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Clinical and Epidemiological Profile of Neonatal Sepsis in Referral Care NICU in South Kerala

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Abstract
Introduction: *Neonatal sepsis continues to be a major cause for mortality and morbidity in neonates. It is 30 per 1000 live birth in India. The prevalence is more in preterm babies. As more preterm babies are now surviving.*
Objective: *To describe the clinical and bacteriologic spectrum of neonatal sepsis in referral neonatal intensive care unit.*
Secondary objective: *To compare risk factors and bacteriologic spectrum in early onset and late onset sepsis.*
Setting: *Tertiary care referral center in a teaching hospital in South Kerala.*
Study period: *January 2014 to December 2016.*
Design: *Retrospective cohort study.*
Methods: *All neonates admitted were assessed for bacterial sepsis.*
Inclusion criteria included presence of one or more of the established clinical features, along with ≥2 of the laboratory criteria (total blood leukocyte count <5000/>15000, absolute neutrophil count (ANC) <500 cells/mm ^{3} or >1500/mm ^{3}, immature to total neutrophil ratio >0.2, micro erythrocyte sedimentation rate (ESR) >15/1 h, C-reactive protein (CRP) >0.6 µg/ml, positive blood culture. Information assessed in a proforma. Cases were divided into early onset sepsis (EOS) (presenting in the first 72 h) and late onset sepsis (LOS) (presenting after 72 h).All cases were started on antibiotics and managed as per SAT hospital protocol and later upgraded or stopped based on culture and sensitivity. Cases were followed-up to discharge/death.
Results: *There were 5202 admissions during study period. Of this 586 were of suspected sepsis.RDT was positive in 346 patients (59.04 %).Of these neonates 126 (36.4%) had culture positive sepsis. The incidence of culture positive sepsis was 126/546(21.5%). Of these 68(54%) was Early onset sepsis (EOS) and 58(46%) late onset sepsis (LOS). The total deaths were 353. Of these 9 deaths has culture positivity. The common organisms were Staphylococcus (35)27.8%, Klebsiella (25)19.8%, Acinetobacterium (24)19%, Pseudomonas (16)12.7% & E coli (8)6.3%, CONS (1) 1%.*
Conclusion: *The incidence of culture positive sepsis was 21.5%. Of these 54%was Early onset sepsis (EOS). The common organisms were Gram negative organisms in both EOS& LOS. Gram positive organism Staphylococcus aureus is also a major contributor in neonatal sepsis in our study. Acinetobacter sepsis is high (19%) in our study.*

Introduction

Neonatal Sepsis characterized by generalized bacterial infection documented by a positive blood culture in the first 4 weeks of life along with a clinical syndrome characterized by systemic signs of infection. [1]It is one of the most important cause of neonatal death worldwide along with prematurity and asphyxia. In USA 1-8/1000 live births suffer from sepsis, in preterm it can be as high as 30/10002. Sepsis occurring in the first 72 hours of life is defined as early-onset sepsis (EOS) and that occurring beyond 72 hours as late-onset sepsis (LOS) [2].Neonatal sepsis is a significant cause of morbidity and mortality among neonates.

In the developing world, Escherichia coli, Klebsiella species, and Staphylococcus aureus are the most common pathogens of EOS, whereas S. aureus, Streptococcus pneumoniae, and Streptococcus pyogenes are the most commonly reported organisms in LOS. The spectrum of organisms causing EOS & LOS are different and they change rapidly over time and is influenced by various external factors .The spectrum of organisms of EOS and LOS sepsis are similar in hospital setting. The significance lies in the fact that the etiological agents of EOS are from maternal flora or during delivery and EOS is usually from community or from health care associates[3].

Kerala is a state with best health indices in India[4]. With India emerging as a country with high Antibiotic resistance rate, it is prudent that the clinical and bacteriological profile are studied[5]. This will help to identify risk factors early and institution of appropriate antibiotics, so that we can reduce the neonatal mortality. Ours is a major tertiary care referral center for all over the state including cardiac care due to proximity with Sree Chitra Thirunal Institute for Medical Science & Technology, a major cardiac surgical center.

Various risk factors are described for neonatal sepsis. Maternal factors include fever, premature rupture of membranes > 24hrs, chorioamnionitis; fetal factors include prematurity, low birth weight[7]. Clinical features of early onset sepsis are apparent in few hours of life. The signs and symptoms may be subtle. Hence treating pediatrician should have high index of suspicion. RDT (micro ESR, CRP, ANC, IT ratio) are commonly used to detect sepsis. Blood culture is needed for bacteriologic conformation. The yield is usually low[4,5] CRP and procalcitonin are also used to identify neonatal sepsis and for prognostication[6]. We have attempted to look at the pattern of neonatal sepsis in our hospital. This will help in identifying the pattern of bacteriologic profile in our sick neonates. This will help in choosing appropriate antibiotics and will also help to develop neonatal antibiotic protocols.

Method

A retrospective cohort study was done in out born unit of the neonatal intensive care unit, Department of Pediatrics Government Medical College, Thiruvananthapuram, Kerala, India, After due permission of the ethical committee of our institute. The culture and sensitivity pattern of cases of neonatal sepsis from 1st January 2014 to 31st December 2016 were collected. Neonates with clinical features of sepsis were included in the study with age 0-28 days. Inclusion criteria included presence of one or more of the established clinical features such a fever/hypothermia, poor feeding, poor activity, respiratory distress/apneic spells, hepatosplenomegaly, abdominal distension, vomiting, seizures, signs of either circulatory or respiratory dysfunction (evidenced by tachycardia/bradycardia/capillary refill time of >3 s and respiratory rate ≥60/chest in drawing and/or grunt respectively) along with ≥2 of the laboratory criteria (total blood leukocyte count <5000/>15000, absolute neutrophil count (ANC) <500 cells/mm 3 or >1500/mm 3 , imamture to total neutrophil ratio >0.2, micro erythrocyte sedimentation rate (ESR) >15/1 h, C-reactive protein (CRP) >6 µg/ml, positive blood culture)

Information regarding maternal (age,, parity, referral hospital, prolonged rupture of membranes, predisposing factors and neonatal (gestational age, sex, birth weight, time of onset of symptoms, antibiotic treatment were assessedin a proforma.

One hundred and twenty six neonates with confirmed sepsis were enrolled. Cases were divided into early onset sepsis (EOS) (presenting in the first 72 h) and late onset sepsis (LOS) (presenting after 72 h) All cases were started on antibiotics and managed as per SAT hospital protocol and later upgraded or stopped based on culture and sensitivity. Cases were followed-up to discharge/death.

Blood culture was routinely sent for all neonates admitted in NICU as per protocol using aseptic technique.2ml of blood is collected in 5ml of liquid broth .Blood culture is reported by the microbiologist. CSF analysis as well as culture was done only in suspected cases of meningitis and the late onset sepsis. Urine examination and culture were performed only for selected cases. Details were entered into MS Excel and analyzed by SPSS 18 for Windows. Rates and proportions were calculated. Significance testing for discrete variables were done by Chi square test. For continuous variables t test was done.

Aims& Objectives

Primary objective

- To describe the clinical and bacteriologic spectrum of neonatal sepsis in referral neonatal intensive care unit

Secondary objective

- To identify prevalence of sepsis in NICU
- To compare risk factors and bacteriologic spectrum in early onset and late onset sepsis

Results

There were 5202 admissions during study period. Of this 586 were suspected sepsis. RDT was positive in346 patients (59.04 %). The presumed sepsis during the same period was 346/5202 (6.65%). Of these neonates 126 (36.4 %) had culture positive sepsis. Hence the incidence of culture positivity in our study was 126/546 (21.5%). Of these 68(54%) was Early onset sepsis (EOS) and 58 (46%) late onset sepsis (LOS). The total deaths were 353. Of these 9 deaths has culture positivity. Male:Female ratio was 73:53(1.37:1). As our unit was a referral unit for out born neonates, 67(53.2%) were delivered in government hospitals, 41(32.5%) in private hospitals, 6 reffered from SCTIMST (4.8%)& others 12 (9.5%).Others included home deliveries, vehicle deliveries etc.60(47.6%) were born normally & 66 (54.45) were born by caesarean section. The referral letter showed maternal complications in only 5(4%).History of perinatal depression was documented in only 3(2.4%).Only 1 baby was given antibiotics before referral. Of the neonates 107(84.9%) were term neonates.105 were AGA (83.3%) 18 (14.3%) were SGA and 3 were LGA.

Table 1 showing common clinical presentations in culture positive sepsis

	N	%
Resp distress	27	21.4%
Temp instability	13	10.3%
Jaundice	12	9.5%
Poor feeding	12	9.5%
seizures	6	4.8%
Abdominal distention	2	1.6%
Cyanosis	3	2.4%
Hypoglycemia	2	1.6%
Bleeding	1	0.8%

Table 2 showing comparison of clinical features in EOS & LOS

	EOS(N =68)	LOS (N=58)	P value
M:F	35:33	38:20	0.14
AGA:SGA	53:15	55:3	0.02(sig)
Preterm; Term	11:57	8:58	0.8
N:LSCS	33:35	27:31	0.85
Maternal infection	4	2	0.66
PROM	5	6	0.68
Asphyxia	3	0	0.24
Resp distress	20	7	0.4
Poor feeding	4	8	0.2
seizures	3	3	0.13
Temperature instability	7	6	0.1
cyanosis	1	2	0.1
Hypoglycemia	1	1	1
Bleeding	0	1	0.1
CRPhigh	27	35	0.03(Sig)
TLC<5000	23	24	0.1
ANC<1500	24	13	0.1
IT ratio>0.2	13	12	0.24
Platelet<1lakh	13	10	0.12
Deaths	6	3	0.72

Table 3 showing bacteriologic spectrum in neonatal sepsis

	EOS 68	LOS 58	(Tota)l%
Staphylococcus	12	23	(35)27.8%
Klebsiella	18	7	(25)19.8%
Acinetobacter	16	8	(24)19%
Pseudomonas	9	7	(16)12.7%
E coli	4	4	(8)6.3%
Hemolytic streptococci	2	2	(4)3.2%
Enterococci	1	2	(3)2.4%
CONS	1	1	(2)1.6%
MRSA	1	1	(2)1.6%
others	4	2	(6)4.8%

Discussion

Neonatal sepsis is a clinical syndrome of bacteremia with features of systemic signs and symptoms of infection in first 4 weeks of life. This is a very vulnerable period. As per National Neonatal Perinatal Database 2002-2003, the incidence of neonatal sepsis in India was 30/1000 live birth.[4] Many studies have reported clinical sepsis rates ranging from 49 to 170/1000 live births in rural India.[5]This study was done in tertiary care of teaching hospital level 2 NICU which admitted neonates born outside hospital. Kerala is in forefront in various child health indicators. Neonatal mortality in Kerala is lowest in India.[4] The rate of hospital delivery in our state is more than 95%.

The presumed sepsis during the study period was 6.65%. Of these neonates 126 (36.4 %) had culture positive sepsis. The incidence of culture positivity in our study was 21.5%. Many of the studies report sepsis in hospital born neonates .A study from Vellore have reported sepsis occurred in 9.8 per 1000 live births and 4.4% of all nursery admissions.[7]. An advantage of inborn neonates is that the data are readily available for observation. But in state like Kerala with more than 60 % of health care is met by private sector, Hence high proportion of deliveries occur there but get referred to our Centre for neonatal care. Hence it is appropriate to look into neonatal sepsis in babies delivered outside our institution. Many of the details are not recorded also. A study from Andhra Pradesh comparing the incidence and mortality rates of neonatal sepsis between two different time periods (June 2003-May 2004 and June 2013-May 2014) of a decade apart found that the overall incidences of sepsis remained same (6.04 and 6.03%) but the incidence of EOS decreased from 3.08% to 2.57% and LOS increased from 2.96% to 3.44% of total pediatric admissions[6]. In a similar study from North India [8, 9] reported an increase in the incidence of LOS from 12 to 16.5/1000 live births. In our study 73 were males (57.9%) In Vellore study, Eighty five (68.3%) were male infants.[7]. In a study from Nepal, 61.4% infants were males and 38.6% were female infants. Similar higher rate of septicemia in male was also reported by Karambin and Zarkesh from Iran [11] and Al-Shamahy et al. from Yemen[12].

As our unit was a referral unit for out born neonates 67 (53.2%) were delivered in government hospitals, 41(32.5%) in private hospitals, 6 referred from SCTIMST, cardiac centre (4.8%)& others 12(9.5%). Others included home deliveries, vehicle deliveries etc. 60(47.6%) were born normally & 66(54.45%) were born by cesarean section. In a study from Egypt, 69.7% were delivered by caesarean section whereas 30.3% were delivered vaginally. The cesarean rate in our study is higher than national average. The referral letter showed maternal complications in only 5(4%). History of perinatal depression was documented in only 3(2.4%). Only 1 baby was given antibiotics before referral. Of the neonates 107(84.9%) were term neonates. 105 were AGA (83.3%) 18 (14.3%) were SGA and 3 were LGA. In our study 15.1% were preterm neonates whereas in Vellore study it was 9.8%. In our study the mean gestational age was 37.1(± 3.34) weeks. In Vellore study, the mean GA of infected babies was 36.1(± 3.5) weeks and mean BW was 2280 (± 805) g. The mean gestational age and birth weight of the study population from another study were 34.4 ± 3.8 weeks and 2124 ± 828 grams, respectively[13]. In our study there were 126 culture positive neonates. The prevalence for culture positive sepsis was 21.6%. Emam El-din

reported, the burden of septicemia among total suspected cases was confirmed in 116 infants by positive blood culture growth giving a prevalence rate of 40.7% [13].Of 126 culture positive sepsis, 68(54%) was Early onset sepsis (EOS) and 58(46%) late onset sepsis (LOS). From Vellore, Kuruvilaetal had thirty (24%)neonates having EOS and 95 (76%) having late onset sepsis (LOS).The cutoff of time they used was 48 hours. In another study, EOS was reported in 82 (70.7%) neonates and LOS in 34 (29.3%) neonates.[12] Emam El-din reported140 (40.7%) cases by positive blood culture: 49 from early-onset and 91 from late-onset sepsis. There was a significant difference in the positivity rate between EOS and LOS groups ($P < 0.05$).[13] The result indicated that the incidence of EOS septicemia was more common than LOS which is consistent with other reports from many developing countries [10, 14,15,16,17,18 .

In our study commonest organisms were Staphylococcus (27.8%), Klebsiella (19.8%). Acinetobacterium (19%). (Table3) Gram negative sepsis was high in EOS & LOS, but Gram positive staphylococci was seen more in LOS. Kuruvila reported Commonest organisms isolated were Klebsiella (31.2%) followed by Escherichia coli (18.7%), Staphylococcus aureus (18.7%) and coagulase negative staphylococci (16.7%). Less frequently isolated organisms were streptococci, Pseudomonas and enterococci. Gram-negative bacteremia carries higher risks of complications and death. Sundaram et al. reported a neonatal mortality rate due to Gram-negative sepsis of 34% to 55% 20. Even in the present study, Gram-positive organism constituted the major group of isolates accounting for 27.8%. A study from Egypt reported 63.8% (higher proportion) of Gram-positive organism in this study corroborates with 74% reported by Jain l et al. from Nepal 21, 69% reported by Dagnew et al. from Ethiopia [22, and 68% reported by Mutlu et al. from Turkey [24]. Early-onset neonatal sepsis is caused by microorganisms acquired from the mother before or during birth. Hence microorganisms from the maternal genital tract are important. In a study from Nepal, CONS was the most common cause of both EOS and LOS accounting for nearly half of the cases (46.6%) followed by S. aureus (14.6%)10. Among Gram-negative organisms, Acinetobacter spp (9.5%) were the most common organism isolated from EOS cases while Enterobacter spp. were the predominant organism from LOS cases.[10] Similar rates of CoNS and S. aureus isolates were also reported by Dagnew et al. from Ethiopia 22. E. coli and E. fecalis were the predominant organisms causing EOS, while Klebsiella and E. fecalis were the predominant organisms in LOS High index of suspicion must be there for early detection of sepsis. Acinetobacter baumannii was isolated in a study from Egypt in 5% of positive blood cultures of septic neonates accounting for 8.16% and 3.30% in EOS and LOS, respectively. [13]In our study there were 24 cases (19%). The total deaths were 353 during the study period. Of these 9 neonates had culture positivity (2.5%). Banghietal had reported that fatality due to sepsis is between 30% and 65%. [5]The mortality rates are much less in our study than others.[4,12,13]

Conclusion

The incidence of culture positive sepsis was 21.5%. Of these 54% was Early onset sepsis (EOS). The common organisms were Gram negative organisms in both EOS& LOS. Gram positive organism Staphylococcus aureus is also amajor contributor in neonatal sepsis in our study. Acinetobacter sepsis is high (19%) in our study.

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Contributors: SSE patient care, data collection
GS wrote the draft and analyzed the data
SKS Head of Neonatal unit, supervised patient care

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