

# **Research Article**

# COMPARATIVE STUDY OF SPUTUM AFB AND CBNAAT IN SUSPECTED TB PATIENTS WITHOUT HIV ATTENDING A TERTIARY CARE HOSPITAL OF WESTERN ODISHA

# MISHRA S., MUKHERJEE S.\*, DASH A. AND TIWARI S.

Department of Microbiology, Hitech Medical College, Rourkela,769004, Odisha, India \*Corresponding Author: Email - shuvankar.mukherjee963@gmail.com

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Abstract- Background: Tuberculosis is a major health problem of India. Sputum AFB smear study is the age -old method of laboratory diagnosis of Pulmonary tuberculosis. CB NAAT is a recent nucleic acid based technology to diagnose Tuberculosis. Although it is highly sensitive and specific for diagnosis of TB it is costly and not available in resource poor area. We have conducted a research to compare efficacy of sputum AFB and CB NAAT to diagnose TB in suspected HIV negative patient attending a tertiary care hospital of Western Odisha. Methods: Sputum sample of 823 suspected TB patient who were HIV negative were collected and subjected to both AFB smear study and CB NAAT. Result: Among 823 samples 61(7.4%) were positive for AFB and 65(7.89%) were positive by CB NAAT.1 patient positive by AFB was negative by CB NAAT. And 4 patients who were negative for AFB were positive by CB NAAT. Conclusion: Sputum AFB is a good screening method for Pulmonary tuberculosis in HIV negative individual.

# Keywords- TB, Sputum, AFB, CBNAAT

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#### Introduction

Tuberculosis is a major scourge in India from ancient age. Prevalence of sputum positive TB in India was 400 per 100000 population during 1955-1958 by the national survey. About 1.5 million people was at risk at that time which led to implementation of NTP (National Tuberculosis Programme) in 1962 [1]. But subsequent sub national surveys in different part of country found out high prevalence rate of sputum positive TB in spite of NTP [2]. DOTS and RNTCP were then launched in a phased manner [3]. RNTCP covered every part of India by 2006. But still now TB is a major public health problem with 2 million incident cases and 500000 TB deaths every year [4]. Cartridge based nucleic acid amplification test (CBNAAT), specific for Mycobacterium tuberculosis, has been recently introduced for detection of TB. It has an added advantage of detecting rifampicin resistance as it targets the rpoB gene of mycobacteria, which is the critical gene associated with rifampicin resistance. The test is highly specific and does not give cross reactions with any other bacterial species including a comprehensive panel of mycobacteria thereby excluding non-tubercular mycobacteria.[5] In a study, the overall sensitivity, specificity, positive predictive value and negative predictive value of CBNAAT test (Gene Xpert MTB/RIF assay) were found to be 98.6%, 100%, 100% and 93.8%, respectively[6]. Considering paucity of data regarding sputum positivity status in Western Odisha we have conducted research to find out sputum positivity status in suspected TB patients attending a tertiary care hospital of Western Odisha. Also we have compared sputum AFB smear with CB NAAT and measured Rifampicin resistance rate.

# Materials and Methods

Study area: This cross-sectional observational study was carried out in Microbiology Dept of Hitech Medical college of Rourkela.

Study population: 823 clinically suspected TB patients who were negative for HIV by card test attending OPD or IPD were enrolled in the study.

Study duration: 1-year Jan 2019 to Dec 2019.

Sample collection: Patients were given the sterile sputum container and asked to collect 2 sputum samples (early morning and spot) after a deep cough without salivary contamination.

Sample processing: smear was made from mucoid part of the sputum and stained with Acid fast stain (Himedia, Mumbai S033, S005, S022) smear was examined under oil immersion objective lens and graded according to RNTCP guideline. All samples were sent to nearby RNTCP certified lab for confirmation by CB NAAT (Gene X pert) and to know rifampicin resistance status. All positive cases were notified and treated accordingly. All patients were screened for HIV by rapid card test and only HIV negative patients were included in the study.

#### Data analysis

Data analysis was done by SPSS software version 17

#### Result

Among 823 samples all were negative for HIV. 61(7.4%) were positive for AFB and 65(7.89%) were positive by CB NAAT. One patient positive by AFB was negative by CB NAAT. Four patients who were negative for AFB were positive by CB NAAT. RNTCP grading was showed in [Fig-1]. Age distribution of sputum positive samples was showed in [Fig-2]. Sex distribution of sputum positive samples was showed in [Fig-3]. Sputum positivity rate, CB NAAT positivity rate and Rifampicin resistance rate were shown in [Fig-4].

#### Discussion

The year 2018 was a milestone towards ending TB in India. Indian Govt has initiated NIKSHAY which is an online notification system all over India. The estimated TB incidence in India was 27 lacks in 2018 RNTCP was able to achieve a notification of 21.5 lack in 2018. This was a 16% increase of notification rate as compared to 2017. Of the total notification 25% cases was from private sector.

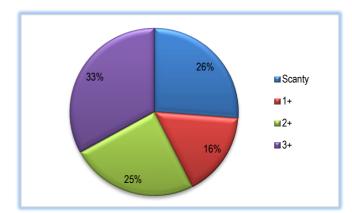


Fig-1 Distribution of Sputum positive sample by RNTCP grading

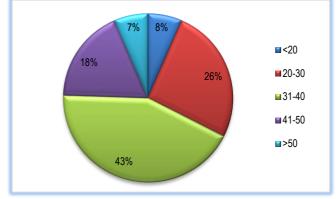


Fig-2 Distribution of Sputum Positive sample according to age group

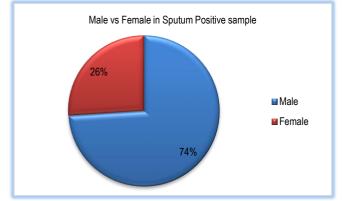


Fig-3 Distribution of Sex in Sputum positive samples

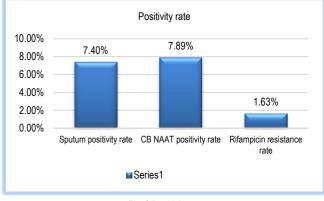


Fig-4 Positivity rate

Majority of the affected individuals was in age group of 15 to 69 years. And 2/3<sup>rd</sup> of positive cases was Male. The laboratory network of RNTCP includes 6 national reference laboratory, 31 Intermediate reference laboratory 48 certified laboratories provide liquid culture and DST service. 62 certified lab provide LPA service1180

CB NAAT facilities developed at district and subdistrict levels offer decentralized testing for TB and Rifampicin resistance and our nearby RGH. Rourkela was one of them. As per NHP 2018 total notified cases of TB in Odisha was 67,162 in 2017. The TB cases rose to a total of 71,131 in 2017 when cases in private hospitals are included. Among total notified cases in 2017 88% were new cases and 12% were recurrent TB cases. Around 2% of TB cases had HIV coinfection. 80% were Pulmonary TB cases and 20% were extrapulmonary TB cases (Most of them were Lymph node TB). Deogarh and Nabrangpur have 94% pulmonary TB cases. In Bhubaneswar, Cuttack and Jagatsinghpur 1/3rd of total new TB cases was extrapulmonary. Paediatric TB was 12% in capital city of Odisha [7]. Our study revealed a small picture of TB status in Sundergarh district of Western Odisha Sputum positivity rate in suspected patient was 7.4%. Most affected sex was male and most affected age group was 31-40 followed by 20-30 which was almost similar to national data. CB NAAT positivity rate was 7.89% and rifampicin resistance rate was 1.63%. Among 65 positive cases by CB NAAT 13 cases (20%) were positive for rifampicin resistance in our study which was lower in comparison to study done by Gupta et al [8] (25%) but higher than Khatawal et al., [9] (16.1%). 0.49% increase of positivity seen in CB NAAT compared to sputum AFB in our study. This finding was not consistent with Rao et al [10] (19.48%), Gupta et al [11] (30%), Khatawkar et al [9] (18%), Dewan et al [12] (29%) where significant increase in positivity was seen in case of CB NAAT compared to sputum AFB. This was because they all had compared CB NAAT with sputum AFB in HIV positive patients. In HIV sputum positivity chances decreases due to less cavity formation as a result of destroyed immunity. In normal individual sputum AFB is fair enough to diagnose Pulmonary tuberculosis which is cheaper and most suitable in resource poor set up.

# Conclusion

In HIV negative patients Sputum AFB is good enough to detect pulmonary TB compared to CB NAAT.

# Study limitation

We have not done culture sensitivity which is the gold standard of diagnosis of tuberculosis due to lack of infrastructure. As a result, we could not directly compare two methods with sensitivity and specificity.

Application of research: This research encouraged that In HIV negative patient pulmonary TB should be diagnosed by sputum AFB. In sputum negative patient CBNAAT should be performed.

Research Category: Medical microbiology

# Abbreviations:

RNTCP: Revised National Tuberculosis Control programme. CBNAAT: Cartridge based nucleic acid amplification test AFB: Acid fast bacillus HIV: Human immunodeficiency virus

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Study area / Sample Collection: Hitech Medical College, Rourkela,769004, Odisha, India

# Conflict of Interest: None declared

**Ethical approval:** Ethical approval taken from Department of Microbiology, Hitech Medical College, Rourkela,769004, Odisha, India Ethical Committee Approval Number: Nil

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