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Original Research Paper

Pulmonary Medicine

THE UTILITY OF RAPID DIAGNOSTICS IN THE DIAGNOSIS AND TREATMENT OF VARIOUS TYPES OF TUBERCULOSIS.

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ABSTRACT

INTRODUCTION: About a quarter of the world's population is infected with M. tuberculosis.1TB can affect anyone anywhere, but most people who develop the disease are adults, men greater than women. Drug-resistant TB continues to be a public health threat. Worldwide in 2019, TB diagnosis was given a major boost by the advent of rapid diagnostic like CBNAAT and urine lipoarabinomannan assay especially in HIV TB co infection.

METHODS: Various body specimen such as sputum, tissue such fine needle aspirate specimen, fluids such as CSF, Pleural fluid and Pus sent from various clinics were tested with culture, CBNAAT, smear microscopy for AFB. The results were compared. Culture was kept as gold standard Univariate analysis were done. Cross tables were used as descriptive. Sensitivity and specificity of CBNAAT established.

RESULTS: Totally 294 cases of pulmonary and extra pulmonary tuberculosis were analysed.

Sensitivity of CBNAAT in all samples is 68 %. Sensitivity of Smear microscopy is 21%. Sensitivity of CBNAAT in sputum, tissue, fluid, pus was 73 %, 68%, 58% and 56% respectively.

The total no of HIV patients tested positive for TB is 118.The average CD4 is 318.8.

The total death among HIV TB coinfection patient is 9. The total number of rifampicin resistance patient is 17. Sensitivity of smear microscopy in sputum, tissue, fluid, pus was 22%,11.7%, 14%, and 0% respectively.

DISCUSSION: The study shows the trend of positivity in sputum, tissue, and fluid in the descending order.

The study shows that the CBNAAT has higher sensitivity in detecting TB in sputum, tissue of samples like FNAC, fluid and pus than conventional test like smear AFB microscopy.

KEYWORDS : Diagnostics, Tuberculosis, CBNAAT, Sensitivity, Smear, HIV TB

INTRODUCTION:

In the pandemic we find large of medical facilities are using up the NAAT machines and technology in the covid diagnosis. This leaves the TB Diagnosis with distinct void.

Globally, an estimated 10.0 million (range, 8.9–11.0 million).[5] people fell ill with TB in 2019, a number that has been declining very slowly in recent years.[5]

Men (aged ≥15 years) accounted for 56% of the people who developed TB in 2019; women accounted for 32% and children (aged <15 years) for 12%. Among all those affected, 8.2% were people living with HIV.[1][2][3]

The WHO TB Report for past four years has reported India (27%), China (14%), Russian federation (8%), as having more than half of Drug resistant Tuberculosis.[4]

This is the time to speed up testing in various symptomatic patients.

The use of CBNAAT in various specimen and its superiority to other diagnostic modalities is presented in this paper.

This paper insists on increasing the NAAT facilities rather reducing it. Which is happening in this period.

METHOD AND MATERIALS:

Various body specimen such as sputum, tissue such fine needle aspirate specimen, fluids such as CSF, Pleural fluid and Pus sent from various clinic such as TB Clinic, Respiratory medicine OP, medical OP, paediatric OP were tested with culture, CBNAAT, Smear microscopy for AFB and results were compared. Culture was kept as gold standard Univariate analysis were done. Cross tables were used as descriptive. Sensitivity and specificity of CBNAAT established. Study period 2016, the study was extraction of data from TB clinic registry and does not contain any patient's personal details, images. We are using it anonymously

INCLUSION CRITERIA:

All cases of pulmonary and extra pulmonary tuberculosis diagnosed by culture in the year 2016 in Government KAPV and MGM hospital were compared with CBNAAT, smear microscopy for AFB,

This includes various specimen such as sputum, tissue, fluid such as CSF, pleural fluid, and pus. All specimens were subjected to solid culture, CBNAAT, Smear microscopy.

RESULTS:

Totally 294 cases of pulmonary and extra pulmonary tuberculosis were analysed.

Total number of males were 199 and females were 95 (Table 1).

Total number of Pulmonary and Extra pulmonary tuberculosis cases were 230 and 64 respectively (Table 1).

The average age in the study was 42.67 (Table 1).

Table 1 gender and age:

NO.OF CASES IN STUDY	AGE	GENDER
294	MEAN=42.67	MALE= 199
	MEADIAN=41	FEMALE=95

Sensitivities of CBNAAT and smear microscopes were calculated.

Sensitivity of CBNAAT in all samples is 68 % (Table 2). Sensitivity of Smear microscopy is 21% (Table 2).

Table 2 SENSITIVITY TOTAL TESTS:

Test	SENSITIVITY
CBNAAT	74%
SMEAR MICROSCOPY	21%

Sensitivity of CBNAAT in sputum is 73 % (Table 3).
Sensitivity of CBNAAT in tissue is 68% (Table 3).
Sensitivity of CBNAAT in fluid is 58% (Table 3).
Sensitivity of CBNAAT in pus is 56% (Table 3).

TABLE 3: sensitivity of CBNAAT IN VARIOUS SAMPLES

Sample	sensitivity
Sputum	73
Tissue	68
Fluid	58
Pus	56

The total no of HIV patients tested positive for TB is 118 (Table 4). The average CD4 is 318.8 (Table 4).

The total death among HIV TB coinfection patient is 9 (Table 4).

TABLE 4:

Total cases	HIV TB CO INFECTION	Death	Average CD4
294	118	9	314.8

The total number of rifampicin resistance patient is 17 (Table 5).

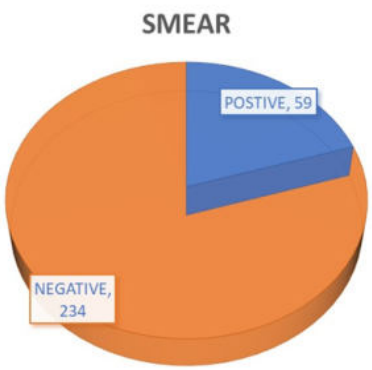
TABLE 5:

Rifampicin resistance	No of cases diagnosed by CBNAAT	Growth in culture
Very Low	5	5
Low	3	3
Medium	8	8
High	1	1
Total	17	17

Total smear positivity in various samples is 58 (Graph 1).

Total smear negativity in various samples is 234 (Graph 1).

Graph 1:



Sensitivity of smear microscopy in sputum is 22% (Table 6).
Sensitivity of smear microscopy in tissue is 11.7% (Table 6).
Sensitivity of smear microscopy in fluid is 14% (Table 6).
Sensitivity of smear microscopy in pus is 0% (Table 6).

TABLE 6:

SMEAR MICROSCOPY FOR AFB SPECIMEN	SAMPLES TOTAL	SMEAR POSITIVE	SMEAR NEGATIVE
SPUTUM	230	52(22%)	178(78%)
TISSUE	34	4 (11.7%)	30 (88.3%)
FLUID	14	2(14%)	12(86%)
PUS	16	0	16

The number of smears of sputum tested was 230 of which 52 were positive (table 7).

The number of smears of tissue FNAC tested was 34 of which 4 were positive (table 7).

The number of smears of fluid tested was 14 of which 2 were positive (table 7).

The number of smears of pus tested was 16 of which none were positive (table 7)

TABLE 7:

SMEAR FOR AFB	POSITIVE	NEGATIVE
SPUTUM	52	178
TISSUE	4	30
FLUID	3	11
PUS	0	16
TOTAL	59	235

The number of sputa tested with CBNAAT was 230 of which 162 were positive (Table 8), (Graph 2).

The number of tissue specimen tested with CBNAAT was 34 of which 23 were positive (Table 8), (Graph 2).

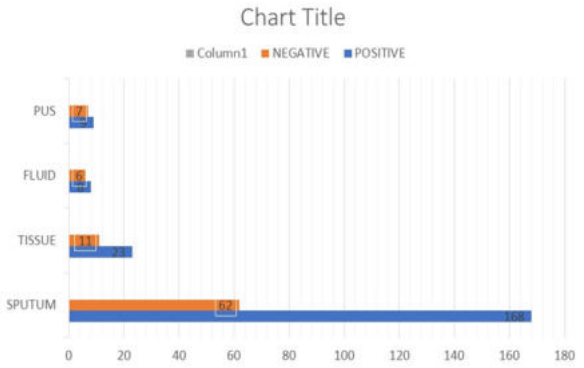
The number of fluids tested with CBNAAT was 14 of which 8 were positive (Table 8), (Graph 2).

The number of pus tested with CBNAAT was 16 of which were 9 positive (Table 8), (Graph 2).

TABLE 8:

SPECIMEN	SAMPLED IN CBNAAT	POSITIVE & PERCENTAGE	NEGATIVE & PERCENTAGE
SPUTUM	230	168 (73%)	62(27%)
TISSUE	34	23 (68%)	11 (32%)
FLUID	14	8(58%)	6 (42%)
PUS	16	9 (56%)	7(44%)

GRAPH 2:



DISCUSSION:

The study shows the trend of positivity in sputum, tissue, and fluid in the descending order.

The study shows that the CBNAAT has higher sensitivity in detecting TB in sputum, Tissue of samples like FNAC, fluid and pus than conventional test like smear AFB microscopy. Tables 6, 7, 8 and graph 1, 2 illustrates the difference in the sensitivity of the two tests.

Increasing access to early and accurate diagnosis using a molecular WHO-recommended rapid diagnostic test is one of the main components of TB laboratory-strengthening efforts under the End TB Strategy. As a first step, countries should adopt policies that include diagnostic algorithms in which a WHO-recommended rapid diagnostic test is the initial test for all people with signs or symptoms of TB.[8] Such policies are particularly important for the countries included in one or more of the lists of high TB, TB/HIV and MDR-TB burden countries such as India. The annual number of TB deaths is falling globally, but not fast enough to reach the 2020 milestone of a 35% reduction between 2015 and 2020 The cumulative reduction between 2015 and 2019 was 14%, less than halfway towards the milestone. [11]

The number of new and relapse case of pulmonary tuberculosis is 2728541 of which 57% were bacteriologically confirmed cases as of 2020 as per WHO Global TB report.[15]

This diagnostic improvement is brought out by rapid diagnostic CBNAAT and urine lipoarabinomannan assay in HIV TB patients.[10]

Thus, initial reliance on smear microscopy and darkfield microscopy was completely replaced with rapid diagnostic tests.

Most of the increase since 2013 is explained by trends in India and Indonesia, the two countries that rank first and second worldwide in terms of estimated incident cases per year.10 In India, notifications of people newly diagnosed with TB rose from 1.2 million in 2013 to 2.2 million in 2019 (+74%).[14]

All forms of drug-resistant TB require treatment with a second-line regimen.[7] With increasing use of Xpert MTB/RIF for simultaneous detection of TB and resistance to rifampicin, a growing number of RR-TB cases are being detected and notified. The End TB Strategy calls for universal access to drug susceptibility testing (DST). The focus in this section is on DST for notified TB patients with bacteriologically confirmed TB, who can then be tested for MDR/RR-TB, using diagnostic tests recommended by WHO.[7]

This can be achieved only when we increase the rapid diagnostic methods with their inclusion in the algorithm for diagnosis of sensitive and resistant tuberculosis.

CONCLUSION:

Rapid diagnostic test has helped many countries in the TB notification and treatment especially after 2011 and now we see drop in use of this test due to pandemic and due usage in covid testing in those countries which immensely benefitted from it. Increasing the facility is the only way forward to achieve success in END TB strategy.so policy change and financial support to prop up the rapid diagnostic test facility is particularly important.

"CONFLICT OF INTEREST: NONE".
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Ethical clearance: Obtained

REFERENCES:

1. For these people, the lifetime risk of developing TB disease is about 5–10%. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE NO 14
2. WHO's annual rounds of global TB data collection and the annual WHO Global TB Report are key elements of "monitoring and reporting" in the WHO multisectoral accountability framework for TB. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 14
3. The UN Secretary General's report was released in September 2020. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 14.
4. The treatment targets were built on the WHO Flagship Initiative "Find. Treat. All. #EndTB" and the funding targets were based on the Stop TB Partnership's Global Plan to End TB, 2018–2022. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 14.
5. Here and elsewhere, "range" in the context of estimates of TB disease burden refers to the 95% uncertainty interval. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE
6. When an HIV-positive person dies from TB disease, the underlying cause is coded as HIV in the International Classification of Diseases system. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 17.
7. MDR-TB is defined as resistance to rifampicin and isoniazid. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 15,16
8. Reductions in other WHO regions were 3.5% in the Eastern Mediterranean Region, 8.7% in the South-East Asia Region and 6.1% in the Western Pacific Region. In the WHO Region of the Americas, incidence is slowly increasing, owing to an upward trend in Brazil. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 16.
9. Other countries with large relative increases in 2017–2019 are shown in Fig. 5.2. WHO GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE
10. Framework of indicators and targets for laboratory strengthening under the End TB Strategy (WHO/HTM/ TB/2016.18). Geneva: World Health Organization; 2016 (https://www.who.int/tb/publications/labindicators/en/, accessed 18 August 2020). WHO GLOBAL TB REPORT TB DIAGNOSIS AND TREATMENT CHAPTER PAGE 72
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12. Lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis of active tuberculosis in people living with HIV. Policy update 2019. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/329479/9789241550604-eng. pdf? sequence= 1& is Allowed= y & ua=1, accessed 26 August 2020). WHO GLOBAL TB REPORT TB DIAGNOSIS AND TREATMENT CHAPTER PAGE 73.
13. Including TB deaths among both HIV-negative and HIV-positive people. GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 14.
14. GLOBAL TB REPORT EXECUTIVE SUMMARY PAGE 16.
15. WHO GLOBAL TB REPORT TB DIAGNOSIS AND TREATMENT CHAPTER PAGE 73.