Original Research Article

A study of maternal risk factors associated with early onset neonatal sepsis at tertiary health care centre

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Abstract

Background: Neonatal sepsis is a clinical syndrome of bacteraemia characterized by systemic signs and symptoms of infection in the first month of life. It may be categorized as early or late onset sepsis. **Materials and Methods:** The study will be carried out as observational study in PESIMSR, Department of Obstetrics and Gynecology between 2018 to 2019. Total number of deliveries during the study period in our institution- 4393 deliveries, Total number of beds in NICU with facilities -24. Babies born with alleged maternal risk factors for sepsis were included in the study Infants were assessed at birth and followed up by the neonatologists. All the mothers with various risk factors for development of Early onset of sepsis admitted in OBG department, PESIMSR, KUPPAM. All the inborn neonates born to the mothers of various risk factors for development of Early onset of sepsis will be followed up till discharge for development of sepsis. **Results:** In the present study, prelabour rupture of membranes/preterm pre labour rupture of membranes as a risk factor for early onset sepsis was found in 52.3%. In the present study, multiple per vaginal (PV) examinations after rupture of membranes during labour was found only in 22% of study subjects. **Conclusion:** Maternal risk factors are not the only cause for development of EOS, neonatal risk factors and interventions are also important. Early onset Neonatal sepsis is due to interplay of multiple and complex maternal and fetal treatment protocols. Current study showed that conventional maternal risk factor which was earlier thought to be strongly associated with early onset neonatal sepsis were not significant due to early identification of risk factors in mother and their management.

Key Words: Neonatal sepsis, bacteraemia, NICU.

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INTRODUCTION

Neonatal sepsis is a clinical syndrome of bacteraemia characterized by systemic signs and symptoms of infection in the first month of life. It may be categorized as early or late onset sepsis.

Early onset neonatal sepsis – sepsis occurring within 72 hours of life

Early onset sepsis syndrome is associated with acquisition of microorganism from mother. Transplacental infection or an ascending infection from cervix may be caused by organisms that colonize in the mother's genitourinary tract. The infant may acquire the microbe by passage through a colonized birth canal during delivery.[1]

Late onset neonatal sepsis – sepsis occurring after 72 hours of life

Late onset sepsis syndrome is acquired from environment. The infant's skin, respiratory tract, conjunctiva, gastrointestinal tract and umbilicus may become colonized from the environment, leading to the

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possibility of late onset sepsis from invasive microorganisms. Vector for such colonization include vascular or urinary catheters, other indwelling lines or contact from caregivers with bacterial colonization[1]. Neonatal sepsis encompasses systemic infection of the newborn including septicemia, meningitis, pneumonia, arthritis, osteomyelitis and urinary tract infection of the newborn[2].Globally of the 130 million babies born every year, about 4 million die in the first 4 weeks of life, i.e. neonatal period. The main direct causes of neonatal deaths are Estimated to be preterm birth (28%), severe infection (26%), and birth asphyxia (23%)[3].According to recent data from National Neonatal Perinatal Database (NNPD) 2002-03 collected from 18 centers from various parts of India, incidence of neonatal sepsis has been reported to be 29.9 per 1000 live births. Early onset sepsis contributed 67% of all sepsis. Meningitis contributed to 10.6% of all cases of sepsis. Neonatal sepsis was one of the common causes of neonatal mortality contributing to 16% of all intramural deaths[4]. Neonatal septicemia with its high incidence and its grave prognosis, in spite of adequate treatment with modern antibiotics, has been a challenge for all times. Optimal diagnosis and treatment strategies are difficult to define. The signs and symptoms are associated with a high mortality and thus there is urgent need to know whether the baby has sepsis, to institute treatment as quickly as possible, Confirmation of the diagnosis by definitive culture is not possible rapidly[5].

AIMS AND OBJECTIVES

- To determine the maternal risk factors associated with early onset of sepsis in neonates
- To identify and explore each maternal risk factor and to develop a predictable septic score.

MATERIALS AND METHODS

The study will be carried out as observational study in PESIMSR, Department of Obstetrics and Gynecology between 2018 to 2019.

- Total number of deliveries during the study period in our institution- 4393 deliveries
- Total number of beds in NICU with facilities – 24

Babies born with alleged maternal risk factors for sepsis were included in the study Infants were assessed at birth and followed up by the neonatologists.

STUDY PERIOD: 18 months (January 2018 – June 2019)

STUDY DESIGN: Cross-sectional Observational study

STUDY AREA: PES Institute of Medical sciences, Kuppam

STUDY POPULATION:

- All the mothers with various risk factors for development of Early onset of sepsis admitted in OBG department, PESIMSR, KUPPAM.
- All the inborn neonates born to the mothers of various risk factors for development of Early onset of sepsis will be followed up till discharge for development of sepsis

INCLUSION CRITERIA

Babies born to mothers with alleged risk factors for sepsis were included in the study. These alleged risk factors included:

- Pre-labour rupture of membranes – rupture of membranes at least one hour before onset of labour pain
- Mothers having had three or more vaginal examinations after rupture of membranes
- Intrapartum fever
- Foul smelling liquor
- Meconium stained amniotic fluid
- Untreated or partially treated maternal urinary tract infection in the antenatal period.
- High risk neonates like LBW , prematurity more than 28 weeks, low APGAR <4 at 5 min needing resuscitation

EXCLUSION CRITERIA

- Babies born at gestational age less than 28 weeks, weighing less than 1000 grams
- Newborns with severe congenital anomalies
- Mothers not willing to be part of this study

SAMPLE SIZE CALCULATION

Based on the incidence of sepsis as 20.6% among early onset sepsis in a Punjab study, Formula :

$n = Z2\ 1\text{-}\alpha/2 * p\ (100\text{-}p) \div d2$

- Z value for 95% CI = 1.96
- Expected prevalence p = 20.6
- Precision = 0.07 (7%)

By applying these values, sample size is 128.

SAMPLING TECHNIQUE: Convenient sampling

Procedure for data collection:

- All patients attending the outpatient department of OBG and satisfying the fore mentioned inclusion and exclusion criteria will be recruited in the study after informed consent and approval from ethical committee.
- A detailed history will be taken as per the prepared questionnaire along with complete physical examination.

Tools and techniques to be used:

Information regarding following investigations will be collected from the patients

- MOTHER: CBC, Urine R/E, high vaginal swabs, cervical swabs, urine c/s depending on clinical diagnosis
- New Born: Blood culture and sensitivity, septic screen , CXR/CSF examination depending on clinical diagnosis

Plan of Analysis of data:

The data will be entered In to MS Excel 2007 version and further analyzed using STATA14.

- For descriptive analysis, the categorical variables will be analyzed by using percentages and continuous variables will be analyzed by calculating mean +/- Standard deviation.
- For inferential analysis, tests such as 't test' , chi square test etc, will be applied and $p < 0.05$ will be considered as statistically significant.

RESULTS

Table 1: FREQUENCY AND PERCENTAGE DISTRIBUTION OF PROM /PPROM (N=128)

PROM/PPROM	Frequency	Percentage (%)
PRESENT	67	52.3%
ABSENT	61	47.7%

In the present study, prelabour rupture of membranes/preterm pre labour rupture of membranes as a risk factor for early onset sepsis was found in 52.3%.

Table 2: FREQUENCY AND PERCENTAGE DISTRIBUTION OF MULTIPLE PV (N=128)

MULTIPLE PV	Frequency	Percentage (%)
PRESENT	29	**22.6%**
ABSENT	**99**	**77.4%**

In the present study, multiple per vaginal (PV) examinations after rupture of membranes during labour was found only in 22% of study subjects.

Table 3: FREQUENCY AND PERCENTAGE DISTRIBUTION OF LIQUOR STATUS(N=128)

LIQUOR STATUS	Frequency	Percentage (%)
MECONIUM STAINED	38	29.7%
CLEAR	90	70.3%

In the present study, thick meconium stained liquor was found only in 29% of study subjects.

Table 4: FREQUENCY AND PERCENTAGE DISTRIBUTION OF FOUL SMELLING LIQUOR (N=128)

FOUL SMELLING LIQUOR	Frequency	Percentage (%)
PRSENT	5	4.0%
ABSENT	123	96.0%

In the present study, foul smelling liquor was found only in 4% of study subjects.

Table 5: FREQUENCY AND PERCENTAGE DISTRIBUTION OF INTRAPARTUM FEVER (N=128)

INTRA PARTUM FEVER	Frequency	Percentage (%)
PRESENT	5	4.0%
ABSENT	123	96.0%

In the present study, intra partum fever was found only in 4% of study subjects.

Table 6: FREQUENCY AND PERCENTAGE DISTRIBUTION OF UTI IN ANTENATAL PERIOD (N=128)

UTI IN ANTENATAL PERIOD	Frequency	Percentage (%)
PRESENT	6	4.7%
ABSENT	122	95.3%

In the present study, urinary tract infection during ante natal period was found only in 4.7% of study subjects.

Table 7: FREQUENCY AND PERCENTAGE DISTRIBUTION OF SEPTIC SCORE (N=128)

SEPTIC SCORE	Frequency	Percentage (%)
<4	78	60
4 OR >4	50	40

In the present study, septic score 4 or >4 were found in 50% of newborn babies born to mothers with risk factors.

Table 8: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH PROM/PPROMRISK (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	PROM/PPROM	Frequency	Percentage	Frequency	Percentage	
	ABSENT	10	43.5	51	48.6	
	PRESENT	13	56.5	54	51.4	0.658

Early onset proven neonatal sepsis was found to be more among the mothers with prelabour rupture of membranes/preterm prelabour rupture of membranes (56.5%), however this difference was not statistically significant(P>0.05)

Table 9: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH MULTIPLE PER VAGINAL EXAMINATIONS AFTER RUPTURE OF MEMBRANES RISK (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	MULTIPLE PV'S	Frequency	Percentage	Frequency	Percentage	
	ABSENT	15	65.2	84	80	
	PRESENT	8	34.8	21	20	0.125

Early onset neonatal sepsis was found to be more among the mothers without multiple per vaginal examinations after rupture of membranes, however this difference was not statistically significant (P>0.05)

Table 10: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH LIQUOR STATUS (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	LIQUOR STATUS	Frequency	Percentage	Frequency	Percentage	
	CLEAR	19	82.6	71	67.6	
	THICK MSL	4	17.4	34	32.4	0.154

Early onset neonatal sepsis was found to be more among the mothers without thick meconium stained liquor during intrapartum period (82%), however this difference was not statistically significant (P>0.05)

Table 11: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH FOUL SMELLING LIQUOR (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	FOULSMELLING LIQUOR	Frequency	Percentage	Frequency	Percentage	
	ABSENT	22	95.6	101	96.0	
	PRESENT	1	4.4	4	4.0	0.904

Early onset neonatal sepsis was found to be more among the mothers without foul smelling liquor during intrapartum period (95%), however this difference was not statistically significant(P>0.05)

Table 12: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH INTRAPARTUM FEVER (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	INTRAPARTUM FEVER	Frequency	Percentage	Frequency	Percentage	
	ABSENT	23	100	100	95.2	
	PRESENT	0	0.00	5	4.8	0.286

Early onset neonatal sepsis was found to be more among the mothers without fever during intrapartum period (100%) , however this difference was not statistically significant(P>0.05)

Table 13: ASSOCIATION OF EARLY ONSET NEONATAL SEPSIS WITH UTI IN ANTENATAL PERIOD (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	UTI IN ANTENATAL PERIOD	Frequency	Percentage	Frequency	Percentage	
	ABSENT	22	95.6	100	95.2	
	PRESENT	1	4.4	5	4.8	0.932

Early onset neonatal sepsis was found to be more among the mothers without urinary tract infection in the ante natal period (95%) , however this difference was not statistically significant(P>0.05)

Table 14: ASSOCIATION OF SEPTIC SCORE (Perinatal and neonatal risk factors)WITH EARLY ONSET NEONATAL SEPSIS (N=128)

S.No	Variables	RESULT				P Value
		PROVEN SEPSIS (CULTURE POSITIVE)		PROBABLE SEPSIS (CULTURE NEGATIVE/CLINICAL SEPSIS)		
1.	SEPTIC SCORE	Frequency	Percentage	Frequency	Percentage	
	< 4	15	65.3	63	60	
	4 OR> 4	8	34.7	42	40	0.642

Early onset neonatal sepsis was found to be more among the mothers with septic score less than 4 (65%) , however this difference was not statistically significant(P>0.05).

DISCUSSION

Neonatal septicaemia is one of the major contributors of neonatal morbidity and mortality. The present study was undertaken to determine the association of maternal risk factors on early onset neonatal sepsis. In this section we compared the results of our study with the studies done by different authors.

TABLE 15: Distribution of PROM/PPROM among participants in different studies

SL.NO	YEAR	STUDY	% of PROM/PPROM
1	2014	Gauri Shankar shah *et al*[58]	38%
2	2015	Muhammad hayun *et al*[59]	43%
3	2015	Mamtajajoo *et al*[60]	56%
4	2016	Asia jabiri *et al*[61]	49%
5	2016	Usha Christopher *et al*[62]	70%
6	2017	Rajukumar *et al*[63]	28%
7	2018	Violet Okabakayom *et al*[64]	94%
8	2019	Aberamersha *et al*[65]	17%
9	2019	Present study	52%

With regard to pre labour/preterm pre labour rupture of membranes, similar findings were reported in other studies as in the present study were Muhammad hayun *et al*(43%), Mamtajajoo *et al* (56%) , Aslajabiri *et al*(49%). Contrast to present study, studies of Aberamersha *et al* (17%), Rajukumar *et al* (28%) , Gauri Shankar shah *et al*(38%) were reported slightly lower values and studies of Violet Okabakayom *et al* (94%),Usha Christopher *et al*(70%)were reported slightly higher values.

TABLE 16: Distribution of Multiple per vaginal examinations among participantsin different studies

SL.NO	YEAR	STUDY	% OF MULTIPLE PV'S
1	2015	Mamtajajoo *et al*	35%
2	2016	Usha Christopher *et al*	45%
3	2017	Rajukumar *et al*	36%
4	2018	Violet Okaba Kayom *et al*	6.2%
5	2019	Aberamersha *et al*	23%
6	2019	Present study	22%

With regard to Multiple per vaginal examinations, similar findings were reported in other study as in the present study was Abersamersha *et al* (23%). Contrast to present study, study of Violet Okabakayom *et al* (6%) was reported lower value and studies of Usha Christopher *et al* (45%), Rajukumar *et al* (36%), mamtajajoo *et al* (35%) were reported slightly higher values.

TABLE 17: Distribution of meconium stained liquor among participants in different studies

SL.NO	YEAR	STUDY	% of MECONIUM STAINED
1	2014	Gauri Shankar shah *et al*	17%
2	2015	Muhammad hayun *et al*	14%
3	2015	Mamtajajoo *et al*	22%
4	2017	Rajukumar *et al*	26%
5	2019	Aberamersha *et al*	6.2%
6	2019	Present study	29%

With regard to liquor status (colour of liquor) , similar findings were reported in other studies as in the present study were rajukumar *et al* (26%), mamtajajoo *et al* (22%). Contrast to present study, studies of Aberamersha *et al* (6.2%), muhammadhayun *et al* (14%), Gauri Shankar shah *et al* (17%) were reported slightly lower values

TABLE 18: Distribution of foul smelling liquor among participants in different studies

SL.NO	YEAR	STUDY	% of FOUL SMELLING LIQUOR
1	2014	Gauri Shankar shah *et al*	0.7%
2	2015	Mamtajajoo *et al*	22%
3	2016	Ushachristopher *et al*	2.4%
4	2019	Aberamersha *et al*	33%
5	2019	Present study	4%

With regard to foul smelling liquor, similar findings were reported in other studies as in the present study were Gauri Shankar *et al*(0.7%), Ushachristopher *et al*(2.4%).Contrast to present study, studies of Aberamersha *et al*(33%), mamtajajoo *et al*(22%)were reported higher values. Similar to the present study pre labour/preterm pre labour rupture of membranes was found to be not significantly associated with early onset neonatal sepsis in Usha Christopher *et al*, Rajukumar *et al*, Aberamersha *et al* studies. contrast to the present study , Gauri Shankar shah *et al* , Aslajabiri *et al* , Violet Okabakayom *et al* studies reported significant association between pre labour/preterm pre labour rupture of membranes and early onset neonatal sepsis . In A systematic review and meta-analysis done by shrutimurthy *et al* which included several epidemiological studies and reported that PROM/PPROM is an important risk factor in early onset neonatal sepsis even though it is not significant statistically. Present study shows higher proportion of culture positive cases with PROM/PPROM even though it was not significant statistically, which is comparable with other studies. This probably reflects that Hospital, being a tertiary referral hospital, has maximum late referral and intervened cases with higher proportion of babies born with adverse intrapartum and neonatal risk factors for neonatal sepsis.

CONCLUSION

Maternal risk factors are not the only cause for development of EOS, neonatal risk factors and interventions are also important. Early onset Neonatal sepsis is due to interplay of multiple and complex maternal and fetal treatment protocols. Current study showed that conventional maternal risk factor which was earlier thought to be strongly associated with early onset neonatal sepsis were not significant due to early identification of risk factors in mother and their management. High index of suspicion is needed for the diagnosis of early onset neonatal sepsis as early management is life saving. Hence high risk maternal and fetal risk factors to be taken in to consideration for monitoring and investigating newborn. This current study shows early identification and effective management of maternal risk factors results in reduced EOS. Presence of maternal risk factors just mean there is possibility for development of neonatal sepsis and doesn't establish the diagnosis.

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