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Diagnostic Accuracy of Leukocyte Esterase Dipstick Test in Early Detection of Spontaneous Bacterial Peritonitis in Cirrhotic Patients

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ABSTRACT

Objective: To assess the diagnostic accuracy of the leukocyte esterase dipstick test in detecting SBP in cirrhotic patients, using ascitic fluid routine examination as the gold standard.

Methodology: This cross-sectional comparative study was conducted in the Department of Gastroenterology, Holy Family Hospital, Rawalpindi. All cirrhotic patients of either sex with Grade 2 or Grade 3 ascites were included in the study. Diagnostic paracentesis was performed under aseptic conditions. 10–20 mL ascitic fluid sample was sent for routine analysis, while 30 mL was used for the bedside dipstick test to detect granulocyte esterase activity. Leukocyte levels were assessed with a color-calibrated scale, and dipstick results of ++ and +++ were considered positive. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each dipstick grade.

Results: A total of 132 patients aged 18–70 years were enrolled. Among those with a leukocyte esterase result (LERS) of ++, 85.7% were confirmed to have SBP with ascitic fluid R/E; for LERS +++, the confirmation rate was 87.5%. For LERS (++), sensitivity was 42.9%, specificity 96.7%, PPV 85.7%, NPV 78.4%, and diagnostic accuracy 79.5%. For LERS (+++), sensitivity was 50%, specificity 80.6%, PPV 87.5%, NPV 80.6%, and diagnostic accuracy 81.8%.

Conclusion: The leukocyte esterase dipstick test is a rapid, economical, and practical diagnostic tool with reasonable diagnostic accuracy for detecting SBP in cirrhotic patients.

Keywords: Ascitic Fluid Analysis. Cirrhosis, Diagnostic Accuracy, Leukocyte Esterase Dipstick Test, Spontaneous Bacterial Peritonitis,

Authors' Contribution:
[1,2]Conception; Literature research; manuscript design and drafting; [2,3]Critical analysis and manuscript review; [3,4]Data analysis; Manuscript Editing.

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Introduction

Spontaneous bacterial peritonitis (SBP) is a severe and often fatal complication in cirrhotic patients, necessitating prompt diagnosis and treatment.[1] Early detection is crucial to improve outcomes, yet traditional methods like ascitic fluid culture are time-consuming. The LERS test offers a fast and better substitute for primary examination. But confirming for its suitability, the investigative accurateness of the LERS test in consistently recognizing SBP earlier in its progress demands a comprehensive assessment.[2]

Ascites develops in approximately 50% of patients with liver cirrhosis, and the overall two-year survival

following its onset is only about 50%. Among these patients, 10% to 30% may develop spontaneous bacterial peritonitis (SBP), a serious complication with potentially fatal consequences if not promptly diagnosed and treated.[1] Cirrhosis involves progressive inflammation, fibrosis, hepatocellular necrosis, and architectural distortion, all of which contribute to a four-fold increased susceptibility to infections.[2]

SBP patients often present with nonspecific symptoms as abdominal pain, fever, vomiting, diarrhea, and altered mental status. However, many cases remain asymptomatic or are clinically ambiguous, potentially delaying diagnosis.[4,5] Untreated or delayed treatment may lead to severe complications including hepatic encephalopathy, gastrointestinal hemorrhage, hepatorenal syndrome, and death.[6,7] Ascitic fluid analysis and culture are considered the gold standards for diagnosing SBP, they are time-consuming and may delay appropriate therapy. Empirical antibiotic therapy is often initiated based on clinical suspicion, but the growing issue of multidrug resistance underscores the need for rapid diagnostic tools.[8–10]

The aim of this study was to evaluate the diagnostic accuracy of the leukocyte esterase dipstick test for the early detection of SBP in patients with liver cirrhosis and ascites. The dipstick test provides a convenient, rapid bedside screening alternative to conventional methods.

Methodology

This cross-sectional comparative study was conducted at the Department of Gastroenterology, Holy Family Hospital, Rawalpindi, from August 1, 2023, to January 31, 2024. A total of 132 patients were enrolled based on a calculated sample size using previously reported sensitivity (63.6%) and specificity (94.1%) values[8], with a confidence level of 95% and an assumed prevalence of 67.7%.[9]

Inclusion criteria

- Hospitalized cirrhotic patients of either gender, aged 18–70 years,
- Patients with presence of Grade 2 or Grade 3 ascites.
- Patients having clinical suspicion of SBP.

Exclusion criteria

- Patients with non-cirrhotic ascites like tuberculous or malignant.
- Patients who are on secondary prophylaxis of SBPs or received antibiotics within the last 2 weeks

The study captured both dependent and independent variables for the study. Independent variable was Leukocyte esterase dipstick test result whereas dependent variable was ascitic fluid polymorphonuclear cell count. Other variables were the presence/absence of SBP, patient demographics, etiology of cirrhosis, severity of liver disease, clinical symptoms/signs of SBP, and ascitic fluid culture results.

Each eligible patient underwent an interview using a structured proforma to collect demographic and clinical data, including presenting symptoms (abdominal tenderness, fever, vomiting, diarrhea, upper gastrointestinal bleed, recent therapeutic ascitic tap, new onset ascites, altered mental status) and etiology of cirrhosis and any comorbidity.

Diagnostic paracentesis was performed under strict aseptic conditions. The ascitic fluid sample was divided into two parts:

I. 10–20 mL was sent for routine examination (cell count, culture, and sensitivity)
II. 30 mL was used for the leukocyte esterase dipstick test

The bedside test was performed using **ALLTEST® Urinalysis Reagent Strips URS 10U** (Hangzhou AllTest Biotech Co., Ltd.). Strips were immersed in the ascitic fluid for two minutes, then compared visually to a colour chart provided on the container label. Leukocyte levels were graded as follows:

- Grade 0: Trace/Negative
- Grade +: 70cells/mm³

- Grade ++: 125cells/mm³
- Grade +++: 500cells/mm³

SBP positivity was labelled by dipstick scores of **++ or +++**. Succeeding validation of all affirmative dipstick results was accomplished using standard ascitic fluid assessment. The investigative execution of the test, involving sensitivity, specificity, positive and negative predictive values (PPV, NPV), and overall accuracy, was objectively measured for the Grade ++ and Grade +++ types.

To weaken the effect of biasness, numerous approaches were carried out. Conspicuously, the problem of choice bias got its solution via the sensible addition of study subjects whose appearances perfectly characterized the full targeted patient group.

Data were analyzed using SPSS version 25. For qualitative variables, frequencies and percentages were used. While quantitative variables were presented as mean±SD. A p value of 0.05 was considered as significant. Contingency table of 2x2 was also applied.

The research evaluation unit of CPSP approved this study via letter no CPSP/REU/GAS-2022-126-1326 dated July 2023**. Ethical approval** was also taken from the research and ethical committee of Rawalpindi Medical University (Ref. 384/IRB/RMU-2023) on 28-08-2023. To protect patient confidentiality, data were anonymized and stored securely, accessible only to authorized research personnel.

Results

We enrolled 132 patients showing both the cirrhosis and ascites. The age range was calculated as 18-70. Both male and female were enrolled in the study. The proportion of male was 69 (52.3%) and female was 63 (47.7%). The mean age was recorded as 53.97±11.02 years.

Among the presenting symptoms of selected patients, abdominal pain was the most common, reported in 123 patients (93.2%), followed by fever in 48 patients (36.4%), altered sensorium in 30 patients (22.7%), gastrointestinal bleeding in 24 patients (18.2%), and vomiting with diarrhea in 3 patients (2.3%).

Regarding etiology, 117 patients (88.6%) had cirrhosis secondary to viral hepatitis B or C. According to Child-Turcotte-Pugh (CTP) classification, 48 patients (36.4%) were in Class B, while 84 patients (63.6%) were in Class C. Most patients presented with Grade 3 ascites (81.8%), while 18.2% had Grade 2 ascites (Table 2 & 3 respectively).

Table I: Frequency distribution of presenting complaints (n=132)

	Frequency (n=%)	
Variables	**Yes (n=%)**	**No (n=%)**
Fever	48 (36.4)	84 (63.6)
Abdominal pain	123 (93.2)	9 (6.8)
Vomiting and diarrhea	3 (2.3)	129 (97.7)
Upper gastrointestinal bleeding	24 (18.2)	108 (81.8)
Altered sensorium	30 (22.7)	102 (77.3)

Table II: Frequency of distribution of liver cirrhosis etiology (n=132)

Variables	**Frequency n(%)**
Viral Hepatitis C/B	117 (88.6)
Others (like alcoholic, NASH etc)	15 (11.4)
Variables	**Frequency n(%)**
Class A	(0)
Class B	48(36.4)
Class C	84 (63.6)

A total of 21 patients showed LERS of ++. Among these, 18 patients (85.7%) were confirmed to have spontaneous bacterial peritonitis (SBP) based on standard ascitic fluid routine examination (R/E), while 3 patients (14.3%) were negative for SBP (table

4). While 24 patients with LERS of +++, 21 cases (87.5%) were confirmed positive for SBP on standard ascitic fluid R/E, whereas 3 patients (12.5%) were negative (Table 5).

These findings demonstrate a high positive predictive value for both ++ and +++ LERS grades when compared to the gold-standard diagnostic method. The sensitivity, specificity, predictive values, and overall diagnostic accuracy of the leukocyte esterase dipstick test at thresholds of **(++)** and **(+++)** were calculated separately, using standard ascitic fluid routine examination (R/E) as the diagnostic gold standard for spontaneous bacterial peritonitis (SBP).

The results of the study showed that with LERS++, the confirmation rate for SBP was 85.7% in contrast to the patients with LERS+++ which was increased to 87.5%. LERS++ threshold was calculated as follows: overall diagnostic accuracy, 79.5%, specificity, 96.7%, sensitivity, 42.9%, PPV, 85.7%, NPV, 78.4%. LERS+++ threshold was as follows: overall diagnostic accuracy 81.8%, sensitivity 50%, specificity, 80.6%, PPV 87.5%, and NPV 80.6%.

Table III: Frequency distribution of ascites grades (n=132)

Variables	Frequency (n=%)
Grade 2	24 (18.2)
Grade 3	108 (81.8)

Table IV: Frequency distribution of positive & negative ascites R/E results in LERS 2(++) cases (n=21)

Variables	2 (++) Positive LERS Results	
Standard Ascitic Fluid R/E Results	Frequency	(%)
Positive Ascitic Fluid R/E Cases	18	85.7%
Negative Ascitic Fluid R/E Cases	3	14.3%

Table V: Frequency distribution of positive & negative ascites R/E results in LERS 3(+++) cases (n=24)

Variables	3 (+++) Positive LERS Results	
Standard Ascitic Fluid R/E Results	Frequency	(%)
Positive Ascitic Fluid R/E Cases	21	87.5%
Negative Ascitic Fluid R/E Cases	3	12.5%

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Discussion

Spontaneous bacterial peritonitis (SBP) remains a serious complication in patients with liver cirrhosis and ascites, with prevalence rates between 20–40% globally and 29–40% in Pakistan. [11-15] Without timely antibiotic treatment, SBP carries a high mortality rate of up to 90%, often due to complications like renal failure and septic shock. In contrast, with early diagnosis and appropriate antibiotic therapy mortality rates significantly drop to 20–30%, and the risk of hepatorenal syndrome is reduced.[16,17] Nevertheless, the growing challenge of antimicrobial resistance is impacting management both internationally and within Pakistan. Based on researcher's work, the fact has been established that the LERS test serves a remarkable bedside screening that results in early detection and antibiotics intervention. This action plan is crucial for reducing and mitigating SBP-associated illnesses and deaths. Our research into the LERS test's usefulness showed better performance based on the scoring threshold. At the (++) threshold, the test demonstrated a sensitivity of 42.9% coupled with an excellent specificity of 96.7%. When the threshold was elevated to (+++), sensitivity rose to 50%, though specificity concurrently decreased to 80.6%. These observations collectively indicate that the LERS test possesses high specificity but a comparatively low sensitivity. Consequently, the test proves to be more trustworthy in confirming the presence of SBP when the result is positive, yet it is less effective for the

purpose of reliably ruling out the condition when a negative result is obtained. Our study results aligned with a previous systematic review and meta-analysis by Patel, K.P, et al. reported sensitivities ranging from 80.6% to 96.2% and specificities from 67.2% to 97.4%, depending on the type of reagent strip used.[16] The study conducted by Shrestha, P., and R. Shrestha found that using grade 3 as a cutoff, the LERS test had a sensitivity of 96.3% and specificity of 90.2%, while using grade 4 as a cutoff, sensitivity decreased to 81.5% but specificity increased to 99.1% .[17] A study by Patel. K.P, evaluating the CYBOW™ 10 reagent strip reported a sensitivity of 82.14% and specificity of 99.39% at the +2 cutoff, with an area under the curve (AUC) of 0.9074, indicating high diagnostic accuracy. These results indicate that the choice of reagent strip and threshold value remarkably effect the investigative functioning of the LERS test.[18] In spite of the recorded variation in sensitivity, the high specificity and negative predictive value constantly testified across numerous studies—comprising the present study—strengthen the use of the LERS test as an effective screening technique for SBP. The test's speedy processing time and total effortlessness of usage allow it substantial value, principally in locations where assets are limited and fast lab analysis may not be feasible. The relatively low sensitivity recorded in certain studies shows the necessity for careful display of a negative LERS result. Clinicians are recommended to employ confirmatory tests and ensure robust clinical correlation, particularly in cases where patients present with a strong suspicion of SBP.

Conclusion

Our study concludes that LERS can be a time saving and cheaper diagnostic option for SBP in cirrhotic patients with ascites in our resource constrain health care facilities. Although it cannot replace Standard diagnostic Ascitic Fluid R/E method, it can help remote health care facilities and less affluent hospitals to diagnose SBP and start timely empirical treatment, to prevent the drastic outcomes of late diagnosis of SBP.

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