ISSN: 2581 – 3633

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at: *https://www.ijmacr.com*

Volume – 9, Issue – 5, September – 2026, Page No.: 233 – 245

Diagnostic Utility of Gastric Aspirate Culture in Early - Onset Neonatal Sepsis in A Tertiary Care Hospital in North Karnataka

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How to citation this article: Dr. Shweta Sheri, Dr. Meghana M. M., Dr. Akshata C. M, "Diagnostic Utility of Gastric Aspirate Culture in Early - Onset Neonatal Sepsis in A Tertiary Care Hospital in North Karnataka", IJMACR– September– 2026, Volume – 9, Issue – 5, P. No. 233 – 245.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Early-onset neonatal sepsis (EOS) is a major cause of neonatal morbidity and mortality, and early diagnosis is challenging because clinical manifestations are often nonspecific. Blood culture remains the standard diagnostic method but may require time for confirmation. Gastric aspirate culture (GAC), obtained soon after birth, may provide an early indication of infection in high-risk neonates.

Aim: To evaluate the diagnostic utility of gastric aspirate culture in identifying early-onset neonatal sepsis among newborns with risk factors for EOS.

Materials and Methods: A prospective observational study was conducted in the Neonatal Intensive Care Unit, Department of Paediatrics, Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka. Eighty newborns with at least two risk factors for EOS were enrolled from the date of ethical clearance to March 2023. Gastric aspirate was collected immediately after birth and cultured using standard microbiological methods. Peripheral venous blood was collected within 24 hours for sepsis screening and blood culture. The diagnostic performance of GAC was assessed using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and receiver operating characteristic (ROC) analysis.

Results: Among the 80 neonates, 19 (23.8%) had positive GAC, while 16 (20.0%) had positive peripheral

venous blood culture. GAC positivity was significantly associated with clinical manifestations of sepsis, including temperature instability, tachycardia, tachypnea, and abnormal white blood cell count. Prematurity was also significantly associated with GAC positivity (p=0.002). Compared with the sepsis screen, GAC showed a sensitivity of 60.0%, specificity of 92.7%, PPV of 78.9%, and NPV of 83.6%. Compared with peripheral venous blood culture, GAC demonstrated a sensitivity of 87.5%, specificity of 92.2%, PPV of 73.7%, and NPV of 96.7%. ROC analysis showed an area under the curve of 0.89 (p<0.001).

Conclusion: Gastric aspirate culture demonstrated good diagnostic performance for early identification of neonates at risk of EOS, particularly among preterm newborns. It may serve as a useful adjunct to clinical assessment and blood culture for early evaluation of EOS; however, blood culture remains essential for definitive diagnosis.

Keywords: Early-Onset Neonatal Sepsis, Gastric Aspirate Culture, Neonatal Sepsis, Blood Culture, Preterm Neonates, Diagnostic Accuracy, Neonatal Infection.

Introduction

Neonatal sepsis is a life-threatening systemic infection occurring during the neonatal period and remains an important cause of neonatal morbidity and mortality, particularly in low- and middle-income countries. Neonatal infections, including sepsis, pneumonia and meningitis, continue to contribute substantially to preventable neonatal deaths, emphasising the importance of early recognition and timely treatment. [1,2]

Early-onset neonatal sepsis (EOS) generally refers to infection presenting during the first 72 hours of life and is predominantly associated with vertical transmission of microorganisms from the maternal genital tract before or during delivery. Important risk factors include prematurity, low birth weight, prolonged rupture of membranes, maternal fever or intra-amniotic infection, maternal urinary tract infection and other Peripartum risk factors. [3,4]

The diagnosis of EOS remains challenging because its clinical manifestations are often nonspecific. Respiratory distress, tachypnea, temperature instability, lethargy, poor feeding and cardiovascular abnormalities may occur in sepsis but can also be seen in other neonatal conditions. Consequently, clinical findings alone may neither reliably confirm nor exclude infection. [4,5]

Blood culture remains the reference standard for microbiological confirmation of neonatal sepsis. However, its diagnostic yield may be affected by the small volume of blood obtained from neonates, low-level bacteremia, prior exposure to antibiotics and delays in obtaining results. These limitations have led to continued interest in adjunctive diagnostic and screening methods that can facilitate early identification of neonates at risk for sepsis. [5,6]

Gastric aspirate obtained shortly after birth provides a potential source of information regarding microorganisms acquired from the maternal genital tract during the perinatal period. Because the sample can be obtained relatively easily and without an additional invasive procedure beyond routine gastric aspiration, gastric aspirate examination and culture have been investigated as potential tools for early identification of neonatal infection. Earlier studies have reported variable sensitivity and specificity, suggesting that gastric aspirate findings may have diagnostic value in selected

high-risk neonates but cannot independently replace blood culture. [7,9]

Jiang et al. evaluated gastric aspirate culture in premature neonates with risk factors for early-onset sepsis and reported a higher positivity rate among neonates with sepsis, particularly among premature infants delivered vaginally. Their findings suggested that gastric aspirate culture may provide useful diagnostic information in selected high-risk premature neonates.[9] Similarly, studies from India have demonstrated the potential value of gastric aspirate examination, particularly as an adjunct to conventional sepsis screening parameters. [10,11]

The diagnostic utility of gastric aspirate culture is particularly relevant in resource-limited settings, where rapid and reliable identification of neonates requiring antimicrobial therapy is essential. However, positive gastric aspirate cultures may also reflect colonisation or contamination, and therefore interpretation requires correlation with clinical findings and blood culture results. Current recommendations continue to regard blood culture as the microbiological standard for confirming neonatal sepsis. [5,6,12]

Therefore, the present study was undertaken to evaluate the diagnostic utility of gastric aspirate culture in early-onset neonatal sepsis among high-risk newborns in a tertiary care hospital in North Karnataka, with particular emphasis on its association with clinical manifestations, maternal and neonatal risk factors, blood culture results and its diagnostic performance in terms of sensitivity, specificity, positive predictive value and negative predictive value.

Materials and Methods

Study Setting

The present prospective observational study was conducted in the Neonatal Intensive Care Unit (NICU), Department of Paediatrics, Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka, India.

Study Population

The study population comprised newborns delivered at Karnataka Institute of Medical Sciences, Hubballi, who had two or more recognised risk factors for early-onset neonatal sepsis (EOS).

Study Design

This was a prospective observational study designed to evaluate the utility of gastric aspirate culture in the microbiological assessment of newborns at high risk for early-onset neonatal sepsis.

Study Period

The study was conducted from the date of obtaining Institutional Ethics Committee approval until March 2023.

Sample Size

A total of 80 newborns with two or more risk factors for early-onset neonatal sepsis were included in the study.

The sample size was calculated based on the prevalence of neonatal sepsis detected by gastric aspirate culture reported in a previous study from China by Saizhi Jian et al., which was 25.6%. Assuming an absolute precision of 10% and a 95% confidence level, the sample size was calculated using the formula:

$N = Z^2 \times p \times q / d^2$

Where:

- N = required sample size
- $Z^2 = 3.84$ at 95% confidence level
- p = 25.6%
- q = 100 − p = 74.4%

- d = 10% absolute precision

Thus,

- $N = 3.84 \times 25.6 \times 74.4 / 10^2 \approx 73$

Considering a possible 10% non-response/attrition, the final sample size was rounded to 80 newborns.

Inclusion Criteria

Newborns were eligible for inclusion if they had two or more risk factors for early-onset neonatal sepsis, including:

- Prelabour rupture of membranes (PROM) for >18 hours
- Prolonged labour for >24 hours
- Peripartum maternal febrile illness
- Low birth weight (<2.5 kg) and/or prematurity (<37 completed weeks of gestation)
- Meconium-stained liquor
- Foul-smelling liquor
- Frequent per-vaginal examinations during labour (>3 examinations)

Exclusion Criteria

Newborns with major congenital anomalies, including oesophageal atresia, were excluded from the study.

Ethical Considerations

The study was initiated only after obtaining approval from the Institutional Ethics Committee of Karnataka Institute of Medical Sciences (KIMS), Hubballi. Written informed consent was obtained from the parents or legally authorised guardian of each participating newborn. All information collected during the study was kept confidential.

Data Collection Procedure

Eligible newborns were identified immediately after birth based on the presence of two or more risk factors for early-onset neonatal sepsis. After obtaining written informed consent, relevant maternal and neonatal clinical information was recorded using a structured data collection proforma.

A gastric aspirate sample was collected immediately after delivery, preferably within 30 minutes to 1 hour and not later than 6 hours after birth, before initiation of feeding. A peripheral venous blood sample was collected within 24 hours of birth for sepsis screening and blood culture.

Gastric Aspirate Collection and Microbiological Examination

Following delivery and before the initiation of feeding, approximately 2–4 mL of gastric aspirate was obtained using a sterile orogastric tube. The sample was collected within 30 minutes to 1 hour after birth, with a maximum permissible interval of 6 hours.

The gastric aspirate specimen was transported promptly to the microbiology laboratory and processed using standard microbiological techniques. The specimen was inoculated onto appropriate culture media, including chocolate agar and Mac Conkey agar, followed by aerobic incubation and identification of bacterial isolates using standard laboratory procedures.

When immediate processing was not possible, particularly for samples collected during night hours, the specimens were stored under appropriate refrigerated conditions and processed at the earliest opportunity.

Peripheral Venous Blood Collection

Approximately 1 mL of peripheral venous blood was collected under aseptic precautions. The venepuncture site was disinfected using 70% isopropyl alcohol and povidone-iodine according to standard institutional practice.

The collected blood was inoculated into an appropriate BACT/ALERT blood culture bottle and transported to

the microbiology laboratory for bacterial culture and identification.

Statistical Analysis

The collected data were entered into Microsoft Excel and analysed using IBM SPSS Statistics, version 30. Descriptive statistics were used to summarise the data. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarised using mean and standard deviation (SD).

For inferential analysis, the Chi-square test/Fisher's exact test was used to assess associations between categorical variables, as appropriate. For comparison of continuous variables, the Student's *t*-test was used for normally distributed data, while appropriate non-parametric tests were considered when the assumptions of parametric testing were not met. Statistical significance was considered at a 95% confidence level with $p < 0.05$.

The diagnostic performance of gastric aspirate culture and other sepsis-related investigations was assessed using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

- Sensitivity: The ability of a test to correctly identify newborns with the disease.
- Specificity: The ability of a test to correctly identify newborns without the disease.
- Positive Predictive Value (PPV): The probability that a newborn with a positive test result truly has the disease.
- Negative Predictive Value (NPV): The probability that a newborn with a negative test result does not have the disease.

Results and Observations

A total of 80 newborns fulfilling the predefined eligibility criteria were included in the study. The demographic characteristics, maternal and neonatal risk factors, clinical findings, gastric aspirate culture (GAC), peripheral venous blood culture (PVBC), sepsis screening results, and diagnostic performance of GAC were evaluated.

Table 1: Demographic and maternal characteristics of the study population (n=80)

Variable	Category	Frequency	Percentage
Gender	Male	49	61.2
	Female	31	38.8
Maternal age	≤20 years	9	11.3
	21–30 years	60	75.0
	>30 years	11	13.7
Gravida	Primigravida	44	55.0
	Multi gravida	36	45.0

The majority of newborns were male (61.2%), while females constituted 38.8%. Most mothers (75%) were in the 21–30-year age group, followed by those aged >30 years (13.7%) and ≤20 years (11.3%). The mean maternal age was 24.8 ± 4.6 years. Primigravida mothers constituted 55% of the study population, while 45% were multi gravida.

Table 2: Distribution of newborns according to gestational age, mode of delivery and birth weight (n=80)

Variable	Category	Frequency	Percentage
Gestational age	Term (≥37 weeks)	40	50.0
	Moderate–late preterm (32–36+6 weeks)	34	42.0
	Very preterm (28–31+6 weeks)	5	6.0
	Extremely preterm (<28 weeks)	1	1.0
Mode of delivery	Normal vaginal delivery	51	63.8
	LSCS	29	36.2
Birth weight	Normal (>2500 g)	19	23.8
	Low birth weight (1501–<2500 g)	47	58.8
	Very low birth weight (1001–1500 g)	11	13.8
	Extremely low birth weight (<1000 g)	3	3.6

Half of the newborns were delivered at term, while the remaining 50% were preterm. Normal vaginal delivery was the predominant mode of delivery (63.8%). Regarding birth weight, low birth weight was the most common category (58.8%), followed by normal birth weight (23.8%), very low birth weight (13.8%) and extremely low birth weight (3.6%).

Table 3: Distribution according to sepsis screening, gastric aspirate culture and blood culture results (n=80)

Investigation	Result	Frequency	Percentage
Sepsis screening	Positive	25	31.2
	Negative	55	68.8
Gastric aspirate culture	Positive	19	23.8
	Negative	61	76.2
Peripheral venous blood culture	Positive	16	20.0
	Negative	64	80.0

Sepsis screening was positive in 25 (31.2%) newborns. Gastric aspirate culture was positive in 19 (23.8%), whereas PVBC was positive in 16 (20%) newborns.

Table 4: Comparison of gastric aspirate culture results according to presence of symptoms (n=80)

Symptoms	GAC Positive	GAC Negative	Total
Symptomatic	16 (84.2%)	21 (34.4%)	37
Asymptomatic	3 (15.8%)	40 (65.6%)	43
Total	19 (100%)	61 (100%)	80

χ^2 test; p=0.0004

Among newborns with positive GAC, 16/19 (84.2%) were symptomatic, compared with only 3/19 (15.8%) who were asymptomatic. There was a statistically significant association between the presence of symptoms and GAC positivity (p=0.0004).

Table 5: Frequency of clinical symptoms among newborns with gastric aspirate culture positivity

Clinical symptom	Within 6 hours, n	Within 48 hours, n
Lethargy	16	10
Tachypnea	37	30
Poor feeding	27	22
Tachycardia	2	5
Prolonged capillary refill time	5	5

Table 6: Association of SIRS components with gastric aspirate culture positivity

SIRS component	Category	GAC Positive	GAC Negative	OR (95% CI)	χ^2	p-value
Temperature instability	Yes	12 (60%)	8 (40%)	11.35 (3.44–37.41)	19.10	0.0001
	No	7 (11%)	53 (88%)			
Tachycardia	Yes	5 (100%)	0 (0%)	46.65 (2.43–892.3)	16.90	0.0107
	No	14 (18%)	61 (81%)			
Tachypnea	Yes	14 (46%)	16 (53%)	7.87 (2.44–25.36)	13.74	0.0005
	No	5 (10%)	45 (90%)			
Abnormal WBC count	Yes	15 (60%)	10 (40%)	19.12 (5.24–69.79)	26.05	0.0001
	No	4 (7.3%)	51 (92.7%)			

All four evaluated SIRS components showed significant associations with GAC positivity. Temperature instability, tachypnea and abnormal WBC count demonstrated highly significant associations ($p<0.001$). Tachycardia also showed a significant association (p=0.0107) and had the highest estimated odds ratio, although the confidence interval was wide.

Table 7: Association of maternal characteristics with gastric aspirate and blood culture results

Maternal characteristic	GAC p-value	PVBC p-value
Maternal age	0.090	0.129
Gravida	0.190	0.314
Mode of delivery	1.000	0.064

There was no statistically significant association between maternal age, gravida or mode of delivery and either gastric aspirate culture or blood culture positivity.

Table 8: Association of maternal/neonatal risk factors with gastric aspirate culture and blood culture positivity

Risk factor	GAC-positive	GAC p-value	Blood culture-positive	PVBC p-value
Frequent PV examination	18	0.070	11	0.275
PROM >18 hours	10	0.610	5	0.003
Peripartum febrile illness	0	0.320	0	0.507
Spontaneous premature delivery	17	0.008	12	0.002
UTI	1	0.070	0	0.528
Birth weight <2.5 kg	18	0.530	12	0.0463

Spontaneous premature delivery showed a statistically significant association with both GAC positivity (p=0.008) and blood culture positivity (p=0.002). PROM >18 hours was significantly associated with blood culture positivity (p=0.003). Low birth weight also showed a significant association with blood culture positivity (p=0.0463). The associations with frequent PV examination and UTI did not reach statistical significance.

Table 9: Association of gestational age and birth weight with gastric aspirate and blood culture results

Variable	Category	GAC Positive	GAC Negative	PVBC Positive	PVBC Negative
Gestational age	Term	5 (26.4%)	35 (57.3%)	—	—
	Moderate–late preterm	11 (57.9%)	23 (37.7%)	—	—
	Very preterm	2 (10.5%)	3 (4.9%)	—	—
	Extremely preterm	1 (5.3%)	0	—	—
Birth weight	Normal	2 (10.5%)	17 (27.9%)	0 (0%)	19 (29.7%)
	Low birth weight	11 (57.9%)	36 (59.0%)	9 (56.3%)	38 (59.4%)
	Very low birth weight	5 (26.3%)	6 (9.8%)	6 (37.5%)	5 (7.8%)
	Extremely low birth weight	1 (5.3%)	2 (3.3%)	1 (6.3%)	2 (3.1%)

GAC and gestational age: p=0.002, PVBC and birth weight: p=0.004

GAC positivity was significantly higher among preterm newborns compared with term newborns (p=0.002). Similarly, blood culture positivity varied significantly according to birth-weight category (p=0.004), with the highest proportion occurring among low birth weight newborns, followed by very low birth weight newborns.

Table 10: Diagnostic performance of gastric aspirate culture compared with sepsis screening and blood culture

Diagnostic parameter	GAC vs Sepsis screening	GAC vs PVBC
Sensitivity	60.0%	87.5%
Specificity	92.7%	92.2%
Positive predictive value	78.9%	73.7%
Negative predictive value	83.6%	96.7%

When compared with sepsis screening, GAC demonstrated a sensitivity of 60% and specificity of 92.7%, with PPV and NPV of 78.9% and 83.6%, respectively. When PVBC was considered the reference standard, GAC demonstrated 87.5% sensitivity and 92.2% specificity, with a PPV of 73.7% and NPV of 96.7%.

Table 11: Association of symptom onset and mortality with gastric aspirate culture results

Variable	Category	GAC Positive	GAC Negative	OR (95% CI)	χ^2	p-value
Symptoms within 6 hours	Yes	16 (43.2%)	21 (56.8%)	10.15 (2.65–38.85)	14.44	<0.01
	No	3 (7.0%)	40 (93.0%)			
Symptoms within 48 hours	Yes	15 (50.0%)	15 (50.0%)	11.50 (3.3–40.0)	18.26	<0.01
	No	4 (8.0%)	46 (92.0%)			
Death within 3 days	Yes	5 (26.3%)	0	—	—	<0.01*
	No	14 (73.7%)	61 (100%)			

Table 12: Microorganisms isolated from gastric aspirate and peripheral venous blood cultures

Organism	GAC, n (%)	PVBC, n (%)
No growth	61 (76.0)	64 (80.0)
Escherichia coli	9 (11.0)	5 (6.0)
Candida albicans	3 (4.0)	2 (2.0)
Enterococcus spp.	3 (4.0)	—
Coagulase-negative Staphylococci	2 (3.0)	1 (1.0)
Klebsiella pneumoniae	1 (1.0)	3 (4.0)
Non-Candida albicans	1 (1.0)	2 (3.0)
Staphylococcus aureus	—	2 (3.0)
Pseudomonas aeruginosa	—	1 (1.0)

The majority of gastric aspirate samples (76%) and blood culture samples (80%) showed no microbial growth. Among positive cultures, E. coli was the most frequently isolated organism in both gastric aspirate culture (11%) and blood culture (6%). Other organisms isolated included Candida albicans, Enterococcus, coagulase-negative Staphylococci, Klebsiella pneumoniae, Staphylococcus aureus, non-Candida albicans species and Pseudomonas aeruginosa.

Discussion

The present prospective observational study evaluated the diagnostic utility of gastric aspirate culture (GAC) in 80 newborns with two or more risk factors for early-onset neonatal sepsis. The study population represented a high-risk neonatal group in whom early identification of infection is clinically important. In our study, GAC was positive in 19 (23.8%) neonates, while peripheral venous blood culture (PVBC) was positive in 16 (20%) and sepsis screening was positive in 25 (31.2%) neonates.

Demographic and neonatal characteristics

Male neonates constituted the majority of the study population (61.2%), while females accounted for 38.8%. Most mothers (75%) were aged 21–30 years, with a

mean maternal age of 24.8 ± 4.6 years. Primigravida mothers constituted 55% of the study population. Maternal age and gravida, however, were not significantly associated with GAC or blood culture positivity. These findings suggest that, within this high-risk cohort, demographic maternal characteristics were less important determinants of culture positivity than specific perinatal and neonatal risk factors.

Half of the neonates were born at term, whereas the remaining half were preterm. Low birth weight was the most frequent birth-weight category (58.8%), followed by normal birth weight (23.8%), very low birth weight (13.8%) and extremely low birth weight (3.6%). Prematurity and low birth weight are established risk factors for neonatal infection because of immature immune function and reduced host defence mechanisms. [3,4]

In the present study, GAC positivity was significantly associated with gestational age (p=0.002). Among GAC-positive neonates, 73.7% were preterm, whereas only 26.4% were term. This finding is consistent with previous evidence indicating a greater vulnerability to neonatal infection among premature infants. Jiang et al. also reported diagnostic value of gastric aspirate culture particularly among premature neonates with risk factors for early-onset sepsis.[9]

Gastric aspirate culture and clinical manifestations

A significant association was observed between the presence of clinical symptoms and GAC positivity (p=0.0004). Among neonates with positive GAC, 84.2% were symptomatic, compared with 15.8% who were asymptomatic. This finding supports the importance of interpreting gastric aspirate culture in conjunction with the clinical condition of the newborn rather than as an isolated microbiological test.

Tachypnea was an important clinical manifestation in the study population, followed by poor feeding and lethargy. These findings are consistent with previous studies in which respiratory manifestations, feeding difficulty and lethargy were commonly observed among neonates evaluated for early-onset sepsis. Kaur and Singh reported tachypnea as the most frequent presenting feature among neonates evaluated for suspected EOS. [10,11]

The association between early symptom onset and GAC positivity was also statistically significant. Neonates developing symptoms within 6 hours of birth had higher odds of GAC positivity (OR 10.15; 95% CI: 2.65–38.85; p<0.01). Similarly, symptom onset within 48 hours was associated with increased odds of GAC positivity (OR 11.50; 95% CI: 3.3–40.0; p<0.01). These findings are biologically plausible because EOS is predominantly related to perinatal or vertical transmission and may manifest very early after birth. [3,4]

Association with SIRS components

All four evaluated SIRS components—temperature instability, tachycardia, tachypnea and abnormal WBC count—were significantly associated with GAC positivity. Temperature instability showed an OR of 11.35 (95% CI: 3.44–37.41; p=0.0001), while tachypnea showed an OR of 7.87 (95% CI: 2.44–25.36; p=0.0005). Abnormal WBC count showed a strong association with GAC positivity (OR 19.12; 95% CI: 5.24–69.79; p=0.0001). Tachycardia also demonstrated a significant association (OR 46.65; p=0.0107), although the very wide confidence interval indicates considerable statistical uncertainty due to the small number of neonates with tachycardia.

These findings emphasize that gastric aspirate culture positivity was more frequently observed in neonates

exhibiting systemic clinical or laboratory abnormalities. Previous literature has similarly highlighted the nonspecific nature of individual clinical signs and the importance of combining clinical assessment with laboratory investigations in suspected neonatal sepsis. [5,10]

Maternal and perinatal risk factors

Spontaneous premature delivery was significantly associated with both GAC positivity (p=0.008) and blood culture positivity (p=0.002). PROM >18 hours was significantly associated with blood culture positivity (p=0.003), although its association with GAC positivity was not statistically significant (p=0.610). Low birth weight was also significantly associated with blood culture positivity (p=0.0463).

Prolonged rupture of membranes, prematurity and maternal infection are well-established risk factors for EOS because they increase the possibility of ascending infection and vertical transmission. WHO recommendations similarly recognize prolonged rupture of membranes, maternal fever, foul-smelling amniotic fluid and prematurity as important risk factors for neonatal infection. [3,12]

The association between spontaneous premature delivery and GAC positivity in our study is also comparable with the findings of Jiang et al., who reported increased diagnostic value of gastric aspirate culture among premature neonates.[9] However, the limited number of mothers with Peripartum febrile illness and UTI in our cohort restricts the ability to draw firm conclusions regarding these individual risk factors.

Gastric aspirate culture versus blood culture

Blood culture remains the reference standard for microbiological confirmation of neonatal sepsis.[5,6] In the present study, 16 neonates had positive blood cultures, compared with 19 positive GAC results.

When GAC was compared with PVBC, GAC demonstrated a sensitivity of 87.5% and specificity of 92.2%. The positive predictive value was 73.7%, while the negative predictive value was 96.7%. These findings suggest that, in this study population, a negative GAC was associated with a high probability of a negative blood culture.

The high negative predictive value observed in our study is clinically relevant because a readily obtainable early test with good negative predictive performance may provide useful supplementary information during the initial assessment of high-risk neonates. Nevertheless, GAC should not be interpreted as a replacement for blood culture because gastric aspirate may reflect organisms acquired from the maternal genital tract or colonisation rather than invasive bloodstream infection.

Earlier studies have also reported variable diagnostic performance of gastric aspirate examination. Leibovich et al. reported a sensitivity of 75% and specificity of 68% for gastric aspirate examination when blood culture was used as the definitive criterion, while Garland and Bowman reported a sensitivity of 57% for gastric aspirate in their evaluation of neonatal sepsis screening. [7,8] The variation between studies may be related to differences in study populations, sampling time, definitions of sepsis, microbiological techniques and the type of gastric aspirate test performed.

Our findings are also broadly consistent with the study by Jiang et al., which demonstrated that gastric aspirate culture may have diagnostic value in selected premature neonates with risk factors for EOS.[9] However, contemporary guidance continues to consider blood culture the diagnostic standard and does not recommend

gastric aspirate culture as a standalone diagnostic test for EOS. [5,6]

Diagnostic performance compared with sepsis screening

Compared with sepsis screening, GAC showed a sensitivity of 60%, specificity of 92.7%, PPV of 78.9% and NPV of 83.6%. The relatively high specificity indicates that a positive GAC result was more frequently associated with a positive sepsis screen, whereas its moderate sensitivity indicates that GAC alone could miss a proportion of neonates identified by screening.

This observation supports the concept that neonatal sepsis diagnosis should rely on a combination of clinical assessment, risk factors, screening investigations and microbiological testing rather than a single diagnostic parameter. Previous Indian studies have similarly concluded that gastric aspirate-based investigations may be useful as adjunctive screening tools, particularly when combined with other markers such as CRP and haematological parameters. [10,11]

Microbiological profile

Among gastric aspirate samples, 76% showed no growth, while 23.8% were culture-positive. Escherichia coli was the most frequently isolated organism (11%), followed by Candida albicans (4%), Enterococcus spp. (4%) and coagulase-negative Staphylococci (3%). In blood cultures, 80% showed no growth, while E. coli was again the most frequently isolated organism (6%), followed by Klebsiella pneumoniae (4%), Staphylococcus aureus (3%) and Candida albicans (2%).

The predominance of E. coli in our study is noteworthy. Gram-negative organisms, particularly E. coli, are recognized important causes of neonatal bacterial infection, especially among preterm and low-birth-weight infants.[4] Jiang et al. also reported E. coli as a prominent organism identified in gastric aspirate cultures, particularly following vaginal delivery. [9]

The presence of Candida and coagulase-negative staphylococci in gastric aspirate cultures should be interpreted cautiously because detection does not necessarily establish invasive infection. Correlation with blood culture, clinical findings and other laboratory parameters is essential before attributing clinical significance to such isolates.

Mortality and gastric aspirate culture

Five neonates died within three days, and all five had positive GAC results. Although this represents an important observation, the small number of deaths prevents reliable estimation of the independent association between GAC positivity and mortality. Nevertheless, the finding emphasizes that GAC positivity occurred in a subgroup of neonates with severe clinical outcomes.

ROC analysis

ROC analysis demonstrated an AUC of 0.89 ($p<0.001$) for GAC when compared with PVBC, indicating good discriminatory performance in the present study population. The AUC suggests that GAC had a high ability to distinguish neonates with positive blood cultures from those with negative blood cultures within this selected high-risk cohort.

However, the ROC result should be interpreted in the context of the study design and sample size. The study included only 80 neonates from a single tertiary care centre, and therefore the diagnostic performance estimates may not be directly generalizable to all neonatal populations.

Conclusion

Gastric aspirate culture demonstrated good diagnostic utility in newborns at risk of early-onset neonatal sepsis,

with a sensitivity of 87.5%, specificity of 92.2%, and ROC-AUC of 0.89 when compared with peripheral venous blood culture. Gastric aspirate culture positivity was significantly associated with prematurity and several clinical signs of sepsis. Gastric aspirate culture may therefore serve as a useful adjunctive tool for early identification of neonates at risk of EOS; however, blood culture remains essential for definitive diagnosis.

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