Original Research Article

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Concordance of two sputum smear microscopy for diagnosis of presumptive pulmonary tuberculosis in a tertiary care hospital

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ABSTRACT

Background: Under revised National tuberculosis control program two sputum samples are to be collected for diagnosis of presumptive pulmonary tuberculosis case. The objective of this study is to find the concordance of both sputum smear microscopy samples at a tertiary care hospital.

Methods: Hospital based record was collected from designated microscopy center laboratory register. The data collected were from January 2015 to November 2016.

Results: A total of 2117 paired of sputum sample were collected for the year 2015-16 in one of the DMC of a tertiary care hospital. A total of 183 patient (at least one sputum sample) were positive (8.64%) and 1934 were both negative. Among the positive sample concordance for both spot and morning samples were 89% (163/183) and discordance where spot sample positive and morning sample negative was 4.91% (9/183) and where spot sample negative and morning sample positive was 6.01% (11/183). Overall discordance between spot and morning samples were only 0.94% (20/2117).

Conclusions: There is a good concordance of two sputum samples. Discordance of two sputum samples were <1% in a tertiary care hospital. One sample may be sufficient for operational purpose for diagnosis of pulmonary Tb. But to have a robust recommendation a RCT will be required to see the extent of discordance by ruling out bias in sputum smear examination.

Keywords: Sputum samples, Pulmonary tuberculosis, Concordance of spot and morning samples

INTRODUCTION

Tuberculosis (TB) is caused by *Mycobacterium tuberculosis* since ancient times, is still a major public health problem in India. India has highest burden of both Tuberculosis and MDR TB based on estimates reported in Global TB Report 2016. The TB epidemic is larger than previously estimated, reflecting new surveillance and survey data from India particularly including private treated patients. However, the number of TB deaths and the TB incidence However the rate of tuberculosis continues to fall globally and in India.¹⁻²

Sputum microscopy is still a standard for the diagnosis of pulmonary tuberculosis. Earlier three sputum samples were used for the diagnosis of pulmonary tuberculosis which was reduced to two sputum smears (one spot and early morning sputum sample) as per WHO recommendation in 2007 and RNTCP in 2012. 3-6

In a systematic review by Mase et al the role of three sputum smear sample the role of second and third samples are minimal.⁷⁻⁸

Under RNTCP two method of smear microscopy were practice, conventional Z-N stain method using binocular

microscope at designated microscopic centres (DMC) and LED fluorescent microscope at district tuberculosis centres (DTC), intermediate reference laboratory (IRL) and selected high load facility like tertiary care hospital/medical college.⁹

With two day sputum microscopy it becomes inconvenience for patient and loss to follow up of sputum sample. 10 Recently many studies from India and other countries have shown that same day sputum smear microscopy (two spots 1 hour apart) are as good as two day standard sputum smear (spot and morning samples). 11-17 But few studies have also shown that same day sputum microscopy may lead to missed cases from 5-17% of cases. 18-22

RNTCP have a good system of internal and external quality assurance system for sputum microscopy in India. An effective quality assurance (QA) system of the RNTCP, sputum smear microscopy network is of crucial importance for the future of the programme.²³ Spot sputum sample alone are having a good correlation in comparison with spot along with morning sputum sample as reported by Patel.²⁴

METHODS

A retrospective analysis among presumptive cases of pulmonary tuberculosis visiting a designated microscopic centre (DMC) of a teaching tertiary care hospital, NEIGRIHMS, Shillong referred for sputum microscopy during January to December 2016. Data were collected from the Laboratory Register available at DMC. Only patients who came for diagnosis and who have submitted both spot and morning sputum sample during the above period were included in the study. Trained and experienced laboratory technician under RNTCP were posted in the DMC conducted sputum smear microscopy by LED fluorescent Microscopy. To see the correlation between spot and morning sample, kappa statistics was analysed using SPSS version 22. Also chi square test was used to analyses the categorical variables with p<0.05 is considered as statistically significance.

RESULTS

A total of 2117 paired of sputum sample were collected during the year 2016. Majority of the study participants were males (58.5%) and most of them are in the age group of 16-45 years (57%) as shown in figure-1. A total of 183 patient (at least one sputum sample) were positive (8.64%) and 1934 were both samples were negative. Among the positive sample concordance for both spot and morning samples were 89% (163/183) and discordance where spot sample positive and morning sample negative was 4.92% (9/183) and where spot sample was negative and morning sample positive was 6.01% (11/183). The grading of sputum microscopy between spot and morning samples and their correlation

is given I Table 1. Overall discordance between spot & morning samples were only 0.94% (20/2117).

Table 1: Grading of sputum smear positivity among spot and morning sample.

Sl no	Category of grading	Frequency (n=183)	
1	Spot = morning	101 (55.2%)	
2	Spot < morning	39 (21.3%)	
3	Spot > morning	23 (12.6%)	
4	Spot + morning -	9 (4.92%)	
5	Spot – morning +	11 (6.01%)	
6	Total	183 (100%)	

Table 2: Grading of sputum smear positivity among spot and morning sample by gender.

S. no	Category of grading	Male (%)	Female (%)
1	Spot = morning	65 (58.6)	36 (50)
2	Spot < morning	22 (19.82)	17 (23.61)
3	Spot > morning	12 (10.81)	11 (15.3)
4	Spot + Morning -	7 (6.31)	2 (2.77)
5	Spot – Morning +	5 (4.5)	6 (8.33)
6	Total	111	72

There were small difference in discordance between spot and morning samples among gender but not statistically significance (p>0.05) as shown in Table 2.

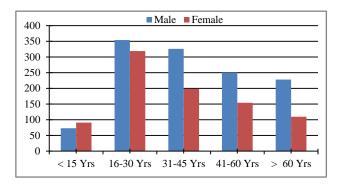


Figure 1: Bar diagram showing age and gender distribution of study participants.

The measurement of agreement between spot and morning sample using kappa statistic have shown excellent result of 94% with observed agreement of 99% and expected agreement of 84.47%.

DISCUSSION

The revised National TB control programme (RNTCP), based on the Internationally recommended directly observed treatment short-course (DOTS) strategy, was launched in 1997 and expanded across the country in a phased manner with support from World Bank and other development partners. RNTCP has been recognized as

the largest and the fastest expanding TB control programme in the world.

To achieve universal access to early accurate diagnosis of TB and enhancing case finding efficiency, identification of presumptive TB cases at the point of care and linking them to the best available diagnostic tests is of paramount importance.

The cornerstone strategy in case detection of TB is quality assured diagnosis. Diagnosis of tuberculosis is done primarily using smear microscopy for microbiological diagnosis of TB. RNTCP recommends two sputum examinations, one and one early morning or spot and spot. If the first smear is positive and patient is not at risk for drug resistant (DR TB), he/she will be categorized as microbiologically confirmed TB.²⁵

A total of 183 (8.64%) out of 2117 patients sent for sputum examination were (at least one sputum sample) were diagnosed in our study. Among the positive sample concordance for both spot and morning samples were 89% (163/183) and discordance where spot sample positive and morning sample negative was 4.92% (9/183) and where spot sample was negative and morning sample positive was 6.01% (11/183). The sensitivity of spot samples alone compare with spot and morning samples is 94% (172/183) and morning samples in comparison with both is 95% (174/1830 which were of good and in comparable with one study conducted from similar setting in Gujarat 92.67% and 97.88% respectively.²⁴

Overall discordance between spot and morning samples were only 0.94% (20/2117). The measure of agreement of observation of sputum results on two occasions for spot and morning sample was excellent at 94%.²⁶

Most of the patients could be diagnosed through the examination of one sample and this is encouraging in developing countries where trained manpower is still lacking. By decreasing the workload it will enhance better chance of detecting positive samples. This is the first study to explore the sensitivity of singly spot samples in the North Eastern Region and only few studies have done this in other part of the world.

CONCLUSION

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REFERENCES

- World Health Organization. World Global TB Reports. 2016
- Central TB Division, Directorate General of Health Services, MoHFW, GOI. India Tuberculosis Report; 2017.

- World Health Organization. Framework for effective tuberculosis control. World Health Organization document 1994; WHO/TB/94.179:1-7.
- World Health Organization. International Union Against Tuberculosis and Lung Disease, Royal Netherlands Tuberculosis Association. Revised international definitions in tuberculosis control. Int J Tuberc Lung Dis. 2001;5:213-5.
- 5. Reduction of number of smears for the diagnosis of pulmonary TB, 2007. TB diagnostics and laboratory strengthening WHO policy.
- Central TB Division, Directorate General of Health Services. Diagnosis of Smear Positive Pulmonary TB—New Guidelines, effective from 1 April 2009. Ministry of Health and Family Welfare, GOI; 2009. Available at: http://tbcindia.nic.in/pdfs Accessed on 4 April 2017.
- Frieden T. Toman's Tuberculosis Case Detection, treatment and monitoring- questions and answers. WHO Geneva, 2004, 2nd Edition.
- 8. Mase SR, Ramsay A, Ng V, Henry M, Hopewell PC, Cunningham J, et al. Yield of serial sputum specimen examination in the diagnosis of pulmonary tuberculosis: a systematic review. Int J Tuberc Lung Dis. 2007;11(5):485-95.
- 9. Central Tb Division, MohFW, GOI. Technical and Operational Guidelines for TB Control in India 2016. Available at: http://tbcindia.gov.in/showfile.php?lid=3216 Accessed on 4 April 2017.
- 10. Squire SB, Belaye AK, Kashoti A, Salaniponi FM, Mundy CJ, Theobald S, et al. 'Lost' smear-positive pulmonary tuberculosis cases: where are they and why did we lose them? Int J Tuberc Lung Dis. 2005;9(1):25-31.
- 11. Cambanis A, Yassin MA, Ramsay A, Squire SB, Arbide I, Cuevas LE. A one-day method for the diagnosis of pulmonary tuberculosis in rural Ethiopia. Int J Tuberc Lung Dis. 2006;10(2):230-2.
- Davis JL, Cattamanchi A, Cuevas LE, Hopewell PC, Steingart KR. Diagnostic accuracy of same-day microscopy versus standard microscopy for pulmonary tuberculosis: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(2):147-54.
- 13. Chandra TJ, Selvaraj R, Sharma YV. Same day sputum smear microscopy for the diagnosis of pulmonary tuberculosis: Ziehl-Neelsen versus fluorescent staining. J Family Med Prim Care. 2015;4(4):525-8.
- 14. Chandra TJ, Selvaraj R, Sharma YV. Same-day sputum smear microscopy for the diagnosis of pulmonary tuberculosis: direct vs. concentrated smear. Int J Tuberc Lung Dis. 2016;20(2):247-51.
- 15. Chandra TJ, Raj RS, Sharma YV. Same day sputum smear microscopy approach with modified ZN staining for the diagnosis of pulmonary tuberculosis in a microscopy centre at Rajahmundry. Indian J Med Microbiol. 2014;32(2):153-6.

- 16. Chandra TJ. Same day sputum smear microscopy approach for the diagnosis of pulmonary tuberculosis in a microscopy centre at Rajahmundry. Indian J Tuberc. 2012;59(3):141-4.
- 17. Juyal D, Thaledi S. Same day sputum microscopy: Optimizing the diagnosis of pulmonary tuberculosis. OA Case Reports. 2014;3(3):25.
- Nayak P, Kumar AM, Claassens M, Enarson DA, Satyanarayana S, Kundu D, et al. Comparing same day sputum microscopy with conventional sputum microscopy for the diagnosis of tuberculosis --Chhattisgarh, India. PLoS One. 2013;8(9):e74964.
- 19. Deka DJ, Choudhury B, Talukdar P, Lo TQ, Das B, Nair SA, et al. What a difference a day makes: same-day vs. 2-day sputum smear microscopy for diagnosing tuberculosis. Public Health Action. 2016;6(4):232-6.
- 20. Ssengooba W, Kateete DP, Wajja A, Bugumirwa E, Mboowa G, Namaganda C, et al. An Early Morning Sputum Sample Is Necessary for the Diagnosis of Pulmonary Tuberculosis, Even with More Sensitive Techniques: A Prospective Cohort Study among Adolescent TB-Suspects in Uganda. Tuberculosis Research and Treatment. 2012(2012):970203.
- 21. Nayak P, Kumar AM, Agrawal TK, Chandraker S, Nair SA. Same-day light-emitting diode fluore-scence microscopy for the diagnosis of tuberculosis in Chhattisgarh, India. Int J Tuberc Lung Dis. 2014;18(6):666-70.
- 22. Myneedu VP, Verma AK, Sharma PP, Behera D. A pilot study of same day sputum smear examination, its feasibility and usefulness in diagnosis of pulmonary TB. Indian J Tuberc. 2011;58(4):160-7.
- Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, GOI New Delhi 2005. Guidelines for Quality Assurance of smear microscopy for diagnosing tuberculosis.
- 24. Patel MM, Patel AN, Sisodia JA, Patel KR, Shringarpure K. Spot and early morning sputum report study for diagnosis of pulmonary tuberculosis at DMC of medical college Vadodara, Gujarat: a retrospective analysis. Int J Cur Res Rev. 2014;6(10):45-50.
- Central TB Division Directorate General of Health Services Ministry of Health and Family Welfare, GOI, Manual for Sputum Smear Fluorescence Microscopy. New Delhi, 2011.
- Measurement error: assessment and implications.
 In: Betty R. Kirkwood and Jonathan A.C. Sterne.
 Essential Medical Statistics. 2nd ed. Massachusetts,
 USA: Blackwell Sciences; 2003: 429-446.

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