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Yielding Accuracy of Morning and Spot Sputum Samples for Diagnosis Mycobacterium Tuberculosis Using Gene Xpert MTB/RIF Assay at EPHI, Addis Ababa, Ethiopia

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ARTICLE INFORMATION

ABSTRACT

Background: Tuberculosis is a global health problem and leading cause of mortality and morbidity in the world. Correct diagnosis of tuberculosis is the main challenge for control of tuberculosis. World health organization has prioritized improving diagnostic guidelines and tests for TB diagnosis. Priority has been given for development of new Tuberculosis diagnostic methods. But diagnosis of Tuberculosis highly affected by quality specimen collected which has been given less attention. The aim of this is to assess Yielding accuracy of morning and spot sputum samples for diagnosis Mycobacterium tuberculosis using Gene Xpert Mycobacterium Tuberculosis (MTB)/ Rifampicin Resistance (RIF).

Methodology: Cross sectional study was conducted and convenient sampling technique used to select participants. Checklists used to collect the data from April 1 to May 30, 2018 G.C. A total of two hundred twenty two (222) sputum samples from 111 suspected tuberculosis patients were analyzed using Gene Xpert MTB/RIF Assay. SPSS version 20 was used for statistical analysis.

Results: From 111 TB suspected patients, 55.9% were male and the rest of 44.1% was female. In terms of sample quality, 81.1% morning sputum samples and 79.3% spot sputum samples were had good sample quality. The outcomes of the research show an increase in odds value in sputum quality and sputum consistency for TB diagnosis. But, the relation is not significant association with TB positivity.

Conclusion: Based on the results of this study, the diagnosis of TB using spot sputum samples as well as using morning sputum samples is almost similar for detection of MTB by Gene Xpert MTB/RIF Assay. Physical Quality of sputum sample or consistency is not association with TB positivity using Gene Xpert MTB/RIF Assay.

1. Introduction

Per year around 10.4 million people are affected globally by tuberculosis infection. Among these around 1.4 million are dead, with pulmonary type of TB is the main cause. The main challenge for global tuberculosis control is accurate and correct diagnosis of tuberculosis. World health organization has prioritized improving tuberculosis diagnosis guidelines and testing procedures. But the accuracy of laboratory diagnostic procedures affected by quality of sputum sample collection and processing. Nowadays the impact of quality sputum sample has been given less concern rather priority given for development of new TB diagnostic methods (Jochei & Akolhatkar, 1982; Charles *et al.,* 2000). Most frequently used for laboratory diagnosis

of TB is microscopy, which is inexpensive. But microscopy is less sensitive when the amount of acid fast bacilli low (most likely below 10,000 per ml not detected). Culture techniques for tuberculosis diagnosis have higher sensitivity than microscopic TB diagnosis. Gene Xpert MTB/RIF Assay has moderate sensitivity between culture techniques and microscopy. But Gene Xpert and culture techniques are more expensive than microscopy and only diagnosis when the amount of acid fast bacilli concentration is sufficient on the sputum sample (FMOH, 2012; Chemhuru *et al.,* 2010; FMOH, 2014).

Inappropriate or poor quality sputum samples lead to false laboratory results for diagnosis of tuberculosis. Mostly poor sputum samples contain secretions from respiratory track with different amount saliva. The positivity of

laboratory diagnosis of TB varies among different sputum samples from the same patient. For this reason more than one sputum sample is tested for suspected TB patients (Ethiopian Public Health Institute, the 2nd BSC Based EPHI's Strategic Management Plan, 2015/16 to 2019/20; FMOH, 2014; Daniel, 2014; Minaleshewa *et al.,* 2016).

Spot-morning-spot sputum samples collection methods were used for TB microscopy. Recommended sputum sample collection methods are different in different and their relative advantage for tuberculosis diagnosis is not well explained. Using spot sputum samples reduces possible transmission of tuberculosis. This study has been done to assess yielding of spot and morning sputum samples for tuberculosis diagnosis using Gene Xpert MTB/RIF Assay and possible effect of sputum sample quality on TB diagnosis.

2. Methodoloy

2.1 Study Area

This study was conducted at Ethiopian Public Health Institute. It is located at Addis Ababa, capital city of Ethiopia. The institute is the center of health related researches, trainings and quality control of health service in Ethiopia.

2.2 Study Period and Study Design

Descriptive cross sectional study design was used to collect the data at Ethiopian Public Health Institute from April 1 to May 30, 2018 G.C.

2.3 Population

2.3.1 Source population

All TB suspected patients living in Addis Ababa city and around the city were source population for the study.

2.3.2 Study population

All TB suspected patients requested to Ethiopian Public Health Institute TB national reference laboratory section during the study period.

2.4 Sample size and sampling technique

A total of two hundred twenty two (222) morning and spot sputum specimens from one hundred eleven (111) individual were analyzed using Gene Xpert MTB/RIF Assay. All suspected TB patients who came to EPHI for TB diagnosis during the study period were included.

2.5 Study Variables

- Dependent variables: Presence of Mycobacterium Tuberculosis
- Independent variables: Age, Sex, Patient preparation, Sputum quality, Sputum consistency

2.6 Data Collection Procedure

Data was collected directly from M.TB suspected individuals by research participants and tested by Gene Xpert machine using both morning and spot sputum specimen.

The sample was collected by clean, leak-proof and wide mouthed falcon tube about 2-4 ml of each morning and spot specimen. Gene Xpert MTB/RIF Assay used for testing the samples. If delay was unavoidable in testing, refrigeration 2-8°c was used to store the specimen.

The whole process of patient preparation, specimen collection and testing were based on standard operating procedures manual. Mucoid and purulent sputum sample consider as good quality.

2.7 Data Processing and Analysis

The data was recorded, controlled and checked for its completeness everyday during the data collection period. All data was entered into an excel spreadsheet, and then transferred to SPSS version 20 for analysis. Descriptive statistics were performed and presented in tables and graph. Adjusted odds ratio and p value were used to assess relation of TB detection with sputum quality and consistency.

2.8 Ethical Consideration

Ethical clearance to do this research was obtained from Department of Medical Laboratory Science, Addis Ababa University. Written consent forms were agreed with patients to conduct the research.
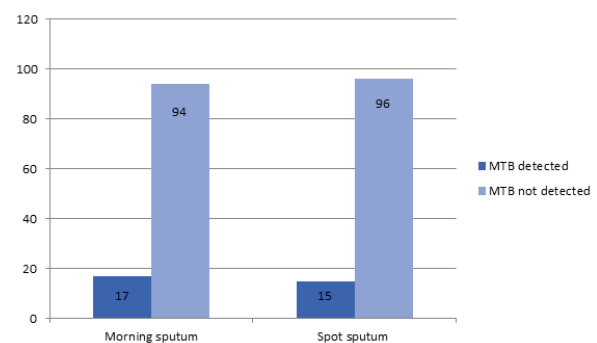
3. Results

Figure 1: Distribution of MTB detection for both morning and spot sputum samples.

Table 1: Age and Sex distribution of study participants.

Variables	Number (%)
Gender	
Male	62(55.9)
Female	49(44.1)
Total	111(100.0)
Age group	
0-14 years	3(2.7)
15-44 years	63(56.8)
45-64 years	33(29.7)
>65 years	12(10.8)
Total	111(100.0)

Table 2: Sputum sample quality and consistency in both morning and spot collection methods.

Variables Number		Morning sample		Spot sample	
		Percent	Number	Percent	Number
Sputum quality	Good quality	90	81.1%	88	79.3%
	Poor quality	21	18.9%	23	20.7%
	Total	111	100.0%	111	100.0%
Sputum consistency	Mucoid	74	66.7	65	58.6
	Purulent	16	14.4	20	18.0
	Saliva	18	16.2	22	19.8
	Muco-purulent	3	2.7	4	3.6
	Total	111	100.0%	111	100.0%

Table 3: Association of MTB positivity with sputum sample quality and consistency for both spot and morning.

Variables Total N (%)		TB positivity			AOR	P value
		Negative N (%)	Positive N (%)			
Morning Sputum quality	Good	90 (81.1)	77 (85.6)	13(14.4)	0.505(0.12-2.08)	0.35
	Poor	21(18.9)	17 (81)	4 (19)	1	
Spot sputum quality	Good	88 (79.3)	74 (86.6)	14(13.4)	1.44(0.31-6.67)	0.64
	Poor	23(20.7)	20 (87)	3(13)	1	
Morning Sputum consistency	Mucoid	74(66.7)	63(85.1)	11(14.9)	0.35(0.029-4.188)	0.41
	Purulent	16(14.4)	15(93.8)	1(6.2)	0.13(0.006-3.08)	0.21
	Saliva	18(16.2)	14(77.8)	4(22.2)	0.57(0.041-8.05)	0.68
	Muco-purulent	3(2.7)	2(66.7)	1(33.3)	1	
Spot sputum consistency	Mucoid	62(55.9)	56(90.3)	6(9.7)	1.58(0.31-8.15)	0.93
	Purulent	20(18.0)	16(80)	4(20)	1.58(0.31-8.15)	0.58
	Saliva	22(19.8)	19(86.4)	3(13.6)	6.33(0.63-63.6)	0.12
	Muco-purulent	4(3.6)	2(50)	2(50)	1	

4. Discussion

In this study, the detection of the morning and spot sputum samples were assesses using Gene Xpert MTB/RIF Assay. In this study, the yielding accuracy of spot and sputum samples were almost similar. This is almost similar to the study done by Tingyu Tang and his colleagues in china in 2017G.C (Tingyu & Fang, 2017).

The study conducted in Uganda in 2017G.C by Amanda J and his colleagues stated that, there was no significance difference in diagnosis result Gene Xpert testing between salivary and non salivary (good quality) specimens. This was also similar in this research, which shows no relation with quality and consistency for TB detection using Gene Xpert MTB/RIF Assay (Amanda *et al.,* 2017).

Another study conducted in Uganda in 2017 by Michael E concluded that spot sample is as good as early morning sputum samples for TB diagnosis. This study also concluded that there is no yielding difference between spot and morning collection methods for diagnosis of TB using Gene Xpert MTB/RIF Assay (Michael *et al.,* 2017).

Among 111 suspected TB patients in this study, 15.3% were positive and 84.7% were negative using morning sputum sample. At same time, using spot sputum samples 13.5% positive and 86.5% were negative. This shows both morning and spot samples have almost similar yielding accuracy using GeneXpert MTB/RIF Assay. It was similar to the study in Kenyan 2016G.C, Gene Xpert testing of spot specimens identified 48 (57.0%) of 84 cases; whereas GeneXpert testing of morning specimens identified 50 (66.0%) of 76 cases were observed (Joseph *et al.,* 2016).

Conclusion

Based on results of this study, yielding accuracy of both morning sputum samples and spot sputum samples is almost similar using Gene Xpert MTB/RIF Assay for detection of MTB. Additionally, the value difference between morning and spot result besides the quality and consistency of samples is not significant.

Competing Interests

We, authors declare that we have no competing interests.

Authors' Contributions

Habtamu M. has contributed to the conception of the study question, designed the study, collected the data, analyzed the data, interpreted the data and drafted the manuscript.

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