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A Comparative Study on Same Day Sputum Smear Microscopy with the Conventional Method in the Diagnosis of Sputum Positive Pulmonary Tuberculosis

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ABSTRACT

Introduction: The World Health Organization (WHO) declared tuberculosis(TB) as a global emergency in 1993 and still is a major health problem across the world.The basis of the WHO recommendation comes from a Meta analysis and several studies which showed same day sputum microscopy has similar diagnostic accuracy as compared to the conventional technique.The rationale behind this research is to generate evidence in favour for same day microscopy with the conventional technique in routine programme settings.

Objective: Comparative assessment of same day (Spot1-Spot2) and Conventional (Spot1-Morning sputum) methods in TB suspects.

Material & Method: The study was Cross sectional conducted from the 1st March 2015 to 28th Feburary.2016. Data was collected by using predesigned questionnaire for sample collection.

Results: On comparison with conventional approach it was found that same day approach had sensitivity 95%, specificity 100% and PPV, NPV in same day approach are 100%, 99.03% respectively. McNemar test (p =0.074), it indicates statistically insignificant difference in the two approaches.

Conclusion: Implication of same day approach helps the patients to get results and initiation of TB treatment on same day, will help to reduce the burden of TB treatment and make the programme successful in real way.

Key Words: Sputum, same day, Conventional, Tuberculosis

INTRODUCTION

The World Health Organization (WHO) declared this disease as a global emergency in 1993 Tuberculosis (TB) is a major health problem across the world. [1] India has highest burden of TB. [2] Global incidence of TB is 9.6 million and India contributed incidence of TB about 2.2 million (167 per 100,000). [3] Prevalence of TB in India is 2.5 million (195 per 100,000). [3] Still mortality due to TB is 0.22 million (17 per 100,000). [3] Early diagnosis and prompt treatment of TB are crucial to reduce morbidity and mortality, secondary drug resistance, and transmission of TB. Direct smear microscopy is one of the most reliable diagnostic methods for pulmonary tuberculosis. Sputum smear microscopy has been the primary method for diagnosis of pulmonary tuberculosis. [4] It is simple, rapid and inexpensive technique which is highly specific in areas with a very high prevalence of tuberculosis [5] Due to the requirement of serial sputum examinations, some patients who do not come back for repeated sputum examinations become "diagnostic defaulters". Some do not come back for results, and are lost to treatment and follow up. This burdens

the TB suspect and hence, many TB suspects drop out during the diagnostic procedure and remain untreated in the community, providing more opportunities for transmission of the disease. [6] If tuberculosis left untreated, active TB kills more than 50% of its cases.[7] Same day microscopy would create major impact by reducing transmission of the disease by earlier diagnosis.[8] Problem of dropout can be reduced by same day microscopy [9]

The WHO recommends that countries that have successfully implemented the policy for a two specimen Case finding strategy should consider switching to same day diagnosis, especially in settings where patients are likely to be lost during the diagnostic process. The basis of the WHO recommendation comes from a Meta analysis and several studies which showed same day sputum microscopy has similar diagnostic accuracy as compared to the conventional technique. [10] Thus, there is an urgent need and operational demand to explore the possibility of reducing the number of samples from two to one, taking into consideration the patients dropouts, convenience of the patient and health care providers. This is the first study of its kind in, Central India Bhopal, and the rationale behind this research is to generate evidence in favour for same day microscopy with the conventional technique in routine programme settings.

MATERIAL AND METHOD

The design of the study is Cross sectional. Study was carried out in DOTS Centre Hamidia Hospital, Bhopal, Madhya Pradesh, India. Patients with suspected tuberculosis are referred by physicians at Hamidia Hospital to DMC for sputum testing. Study was undertaken from the 1st March 2015 to 28th Feburary.2016, for a period of One year. All TB suspect patients referred to DMC for sputum smear microscopy by the physicians at Hamidia Hospital were included and seriously ill patients and patients below 5 year of age were excluded.

Sample Size and Sampling Technique: - A pilot study was done for a month, daily visit to DOTs centre was done and all patients reported to DOTs centre irrespective to their age were included. All the new cases were classified into five different age group i.e.<15 yrs,15-29yrs,30-44yrs,45-59yrs and 60 yrs and above. The least reported group which was found to >60 yrs and above .The proportion of such cases was found to be 9% of the total cases.

That data was used for sample size calculation. Sample size was calculated as 164 with an estimated proportion of 0.12 calculated based on pilot study, precision of 5%, and confidence interval of 95. With the design effect 3.30 calculated based on pilot study sample become 538 by using a simple random sampling method. So we are taking **610 TB** suspected cases in this study. Approval was taken from the Institutional Ethics Committee.

Study Tool: –After obtaining consent, data was collected by face to face interview of the patients using predesigned questionnaire was used.

Study procedure: Data was collected on the working days of DMC. Two sputum specimens (spot–early morning) were collected from consecutively enrolled presumptive T.B. patient as per current national guidelines. The patient whose sputum was collected on spot was approached and was counselled and verbal consent was taken for the second spot sputum sample (one hour after the collection of first spot sample) from the same patient. Results of sputum smear microscopy were cross checked by the senior tuberculosis laboratory supervisors to ensure quality of sputum microscopy testing.

Statistical analysis:-Data were entered into MS excel, analysis was done with the help of Epi-Info-7 software and online GraphPad. The McNemar test was used to compare the smear results among the two methods.

RESULTS

In this study most of the participants were males i.e. (69.34%) and one third of them were females i.e. (30.66%). The expenditure incurred while going for the diagnosis of TB, the patients had an extra 48.17% expenditure (more economic burden) in conventional sputum smear method (two day visit) as compared to expenditure in same day sputum smear method in the form of travelling cost, stay, food and wage loss.

Table 1: Distribution according to results of smear microscopy in both the approaches (conventional and same day sputum microscopy) for diagnosis of pulmonary tuberculosis

Approach	Samples (N = 610) (%)	
	Negative	Positive
Conventional Approach (Spot1+ Morning)		
A) Spot 1 sample	517 (84.75)	93 (15.25)
B) Morning Sample	510 (83.61)	**100 (16.39)**
Final reuslt	510 (83.61)	**100 (16.39)**
Same Day Approach (Spot1+Spot 2)		
A) Spot 1 sample	517 (84.75)	93 (15.25)
B) Spot 2 sample	520 (85.25)	90 (14.75)
Final reuslt	515 (84.43)	95 (15.57)

Promptness in seeking health care is important factor in early diagnosis and treatment. On enquiring the respondents regarding the preferences for two day and same day sputum smear examination, they preferred for giving both the samples on same

day (94.26%). The reasons of preference were reduced expanses in terms of travelling, food, lodging and wage loss and time as well. Table no.1 shows total no of Positive and Negative cases by conventional and same day sputum microscopy method for diagnosis of Pulmonary TB. Table No. 3 shows no significant difference between both conventional and same day sputum microscopy method for diagnosis of Pulmonary TB.

Table 2: Distribution according to grading of smear microscopy in both the approaches (conventional and same day sputum microscopy) for diagnosis of pulmonary tuberculosis

Approach	Smears grading (N=610) (%)				Total
	Scanty	1+	2+	3+	
Conventional Approach (Spot1+ Morning)					
A) Spot 1 sample	7 (1.15)	47 (7.70)	23 (3.77)	16 (2.62)	93
B) Morning Sample	**10 (1.64**	35 (5.74)	24 (3.93)	31 (5.08)	**100**
Same Day Approach (Spot1+Spot 2)					
A) Spot 1 sample	7 (1.15)	47 (7.70)	23 (3.77)	16 (2.62)	93
B) Spot 2 sample	5 (0.82)	48 (7.87)	23 (3.77)	14 (2.30)	90

Table 3: Comparison between Same Day sputum microscopy with Conventional (two day) sputum smear microscopy examination

Same Day Approach (Spot1+Spot2)	Conventional Approach (Spot 1+ Morning)	
	+ ve	-ve
+ve	95 (95%)	0
-ve	5 (5%)	510 (100%)
Total (n=610)	**100**	**510**

Sensitivity (%) = 95% (88.17-98.14%)
Specificity (%) = 100% (99.07-100%)
PPV (%) = 100% (95.16-100%)
NPV (%) = 99.03% (97.61-99.64%)
McNemar test Statistic = 3.2
P value (Yates correction) = 0.07364

DISCUSSION

Our study found that morning sample detected more positive sputum smear (16.39%) as compared to the spot1 (15.25%) and spot2 sample (14.75%) while other studies of V.P. Myneedu et al [11] 2011 conducted at New Delhi, morning sample detected 61/330 (18.48%) positive smears as compared to spot1 detected 42 (12.72%) and spot2 detected 39(11.8%) positive smears and in study of Shafiyabi S et al [12] 2013 conducted at Bellary, morning sample detected 101 (40.4%) positive smears as compared to spot1 99 (39.6%) and spot 2 detected 95 (38%) positive smears.

The study shows Grading of positive smears in conventional approach, out of 93 spot1 positive, 7 smears were graded as scanty, 47 smears graded as 1+, 23 as 2+ and 16 were graded as 3+. In morning, out of 100 positive smears 10 smears were graded as scanty, 35 smears graded as 1+, 24 smears graded as 2+ and 31 smears were graded as 3+.

While in same day approach, spot1 positive smears showed same grading as the spot1 sputum smear results of conventional methods and the spot2 sputum sample which was collected one hour after spot1 sputum under the vigilance of the laboratory staff, out of 90 spot2 positive smears, 5 smears were graded as scanty, 48 smears were graded as 1+ and 23, 14 smears were graded as 2+ and 3+ respectively. In study of Myneedu V.P. et al [11] 2011 grading of positive smears in conventional method were as, 12 smears were graded as 1+, 8 smears as 2+, 22 smears graded as 3+ among the 42 positive smears of spot 1. Out of total 61 positive morning sputum smears, 27 smears were graded as 1+, 18 smears were graded as 2+ and 16 smears graded as 3+. While in newer same day method, spot1 positive smears showed same grading as the spot1 sputum smear results of conventional methods and out of 39 smears of the spot2 sputum samples, 12 positive smears were graded as 1+, 5 smears graded as 2+ and 22 smears were graded as 3+.The maximum positivity (3+) of sputum smears were seen in spot1 sputum samples (7%). Overall conventional method diagnosed only five more sputum positive cases 100/610(16.39%) as compared to the same day approach 95/610(15.57%). Among the spot1 samples, two samples that were negative were diagnosed as 'smear positive' in spot2 sputum samples of same day method.

Diagnostic comparison, Comparison of sensitivity & specificity of Spot- Spot and Spot-Morning Approach: On comparison with conventional approach as showed in table no.3 it was found that same day approach had sensitivity 95% , specificity 100% and PPV, NPV in same day approach are 100%, 99.03% respective. On applying McNemar test, it indicates statistically insignificant difference in the two approaches means both conventional approach and same day approach are equally effective for diagnosis of pulmonary tuberculosis (p =0.074). In other study such as Hirao S. et al [13] 2007, Chandra TJ [14] 2012(p> 0.05), Shafiyabi S. et al [12] (p = 0.24), showed there was no difference in same day

and two day approaches. Nayak P. et al [15] 2013 conducted at Chhattisgarh ,same day microscopy missed 17% of smear –positive as compared to conventional method for diagnosis of pulmonary TB. Devis JL et al [16] 2013, Tiwari V.K. et al [17] 2015 (p> 0.05) & Bazira et al [18] 2015 (P> 0.05) also showed that same day approach and conventional approach are equally effective for the diagnosis of pulmonary tuberculosis, similar to our study

CONCLUSION

On the basis of finding in our study, sensitivity of the same day approach was nearly similar i.e. 95% as compared to conventional two day approach and specificity was (100%) which was similar to two day (spot1- morning) approach. Sputum positivity of same day approach found to be statistically insignificant (p = 0.073, both the methods are equally effective for the diagnosis of pulmonary tuberculosis. In a country like India, most of the TB patients belonged to low and middle income and our study showed conventional (two) day approach accentuated 48.17% extra cost (economic burden) in the form of travelling , food, stay, wage loss, and time as well in comparison to same day approach. This was evident that more that 94% of responded in favour of same day delivery system & getting results on the same day. Implication of same day approach helps the patients to get results and initiation of TB treatment on same day, will help to reduce the burden of TB treatment and make the programme successful in real way.

RECOMMENDATION

As evident from the study that conventional approach (spot and morning sample) and same day two sample approach are having no significant difference in sensitivity & specificity. The same day approach may provide two more benefits; first, it is cost beneficial to the patients and patients friendly for rural and poor patients. Second, the treatment can be planned from the same day thereby increasing the compliance.

Therefore it is recommended that the two day sample approach should be switched to single day (two) sample approach and laboratory operations and procedures should be realigned with sputum collection and reporting of results on the same day, within the constraints of existing human resources and laboratory workload.

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