Merowe Technological University Abdullatif HamadUniversity

College of Medical Laboratory Sciences

Title: Diagnostic Performance of Sputum Smear Microscopy and GeneXpert in Pulmonary Tuberculosis: A Comparative Study

A proposal submitted for the partial fulfillment for the requirements of the Bsc in medical laboratory science (Microbiology)

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June 2026

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1. Introduction:

1.1 Background:

Tuberculosis (TB), caused by Mycobacterium tuberculosis, remains one of the leading infectious diseases and continues to pose a major public health challenge worldwide (1, 2). In Sudan, TB remains an important health problem due to delayed diagnosis, limited access to advanced diagnostic methods, and the increasing burden of drug-resistant tuberculosis (3, 4). These challenges are further aggravated by limited healthcare resources, particularly in rural and resource-constrained settings (1).

Early and accurate diagnosis is essential for prompt treatment, reducing disease transmission, and improving patient outcomes (5). Although sputum smear microscopy remains the most widely used diagnostic method because of its simplicity and low cost, its sensitivity is limited, especially in patients with low bacillary load (6). GeneXpert has significantly improved TB diagnosis by providing rapid and accurate detection of M. tuberculosis and rifampicin resistance (7, 8), Therefore, comparing the diagnostic performance of these methods is essential to improve TB diagnosis in Sudan.

1.2 Problem Statement:

Although several diagnostic methods are available for pulmonary tuberculosis (TB), challenges remain regarding their accuracy, accessibility, and applicability in resource-limited settings. Sputum smear microscopy is inexpensive and widely available but has limited sensitivity, especially in paucibacillary disease and HIV-associated TB (1). GeneXpert MTB/RIF provides rapid and highly sensitive detection of TB and rifampicin resistance, yet its implementation is constrained by cost and infrastructure requirements (8). Consequently, there is a need for comparative evaluation of these diagnostic modalities within the same patient population to determine their real-world diagnostic performance and support evidence-based clinical decision-making.


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Early and accurate diagnosis of pulmonary TB is essential for prompt treatment and prevention of disease transmission (5). Delayed or missed diagnosis can lead to increased morbidity, mortality, and ongoing community spread (5). Accurate diagnosis also helps identify drug-resistant TB, especially resistance to Rifampicin, which is important for selecting appropriate treatment (2). Since traditional methods such as AFB smear microscopy have limited sensitivity, more sensitive diagnostic tools like GeneXpert are important to reduce false-negative results and avoid missed cases, particularly smear-negative TB (7, 8). Proper diagnosis improves patient outcomes and supports better TB control programs (5).

Diagnosis of pulmonary TB can be challenging, especially in the early stages of the disease or in patients co-infected with HIV/AIDS due to weakened immunity (9). Clinical symptoms such as cough, fever, and weight loss are not specific to TB and may overlap with other respiratory diseases (1). Sputum smear microscopy may fail to detect cases with low bacillary load, particularly smear-negative TB cases (6). Limited healthcare resources in many settings may restrict access to advanced diagnostic tests, leading to delayed or missed diagnosis (1).

1.3 Justification:

Although GeneXpert has demonstrated superior diagnostic accuracy for pulmonary tuberculosis (7, 8), sputum smear microscopy continue to be widely used in routine clinical practice, particularly in resource-limited settings (1, 2). However, there is limited local evidence directly comparing the diagnostic performance of these two methods within the same patient population. In Northern Sudan, particularly in Dongola Specialized Hospital, Halfa Tuberculosis Center, and Karima Hospital

data evaluating the sensitivity, specificity, and overall diagnostic accuracy of sputum smear microscopy and GeneXpert are scarce (3, 4). This lack of comparative evidence makes it difficult to determine the most effective diagnostic approach for early detection of pulmonary tuberculosis in the


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local healthcare setting. Therefore, this study aims to compare the diagnostic performance of these methods to provide evidence that can support clinical decision-making and improve TB diagnosis.

2.Research Question:

1. What are the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of sputum smear microscopy for pulmonary tuberculosis?
2. What are the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of GeneXpert MTB/RIF Ultra for pulmonary tuberculosis?
3. Which diagnostic method demonstrates the highest diagnostic performance among the two methods?
4. Is there a statistically significant difference in the diagnostic performance of the two diagnostic methods?

3.Objectives:

3.1 General objective:

To compare the diagnostic performance of sputum smear microscopy, and GeneXpert MTB/RIF Ultra in the diagnosis of pulmonary tuberculosis among presumptive patients in Sudan.

3.2 Specific objectives:

1. To determine the sensitivity, specificity, PPV, NPV, and diagnostic accuracy of sputum smear microscopy for PTB.
2. To evaluate the sensitivity, specificity, PPV, NPV, and diagnostic accuracy of GeneXpert MTB/RIF Ultra for PTB.
4. To compare the diagnostic performance parameters of the two methods using ROC analysis.
5. To identify the most reliable and feasible diagnostic method for pulmonary tuberculosis in a resource-limited setting.

4. Materials and Methods :

4.1Study design

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This study will be a hospital-based retrospective comparative cross-sectional study. Medical records of patients with suspected pulmonary tuberculosis who underwent sputum smear microscopy and GeneXpert MTB/RIF Ultra during the study period will be reviewed. The diagnostic performance of these methods will be compared by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy.

4.2 study area:

Halfa HOSPITAL ,KARIMA HOSPITAL AND DONGOLA HOSPITAL .

4.3 study population

Inclusion criteria:

Patients with suspected pulmonary tuberculosis..

Patients aged 18 years or older.

Patients who undergo sputum smear microscopy,and GeneXpert testing.

Exclusion criteria :

Patients currently receiving anti-tuberculosis treatment.

Patients with incomplete clinical or laboratory data.

Patients unable to provide a sputum sample.

4.4 Sampling technique

A total (census) sampling technique will be applied, in which all eligible patient records meeting the inclusion criteria within the study period will be reviewed and included in the study. This approach is appropriate given the retrospective, records-based nature of the study and helps minimize selection bias.

4.5 Sample Size

All available data

4.6 Study variables:

Dependent variables:

Diagnosis of pulmonary tuberculosis (TB result / TB positivity or negativity)

Independent variables :

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Sputum smear microscopy result (positive / negative)

GeneXpert MTB/RIF result (detected / not detected)

Rifampicin resistance status .

4.7 Data collection methods

Data will be collected retrospectively from the medical records of eligible patients at Dongola Specialized Hospital, Halfa Tuberculosis Center, and Karima Hospital using a structured data extraction checklist. The checklist will include demographic information (age, sex, and residence), sputum smear microscopy results GeneXpert MTB/RIF Ultra results, rifampicin resistance status and the dates of the diagnostic investigations.

4.8 Data analysis:

Statistical analysis of the diagnostic performance of sputum smear microscopy,and GeneXpert will be performed using IBM SPSS Statistics Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy will be calculated. A p-value of <0.05 will be considered statistically significant.

4.9 Ethical considerations:

Ethical approval will be obtained from the Ethical Committee of Merowe Technological University – Abdullatif Hamad. Written permission will also be obtained from the administrative authorities ofDongola Specialized Hospital, Halfa Tuberculosis Center, and Karima Hospital before reviewing the medical records.

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