RESEARCH PAPER

CSF Analysis Using Urinary Reagent Strip- A Reliable Bedside Diagnostic Tool for Bacterial Meningitis

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ABSTRACT

Background: Acute bacterial meningitis is a life-threatening neurological emergency requiring rapid diagnosis and prompt treatment. Conventional cerebrospinal fluid (CSF) analysis is time-consuming and often unavailable in resource-limited settings. Urinary reagent strips offer a rapid bedside alternative for semi-quantitative assessment of CSF glucose, protein, and leukocyte esterase.

Objective: To determine the diagnostic accuracy of urinary reagent strips for cerebrospinal fluid analysis in patients with suspected meningitis.

Methods: This cross-sectional validation study was conducted over six months at the Department of Neurology, Pakistan Institute of Medical Sciences (PIMS), Islamabad. A total of 132 patients with suspected meningitis were enrolled through non-probability consecutive sampling. Each CSF sample underwent standard laboratory analysis and simultaneous urinary reagent strip testing for leukocyte esterase, protein, and glucose. Diagnostic performance was evaluated by calculating sensitivity, specificity, and receiver operating characteristic (ROC) curves using SPSS version 26.

Results: The mean age of participants was 39.37 ± 15.30 years; 57 (43.2%) were male and 75 (56.8%) were female. Leukocyte esterase positivity demonstrated a sensitivity of 80.5% and specificity of 86.7% for detecting CSF leukocytes >10/mm³. For CSF glucose <50 mg/dL, the strip showed a sensitivity of 50.0% and specificity of 97.6%. Protein detection at the 2+ threshold (corresponding to CSF protein >100 mg/dL) achieved a sensitivity of 91.2% and specificity of 85.6%. Combining positive leukocyte esterase with protein ≥2+ yielded a sensitivity of 87.0% and specificity of 82.6%, indicating good diagnostic performance for identifying abnormal CSF suggestive of bacterial meningitis.

Conclusion: Urinary reagent strips provide a rapid, simple, and reasonably accurate bedside method for preliminary CSF assessment in suspected meningitis. Their high diagnostic performance, particularly when leukocyte esterase and protein parameters are interpreted together, makes them a valuable adjunct in resource-constrained settings where conventional laboratory facilities are unavailable or delayed. Further multicenter studies with larger sample sizes are recommended to standardize this approach.

Keywords: Bacterial Meningitis, Cerebrospinal Fluid, Urinary Reagent Strip, Bedside Diagnosis, Leukocyte Esterase, Protein, Glucose, Diagnostic Accuracy

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INTRODUCTION

One of the most serious diseases that can affect both adults and children is acute meningitis. In order to manage these patients and reduce morbidity and death, prompt and accurate diagnosis and treatment are crucial. Meningitis is categorized as a medical emergency since it can be fatal because the inflammation is close to the spinal cord and brain. [1] Cerebrospinal fluid (CSF) analysis, which includes CSF chemistry, microscopy, and microbiology tests, is used to diagnose meningitis. A skilled microscopist is required to estimate the number of cells in cerebrospinal fluid, while skilled laboratory assistance is required to measure protein and glucose levels. In situations with limited resources, these capabilities are frequently unavailable, and even when they are, the response times are lengthy. [2] As of right now, there is no quick point-of-care testing for meningitis.

In most facilities, it takes about 6–8 hours to achieve the chemical analysis and cell count, 8–24 hours for gram staining, and 72 hours for culture analysis. On the other hand, many establishments that are essential to our medical system, such community health clinics and district hospitals, lack laboratory equipment designed expressly for cerebrospinal fluid analysis. Having a diagnostic method that is simple to use in first referral units (FRUs) and basic health clinics is essential for developing nations.

Existence of red and white blood cells protein, glucose can be detected with the help of reagent strips that are

commonly used for urinalysis.[3] Reagent strips have been used in the past to assess the chemistry and cellularity of CSF, but the outcomes have been inconsistent, making this approach unpopular. If successful, these strips could be a useful tool for doctors to quickly diagnose meningitis at the bedside and start treatment. [4] The aim of this study was to evaluate the performance of urinary reagent strips for semi-quantitative detection of glucose, proteins and leukocyte esterase in cerebrospinal fluid (CSF) samples for differentiation between healthy and abnormal CSF.

Reagent strips have been previously utilized to quantify the cellularity and chemistry of CSF but results have been inconsistent and the method has not been widely accepted. [5] These strips can be a great test to assist medical professionals in quickly diagnosing meningitis at the bedside and starting treatment if they prove to be beneficial. Health workers working in situations with limited resources would tremendously benefit from this.

The aim of this study was to evaluate if semi-quantitative analysis of proteins, glucose and leukocyte esterase (instead of CSF glucose, levels of protein, and cell number) using a urinary reagent strip can provide an accurate differentiation between a normal and an aberrant CSF sample.

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STUDY METHODS

Objective: To ascertain the urine reagent strip's diagnostic precision for meningitis CSF analysis.

Study design: Cross sectional validation study

Duration: Six months after approval of study.

Setting: Study was carried out at Department of Neurology, Pakistan Institute of Medical Sciences Islamabad.

Sample size: Sample size was calculated using WHO sample size calculator with following parameters.

Sensitivity = 98.1%

Specificity = 57.9%

Expected Prevalence = 50%

Precision Level = 10%

Confidence Level =95%

Sample size turned out to be 132 expected patients of meningitis.

Sampling technique: Non-probability consecutive sampling

Method: The study was conducted at the Department of Neurology, Pakistan Institute of Medical Sciences, Islamabad, to evaluate the diagnostic precision of urinary reagent strips for cerebrospinal fluid analysis in meningitis.

The PIMS Hospital/SZABMU Ethical Review Board provided ethical approval. 132 patients suspected of having meningitis were chosen using non-probability sequential sampling after obtaining informed consent from all participants. Baseline examinations were sent to rule out thrombocytopenia and detect abnormalities in the coagulation profile following a comprehensive clinical examination and detailed history. One CSF sample was sent to a lab for CSF examination, while another was used for urinary reagent strip analysis. Leucocytes, glucose, and protein are measured semi-quantitatively using urine reagent strips. As a result, they offer a simple way to test the pertinent chemical characteristics of the CSF. The leukocyte, glucose, and protein reagent strip was treated with three drops of CSF. Combur-Test reagent strips were utilized in this investigation. The "test pad" is a tiny, designated location on these strips for an enzymatic reaction. These test pads offer semi-quantitative measures of protein, glucose, and leucocytes. Protein was measured at 60 seconds, glucose at 30 seconds, and the leukocyte test pad for color change at 120 seconds. SPSS 26 was used to analyze the gathered data.

Index Tests

CSF Leukocytes: The reagent strip has a detection limit of 500 cells/mm3 and needs at least 10 cells to identify a normal CSF WBC count of fewer than 5 cells/mm3.

Test findings were determined by the manufacturer's color grading scheme (less than 10 granulocytes/mm3 appears as no color; 10-75 granulocytes/mm3 correspond to 1+; 75-500 granulocytes/mm3 correlate to 2+and >500 granulocytes/mm3 correspond to 3+) of undiluted CSF.

CSF Glucose: The CSF glucose level is about 2/3 of the plasma glucose. Both of them bacterial and fungal meningitis are associated with decreased CSF glucose levels. The CSF glucose was evaluated using the reagent strip for glucose either below or above 50 mg/dL.Any change in color was considered as >50 mg/dL and no change in color was read as <50 mg/dL.

CSF Proteins: The strip detects protein in the range of 30 to 500 mg/dL, whereas normal CSF protein is 15 to 45 mg/dL. We determined if the CSF protein was >100 mg/dL, within 30 and 100 mg/dL, or <30 mg/dL (normal). The reagent strip was interpreted as no color change if the reading was below 30 mg/dL, 1+ if the reading was 30 to 100 mg/dL, 2+ if the reading was 100 to 500 mg/dL, and 3+ if the reading was greater than 500 mg/dL.

Reference Tests: Full cell counts in the CSF were performed by microscopy in a Neubauer's chamber within 1 h of CSF sample collection. Differential cell counts were also done on a centrifuged sample of CSF stained with Giemsa. The amounts of glucose and protein in CSF were measured by conventional biochemistry.

DATA ANALYSIS

The data collected was analyzed using the Statistical Package for the social sciences (SPSS) version 26. The results were summarized using mean ± SD (standard deviation) for quantitative variables such as age and positive urine strip test, while frequency with percentages

were provided for qualitative variables such as gender. A 2x2 table was created to assess the diagnostic accuracy of the urinary reagent strips based on sensitivity and specificity along with 95% confidence interval to check the precision of estimates and Receiver operating characteristic (ROC) curves are utilized to assess the overall efficacy of the individual index tests and to identify the corresponding cutoff levels for each index test.

		Lab CSF analysis	
		Positive	**Negative**
Urinary Reagent Strip	Positive	a	B
	Negative	c	D

Sensitivity = a/a+c×100
Specificity = d/b+d × 100

RESULTS

We enrolled 132 patients in our study. The mean age of patients was 39.37±15.30 years. Total male in our study was 57(43.2%) and female was 75(56.3%).

Table 1

Shows the Demographics Characteristics and Presenting Symptoms of our Study Population

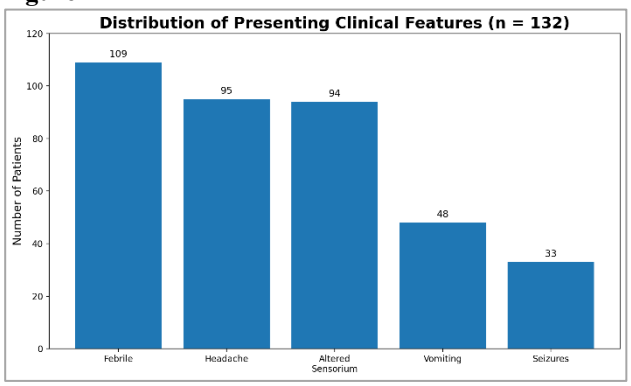
	Number	**Percentage**
Male	57	43.2
Female	75	56.3
Febrile	109	82.5
Afebrile	23	17.4
Headache	95	71.9
No Headache	37	28.0
Vomiting	48	36.4
No Vomiting	84	63.6
Seizures	33	25.0
Seizure Free	99	75.0
Altered Sensorium	94	71.2
Normal Sensorium	38	28.8

We assessed the diagnostic accuracy of significant indicator tests independently and in combination with laboratory test results or microscopy as benchmark standards, alongside rapid strip-based testing as index tests. The identification of CSF granulocytes over 10/mm3 revealed that leukocyte esterase positivity via test strip had a sensitivity of 80.5% and a specificity of 86.7%. A negative glucose level below 50 mg/dl exhibits a sensitivity of 50% and a specificity of 97.6%. For the identification of CSF proteins larger than 30 mg/dL, protein reagent strip positivity had a high sensitivity 93.1%, but the specificity was poor 54.7% because there were more false positives found using the strip test. Utilizing a higher threshold for detection of 2+ or above and cerebrospinal fluid proteins exceeding 100 mg/dL enhanced selectivity. The new sensitivity and specificity at 2+ cutoff were 91.2% and 85.6% respectively.

Employing both the positive leukocyte esterase and 2+ protein gave high sensitivity and specificity of 87% and 82.6% respectively.

Increased levels of CSF leukocytes and protein correlated with elevated readings of the test strip's leukocyte esterase and protein indicators, respectively. ROC analysis indicates that the urinary protein strip exhibited optimal performance at a cut-off of 1+ for estimating CSF protein levels of 30 mg/dL or greater, with an area under the curve of 0.92, and at 2+ for estimating CSF protein levels of 100 mg/dL or greater, with an area under the curve of 0.96.

Figure 1



DISCUSSION

Meningitis, an infection of the spinal cord and brain, represents a medical emergency for prompt diagnosis and treatment to save irreversible neurological damage and death. Concurrently, disorders like febrile seizures, particularly in juvenile patients, may mimic meningitis, creating a diagnostic challenge for physicians.

Meningitis is diagnosed by analyzing cell count in cerebrospinal fluid, evaluating glucose and protein levels, and doing microbiological tests. Precise cell enumeration, as well as sugar and protein quantification, requires the involvement of a certified pathologist and sufficient laboratory apparatus. These services may be unavailable in rural areas, and even when accessible, the waiting period for laboratory-based CSF examination is extended. Despite extensive study on the application of urinary reagent strips, a dependable semi-quantitative method commonly utilized in urine analysis—for diagnosing meningitis, this methodology has not yet garnered the recognition it deserves.[7,8,9] Subject to additional confirmation via lab findings, the reagent strip test may function as an expedient bedside diagnostic instrument for evaluating CSF pleocytosis and measuring protein and glucose concentrations. [10,11]

In our investigation, the diagnostic precision of urine strips for cerebrospinal fluid leukocytes in meningitis patients was High the sensitivity was 80.5%, specificity was 86.7%. CSF Protein sensitivity and specificity at 2+ cutoff were 91.2% and 85.6% respectively. Using both the positive leukocyte esterase and 2+ protein gave high sensitivity and specificity of 87% and 82.6% respectively. The results of this study show that by using following thresholds, Normal Glucose, 1+ leukocyte esterase and 2+ proteins, the overall utility and specificity of urine strips become very high and they can be used a safe and reliable measure to diagnose meningitis quickly Our research results, in conjunction with the reviewed literature, demonstrate a robust association between laboratory testing procedures and strip methods for evaluating CSF glucose, protein, and leukocyte concentrations. Parmar et

al. reported the specificity and sensitivity of the urine strip use as 96.42% and 97.14%, respectively.[12]

In another investigation, the sensitivity for bacterial meningitis and tuberculous meningitis was 96.55% and 100%, respectively. The results for aseptic meningitis are 96.55% and 70%. The overall diagnostic accuracy for meningitis was 96.78% for meningitis in general, 83.0% for aseptic meningitis, 98.27% for tuberculous meningitis, and 96.78% for bacterial meningitis.[13]

Romanelli et al. compared the efficacy of strip reagents with biochemical assays and cytological discoveries, resulting in a specificity of 98.1%, sensitivity of 90.7%, negative predictive value of 96.4%, positive predictive value of 95.1%, and accuracy of 96.1%.[14]

Salvador et al. and Moosa et al. employed the strip method for meningitis diagnosis, concluding it to be an effective and rapid testing approach. [15,16] Chikkannaiah et al. utilized urine strips for the semi-quantitative assessment of cerebrospinal fluid chemistry and cellularity, demonstrating that the leukocyte estimate displayed a specificity of 94.5% and a sensitivity of 96.6%. At a threshold of 100 mg/dl, the strip displayed a specificity of 87.1% and sensitivity of 96% for proteins, but showed diminished specificity at a cutoff of 30 mg/dl. The strip demonstrated high specificity (100 percent) but reduced sensitivity at both cutoff values (40 mg/dl and 50 mg/dl) for glucose. [17]

Kumar et al. identified a significant correlation between strip and laboratory data for meningitis diagnosis, with P values of 0.0001 for cells, glucose, and protein, respectively.[18]

In their study, Maclennan et al. discovered that the nitrate patch test may provide additional insights. They determined that the nitrate patch, part of the ten- parameter urinary reagent strip, will yield a positive result in bacterial meningitis when granulocyte levels are raised, while the esterase enzyme remains unactivated.[19]

In the era of antibiotic resistance, this test may prove invaluable in averting unnecessary overtreatment in children with febrile seizures or neonates with hypoxic seizures, particularly while meningitis remains a potential diagnosis. This is essential in our laboratory as we receive the majority of cerebrospinal fluid analyses from patients in the juvenile age group.[20] This approach is easy to apply, requires minimum technical proficiency, and is beneficial for primary health care facilities and rural areas with limited laboratory resources. Operators can be readily trained, and their proficiency can be evaluated before standard deployment. Notwithstanding these findings and our research, clinicians and laboratories in resource-limited environments do not employ this technology for the expedited diagnosis of meningitis. One of the hurdles faced by doctors and lab staff in the use of urinary strips is a different threshold than what's expected of CSF, because they are originally designed for use with urine. However, they can be modified to better reflect the thresholds appropriate for cerebrospinal fluid. When used for urine the different gradients correspond to 30mg/dl, 100mg/dl and 500mg/dl proteins, while abnormal CSF protein is widely considered abnormal above 45mg/dl, accordingly when modifying CSF use the thresholds can start from 45mg/dl of proteins instead of 30mg/dl. Similarly, the cut-off value for sugar detection in the CSF might be set at 40 mg/dL compared to 50 mg/dL in the strip used for urine, as the low glucose levels in CSF are more clinically relevant. Normally there are zero white blood cells in CSF and up to five can be a doubtful case, but any cells above are confirmed abnormal so there is no need to modify the glucose part of the strips.

For this reason, the authors decided to use a cut off 10 instead of 1, because minimal traumatic lumbar puncture procedure can result in cell counting more than 1.

Another possible modification is to limit the number of parameters checked by the strip, there is no need for pH, specific gravity, nitrates etc. Including only protein glucose and leukocyte esterase will reduce cost and reduce the time needed to perform the procedure.

CONCLUSION

As a consequence of our research, urinary Reagent Strip can be used as an early diagnostic tool for meningitis and based on the findings of comparable studies conducted by other observers, we may infer that urine reagent strips can be utilized to aid therapeutic decisions in instances of suspected meningitis, particularly in resource-limited situations. More research with a bigger sample size and comparisons with various manufacturer strips are possible. This technique, if standardized, has the potential to change the entire meningitis diagnosis procedure.

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