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Original Research Article

Study comparing rapid diagnostic test with conventional method in diagnosis of spontaneous bacterial peritonitis in liver cirrhosis

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ABSTRACT

Background: Spontaneous bacterial peritonitis (SBP) is a severe and frequent complication of liver cirrhosis with ascites. Conventional diagnostic methods such as manual polymorphonuclear leukocyte (PMN) count and ascitic fluid culture are time-consuming, delaying treatment. Rapid diagnostic tests based on leukocyte esterase activity offer a simple bedside alternative. This study aimed to assess the diagnostic accuracy of a rapid reagent strip test compared with the conventional method in detecting SBP.
Methods: A hospital-based observational study was conducted among 104 patients with liver cirrhosis and new-onset ascites admitted to a tertiary care center between August 2022 and August 2024. Ascitic fluid from each patient was analyzed by both conventional PMN count and leukocyte esterase reagent strip testing. Diagnostic parameters including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated using SPSS v24.
Results: SBP was detected in 15 (14.4%) patients by the conventional method and in 23 (22.1%) using the rapid test. The rapid diagnostic test demonstrated a sensitivity of 100%, specificity of 91.01%, PPV of 65.21% and NPV of 100%.
Conclusions: The leukocyte esterase reagent strip test provides a rapid, inexpensive and reliable alternative for early bedside diagnosis of SBP in cirrhotic patients. Its excellent sensitivity and high NPV make it particularly useful in resource-limited and emergency settings for timely initiation of treatment.

Keywords: Ascitic fluid, Cirrhosis, Leukocyte esterase, Rapid diagnostic test, Spontaneous bacterial peritonitis

INTRODUCTION

Spontaneous bacterial peritonitis (SBP) is a frequent and severe complication in patients with liver disease and ascites. The incidence of SBP ranges from 25% to 46% per year among individuals with decompensated cirrhosis, with mortality increasing from 30% to nearly 63% within one month to one year of diagnosis respectively.[1,2] The clinical presentation of SBP is often variable and non-specific.[3] A considerable proportion of patients may remain completely asymptomatic and therefore diagnostic paracentesis is recommended in all cases of ascites to establish the diagnosis.[4-6] Typical symptoms, when present, include fever, diarrhea, abdominal pain, tenderness or vomiting.[7] Traditionally, SBP is diagnosed based on a positive ascitic fluid culture and a neutrophil count exceeding 250 cells/µl. Two variants of SBP-culture-negative neutrocytic ascites (CNNA) and bacterascites (BA)- are also recognized. In CNNA, the culture remains sterile despite a high neutrophil count (≥250/µl), whereas in bacterascites, culture is positive but the neutrophil count is <250/µl. The pathogenesis involves complex interactions among altered intestinal microbiota, increased intestinal permeability, bacterial translocation and immune dysfunction, all contributing to the development of SBP. Bacteria migrate from the intestinal lumen to mesenteric lymph nodes and subsequently enter the portal and systemic circulation, leading to colonization of ascitic fluid under favorable conditions.

Several factors increase the risk of SBP in cirrhotic patients, including upper gastrointestinal bleeding, low ascitic protein levels and advanced liver dysfunction, particularly in those with Child-Pugh score ≥9, serum bilirubin ≥3 mg/dl, renal impairment (creatinine ≥1.2 mg/dl or blood urea nitrogen ≥25 mg/dl) or hyponatremia ≤130 mEq/L.[8,9] Historically, gram-negative organisms such as Escherichia coli and Klebsiella species were the predominant etiologic agents.[10] Third-generation cephalosporins have long been recommended as first-line therapy, but resistance to agents such as cefotaxime is increasingly reported.[11] Over the past decades, there has been a notable epidemiological shift toward gram-positive, quinolone-resistant and multidrug-resistant bacteria. Recent data from various continents indicate that 48-62% of isolates are now gram-positive, primarily *Streptococcus*, *Enterococcus* and *Staphylococcus* species.[12,13] This trend has been attributed to indiscriminate antibiotic use, frequent invasive procedures and prolonged hospitalization.[14,15] The diagnosis of SBP is confirmed by ascitic fluid culture and neutrophil count ≥250 cells/µl. Early diagnosis and prompt treatment significantly improve survival; however, conventional culture methods are time-consuming, leading to treatment delays.[16-18] In this context, rapid diagnostic methods such as reagent strip testing for leukocyte esterase have been explored for body fluids including pleural, synovial and peritoneal infections. The reaction between leukocyte esterase and a chromogenic substrate on the strip produces a color change that can be interpreted visually within minutes. Studies have demonstrated high sensitivity (85-100%) and specificity (98-100%) for such reagent strip tests in detecting bacterial infections.[19,20] Given the clinical importance of early identification and treatment of SBP in cirrhotic patients, this study was undertaken to determine the accuracy of a rapid diagnostic test compared with the conventional method for diagnosing spontaneous bacterial peritonitis in liver cirrhosis.

Objectives

To determine the sensitivity and specificity of the rapid diagnostic test. To evaluate the positive predictive value (PPV) and negative predictive value (NPV) of the rapid diagnostic test.

METHODS

Study design and setting

This hospital-based observational study was conducted in the in-patient department (IPD) of a Government Medical College, Nagpur. The study period extended from August 2022 to August 2024, during which consecutive eligible patients were recruited.

Sample size

A total of 104 patients were included. The sample size was calculated with reference to the study by Jha et al (2012)18, using the formula: $n = z^1_{1-\alpha/2} P (1 - P)/d^2$, where the absolute precision (d) =8% and the desired confidence level =95%. The required sample size was thus determined to be 104.

Study population

Patients with new-onset ascites admitted to the IPD were enrolled.

Inclusion criterion

All hospitalized patients with newly detected ascites.

Exclusion criteria

Patients who did not provide informed consent; those already receiving antibiotics; and patients with ascites due to causes other than cirrhosis (e.g., tuberculosis or malignancy).

Data collection

Data were recorded prospectively in a structured case-record form. Demographic characteristics, clinical history and risk factors such as alcohol use, prior liver disease, tuberculosis or other etiologies of ascites were documented. Information was obtained from patients admitted in the casualty, wards or intensive-care settings until the target sample size was reached.

Diagnostic methods

All enrolled patients underwent diagnostic paracentesis at admission. Ascitic fluid was analyzed by both conventional and rapid diagnostic methods.

Conventional method

Manual total and differential cell count and cytological examination to determine the absolute polymorphonuclear neutrophil (PMN) count.

Rapid diagnostic test

Reagent-strip method detecting leukocyte esterase activity, interpreted according to manufacturer's instructions.

Spontaneous bacterial peritonitis (SBP) was diagnosed when the ascitic PMN count was ≥250 cells/µl, with or without a positive culture.

Statistical analysis

Data were entered in Microsoft Excel and analyzed using SPSS v24. Continuous variables were summarized as mean±standard deviation and categorical variables as frequency and percentage. Diagnostic accuracy

parameters- including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV)- were calculated with 95% confidence intervals. Results were presented in tabular and graphical formats.

RESULTS

A total of 104 patients with liver cirrhosis and ascites were included in the study. The mean age of the study population was 49.38±1.16 years, with a marked male predominance (male:female =88:16) (Table 1). Among the study participants, abdominal pain was the most common symptom, observed in 63.5%, followed by fever in 36.5% and altered sensorium in 26%. On clinical examination, jaundice was present in 80.8% of patients, while abdominal tenderness was elicited in 15.4% (Table 1). The mean hemoglobin was 7.14±0.19 gm/dl, mean serum creatinine 2.17±0.31 mg/dl and mean total bilirubin 3.66±0.17 mg/dl. The mean serum sodium and potassium levels were 135.84±0.66 mEq/l and 7.57±1.69 mEq/l, respectively. Liver enzyme levels were elevated, with mean SGOT 160.38±25.81 U/l and SGPT 126.61±8.22 U/l. The mean serum albumin was 2.20±0.07 gm/dl (Table 2). Based on diagnostic evaluation, SBP was detected in 15 (14.4%) patients using the conventional method and in 23 (22.1%) using the rapid diagnostic method (Table 3).

Table 1: Baseline demographic and clinical profile of study participants.

Variables	Category	Frequency	Percentage
Gender	Male	88	84.6
	Female	16	15.4
Symptoms	Abdominal pain	66	63.5
	Fever	38	36.5
	Altered sensorium	27	26.0
Signs	Jaundice	84	80.8
	Abdominal tenderness	16	15.4

Table 2: Laboratory investigations.

Parameters	Minimum	Maximum	Mean	SD
Hemoglobin (gm/dl)	4.0	10.0	7.14	0.19
Urea (mg/dl)	22.0	164.0	49.43	2.88
Creatinine (mg/dl)	0.40	16.0	2.17	0.31
Sodium (mEq/l)	122.0	154.0	135.84	0.66
Potassium (mEq/l)	1.20	89.0	7.57	1.69
Total bilirubin (mg/dl)	0.50	8.50	3.66	0.17
SGOT (U/l)	23.0	1960.0	160.38	25.81
SGPT (U/l)	22.0	414.0	126.61	8.22
Serum albumin (gm/dl)	1.0	4.0	2.20	0.07

Table 3: Comparison of diagnostic methods and accuracy of rapid test.

Diagnostic methods	SBP present		SBP absent	
	Frequency	Percentage	Frequency	Percentage
Conventional method	15	14.4	89	85.6
Rapid diagnostic method	23	22.1	81	77.9

Table 4: Sensitivity analysis for rapid method.

Sensitivity analysis		Conventional method		Total	Sensitivity	Specificity
		Positive	Negative			
Rapid method	Positive	15	8	23	100.00%	91.01%
	Negative	0	81	81		
Total		15	89	104		

When both methods were compared, the rapid diagnostic test showed a sensitivity of 100%, specificity of 91.01%, positive predictive value (PPV) of 65.21% and negative predictive value (NPV) of 100% (Table 3). Among all patients studied, 10 (9.6%) succumbed during hospital

stay, whereas 94 (90.4%) were successfully discharged following treatment (Table 4).

Table 5: Outcome of patients with liver cirrhosis and ascites.

Outcome	Frequency	Percentage
Death	10	9.6
Discharge	94	90.4

DISCUSSION

Spontaneous bacterial peritonitis (SBP) represents a serious and common infectious complication in patients with liver cirrhosis and ascites, with an incidence ranging from 3.5% to 30% depending on the patient setting.[21] Approximately half of all SBP cases are present at the time of admission, while the remainder develop during hospitalization.[22] Early and accurate diagnosis is critical because untreated SBP carries a mortality rate exceeding 80%, whereas prompt initiation of antibiotics markedly improves survival.[23] Conventionally, SBP is diagnosed when the ascitic fluid polymorphonuclear (PMN) leukocyte count is ≥250 cells/mm^3, irrespective of culture results.[24] Although ascitic fluid culture remains confirmatory, its results are delayed (often up to 48 hours) and positivity rates are limited, contributing to treatment delays.[25] Manual PMN counting, though standard, is laborious, time-consuming and may not be feasible in emergency or resource-limited settings.[26] Hence, there is an increasing demand for a simple, rapid and cost-effective bedside test to facilitate early diagnosis. Leukocyte esterase reagent strips (LERS), originally developed for urinary tract infection screening, have shown potential for detecting SBP by identifying the esterase activity of neutrophils in ascitic fluid.[27]

Several studies have demonstrated that LERS can rapidly and accurately differentiate infected from non-infected ascitic fluid samples, providing results within minutes.[28-30] Butani et al were among the first to report the use of LERS in SBP, with a sensitivity of 83% and specificity of 99%.[31] Sapey et al observed sensitivity and specificity of 64.7% and 99.6%, respectively, while Kim et al reported 50% sensitivity and 100% specificity.[32,33] Li et al and Ribeiro et al found sensitivities between 86-93% and specificities of 84-96%, whereas De Araujo et al reported 80% sensitivity and 98.5% specificity.[34-36] Together, these data support the high negative predictive value (NPV) of LERS as a screening tool to rule out SBP. In the present study, 104 patients with liver cirrhosis and ascites were evaluated using both conventional and rapid diagnostic methods. SBP was identified in 15 patients (14.4%) by the conventional method and in 23 patients (22.1%) using the rapid test. The rapid diagnostic method showed a sensitivity of 100%, specificity of 91.01%, positive predictive value (PPV) of 65.21% and NPV of 100%. These findings align with Chugh et al (95% sensitivity, 96.4% specificity) and Gupta et al (95% sensitivity, 97.3% specificity).[37,38] Our results reinforce that leukocyte esterase testing is a reliable, inexpensive and rapid bedside alternative to manual PMN counting. Its very high NPV allows confident exclusion of SBP in ascitic samples, helping clinicians initiate timely therapy in positive cases and avoid unnecessary antibiotics in negative ones.[39] Moreover, the simplicity of this method makes it particularly valuable in resource-limited or emergency settings where access to laboratory facilities is constrained.[26,40]

Overall, the findings align with the existing evidence that LERS can serve as a sensitive, specific and cost-effective tool for the rapid diagnosis of SBP in cirrhotic patients. Incorporating this rapid diagnostic test into routine practice may shorten the time to diagnosis and treatment initiation, thereby improving patient outcomes.[40]

The present study has certain limitations. It was conducted at a single tertiary care hospital, which may limit the generalizability of the findings to broader populations and different healthcare settings. Although the sample size was adequate, it remains relatively small and may have limited the ability to detect less common findings or perform detailed subgroup analyses. Furthermore, patients who were already on antibiotic therapy were excluded, which may have introduced selection bias, as these individuals often represent a clinically relevant subgroup with altered diagnostic accuracy due to partial treatment. Lastly, being a cross-sectional study, it could not evaluate long-term outcomes such as recurrence, mortality or the prognostic impact of early diagnosis and intervention.

CONCLUSION

The present study corroborates the findings of prior research by establishing that leukocyte esterase reagent strips are a rapid, inexpensive and reliable bedside diagnostic tool for detecting spontaneous bacterial peritonitis in patients with cirrhosis. The 100% sensitivity and high specificity observed in our study underscore the potential of this method to significantly reduce diagnostic delay. Given the high morbidity and mortality associated with SBP, the incorporation of LERS into routine ascitic fluid analysis can enhance clinical decision-making, especially in resource-limited or emergency care settings.

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