Original Article

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Paediatrics Section

Early Onset Sepsis and its Relation with Maternal Vaginal Infection: A Prospective Observational Study

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ABSTRACT

Introduction: The risk of Early Onset Sepsis (EOS) is higher in newborns born to mothers with vaginal infections. High Vaginal Swab (HVS) is a simple technique for identifying causative organisms and for early detection of newborns at risk of sepsis. This method helps us to detect the organism in the vaginal canal, and thus help in understanding the causative organism and early initiation of empiric antibiotics for EOS in newborn infant.

Aim: To evaluate the role of HVS culture in detecting the maternal vaginal infection and its relationship with EOS in newborns.

Materials and Methods: The present prospective observational study was conducted at Department of Paediatrics, Prashanthi Hospital a tertiary care hospital at Warangal, Telangana state of India, over a period of two years, extending from June 2022 to May 2024. The study included all mothers with term gestation having vaginal discharge, Prolonged Rupture of Membranes (PROM) and chorioamnionitis. A total of 112 cases were collected, from the mothers included age, parity, delivery method, PROM, presence of chorioamnionitis, and maternal fever. The neonatal birth weight, gender, A- Appearance (skin color), P- Pulse (heart rate), G- Grimace (reflex irritability), A- Activity (muscle tone) and R- Respiration (breathing effort) (APGAR) scores, need for resuscitation, respiratory distress, lethargy, feeding difficulty, and need for treatment along with lab parameters were collected. Chi-square test was applied to test the association between the maternal HVS status and early onset neonatal sepsis. A p-value of <0.05 was considered significant.

Results: The mean age of mothers was 26±2.47 years. Among 112 patients with suspected infection, HVS culture was positive in 75 (66.9%) and was found to be culture negative in 37 (33.1%) of women. The newborns, who were born to mothers who's HVS culture was positive, 64 (85.3%) of newborns had sepsis screen positive. The association between the maternal HVS positive culture and sepsis screen in newborn were statistically significant (p<0.001).

Conclusion: The risk of developing EOS in newborns born to mother with vaginal infection is high. Hence, HVS is simple and easy technique to identify the causative organism and prevent the morbidity and mortality in both mother and newborns.

Keywords: Chorioamnionitis, Newborn, Prolonged rupture of membranes, Swab culture, Vaginal discharge

INTRODUCTION

Neonatal sepsis occurs from birth to 28 days of life. It is a cause for concern in the current era. About 28 newborns per 1000 live births develop sepsis in the neonatal period and approximately five of them will die of sepsis. The global burden of disease estimates 1.3 million cases of neonatal sepsis, approximating to 937 cases per 100,000 live births annually [1]. In a hospital-based Indian study, the incidence of EOS was reported as 20.7 per 1000 live births [2]. Morbidity and mortality following neonatal sepsis is higher in Low and Middle-Income Countries (LMICs) [3]. Chaurasia S et al., in their study found that the pooled incidence of culture positive sepsis in hospital-based reports from South Asia is 15.8 per 1000 live births. This shows a twofold to fourfold higher incidence than that reported in high income countries [4].

Vaginal colonisation by pathogenic microorganisms, particularly Multidrug-Resistant Organisms (MDROs), poses a serious risk for vertical transmission to newborns either before or during delivery cause about 80% of cases of Early-Onset Sepsis (EOS) occuring in the first week of life [5]. Nearly 30-45% of newborns are prone for surface colonisation if they were born to a colonised mother, suggesting a high rate of transmission of infection via direct contact through the birth canal. Infections or colonisation with some species of bacteria in the vaginal compartment during pregnancy may cause amniotic fluid infection, thus vertically transmitting infection to fetuses [6].

Easily available and affordable tools are needed to aid in early identification of risk factors associated with EOS. HVS is a simple method by which mothers who have the risk factors can be screened at an early stage and identify those newborns at risk of developing EOS. This method helps us to detect the organism in the vaginal canal, and thus help in understanding the causative organism of EOS in newborn infant. HVS is a technique that can be easily expertise and implemented in health centers. Simplicity of the technique enables it to be used widely and making it a possibility to confirm vaginal infection microbiologically [7,8].

The facilities for identification of maternal vaginal infection through HVS are unavailable in most healthcare centers which is leading to late identification of causative organism of sepsis in neonates and thus contributing to high incidence of morbidity and mortality. While maternal vaginal colonisation has been described previously [9,10], there is limited and antiquated evidence on the association of intrapartum HVS culture for early-onset neonatal sepsis, particularly in Low- and Middle-Income Countries (LMIC) [6,11-13]. Early detection of the organism causing the vaginal infection by HVS culture is helpful in starting empirical antibiotics before the symptomatic baby's blood culture findings are received. Hence, the present study was conducted to evaluate the role of HVS in detecting the maternal vaginal infection and its relationship with EOS in newborns.

MATERIALS AND METHODS

This prospective observational study was conducted at Prashanthi Hospital located in Warangal city in the state of Telangana, India, over a period of two years, extending from June 2022 to May 2024. The hospital is a 240 bedded unit with annual deliveries of around 1500 which caters mainly to lower and upper middle socioeconomic class population according to modified Kuppuswamy classification [14]. The Neonatal Intensive Care Unit (NICU) receives both intramural and extramural newborns. The study was approved by the Institutional Ethical Committee (IEC no: ECR/1301/Inst/TG/2019). Written informed consent of all patients involved in the study was taken in a language easily understood by the patient.

Inclusion criteria: The study included all mothers who completed ≥37 weeks of gestation and who were having vaginal discharge, chorioamnionitis, and PROM of >18 hours.

Exclusion criteria: The exclusion criteria of the study were mothers who were haemodynamically unstable, newborns with perinatal asphyxia, and those mothers not giving consent.

Sample size: A convenience sample size of 112 was considered for the study over a period of two years from June 2022 to May 2024.

Study Procedure

The data was collected in a predesigned proforma. The maternal data included age at pregnancy, obstetric index, gestational age at delivery, concerns at the time of admission, intrapartum antibiotics taken, and mode of delivery. A HVS was taken from these antenatal women and sent for culture and sensitivity on the day of delivery. The infant data collected was the birth weight, APGAR score, resuscitation required at birth, clinical manifestation at admission, timing of admission, laboratory details, therapeutic measures undertaken and the outcome of the infant.

Terminologies used are defined as follows [15]:

- Suspected sepsis: Regardless of whether there is a clinical symptom or not, the presence of sepsis risk factors in the baby or findings suggesting sepsis in follow-up during birth hospitalisation.
- Proven sepsis: clinical and laboratory findings are present and demonstration of pathogenic microorganism in blood culture taken from a sterile field.

Clinical chorioamnionitis [16] is an intrapartum clinical diagnosis based on presence of fever - either ≥39.0° C once or 38.0° C to 38.9°C on two or more measurements 30 minutes apart without another clear source PLUS one or more of the following:

a) Baseline foetal heart rate >160 beats/min for ≥10 minutes, excluding accelerations, decelerations, and periods of marked variability;

b) Maternal White Blood Cell (WBC) count >15,000 cells/mm3 in the absence of corticosteroids and ideally showing a left shift;

c) Purulent-appearing fluid coming from the cervical os is visualised on speculum examination.

High Vaginal Swab (HVS): After reassuring the mother, the technique employed for HVS collection involved the application of a sterile, bivalve speculum per vaginum and an autoclaved swab stick is introduced into posterior vaginal fornix carefully by gynaecologist and sample is collected which is then immediately transferred to laboratory.

Risk factors and clinical features of sepsis in neonates: clinical chorioamnionitis, foul smelling liquor, preterm PROM (pPROM), PROM, intrapartum fever of ≥38° C. The clinical features suggestive of sepsis in newborns include, not feeding well, convulsions, movement only when stimulated, respiratory rate >60/min, severe chest in drawing and axillary temperature >38° C or <35.50° C [17].

The blood sample of neonates born to mothers with HVS swab culture positive was sent for sepsis screening. The neonates of culture negative mothers but with risk factors of sepsis, were also followed-up and observed for 72 hours for signs suggestive of sepsis.

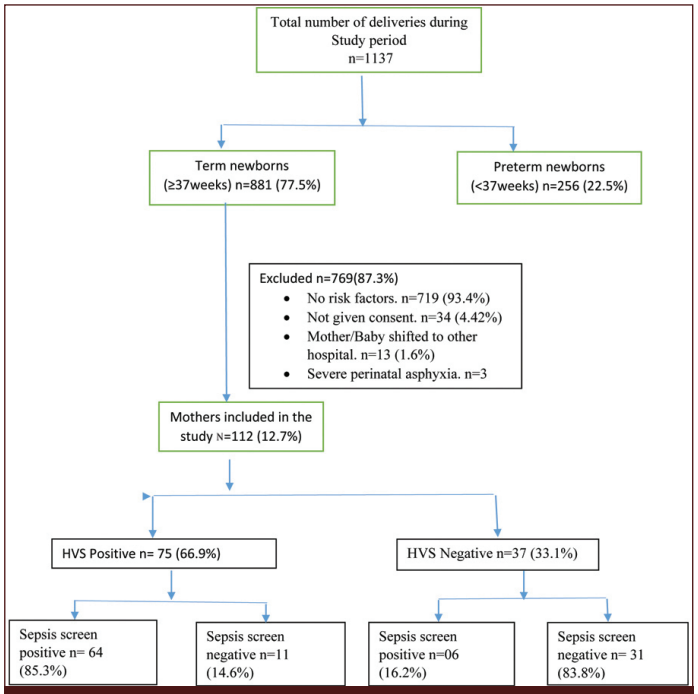
Sepsis screen was sent for those with above mentioned clinical manifestations along with blood culture. Blood culture positive babies were done lumbar puncture to rule out meningitis n=3 (0.4%).

STATISTICAL ANALYSIS

Data entry was done using MS Excel and analysed using Statistical Package for Social Sciences (SPSS) version 22.0 for MS Windows. Descriptive statistical analysis was carried out to explore the distribution of several categorical and quantitative variables. Categorical variables were summarised with n (%) while quantitative variables were summarised by Mean±SD. the categorical variables tested by Chi-square test. The p-value less than 0.05 considered to be statistically significant.

RESULTS

A total of 1137 babies were born during the study period. Amongst them 881 (77.5%) were term and 256 (22.5%) were born preterm. A total of 769 (87.3%) term babies were excluded from the study based on exclusion criteria. A total 112 (9.85%) newborns who were eligible after applying the inclusion and exclusion criteria were included in the study [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart of study participants.
HVS: High vaginal swab

Maternal demography [Table/Fig-2]: Majority of the antenatal mothers in the present study were less than 30 years old with a mean age of 26±2.47 years. The study had most 103 (91.9%) patients registered with their obstetrician. Spontaneous conception was seen in 71 (63.3%) patients with 66 (58.9%) of them were multigravida in the current study. The Lower Segment Caesarean Section (LSCS) was done in 60 (53.6%) cases of study population

forming the mode of delivery in the study group. A total of 70 (62.5%) of the included patients had fever at presentation followed by PROM in 19 (16.9%) and per vaginal discharge in 11 (9.82%). The HVS sample was taken from these mothers who were suspected of having infection. Among those patients with suspected infection HVS culture was positive in 75 (66.9%) and negative in 37 (33.1%) of the women.

Maternal parameters	n (%)
Age (Mean±SD)	26.6±2.47 years
Registration	103 (91.9%)
Obstetric index	
Primi	46 (41.1%)
Multi	66 (58.9%)
Type of conception	
Spontaneous	71 (63.3%)
ART	41 (36.6%)
Mode of delivery	
NVD	52 (46.4%)
LSCS	60 (53.6%)
Clinical feature	
Fever	70 (62.5%)
PV discharge	11 (9.82%)
PROM	19 (16.9%)
Culture positive UTI	12 (10.7%)
HVS in at risk women	
Positive	75 (66.9%)
Negative	37 (33.1%)

[Table/Fig-2]: Maternal baseline demographic and clinical parameters (N=112).
ART: Artificial reproductive technique; NVD: Normal vaginal delivery; LSCS: Lower segment caesarian section. PV: Per vaginal. PROM: Premature rupture of membranes; HVS: High vaginal swab; UTI: Urinary tract infection

Neonatal demography: The mean gestational age of the infants was 38.3±1.1 weeks. The mean birth weight of the neonates was 2600±290 grams. Majority (63.4%) of the newborns were boys. The LBW was seen in 40 newborns (35.7%). Of the babies included in the study, 98 (87.5%) had symptoms and 14 (12.5%) did not have symptoms of EOS. The most common symptoms in newborns were lethargy in 76 (67.9%) followed by respiratory distress in 66 (58.9%), fever in 16 (14.2)%, feeding difficulty in 8 (7.1%) of the newborns. Among the newborns who were symptomatic the sepsis screen was positive in 64 (65.3%) newborns. All the included babies had mean APGAR score of 8.92±0.7 at five minutes of life. Only 11 (9.8%) babies required tactile stimulation and 2 (1.8%) required positive pressure ventilation at the time of birth. The newborns who had sepsis screen positive, 23 (20.6%) of them had blood culture positive for pathogenic organism. Neonatal baseline characteristics, clinical features, management and outcome in neonates with EOS are shown in [Table/Fig-3]. Majority of the newborns who had sepsis were discharged with no morbidity at the time of discharge.

Variables	n (%)
Baseline characteristics	
Gestational age (Mean±SD)	38.3±1.1 weeks
Birth weight (Mean±SD)	2600±290 gm
LBW (2500 gm) n (%)	40 (35.7%)
APGAR score at 5 min (mean±SD)	8.92±0.7
Tactile stimulation	11 (9.8%)
PPV	02 (1.8%)
Gender of newborns	
Male	71 (63.4%)
Female	41 (36.6%)
Clinical features	
Symptomatic	98 (87.5%)
Asymptomatic	14 (12.5%)
Time of admission (Mean±SD)	5.73±10.98 hours
Fever	16 (14.2%)
Feeding difficulty	08 (7.1%)
Lethargy	76 (67.9%)
Respiratory distress	66 (58.9%)
Combination of ≥2 features	08 (7.1%)
Laboratory values (Mean±SD)	
TLC	12220.26±6617.28
ANC	3534.54±1313.24
ITR	0.15±0.12
CRP	11.30±13.21
Micro ESR	6±4.80
Positive sepsis screen	
Symptomatic (n=98)	64 (65.3%)
Asymptomatic (n=14)	06 (42.85)
Management n (%)	
Antibiotics	41 (36.6%)
Inotropes	20 (17.8%)
CPAP for ≥24 hours	34 (30.3%)
Blood culture n (%)	
Positive	23 (20.6%)
Negative	89 (79.4%)
Outcome n (%)	
Discharge	104 (92.8%)
Death	8 (7.2%)
Duration of hospital stay with EOS overall (Mean±SD)	7.5±2.6 days

[Table/Fig-3]: Neonatal baseline characteristics, clinical features, management and outcome in neonates with Early Onset Sepsis (EOS) (n=112).
LBW: Low birth weight; CPAP: Continuous positive airway pressure; TLC: Total leucocyte count; ANC: Absolute neutrophil count; ITR: Immature to total neutrophil ratio; CRP: C-reactive protein; ESR: Erythrocyte sedimentation rate; PPV: Positive pressure ventilation

The newborns, who are born to mothers who's HVS culture was positive, 64 (85.3%) of newborns had sepsis screen positive. The association between the maternal HVS positive culture and sepsis screen in newborn were statistically significant (p<0.001) [Table/Fig-4].

HVS	Sepsis screen positive (n=70)	Sepsis screen negative (n=42)	p-value
Positive (n=75)	64 (85.3%)	11 (14.6%)	0.001
Negative (n=37)	06 (16.2%)	31 (83.7%)	

[Table/Fig-4]: Relationship of HVS with Neonatal EOS screening (N=112).
HVS: High vaginal swab; EOS: Early onset sepsis

DISCUSSION

The present study had shown that the newborns who were born to mothers who had HVS culture positive are at increased risk of developing the EOS. Among the infants born to HVS culture positive mothers, 64 (85.3%) out of 75 were having sepsis screen positive.

Among the infants who were sepsis screen positive, 23 (30.6%) were positive for the blood culture for pathogenic organism similar to the organism isolated from HVS culture from their mothers.

Lower Genital Tract Infections (LGTI) are strongly associated with major adverse pregnancy outcomes such as Spontaneous Preterm Delivery (SPTD), PROM, and Low-Birth-Weight (LBW) babies [18,19]. In the study by Nagdev N et al., neonatal admissions were required in 60% of cases of mothers with LGTI. Intra Uterine Fetal Deaths (IUFD) and neonatal deaths were observed in only laboratory-positive cases. The study had concluded that there is a strong association between HVS culture positivity and adverse pregnancy outcomes such as Preterm Delivery (PTD), PROM, IUFD, neonatal deaths, and neonatal admissions due to sepsis in newborn caused due to maternal vaginal infection [20]. The present study also has shown a significant association between the maternal vaginal infection and presence of EOS in newborn.

In a study of 1792 mothers, Ayengar V et al., observed that 72% of the cases involved vertical transfer of infection from the mother's vaginal infection to the newborn (13). In contrast to the 56.6% (1001) in the low-risk group, the mothers of the 26 infants who were deemed to be at high-risk of developing sepsis displayed 100% blood culture positive for EOS. Twenty-four of the 48 infected babies had organisms which were identical to those isolated from their mother's vaginal flora, showing vertical transmission of organisms in 1.3% of the total population included in the study. The same organisms could be identified in 18 of 25 mother-baby- dyads in high-risk group, constituting 72% vertical transmission. In the low-risk dyads it was six out of 1001 constituting vertical transmission 0.6%. The organisms which were transmitted vertically and were responsible for infections were *S. aureus*, *E. coli*, Group-B Streptococcus (GBS), proteus and *Klebsiella pneumoniae*. Transmission rate for klebsiella and proteus was very high [13].

A study by Okomo UA et al., enrolled 203 maternal-newborn pairs. Two-thirds (67%; 137/203) of neonates presented with EOS of which 26% (36/137) were because of a pathogenic organism. The organisms isolated from blood culture in newborns with EOS were *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Enterococcus faecalis*. These organisms were similar to their maternal genital tract isolates. This probably representing vertical transmission with a transmission rate of 5/36 (14%) [21].

A systematic review by Chan GJ et al., of vertical transmission of EOS showed that 1.1% (95% CI 0.2-2.0) of newborns of colonised mothers not exposed to intrapartum antibiotics developed laboratory-confirmed bacterial infection. Most studies included in the review focused on maternal group B Streptococcus (GBS) colonisation and were from high-income countries. These review highlights that newborns born to mother with GBS colonisation are at risk of EOS which is similar to the current study results [6].

In the study conducted by Shimeless G et al., found that the vaginal colonisation and vertical transmission of potential pathogens had a strong correlation except for *Pseudomonas* spp., where there was a moderate association between vaginal colonisation and vertical transmission. This study indicates that there is a correlation between maternal vaginal infection and EOS in newborn [22].

In the present study, the most common organisms obtained from HVS were gram negative with Klebsiella in 25% of mothers. Study by Ayengar V et al., also got a higher number of gram-negative organisms in HVS study of mothers of neonates with EOS [13]. Kishore K et al., and Udani RH et al., in their study had gram-negative organisms as the most common isolate from mothers [23,24]. The present study also had *Klebsiella spp.* as the most common pathogenic organism causing EOS in newborn similar to other studies, where the same organism was vertically transferred from maternal genital tract.

The present study has been conducted in a LMIC country with a resource limited setting where the risk of EOS and its consequences are high. The unmatched importance of low-cost diagnostic technique that is HVS culture, for the diagnosis of maternal genital infection plays a valuable role in preventing morbidities and mortalities associated with EOS in newborns.

Limitation(s)

The present study has been conducted with a small sample size considering convenient sampling technique method. A large study with specific sample size having good power needs to be conducted to recognise the exact impact of maternal vaginal infection and incidence of EOS in neonates born to these mothers.

CONCLUSION(S)

The present study shows that there is an association of EOS in term neonates born to mother's having vaginal infection. HVS is a simple tool that should be used in any center for early detection of maternal vaginal infection. Hence, timely screening of mothers with risk factors would be helpful in early identification and follow-up of newborns born to these mothers. The present study concludes that all antenatal mothers with risk factors which lead to EOS in newborns should undergo HVS culture for identification of organism causing vaginal infection. Thereby preventing the adverse effects on pregnancy outcome and their newborn.

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