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A STUDY ON THE COMPARISON OF SENSITIVITY AND SPECIFICITY OF CBNAAT AND SPUTUM SMEAR AFB IN THE DIAGNOSIS OF PULMONARY TUBERCULOSIS

Yash Chandan[1], Yogesh V. Khithani[2], Amar Pazare[3]

[1]PG DNB Resident, Department of Medicine, K J Somaiya Medical College, Sion, Mumbai, India.
[2]Assistant Professor, Department of Medicine, K J Somaiya Medical College, Sion, Mumbai, India.
[3]Professor, Department of Medicine, K J Somaiya Medical College, Sion, Mumbai, India.

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Corresponding Author:
Dr. Yogesh V. Khithani,
Email: dr.yogeshkhithani@gmail.com

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ABSTRACT

Background: Pulmonary tuberculosis (PTB) continues to be a major public health challenge in India, contributing substantially to global TB morbidity. Early and accurate diagnosis is essential for disease control. While sputum smear microscopy remains widely used in resource-limited settings, its sensitivity is suboptimal. Cartridge-Based Nucleic Acid Amplification Test (CBNAAT) offers rapid molecular detection and rifampicin resistance profiling, yet comparative performance data from clinical settings remain crucial. **Materials and Methods:** A single-centre analytical cross-sectional study was conducted among 139 presumptive PTB patients aged ≥18 years at a tertiary care hospital in Mumbai. Sputum samples underwent Ziehl–Neelsen smear microscopy, CBNAAT testing, and liquid culture (gold standard). Diagnostic performance parameters including sensitivity and specificity were calculated. **Result:** Liquid culture was positive in 77/139 samples (55.4%). CBNAAT detected 69 positives (49.6%), while smear microscopy detected 37 positives (26.6%). Compared with liquid culture, CBNAAT demonstrated a sensitivity of 81.8% and specificity of 90.3%. Sputum smear microscopy displayed lower sensitivity (40.3%) but similar specificity (90.3%). **Conclusion:** CBNAAT demonstrates significantly superior diagnostic sensitivity compared to sputum smear microscopy while maintaining high specificity, supporting its role as a primary diagnostic tool in PTB evaluation. Routine implementation may enable earlier diagnosis and treatment initiation, aligning with National TB Elimination Program goals.

INTRODUCTION

Globally, an estimated 10.0 million people developed TB disease in 2019, and there were an estimated 1.2 million TB deaths among HIV-negative people and an additional 208,000 deaths among people living with HIV.[1] India has the world's largest tuberculosis epidemic, accounting for 26% of the estimated 10 million incident TB cases globally in 2020.[2,3] The incidence rate is 192 cases per 100,000 population.[3] According to a systematic review and meta-analysis, the pooled prevalence of bacteriologically positive pulmonary tuberculosis in India was estimated to be 295.9 per 100,000 population, with higher prevalence among males and in rural areas compared to urban areas.[2] Despite the best governmental efforts, the burden of disease is rising rapidly in the country and is a significant strain on the medical services and therefore needs to be tackled diligently.

Accurate and rapid diagnosis is crucial for effective treatment and control of the disease. Despite several advancements in the diagnosis of tuberculosis, the sputum smear microscopy for acid-fast bacilli (AFB) remains the primary diagnostic tool in patients with pulmonary tuberculosis in resource-limited settings due to its rapidity and low cost.[4] However, sputum smear microscopy has limited sensitivity between 51% to 53.3%,[5,6] which decreases further in patients infected with HIV.[7]

The Xpert MTB/RIF assay, an automated cartridge-based nucleic acid amplification test (CBNAAT), is a promising tool for the rapid diagnosis of TB.[8,9] CBNAAT can simultaneously detect Mycobacterium tuberculosis (MTB) and rifampicin resistance, a surrogate marker for multidrug-resistant TB.[8,9] Several studies have evaluated the performance of CBNAAT compared to sputum smear microscopy and culture in diagnosing pulmonary TB.[8,10,11]

A study in India comparing the performance of CBNAAT to sputum smear microscopy and culture in 831 suspected pulmonary TB cases found that the sensitivity and specificity of CBNAAT were 84.43%,

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using culture as the reference standard.[8] Another study in Thailand found that the sensitivity of CBNAAT was higher than sputum smear microscopy (84% vs 48%), with comparable specificity (>90%).[9]

These studies suggest that CBNAAT has superior sensitivity compared to sputum smear microscopy in diagnosing pulmonary TB, while maintaining high specificity.[8,9] The rapid turnaround time and ability to detect rifampicin resistance make CBNAAT a valuable tool in the TB diagnostic algorithm, particularly in high-burden settings.[8,9] However, further research is needed to assess the cost-effectiveness and feasibility of implementing CBNAAT in resource-limited settings.

MATERIALS AND METHODS

The study was conducted at K. J. Somaiya Hospital, Mumbai, among patients diagnosed with pulmonary tuberculosis who were attending the outpatient department as well as those admitted as inpatients. The total study duration was eighteen months, extending from August 2022 to January 2024. During this period, patients meeting the inclusion and exclusion criteria were informed about the study objectives, assured of confidentiality, and enrolled after obtaining written informed consent. Data collection was performed using a predesigned and pretested proforma to document sociodemographic characteristics and disease-related variables. Relevant clinical and diagnostic information was obtained, including CBNAAT GeneXpert reports, sputum AFB smear results, chest X-ray or CT scan findings, liquid culture reports, and case records. All participants underwent chest imaging, routine biochemistry, and complete blood counts, while additional investigations were carried out as required for patient management. Data were entered into Microsoft Excel and summarized using descriptive statistics, with mean and standard deviation calculated for numerical variables and frequencies and percentages for categorical variables. Diagnostic performance of CBNAAT and AFB smear was compared against liquid culture by calculating sensitivity and specificity. ROC curves were generated to compare the area under the curve for the diagnostic tests, and statistical analysis was performed using SPSS software (Version 20).

RESULTS

A total of 139 patients were included in the study. The mean age of the study population was 41.7 years, with the highest proportion belonging to the 31–40 year age group (33.1%). Females accounted for 53.2% of the participants, while males constituted 46.8%. A history of contact with tuberculosis was documented in only 1.4% of cases. Cough was the most common presenting symptom (82%), followed by chest pain (70.5%) and shortness of breath (43.9%). Laboratory parameters revealed a mean hemoglobin level of 10.94 g/dl, mean leukocyte count of 8435.25/cumm, neutrophil count of 3013.8/cumm, lymphocyte count of 4564.7/cumm, eosinophil count of 350/cumm, and mean ESR value of 71.54 mm/hr. Chest radiographic evaluation showed no abnormalities in 48% of the population, while among abnormal findings, upper lobe infiltrates were most common (67%), followed by hilar lymphadenopathy (7%), diffuse infiltrates (6%), cavitary lesions (5%), pleural effusion (5%), and segmental or lobar consolidation (1%).

In evaluating diagnostic modalities, liquid culture yielded the highest number of positive results, diagnosing 77 cases (89.53%), whereas CBNAAT detected 70 cases (81.40%) and AFB smear detected 37 cases (43.02%). When liquid culture was used as the gold standard, CBNAAT demonstrated a sensitivity of 81.8% and specificity of 90.3%, with 63 true positives, 56 true negatives, 6 false positives, and 14 false negatives. In comparison, AFB smear microscopy showed a substantially lower sensitivity of 40.3% while maintaining the same specificity of 90.3%, with 31 true positives, 56 true negatives, 6 false positives, and 46 false negatives. These findings confirm that CBNAAT detects more tuberculosis cases and has markedly superior sensitivity compared to AFB smear, while both tests demonstrate comparable specificity.

Table 1: Demographic Characteristics of Study Population (n = 139)

Variable	Category / Value	Percentage / Mean
Age (years)	Mean age	**41.7**
Most common age group	**31–40 years**	**33.1%**
Sex distribution	Male	**46.8%**
	Female	**53.2%**
History of TB contact	Present	**1.4%**

Table 2: Clinical Symptoms in Study Participants

Symptom	Percentage (%)
Cough	**82%**
Chest pain	**70.5%**
Shortness of breath	**43.9%**
Weight loss	(reported)
Fever	(reported)

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Table 3: Hematological Parameters

Parameter	Mean (SD)
Hemoglobin (g/dl)	**10.94 (2.67)**
Total leukocyte count (/cumm)	**8435.25 (4018.34)**
Neutrophils (/cumm)	**3013.8 (2080.5)**
Lymphocytes (/cumm)	**4564.7 (2518.8)**
Eosinophils (/cumm)	**350 (194.2)**
ESR (mm/hr)	**71.54 (22.72)**

Table 4: Radiological Findings (Chest X-ray)

Finding	Percentage (%)
Normal	**48%**
Upper lobe infiltrates	**67%**
Hilar lymphadenopathy	**7%**
Diffuse infiltrates	**6%**
Cavitary lesions	**5%**
Pleural effusion	**5%**
Segmental/lobar consolidation	**1%**

Table 5: Positivity Rates by Diagnostic Method (n = 139)

Diagnostic Method	Positive Cases	Percentage (%)
AFB Smear	**37**	**43.02%**
Liquid Culture	**77**	**89.53%**
CBNAAT	**70**	**81.40%**

Table 6: Diagnostic Accuracy of CBNAAT vs Liquid Culture

Parameter	Value
True Positive	**63**
True Negative	**56**
False Positive	**6**
False Negative	**14**
Sensitivity	**81.8%**
Specificity	**90.3%**

Table 7: Diagnostic Accuracy of AFB Smear vs Liquid Culture

Parameter	Value
True Positive	**31**
True Negative	**56**
False Positive	**6**
False Negative	**46**
Sensitivity	**40.3%**
Specificity	**90.3%**

DISCUSSION

The present study cohort was similar to presumptive pulmonary tuberculosis cohorts reported from other parts on India. The mean age was 41.7 years; the youngest patient in the study was 18 years old while the oldest one was 67 years old. Most of the patients belonged to the age group of 30-44 years. In their prospective study on 84 suspected pulmonary tuberculosis patients visiting Government Chest disease and TB hospital Warangal, Kurdula et al,[12] reported that the maximum number of patients with presumptive symptoms were in the age groups of 40-60 years of age; the youngest patients were 17-year-old while the oldest was 80 years old. Tuberculosis mostly affects adults in their most productive years. However, all age groups are at risk.[12]

Kurdula et al,[12] also reported that in their cohort, out of 84 presumptive tuberculosis patients 52.4 % were males & 47.6 % were females. Some other studies have also reported a male preponderance in their studies.[13,14] The primary reason for the increased number of males in presumptive TB patients has been explained by an increased likelihood of contracting the disease due travel and increased contact with people due to wage earning responsibilities. In addition, men are more likely to acquire habits like smoking and alcoholism which predispose to TB. In contrast, more than half the patients in the present study were females (53.2%). Higher female preponderance has been reported in other studies too. In a study on 907 presumptive tuberculosis patients from a tertiary care hospital, Vijayageetha et al,[15] reported that 53% of their patients were females while 47% were males. The reason for the increased number of female patients among chest symptomatics in these studies has not been explained in their studies.

The present study employs the NTEP definitions to identify presumptive tuberculosis cases. Most patients had cough of some duration (82%), similar to other reported studies.[15,16] However, one of these studies examined “cough of any duration” instead of the program recommendation of two weeks and found a much higher prevalence of cough among presumptive tuberculosis patients.[16]

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Mycobacterial are commonly cultured on solid LJ media (Lowenstein Jensen) or liquid broth system (MGIT 320). Both these procedures are time-consuming, require biosafety precautions and need educated laboratory personnel.[17] Although the results of MGIT are relatively faster than the solid cultures, the minimum yield time is around 42 days. In contrast, molecular techniques (CBNAAT) are POC (point of care) tests that return results within 2 hours, much earlier than the culture results. Not surprisingly, these tests have substantially changed the field of tuberculosis diagnosis and have been proven to yield rapid results as well as being highly sensitive.[18] CBNAAT, which can simultaneously detect the presence of M. tuberculosis and rifampicin resistance in sputum specimens, has shown great promise in the rapid diagnosis of TB, with an average sensitivity and specificity of 90.4% and 98.4%, respectively.[19]

In the present study, the results of CBNAAT are compared against liquid culture results, which have been considered the gold standard for diagnosis. The overall reported sensitivity of CBNAAT was 81.8%, specificity was 90.3%. In a study by Agrawal et al,[20] the sensitivity and specificity of CBNAAT were 72.7% and 100% respectively. A study by Sharma et al,[21] on 1492 consecutive samples from New Delhi, India, yielded a sensitivity and specificity, of 96.9% and 99.8% respectively. A meta-analysis from 15 studies involving 3518 patients from Iran,[22] reported a pooled sensitivity and specificity of PCR (CBNAAT) relative to sputum culture were 88.02% and 91.82% respectively. A WHO meta-analysis indicated that suspected adult TB patients, when tested by CBNAAT against culture for samples of expectorated, or induced sputum, the pooled sensitivity was 66% and specificity was 98%.[23] The present study, along with the previous ones, thus, further strengthens the use of CBNAAT in smear positive pulmonary samples as endorsed by WHO. However, CBNAAT does not do away with the need of conventional microscopy, culture and anti-tubercular drug sensitivity, that are required to monitor the progression of treatment and to detect resistance to drugs other than Rifampicin.[24]

In the present study, using liquid culture as the gold standard, the sensitivity and specificity, for AFB smear by ZN stain were 40.3% and 90.3% respectively. e-Castro et al, 25 reported a sensitivity and specificity of 55.4% and 96.1% in three sputum samples when compared against the MGIT culture gold standard. Rahmati et al, in their meta-analysis from Iran, reported that the pooled sensitivity and specificity of sputum smear that used Ziehl–Neelsen method were 76.74% and 93.42% respectively. Bunsow et al,[26] reported AFB smear sensitivity of 78.5% and specificity of 98.3% when compared with LJ culture as gold standard.

CONCLUSION

The present study finds that CBNAAT is a powerful tool for PTB diagnosis with good sensitivity and specificity, higher than that of sputum AFB smear when compared to liquid culture as gold standard. Thus, evidence in favour of the routine use of CBNAAT in TB diagnosis, under the National Tuberculosis Elimination Program, is further strengthened by findings of the present study. This will expedite management of patients with presumptive TB. There is a need for more studies for evaluation of CBNAAT in different clinical settings in India to further substantiate the role of CBNAAT different settings.

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