

## ORIGINAL ARTICLE

# Study on Validity of Diagnosed Smear-positive Pulmonary Tuberculosis (PTB) cases at DOTS Centres

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### Abstract:

**Background:** Tuberculosis is still a leading cause of death in Bangladesh and worldwide. Though there is an increase in tuberculosis case detection rates than previous years, case detection rate still needs to be expanded to reach the goal of stop TB. There are significant differences in case notification in different levels. So, doubt have been raised regarding how correctly diagnosis is made. This study intended to explore the real scenario regarding validity of diagnosis of smear-positive tuberculosis cases and reveal the underlying pitfalls and thus the study will enhance the TB control program in Bangladesh.

**Methods:** This cross-sectional study was carried out among 150 PTB patients at six DOTS centre of Dhaka city from January 2011 to June 2011. Data was collected randomly. Relevant investigations (Chest X-ray and Sputum AFB) of cases were done. Descriptive statistics included univariate and multivariate analysis. Relevant statistical tools were used to compare the study findings with findings of the DOTS centers and to compare with the achievements of national TB control program. Sensitivity, specificity, negative predictive value and positive predictive value were measured to see the validity of existing data. Data was analyzed by statistical software using SPSS (version 19.0).

**Results:** The diagnosis of smear-positive TB could not be confirmed in a bit less than 10% of the patients rechecked in validation project. On the basis of X-ray findings conducted by the DOTs center, majority of patients 120(80%) diagnosed with smear-positive TB had X-ray findings compatible with TB. Negative chest X-ray was found 30(20.0%)

**Conclusion:** There was significant difference in results of sputum AFB between DOTS centre and validation project. This may be due to inferior sputum collection, staining or reading techniques in the validation project and/or an over diagnosis of smear-positive TB in the field.

**Keywords:** DOTS, Pulmonary tuberculosis (PTB), Smear-positive TB

[Chest & Heart Journal 2016; 40(2) : 104-109]

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## Introduction:

Tuberculosis is the leading cause of death in the world from a single infectious disease.<sup>1</sup> In line with the global tuberculosis-related MDGs to halt and begin to reverse the incidence of tuberculosis by 2015, STOP-TB partnerships set targets to halve TB prevalence and death by 2015.<sup>2</sup> Recent analysis of TB control goals found that proportionate increase in case detection rates has been achieved than previous years.<sup>3,4</sup> Case detection rate still needs to be expanded because patients do not have adequate access to public health facilities or seek treatment from providers not linked to national TB control program or the public health system.<sup>5,6</sup>

In Bangladesh, National Tuberculosis Control Program DOTS in 1993 and expanded at all upazilas in collaboration with partner NGOs by June 1998.<sup>7</sup> By the end of 2006, DOTS population coverage has reached to 99% and case detection rate for sputum smear-positive patients has been increased to 72% in 2007 against the target of 70% with 92% treatment success of the patients diagnosed during 2006 against the target of 85% adopting STOP-TB strategy by the WHO.<sup>8</sup>

Despite Bangladesh's progress over the last few years in increasing coverage and improving quality TB services, the case detection rate yet to be increased to control TB. In context of Bangladesh, there are significant differences in case notification between districts and upazilas in Bangladesh with some areas reaching more than 100% of the estimated new smear-positive cases and other areas reaching substantially less. Doubts have been raised in some quarters as to how correctly diagnosis is made.<sup>9</sup>

External quality assessment of sputum microscopy is performed nationwide and in quiet robust. However, this mechanism does not allow detecting all possible errors. Because it could not be that some patients are classified as smear-positive while they were negative and a smear was used for confirmation originating from another known smear-positive patient. On the basis of these realities, this study intended to explore the real scenario reading validity of diagnosis of smear-positive tuberculosis cases and revealed the underlying hindrances and thus the study will enhance the TB control program in Bangladesh.

## Materials and methods:

This cross-sectional study was carried out among 150 PTB patients at DOTS centres of Dhaka city from January 2011 to June 2011 with the aim to

assess the validity of smear-positive PTB cases in Bangladesh. The study was conducted at six DOTS centers in Dhaka city. Study places were National Institute of Diseases of the Chest and Hospital (NIDCH); Mohakhali, National TB Control Program (NTCP), Shyamoli; Dhaka Medical College Hospital (DMCH); Chankhar TB Clinic, Chankhar pool; SurjerHasi Clinic, Mohammadpur and SurjerHasi Clinic, Mouchack.

The study included two types of study subjects: 1. DOTS centers: To assess laboratory register, treatment register & quarterly report, 2. TB Patients: Who were diagnosed smear-positive PTB cases at DOTS centers within three days of diagnosis to assess treatment card, findings sputum for AFB and X-ray chest findings.

## Inclusion criteria:

Study subjects were selected considering following criteria:

- Only PTB cases who attended the DOTS centers for confirmation of diagnosis by Sputum for AFB examination and for taking therapy within three days of diagnosed as TB.
- Patients were included irrespective of age and sex.
- Each subject was included in the study by obtaining informed written/verbal consent. In case of psychologically abnormal patients, children, consent was taken from legal guardian.

## Exclusion criteria:

Patients with following criteria were excluded from the study

- Transfer out patients who were transferred to another reporting unit/center.
- Complicated TB patients who are suffering from other diseases.
- Patients who are seriously ill and unconscious.
- Patients who have no willingness to participate in the study.

Random sampling technique was used for selection of the PTB cases. Six DOTS Centers in Dhaka city were visited randomly during the period of data collection. Three centers were visited by the data collectors every alternate day. Every day odds numbers of TB cases were interviewed and examined as respondent. Only diagnosed cases on the day of data collection and within three days of diagnosis as smear-positive TB were included in the study. Data was collected by – 1. Reviewing

documents such as laboratory register, treatment register, quarterly report and patient card; 2. Conducting investigations such as sputum for AFB and chest X-ray. One spot and one morning sputum were collected from each study subject; 3. Interviewing patients.

Collected data was analyzed by computer using SPSS (version 19.0). Descriptive statistics included univariate and multivariate analysis. Relevant statistical tools were used to compare the study findings with findings of the DOTS centers and to compare with the achievements of national TB control program. Descriptive part was presented as statistics of mean, frequency, SD of collected data. Analytical part included sensitivity, specificity, negative predictive value, positive predictive value to see validity of existing data. Furthermore factors responsible for performance had been explored.

Informed written/verbal consent of the patients and providers was obtained prior to data collection. During interview, all sorts of privacy of the patients and providers were maintained. Confidentiality of data was ensured strictly. Data was preserved in computer with safety and used only for the purpose of this study. Ethical clearance was obtained from the Ethical Committee of Bangladesh Medical Research Council.

### Results:

A total number of 150 newly diagnosed smear-positive TB cases (male 95, female 55) were enrolled in the study. Maximum number of subjects (34.7%) was within 21-30 year (Table I).

**Table-I**

*Distribution of study population according to age and sex (n=150)*

Age (years)	Frequency	Percentage
11-20	37	24.7
21-30	52	34.7
31-44	29	19.3
45 and above	32	21.3
Total	150	100.0
Sex		
Male	95	63.3
Female	55	36.7
Total	150	100.0

Three samples were collected from each patient through the routine practice. Table II shows the distribution of the sample results at DOTS centre.

Table III shows the distribution of the sputum results as obtained from the PTB validation study where two samples were collected from each patient.

**Table-II**

*Distribution of sputum sample results among of DOTS centers*

Sputum result	Frequency (Percentage)		
	Sample 1	Sample 2	Sample 3
Negative	8(5.3)	1(0.7)	0(0)
Scanty(1-9/100 hpf)	0	1(0.7)	0(0)
1+	56(37.3)	26(17.3)	24(16.0)
2+	33(22.0)	51(34.0)	39(26.0)
3+	53(35.4)	71(47.3)	87(58.0)
Total	150(100.0)	150(100.0)	150(100.0)

**Table-III**

*Distribution of sputum results among samples in validation study*

Sputum result	Frequency (Percentage)	
	Sample 1	Sample 2
Negative	0(0)	0(0)
Scanty (1-9/100 hpf)	25(16.7)	06(4.0)
1+	54(36.0)	46(30.7)
2+	63(42.0)	71(47.3)
3+	08(5.3)	27(18.0)
Total	150(100.0)	150(100.0)

On the basis of X-ray findings conducted by the DOTS center, Majority of patients 120(80%) diagnosed with smear-positive TB had X-ray findings compatible with TB. Negative chest X-ray was found 30(20.0%). (Table IV)

**Table-IV**

*Distribution of patients by Chest X-ray pattern in DOTS center*

X-ray result	Frequency	Percentage
TB Positive	120	80.0
TB Negative	30	20.0
Total	150	100.0

Regarding sputum smear for AFB for sample-1, in DOTS centers, out of all the patients, 5.3% were negative, 0% were scanty, 37.3% were 1+, 22% were 2+ and 35.3% were 3+. On the other hand, in project examination, out of all the patients, 0% were negative, 16.7% were scanty, 36% were 1+, 42% were 2+ and 5.3% were 3+ (Table V)

**Table-V**

*Findings of Sputum Smear (Sample-1) between DOTS Center and Validity Project*

Findings of Sample-1	Frequency	
	Dots Center (%)	Project (%)
Negative	08(5.3)	0(0)
Scanty (1-9)	0(0)	25(16.7)
1+	56(37.3)	54(36.0)
2+	33(22.0)	63(42.0)
3+	53(35.3)	08(5.3)
Total	150(100.0)	150(100.0)

Regarding sputum smear for AFB for sample-2, in DOTS centers, out of all the patients, 0.7% were negative, 0.7% were scanty, 17.3% were 1+, 34% were 2+ and 47.3% were 3+. On the other hand, in project examination, out of all the patients, 0% were negative, 4% were scanty, 30.7% were 1+, 47.3% were 2+ and 18% were 3+. (Table-VI)

**Table-VI**

*Findings of Sputum Smear (Sample-2) between DOTS Center and Validity Project*

Findings of Sample-2	Frequency	
	Dots Center (%)	Project (%)
Negative	01(0.7)	0(0)
Scanty (1-9)	01(0.7)	06(4.0)
1+	26(17.3)	46(30.7)
2+	51(34.0)	71(47.3)
3+	71(47.3)	27(18.0)
Total	150(100.0)	150(100.0)

Regarding sputum smear for AFB for sample-3, in DOTS centers, out of all the patients, 0% were negative, 0% were scanty, 16% were 1+, 26% were 2+ and 58% were 3%. (Table-VII)

**Table-VII**

*Findings of Sputum Smear for AFB of DOTS centre (Sample-3)*

Findings of Sample-3	Frequency	Percent
Negative	0	0
Scanty(1-9)	0	0
1+	24	16.0
2+	39	26.0
3+	87	58.0
Total	150	100.0

### Discussion:

This cross-sectional study was conducted among 150 newly detected smear-positive TB cases within three days of diagnosis. All cases were interviewed and examined (Sputum for AFB and chest X-ray) at six DOTS centers in Dhaka city. Those three centers were visited by the data collectors every alternate day. Every day odds number of TB cases were interviewed and examined as respondent. Data was finally confirmed from the respondents who were agreed for re-examine two samples of sputum and to do a chest X-ray.

Out of all the cases, majority (63.3%) was male and the rest(36.7%) was female. Majority (59.4%) was in the age 11-30 years. The mean age of the patients was  $40.29 \pm 17.43$  years. It was found that the majority of the TB patients (56.0%) had a low monthly income less than Tk.5000. The study revealed that 44.7% TB patients used tobacco. Out of the total 150 enrolled TB patients, 22.0% suffered from some diseases other than TB while the rest (78.0%) did not suffer from any other diseases. Nearly eighty two percent suffered from diabetes mellitus, 12.1% from different forms of lung diseases, and 6.1% from malnutrition. Majority (82.0%) had no family history of TB.

Regarding symptoms of TB, 81.3% patients complained of evening rise of temperature, 62.7% cough, 54.0% chest pain, 44.7% weight loss, 31.3% loss of appetite, and 29.3% coughing out of blood. Majority of the TB patients (84.7%) were diagnosed as TB cases in government hospital at DOTS centers followed by 8.0% in private chamber, 4.0% in private hospitals/clinics, 1.3% by village doctor and 0.7% in NGOs' health centers. Halim KS et al in his study found majority of the TB patients



66.7% were diagnosed as TB cases in government hospital.<sup>16</sup>

Before confirmation of diagnosis as TB case, most of the TB patients (90.0%) were done Sputum for AFB followed by X-ray chest(80.7%), 15.3% CBC & ESR and 2.7% were done tuberculin test for the diagnosis of disease.

Regarding sputum smear for AFB for sample-1 in DOTS centers, out of all the patients, 5.3% were negative, 0% were scanty, 37.3% were 1+ , 22% were 2+ and 35.3% were 3+ . On the other hand, in project examination , out of all the patients, 0% were negative, 16.7% were scanty, 36% were 1+, 42% were 2+ and 5.3% were 3%. Halim KS et al<sup>16</sup> in their study found nearly same result.

Regarding sputum smear for AFB for sample-2, in DOTS centers, out of all the patients, 0.7% were negative, 0.7% were scanty, 17.3% were 1+, 34% were 2+ and 47.3% were 3+. On the other hand ,in project examination, out of all the patients, 0% were negative, 4% were scanty 30.7% were 1+, 47.3% were 2+ and 18% were 3+.

Regarding sputum smear for AFB for sample-3, in DOTS centers, out of all the patients, 0% were negative, 0% were scanty, 16% were 1+, 26% were 2+ and 58% were 3+. Halim KS et al<sup>16</sup> in their study found sputum smear for AFB for sample-3, in DOTS centers, out of all the patients, 1.8% were negative, 6.9% were scanty, 33.0% were 1+, 22.8% were 2+ and 35.4% were 3+.

On the basis of X-ray findings conducted by this project majority of patients (80.0%) diagnosed with smear-positive TB had positive X-ray findings compatible with TB. Negative chest X-ray findings was observed from 20.0% of cases who were AFB positive sputum both from DOTS centers cases and these project respondents. From the study of Halim KS al, we see that X-ray findings virtually among all patients(99.0%) diagnosed with smear-positive TB had radiological finding consistent with PTB and negative chest X-ray was found in only in three cases (1.0%). This finding was different from our study and may be due to the reason that most of the cases of their study were from rural area.<sup>16</sup>

### Conclusion:

The diagnosis of smear-positive TB could not be confirmed in a bit less than 10% of the patients

rechecked. This may be due to inferior sputum collection, staining or reading techniques in the validation project and/or an over diagnosis of smear-positive TB in the field. This study has observed a different thing on X-ray findings that the urban population TB cases have more negative X-ray chest findings than the rural cases. This study was conducted among the urban population of Dhaka city and twenty percent cases were X-ray negative. The study has remarkable academic and policy implication and has some recommendations. Special strategies should be taken to find out the constraints and errors in the investigation process of sputum examination in detection of TB cases and ensure quality in performing sputum smear for AFB examination especially at DOTS centres run by non-government organizations. Every DOTS centre should have X-ray facilities to exclude unwanted case detection. To ensure validity of the diagnosis of smear-positive TB cases, close supervision, monitoring and quality management must be ensured in all stages of sample collection, smear preparation and microscopic examination at the DOTS centres.

### References:

1. Bloom BR, Murray CJ. Tuberculosis: commentary on a re-emergent killer. *Science* 1992; 257: 1055-64.
2. Stop TB Partnership and World Health Organization. Global plan to stop TB 2006-2015. World Health Organization, Geneva; 2006.
3. Elzinga G, Raviglione MC, Maher D. Scale-up: meeting targets in global tuberculosis control. *The Lancet* 2004; 363: 814-19.
4. Uplekar M. Private health care. *Social Science and Medicine* 2000; 51: 897-904.
5. Uplekar M, Pathania V, Raviglione M. Private practitioners and public health: weak links in tuberculosis control. *The Lancet* 2001; 355: 912-16.
6. Hurtig AK, Pande SB, Baral SC, Porter JDH, Bam DS. Anti-tuberculosis treatment in private pharmacies, Kathmandu Valley, Nepal. *International J of Tuberculosis and Lung Disease* 2000; 4(8): 730-36.

7. National Tuberculosis Control Program, Directorate General Health Services (DGHS) and WHO. Tuberculosis Control in Bangladesh: Annual Report 2007. Dhaka, Bangladesh 2007; 1-20.
8. National Tuberculosis Control Program, Directorate General Health Services (DGHS). National Guidelines and Operational Manual for Tuberculosis Control. Third edition. Dhaka, Bangladesh 2006; 13-17.
9. National Tuberculosis Control Program, Mycobacterial Disease Control, Directorate General Health Services (DGHS) and Ministry of Health and Family Welfare, Bangladesh. Guidelines on Public Private Mix for Tuberculosis Control. First edition. Dhaka, Bangladesh 2006; 1-15.
10. Henry M, Michael K, Leonard Jr. Tuberculosis: Epidemiology. Emory University School of Medicine, New York, USA. Medscape 2006; 1-6.
11. World Health Organization (WHO). Tuberculosis, epidemiology. *Bull World Health Organ* 2007; 85 (5): 415-7.
12. Bates IC, Fenton J, Gruber D et al. Vulnerability to malaria, tuberculosis and HIV/AIDS infection and disease. Part 1: determinants operating at individual and household level. *Lancet Infect Dis*. 2004; 4: 267-77.
13. Sahly E, Adams GJ, Soini H, Teeter L, Musser JM, Graviss EA. Epidemiologic differences between United States and foreign-born tuberculosis patients in Houston, Texas. *J Infect Dis*. 2001; 183: 461-68.
14. Hernandez GED, Kunimoto L, Wang M et al. Predictors of clustering of tuberculosis in greater Vancouver: a molecular epidemiologic study. *Can. Med. Assoc. J*. 2002; 167: 349-52.
15. Lukacs J, Tubak V, Mester J, David S et al. Conventional and molecular epidemiology of tuberculosis in homeless patients in Budapest, Hungary. *J Clin Microbiol*. 2004; 42: 5931-34.
16. Halim KS et al. Validation of Diagnosis of smear-positive tuberculosis in Bangladesh national Tuberculosis Control Programme. WHO Study Report: 15 April 2011.