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Clinical Profile, Outcome of Neonatal Sepsis and Statistical Analysis of Sepsis Screening Markers for Early Diagnosis

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Abstract:
Introduction*: neonatal septicemia is a major cause of morbidity and mortality,overall incidence varies between 1-8 cases/1000 live births,It accounts for 50%of neonatal mortality,clinical features are non specific and early diagnosis of sepsis poses great difficulties.Though the positive blood culture is diagnostic but it is time consuming and has success rate of only 40%,so its highly necessary to analyse early indirect septic marker to diagnose septicemia in early stage.*
Aim & objectives.*: 1.To analyse the clinical profile,predisposing factors and outcome of neonatal sepsis 2.To analyse statistical signicance of various septic markers.*
Materials & methods: *The study was descriptive prospective study conducted in meenakshi medical college hospital over 1 year period from June 2014 to June 2015.100 neonates with strong suspicion of sepsis were included in this study.*
Results*: The male female ratio was nearly 2:1, majority of them were low birth weight and prematurity 68% and 60% respectively, c-reactive protein had highest sensitivity(88.2%),specificity(87.8%)and positive predictive value(78.9%) followed by m-ESR sensitivity(70.6%),specificity(84.8%) and positive predictive value(70.5%), case fatality rate was 28%.Out of 28 deaths premature(64.2%) and low birth weight babies(64.2%) constitute major group. higher mortality observed in gram negative sepsis (64.25%).*
Conclusion*: There were male preponderance, mortality was high in ealry onset, gram negative sepsis. As an individual test c- reactive protein had highest sensitivity,specificity and positive predictive value .Combination of 3 tests(CRP,m-ESR,toxic granulation) increase specificity and positive predictive value but decrese the sensitivity.****keywords: CRP,*** *m-esr,sepsis,*

I. Introduction

Systemic infection in first month of life have remained as major cause of mortality and morbidity despite the development of broad spectrum antimicrobial agents. Overall incidence varies between 1-8 cases/1000 live births[1].It accounts for 50%of neonatal mortality,clinical features are non specific and symptomatology is mimicked by various other disorders affecting the newborn[2]. Early diagnosis of sepsis poses great difficulties.though the positive blood culture is diagnostic but it is time consuming that demands a well equipped laboratory and has success rate of only 40%,therefore blood culture has its own limitation.

Early treatment with rationale antibiotic therapy is possible with the help of certain indirect markers such as leucopenia,toxic granules,band form tol neutrophil ratio,mESR.c rective protein.this investigations are collectively known as sepsis screening. The early diagnosis of neonatal sepsis by clinical examination is vital.In the precence of predisposing fators,early clinical suspicion coupled with sepsis screening will detect neonatal sepsis earlier,which will enable the clinician to treat the infection timely and accurately, which in turn will to reduce the neonatal morbidity and mortality

II. Materials and Methods

The study was conducted in rural teaching institute over a period of one year from June2014 to June2015.100 neonates with strong clinical feature suggestive of sepsis in the form of,irritability, lethargy,refusal of feeds,vomiting, abdomen distension,skin rashes, apnea,respiratory distress,with or without fever were included in this study.Neonates admitted in our hospital from outpatient department and neonates born in our hospital were included in this study group.After admission the study group subjected to detailed history,thorough clinical examination.Sepsis screening done including complete blood count,peripheral smear for toxic granules and band cell to neutrophil ratio,m-ESR and c reactive protein.Bio chemical investigations-blood sugar,calcium,electrolytes, microbiological investigations including nonenteric culture also were done. CXR was taken when indicated.The clinical progression and outcome were monitored.Outcome measure noted were death due to illness and recovery.Recovery was defined as neonates who showed improvement in the form of good activity,feeding,themostability.Sensitivity,specificity,and positive predictive value of each sepsis markers were analysed.

III. Results and Analysis

100 neonates were included in this study.Out of them 66 (66%) were male and 34 (34%)were female, male babies were more affected than female babies,the male female ratio was 2:1. Early onset sepsis was present in 68 cases (68%) and late onset sepsis in 32 babies (32%). Majority of them 68 (68%) had birth weight of <2.5 kg while 32 (32%) had >2.5 kg, There were 60 (60%) preterm and 40 (40%) term in the study population as shown in table 1

Major neonatel risk factors were low birth weight and prematurity 68% and 60% respectively.Maternal risk factors observed were poor maternal hygiene(58%), prolonged rupture of membrane>18 hrs(30%), Home delivery(24%)as shown in table 2.Common clinical manifestations of neonatal sepsis were refusal of feeds(56%),temperature bnormality(46%),sclerema(42%),jaundice(42%),pallor(36%),lethargy(24%),rash(20%) and convulsions(16%) shown in table 3 .Out of 100 neonates 0nly 34 (34%) were bacteriologicaly positive. Among, gram positive and gram negative organisims constitute 28(28%) and 6(6%) respectively.Remaining 66(66%)were bacteriologicaly negative.

Statistical analysis of each sepsis screeningmarker were analysed as shown in table4 and comparision of sensitivity, specificity,and positive predictive value of each test showed in table5, c-reactive protein had highest sensitivity(88.2%),specificity(87.8%)and positive predictive value(78.9%) followed by m-ESR sensitivity(70.6%),specificity(84.8%) and positive predictive value(70.5%),specificity and positive predictive value were increased at the cost of sensitivity. When combination of tests done,the best combination was c-reactive protein+mESR+toxic granulation. Outcome measure noted were recovery and death due to illness during hospital stay.Case fatality rate was 28%,Out of 28 deaths premature(64.2%) and low birth weight babies(64.2%) constitute major group. Higher mortality observed in gram negative sepsis (64.25).

Table 1: Distribution of cases according to Sex, age of onset of septicemia, birthweight, Maturity

Sex	**Male**	**Female**	**Total**
No.of cases	66	34	100
Age of onset	**< 7 days**	**>7 days**	**Total**
No. of cases	68	32	100
Birth weight	**≤ 2500 gm**	**>2500 gm**	**Total**
No. of cases	68	32	100
Maturity (Gestational age)	**Preterm**	**Fullterm**	**Total**
No. of cases	60	40	100

Table 2 predisposing factors

predisposing factors	**No of cases**
Low birth weight	68(68%)
prematurity	60(60%)
Poor maternal health and hygiene of genitals	58(58%)
Prolonged rupture of membrane>18 hrs	30(30%)
Home delivery	24(24%)
Resuscitation after birth	16(16%)
Pre mature rupture of membrane <37 wks	14(14%)
H/o intrapartem maternal infection	8(8%)
Bad obstetric history	6(6%)
Umblical discharge	6(6%)
No obvious factors detected	14(14%)

Table-3 Clinical profile of neonatel sepsis

Clinical features	**No of cases**	**%**
Refusal of feeds	56	56%
Temperature abnormality	46	46%
sclerema	44	44%
jaundice	42	42%
pallor	36	36%
lethargy	24	24%
rash	20	20%
convulsion	16	16%
Abdomen distension	20	20%
irritability	8	8%
pustules	6	6%

Table-4 Investigation profile

Variants	Culture		
WBC count	**Bacteriologicaly positive(34)**	**Bacteriologicaly negative(66)**	**Total(100)**
≤ 5000/cmm	16 (47%)	22(33.3%)	38
>5000/cmm	18(53%)	44(66.6%)	62
Toxic granulation			
Present	24(70.5%)	24(36.3%)	48
Absent	10(29.4%)	42(63.6%)	52
Bandcell/neutrophil ratio			
B/N≥ 0.2	30(88.2%)	24(36.3%)	54
B/N<0.2	4(11.8%)	42(63.6%)	46
Micro ESR			
≥ 15mm/1 hour	24(70.5%)	10(15.1%)	34
<15mm/1 hour	10(27.4%)	56(84.8%)	66
C-reactive protein			
positive	30(88.2%)	8(12.2%)	38
negative	4(11.8%)	58 (87.8%)	62

Table-5 Comparison of sensitivity, specificity, positive predictive value of each test and combination of two or more test

Test	sensitivity	specificity	Positive predictive value
Wbc count≤5000cmm	47%	66.6%	42.1%
B/N> 0.2	88.2%	63.6%	62.4%
Toxic granulation	70.5%	63.6%	50%
m-ESR>15mm/hour	70.5%	84.4%	70.5%
CRP	88.2%	87.8%	78.9%
Combination of tests			
CRP +toxic granulation	58.5%	90.9%	76.9%
CRP +m-ESR	64.6%	93.9%	84.6%
Toxic granulation+m-ESR	58.8%	87.8%	71.6%
CRP+mESR+toxic granulation	47.4%	93.9%	88.8%

CRP- c reactive protein

Table 6 Variants affecting outcome of neonatal sepsis

variants	outcome		
	Recovered (72)	**Expired (28)**	**Total (100)**
Maturity			
Preterm	42(58.5%)	18(64.2%)	60
Term	30(41.5%)	10(35.7%)	40
Birth wt			
<2.5kg	50(69.4%)	18(64.2%)	68
≥ 2.5kg	22(30.5%)	10(35.7%)	32
Age of onset			
≤7days	48(66.6%)	20(71.4%)	68
>7days	24(33.3%)	8(28.6%)	32
Gram staining			
Gram positive	4(5.5%)	2(7.1%)	6
Gram negative	10(13.8%)	18(64.2%)	28
Bacteriologicaly negative	58(80.5%)	8(28.5%)	66

IV. Discussion

The neonate is extremely vulnerable to infection in first 28 days of life,death and morbidity during this period are very high. Sepsis accounts for 25 -40% of all neonatal death, hence early diagnosis of sepsis is important to influence outcome. Neonatal sepsis commonly affect male neonates, male preponderance (66%)documented in this study comparable with Nelson et.al2 ,Piyush gupta et.al3 and Khatua et.al4.Majority of them(68%) presented with early onset sepsis consisted with other studies.In this study increased incidence of early onset sepsis may be due to maternal risk factors. In 86% of cases predisposing factors were present,common neonatal factors observed were prematurity(60%) and low birthweight(68%). Which is consistant with other conventional studies[1 2] .Commonly obsevered clinical feature were refusal of feeds(56%),temperature abnormality(47%),sclerema(45%),jaundice(41%)pallor(36%),lethargy(24%) rash(21%) and convulsion(17%) as noted in other studies like khatua et.al4,Agarwal et.al5 and Anand et.al6.All the studies showed that clinical feature of neonatal sepsis were non specific[1 2].In this study among culture positive cases, gram negative organisims constitute 82.3%, which is comparable with khatua et.al4,Sharma et.al7,James overall et.al8

A battery of indirect markers of sepsis when collectively studied provide an extremely reliable index of neonatal sepsis much earlier and serve as a useful guide for initiating antibiotic therapy,in this study leucopenia had poor positive predictive value(PPV)(42.1%). The sensitivity(70.56%),specificity(63.65%), and PPV(50%) of toxic granulation and B/Nratio were comparable with Namedo et.al9 and study done by Xanthou10 .m-ESR had 70.5% sensitivity,84.8% sensitivity,70.5% PPV were higher than leucopenia and B/N ratio. C reactive protein had highest sensitivity (88.2%),specificity(87.8%)andPPV(78.95%) among all septic markers,Squire et.al11 and Singh et.al12 were observed the same in their studies.combination of 3 test had low sensitivity(47%),high specificity(93.9%) and PPV(88.8%) which is consistant with Mishra et.al13 and Singh et.al12.The best combination of septic marker in this study was c- reactive protein and m-ESR The case fatality rate was 28% in this study.Mortality was high in premature(64.2%) and low birth weight(64.2%) neonates consistant with Khauta et.al4 and Mishra et.al13, may be attributed to poor defence mechanisms.In this study mortality was high in eary onset and gram negative sepsis,Khatua et.al4 and Bhatia et.al14 observed the same findings in their study.higher fatality in gram negative sepsis probably due to the emergence of drug resistance for commonly used antibiotics

V. Conclusion

Clinical features of neonatal sepsis are nonspecific and vague. There were male preponderance, mortality was high in ealry onset, gram negative sepsis. As an individual test c- reactive protein had highest sensitivity,specificity and positive predictive value and is a sensitive and renponsive indicator of neonatal sepsis. Combination of 3 tests(CRP,m-ESR,toxic granulation) increase specificity and positive predictive value but decrese the sensitivity.

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