



ROLE OF CB-NAAT IN FNAC NEGATIVE CASES FOR DETECTING TUBERCULOSIS IN A TERTIARY CARE TEACHING HOSPITAL

General Medicine

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ABSTRACT

Background: Tuberculosis is one of the most common opportunistic infections. India has the highest burden of both tuberculosis (TB) and multidrug resistant tuberculosis (MDR-TB) and the second highest burden of HIV associated TB based on WHO Global TB report 2015. This study was done to find out the role of CB-NAAT in FNAC negative cases for the detection of tuberculosis in a tertiary care teaching hospital.

Methods: This descriptive observational study was carried out over a period of 2 months (March 2019 to May 2019) at North Bengal Medical College and Hospital. All presumptive TB patients with FNAC results belonging to various age groups, attending NBMCH during the aforesaid period, were included in the study. The samples were sent for CB-NAAT and the results were tabulated and analysed.

Results: The total number of lymph node samples which were detected FNAC negative for TB were 39. On performing CBNAAT among these samples 33.33% (13/39) samples were positive for TB and 66.67% (26/39) samples were found negative for TB. Resistance to Rifampicin was found in 7.69% (1/13).

Conclusion: CBNAAT proves to be a more sensitive diagnostic tool in presumptive TB cases which were not detected by FNAC. In addition, it offers a rapid detection of Rifampicin-resistant M. Tuberculosis strains which adds as an advantage.

KEYWORDS

FNAC, CBNAAT, Tuberculosis

INTRODUCTION

Fine needle aspiration cytology (FNAC) is a simple and rapid diagnostic technique but with low specificity^[1]. Conventional smear microscopy lacks sensitivity due to the paucibacillary nature of the fine needle aspirates (FNA).^[2] So both FNAC and smear microscopy have limitations by the absence of species confirmation and or lack of drug resistance guidance. Mycobacterial culture and drug susceptibility testing are not always available in resource poor settings or their results may take 4 to 8 weeks or longer.

In December 2010, WHO endorsed CB-NAAT/ GeneXpert MTB/RIF1 (Cepheid, USA) for use in TB laboratories. CBNAAT was adopted in India by RNTCP in 2012. It first started as a pilot project in Maharashtra state, India.^[3] The CB-NAAT assay consists of a closed system that is based on real time polymerase chain reaction (PCR) which requires minimal technical expertise in the diagnosis of TB and rifampicin resistance within 2 hours^[4].

In 2014, WHO recommended CBNAAT over conventional tests (conventional microscopy, culture or histopathology) in patients suspected of having extra pulmonary TB particularly in HIV-associated TB and MDR TB for early diagnosis and treatment^[5,6]. However, in the absence of universal availability of CBNAAT services, some centres continue to follow the Index TB guidelines of using CBNAAT as an additional test to conventional smear microscopy, culture and cytology in FNAC specimens.

Thus, we want to evaluate the role of CB-NAAT for diagnosis of tuberculosis using routinely collected needle aspirate samples and comparing it with FNAC.

Objectives

1. To study the role of CB-NAAT in FNAC negative cases for detection of tuberculosis in a tertiary care teaching hospital.
2. To assess the various associated socio-demographic and clinical variables.

MATERIALS AND METHODS

- ❖ **Type of study:** Observational descriptive study
- ❖ **Study period:** Between March – May 2019
- ❖ **Study Design:** Cross- Sectional study
- ❖ **Study setting:** The study was conducted in the departments of North Bengal Medical College
- ❖ **Study Population:** All FNAC negative cases of patients suffering from Tuberculosis attending NBMCH during the aforesaid study period was included in our study
- ❖ **Exclusion criteria:**
 1. Patients who were detected positive for HIV.
 2. Patients for whom sputum/pus cells examination was ordered
- ❖ **Sample size:** 39

❖ **Sampling technique:** complete enumeration with purposive sampling taking 95% confidence

❖ **Study tools:** -

1. Data collected from medical registers of RNTCP room
2. FNAC data collected from Department of Pathology

Study Technique: -

Ethical clearance was obtained from Institutional Ethics Committee (IEC) prior obtaining data from RNTCP room and department followed by collecting data from medical registers of the mentioned departments. Among those only Lymph node FNAC negative cases were included so as to compare those with CB-NAAT. Results and analysis were done using Microsoft Excel 2019 and presented in the form of tables and charts following the principles of descriptive statistics.

Study Variables: -

1. Socio demographic variables
 1. Age
 2. Sex
2. Clinical Variables
 - History of ATT (>1 month)

Operational Definition:

CB-NAAT Positive Tuberculosis:

CB-NAAT is a cartridge-based nucleic acid amplification test for simultaneous rapid antibiotic sensitivity test. It is an automated diagnostic test that can identify MTB DNA resistance to rifampicin (RIF)

Plan Of Analysis:-

DATA was entered and cleaned using MS Excel 2019, appropriate "7statistical" was used to analyse the data following the principle of descriptive and analytic statistics

RESULTS AND ANALYSIS:-

Total number of FNAC negative cases	:39
Total number of cases in which MTB was detected positive by CB-NAAT	:13
Total number of cases in which MTB was detected negative by CB-NAAT	:26
Percentage of cases in which MTB was detected positive by CB-NAAT	:33.33%
Percentage of cases in which MTB was detected negative by CB-NAAT	:66.67%

N.B. – From The Above Table Only One Individual Was Found To Be Rifampicin Resistant And The Rest Were Non-resistant

Table 1.1 shows the total CBNAAT positive and FNAC negative cases (n=13) among them 53.8% were males and 46.15% were females. The results were found highest among the age group 18-36 with 61.5% followed by individuals with age group 20-40.

Table 1.2 depicts that 76.92% individuals had a past history of ATT (greater than 1 month).

DISCUSSIONS:

India disproportionately shares a huge burden of Tuberculosis and drug-resistant TB. A lot of research is being conducted for early diagnosis and treatment of TB. WHO recommended the use of CBNAAT for the following (2014):

- Diagnosis of drug resistant TB among previously treated TB patients.
- Patients with smear microscopy positive results at any time during treatment.
- HIV-TB patients.
- Diagnosis of TB among children.
- Extra pulmonary presumptive TB patients.
- Person with Chest X-Ray suggestive of TB with smear negative result^[1].

This was a conditional recommendation and due to very low-quality evidence available more studies are needed particularly in settings with high TB prevalence. In this study, we demonstrate the role of CBNAAT in the diagnosis of tuberculosis in FNAC negative cases in a tertiary care centre. Among a study population of 39 individuals who were FNAC negative, 13 (33%) cases reported a CBNAAT positive. Also 1 out of the 13 cases showed rifampicin resistance and others were non-resistant. Out of the 13 positive cases a distribution study was done based on the age group and sex, the results are 53.8% were males, 46.15% were females. Maximum among the age group 18-36 with 61.5%.

The results obtained in our study were comparable to similar studies by L. Aruna et al (40% CBNAAT positive among the FNAC negative cases)^[7]. Also a surge in the age group 16-30 years was seen in the similar study.

From the above evaluation we can imply that CBNAAT is a more accurate technique in comparison to FNAC. Also the property to determine the Rifampicin resistance provides an edge.

CONCLUSION:

Early detection of TB can be done using FNAC in the lower resource setting while WHO recommended CBNAAT though costly, technical expertise, power backup, maintenance and calibration is more specific in detecting TB bacilli. Our study also showed:

1. Positive results were least among the teenage age group
2. More positive results were found in the reproductive age group
3. Patients with a history of ATT for >1 month showed more positive methods
4. CBNAAT is a slightly more accurate as compared to FNAC

Limitations

1. Limited period of time i.e. time constraint.
2. Longitudinal study would have been better.

Table 1.1- Distribution Of FNAC Negative CBNAAT Positive Cases According To Age And Sex

Age Group	Male	Female	Percentage
0-20	1	1	15.38%
21-40	3	5	61.5%
>40	3	0	23.07%

N.B. – From the above table only one individual was found to be Rifampicin resistant and the rest were non-resistant

Table 1.1 shows the total CBNAAT positive and FNAC negative cases (n=13) among them 53.8% were males and 46.15% were females. The results were found highest among the age group 18-36 with 61.5% followed by individuals with age group 20-40.

Table 1.2: Distribution Of FNAC Negative CBNAAT Positive Cases According To History Taken Of >1 Month ATT

History of >1 month ATT	No. of individuals	Percentage
Yes	10	76.92%
No	3	23.08%

Table 1.2 depicts that 76.92% individuals had a past history of ATT (greater than 1 month).

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