

Original Article

ACCURACY OF REAGENT STRIPS IN RAPID DIAGNOSIS OF SPONTANEOUS BACTERIAL PERITONITIS (SBP)

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Objective: The objective of this study was to evaluate the accuracy of reagent strips for diagnosis of spontaneous bacterial peritonitis (SBP) in cirrhotic patients with ascites, taking polymorphonuclear cell count in ascetic fluid as standard criterion..

Material and Methods: One hundred and fifty patients having cirrhosis of liver and suspicion of SBP admitted in the medical ward of Services Hospital, Lahore were included in the study. Ascetic fluid of the patients was tested in the hospital laboratory for polymorph nuclear cell count and at the same time leukocyte esterase activity of the fluid was assessed by reagent strips. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of reagent strips were calculated.

Results: Frequency of SBP in cirrhotic patients with ascites was 28.67%. Specificity, sensitivity, positive predictive value, negative predictive value and diagnostic accuracy of reagent strips for diagnosis of SBP in cirrhotic patients with ascites, taking PMN cell count in ascetic fluid as standard criterion was calculated as 93.02%, 94.39%, 86.97%, 97.12% and 94% respectively.

Conclusion: In view of the results of the current study reagent strip method can be recommended as a rapid and accurate method for diagnosis of SBP in cirrhotic patients.

Key words: Spontaneous bacterial peritonitis, polymorph nuclear cell count, reagent strips, diagnostic accuracy.

Introduction

Cirrhosis is a serious and irreversible consequence of chronic liver disease characterized by replacement of liver tissue by fibrous tissue and regenerative nodules.^{1,2} It is a major cause of mortality and morbidity worldwide.³ Besides other signs and symptoms of the cirrhosis, ascites is an important complication of advanced cirrhosis. It is sometimes refractory to treatment and is complicated by spontaneous bacterial peritonitis.^{4,5} Spontaneous bacterial peritonitis is a frequent and serious complication in cirrhotic patients with ascites. Early diagnosis and treatment are essential for the survival of patients with SBP.^{6,7} The prevalence of SBP among unselected hospitalized cirrhotic patients with ascites is up to 30%.^{6,8} Unfortunately, symptoms of SBP including fever, abdominal pain, nausea and vomiting are not present in all patients with SBP.^{8,9} Mortality rate due to SBP remains high; 30-50% despite a good response to antibiotic treatment. Therefore rapid diagnosis and early treatment with antibiotics is a key for improved survival.⁷ A polymorph nuclear leukocyte (PMN) cell count; more than 250/mm³ in transudative ascetic fluid irrespective of the ascetic fluid culture is currently considered to be the standard criterion for

diagnosis of SBP.^{3,8} However, manual ascetic fluid PMN cell count is not always available every where especially in outpatients department and more ever it takes few hours for diagnosis.

Recently, leukocyte esterase activity testing by dipstick has been used for a rapid diagnosis of infection in many body fluids such as urine, pleural fluid and cerebrospinal fluid. This test is based on the esterase activity of granulocytes present in the biological fluid, which reacts with a chemical compound on the reagent strip to cause a colour change in the azo dye. It has been proposed that reagent strip testing for leukocyte esterase may be utilized to reduce the time between performing paracentesis and obtaining a presumptive diagnosis of SBP from a few hours to a few seconds (sensitivity 97.7%, specificity 89.4%).^{10,11}

Moreover, such strips would be available everywhere, and could be a useful tool for diagnosing SBP, especially in developing countries like ours.

The aim of this study was to evaluate the usefulness of dipstick in rapid diagnosis of SBP in cirrhotic patients with the locally available dipstick test.

Material and Methods

One hundred and fifty patients were included in this cross sectional survey. Sampling technique was non

Probability purposive sampling, All male and female patients coming to medical emergency of Services Hospital, Lahore, with evidence of cirrhosis and ascites on clinical & ultrasonography were included in the study.

Following patients were excluded from the study.

- a Patients having exudative ascites with elevated PMN cell count in ascetic fluid as seen in tuberculosis and secondary peritonitis.
- a Patients having hemorrhagic ascites.
- a Patients with history of abdominal surgical procedure in the previous four weeks.

Informed consent for abdominal paracentesis was taken from the patients fulfilling the inclusion criteria. Ascetic fluid was sent to laboratory for microscopy (to determine PMN count), biochemistry (to determine protein and glucose) in disposable syringes and for culture sensitivity in blood culture bottle (to determine the mono microbial nature of infection).

The reagent strip (Multistix 10 SG®, Bayer Diagnostics) was immersed in 5ml of ascetic fluid placed in a dry and clean container as described by the manufacturer for identification of leukocyte esterase activity. After two minutes, the reagent strip was read comparing the colour of the leukocyte reagent strip area with the colorimetric 5-grad scale depicted on the bottle.

A correlation between PMN cell count and a 5-grade scale suggested by the manufacturer was as follows: grade 0, 0 PMN cells/ mm³ ; grade 1;25 PMN cells /mm³ ; grade2, 75PMN cells /mm³ grade3, 250 PMN cells / mm³ ; and grade 4, 500 PMN cells / mm³. Grade 3 and grade 4 were taken as positive for SBP.

All the data was entered and analyzed using SPSS version 10. The quantitative variable like age was presented as mean \pm SD. Gender was presented as frequency and percentages. Data regarding study variables i.e. reagent strips and microscopic ascetic fluid examination was represented by bar charts, multiple bar charts as descriptive statistics. Sensitivity, Specificity, positive predictive value, negative predictive value and accuracy of reagent strip for diagnosis of spontaneous bacterial peritonitis was calculated taking PMN cell count as standard criterion.

Results

A total of 150 patients fulfilling the inclusion and exclusion criteria were enrolled to evaluate the

accuracy of reagent strips for diagnosing SBP in cirrhotic patients with ascites, taking PMN cell count in ascetic fluid as standard criterion.

Ages of the patients were recorded between 46-55 years (**Table-1**)

There were 83 (55.33%) male and 67(44.067) female patients (**Table-2**).

According to the standard criterion of PMN cell count SBP was found in 43(28.67%) patients, whereas 107(7.33%) patients had no spontaneous bacterial peritonitis (**Table-3**).

Accuracy of reagent strip for diagnosing SBP in cirrhotic patients with ascites, taking PMN cell count in ascetic fluid as standard criterion revealed 40(26.67%) true positive, 6(4%) false positive, 3(2%) false negative and 101(67.33%) true negative patients for SBP.

Whereas specificity, sensitivity, positive predictive value, negative predictive value and diagnostic accuracy were calculated as 93.02%,94.39%,86.96%, 97.12% and 94% respectively (**Table-4**).

Table-1: Age distribution of the subjects (n=150).

Age (in years)	No. Of Patients	Percentage
25-35	09	6%
36-45	23	15.33%
46-55	57	138%
56-65	51	34%
66-70	10	6.67%
Total	150	100%
Mean and sd	84.54\pm3.65	

Table-2: Gender distribution of the subjects (n=150).

Gender	No. Of Patients	Percentage
Male	83	55.33%
Female	67	44.67%
Total	150	100%

Table-3: Frequency of SBP in cirrhotic patients with ascites (n=150).

SBP in cirrhotic patients with ascites	No. Of Patients	Percentage
Yes	43	28.67%
No	107	71.33%
Total	150	100%

Table-4: Accuracy of reagent strips for diagnosing SBP in cirrhotic patients with ascites, taking PMN cell count in ascetic fluid as standard criterion (n=150).

Peagent Strips	SBP In Cirrhotic Patients with Ascites		Total
	Positive	Negative	
Positive	True positive (a) 40 (26.67%)	False positive (b) 6 (4%)	a+b 46(30.67%)
Negative	False negative (c) 3 (2%)	True negative (d) 101 (67.33%)	c+d 104(69.33%)
Total	A+c 43 (28.67%)	B+d 107(71.33%)	150 (100%)

Sensitivity = $a/(a+c) \times 100 = 93.02\%$

Specificity = $d/(d+b) \times 100 = 94.39\%$

Positive predictive value = $a/(a+b) \times 100 = 86.96\%$

Negative predictive value = $d/(d+c) \times 100 = 97.12\%$

Accuracy rate = $(a+d)/(a+d+b+c) \times 100 = 94\%$

Discussion

Spontaneous bacterial peritonitis is a frequent and serious complication in cirrhotic patients having ascites. The prevalence of SBP among unselected hospitalized cirrhotic patients with ascites ranges between 10-30%.^{12,13} Although antibiotic therapy produces a good response, the mortality rate due to SBP remains high, 30-50%.^{14,15} Improved survival in SBP episodes may be obtained through rapid diagnosis and treatment.

SBP is highly likely when the PMN cell count in the ascetic fluid reaches a cut off of 250/mm.¹⁴ Once this cut off has been reached antibiotic therapy must be started immediately without waiting for a culture and sensitivity report of ascetic fluid. Reagent strip testing for leukocyte esterase has been found to be a sensitive and accurate predictor for the presence of PMN cells in body fluids such as urine,^{16,17} cerebrospinal fluid, seminal and peritoneal fluid.¹⁸ This test is based on the esterase activity of granulocytes present in biological fluid which reacts with a chemical compound on the reagent strip to cause a colour change in the azo dye (purple).

This study was planned to evaluate the accuracy of reagent strips for the diagnosis of SBP in cirrhotic patients having ascites taking PMN cell count in the ascetic fluid as the standard criterion.

SBP was diagnosed in 43(28.67%), patients whereas 107(71.33%) patients had no SBP. Specificity, sensitivity, positive predictive value, negative

predictive value and diagnostic accuracy of reagent strips for diagnosing SBP in cirrhotic patients with ascites, taking PMN cell count in ascetic fluid as standard criterion were calculated as 86.97%, 97.12%, 93.02%, 94.39% and 94% respectively.

These findings are in agreement with de aurango¹⁰ and sarwars¹¹ who recorded sensitivity as 97.7% and specificity as 89.4%.

Vanbiervliet et al showed that the multi stick 8SG rapid urine screening test had 100% sensitivity and specificity for SBP diagnosis.¹⁹ Castellote et al demonstrated that urine screening test stick (Aution sticks) had 96% sensitivity and 89% specificity for detecting SBP in cirrhotic patients with ascites.²⁰

In another study, Theovenot et al tested the reagent combur-2 test® LN) and found 89% sensitivity and 100% specificity.²¹ The results of our study are comparable to the results of the above mentioned studies.

Many hospitals in our country have limited laboratory facilities or are unable to perform PMN cell counts in ascetic fluid in emergency situations. Considering the mortality from SBP, this test will help to improve the management of SBP.

Conclusion

In view of the results of the current study with comparability to other studies, this accurate method may be used everywhere, thereby reducing the time from paracentesis to a presumptive diagnosis of SBP from few hours to a few seconds.

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