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Original Research Article

Assessment of Rapid Diagnostic Tests for the Detection of Bacterial Meningitis

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Abstract:

Background: Bacterial meningitis is a life-threatening infection associated with high morbidity and mortality, particularly in infants, young children, and immuno-compromised individuals. Rapid and accurate diagnosis is critical for timely initiation of appropriate antimicrobial therapy. Conventional diagnostic methods are time-consuming or have reduced sensitivity, especially after prior antibiotic exposure, highlighting the need to evaluate rapid diagnostic tests (RDTs).

Methods: A prospective observational diagnostic study was conducted between April 2025 and August 2025, involving 120 clinically suspected cases of bacterial meningitis aged ≥2 months. Cerebrospinal fluid samples were tested using RDTs at Primary Health Centers and compared with real-time polymerase chain reaction (PCR), considered the gold standard. Diagnostic performance was assessed using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Results: Of the 120 cases, 45 were confirmed positive by PCR. RDTs demonstrated a sensitivity of 86.7%, specificity of 93.3%, PPV of 88.6%, and NPV of 92.1%, with an overall agreement of 90.8% between RDT and PCR results. Children under five years constituted the most affected age group. Neisseria meningitidis was the most frequently detected pathogen, followed by Streptococcus pneumoniae.

Conclusion: RDTs showed high diagnostic accuracy and strong agreement with PCR, supporting their use as reliable point-of-care screening tools for bacterial meningitis, particularly in resource-limited settings. PCR remains essential for confirmatory testing in selected cases.

Keywords: Bacterial Meningitis; Cerebrospinal Fluid; Diagnostic Accuracy; Neisseria Meningitidis; Polymerase Chain Reaction; Rapid Diagnostic Tests; Streptococcus Pneumoniae.

Introduction

Bacterial meningitis is an infectious disease that can be fatal and is marked by the inflammation of the meninges located around the brain and spinal cord. Even though there are improvements in antimicrobial therapy and supportive care, bacterial meningitis is still a condition that causes high morbidity and mortality especially among pregnant women, newborn babies, and people with weak immune systems [1] where the survivors may already have the neurological problems such as hearing loss, cognitive impairment, seizures, and motor deficits besides the long wait for medical assistance and treatment to start which greatly reduces the chance of survival [2].

In low- and middle-income countries with limited advanced diagnostic facilities, the problem of bacterial meningitis continues to be a major global health issue [3]. The most frequently isolated pathogens are Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae, Escherichia coli, and Listeria monocytogenes, with variations in pathogen distribution according to age, place, and vaccination status. It is essential to quickly identify the causative pathogen because it is very important to diagnose and treat the patient soon; otherwise, there will be consequences in the form of bad clinical outcome which will be strongly related to delay in diagnosis and treatment [4].

The main method of diagnosing bacterial meningitis in the laboratory is the analysis of cerebrospinal fluid (CSF). This includes several different techniques such as microscopy, Gram staining, culturing the specimen, and determining the biochemical parameters like glucose and protein levels. Although CSF culture is still considered the best method for confirming the diagnosis, it is quite a lengthy process and has a low sensitivity for those patients whose treatment has involved antibiotics prior to culturing [5]. Gram staining is a quick method, but its sensitivity varies a lot depending on the number of bacteria present and the skill of the technician. Such limitations on tests frequently lead to a situation where the doctors would initiate empirical broad-spectrum antibiotic therapy, which may contribute to antimicrobial resistance and increase healthcare costs, thus making the situation around the diagnosis of bacterial meningitis even more complicated and costly [6].

Nevertheless, the diagnostic accuracy of quick tests shows a large range of variability based on the test type, pathogen detection, sample quality, and lab conditions. Problems related to sensitivity, specificity, cost, and availability still have great importance [7]. Incorrect-positive or incorrect-negative results can result in wrong treatment decisions, which makes it necessary to conduct a thorough evaluation of these tests before they are used in routine clinical practice. Thus, it is crucial to evaluate the performance of rapid diagnostic tests against conventional methods to establish their clinical reliability and cost-effectiveness [8].

The study now underway intends to carry out the assessment of diagnostic efficiency of rapid diagnostic tests through bacterial meningitis detection with laboratory gold standard methods to get their sensitivity, specificity, positive predictive value, and negative predictive value compared to [9]. The study not only hopes to clarify the clinical position of rapid diagnostic tests but also to indirectly support the use of these tests in the understanding and hence improving early diagnosis, timely antimicrobial therapy, and thus reducing the overall case load of bacterial meningitis through evidence-based insights [10].

Methodology

Study Design: This was a forward-looking observational study on diagnosis conducted for the purpose of assessing the performance of rapid diagnostic tests (RDTs) in the identification of bacterial meningitis. The outcomes of the RDTs were measured against real-time polymerase chain reaction (PCR), which was regarded as the gold standard.

Study Area: The research took place in the Department of Microbiology, Himalaya Medical College and Hospital, Paliganj, Patna, and Primary Health Center, Paliganj, Patna Bihar, India from April 2025 and August 2025

Study Population: The study included all patients of a month and older, who showed clinical signs of bacterial meningitis and presented them to the selected public health centers (PHCs), after getting informed consent.

Sample Size: It was the sample size that helped determine the evaluation of the rapid diagnostic tests on their diagnosis of bacterial meningitis. The total number of patients suspected of meningitis who took part in the study was approximately 120.

Selection Criteria:

- **Inclusion Criteria**
  - Patients aged ≥ 2 months
  - Patients presenting clinical features suggestive of bacterial meningitis as per WHO case definition
  - Patients who provided written informed consent (or consent from parents/guardians)
- **Exclusion Criteria**
  - Patients with contraindications for lumbar puncture
  - Patients who refused to give consent
  - Inadequate or insufficient cerebrospinal fluid (CSF) sample for testing

Variables (CVO)

- **Independent Variables**
  - Age
  - Sex
  - Clinical symptoms
  - Prior antibiotic intake
  - Time interval between symptom onset and lumbar puncture
- **Dependent Variables**
  - RDT results (positive/negative)
  - PCR results
- **Outcome Variables**
  - Sensitivity
  - Specificity
  - Positive predictive value (PPV)
  - Negative predictive value (NPV) of the RDTs

Data Collection: A predesigned and structured proforma was used for collecting data. For every patient, the demographic details such as age and sex together with clinical information like symptoms duration of illness and history of antibiotic intake prior to admission were noted. In addition to these patient-specific details rapid diagnostic test (RDT) results and PCR results were also documented as part of laboratory findings. Subsequently, all the data that was collected was compiled and entered into a master data sheet for analysis purposes.

Procedure: The process of collecting and testing samples was conducted in a very careful and systematic manner. After getting consent from the patients, CSF samples were taken from all the suspected cases through lumbar puncture, using aseptic techniques. The Primary Health Centers conducted rapid diagnostic testing on the freshly collected CSF samples. The CSF sample was divided; one part was refrigerated and the other part was sent to the Patna medical college and hospital for confirmatory real-time PCR testing under cold-chain conditions. Standard procedures were adhered to for sample handling, testing, and reporting.

Statistical Analysis: The data were processed with Microsoft Excel and appropriate statistical software was used for analysis. The descriptive statistics which included frequency and percentage, were employed to represent the demographic and clinical characteristics of the study population. The evaluation of the diagnostic accuracy of the rapid diagnostic tests was done through the computation of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), where real-time polymerase chain reaction (PCR) was considered the gold standard. To evaluate the concordance between the two techniques, a comparative analysis of RDT and PCR results was conducted. The findings were displayed in tables and charts where applicable. A p-value of less than 0.05 was deemed as statistically significant.

Results

Between April 2025 and August 2025, a total of 120 patients suspected of having bacterial meningitis were included in the research. Every single patient was subjected to rapid diagnostic testing (RDT) at Primary Health Centers (PHCs), and accordingly, the samples of cerebrospinal fluid (CSF) were dispatched to the Patna medical college and Hospital for positive detection through real-time polymerase chain reaction (PCR), which was regarded as the gold standard. The demographic, clinical, and laboratory characteristics of the individuals participating in the study were assessed to examine the ability of RDT to give a positive result when compared to PCR, ground-truth sample. Apart from this, the study also aimed to identify the bacterial pathogens most often detected in the case of suspected infections, as well as to assess the agreement between the RDT and PCR results.

Table 1: Demographic Distribution of Study Participants (n = 120)

Variable	Number	Percentage (%)
Age < 5 years	48	40
Age 5–18 years	31	25.8
Age > 18 years	41	34.2
Male	69	57.5
Female	51	42.5

As evidenced in Table 1, it is the subgroup of children aged under 5 that received most of the suspected meningitis cases (40%), thus showing that the very young are at a very high risk of bacterial meningitis because of their still-developing immune systems. The group of patients 5 to 18 years old constituted 25.8% of cases, while adults older than 18 years made up 34.2%, thus it becomes clear that meningitis is a problem across the entire lifespan. Males accounted for 57.5% of cases, thus the proportion is just slightly higher than that of females (42.5%). The difference, if any, might be the result of variances in healthcare-seeking behavior, social exposure, or even susceptibility. The knowledge of the age and sex distribution is of paramount importance for the crafting of preventive strategies, vaccination programs, and healthcare interventions targeting the high-risk population.

Table 2: Distribution of Clinical Features among Suspected Cases

Clinical Feature	Number	Percentage (%)
Fever	108	90
Neck stiffness	89	74.2
Altered sensorium	48	40
Headache	66	55
Seizures	32	26.7

Fever, recorded as the most prevalent presenting sign, occurred in 90% of patients and neck stiffness in 74.2% of the cases, as per Table 2. A considerable number of patients had experienced neurological symptoms, namely altered sensorium (40%) and seizures (26.7%), which were a sign of severe disease progression in some instances. Headache was mentioned by 55% of patients, thus underlining the need for simultaneous careful assessment of general and neurological symptoms. The results depict the typical manifestation of bacterial meningitis and accentuate the need for quick diagnostic testing that will not only avert complications but also lessen the overall impact in terms of morbidity and mortality.

Table 3: Comparison of RDT and PCR Results

Test Result	PCR Positive	PCR Negative	Total
RDT Positive	39	5	44
RDT Negative	6	70	76
Total	45	75	120

In table 3, it is indicated that among the 45 cases which were confirmed as positive by PCR, rapid diagnostic tests (RDTs) successfully detected 39 cases, and 6 cases were reported as false negatives. Out of the 75 cases which were negative by PCR, RDTs produced 5 false-positive results and accurately recognized 70 cases as true negatives. The results show that RDTs have high diagnostic accuracy and are good for the quick testing of bacterial meningitis. Nevertheless, the existence of false-negative and false-positive results recommends that RDT findings should be verified by PCR, especially in critically ill patients. The remarkable concordance noticed between RDT and PCR underlines the possible application of RDTs for prompt decision-making in places where the molecular diagnostic facilities are not available.

Table 4: Diagnostic Performance of RDTs

Parameter	Value (%)
Sensitivity	86.7
Specificity	93.3
Positive Predictive Value (PPV)	88.6
Negative Predictive Value (NPV)	92.1

RDTs, as displayed in Table 4, performed remarkably well in terms of diagnostic accuracy, having an 86.7% sensitivity and a 93.3% specificity. The positive predictive value (PPV) of 88.6% signifies that a vast majority of RDT positive results reflect actual infections, whereas the high negative predictive value (NPV) of 92.1% implies that negative results can be trusted to rule out the disease in most cases. These performance indicators are in favor of RDTs being efficient and practical point-of-care diagnostic tools for bacterial meningitis, especially in primary healthcare settings or during outbreaks where swift initiation of treatment is of utmost importance.

Table 5: Distribution of Bacterial Pathogens Detected by PCR (n = 45)

Pathogen	Number	Percentage (%)
Neisseria meningitidis	21	46.7
Streptococcus pneumoniae	15	34.4
Other bacteria	9	18.9

The findings in Table 5 depict the different types of bacteria that were detected through PCR method in the 45 confirmed bacterial meningitis cases. Neisseria meningitidis was the pathogen that was most often found, it made up 21 cases (46.7%), then followed Streptococcus pneumoniae with 15 cases (34.4%). Other types of bacterial pathogens were involved in 9 cases (18.9%) all together. Thus, it can be said that N. meningitidis and S. pneumoniae are still the main agents causing bacterial meningitis among the study people. The distribution of pathogens reveals the epidemiological significance of these microorganisms and the importance of rapid diagnostics and targeted therapies. Thus, it is essential to develop vaccination and health campaigns that will effectively curb the disease burden.

Table 6: Agreement between RDT and PCR Results

Agreement	Number	Percentage (%)
True Positive	39	32.5
True Negative	70	58.3
False Positive	5	4.2
False Negative	6	5
Overall Agreement	109	90.8

Table 6 demonstrates the level of agreement between rapid diagnostic tests (RDTs) and polymerase chain reaction (PCR) results among the study participants. Of the total cases analyzed, 39 cases (32.5%) were true positives, and 70 cases (58.3%) were true negatives, indicating correct classification by RDT when compared with PCR. False-positive results were observed in 5 cases (4.2%), while false-negative results occurred in 6 cases (5.0%). Overall, an agreement of 90.8% was achieved between RDT and PCR findings, reflecting a high concordance between the two diagnostic methods. This high level of agreement supports the utility of RDTs as a reliable screening tool for bacterial meningitis, although confirmatory PCR testing remains essential, particularly in clinically critical cases.

Discussion

The present study assessed the diagnostic accuracy of rapid diagnostic tests (RDTs) for bacterial meningitis in 120 suspected cases, and real-time PCR was used as the reference standard. The rapid and precise identification of bacterial pathogens is essential for the prompt initiation of the correct antimicrobial therapy, which can significantly lower morbidity, mortality, and long-term neurological complications like hearing loss, mental impairment, seizures, and motor deficits. According to Boisier et al. (2009), RDTs could provide quick, field-based detection of Neisseria meningitidis, thus allowing early outbreak recognition and enabling them to carry out preventive measures in epidemic-prone areas [11]. Likewise, Meiring., (2020) found that precise diagnosis of Neisseria meningitidis is necessary throughout all seasons, even during low endemicity, to prevent further transmission and thus, to support the development of the right public health measures [12].

Uadiale et al., (2016) reported that the Pastorex meningitis kit exhibited a very high level of accuracy in diagnosing Neisseria meningitidis serogroup C during outbreaks in Nigeria while the antigen-based rapid diagnostic tests (RDTs) were thereby indicated to be of great benefit in lowresource health care settings [13]. On the other hand, Boulos et al., (2017) showed that the quick tests for Streptococcus pneumoniae in spinal fluid give prompt diagnosis and basically provide the requisite information for early treatment intervention and at the same time, prevent the use of antibiotics that are not really needed [14].

In addition, Wu et al., (2013) found that the use of both PCR and antigen-based RDTs together not only increases the overall diagnostic accuracy but also makes it possible to overcome the pitfalls of each method when they are applied separately, especially in the case of patients who have already been treated with antibiotics [15].

Agnememel et al., (2015) have discovered that the testing of Neisseria meningitidis serogroup X by dipstick is a method that can be combined quite conveniently with the use of peripheral health centers and is able to detect the infections reliably even in the most adverse of conditions [16]. Ciftci et al., (2025) disclosed that the application of contemporary diagnostics, including rapid testing and molecular assays, resulted in significant reduction of turnaround time, thus allowing earlier clinical decisions and consequently, better patient outcomes in invasive meningococcal disease [17]. The WHO Collaborating Centre for Meningitis (2017) found that the incorporation of RDTs into national surveillance systems not only increases outbreak preparedness but also improves case detection and allows timely public health response [18].

Nour and Alaidarous (2018) found out that for bacterial meningitis diagnosis PCR is still the gold standard because of its high sensitivity and specificity, especially in situations with low bacterial burden or previous antibiotic treatment [19]. Van de Beek et al., (2016) demonstrated that the combination of rapid testing and confirmatory molecular methods not only allows early medical intervention but also minimizes the chances of incorrect antibiotic usage and contributes to the monitoring of epidemics [20].

The age distribution noted in this research, which indicates a greater occurrence in toddlers under the age of five, is consistent with earlier research and underlines the susceptibility of infants and toddlers to severe bacterial meningitis. The predominance of males among suspected cases might be an indication of differential healthcare-seeking behavior or exposure patterns, hence agreeing with the trend of male predominance among infected people reported in the regions where meningitis outbreaks are common. The high level of agreement (90.8%) between RDT and PCR results endorses the application of RDTs for the quick detection of pathogens at the point of care, but it also recognizes the limitations associated with false negatives in situations where there is a low count of bacteria.

The age distribution outlined in this study, which shows a higher prevalence in children under five years, agrees with previous studies and points out the high vulnerability of infants and toddlers to severe bacterial meningitis. The higher ratio of boys to girls among the suspected cases could point to different health-seeking behaviors or exposure patterns, thus supporting the already established trend of more males being infected in the regions with frequent meningitis outbreaks. The very high level of agreement (90.8%) between the results of RDT and PCR is a strong endorsement of using RDTs for fast pathogen detection at the point of care, but at the same time it accepts the inadequacy of detecting false negatives in the situations of low bacterial counts.

Conclusion

Among the 120 suspected cases, RDTs (rapid diagnostic tests) were highly accurate, achieving a sensitivity of 86.7% and a specificity of 93.3%, and showed very strong agreement with realtime PCR results. The youngest children, particularly those less than five years old, were the most affected groups thereby pointing to the necessity for rapid diagnosis and timely treatment. RDTs provide a rapid, straightforward, and point-of-care method that promotes immediate antimicrobial therapy, especially in areas with limited resources. Even though PCR confirmation is still needed for low bacterial loads or atypical cases, RDTs are reliable as a screening tool, thus helping to monitor diseases, early outbreak detection, and the reduction of inappropriate antibiotic use. All in all, RDTs are very good at complementing standard laboratory methods, thus improving patient care and public health response for bacterial meningitis.

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