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# Clinico-Demographic Profile and Diagnostic Yield of CBNAAT and AFB Staining in Patients with Cervical Tuberculous Lymphadenopathy.

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## Abstract

***Background:*** Cervical tuberculous lymphadenopathy is the most common form of extrapulmonary tuberculosis. Conventional diagnostic methods such as acid-fast bacilli (AFB) staining have limited sensitivity because of the paucibacillary nature of lymph node aspirates. Cartridge-Based Nucleic Acid Amplification Test (CBNAAT) has emerged as a rapid molecular diagnostic tool with improved diagnostic performance. ***Aim:*** To study the clinico-demographic profile and diagnostic yield of CBNAAT and AFB staining in patients with cervical tuberculous lymphadenopathy. ***Materials and Methods:*** This hospital-based observational study was conducted in the Department of Respiratory Medicine at a tertiary care center. Eighty patients with clinically suspected cervical tuberculous lymphadenopathy were included. Detailed demographic and clinical data were recorded. Fine needle aspiration cytology samples were subjected to AFB staining, CBNAAT, and culture. Diagnostic performance parameters including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Statistical analysis was performed using appropriate tests, and $p<0.05$ was considered statistically significant. ***Results:*** The mean age of patients was 33.9 ± 10.4 years, and females constituted 62.5% of cases. The posterior triangle was the most commonly involved site (48.8%). Fever (83.8%), cough (63.8%), and loss of appetite (62.5%) were the predominant symptoms. Lymph node AFB staining was positive in 18.8% of patients, CBNAAT in 40.0%, and AFB culture in 56.3%. CBNAAT demonstrated a sensitivity of 80.0%, specificity of 84.85%, PPV of 70.59%, and NPV of 90.91%. AFB staining showed a sensitivity of 66.67% and specificity of 93.75%. Both diagnostic modalities showed statistically significant diagnostic utility ($p<0.001$). ***Conclusion:*** Cervical tuberculous lymphadenopathy predominantly affects young adults and females. CBNAAT provides superior sensitivity and diagnostic yield compared with AFB staining and serves as a valuable rapid diagnostic tool for early confirmation of disease. Incorporation of CBNAAT into routine diagnostic algorithms may improve timely diagnosis and management of cervical tuberculous lymphadenopathy.

**Keywords:** Cervical tuberculous lymphadenopathy; CBNAAT; AFB staining.

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## INTRODUCTION

Tuberculosis (TB) remains one of the most important infectious diseases worldwide and continues to be a major public health problem, particularly in developing countries. It is caused by Mycobacterium tuberculosis and primarily affects the lungs; however, extrapulmonary tuberculosis (EPTB) constitutes a significant proportion of the disease burden. Among the various forms of EPTB, tuberculous lymphadenitis is the most common manifestation, accounting for nearly one-third of extrapulmonary tuberculosis cases. Cervical lymph nodes are the most frequently involved lymph nodes, and cervical tuberculous lymphadenopathy (CTL) often presents as painless swelling in the neck region, frequently affecting young adults and females.[1]

The diagnosis of cervical tuberculous lymphadenopathy remains challenging because the disease is usually paucibacillary, resulting in a low yield of conventional microbiological methods. Clinical manifestations such as fever, weight loss, loss of appetite, cough, and neck swelling are nonspecific and may mimic other infectious, inflammatory, or malignant conditions. Therefore, laboratory confirmation plays a crucial role in establishing the diagnosis and initiating appropriate treatment. Fine-needle aspiration cytology (FNAC) is commonly used as an initial diagnostic tool because it is simple, minimally invasive, and cost-effective. The presence of epithelioid granulomas with caseous necrosis strongly suggests tuberculosis, but microbiological confirmation is desirable whenever possible. [2]

Acid-fast bacilli (AFB) staining using the Ziehl-Neelsen method has traditionally been employed for rapid detection of mycobacteria. It is inexpensive and widely available, particularly in resource-limited settings. However, its sensitivity is often low in lymph node aspirates due to the paucibacillary nature of the specimens. Mycobacterial culture remains the gold standard for diagnosis but requires several weeks for growth and drug susceptibility testing, resulting in delays in diagnosis and treatment initiation. [3]

The introduction of Cartridge-Based Nucleic Acid Amplification Test (CBNAAT), also known as GeneXpert MTB/RIF, has revolutionized tuberculosis diagnosis. CBNAAT is an automated molecular test that detects Mycobacterium tuberculosis complex DNA and rifampicin resistance within a few hours. The World Health Organization (WHO) recommends CBNAAT as an initial diagnostic test for many forms of extrapulmonary tuberculosis because of its high sensitivity, specificity, rapid turnaround time, and ability to identify drug resistance. Several studies have demonstrated superior diagnostic performance of CBNAAT compared with conventional AFB staining in tuberculous lymphadenitis.[4]

### AIM

To study the clinico-demographic profile and diagnostic yield of CBNAAT and AFB staining in patients with cervical tuberculous lymphadenopathy.

### OBJECTIVES

1) To describe the demographic and clinical characteristics of patients presenting with cervical tuberculous lymphadenopathy.
2) To determine the diagnostic yield of CBNAAT in patients with suspected cervical tuberculous lymphadenopathy.
3) To compare the diagnostic performance of CBNAAT and AFB staining in the diagnosis of cervical tuberculous lymphadenopathy.

## MATERIALS AND METHODS

### Source of Data

The data were collected from patients attending the Outpatient Department (OPD) and admitted to the Inpatient Department (IPD) of the Department of Respiratory Medicine at a tertiary care teaching hospital. Patients presenting with cervical lymph node enlargement clinically suspected to be tuberculous lymphadenopathy were enrolled consecutively after obtaining informed written consent.

### Study Design

Hospital-based observational cross-sectional study.

### Study Location

The study was conducted in the Department of Respiratory Medicine of a tertiary care teaching hospital.

**Study Duration**
The study was conducted over a period of 24 months, including patient recruitment, data collection, laboratory investigations, data analysis, and report preparation.

**Sample Size**
A total of 80 patients with clinically suspected cervical tuberculous lymphadenopathy were included in the study.

**Inclusion Criteria**
Patients fulfilling any of the following criteria were included:
- Patients of either sex aged ≥15 years.
- Patients presenting with cervical lymphadenopathy clinically suspected to be tuberculous.
- Patients with neck lesions showing active discharge suggestive of tuberculosis.
- Patients with abscesses in the head and neck region suspected to be tuberculous in origin.
- Patients willing to participate and provide written informed consent.

**Exclusion Criteria**
- Patients with proven head and neck malignancy.
- Patients with metastatic cervical lymphadenopathy (neck secondaries).
- Patients already receiving anti-tubercular treatment.
- Patients unwilling to provide informed consent.
- Inadequate or insufficient aspirate samples for diagnostic evaluation.

**Procedure and Methodology**
After obtaining approval from the Institutional Ethics Committee, eligible patients were recruited. A detailed clinical history was obtained, including age, sex, socioeconomic status, duration of lymph node swelling, fever, cough, weight loss, loss of appetite, previous history of tuberculosis, contact history with TB patients, and associated comorbidities.

A thorough general and systemic examination was performed. Particular attention was paid to the site, size, consistency, number, mobility, matting, tenderness, and laterality of cervical lymph nodes.
Baseline investigations included:
- Complete blood count (CBC)
- Erythrocyte sedimentation rate (ESR)
- Blood sugar estimation
- HIV testing after counselling and consent
- Chest X-ray (PA view)
- Sputum examination for AFB where indicated

Fine Needle Aspiration Cytology (FNAC) of the cervical lymph node was performed under aseptic precautions using a 21-23 gauge needle. Aspirated material was utilized for cytological examination, AFB staining, and CBNAAT testing.
The clinico-demographic profile of all patients was recorded using a predesigned case record form.

**Sample Processing**
**For Cytology**
Aspirated material was smeared onto clean glass slides. Air-dried and alcohol-fixed smears were prepared and stained using May-Grunwald-Giemsa (MGG) and Papanicolaou stains. Cytological findings suggestive of tuberculosis such as epithelioid granulomas, Langhans giant cells, and caseous necrosis were documented.

**For AFB Staining**
One smear was stained using the Ziehl-Neelsen (ZN) staining technique. Slides were examined under oil immersion microscopy and reported as AFB positive or negative.

**For CBNAAT**
A portion of the aspirate was transferred into the CBNAAT sample reagent according to standard operating procedures. Samples were processed using the GeneXpert MTB/RIF system. Results were recorded as:
- MTB detected / MTB not detected
- Rifampicin resistance detected / not detected / indeterminate

**Data Collection**
Data were collected using a structured and pretested case record form that included:
- Demographic variables (age, sex)

- Clinical presentation
- Site and characteristics of lymphadenopathy
- Laboratory findings
- Cytological diagnosis
- AFB staining results
- CBNAAT results
- Final diagnosis

All collected data were checked for completeness and accuracy before entry into the database.

**Statistical Methods**

Data were entered into Microsoft Excel and analyzed using SPSS version 25.0.

- Continuous variables were expressed as Mean ± Standard Deviation (SD).
- Categorical variables were expressed as frequencies and percentages.
- Chi-square test or Fisher's exact test was used for comparison of categorical variables.
- Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of CBNAAT and AFB staining were calculated using the final diagnosis as the reference standard.
- A p-value <0.05 was considered statistically significant.
- Results were presented in tables, charts, and graphs wherever appropriate.

## RESULTS

**Table 1: Overall clinico-demographic profile and diagnostic yield (n=80)**

| Variable | n (%) / Mean ± SD | 95% CI | Test value | p-value |
|---|---|---|---|---|
| Age, years | 33.9 ± 10.4 | | | |
| Female | 50 (62.5%) | 51.5-72.3 | $\chi^2$=5.00 | 0.025* |
| Posterior triangle swelling | 39 (48.8%) | 38.1-59.5 | $\chi^2$=64.30 | <0.001* |
| Size 2.1-4 cm | 47 (58.8%) | 47.8-68.9 | $\chi^2$=41.28 | <0.001* |
| Fever present | 67 (83.8%) | 74.2-90.3 | $\chi^2$=36.45 | <0.001* |
| Cough present | 51 (63.8%) | 52.8-73.4 | $\chi^2$=6.05 | 0.014* |
| Loss of appetite | 50 (62.5%) | 51.5-72.3 | $\chi^2$=5.00 | 0.025* |
| Weight loss | 41 (51.3%) | 40.5-61.9 | $\chi^2$=0.05 | 0.823 |
| Lymph node AFB positive | 15 (18.8%) | 11.7-28.7 | $\chi^2$=31.25 | <0.001* |
| Lymph node CBNAAT positive | 32 (40.0%) | 30.0-51.0 | $\chi^2$=3.20 | 0.074 |
| AFB culture positive | 45 (56.3%) | 45.3-66.6 | $\chi^2$=1.25 | 0.264 |

The mean age of the study participants was 33.9 ± 10.4 years, indicating that cervical tuberculous lymphadenopathy predominantly affected young and middle-aged adults. Females constituted a significantly higher proportion of cases (62.5%; 95% CI: 51.5-72.3%; p=0.025).

The posterior triangle of the neck was the most commonly involved site (48.8%; 95% CI: 38.1-59.5%; p<0.001), and the majority of lymph nodes measured 2.1-4 cm in size (58.8%; p<0.001). Among clinical symptoms, fever was the most common presentation (83.8%), followed by cough (63.8%) and loss of appetite (62.5%), all showing statistically significant predominance.

Weight loss was present in 51.3% of patients but was not statistically significant (p=0.823). Regarding microbiological investigations, AFB positivity in lymph node aspirates was observed in 18.8% of cases (p<0.001), whereas CBNAAT detected Mycobacterium tuberculosis in 40.0% of cases, demonstrating a higher diagnostic yield, although the distribution was not statistically significant (p=0.074). AFB culture was positive in 56.3% of patients, indicating the highest positivity among diagnostic modalities assessed.

**Table 2: Demographic and clinical characteristics (n=80)**

| Variable | n (%) | 95% CI | Test value | p-value |
|---|---|---|---|---|
| Age 15-25 years | 17 (21.3%) | 13.7-31.4 | $\chi^2$=32.00 | <0.001* |
| Age 26-35 years | 31 (38.8%) | 28.8-49.7 | | |
| Age 36-45 years | 22 (27.5%) | 18.9-38.1 | | |
| Age 46-55 years | 7 (8.8%) | 4.3-17.0 | | |
| Age >55 years | 3 (3.8%) | 1.3-10.5 | | |
| Female | 50 (62.5%) | 51.5-72.3 | $\chi^2$=5.00 | 0.025* |
| Male | 30 (37.5%) | 27.7-48.5 | | |
| Posterior triangle | 39 (48.8%) | 38.1-59.5 | $\chi^2$=64.30 | <0.001* |
| Upper jugular | 14 (17.5%) | 10.7-27.3 | | |
| Mid jugular | 11 (13.8%) | 7.9-23.0 | | |
| Lower jugular | 6 (7.5%) | 3.5-15.4 | | |
| Submental | 5 (6.3%) | 2.7-13.8 | | |
| Submandibular | 5 (6.3%) | 2.7-13.8 | | |
| Fever present | 67 (83.8%) | 74.2-90.3 | $\chi^2$=36.45 | <0.001* |
| Cough present | 51 (63.8%) | 52.8-73.4 | $\chi^2$=6.05 | 0.014* |
| Loss of appetite present | 50 (62.5%) | 51.5-72.3 | $\chi^2$=5.00 | 0.025* |
| Weight loss present | 41 (51.3%) | 40.5-61.9 | $\chi^2$=0.05 | 0.823 |

The age distribution revealed that the 26-35 years age group accounted for the largest proportion of patients (38.8%), followed by 36-45 years (27.5%) and 15-25 years (21.3%), indicating that cervical tuberculous lymphadenopathy predominantly affects economically productive age groups (p<0.001). Females were significantly more affected than males (62.5% vs. 37.5%; p=0.025). With respect to lymph node involvement, the posterior triangle was the most frequently involved site (48.8%), followed by the upper jugular group (17.5%) and mid-jugular group (13.8%), showing a highly significant distribution (p<0.001). Clinically, fever was present in 83.8% of patients, making it the most common constitutional symptom, followed by cough (63.8%), loss of appetite (62.5%), and weight loss (51.3%). Fever, cough, and loss of appetite showed statistically significant occurrence, whereas weight loss did not reach statistical significance (p=0.823).

**Table 3: Diagnostic yield of CBNAAT (n=80)**

| CBNAAT variable | n (%) | 95% CI | Test value | p-value |
|---|---|---|---|---|
| Sputum CBNAAT: MTB detected | 5 (6.3%) | 2.7-13.8 | $\chi^2$=31.83 | <0.001* |
| Sputum CBNAAT: MTB not detected | 46 (57.5%) | 46.6-67.7 | | |
| Sputum CBNAAT: Not done | 29 (36.3%) | 26.6-47.2 | | |
| Lymph node CBNAAT: MTB detected | 32 (40.0%) | 30.0-51.0 | $\chi^2$=3.20 | 0.074 |
| Lymph node CBNAAT: MTB not detected | 48 (60.0%) | 49.0-70.0 | | |

Evaluation of CBNAAT demonstrated that sputum CBNAAT detected Mycobacterium tuberculosis in only 6.3% of patients, while 57.5% were negative and 36.3% did not undergo sputum testing. The distribution of sputum CBNAAT results was statistically significant ($\chi^2$=31.83, p<0.001), reflecting the limited utility of sputum examination in predominantly extrapulmonary disease. In contrast, lymph node CBNAAT identified MTB in 32 patients (40.0%), while 48 patients (60.0%) were negative. Although lymph node CBNAAT yielded substantially higher positivity than sputum CBNAAT, the difference between positive and negative lymph node results was not statistically significant (p=0.074).

**Table 4: Diagnostic performance of CBNAAT and AFB staining**

| Test | Sensitivity % (95% CI) | Specificity % (95% CI) | PPV % (95% CI) | NPV % (95% CI) | Test value | p-value |
|---|---|---|---|---|---|---|
| AFB staining | 66.67 (41.7-84.8) | 93.75 (79.9-98.3) | 83.33 (55.2-95.3) | 85.71 (70.6-93.7) | $\chi^2$=19.61 | <0.001* |
| CBNAAT | 80.00 (54.8-93.0) | 84.85 (69.1-93.3) | 70.59 (46.9-86.7) | 90.91 (75.1-96.7) | $\chi^2$=18.96 | <0.001* |
| AFB culture | 80.00 (54.8-93.0) | 93.33 (82.1-97.7) | 80.00 (54.8-93.0) | 93.33 (82.1-97.7) | $\chi^2$=32.27 | <0.001* |

*Significant at p<0.05.*

Comparison of diagnostic modalities showed that CBNAAT exhibited the highest sensitivity (80.0%), equal to that of AFB culture, and substantially higher than AFB staining (66.7%). The specificity of AFB staining was highest (93.75%), followed closely by AFB culture (93.33%), whereas CBNAAT demonstrated a specificity of 84.85%. CBNAAT also provided the highest negative predictive value (90.91%), indicating its usefulness in ruling out disease when the test result is negative. AFB staining showed the highest positive predictive value (83.33%), reflecting its strong confirmatory value when positive. AFB culture demonstrated balanced diagnostic performance with both sensitivity and specificity around 80-93%, supporting its role as the reference standard despite its longer turnaround time. All three diagnostic methods showed statistically significant diagnostic performance ($p<0.001$), confirming their utility in the diagnosis of cervical tuberculous lymphadenopathy.

## DISCUSSION

In the present study, the mean age of patients was 33.9 ± 10.4 years, with the maximum number of cases in the 26-35 years age group (38.8%), followed by 36-45 years (27.5%). This finding suggests that cervical tuberculous lymphadenopathy commonly affects young adults. Similar observations were reported by Alakunta et al. (2022)[1], who found a mean age of 33.78 years among patients with tuberculous cervical lymphadenopathy. Patel et al. (2019)[2] also observed that most cases occurred in the 20-35 years age group. Female predominance was noted in the present study, with 50 females (62.5%), which was statistically significant ($p=0.025$). This is comparable with Patel et al. (2019)[2], who reported female predominance of 58%, and Chandrappa et al. (2019)[3], who also found more females among CBNAAT-positive lymph node tuberculosis cases.

The most common site of lymph node involvement in the present study was the posterior triangle (48.8%), followed by upper jugular nodes (17.5%) and mid-jugular nodes (13.8%). This distribution was statistically significant ($p<0.001$). Similar findings were reported by Gautam et al. (2018)[4], who observed that cervical lymph nodes were commonly unilateral and frequently involved the neck region, while Moualed et al. (2018)[5] reported posterior triangle lymph nodes as the most commonly affected site. In the present study, most lymph nodes measured 2.1-4 cm (58.8%), which was also statistically significant. Gautam et al. (2018)[4] reported that most lymph nodes measured 3-6 cm, supporting the observation that clinically significant nodal enlargement is common in cervical tuberculous lymphadenopathy.

Among clinical symptoms, fever was present in 83.8%, cough in 63.8%, loss of appetite in 62.5%, and weight loss in 51.3% of patients. Fever, cough, and loss of appetite were statistically significant, whereas weight loss was not significant. These findings are in agreement with Singh et al. (2022)[6], who reported constitutional symptoms such as fever, cough, and weight loss in patients with tuberculous cervical lymphadenopathy. However, Jha et al. (2001)[7] noted that many patients with cervical tuberculous lymphadenitis may present without prominent constitutional symptoms, indicating variation in clinical presentation across studies.

In the present study, lymph node AFB staining was positive in 15 cases (18.8%), while lymph node CBNAAT detected MTB in 32 cases (40.0%). AFB culture was positive in 45 cases (56.3%). This shows that CBNAAT had a higher diagnostic yield than AFB staining. Similar findings were reported by Gouda et al. (2021)[8], where CBNAAT showed higher sensitivity than AFB smear microscopy. Kumari et al. (2020)[9] also observed that CBNAAT detected more cases of tubercular lymphadenopathy than ZN staining. In the present study, sputum CBNAAT detected MTB in only 6.3%, suggesting that sputum testing has limited yield in isolated extrapulmonary disease, whereas direct lymph node aspirate CBNAAT provides better diagnostic value.

Diagnostic performance analysis showed that CBNAAT had sensitivity of 80.0% and specificity of 84.85%, while AFB staining had sensitivity of 66.67% and specificity of 93.75%. Thus, CBNAAT was more sensitive, whereas AFB staining was more specific. The higher NPV of CBNAAT (90.91%) indicates its usefulness in ruling out disease when negative. Similar results were reported by Chandrappa et al. (2019)[3], who found CBNAAT sensitivity of 93.42% and specificity of 86.96%. Goyal et al. (2019)[10] also reported that CBNAAT improved rapid diagnosis of lymph node tuberculosis compared with conventional methods.

## CONCLUSION

The present study demonstrated that cervical tuberculous lymphadenopathy predominantly affected young adults, particularly females, with the posterior triangle being the most commonly involved lymph node group. Fever, cough, and loss of appetite were the most frequent clinical manifestations. Among the diagnostic modalities evaluated, CBNAAT showed a substantially higher diagnostic yield than conventional AFB staining and exhibited superior sensitivity and negative predictive value. Although AFB staining demonstrated excellent specificity, its lower sensitivity limited its ability to detect all cases of tuberculous lymphadenopathy. AFB culture remained an important confirmatory test but was constrained by longer turnaround time. The findings indicate that CBNAAT is a rapid, reliable, and effective diagnostic tool for cervical tuberculous lymphadenopathy and should be incorporated routinely into the diagnostic workup,

particularly in patients with paucibacillary disease where conventional smear microscopy may be negative. Early utilization of CBNAAT can facilitate prompt diagnosis, timely initiation of treatment, and improved patient outcomes.

## LIMITATION OF STUDY

1) The study was conducted at a single tertiary care center, which may limit the generalizability of the findings to other healthcare settings and populations.
2) The sample size of 80 patients was relatively small and may not fully represent the entire spectrum of cervical tuberculous lymphadenopathy.
3) Follow-up of patients after treatment initiation was not included; therefore, the impact of diagnostic modality on treatment outcomes could not be assessed.
4) Histopathological confirmation was not available in all cases, limiting comprehensive comparison between diagnostic methods.
5) The study primarily evaluated microbiological diagnostic yield and did not assess the cost-effectiveness of CBNAAT in routine clinical practice.
6) Culture, although considered a reference standard, may have yielded false-negative results due to the paucibacillary nature of lymph node aspirates.
7) Rifampicin resistance patterns and drug-resistant tuberculosis outcomes were not analyzed separately because of the limited number of resistant cases.

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