Reliability of tuberculosis rapid test in diagnosis of pulmonary tuberculosis in Al-Hawija district.

Mohemid M. Al-Jebouri , Hasan I. Sultan***
**Dept. of Microbiology, College of Medicine, Tikrit University, **Dept. of Medicine, College of Medicine, Tikrit University.*

Abstract

Tuberculosis (TB) is common in Iraq, early diagnosis, especially for active pulmonary cases, allows to start therapy of the disease rapidly. Pulmonary tuberculosis is usually diagnosed by presence of clinical features, direct sputum smears examination for acid fast bacillus (AFB), and chest X ray (CXR). Advances in serological assays for tuberculosis have made serology an attractive surveillance method, tuberculosis rapid test is one of these new methods. This employed to detect antibodies specific for mycobacterial antigens in the serum of suspected TB patients. The aim of this study is to evaluate the reliability of tuberculosis rapid test in diagnosis of pulmonary TB patients in Al-Hawija district. A fifty patients were studied between August 2010 and February 2011, who were then classified into two groups; a group of pulmonary tuberculosis (n = 30) and a group of non-tuberculous pulmonary infection (control group) (n = 20). Direct sputum smears examination for AFB, CXR, and tuberculosis rapid test were performed to all patients. The mean age of pulmonary TB group was 37.3±16.4 years and 17(57%) patients of them were men, while the mean age of the control group was 36±16.2 years and 11(55%) patients of them were men. Direct sputum microscopic examinations for AFB were positive in 9 (30%) patients of pulmonary TB group, while none of the control group was sputum smear positive. The results of the tuberculosis rapid test revealed that 21(70%) of pulmonary TB group and 3(15%) of control group were positive. The sensitivity, specificity, positive predictive value and negative predictive value of tuberculosis rapid test were 70%, 85%, 87.5% and 40% respectively, which also compared to sputum smears results.

Conclusion: It was concluded that tuberculosis rapid test in comparison to sputum smears examination, it can be used as a rapid diagnostic test of pulmonary TB along with traditional diagnostic tests in endemic areas.

Introduction

Tuberculosis (TB) is an airborne, infectious disease caused by

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bacteria which primarily affect the lungs. While both preventable and curable, remains one of the world's major causes of illness and death[1], the World Health Organization (WHO) declared that TB to be a global health emergency. Incidence has been rising all over the world but is worse in developing countries[2,3]. Iraq has a high burden of TB, the estimated incidence was 300 per 100,000 in 2010[2,3,4].

Direct sputum smears examination and mycobacterial culture still remain the most widely used diagnostic procedures[5]. It has been estimated that 5000-10000 acid-fast bacilli must be present in sputum for a patient to be smear-positive, whereas only 10-100 viable organisms are required for sputum to be culture-positive[4]. Smear microscopy allows direct detection of acid fast bacilli (AFB) in the specimen and identification of the most contagious patients, it is rapid and inexpensive ways to diagnose TB, but it has an important limitation that is low sensitivity[6]. Culture is the gold standard for the detection of mycobacteria but it require several weeks of incubation to be detected[7].

The purified protein derivative (PPD) skin test, for detection of active TB has low sensitivity and in individuals vaccinated with Bacillus Calmette-Guerin (BCG), it is often associated with a false-positive result because of cross-reactive immune responses results to antigens common to mycobacterium TB[8].

Polymerase chain reaction (PCR) offers another technique for the direct detection of TB in clinical specimens but it is laborious and expensive and require highly trained technicians[9,10].

As a need for a rapid diagnosis of TB, a number of new serological tests were developed for the diagnosis[11]. Tuberculosis rapid test is an immunochromatographic test based on detection of antibodies directed against specific antigens, secreted by *M. tuberculosis* during active infection, interaction of these specific antibodies to these antigens are present as central red-pink color lines on the filter. It is a rapid, simple, and an expensive test[12,13].

The aim of this study is to determine reliability of tuberculosis rapid test as a diagnostic method in diagnosis of pulmonary tuberculosis in Al-Hawija locality.

Materials and Methods

A case control study covered two groups of patients, were collected between August 2010 and February 2011, which includes 50 patients for comparison.

Pulmonary TB group:

30 patients with active pulmonary TB were attend the Al-Hawija TB centre, they were subjected to detailed history taking, clinical evaluation and number of investigations that included direct sputum smears examination for acid fast bacillus (AFB) by using Ziehl_Neelsen stain (3 samples), erythrocyte sedimentation rate (ESR), and chest X ray (CXR). The diagnosis was made according to WHO criteria[2,3]: A patient was considered as pulmonary TB case if he/she has symptoms for 3 weeks or more with one of the following:

- At least 2 direct smears positive sputum.
- One direct smear positive sputum and positive CXR finding.
- 3 consecutive negative sputum smears but strong evidence of pulmonary TB by CXR and clinical features .

Control group:

It consisted of 20 patients with pulmonary infections other than tuberculosis (mostly pneumonia and chronic bronchitis) who attended outpatient clinic. All patients of control group had no previous history of TB, no signs or symptoms suggestive of pulmonary TB, no evidence of TB on chest x rays. Same investigations done to this group.

Tuberculosis rapid test:

It is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM, and IgA) in whole blood, serum or plasma specimens. The test device produced by ACON laboratories (USA). In this study, tuberculosis rapid test performed to all patients groups and interpreted according to the manufacturer's instructions[12].

Statistical analysis

Data were analyzed using the SPSS software, version 12. The Chi square test was used to assess the associations between variables, P value of 0.05 or less was considered statistically significant. The sensitivity, specificity, positive predictive value, and negative predictive value of tuberculosis rapid test were calculated. Sensitivity was defined as the ability of the test to detect cases of active pulmonary TB. Specificity was defined as the ability of the control group to be test negative (free from pulmonary TB). Positive predictive value (PPV) was defined as the probability that a patient with positive test actually have pulmonary TB, and negative predictive value (NPV) that a patient with negative test truly did not have pulmonary TB[14,15].

Results

This study included 50 patients. Who were classified into two

groups: a pulmonary TB group (n:30), and non-tuberculous pulmonary infection (control) group (n:20). The mean age of pulmonary TB group was 37.3±16.4 years and 17(57%) patients of them were men, while the mean age of the control group was 36±16.2 years and 11(55%) patients of them were men (Table 1).

In this study the most common presenting symptoms in both groups were cough, fever, sputum and sweating, but there is significant difference regarding: anorexia, weight loss and haemoptysis (Table1).

The ESR results were significantly higher in pulmonary TB group than control group (Figure 1).

The presence of BCG scar was seen in 33.4% of pulmonary TB group comparing to 45% of control group without significant difference between them (Table 2).

Direct sputum microscopic examinations for AFB were positive in 9(30%) patients in pulmonary TB group, while none of the control group was smear positive. It is statically significant (Table 3).

The results of tuberculosis rapid test reveals that 21(70%) of pulmonary TB group and 3(15%) of control group were positive, with highly significant difference (P 0.01), (Table 4).

The sensitivity, specificity, positive predictive value and negative predictive value of tuberculosis rapid test of this study were 70%, 85%, 87.5% and 40% respectively, which also compared to sputum smears results. BCG scar has lack of it's sensitivity and specificity in diagnosis of pulmonary TB (Table 5).

Discussion

Tuberculosis is one of the major leading causes of death among infectious diseases world wide[6,16]. The incidence of TB is very high in Iraq according to WHO report 2010, therefore early and rapid detection of mycobacterium TB in clinical ground is essential for TB control[17].

ESR is a predictor of disease activity, but not diagnostic test of pulmonary TB and it is regarded as a good indicator of treatment response and follow up[18,19].

However, previous childhood vaccination by Bacillus Calmette-Guerin represented by presence of BCG scar does not affected the results of tuberculosis rapid test and no more prevention of pulmonary TB than control group. The same results was observed by Bartoloni et al 2003[14,20,21].

Direct microscopic sputum examination is the most

commonly used method in our laboratories to diagnosed pulmonary TB. However, it was low sensitivity, in present study it was 30% it is below that of WHO target, which is 60%[2,3].

Ben-Selma et al 2009, said that lower sensitivity of sputum smears examination is due to insufficient numbers of bacilli per ml of a sample[7].

Therefore the appearance of new assay like tuberculosis rapid test as a simple, rapid, inexpensive, better sensitivity and could be performed to a number of patients in a short period, make it an attractive method of diagnosis[12,22]. In this study the sensitivity, specificity and positive predictive value of tuberculosis rapid test were found satisfactory, it is in accordance with those obtained by other researchers like Gounder et al 2002[6], Bartoloni et al 2003[14], and Adjei et al 2003[23], who confirmed high sensitivity of tuberculosis rapid test for diagnosis of pulmonary TB. The present study conclude that a good sensitivity and positive predictive value of tuberculosis rapid test in comparison to sputum smears examination, it can be used as a rapid diagnostic test of pulmonary TB along with traditional diagnostic tests in endemic areas.

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Table 1. The common clinical findings and ESR results in study groups

	Pulm. TB group(n:30)	Control group(n:20)
Age(yr) (Mean±SD)	37.3±16.4	36.8±16.2
Gender	M17(57%):F13(43%)	M11(55%):F9(45%)
Cough	97%	95%
Fever	92%	90%
Sputum	89%	85%
weight loss	87%	12%
Sweating	75%	36.70%
Anorexia	55%	24%
Hemoptysis	13%	6%
ESR (Mean±SD)	80.5±22	30.9±21.4

Table 2. Results of BCG scar in study groups

BCG Scar	Pulm. TB group	Control group	Total
Positive	10 (33.4%)	9 (45%)	19(38%)
Negative	20 (66.6%)	11 (55%)	31 (62%)
Total	30 (100%)	20 (100%)	50 (100%)

Table 3. Results of sputum smear exam. in study groups

Sputum of AFB	Pulm. TB group	Control group	Total
Positive	9 (30%)	0	9 (18%)
Negative	21 (70%)	20 (100%)	41 (82%)
Total	30 (100%)	20 (100%)	50 (100%)

Table 4. Results of tuberculosis rapid test in study groups

Tuberculosis rapid test	Pulm. TB group	Control group	Total
Positive	21 (70%)	3 (15%)	24 (48%)
Negative	9 (30%)	17 (85%)	26 (52%)
Total	30 (100%)	20 (100%)	50 (100%)

Table 5. Statistical results of tuberculosis rapid test comparing to other results in study groups.

Test performance	Sensitivity	Specificity	PPV	NPV	P value
BCG scar	33.3%	55%	52.6%	35.4%	0.40
Sputum for AFB	30%	100%	100%	48.7%	0.007
Tuberculosis rapid test	70%	85%	87.5%	40%	0.0001

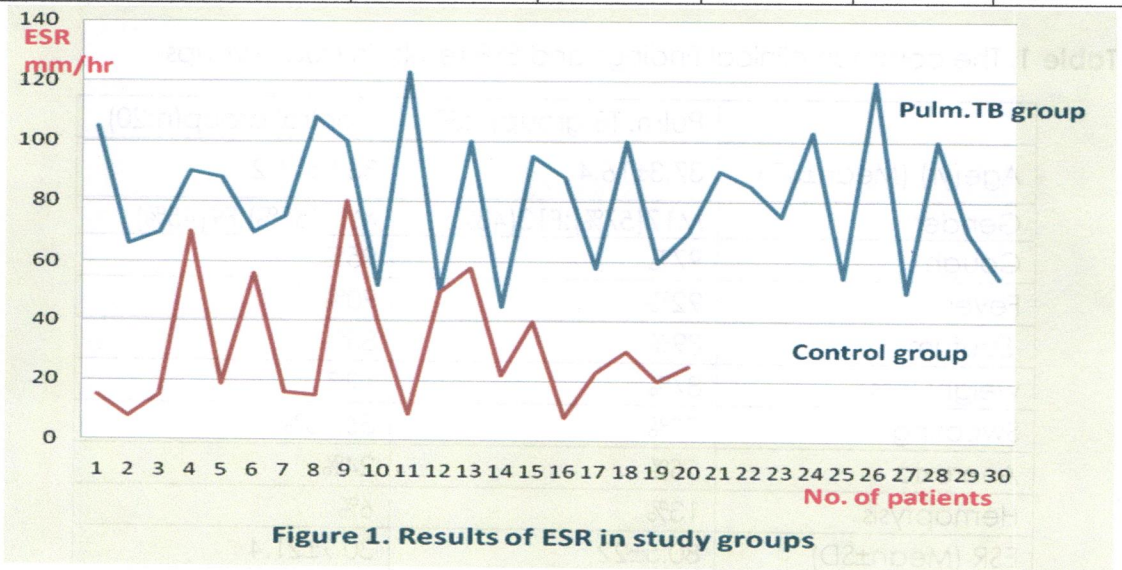

Figure 1. Results of ESR in study groups