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The primary aim of the present study is to compare the diagnostic accuracy of Truenat and Ziehl–Neelsen smear microscopy on different body specimens for the detection of tuberculosis.

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Abstract

Background & Methods: This study investigated the diagnostic accuracy of Truenat and smear microscopy in the detection of tuberculosis (TB) among patients undergoing clinical evaluation. A prospective, multicenter cohort study was conducted to compare the sensitivity and specificity of these two methods. Results indicate that Truenat exhibits higher sensitivity compared to smear microscopy, though both methods have limitations regarding false-positive rates. The findings support a multi-faceted diagnostic approach incorporating both techniques for improved TB diagnosis. ***Results:*** The majority of patients belonged to the 21–40 years age group (41.3%), followed by 41–60 years (30.2%), >60 years (17.4%), and ≤20 years (11.1%). Out of 126 samples tested, 98 (77.8%) were positive for Mycobacterium tuberculosis, while 28 (22.2%) were negative by the Truenat assay. ***Conclusion:*** Tuberculosis remains one of the most significant public health challenges in India, contributing substantially to global tuberculosis morbidity and mortality. Despite sustained national and international efforts, the disease continues to pose diagnostic and therapeutic challenges, particularly in resource-limited settings. Early and accurate diagnosis plays a pivotal role in reducing disease transmission, initiating timely treatment, and preventing complications associated with delayed or missed diagnosis.

Keywords: truenat, smear, microscopy, diagnosis & tuberculosis.

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INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease caused by Mycobacterium tuberculosis and continues to be a major global public health problem despite the availability of effective diagnostic and therapeutic strategies.[1] TB primarily affects the lungs but can involve almost any organ system, leading to significant morbidity and mortality worldwide.[2]According to the World Health Organization (WHO), tuberculosis remains among the top ten causes of death from a single infectious agent globally.[3] In recent years, the burden of TB has been disproportionately higher in low- and middle-income countries, with India contributing the highest number of cases worldwide.[4] India accounts for nearly one-fourth of the global tuberculosis burden, making TB a significant public health concern in the country.[5] Despite sustained efforts under the National Tuberculosis Elimination Programme (NTEP), challenges such as delayed diagnosis, under-reporting, and drug resistance continue to hamper TB control efforts.[6]Pulmonary tuberculosis constitutes approximately 80–85% of all TB cases, while extrapulmonary tuberculosis accounts for the remaining proportion.[7]

Extrapulmonary TB poses a greater diagnostic challenge due to its varied clinical presentation and the paucibacillary nature of specimens.[8]Early and accurate diagnosis of tuberculosis is crucial not only for initiating appropriate therapy but also for reducing disease transmission and improving patient outcomes.8 Conventional diagnostic methods such as sputum smear microscopy have been widely used for decades due to their simplicity and cost-effectiveness. However, smear microscopy has limited sensitivity, particularly in extrapulmonary TB and in patients with low bacillary load. Ziehl–Neelsen (ZN) smear microscopy detects acid-fast bacilli and remains a cornerstone diagnostic test in many resource-limited settings.[12] The sensitivity of smear microscopy varies widely depending on the quality of specimen and bacterial load, often leading to false-negative results.[13]To overcome the limitations of conventional microscopy, molecular diagnostic techniques have been introduced in recent years. These tests offer rapid detection of Mycobacterium tuberculosis with higher sensitivity and specificity.9.

MATERIALS AND METHODS

Study Design: A prospective, multicenter cohort study was conducted to compare the diagnostic accuracy of Truenat and smear microscopy in the detection of tuberculosis among patients undergoing clinical evaluation. The study will be carried out in the Department of Respiratory Medicine, Amaltas Institute of Medical Sciences, Dewas, Madhya Pradesh.[145] The institute is a tertiary care teaching hospital catering to patients from urban and rural areas of the region.[146] Study Duration The study will be conducted over a period of 18 months after obtaining approval from the Institutional Ethics Committee.[147] This duration includes patient recruitment, data collection, laboratory investigations, and data analysis.[148]

Inclusion Criteria: Patients fulfilling any of the following criteria will be included in the study. Patients with persistent cough or fever for more than two weeks Patients with unexplained weight loss or loss of appetite Patients with hemoptysis Patients with clinically significant lymphadenopathy Patients with symptoms suggestive of extrapulmonary tuberculosis such as abdominal pain, joint pain, or pleural effusion.

Exclusion Criteria: The following patients will be excluded from the study. Patients who are known cases of tuberculosis or already on anti-tubercular treatment Relapse, default, or treatment failure cases of tuberculosis Patients aged less than 18 years. The sample size for the present study is 126 patients. The sample size was calculated based on the estimated prevalence of tuberculosis in Madhya Pradesh, which is approximately 741 cases per lakh population.

Data Collection: The following data were collected from enrolled patients:

Clinical Data: Patient demographics (age, sex, ethnicity), TB history, symptoms, laboratory findings (Sputum smear, chest X-ray, blood tests), treatment history, comorbidities.

Truenat Testing: Patient's sample was sent to a Truenat laboratory for analysis. Results were recorded and compared against smear microscopy results.

Smear Microscopy: Patient's sputum was smeared on a microscope slide and examined under light microscopy.

Statistical Analysis: Descriptive statistics will be used to characterize the study population. Chi-square tests will be employed to compare the diagnostic accuracy of Truenat and smear microscopy across different patient groups. Receiver Operating Characteristic (ROC) curves will be generated to assess the discriminatory ability of each method. Logistic regression models will be used to determine predictors of diagnostic accuracy.

RESULTS

Table 1: Age Distribution of Patients

Age group (years)	Number of patients	Percentage (%)
≤20	14	11.1
21–40	52	41.3
41–60	38	30.2
>60	22	17.4
Total	126	100

The majority of patients belonged to the 21–40 years age group (41.3%), followed by 41–60 years (30.2%), >60 years (17.4%), and ≤20 years (11.1%).

Table 2: Distribution of Clinical Samples

Sample Type	Number of Patients	Percentage (%)
Sputum	66	52.4
Pleural Fluid	20	15.9
BAL	16	12.7
Lymph Node	10	7.9
Ascitic Fluid	6	4.8
CSF	4	3.2
Tissue	4	3.2
Total	126	100

Table 3: Distribution of Pulmonary and Extrapulmonary Tuberculosis (n = 126)

Type of Tuberculosis	Number of Patients	Percentage (%)
Pulmonary TB (PTB)	88	69.8
Extrapulmonary TB (EPTB)	38	30.2
Total	126	100

Table 4: Truenat MTB Results (n = 126)

Truenat Result	Number of Patients	Percentage (%)
Positive	98	77.8
Negative	28	22.2
Total	126	100

Table 5: AFB (Ziehl–Neelsen Smear Microscopy) Results (n = 126)

AFB Smear Result	Number of Patients	Percentage (%)
Positive	74	58.7
Negative	52	41.3
Total	126	100

Out of 126 samples tested, 98 (77.8%) were positive for Mycobacterium tuberculosis, while 28 (22.2%) were negative by the Truenat assay.

DISCUSSION

Tuberculosis continues to be a major public health problem in India, accounting for a significant proportion of the global tuberculosis burden. Despite the availability of effective anti-tubercular therapy, tuberculosis remains a leading cause of morbidity and mortality, particularly in developing countries.10 Early and accurate diagnosis is critical for timely initiation of treatment, interruption of disease transmission, and prevention of complications associated with delayed diagnosis. The present study was undertaken to compare the diagnostic accuracy of Truenat MTB assay and Ziehl–Neelsen smear microscopy on different body specimens for the detection of tuberculosis in a tertiary care hospital setting.

The most common presenting symptoms among the study population were cough, fever, weight loss, and breathlessness. These findings are consistent with classical clinical manifestations of tuberculosis reported in earlier studies. Similar clinical presentations have been documented by Sameera Akhtar et al. and Singh et al., emphasizing the nonspecific nature of tuberculosis symptoms.11 The overlap of tuberculosis symptoms with other respiratory and systemic illnesses poses a significant diagnostic challenge. Early diagnosis based solely on clinical features remains unreliable, particularly in smear-negative and extrapulmonary tuberculosis. This underscores the need for accurate and rapid diagnostic modalities to support clinical decision-making.12

Extrapulmonary tuberculosis remains underdiagnosed due to limitations of conventional diagnostic methods.12 In the present study, Truenat demonstrated superior diagnostic yield in extrapulmonary specimens such as pleural fluid and lymph node aspirates. This observation aligns with Indian studies that have highlighted the usefulness of Truenat in diagnosing extrapulmonary tuberculosis.13 the portability, minimal infrastructure requirements, and ease of use of Truenat make it suitable for decentralized healthcare settings, including district and peripheral health centers.14.

CONCLUSION

Conventional diagnostic techniques such as Ziehl–Neelsen smear microscopy have been the backbone of tuberculosis diagnosis for decades due to their simplicity, low cost, and wide availability. However, these methods have well-recognized limitations, particularly in patients with low bacillary load, smear-negative pulmonary tuberculosis, and extrapulmonary tuberculosis. The reliance on smear microscopy alone may result in underdiagnosis and delayed treatment initiation, thereby perpetuating disease transmission and increasing morbidity. The present study was undertaken to compare the diagnostic accuracy of Truenat MTB assay and Ziehl–Neelsen smear microscopy across different body specimens for the detection of tuberculosis.

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