.5% and L=20% allowable error in 'P' that is 7%, so N=182 and assuming there may be 10% attrition, additional 10% was taken which was calculated and rounded to 200. All the cases of clinically diagnosed Neonatal septicemia admitted in NICU during the above period up to reach the required sample size was included in the study after duly following the inclusion and exclusion criteria and obtained the informed written consent from the mother by duly explaining the detailed procedure and purpose of the study. The babies of the mothers those who were given willingness to come into study was used as inclusion criteria. The objectives of the study were 1.To isolate and identify the pathological bacterial agents responsible for Neonatal Septicemia and to determine the drug susceptibility pattern of these organisms. 2. To study the clinical features and associated factors of Early and Late Onset Neonatal Septicemia.

After receiving the Ethical committee clearance from the institution the study was began and the required data was collected by using a pretested proforma pertaining to their socio-demographic profiles, risk factors, clinical features and the results of blood culture along with antimicrobial susceptibility pattern etc. All the cases (patients) of the study were managed and followed until discharge. In this study the antimicrobial susceptibility testing was performed by "Kirby –Bauer disc diffusion susceptibility method" in accordance to the guidelines framed by clinical laboratory standards institutes.

Finally the collected data was analyzed by using appropriate statistical tools like percentages, proportions, measures of central tendency, measures of dispersion, standard error of mean and tests of significance with the help of computer software. The study results were compared and discussed in the light of published material of various similar studies belongs to different authors and there by conclusions and recommendations were framed.

III.   RESULTS:

Table-1
Sex wise distribution of LBW factor among EOS & LOS Cases

SI.No.	Sex	LBW (n = 164 % = 82%)		Total
		EOS	LOS	
1.	Male	72(31%)	34(17%)	106(64.6%)
2.	Female	38(19%)	20(10%)	58(35.3%)
Total		**110(67%)**	**54(33%)**	**164(100%)**

Source: Primary Data   **P<0.01**

Significant difference was observed between EOS & LOS cases with regard to LBW distribution among male and female study group.
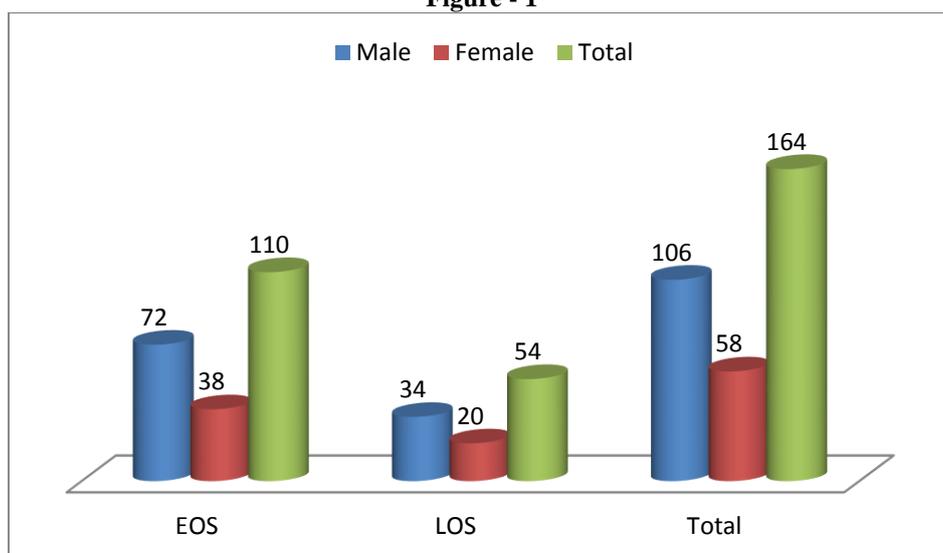
Figure - 1

Table-2
Early Onset Septicemia Vs. Late Onset Septicemia

Factor of High risk	< 72 hrs EOS	>72 hrs LOS	P-Value	Total
1.Number of cases	134 (67%)	66 (33%)	P<0.01	200(100%)
2. Mean birth weight	2.07 kg	2.25 kg	-	1.16 G
3.Preterm	40 (30%)	16 (8%)	P<0.01	56 (28%)
4. Birth Anoxia	62 (46.2%)	18 (27%)	P<0.01	80 (40%)
5 .Positive Blood Culture	36 (26.8%)	17 (25.7%)	P>0.05	53 (26.5%)
6. Mortality	25 (19%)	15 (15%)	P<0.01	40 (20%)

Source: Primary Data

It was observed that there was significant difference between EOS & LOS Neonatal Septicemia with reference to mean birth weight, preterm, positive blood culture and mortality pattern except H/o birth anoxia.

Table-3
Clinical Presentation of Neonatal Septicemia

SI.No.	Sign/Symptom	No.of Cases	Percentage
1.	Refusal to feed	132	66%
2.	Respiratory Distress	100	50%
3.	Lethargy	90	45%
4.	Jaundice	80	40%
5.	Hypothermia	50	25%
6.	Abdominal distention	40	20%
7.	Convulsions	40	20%
8.	Sclerema	24	12%
9.	Fever	20	10%
10.	Hepatomegaly	20	10%
11.	Vomiting	14	7%
12.	Cyanosis	12	6%
13.	Diarrhea	4	2%

Source: Primary Data

Predominant common feature was Lethargy (66%), followed by Respiratory Distress (50%), Refusel to feed (45%), Jaundice ((40%), Hypothermia (25%), Abdominal distension (20%) and Convulsions (20%) etc.
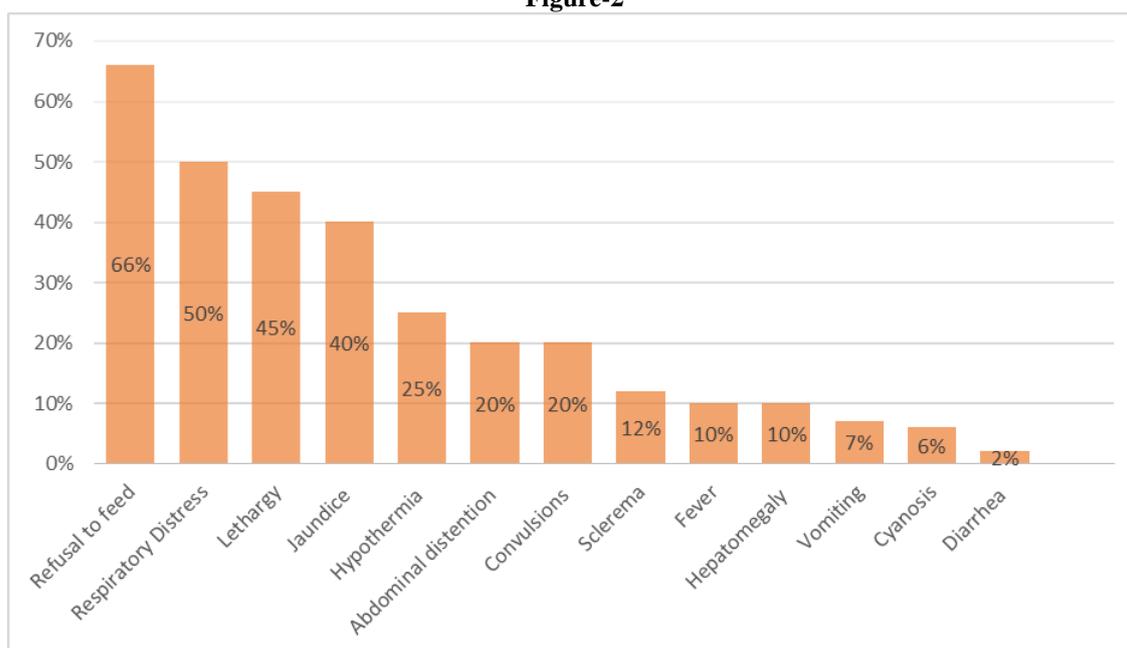
Figure-2

Table-4
Bacteriological Profile and Antibiotic susceptibility Pattern

Bacteria isolated	EOS (m=39 %=67%)	LOS (m=19 %=32.8%)	Total (m=58 %=29%)	Cef Line	Amp	Cip	Amp	Genta	Mero	Van
				Antimicrobial Resistance in %						
Gram -ve organisms Klebsiella Pneumonia	18(46.1%)	8(42.1%)	2.6(44.32%)	68.8	75	80	40	60	0	-	-
Escherichia coli	7(17.9%)	4(2.1%)	11(18.9%)	54	65	80	48	70	25	0	0
Pseudomonas	3(7.6%)	2(10.5%)	5(8.6%)	90	80	90	36	55	0	0	0
Total	28(71.7%)	14(73.6%)	42(72.4%)							
Gram +ve organisms Staphylococcus aureus	8(20.5%)	3(15.7%)	11(18.9%)	70	70	90	36	60	14	0	0
CONS	3(7.6%)	2(10.5%)	5(8.6%)	80	78	70	33	45	0	-	-
Total	11(28.2%)	5(26.3%)	16(27.5%)							

Cef:CefotaximeAmp:Ampicillin,Cip:Ciprofloxacin,Amik:Amikacin,Genta:Gentamicin,Mero:Meropenem ,Van:Vancomicin,Line:Linezolid,CONS:Coagulase Negative Staphylococci. P<0.01
Klebsiella was the commonest pathogen isolated among all the bacteria and among all Gram negatives Staphylococcus was the commonest pathogen isolated among all the Gram positives

IV. DISCUSSION:

It was observed in this study that the neonatal septicemia was more among male babies (64%) when compared to female babies (34%) which correlates with the figures of Rekha Sriram et al study [11], Naeeye et al study [7], and Jyothi P et al [12] study. And significantly it was noticed that out of the total LBW babies (82%) more number of babies (67%) belong to EOS neonatal septicemia as it was also observed in many other studies. In this study the total number of EOS (<72 hrs) were 67% where as LOS (>72 hrs) accounted for 33%. Similar findings were observed in P Jyothi et al [12], Vrishali Avinash Muley et al [13], Movahedian et al [14] and many other studies. With reference to association .of high risk factors like mean birth weight, preterm, percentage of positive blood culture, birth anoxia and mortality rate etc there was significant difference between EOS & LOS seen in this study. As our present study was associated with higher number of LBW babies (82%), preterm babies (28%) and 20% of mortality rate correlating to studies of other workers like NB Mathur et al [15], Rekha

Sriram et al [11], Saxena et al [16], SS Tallur et al [17], Khatua et al [18] and Buetow KC et al [19] which means that the above factors were strongly associated with the higher incidence of Neonatal Septicemia in our set up.

Regard to the clinical presentation of cases in our study predominant common feature was Refusal to feed (66%) followed by Respiratory distress (50%), Lethargy (45%), Jaundice (40%), Hypothermia (25%), and Abdominal Distention (20%) and Convulsions (20%) etc. was observed. But on other studies like Jimba Jotsho et al [20] Respiratory Distress (66%), followed by fever (43%) feeding intolerance (38%), Jaundice (29%) and Lethargy (25%) were noticed as common features and also in studies like Chandan kumar Shawa et al [21] Janudice (80%), SS Tallur et al [17] Respiratory distress and Jaundice, Dr. Deependra Garg et al [22] refusal to feed, poor sucking & Jaundice were quoted as the predominant common features.

In our study the total Blood culture positivity was 29% among which EOS 67.2% & LOS 32.8% contributed in accordance to the other studies Vrishali Avinash Muley et al[13] , (26.6%), Pavan Kumar et al [23] (26.2%), Mathur M et al [24] (24.88%), P Jyothi et al[12] (19.2%) and Mohakud NK et al[25] (25.8%) but lower percentage of positivity was seen in Kaistha N et al[3] (13%), Jimba Jatsha et al[20] (14%) & Nikhita Sing Yadav et al[26] (16.9%) whereas higher percentage was noticed interestingly in Murthy et al[27] (52.6%) ( ) Rajendra Prasad et al[28] (47.5%), & Sharma et al[29] (56%) studies with the significant difference between EOS & LOS. The prior administration of antibiotics and the possibility of infection with anaerobes might be the factors associated with low blood culture isolation rate. Normally the blood culture positivity rate varies between 25% to 60% for aerobic organisms[30].

In our study the Gram negative and Gram positive septicemia was reported to be 72.4% & 27.5% respectively which was comparable to the findings of the studies conducted by P Jyothi et al[12] 68% & 32% , Kaistha N et al[3] 80% & 20% . Kumar GD et al[31] 60% & 40% , Agnihotri et al[32] (59%) & (41%) and Priyam Vada Roy et al[33] (57% & 43%) etc. Klebsiella spp was the predominant Gram negative pathogen (44.8%) isolated in this study which correlates with the report of the National-Neonatal-Perinatal- Database (29%)[30] and reports made by the other workers[3,12,13,17,20,24,25,34]. And similarly Staphylococcus aureus was the predominant Gram positive pathogen (18.9%) isolated in our study which was also the same finding in many other studies [12,13,20,23,24,25,26,31].

And we also studied the antibiotic susceptibility pattern for all the bacterial isolates and the maximum resistance was observed to Ampicillin whereas least was to Linezolid and Vancomycin which was supported by the work of other researchers also [3, 12, 13,23, 25, 26, &36]. The high resistance pattern was observed against the commonly used antibiotics such as Ampicillin, Amikacin, Gentamicin and Cefotaxime etc which were proven by the other studies also [17, 20]. So it is understood that inappropriate and frequent use of antibiotics, not following the therapeutic dose & schedule of usage, over the counter availability of antibiotics and getting prescription from non-qualified medical practitioners etc. may be the factors associated with high & multi drug resistance pattern in developing countries and under developed countries. And in this study the maximum antibiotic sensitivity was observed for Linezolid, Vancomicin and Meropenem etc as these drugs are not being used indiscriminately and the same observation was supported by other studies also [3,12,13,& 26] .

V. CONCLUSIONS AND RECOMMENDATIONS:
- In this study it was observed that as EOS was much common than LOS, more attention should be paid towards strengthening of antenatal services in order to control and prevention of premature deliveries as well as LBW babies in the community, early reach of hospital in case of PROM, increase of awareness levels regarding maternal hygiene among pregnant ladies and peripheral health care workers and overall measures should be taken to raise the standard of living of people belong to below poverty line etc. And also to decrease the incidence of LOS in our setup it is important to implement comprehensive and systematic infection control measures like establishment and proper functioning of "Hospital Infection Control Committees" in every hospital and conducting periodical workshops to the personnel working in the hospital regarding hand working practices, personal hygiene and how to maintain aseptic environment at treating places etc.
- Regular blood culture testing for isolation of organisms and knowing antibiotic susceptibility pattern allows us to use empirical and rational use of appropriate antibiotics in NICUs. And also as our study reported that the higher percentage of resistance was observed mainly against to commonly used antibiotics like Ampicillin, Amikacin, Gentamicin and Cefotaxime etc. it is alarming us to take precautions towards availability and usage of antibiotics through supervision and prescription by qualified medical practioners (Registered at medical council) to the patients.

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