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Diagnostic Accuracy of Three Consecutive Sputum Smear for AFB Among TB Patients Visiting Chest OPD

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ABSTRACT

Background: Sputum smear examination for acid-fast bacilli (AFB) can diagnose up to 50-60% of cases of pulmonary tuberculosis in well-equipped laboratories. In low-income countries, poor access to high-quality microscopy services contributes to even lower rates of AFB detection. **Objective**: To assess diagnostic accuracy of three consecutive sputum smear for tuberculosis taking sputum culture as gold standard. **Study Design**: Cross Sectional retrospective study. **Study Setting:** Study conducted in a tertiary care, teaching hospitals out patient department of Tuberculosis and Chest. **Study Duration:** Three months from June – August 2008. **Material and Methods**: Data was collected retrospectively after fulfilling the inclusion criteria in a structured questionnaire of 88 patients who presented to out door department for diagnosis of pulmonary tuberculosis and was investigated for presence of pulmonary tuberculosis. Reports of three consecutive sputum examinations were taken along with sputum culture for and diagnostic accuracy of sputum for Acid Fast Bacilli was calculated taking sputum culture as Gold standard. Demographic information and symptoms were also taken into account. **Results**: 88 patient's reports were recruited for the study. 55.6% of the respondents were between age group of 15 – 44 years. 51.1% were male in our study groups and 48.9% were females. Diagnostic accuracy of three consecutive sputum for AFB was calculated. Sensitivity turned out to be 93.2%. Specificity was 80.0%. Positive predictive value of sputum turned out to be 95.8% and negative predictive value was 70.6%. **Conclusions:** Sputum smear examination for AFB has appreciable sensitivity, specificity and predictive values and three sputum smears is sufficient for the early detection of AFB in outpatient setting.

Key words: Diagnostic accuracy, Acid Fast Bacilli, Sputum smear.

INTRODUCTION

Sputum smear examination for acid-fast bacilli (AFB) can diagnose up to 50-60% of cases of pulmonary tuberculosis in well-equipped laboratories. In low-income countries, poor access to high-quality microscopy services contributes to even lower rates of AFB detection.[1] Furthermore, in countries with high prevalence of both pulmonary tuberculosis and HIV infection, the detection rate is even lower owing to the paucibacillary nature of pulmonary tuberculosis in patients with HIV infection.[2] In the absence of positive sputum smears for AFB, at primary care level, most cases of pulmonary tuberculosis are diagnosed on the basis of clinical and radiological indicators. Some of the reviews aim to evaluate various criteria, algorithms, scoring systems, and clinical indicators used in low-income countries in the diagnosis of pulmonary tuberculosis in people with suspected tuberculosis but repeated negative sputum smears. Several algorithms and clinical scoring systems based on local epidemiology have been developed to predict smear-negative tuberculosis. Few of these have been validated within the local context. However, in areas where smear-negative tuberculosis poses a major

public-health problem, these algorithms may be useful to national tuberculosis programmes by providing a starting point for development their own context-specific diagnostic guidelines.[3,4]

Tuberculosis is a global threat, someone in the world is newly infected every second,5 people die from TB every minute & nearly one percent of world's population is newly infected with T.B. each year .WHO has attributed 26% of deaths in Pakistan to TB as 150,000 lives claimed by TB every year and 250,000 new cases per annum. Poor compliance and poverty are just two factors that prevent its complete eradication. Pakistan ranks 6th amongst group of 22 countries with high prevalence of TB as 4 out of 5 patients in Pakistan still remain undetected or untreated of TB. The high prevalence of tuberculosis in Pakistan has led to increase in poverty, destruction of social fabric, marginalization of workforce and retardation of overall economic progress. TB day, every year is celebrated worldwide on March 24 and the theme selected for the year 2008: "I am stopping TB"[2]

Current guidelines recommend that patients suspected of having active pulmonary tuberculosis (TB) in a health care facility should be placed in a TB isolation room. These recommendations state that isolation can be discontinued when the diagnosis of TB is ruled out or when a determination has been made that the patient is noninfectious. Once a patient has been diagnosed with TB, "isolation should be discontinued only when the patient is on effective therapy, is improving clinically, and has had 3 consecutive negative sputum acid fast bacillus (AFB) smear examinations collected on different days. Every TB patient infects 10-15 new persons on an average, every year. A presumptive diagnosis is crucial to guide treatment, to limit the person-to-person spread of the disease and to assess the degree of activity of the disease. Acid-fast bacilli (AFB) microscopy, which is a means of detecting/screening of pulmonary tuberculosis, has been used worldwide as a mainstay of case finding.[2.4]

The technique is simple and can be easily mastered by relatively untrained personnel. But the use of sputum smears as a screening procedure for the presumptive diagnosis of pulmonary tuberculosis has recently been criticized following the finding by several large laboratories that up to 55% of specimens with positive smear failed to grow in culture while 30% are smear negative but culture positive.[4,5]

The diagnostic quality of testing in developing country is not that accurate. The importance of this study was to evaluate the diagnostic accuracy of AFB as this corner stone of DOT strategy and patient future treatment plan depends upon.

Objectives

The objective of study was to assess the diagnostic accuracy of three consecutive sputum AFB by taking mycobacterium culture as gold standard.

MATERIAL AND METHODS

Study design

Cross-sectional study

Study-setting

Tuberculosis & Chest ward Jinnah hospital Lahore.

Study-duration

Three months from June – August 2008.

Sample-size

Sample size for determination of proportion

- Confidence interval: 95%
- Estimated true proportion: 24%
- Worst acceptable: 10%
- Estimated sample size: 88

Sampling technique

Non probability / Purposive sampling

Sample selection

Inclusion criteria

- All patients admitted in TB & Chest ward with active pulmonary tuberculosis for first time.
- Patients having reports of three consecutive AFB reports.
- Patients having a culture reports done.

Exclusion criteria

- All patients admitted in TB & Chest ward with reactivation of diagnosed pulmonary tuberculosis for first time.
- Patients with known immunosuppressive diseases of chest.
- Patients without culture reports.
- Patients on steroids.

Data collection procedure

Data was collected retrospectively in a structured questionnaire from patient's chart of those fulfilling the inclusion criteria. 88 patients with reports of three consecutive sputum examinations were selected along with sputum culture. Diagnostic accuracy of sputum for Acid Fast Bacilli was calculated taking sputum culture as Gold standard. Demographic information and symptoms were also taken into account.

Data analysis procedure

Frequency table for patients demographic variables like age, sex, educational status, occupational status, rural or urban living will be generated. Diagnostic accuracy of sputum AFB was calculated. Culture of Patients for mycobacterium tuberculosis was used as Gold Standard. Cross tabulation was made for screening test results and diagnosis and sensitivity, specificity and predictive values was calculated to check the diagnostic accuracy of three sputum AFB.

RESLUTS

Eighty eight patient's reports were recruited for the study. 55.6% of the respondents were between age group of 15–44 years. 44.4% of the respondents were between age group of 45 years and above. 51.1% were male in our study groups and 48.9% were females. 93.1% were Pakistani nationals and 6.9% were foreign national. 75.0% were from urban area and 25.0% were from rural back ground (Table 1).

Nine percent (9%) of the respondents were drinking alcohol. 80.7% of the respondents were smoking.1.14% of the respondents had a positive history of intravenous drug use. BCG Scar was present among 34.0% of the respondents and 66.0% did not have a BCG scar. 86.4% had no chronic disease or conditions, 13.6% were suffering from diabetes Mellitus. Diagnostic accuracy of three consecutive sputum for AFB was calculated. Sensitivity turned out to be 93.2%. Specificity was 80.0%. Positive predictive value of sputum turned out to be 95.8% and negative predictive value was 70.6%.

Table 1: Demographic profile of subjects (n=88).

Characteristics		No.	Percent
Age	15-44	49	55.6
	45 & Above	39	44.4
Sex	Male	45	51.1
	Female	43	48.9
Place of birth	Pakistan born	82	93.18
	Foreign born	6	6.82
Marital status	Married	57	64.77
	Unmarried	25	28.41
	Widow	6	6.82
	Divorced	0	0
Residential background	Urban	66	75
	Rural	22	25
BCG Scar	Present	30	34.0
	Not present	58	66.0
Co-morbid	No	76	86.4
	Diabetes mellitus	12	13.6
Alcoholism	Yes	8	9.0
	No	80	91.0
Use of tobacco	Yes	71	80.7
	No	17	19.3
Intravenous drug abuse	Yes	1	1.14
	No	84	95.45

Table 2: Smear and culture results of 88 registered patients

Sputum AFB	Pulmonary Tuberculosis		Total
	Yes	No	
Positive	68	3	71
Negative	5	12	17
Total	73	15	88

1. Sensitivity = a / a + c = 68 * 100 / 73 = 93.2 %
2. Specificity = d / b + d =12 * 100 / 15 = 80.0 %
3. Positive predictive value = a / a + b = 68 * 100 / 71 = 95.8 %
4. Negative predictive value= d / c + d = 12 * 100 / 17 = 70.6 %

DISCUSSION

The simplest, cheapest, and fastest diagnostic method for tuberculosis (TB) is the detection of acid-fast bacilli (AFB) by microscopy. The

algorithm advised for the diagnosis of TB recommends examination of three consecutive sputum specimens from TB suspects for the presence of AFB.[6] In the present study; we evaluated the contribution of each specimen to the final detection of TB suspect patients with culture-proven disease. AFB was detected from one or more sputum specimens with direct microscopy. Our results showed a sensitivity of 93.2%. Specificity of three consecutive sputum for AFB was 80.0%. Positive predictive value of sputum turned out to be 95.8 % and negative predictive value was 70.6%.

Similar study was done at National Tuberculosis and Leprosy Programme, Ministry of Health, Tanzania. To evaluate technical quality and results of smear microscopy for acid-fast bacilli (AFB) in peripheral health care facilities. In their study the proportion of well prepared smears was 86.2% and that of well stained smears was 81.2%. The overall average agreement in reading was (89.2%). The overall sensitivity was 88.5% and specificity was 100%. High false negatives (HFN) were the major errors found in this study and Low false negative (LFN) and quantification errors (QE) were the minor errors found. There were no false positive errors. Minor errors occurred more frequently in hospitals than dispensaries, while major errors occurred more frequently in dispensaries than in hospitals.[7]

In another study to examine more than one sputum smear per patient for the diagnosis of pulmonary tuberculosis by Ozkutuk A, and they found out that analysis of results of smear examination showed that 97% of AFB were detected from the first specimen and only 3% were obtained from the second smear. The third specimen did not have any additional diagnostic value for the detection of AFB by microscopy and concluded that examining two sputum smears is sufficient for the early detection of AFB in our laboratory.[8]

Microscopic examination of respiratory specimens for acid-fast bacilli (AFB) plays a key role in the initial diagnosis of tuberculosis, monitoring of treatment, and determination of eligibility for release from isolation. In one of the study comparison of the sensitivity obtained with smears for detection of AFB (AFB smears) made directly from respiratory specimens (direct AFB smears) to that obtained with parallel smears made from concentrates of the specimens (concentrated AFB smears). A total of 2,693 specimens were evaluated. Of the 353 AFB culture-positive specimens there was a statistically significant difference in the sensitivity of the direct AFB smear (34%) and that of the smear made from the concentrated specimen (58%) ($P<0.05$) at one laboratory. This was also true for the 208 specimens positive for Mycobacterium tuberculosis, for which the sensitivity of the direct smear was 42% (87 of 208) and that for the smear made from the concentrated specimen was 74% (154 of 208) in another laboratory. In the third tertiary care laboratory, where all but 1 of the 45 culture-positive specimens grew M. tuberculosis, the sensitivity of the smear made from the concentrated specimen was 93% (42 of 45) and was not significantly higher than the sensitivity of the direct smear, which was 82% (37 of 45). By combining the results from both laboratories, 42 patients from whom at least three specimens were received were culture positive for M. tuberculosis. The cumulative results for the initial three specimens from these patients showed that the direct smear detected M. tuberculosis in 81% of these patients, whereas the smear made from the concentrate detected M. tuberculosis in 91% of these patients.[9]

In summary, when all culture-positive specimens are considered, the sensitivity of the direct smear compared to that of a smear made from the concentrated specimen was significantly different overall in the two different laboratory settings. However, this difference was reduced only if the cumulative results for the initial three specimens received from patients who were culture positive for M. tuberculosis were evaluated.

CONCLUSIONS

- Sputum smear examination for AFB has appreciable sensitivity, specificity and predictive values.
- The present study shows that examining three sputum smears is sufficient for the early detection of AFB in outpatient setting.

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