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Assessment of TB centers having CBNAAT facility and to find out the impact of CBNAAT in MDR Tuberculosis cases detection in a cosmopolitan city of Madhya Pradesh- A cross sectional study

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ABSTRACT

The global burden of TB remains enormous. More than 9 million new Mycobacterium tuberculosis (MTB) cases and 1.7 million deaths occur annually globally. The Xpert MTB/RIF assay is a cartridge based nucleic acid amplification test, which is an automated test that can identify MTB DNA and resistance to Rifampicin (RIF) by nucleic acid amplification test or NAAT.

Methods- It was a cross sectional study done for period of 1 Years (2017-18). Three health care centres (Two governments and one private) in Indore city of Madhya Pradesh. Data collection was done by using checklist based questionnaire which assess the Infrastructure, logistics, safety measures, workload etc. Demographic profile of 200 MDR TB patients enrolled between 2017-18 was taken for the study. For calculation of case detection rate, secondary data of MDR TB patients enrolled between 2013 to 2017 was taken.

Results- Proportion of MDR TB cases have risen gradually over the years. From 2013 to 2017, there was an increase in the numbers of MDR TB cases as well as TB cases. All the three centres had enough separate area for specimen receipt, Power supply with back up, Air conditioner in running condition. There was proper disposal of cartridges, sputum containers and all disinfected materials.

Conclusion- There has been a gradual increase in numbers of MDR TB cases as well as TB cases but case detection rate of MDR TB has not increased significantly from 2013 to 2017. Majority of the patients (65%) were males belonging to productive age group.

Keywords: MDR TB, CBNAAT, Xpert MTB/RIF assay

INTRODUCTION

The global burden of TB remains enormous. More than 9 million new Mycobacterium tuberculosis (MTB) cases and 1.7 million deaths occur annually globally.[1] Most of them occur in resource-limited settings. Smear microscopy is the cornerstone for the diagnosis of TB in resource-limited settings. However it is rapid and inexpensive but has only modest (35-80%) sensitivity and a poor positive predictive value (PPV).The development of drug resistance in Tuberculosis is almost invariably as a result of monotherapy. In addition, the usage of substandard quality drugs can also cause drug resistant Tuberculosis. Yet another, but the most important factor is patient compliance to treatment which has to be ensured for the prevention of a dreadful global burden- the drug resistant Tuberculosis.[2]

The Xpert MTB/RIF assay is a cartridge based nucleic acid amplification test, which is an automated test that can identify MTB DNA and resistance to Rifampicin (RIF) by nucleic acid amplification test or NAAT.[3]

The Xpert MTB/RIF assay has high sensitivity & specificity for detection of pulmonary TB. An in vitro study demonstrated detection of as small as 131 colony forming units (cfu) per ml, compared to about 10,000 cfu with conventional smear microscopy.[4]

CBNAAT was launched in India by RNTCP in 2012. Initially it was started as a pilot project in Maharashtra state, India. CBNAAT is currently available at more centers and the aim is to establish a link with all the peripheral hospitals to nearby medical college hospitals and also to implement in private set ups.

Aims & Objectives-(1) To assess the Infrastructure, logistics, safety measures and workload by facility survey.(2) To find out demographic profile and case detection of MDR TB patients

Methodology- It was a cross sectional study done for period of 1 Years (2017-18). Three health care centres(Two government and one private)in Indore city of Madhya Pradesh were selected for the facility survey under study where gene Xpert machine was working for the diagnosis of MDR TB under RNTCP programme. Data collection was done by using checklist based questionnaire which assess the Infrastructure, logistics, safety measures' workload etc. Demographic profile of 200 MDR TB patients enrolled between 2017-18 was taken for the study by interview of those present on the centre on the day of assessment and by telephone those were not present. For calculation of case detection rate, secondary data of MDR TB patients enrolled between 2013 to 2017 was taken because CBNAAT machine was installed in all the centers after 2013.Data were collected and entered in Microsoft Excel sheet and analysed using appropriate statistical tests by using software, SPSS version 21. P value less than 0.05 ($p<0.05$) was considered significant. Health Care Personnel involved in CBNAAT centres in selected health care centres of Indore who gave consent were included and personnel not involved or didn't gave consent were excluded for the study.Patients also who gave consent were included in the study.

Results- The following findings of the study is presenting in table forms.

Table.1 Case detection rate of MDR TB cases after introduction of CBNAAT

Types of TB	No. of Case detection of MDR TB in following years					
	(2013)	**(2014)**	**(2015)**	**(2016)**	**(2017)**	**Statistical significance**
MDR	84 (1.5%)	82 (1.4%)	85 (1.4%)	97 (1.45%)	117 (1.67%)	**.7076**
NON MDR	5233	5611	5986	6552	6881	

Above table depicts that proportion of MDR TB cases have risen gradually over the years. From 2013 to 2017, there was an increase in the numbers of MDR TB cases as well as TB cases. The case detection rate was 1.5 in 2013, 1.4 in 2014, 1.45 in 2016 and 1.67 in 2017. There was a gradual increase in case detection but the increase was not statistically significant i.e. **p value is >0.05.** (0.7076).

Table.2 Facility survey for assessment of manpower and infrastructure required for the services(N=3)

S.No.	Manpower	Required	Available
1	Microbiologist	3	3
2	Medical Officer	3	3
3	Lab Technician	3	3
	Infrastructure TB centers		
S.No.	**Material**	**Available**	**Not available**
1	Separate area for specimen receipt	3	0
2	Air conditioner	3	0
3	Device for monitoring temperature	3	0
4	Power supply with back up	3	0
5	Refrigerator for storing consumables	3	0

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6	Cartridges, Reagents	3	0
7	Staining reagents	3	0
8	Disinfectants	3	0

Table depicts that 100% of the posts were filled in all the three centres. All the three centres had enough separate area for specimen receipt, Power supply with back up, Air conditioner in running condition, Device for monitoring temperature, Refrigerator for storing consumables in working condition. There were adequate stock of Cartridges, Reagents Staining reagents and Disinfectants in all the three centres.

Table.3 Table showing Disposal of infected materials by health care facility (N=3)

S.N.	Method of disposal	Done	Not done
1	Foot operated bin with lid	3	0
2	Waste disposal by Autoclave	3	0
3	Disposal of Cartridges	3	0
4	Disposal of sputum containers	3	0
5	Disinfection	3	0

Above table depicts all three centres had Foot operated bin with lid and wastes were disposed by autoclave .There was proper disposal of cartridges, sputum containers and all disinfected materials.

Table 4: Table showing Biological safety Cabinets Procedures and precautions followed at health care facility (N=3)

S.N.	Biological safety Cabinets Procedures and precautions	Followed	Not followed
1	Switching ON the safety cabinets for at least 30 min before use	3	0
2	Wear double pair of gloves, every time	3	0
3	Bio safety cabinets are cleaned with 5% Phenolic solution before work	3	0
4	Do not process more than 8 specimens at a given time,	3	0
5	Discard off the outer glove, too, inside the bio-safety cabinet.	3	0
6	Wipe off inner glove with disinfectant before touching anything else in the lab	3	0

Above table depicts that Standard Operating Procedures (SOP) regarding Biological safety Cabinets Procedures and precautions were followed in all the three centers in a proper way.

Table 5: Table showing Workload at health care facility (N=3)

S.N.	Workload	Health facility 1	Health facility 2	Health facility 3

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1	No. of samples processed per day	16	16	16
2	No. of tests performed per month	409	412	380
3	No. of MDR detected in last month	4	5	3
4	No. put on treatment	4	5	3
5	No. of invalid results	0	5	4
6	No. of errors	4	6	3

Above table depicts that No. of samples processed per day in all three centres were sixteen as gene Xpert machine had only four sockets and it took two hours for processing. Hence in eight hours working time per day, only sixteen samples could be processed at a time. Numbers of tests performed in all three centres were 409,412 and 380 respectively in the month of May 2018. All the detected cases were put on treatment.

Table 6: Table showing demographic profile of the MDR TB patients (N=200)

S.N.	Demographic profile	Frequencies(Percentages)
1	**Age Group**(in years)	
	1-15	10(5%)
	16-30	93(46.5%)
	31-45	65(32.5%)
	46-60	24(12%)
	>60	8(4%)
2	**Gender**	
	Male	124(62%)
	Female	76(38%)
3	**Resident**	
	Urban	159(79.5%)
	Rural	41(20.5%)
4	**Education**	
	Illiterate	13(6.5%)
	Primary	20(10%)
	Secondary	79(39.5%)
	High-secondary	43(21.5%)
	Graduate	45(22.5%)

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5	**Occupation**	
	Professional	1(0.5%)
	Semi professional	23(11.5%)
	Arithmatic	4(2%)
	Skilled	12(6%)
	Semiskilled	4(2%)
	Unskilled	54(27%)
	Unemployed	102(51%)

Above table and chart depicts most of the MDR TB cases (79%) belonged to productive age group of 16-30 & 30-45 years while only 9% cases were from paediatric and elderly age groups. Among MDR TB patients 62% were males and 38% were females. About 80% cases belonged to urban area while 20% belonged to rural population. About 80% cases of MDR TB were educated above secondary level. Most of the MDR TB patients were unemployed (51%) and only (0.5%) were professionals.

Discussion- According to the present study, proportion of MDR TB cases in the years 2013, 2014, 2015, 2016, 2017 were (1.5%), (1.4%), (1.4%), (1.45%) and (1.67%) respectively. This showed that in the last 5 years, proportion of MDR TB was not changed much, however the disease burden of MDR TB has increased. While Vidyaraj C K et al in their study observed that rifampicin mono resistance was 2.31% in MDR-TB cases and combined rifampicin and isoniazid resistance was 3.24%. [5]

In present study, facility survey of TB centres having CBNAAT facility was done and it was found that all posts were filled i.e. all centres had one Microbiologist, one Medical Officer and one Lab Technician as per the requirement. All three centres had enough separate area for specimen receipt, as per the norms, power supply with back up, air conditioner in running condition , device for monitoring temperature, refrigerator for storing consumables was in working condition, facility for recording results and refrigerator for storing consumables was in good condition. There were adequate stock of cartridges, reagents, staining reagents and disinfectants. As per norms all three centres had foot operated bin with lid and there was a proper disposal of cartridges, sputum containers and all disinfected materials. According to present study most of the MDR TB cases (79%) belonged to productive age group of 16-30 & 30-45 years while only 9% were from paediatric and elderly age group. 62% males were suffering from MDR TB while 38% females were. According to U venkatesh et al more than 2/3rd of patients were males and the mean age was 32 years.[6] A study done by Atre SR et al in Mumbai showed that nearly 69% of patients belonged to the younger (15–35 years) age group with a median age of 26 years.[7] Another study done by Bhatt G et al in Ahmedabad, India, showed 83.7% of patients were in reproductive age group of 16–45 years with a mean age of 33.64 ± 11.03. 68.5% were males.[8] Udwadia ZF also reported prevalence of younger age group among MDR-TB patients with the mean age of their study groups being 29.7years and 33.25 years, respectively.[9]

According to present study 80% cases belonged to urban areas and 20% from rural areas. 80% cases of MDR TB were educated above secondary level. 51% of the cases were unemployed and only 0.5% were professionals. According to U venkatesh et al more than 3/4th of patients were from rural area and 1/3rd were illiterate.[6] These results were consistent with other reported findings.[7,8,10,11,12] The occupational profile of patients in Gorakhpur revealed that a majority of them were unemployed (29.3%) and daily labourers (23.6%) followed by housewives (19.1%), students (7.6%), merchants (5.1%), farmers (5.1%), employee (5.1%), and skilled worker (4.5%). In the study of Mukherjee *et al*. the majority of them were household workers (27.90%) and labourers (20.34%).[11]

Conclusion- All the TB centres with CBNAAT facility were following norms laid by Standard Operating Procedures (SOPs) for Tuberculosis laboratory for Biological safety Cabinets Procedures

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and precautions and Waste disposal and handling. There has been a gradual increase in numbers of MDR TB cases as well as TB cases but case detection rate of MDR TB has not increased significantly from 2013 to 2017. Majority of the patients (65%) were males belonging to productive age group

Recommendation- Empowering both TB patients and communities by increasing their knowledge through proper education programmes will effectively contribute to the efforts of controlling TB as well as MDR TB. There is a need of establishing more CBNAAT centres for the diagnosis of MDR TB.

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