

Comparison of Tuberculin Skin Test (TST) and Quantiferon Test (QFT) for detection of Latent TB infection among Health Care Workers (HCWs) in a Tertiary Care Hospital in Riyadh, Saudi Arabia.

Nasser AE. AlHamdan¹; Moustafa A.F. Abbas^{1,2}, Mohamed S. AlQahtani³ Suhail Klantan³; Lamiaa A.Fiala² and Gehad ElGhazali^{3,4}

¹ Community Medicine Dept., Faculty of Medicine, King Fahad Medical City, KSAU-HS, Riyadh, Saudi Arabia

² Community Medicine Dept., Faculty of Medicine, Suez Canal University, Ismailia, Egypt

³ King Fahad Medical City, Ministry of Health, Riyadh, Saudi Arabia

⁴ SEHA hospital, Abu Dhabi, United Arab Emirates

mostafafouad@gmail.com

Abstract: Background: Latent TB Infection is a common finding among HCWs in the Middle East, that is usually discovered on routine pre-employment examination or during regular health check, it needs a course of anti-tuberculous drug medication for months with subsequent side effects. Tuberculin Skin Test (TST) is the traditional testing method for diagnosing LTBI, but it has a known high rate of false positive with subsequent needless loss of time, efforts, loss of productivity and side effects. QFT test has a higher sensitivity and specificity. **Aim:** To determine the sensitivity, specificity, positive and negative predictive value of TST versus QFT Test as a diagnostic tool for latent TB among new hires of health care workers at KFMC, Riyadh, Saudi Arabia. **Methods:** A descriptive study of 268 new HCWs agreed to participate, questionnaire with socio-demographic data and work history was filled, and both test were done TST and QFT test. Recent BCG vaccination and TST result of 5 mm or less were excluded, since there is a low positive rate. **Results:** Sensitivity and specificity of TST at standard 10mm or more to be positive, was 100 % and 53.4% as compared to QFT test. Using different cutoff measurements of size of TST indurations specificity was improved at the expense of sensitivity; at 13mm or more, sensitivity, specificity and κ were 95.5%; 73.2 and 0.611 respectively; while at 15mm or more it was 74.8%; 84.1% and 0.605 respectively. Frequency distribution of sizes of induration according to QFT test results and ROC curve showed that at 13 mm or more specificity would be improved to 70 percent approximately and sensitivity to be still at 90% approximately. **Conclusion:** When comparing TST and QFT, Rates of True negatives and Agreement were improved from (specificity = 53.4%) and ($\kappa=0.536$), to (Specificity=63.9%) and ($\kappa=0.611$) when using a different cut off point for induration sizes of 13 mm or more, rather than the traditional 10 mm or more cutoff point. Large scale study is required to confirm such findings in Middle Eastern health care settings.

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1. Introduction

Latent TB simply means presence of TB bacilli within the human body without developing the clinical case, such as chest x-ray findings or clinical findings. It is estimated the one third of the world population could have LTB¹. QFT is claimed to be more sensitive and specific than TST in multiple research²⁻⁵. Most of research were done in western communities, with totally different prevalence and different risk factors than our middle eastern societies.

Routine use of QFT as a test for detecting latent TB proved to be useful in Italy where up to 50% of positive TST were proved to be negative using the blood testing⁶.

The test QFT indeed allows to eliminate the false positive of the skin test so avoiding useless,

expensive treatments and unwanted effects of anti-tuberculosis medicines⁷.

The QFT testing has to be carefully on interpreted especially among children, immuno-compromized and recent BCG vaccination. In published work of Kimpmann *et al.*, he reported that among children QFT did not give any extra advantage than regular TST as a routine method for testing for TB⁸.

Diagnosis and treatment of LTB is a cornerstone in TB control in both developing and developed countries. TST was the only available test for TB during past century. Now with the availability of QFT blood testing, it is more accurate to detect and treat both LTB and active TB, consequently reduction in morbidity and mortality due to TB⁹.

This research is to compare TST versus QFT blood testing as a diagnostic tool for latent TB among

new hires. On comparing results for sensitivity, specificity and predictive value of TST vs. the QFT as gold standard; results will help policy makers to decide on better resource allocation.

Aim of the study was to determine the sensitivity, specificity, positive and negative predictive value of TST vs. QFT Test as a diagnostic tool for latent TB among new hires of health care workers at KFMC, Riyadh, Saudi Arabia.

2. Materials and Methods:

On comparing results of Tuberculin Skin Test (TST) and blood QFT test for diagnosis of latent TB for same persons we will conclude sensitivity, specificity, positive predictive value, and negative predictive value of TST vs. blood test and better detection of positive LTB, and so reducing complications and costs due to LTB.

Study design: A descriptive study for results of the TST and the QFT test.

Population and sample: 268 HCWs at KFMC who had a routine pre-employment examination and periodic health exams included into the study. During the period of September 2011 to September 2012 all (new hires and periodic exams) that had a TST were candidates to be included; and were asked for voluntary participation in the study. Exclusion criteria was recent BCG vaccination (<2 years); and no induration but not willing to give blood sample for QFT (about 1000 HCWs).

Data collection instruments: a questionnaire was filled containing socio-demographic data and work data, also included work history e.g. previous work at TB/Chest hospital and whether there has been exposure to TB patient in the past 5 years.

TST procedure: TST (PPD) 5 T.U. Lot number C3584AA, Exp. Date: March 2013.

0.1 ml given at R/L forearm (intra-dermal); reading in 48 to 72 hours; Positive where those who had a size of induration 10mm or more-means exposure to TB Bacilli.

QFT Procedure: QFT assay was used for this study. This test involves the collection of blood samples in tubes pre-filled with antigen (typically a negative control tube, an M. tuberculosis-antigen tube, and an optional mitogen tube), which simplifies laboratory procedures.¹⁰ The QFT-in tube test was performed and results interpreted in accordance with the manufacturer's guidelines.

Statistical analysis: Frequency of positive TST and QFT test was calculated to according each socio-demographic data such as age group, gender, nationality and occupation, also cross table for TST and QFT was made to calculate sensitivity, specificity, positive predictive value and negative predictive value. ROC curve was made to test for the

optimum size of TST indurations to fit with the positive QFT test. SPSS version 17 was used for the data management and statistical analysis also for production of the figures and ROC curve.

Ethical considerations: KFMC IRB committee approved the research on October 1st, 2011, number 11-151. Each of study Participants was explained study objectives and procedures, it was clearly explained to participants that it is optional. Also participants were explained clearly that participation in the study has nothing to do with their recruitment process. If a candidate approved to join the study, was given consent form to participate to sign.

3. Results:

This is a comparative study for the findings of TST and QFT among new hires and periodic HCWs checkups. 268 Health care workers participated in the study with mean age 29.1±5.2 years. 152 nurses (56.7%) represented the main occupation in the study subjects. 137 (51.1%) East Asian were most frequent participants, approximately 40% of study subject reported previous exposure to TB patients. With a 6.2±4.9 years of work, and 64 (24% reported previous work at TB/ chest hospital or ward (Table 1).

In table 2, 135 (68.5%) of TST positive were truly positive by QFT test, and 71 (100%) of TST negative were truly negative by QFT test. It's found that Sensitivity 100%; specificity 53.4%; Positive predictive value 68.5% and negative predictive value to be 100%. As for test of agreement we found that at cutoff point of 10 mm or more the kappa test to be $\kappa = 0.536$; Variance=0.00293; S.E.=0.0541 and 95%CI=0.430 < $\kappa = 0.536 < 0.642$; which is considered as average agreement.

On using a different cutoff points for positive TST (at 13mm or more and at 15 mm or more to be positive in tables 3 and 4), specificity was improved significantly to 63.9% and 85.7%, but on the expense of sensitivity as expected, to be lowered to 95.6% and 74.8%.

As for test of agreement we found that at cutoff point of 13 mm or more the kappa test to be $\kappa = 0.611$; Variance=0.0033; S.E.=0.0571 and 95%CI=0.498 < $\kappa = 0.611 < 0.748$; which is a better agreement than at test at 10mm or more.

And for the cutoff point of 15 mm we found that the agreement to be $\kappa = 0.605$; Variance=0.00386; S.E. =0.0607; and 95%CI=0.486 < $\kappa = 0.605 < 0.724$; which is less than that of the 13mm or cutoff point.

Figure 1 is a line graph represents frequency of sizes TST indurations in mm according to whether QFT test result. We can see clearly the bimodal pattern for hi frequency for negative in these sizes

less than 13 mm and increased frequency for sizes 30 or more for positives by QFT test.

Figure 2 is the ROC curve for TST indurations sizes in mm and QFT test results. Which shows that at 90% sensitivity specificity will be improved to 70% approximately. Also shown ROC area under the curve and $p=0.000$; also from the ROC table at sensitivity at 13mm or more, sensitivity is approximately to be 95% and specificity is improved to be 70%.

Tables (1): Characteristics of study subjects (n=268)

Variable	Frequency	Percent
Age (mean ± SD)	29.1±5.2	
Gender:		
Male	92	34.3%
Female	176	65.7%
Occupation:		
Nurse	152	56.7%
Physician	43	16.0%
Technician	28	10.4%
Administrator	45	16.8%
Nationality:		
Western	4	1.5%
Middle East	114	42.5%
South Asia	13	4.9%
East Asia	137	51.1%
Exposure to TB pts:		
Yes	106	39.6%
No	162	60.4%
Work years: (mean ± SD)	6.2±4.9	
Previous work at TB Hospital:		
Yes	64	24%
No	204	76%

Table (2): Comparison of TST and QFT test among new Health care staff at KFMC, Saudi Arabia

	QFT Test		P value
	Positive	Negative	
Positive (10mm)	135(68.5%)	62 (31.5%)	0.0000
Negative (<10)	0 (0.0%)	71	

Tuberculin Skin TEST	mm)	(100.0%)
	Sensitivity = 135/135+0 = 100.0%	
	Specificity = 71/62+71 = 53.4%	
	Positive PV = 135/135+62 = 68.5%	
	Negative PV = 71/71+0 = 100.0%	
	$\kappa = 0.536$	
Variance=0.00293		
S.E.=0.0541		
95%CI=0.430 < κ = 0.536 < 0.642		

Table (3): Comparison of different cutoff (13mm) for TST and QFT test among new Health care staff at KFMC, Saudi Arabia

		QFT Test		P value
		Positive	Negative	
Tuberculin Skin TEST	≥13 mm	131(73.2%)	48(26.8%)	0.0000
	<13 mm	4(4.5%)	85(95.5%)	
	Sensitivity = 131/131+4 = 95.6%			
	Specificity = 85/85+48 = 63.9%			
	Positive PV = 131/131+48 = 73.2%			
	Negative PV = 85/85+4 = 95.5%			
$\kappa = 0.611$				
Variance=0.0033				
S.E.=0.0571				
95%CI=0.498 < κ = 0.611 < 0.748				

Table (4): Comparison of different cutoff (15mm) for TST and QFT test among new Health care staff at KFMC, Saudi Arabia

		QFT Test		P value
		Positive	Negative	
Tuberculin Skin TEST	≥15 mm (very positive)	101(84.2%)	19 (15.8%)	0.0000
	<15 mm	34 (23.0%)	114(77.0%)	
	Sensitivity = 101/101+34 = 74.8%			
	Specificity = 114/114+19 = 85.7%			
	Positive PV = 101/101+19 = 84.1%			
	Negative PV = 114/114+34 = 77.0%			
$\kappa = 0.605$				
Variance=0.00386				
S.E.=0.0607				
95%CI=0.486 < κ = 0.605 < 0.724				

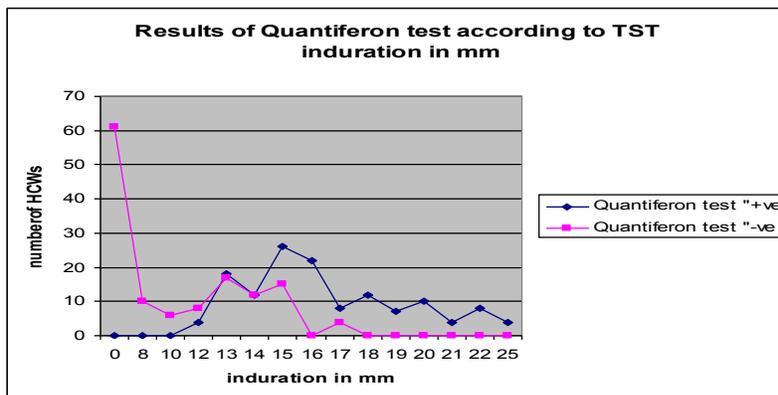


Figure (1): Results of QFT according to TST induration in mm

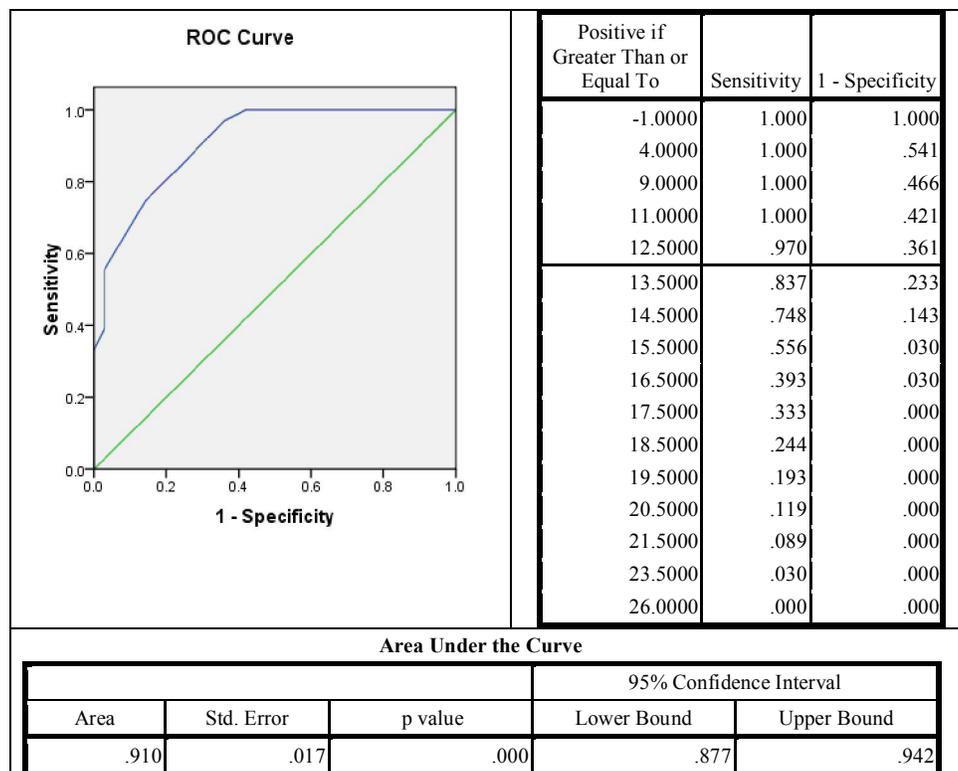


Figure 2: Recipient Observer Curve (ROC) for the size of the induration and QFT test for detection of LTBI.

4. Discussion:

The present study compared results of TST and QFT as a method for diagnosing LTBI among HCWs, results showed the following three major findings. First, agreement between the two tests improved when using 13mm cutoff point for induration reading on TST. Second, specificity (ability to exclude true negative by the TST) was improved also. Third, sensitivity did not deteriorate greatly by using such cutoff point. In a previous work, by the same authors for the current study, Abbas *et al.*,¹¹ found that prevalence of LTB among new hires at KFMC, Riyadh Saudi Arabia was 11% using the standard routine of TST. Our findings in table 2, explain that 135 (68.5%) of those who were classified by TST as Positive were classified by the QFT test as true positives, the rest were false positive 62 (31.5%), with a *Kappa* value of 0.536 at a cut off point of 10mm or more which is improved to be 0.611 on using 13mm as a cutoff point. Which is comparable improvement to agreement when compared to the work done by Anibarro *et al.*,¹² who used presence of erythema as improvement to the measurement of induration.

In a study examining surveillance data for TB among HCWs in the United States; Lambert *et al.*,¹³ reported that in the United States 3% of the those who developed open TB in the US were HCWs, and recommended to intensify TB screening

and encourage treatment of LTBI among HCWs to prevent progression to TB disease. The problem with this recommendation is that the specificity of TST is poor as reported in the study done by Klein *et al.*,¹⁴ who compared QFT and TST and reported that TST even to be non specific for LTBI. This will lead to higher numbers of false positives with subsequent waste in costs, absenteeism, investigations and loss of productivity. Here comes importance of our work, it cover a gap in the cutoff point in TST through which many false positive cases are identified by TST.

TST is also affected by immune status of the subjects as revealed by the study conducted by Mardani *et al.*,¹⁵ on 50 HV positive subjects, they reported that even with high agreement between TST and QFT, but still QFT renders more accurate results of LTBI among HIV patients rather than the TST. Which again is congruent with our findings.

Accurate testing to identify positive and exclude negative LTBI will reduce the number needed to be treated to prevent a case of tuberculosis, this will be achieved by use of modern new generation of immunodiagnostic tests as explained by Chee *et al.*,¹⁶ which is achieved by our study, since we benefited from the new immunodiagnostic test of QFT to increase accuracy of the traditional TST.

Study subjects were non BCG vaccinated, even with this status results showed average agreement ($\kappa=0.611$) which is less than the work done by Brock *et al.*,¹⁷ who compared agreement of TST and QFT among bcg vs. non BCG vaccinated students, who reported that agreement among non BCG vaccinated was high ($\kappa=0.866$), difference again might be due to different exposure pattern between western community and middle eastern settings.

We as health care professionals are after high specificity tests for the LTBI in order to avoid false positive results by TST who are unnecessarily treated with anti-tuberculous drugs, same concept explained by the work done by Lalvant,¹⁸ who compared two new immuno-diagnostic tests at this time, one of which was the QFT and reported that it will benefit to reduce false positive and increase diagnostic sensitivity for LTBI. Comparing TST and QFT in our Middle Eastern health care settings will help improve diagnostic utility for TST by trying to readjust the cutoff points.

M tuberculosis infection is a global health problem with estimated 1.7 million deaths in 2009¹⁹, about 2 billion are LTBI and About 10% of LTBI will progress to open TB during their lifetime^{20, 21}, here comes the importance for of increasing the specificity for the diagnostic tests, by the current work with increased specificity, the false positive rate will be reduced and subsequently there is a reduction of wasted resources on treating false positives and allocating these resources to LTBI who are in real need for it. Conneli *et al.*,²² reported that use of the new diagnostic tests for LTBI will help reduce progression of LTBI to open TB especially for immigrants from high burden countries to low burden countries as regards TB prevalence, but in this work we can use a low cost traditional TST to diagnose LTBI with increased specificity and reduce false positives. The high false positive in on using TST Saudi Arabia might be due to the noticed common practice of drinking milk without boiling.

Costa *et al.*,²³ used Interferon Gama Release Assay (IGRA) to increase the specificity of diagnosing LTBI and concluded that by use IGRA, could prevent half of chest x-rays to discover TB among HCWs, and even none of TST +ve and IGRA – ve developed open TB on follow up. This explains importance of avoiding false positive due to TST. This can be achieved as we mentioned in results that increasing the cutoff point for TST to diagnose LTBI to 13mm or more will increase specificity and subsequent decrease in sensitivity is not harmful. These findings is in agreement also with the work done by Girardi *et al.*,²⁴ who reported that when

used with HCWs, *in vitro* testing for LTBI provide higher specificity than traditional TST.

In this matter, Abdel Hamid *et al.*,²⁵ suggested a two step TST and a QFT for positive will increase specificity and will at the same time make a cost reduction of 50 %.which is in agreement with our finding, but subject of cost reduction need to be addressed in another study.

So, QFT has a high specificity which benefited us to increase specificity of TST by increasing the cutoff point from 10mm or more to 13 mm or more to diagnose LTBI among HCWs.

Our study had several limitations that had to be addressed. The population is a mixture of many nationalities with different pattern of exposures and different patterns of prevalence of TB, also, needed a larger number of subjects to improve significance of testing, and since it is voluntary to take the Anti-tuberculous drugs in case of positive TST, many HCWs refuse to participate after being either negative on TST or even after being positive TST to go on and give blood samples for the QFT testing.

5. Conclusion and Recommendations:

When comparing TST and QFT, Rates of True negatives and Agreement were improved from (specificity = 53.4%) and ($\kappa=0.536$), to (Specificity=63.9%) and ($\kappa=0.611$) when using a different cut off point for induration sizes of 13 mm or more, rather than the traditional 10 mm or more cutoff point. Large scale study is required to confirm such findings in Middle Eastern health care settings.

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Corresponding Author:

Prof. Mostafa AF Abbas,

Community Medicine Dept., Faculty of Medicine,
King Fahad Medical City, KSAU-HS, Riyadh, Saudi
ArabiaCommunity Medicine Dept., Faculty of Medicine,
Suez Canal University, Ismailia, EgyptE-mail: moustafafouad@yahoo.com**References:**

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