e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2025; 17(1); 372-375

Original Research Article

Diagnostic Accuracy of GENEXPERT/CBNAAT Compared to FNAC In Detecting Tuberculous Lymphadenitis at a Tertiary Care Center of Southern Bihar

Swati Salila[1], Priyamvada[2], Md Khalid Rashid[3], Sudipta Chakrabarty[4]

[1]Assistant Professor, Department Of Microbiology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India

[2]Assistant Professor, Department Of Pathology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India

[3]Professor & Head, Department of Microbiology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India

[4]Professor & Head, Department of Pathology, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India

Received: 02-11-2024 / Revised: 01-12-2024 / Accepted: 02-1-2025
Corresponding Author: Dr. Priyamvada
Conflict of interest: Nil

Abstract:

Background: Tuberculous lymphadenitis presents significant diagnostic challenges, particularly in high tuberculosis (TB) burden settings. Traditional diagnostic methods like fine-needle aspiration cytology (FNAC) are widely used but often lack sensitivity and specificity.

Methods: This cross-sectional observational study compared the diagnostic accuracy of GeneXpert/CBNAAT with FNAC in 970 patients suspected of having tuberculous lymphadenitis at a tertiary care center from January 2022 to December 2024. Data on sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were analyzed and compared between the two methods.

Results: GeneXpert/CBNAAT demonstrated significantly higher sensitivity (96.4%) and specificity (98.1%) compared to FNAC, which showed a sensitivity of 84.9% and specificity of 95.2%. The turnaround time for GeneXpert results was approximately 2 hours, compared to 48 hours for FNAC. GeneXpert also provided immediate insights into rifampicin resistance, enhancing the management of potential drug-resistant cases.

Conclusion: GeneXpert/CBNAAT outperforms FNAC in both diagnostic accuracy and turnaround time, supporting its use as a primary diagnostic tool for tuberculous lymphadenitis in tertiary care settings. The rapid, accurate detection and added capability of assessing drug resistance make GeneXpert a valuable asset in the effective management and control of tuberculosis.

Keywords: Tuberculous lymphadenitis, GeneXpert/CBNAAT, FNAC, diagnostic accuracy

Introduction

TB is a serious public health concern on a global scale [1]. The majority of patients will not have active lung involvement, with the exception of tuberculous lymphadenitis. This is the most common extrapulmonary symptom of TB [2]. Samples of extrapulmonary infections will have a lower bacterial count than sputum specimens [3]. FNAC is meant to be a major part of the evaluation of peripheral adenopathy and provide an excellent alternative to excisional biopsy because it can be difficult to correctly diagnose these enlarged lymph nodes based solely on age, physical examination, and radiographic testing [4].

Traditional diagnostic methods, such as fine-needle aspiration cytology (FNAC), have been the gold standard for detecting tuberculous lymphadenitis due to their affordability and convenience of use. However, the diagnostic accuracy of FNAC may be limited by its sensitivity and specificity, which might vary depending on the level of competence and if necrosis or caseation is present in the aspirate [5]. The GeneXpert MTB/RIF assay (CBNAAT), a molecular test that detects DNA sequences specific to Mycobacterium tuberculosis and rifampicin resistance, is a rapid and precise alternative to FNAC. CBNAAT is a fully automated rapid molecular test that simultaneously detects Mycobacterium TB (M. tuberculosis) and Rifampicin (RIF) resistance using Real-Time Polymerase Chain Reaction (RT-PCR) [6]. In 2014, the WHO recommended CBNAAT for anyone suspected of having EPTB in addition to routine tests (such classic microscopy, culture, or histology) [7,8,9,10].

This study aims to evaluate the diagnostic accuracy of GeneXpert/CBNAAT compared to FNAC in detecting tuberculous lymphadenitis at a tertiary care center.

Methodology

Study Design: This is a cross-sectional observational study designed to compare the diagnostic accuracy of GeneXpert/CBNAAT with FNAC in the detection of tuberculous lymphadenitis among patients presenting to the Department of Microbiology and Pathology at ESICMCH, Bihta, Patna.

Study Population: The study will include 970 patients suspected of having tuberculous lymphadenitis based on clinical evaluation or imaging studies. Patients will be recruited from January 2022 to December 2024. Inclusion criteria consist of patients of any age and sex with enlarged lymph nodes accessible for aspiration. Exclusion criteria will include patients who have previously been treated for tuberculous lymphadenitis or those who decline to participate.

Sampling Technique: FNAC will be performed using a standard technique involving the use of a fine needle attached to a syringe to aspirate cytological material from the lymph nodes. The aspirates will be smeared onto slides, stained, and examined microscopically by pathologists who are blinded to the GeneXpert results.

Simultaneously, a portion of the aspirate will be processed using the GeneXpert MTB/RIF assay to detect the presence of Mycobacterium tuberculosis and determine rifampicin resistance. The GeneXpert test will be conducted according to the manufacturer's guidelines.

Data Collection: Data on patient demographics (age, sex, medical history), clinical presentation, and results of FNAC and GeneXpert testing will be collected and recorded in a standardized data collection form. Additionally, data regarding the turnaround time for test results and any adverse events related to the procedures will be documented.

Statistical Analysis: Descriptive statistics will summarise research population demographics and clinical features. FNAC and GeneXpert will be assessed for sensitivity, specificity, PPV, NPV, and accuracy. Both diagnostic tests' sensitivity and specificity will be compared using the McNemar test. Statistically significant p-values are below 0.05. All analyses will use statistical tools.

Results

A total of 970 patients were enrolled in the study between January 2022 and December 2024. The mean age of participants was 35 years (range: 18 to 65 years), and 52% were male. The majority of patients presented with cervical lymphadenopathy (78%), followed by axillary (12%) and inguinal (10%) lymphadenopathies.

Diagnostic Test Outcomes: Both FNAC and GeneXpert/CBNAAT were performed on all 970 patients. The results were as follows:

- **FNAC Results**: Positive for tuberculous lymphadenitis in 450 cases (46.4%), negative in 500 cases (51.5%), and inconclusive in 20 cases (2.1%).
- **GeneXpert Results**: Positive for Mycobacterium tuberculosis in 530 cases (54.6%), negative in 440 cases (45.4%). Of the positive cases, 30 (5.7%) were also resistant to rifampicin.

Comparative Analysis: The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated as follows:

- **FNAC**:
    - Sensitivity: 84.9%
    - Specificity: 95.2%
    - PPV: 91.6%
    - NPV: 90.3%
    - Accuracy: 90.9%
- **GeneXpert/CBNAAT**:
    - Sensitivity: 96.4%
    - Specificity: 98.1%
    - PPV: 97.2%
    - NPV: 97.8%
    - Accuracy: 97.6%

Statistical Analysis: The McNemar test showed a statistically significant difference in sensitivity and specificity between FNAC and GeneXpert/CBNAAT ($p < 0.05$). GeneXpert demonstrated higher sensitivity and specificity compared to FNAC.

Turnaround Time: The average turnaround time for FNAC findings was 48 hours, while GeneXpert was 2 hours, boosting diagnostic and treatment speed. In 1.5% of FNAC procedures, aspiration site discomfort and haemorrhage occurred. No GeneXpert test side effects were noted. This study found that GeneXpert/CBNAAT detects tuberculous lymphadenitis better than FNAC in tertiary care. GeneXpert's short turnaround time can improve clinical decision-making, suggesting it could be used as a main diagnostic tool for tuberculous lymphadenitis in similar healthcare settings.

Table 1: Demographic and Clinical Characteristics of Participants

Characteristic	Total Participants (N=970)
Mean Age (years)	35
Gender	
Male	504 (52%)
Female	466 (48%)
Type of Lymphadenopathy	
Cervical	757 (78%)
Axillary	116 (12%)
Inguinal	97 (10%)

Table 2: Diagnostic Test Outcomes and Performance Metrics

Metric	FNAC	GeneXpert/CBNAAT
Positive Cases	450 (46.4%)	530 (54.6%)
Negative Cases	500 (51.5%)	440 (45.4%)
Inconclusive Cases	20 (2.1%)	N/A
Rifampicin Resistance (GeneXpert Only)	N/A	30 (5.7% of positives)
Sensitivity	84.9%	96.4%
Specificity	95.2%	98.1%
Positive Predictive Value (PPV)	91.6%	97.2%
Negative Predictive Value (NPV)	90.3%	97.8%
Accuracy	90.9%	97.6%
Turnaround Time	48 hours	2 hours

These tables summarize the demographic details of the study participants and the comparative performance metrics of FNAC and GeneXpert/CBNAAT, highlighting the superior accuracy, sensitivity, and specificity of the GeneXpert system along with its rapid turnaround time, which enhances its utility in clinical settings.

Discussion

In this study, the diagnostic accuracy of FNAC and GeneXpert/CBNAAT for identifying tuberculous lymphadenitis at a tertiary care facility was compared. In line with findings from earlier comparative studies, our results showed that GeneXpert/CBNAAT has much greater sensitivity and specificity than FNAC, demonstrating the improved diagnostic performance of molecular tests in detecting Mycobacterium tuberculosis. Compared to FNAC, which had a sensitivity of 84.9% and a specificity of 95.2%, GeneXpert/CBNAAT had a much better sensitivity of 96.4% and specificity of 98.1%. These outcomes are consistent with a study by Hillemann et al. that also found that GeneXpert had high sensitivity and specificity, highlighting its usefulness in quickly detecting rifampicin resistance and tuberculosis, which is essential for starting the right treatment and halting the spread of resistant strains [11].

Another important benefit of GeneXpert is its quick turnaround time, which is usually about two hours, as opposed to the 48 hours needed for FNAC results. By enabling early treatment decisions, this capability may lower transmission and enhance patient outcomes. Rapid diagnostics are crucial for bettering TB management, particularly in areas with a high disease burden, according to studies like that of Boehme et al. [12]. Additionally, one of the most important aspects of managing tuberculosis is the capacity of GeneXpert to identify rifampicin resistance straight from the sample, which enables prompt treatment regimen adjustments. Lawn et al.'s work, which emphasised the significance of prompt drug resistance diagnosis in HIV-infected patients with high rates of TB co-infection, emphasised this trait [13].

According to Piatek et al. [14], GeneXpert's adoption is constrained by more expenses and infrastructure needs in comparison to FNAC, despite its benefits. Nonetheless, the expense might be justified when taking into account the overall effect on healthcare systems, especially in terms of shortening the period of infectiousness and stopping the emergence and spread of drug-resistant TB. Contrary to what we found, certain investigations, including those by Theron et al., have demonstrated that although GeneXpert is quite successful, its effectiveness may fluctuate slightly depending on the strains and incidence of TB in various geographical areas [15]. As a result, ongoing performance evaluation and local validation are advised.

Conclusion

The study unequivocally shows that when it comes to identifying tuberculous lymphadenitis at a tertiary care facility, GeneXpert/CBNAAT has a higher diagnostic accuracy than FNAC. GeneXpert provides substantial benefits in terms of cutting turnaround times and enhancing patient care because of its increased sensitivity and specificity as well as its quick detection of rifampicin resistance. Given its ability to speed up treatment decisions and efficiently manage drug-resistant tuberculosis, these findings imply that GeneXpert should be taken into consideration as a primary diagnostic tool in comparable healthcare settings. The advantages of GeneXpert in improving clinical results and reducing the spread of tuberculosis highlight its worth in contemporary healthcare settings aimed at TB prevention, notwithstanding increased expenses and infrastructure needs.

References

1. Khiste JA, Deshpande NM, Pandit GA, Londhe SS. Use of CBNAAT x-pert MTB for rapid diagnosis of tuberculous lymphadenitis from fine needle aspiration cytology specimens at A tertiary care hospital. International Journal of Scientific Research. 2019;8(8):45-47. ?doi?https://doi.org/10.36106/ijsr/0501372#doi#
2. Aruna L, Ghanshyani K, Lakshmi E, Magar LR. Correlation of cytomorphology and cartridge based nucleic acid amplification test (CBNAAT) on fine needle aspirates in the diagnosis of tuberculous lymphadenitis. Med Pulse International Journal of Pathology. 2018;7(3):128-32.
3. Komanapalli SK, Prasad U, Atla B, Vasundhara N, Yendluri D. Role of CB-NAAT in diagnosing extra pulmonary tuberculosis in correlation with FNA in a tertiary care center. Int J Res Med Sci. 2018;6(12):4039-45. ?doi?https://doi.org/10.18203/2320-6012.ijrms20184904#doi#
4. Thakur B, Mehrotra R, Nigam JS. Correlation of various techniques in diagnosis of tuberculous lymphadenitis on fine needle aspiration cytology. Pathology Research International. 2013; 2013:824620. http://dx.doi.org/10.1155/2013/824620. ?doi?https://doi.org/10.1155/2013/824620#doi# ?pmid?24171137#pmid#
5. Salinita N, Supriya L, Usharani M, Singh HL. Detection of pulmonary tuberculosis using cartridge based nucleic acid amplification test (CBNAAT) and fluorescent microscopy. International Journal of Health Research & Medico Legal Practice. 2018;4(1):78-81.
6. Alvarez-Uria G, Azcona JM, Midde M, Praveen NK. Reddy S, Reddy R. Rapid diagnosis of pulmonary and extrapulmonary tuberculosis in HIV-infected patients. Comparison of LED Fluorescent Microscopy and the GeneXpert MTB/RIF Assay in a District Hospital in India. Hindawi Publishing Corporation Tuberculosis Research and Treatment. 2012; 2012:932862. Doi: 10.1155/2012/932862. ?doi?https://doi.org/10.1155/2012/932862#doi# ?pmid?22966426#pmid#
7. Gholoobi A, Masoudi-Kazemabad A, Meshkat M, Meshkat Z. Comparison of culture and PCR methods for diagnosis of mycobacterium tuberculosis in different clinical specimens. Jundishapur J Microbiol. 2014;7(2):e8939. Feb 2014. Doi: 10.5812/ jjm.89398. ?doi?https://doi.org/10.5812/jjm.8939#doi# ?pmid?25147673#pmid#
8. Rock RB, Sutherland WM, Baker C, Williams DN. Extrapulmonary tuberculosis among Somalis in Minnesota. Emerg Infect Dis. 2006;12(9):1434-36. ?doi?https://doi.org/10.3201/eid1209.050295#doi# ?pmid?17073097#pmid#
9. Tadesse M, Abebe G, Abdissa K, Aragaw D, Abdella K, Bekele A, et al. GeneXpert MTB/RIF assay for the diagnosis of tuberculous lymphadenitis on concentrated fine needle aspirates in high tuberculosis burden settings. 2015;10(9):e0137471. https://doi.org/10.1371/journal.pone.0137471. ?doi?https://doi.org/10.1371/journal.pone.0137471#doi# ?pmid?26366871#pmid#
10. Agrawal M, Bajaj A, Bhatia V, Dutt S. Comparative study of GeneXpert with ZN Stain and culture in samples of suspected pulmonary tuberculosis. J Clin Diagn Res. 2016;10(5): DC09-12. ?doi?https://doi.org/10.7860/JCDR/2016/18837.7755#doi# ?pmid?27437212#pmid#
11. Hillemann D, et al. Rapid molecular detection of extrapulmonary tuberculosis by the automated GeneXpert MTB/RIF system. J Clin Microbiol. 2011;49(4):1202-1205.
12. Boehme CC, et al. Rapid molecular detection of tuberculosis and rifampin resistance. N Engl J Med. 2010;363(11):1005-1015.
13. Lawn SD, et al. Early mortality among adults accessing antiretroviral treatment programmes in sub-Saharan Africa. AIDS. 2008;22(15):1897-1908.
14. Piatek AS, et al. Feasibility, diagnostic accuracy, and effectiveness of decentralised use of the Xpert MTB/RIF test for diagnosis of tuberculosis and multidrug resistance: a multicentre implementation study. Lancet. 2011;377(9776):1495-1505.
15. Theron G, et al. Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings in Africa: a multicentre, randomised, controlled trial. Lancet. 2014;383(9915):424-435.