ORIGINAL RESEARCH ARTICLE

Evaluation of the Efficacy of Reagent Strips in the Rapid Bedside Diagnosis of Meningitis

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Abstract: Background: Meningitis is a major cause of morbidity and mortality worldwide, particularly among children. Early diagnosis and prompt treatment are essential to improve patient outcomes. Conventional cerebrospinal fluid (CSF) analysis requires laboratory facilities and may take longer to provide results. Urinary reagent strips offer a rapid, simple, and convenient method for bedside assessment of CSF parameters.**Aim:** To evaluate the utility and efficacy of urinary reagent strips (Combur 10) in the rapid bedside analysis of CSF glucose, protein, and leukocyte count and to compare their results with conventional laboratory methods.**Materials and Methods:** A cross-sectional study was conducted on 100 CSF samples collected from patients with suspected meningitis at Mahatma Gandhi Medical College and Research Institute, Pondicherry, India, from January 2023 to December 2023. CSF glucose, protein, and leukocyte levels were assessed using urinary reagent strips. The results were compared with conventional biochemical assays using an automated analyser and cell counts performed using Neubauer's chamber. Diagnostic performance was evaluated using sensitivity, specificity, positive predictive value, negative predictive value, Cohen's kappa coefficient, and receiver operating characteristic (ROC) curve analysis.**Results:** Among the 100 patients, 58% were male and 42% were female. Bacterial meningitis accounted for 41% of cases, viral meningitis for 56%, and fungal meningitis for 3%. For leukocyte detection, the sensitivity and specificity were 92.86% and 97.22%, respectively, at a cutoff of ≥15 cells/mm³, increasing to 100% for both at higher cutoffs of ≥70 and ≥125 cells/mm³. For protein detection, the sensitivity and specificity were 86.84% and 91.67%, respectively, at ≥30 mg/dL, while both reached 100% at the higher cutoff of ≥300 mg/dL. For glucose detection, the sensitivity and specificity were 46.67% and 100%, respectively, at the cutoff of less than 50 mg/dL, while sensitivity increased to 71.43% with 100% specificity at less than 40 mg/dL. The area under the ROC curve was 95.4% for leukocyte detection, 81.6% for protein detection, and 100% for glucose detection.**Conclusion:** Urinary reagent strips demonstrate considerable potential as a rapid and convenient bedside screening tool for CSF analysis in suspected meningitis. Their diagnostic performance varies according to the cutoff values used, with higher cutoffs demonstrating improved accuracy for leukocyte and protein detection. Although reagent strips cannot replace conventional laboratory investigations, they may serve as a useful preliminary diagnostic tool, particularly in emergency and resource-limited settings. Further multicentre studies are recommended to validate their diagnostic utility.

Keywords: Meningitis; Cerebrospinal Fluid; Urinary Reagent Strips; Combur 10; Bedside Diagnosis; Leukocyte Count; CSF Protein; CSF Glucose; Diagnostic Accuracy; Rapid Diagnostic Test.

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INTRODUCTION

Meningitis is a major cause of morbidity and mortality in children worldwide, accounting for around 180,000 fatalities every year [1]. Before vaccines were developed, the most common causes of bacterial meningitis were supposed to be *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type b (Hib), with the relative contributions of each varying according to time, place, and age group worldwide [1,2]. In high-income countries, the prevalence of bacterial meningitis caused by *S. pneumoniae* and Hib considerably declined with the introduction of their respective vaccinations. According to Indian studies, meningitis and pneumonia are the main causes of death for children under five, accounting for around 22.0% of all pediatric deaths [3]. The severity and necessary treatments vary depending on the cause of the meningitis. Immediate antibiotic treatment is crucial for bacterial meningitis cases.A lumbar puncture can be performed after a clinical examination to confirm the initial diagnosis of meningitis. Examining the spinal fluid under a microscope occasionally reveals the bacteria. Growing the bacteria from blood or cerebrospinal fluid specimens, performing quick diagnostic tests, or using polymerase chain reaction (PCR) all support or validate the diagnosis. Determining the serogroups and antibiotic susceptibility is crucial for formulating control strategies. Whole-genome sequencing and molecular typing reveal additional strain distinctions and guide public health interventions. The cause of meningitis can only be determined through examination of cerebrospinal fluid (CSF) [4-6]. Standard cerebrospinal fluid testing is non-specific and comprises glucose, protein, and white blood cell count with differential [5,7]. Reagent strips have been previously employed to analyze cerebrospinal fluid (CSF), but their results have been inconsistent, preventing widespread adoption. If refined and proven effective, these strips could potentially serve as a valuable tool for rapid bedside diagnosis of meningitis, facilitating prompt initiation of treatment by healthcare providers [8].

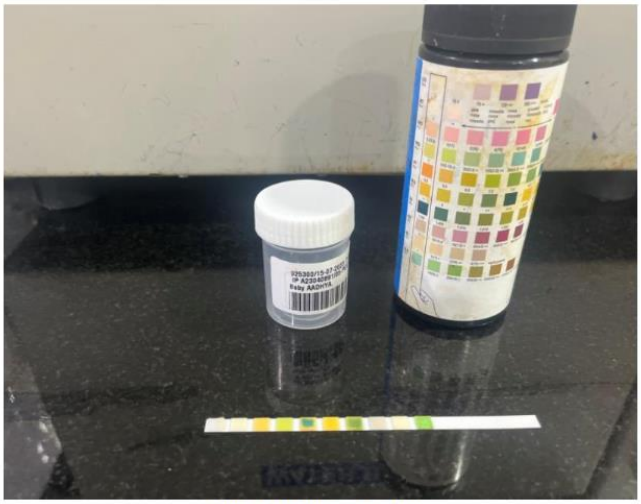

Fig 1: Reagent Strip

In spite of its various advantages, the reagent strip method is less popular among physicians for the diagnosis of meningitis. Hence, the present study aims to understand the accuracy of the reagent strip method for the diagnosis of meningitis.

AIM AND OBJECTIVES

AIM:

To evaluate the utility and efficacy of the Reagent Strip test (Combur 10) in the analysis of CSF sugar, protein, and cell count and to compare the results of sugar and protein with routine biochemical assays and cell count using Neubauer's chamber to aid in the rapid bedside diagnosis of meningitis.

OBJECTIVES:

1. To analyse CSF chemistry and CSF cell counts using reagent strips.
2. To compare the results of reagent strips (sugar and protein) with biochemical assays using an automated analyser.
3. To compare the results of CSF cell counts obtained from reagent strips with the values obtained using Neubauer's chamber.

2. MATERIALS AND METHODS

The study was conducted using CSF samples received within an hour of lumbar puncture from patients admitted with suspicion of meningitis at Mahatma Gandhi Medical College and Research Institute, Pondicherry, India, from January 2023 to December 2023. All CSF samples received in our laboratory with a volume of more than 1 ml were included, and haemorrhagic samples as well as CSF samples with a volume of less than 1 ml were excluded from the study. The study was a cross-

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sectional study involving 100 samples. CSF samples were received within an hour of the tap. Age and sex were recorded, and all samples were subjected to both index and definitive tests.

Index Test:
The index test was performed using urine reagent strips, which can detect 10 parameters, including protein, glucose, and leukocyte esterase. With the help of a pipette, 2–3 drops of undiluted CSF were added to the protein, glucose, and leukocyte esterase patches, and the colour change was recorded and interpreted using the manufacturer-provided colour grading.

Parameter	Result	Interpretation
WBC	<15	Negative
	15-70	1+
	125-500	3+
Protein	<30	Negative
	30-100	1+
	100-300	2+
	300-2000	3+
Sugar	<50	Negative
	50-100	Traces
	100-250	1+
	250-500	2+
	500-1000	3+

Definitive test:
Definitive tests were done by an independent blind observer. The tests done were cell count by Neubauer's chamber followed by differential counting on two centrifuged smears: one stained with hematoxylin and eosin stain and the other with Leishman stain along with protein and sugar estimation by an automated analyser.

Indextest	Goldstandard
Leukocytereagent strip	Microscopicexamination
Nocolor	<10 leukocytes/mm3
1+	10–75 leukocytes/mm3
2+	75–500 leukocytes/mm3
3+	>500 leukocytes/mm3
Glucosereagent strip	Biochemistryvalue
Nocolor	<50 mg/dl
1+	50–100
2+	100–300
3+	300–1000
4+	>1000
Proteinreagentstriptest	Biochemistryvalue
Nocolor	<30 mg/dl
1+	30–100
2+	100–500
3+	>500

Statistical Analysis:
The diagnostic accuracy of the reagent strip versus the standard tests was estimated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Cohen's kappa value. A receiver operating characteristic (ROC) curve showing the relationship between sensitivity and specificity as a function of the strip

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colour cutoff was plotted, and the area under the curve (AUC), along with its standard error, was calculated using the SPSS statistical software package 16.0.

RESULTS

According to the study, 58% of the patients were male and 42% were female. The majority of the patients (36%) in the study were above 16 years of age, 34% were less than 1 month old, 13% were between 2 and 5 years, 9% were between 6 and 15 years, and 8% were between 2 months and 1 year. In the present study, 41% of the patients had bacterial meningitis, 56% had viral meningitis, and 3% had fungal meningitis.

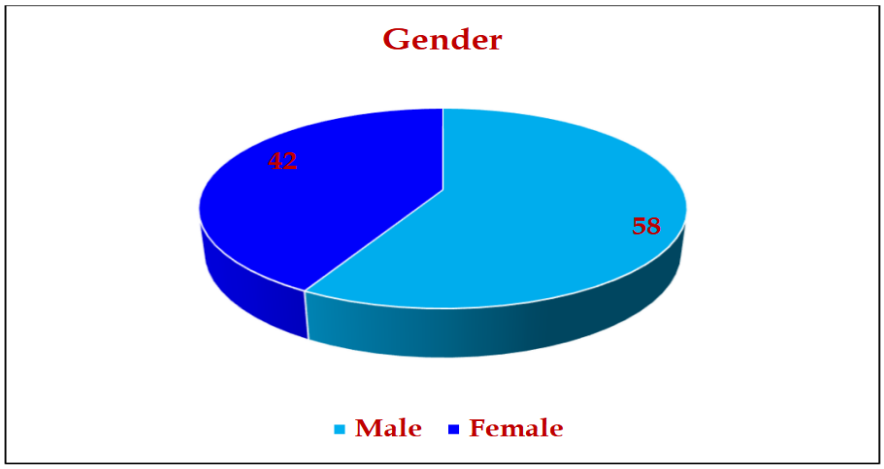

Fig 2: Distribution of Patients based on gender

Table 1: Distribution of Patients based on Age

Age	Frequency	Percent
0 day-– 1 month	34	34.0
2 months – 1 year	8	8.0
2 year – 5 years	13	13.0
6 years – 15 years	9	9.0
>16 years	36	36.0
Total	100	100.0

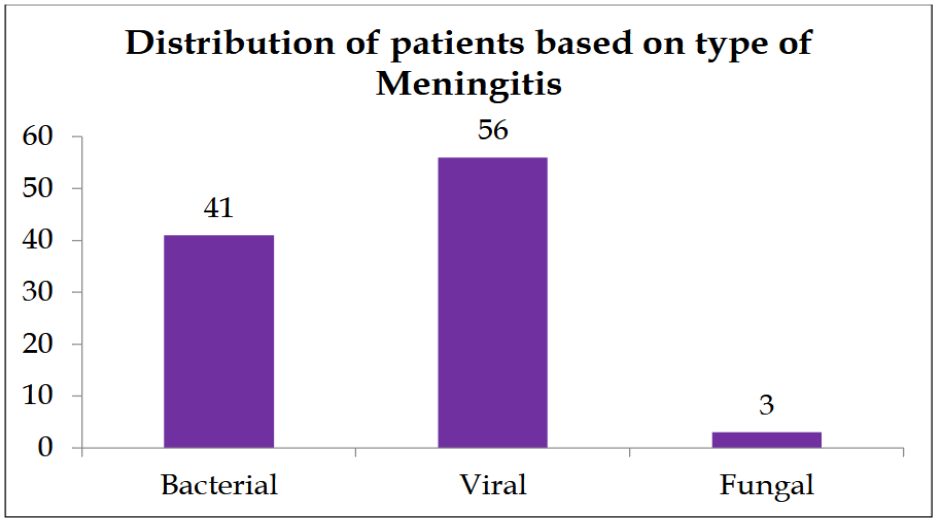

Fig 3: Distribution of Patients based on type of Meningitis



Fig 4: Sample results using Urinary Reagent Strips along with reference colour code

Table 2: Distribution of Patients based on causative Organism for Meningitis

Organism	Frequency	Percent	CumulativePercent
Streptococcusagalactiae	34	34.0	34.0
E.coli	7	7.0	41.0
HumanHerpesvirus	5	5.0	46.0
Enterovirus	51	51.0	97.0
CandidaSp	3	3.0	100.0
Total	100	100.0	

According to the study, 51% of the patients were infected with Enterovirus, 34% were affected by *Streptococcus agalactiae*, 7% were infected with *E. coli*, 5% were infected with Human Herpesvirus, and 3% were infected with *Candida* species.

Table3:Accuracy of Urinary Reagent Striptest for Leucocytes Count

Indextest(Strip test)		Reference standard	TP	FP	FN	TN	SN%	SP%	PPV%	NPV%
Leucocytes (cells/cu.mm)	1+	>15	26	2	2	70	92.86	97.22	92.86	97.22
	2+	>70	12	0	0	88	100.00	100.00	100.00	100.00
	3+	>125	10	0	0	90	100.00	100.00	100.00	100.00

The sensitivity and specificity for leukocytes by the strip method at ≥15 cells/cu. mm were 92.86% and 97.22%, respectively. However, both the sensitivity and specificity for leukocytes by the strip method at ≥70 cells/cu. mm and ≥125 cells/cu. mm were 100%. Thus, the accuracy increased to 100% with higher cutoffs of leukocyte count.

Table4:ReceiverOperatorCurveCharacteristicsforLeucocytes(>15cells/cu.mm)

Parameter	AreaUnderCurve(%)	StandardError
Leucocytes (>15cells/cu.mm)	95.4%	2.6%

Theareaunder Curvefor LeucocytesCount for more than15 cells/cu.mm. was95.4% with a minimum error of 2.6%.

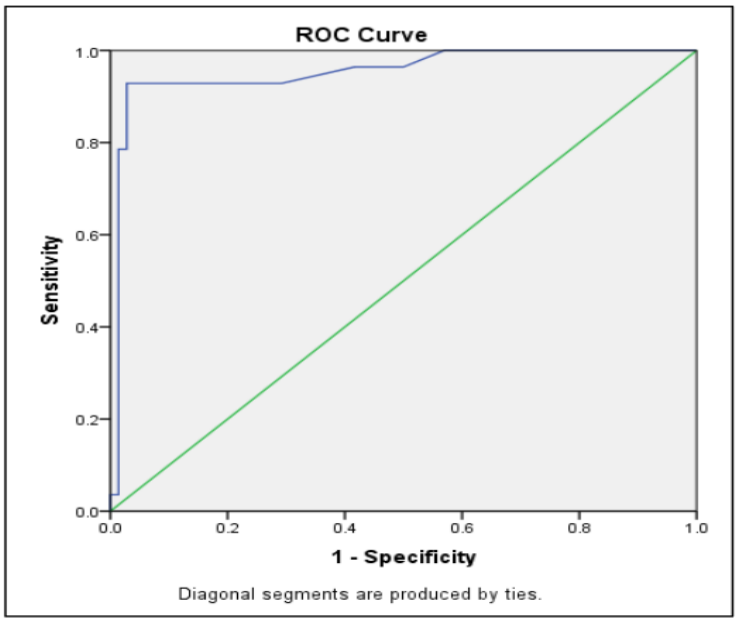

Fig 5: Receiver Operating Curve for Leucocytes >15 cells/cu.mm

Table5:Accuracy of Urinary Reagent Striptest for Protein Concentration

st(Strip test)		Reference standard	TP	FP	FN	TN	SN%	SP%	PPV%	NPV%
Protein (mg/dl)	1+	> 30 mg/dl	66	2	10	22	86.84	91.67	97.06	68.75
	2+	> 100 mg/dl	22	2	0	76	100.00	97.44	91.67	100.00
	3+	> 300 mg/dl	8	0	0	92	100.00	100.00	100.00	100.00

The sensitivity and specificity for Protein by the strip method for ≥30 mg/dl were 86.84% and 91.67%, respectively. The sensitivity for Protein by the strip method for ≥100 mg/dl was 100% and Specificity was 97.44%. But,both Sensitivityand Specificity for Protein by the strip method for ≥100 mg/dl was 100%. Thus, the accuracy increased to 100% with higher cutoffs of Protein Concentration. The area under Curve for Protein Concentration for more than 30 mg/dl was 81.6% with minimum error of 5.3%.

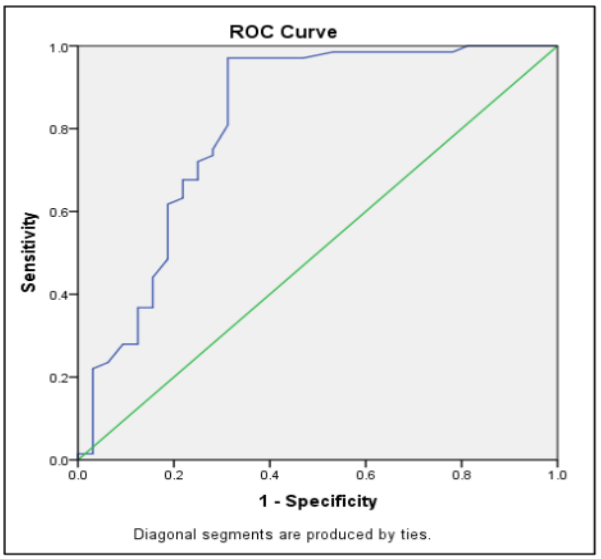

Fig 6: Receiver Operating Curve for Protein concentration >30 mg/dl

Table6:Accuracy of Urinary Reagent Striptest for Sugar Concentration

Indextest(Strip test)		Reference standard	TP	FP	FN	TN	SN%	SP%	PPV%	NPV%
Sugar (mg/	<50	< 50 mg/dl	14	0	16	70	46.67	100.00	100.00	81.40
	<40	<40 mg/dl	10	0	4	86	71.43	100.00	100.00	95.56

The sensitivity and specificity for Sugar by the strip method for<50 mg/dl were 46.67% and 100% respectively. The sensitivity for Sugar by the strip method for < 40 mg/dl was 71.43% and Specificity was 100%. Thus, the accuracy increased to 100% with higher cutoffs of Sugar Concentration. The area under Curve for Sugar Concentration for less than 50 mg/dl was 100% with no error.

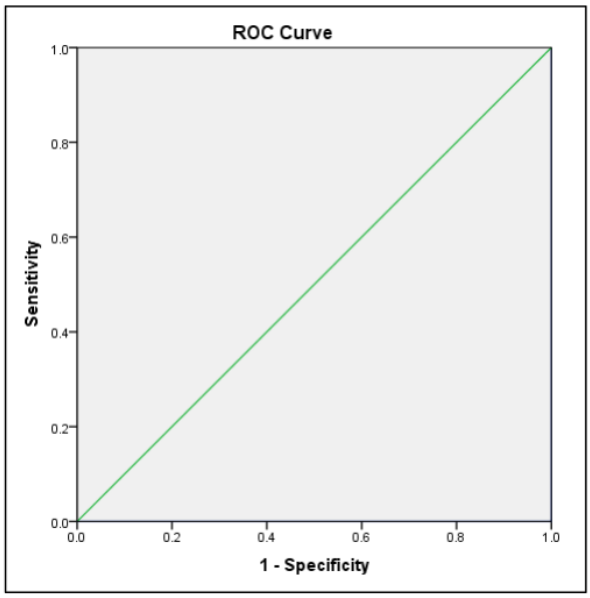

Fig 7: Receiver Operating Curve for Sugar concentration <50 mg/dl

DISCUSSION

In the present study, 58% of the patients are male and 42% are female. Similarly in a study by Archana et al, [9] 60% of the patients were male and 40% were female. In a study by Singh et al, [10] the number of male (16%) and female (13%) meningitis patients were almost equal.

Majority of the patients (36%) in the study are above 16 years of age, 34% are less than 1 month old which is almost equal to a study by Archana et al, [9] where 26% of the patients were less than 1 year. In the study, 13% are between 2 and 5 years, 9% are between 6 and 15 years and 8% are between 2 months and 1 year. Majority of the Male (24) are more than 16 years old whereas, majority of the female (14%) are less than 1 year old.

Leucocyte count using Urinary reagent strip is exactly similar for patients with more than 70 cells/cu.mm and 125 cells/cu/mm. However, Urinary reagent strip could not detect 2 cases with more than 15 leucocytes/cu.mm.

The sensitivity and specificity of the strip method for detecting leukocytes at ≥15 cells/cu.mm were 92.86% and 97.22%, respectively. For higher thresholds of ≥70 cells/cu.mm and ≥125 cells/cu.mm, both sensitivity and specificity were 100%. Thus, the accuracy increased to 100% with higher cutoffs of Leucocyte count. But in a study by Joshi et al, [11] sensitivity (85.25) and specificity (89.6%) leukocyte esterase positivity was lower than the present study. The Sensitivity, Specificity and Accuracy of Leucocyte count was 89.28%, 98.6% and 98.7% respectively in a study by Mazumder et al, [12] which is almost the same in the present study. But, the sensitivity for Leucocyte Count was 100% in a study by Gupta and Dwivedi,[13] In the other studies, [14-16] the sensitivity was above 90%, but in a study by Buch et al, [17] the sensitivity was very low (26%).

Protein concentration using Urinary reagent strip is exactly similar for patients with more than 100 mg/dl protein concentration and 300 mg/dl protein concentration. However, Urinary reagent strip could not detect 2 cases with more than 30 mg/dl Protein Concentration. The sensitivity and specificity for Protein by the strip method for ≥30 mg/dl were 86.84% and 91.67%, respectively. In the study by Joshi et al. [10], the reagent strip demonstrated a higher sensitivity of 98.1% for detecting CSF proteins greater than 30 mg/dL, but a lower specificity of 57.1%. This indicates that the test is very good at correctly identifying positive cases (high sensitivity), but it may also yield a significant number of false positive results (lower specificity). On the other hand, in the study by Archana et al. [9], the reagent strip showed a high sensitivity of 100% for detecting CSF proteins greater than 30 mg/dL, but the specificity was notably lower at 28.57%. This suggests that while the test is excellent at ruling out negative cases (high sensitivity), it may also incorrectly identify many negative cases as positive (low specificity). The Sensitivity%, Specificity% and Accuracy% of protein detection was 85.7%, 95.6% and 92.9% respectively in a study by Mazumder et al [12] which is almost equal in the present study. Similarly, in none of the previous studies [14-16] the sensitivity of reagent strip for protein detection was 100% but above 90%. In contrast in a study by Buch et al, [17] the sensitivity was only 56%. The sensitivity for Protein by the strip method for ≥100 mg/dl was 100% and Specificity was 97.44%. But, both Sensitivity and Specificity for Protein by the strip method for ≥100 mg/dl was 100%. Thus, the accuracy increased to 100% with higher cutoffs of Protein Concentration.

Sugar levels using Urinary reagent strip could not be detected in 20 cases. But, the detection was approximately similar in Urinary Reagent Strip test and Neubauer's Chamber (10 against 14) for a sugar level below 40 mg/dl. The sensitivity and specificity for Sugar by the strip method for<50 mg/dl were 46.67% and 100% respectively. The sensitivity for Sugar by the strip method for < 40 mg/dl was 71.43% and Specificity was 100%. Thus, the accuracy increased to 100% with higher cutoffs of Sugar Concentration. Thus, the accuracy increased to 100% with higher cutoffs of Sugar Concentration. But in a study by Mazumder et al, [12] the sensitivity of Sugar detection was very low but specificity was 100% with an accuracy of 92.8%. But, the sensitivity for sugar detection was 100% in a study by Wankhade et al, [18] and Gupta and Dwivedi [13]. The accuracy was 84% with Coefficient of agreement, the Cohen's Kappa value as 0.551 indicating moderate agreement of the results between the reference test and Urinary Reagent Strip test for Sugar concentration of less than 50 mg/dl. The area under Curve was 100% with no error. Similarly, in a study by Singh et al, [10] the diagnostic accuracy of urine reagent strips for detection of sugar was little lower than the present study (79.41%) with a Cohen's kappa of 0.86.

The efficacy of reagent strips for diagnosis of Meningitis is improved with increase in cutoff values for Leucocyte count, Protein detection and Sugar detection. But, the sensitivity, Specificity and accuracy of the strip varies in different studies due to the difference in study design, characteristics of the sample and the brand of reagent strip used.

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CONCLUSION

The purpose of this study was to assess the effectiveness of reagent strips in the quick detection of meningitis at the bedside. The overall diagnostic accuracy, specificity, and sensitivity of reagent strips in comparison to conventional laboratory techniques. Reagent strips have a major benefit over traditional procedures in that they can yield results quickly—usually in minutes as opposed to hours or days. In clinical settings, where timely decision-making can have a major impact on patient outcomes, this immediacy is essential. Reagent strips are especially useful in situations with limited resources or during outbreaks when laboratory facilities are Over burdened or unavailable due to their portability and simplicity of usage. Larger, multicenter trials should be the main focus of future research in order to confirm these results in a variety of situations and demographics. To improve the diagnostic value of reagent strips, it would also be advantageous to design them to detect a wider spectrum of infections, such as fungal and viral agents. Furthermore, a more thorough and quick diagnostic answer might be provided by combining reagent strip diagnostics with other quick diagnostic technologies like PCR and next-generation sequencing. Reagent strips are an effective tool for the quick bedside diagnosis of bacterial meningitis and have several benefits, including speed and convenience of use. Although they shouldn't take the place of conventional laboratory techniques, they are a great first diagnostic tool, especially in emergency and resource-constrained situations. To increase their accuracy and enhance their diagnostic powers, research and development must continue. Healthcare professionals may guarantee prompt and accurate diagnosis by incorporating these developments, which will ultimately improve patient outcomes and lessen the toll that meningitis takes on healthcare systems. It is strongly advised to use the more recent reagent strips with three patches for measuring proteins, leukocytes, and glucose, with cut-off levels that match CSF values. It is also beneficial to add the fourth patch of nitrate in order to obtain more information.

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