Original Article

The use of Quantiferon-TB gold in-tube test in screening latent tuberculosis among Saudi Arabia dialysis patients

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Abstract:

BACKGROUND AND AIM: Screening for tuberculosis (TB) is a key strategy for controlling infection. This study aimed to detect latent TB among dialysis patients.

METHODS: This is a prospective study conducted in King Saud University, Riyadh involving hemodialysis (HD) and peritoneal dialysis (PD) patients aged ≥18 years. Patients were screened for latent TB infection (LTBI) using both TBskin test (TST) and QuantiFERONTB Gold In-Tube test (QFT-GIT). All participants were followed-up clinically and radiologically every 3 months for 2 years.

RESULTS: A total of 243 (181 HD and 62 PD) patients were included and 112(46.1%) were males. 45.3% showed positive QFT in HD patients with sensitivity of 91.7%, specificity of 71.4%, positive predictive value (PPV) of 19.5%, and negative predictive value (NPV) of 91.1%. TST results in HD showed that positive TST was 17.4%, sensitivity was 63.2%, specificity was 95.5%, PPV was 51.5%, and NPV was 91.1%. Five (8.1%) showed positive QFT in PD patients with sensitivity of 7.7%, specificity of 91.8%, PPV of 6.6%, and NPV of 92.3%. TST results in PD showed that positive TST was 9.8%, sensitivity was 35.7%, specificity was 97.9%, PPV was 55.8%, and NPV was 93.3%. Previous TB infection was significantly correlated with QFT only in HD patients, but significantly associated with TST in both HD and PD patients. Also in HD, QFT was significantly associated with TST ($P = 0.043$).

CONCLUSIONS: Due to high variability of QFT-GIT sensitivity, we recommend its use for its NPV and to use either TST or QFT in screening latent TB.

Key words:

Dialysis, King Saud University, King Abdulaziz City of Science and Technology, tuberculosis, quantiferon

Tuberculosis (TB) is caused by the bacillus *Mycobacterium tuberculosis*. The majority of patients infected with TB will not develop an active disease, but as latent TB infection (LTBI).[1-3] Screening and targeted testing for TB is a key strategy for controlling and preventing the infection.

Saudi Arabia is currently listed among countries with "high incidence" of TB (>20 cases per 100,000 population)[4] with a prevalence of 13,267 (55/100,000) in 2004.[5] The prevalence of TB in dialysis patients is several times higher than its prevalence in the general population.[6-8] The prevalence of TB in dialysis ranges from 2.4 to 14.5%, which is 12 times more common than in the general population of Saudi Arabia.[7,8] The estimated numbers of dialysis patients are 12,116 hemodialysis (HD) patients and 1,240 peritoneal dialysis (PD).[9] QuantiFERON-TB Gold In-Tube test (QFT-GIT) measures the amount of interferon (INF) released from sensitized lymphocytes. Compared with the TB skin test (TST), the INF-release assays have the advantage of being completed in a single visit and are more specific with the presence of Bacillus Calmette-Guérin (BCG) vaccination or nontuberculous mycobacterial infection.[10,11]

We aim to determine LTBI in both HD and PD patients and to evaluate the sensitivity, specificity, and predictive values of both interferon-gamma release assay (IGRA) and TST to improve the standard of patient care.

Methods

This is a prospective three-center study conducted in King Khalid University Hospital, Security Forces Hospital and Lehbi Medical Center, all located in Riyadh, Saudi Arabia which involves HD and PD patients. The study was conducted from 5 January 2011 to 31 March 2013 and was supported by King Abdulaziz City of Science and Technology grant with reference no. ARP-245-29.

Adult Saudi HD and PD patients aged ≥18 years were invited to participate in the study and

written informed consent was taken. Patients with major current disease including heart failure or debilitating illness, non-consenting patients, and pregnant women were excluded from the study. Patients were screened for latent and active TB infection using both TST and QFT test. All patients were further investigated clinically and radiologically for TB and followed-up every 3 months for 2 years.

All patients underwent Mantoux TST through intradermal injection with 5 tuberculin units of purified protein derivative (PPD). Complete blood count (CBC), differential count, were regularly performed on patient for 3 months. The criteria for determining false positive results in QFT are no previous and present TB, no contact with TB patients, negative TST, and normal chest examination. Whereas, the criteria for determining false negative results in QFT are previous and present TB, contact with TB patients, TST positive, and abnormal chest examination.

The criteria for determining false positive results in TST are no previous and present TB, no contact with TB patients, negative QFT, and ESR <30. Accordingly, the criteria for determining false negative results in TST are previous and present TB, contact with TB patients, QFT positive, and abnormal chest examination. Positive and negative predictive values (PPV and NPV) were calculated using the formulas based on Bayers' theorem.[12]

Statistical analysis

IBM Statistical Package for Social Sciences (SPSS) for Windows, version 19, 2010, SPSS Inc., was used for statistical analysis. Continuous variables were expressed as mean (standard deviation (SD)). Chi-square test was used for comparing categorical data. Risk was estimated using odds ratio (OR). Nonparametric Mann-Whitney U test was used. For bivariate analysis, Pearson's correlation analysis and Spearman's rank order correlation was used. A *P*-value <0.05 was considered significant.

Results

HD group

Data was completed for 181 patients and TST results were available for 172 (95%) participants. Cause of end-stage renal failure and demographic characteristics of patients are shown in Table 1. The main findings of our study are that the QFT-GIT was positive in 82 (45.3%) participants and positive TST was found in 17.4% of our patient. The prevalence of latent TB after excluding previous patients is 42.5% in TB and 14.3% in TST.

QFT-GIT was significantly associated with TST ($P = 0.043$, $\kappa = 0.119$). The HD group risk factors cross tabulation with QFT and TST are shown in Table 2. Previous TB infection was significantly associated with positive QFT results ($P = 0.009$). ESR was correlated with positive QFT results ($rs = -0.156$, $P = 0.037$) however, this relationship became non-significant after controlling for confounding factors ($rs = -0.104$, $P = 0.198$). Patient with palpable lymph nodes ($rs = 0.21$, $P = 0.012$) and splenomegaly ($rs = 0.18$, $P = 0.032$) were associated with positive QFT results; however, only presence of lymph nodes and not splenomegaly remained statistically significant after controlling for confounding

Table 1: Group demographics and test results

Variables	HD	PD
Total*	181	62
Age (SD)	55.6 (16.4)	50.5 (18.7)
Male gender (%)	82 (45.3)	30 (48.4)
BMI (SD)	26.3 (6.5)	29 (6.9)
BCG scar (%)	68 (42)	35 (56.5)
Previous TB (%)	14 (7.8)	1 (1.6)
TB now (%)	3 (1.9)	9 (15.3)
Contact TB (%)	15 (8.4)	4 (6.8)
Smoker (%) Current	14 (8)	3 (5.1)
Quit	21 (11.9)	10 (16.9)
KT/V (SD)	1.5 (0.4)	N/A
Duration of dialysis, years (SD)	5.1 (5.4)	2.6 (2.5)
DM (%)	61 (33.7)	11 (17.7)
HTN (%)	44 (24)	14 (22.6)
Both DM and HTN (%)	44 (24)	18 (29)
NS (%)	6 (3.3)	5 (8)
Unknown (%)	26 (14)	14 (22.6)
QFT (%) positive	82 (45.3)	5 (8.1)
TST (%) positive	30 (17.4)	6 (9.8)
Abnormal CXR (%)	9 (5.9)	7 (11.5)

DM = Diabetes mellitus, HTN = Hypertension, LN = Lupus nephritis, NS = Nephrotic syndrome, CXR = Chest X-ray (fibrocavitary apical disease, discretenodules, and pneumonic infiltrates, miliary pattern), KT/V = Measurement of adequacy of dialysis, HD = Hemodialysis, PD = Peritoneal dialysis, SD = Standard deviation, BMI = Body mass index, BCG = Bacillus Calmette-Guérin, TB = Tuberculosis, QFT = Quanti FERON, TST = Tuberculosis skin test. *Numbers that do not add up to total count for group are due to missing data

Table 2: Hemodialysis group risk factors cross tabulation with tests

N (%)	QFT			TST		
	+ ve	–ve	*P*-value	+ ve	–ve	*P*-value
Previous TB						
Yes	11 (78.6)	3 (21.4)	0.009*	6 (42.9)	8 (57.1)	0.019*
No	70 (42.2)	96 (57.8)		24 (15.2)	134 (84.8)	
BCG scar						
Present	28 (41.2)	40 (58.8)	0.495	11 (16.2)	57 (83.8)	0.386
Absent	40 (42.6)	54 (57.4)		17 (19.3)	71 (90.7)	
Contact TB						
Yes	5 (33.3)	10 (66.7)	0.252	2 (13.3)	13 (86.7)	0.49
No	75 (46)	88 (54)		28 (17.9)	128 (82.1)	
DM						
Yes	42 (44.2)	53 (55.8)	0.441	13 (14.1)	79 (85.9)	0.144
No	39 (46.4)	45 (53.6)		17 (21.5)	62 (78.5)	
HCV						
Yes	17 (48.6)	18 (51.4)	0.368	12 (34.3)	23 (65.7)	0.006*
No	62 (43.7)	80 (56.3)		18 (13.3)	117 (86.7)	
IHD						
Yes	20 (50)	20 (50)	0.291	12 (31.6)	26 (68.4)	0.012*
No	60 (43.5)	78 (56.5)		18 (13.5)	115 (86.5)	
Steroids						
Yes	8 (36.4)	14 (63.6)	0.257	6 (27.3)	16 (72.7)	0.151
No	71 (46.4)	82 (53.6)		23 (15.8)	123 (84.2)	

HCV = HepatitisC virus, DM = Diabetes mellitus, IHD = Ischemic heart disease, TB = Tuberculosis, BCG = BCG = Bacillus Calmette-Guérin, QFT = QuantiFERON, TST = Tuberculosis skin test. *Numbers that do not add up to total count for group are due to missing data

factors (*rs* = 0.184, *P* = 0.041 and *rs* = 0.151, *P* = 0.096, respectively). Patients with cough (*rs* =–0.17, *P* = 0.023) and those with productive cough (*rs* =–0.16, *P* = 0.034) were less likely to have negative QFT results, which remained significant after controlling for confounding factors (*rs* = 0.226, *P* = 0.005 and *rs* = 0.214, *P* = 0.008, respectively). Patients who reported not being smokers were significantly associated positive QFT results (*P* = 0.016); however, this was not significant after controlling for confounding factors (*rs* = 0.155, *P* = 0.057).

Positive TST was significantly associated with male gender even after controlling for confounding factors (*rs* = 0.22, *P* = 0.007) and significantly associated with previous TB infection (*rs* = 0.212, *P* = 0.009). Abnormal chest examination was associated with positive TST even after controlling for confounding factors (*rs* = 0.24, *P* = 0.008). Nonsmokers were associated with positive TST (*rs* = 0.198, *P* = 0.01); however, this relationship was not significant after controlling for confounding factors (*rs* = 0.17, *P* = 0.002).

PD group

Data was completed for 62 participants and TST results were available for 61(98.4%) participants. Positive QFT was found in five (8.1%) patients and positive TST in six (9.8%) patients. The cause of end-stage renal failure and demographic characteristics of PD patients are shown in Table 1. Bacillus Calmette-Guérin (BCG) vaccination was reported as 25 (41.7%), while the BCG scar was found in 35 (56.5%).

The prevalence of latent TB after excluding previous patients with TB is 8.3% in QFT as well as in TST. There was no significant correlation and poor agreement between QFT and TST in this group (*P* = 0.415, κ = 0.101). The only one participant with previous history of TB infection had a negative QFT, but resulted to be positive in TST.

Patients with splenomegaly from evaluation were significantly associated with positive QFT results (*rs* = 0.481, *P* = 0.001). Previous TB infection and contact with TB person was associated with positive TST results (*r* = 0.391, *P* = 0.002 and*r* = 0.357, *P* = 0.005, respectively), even after controlling for confounding factors. Participants with hepatitis C virus (HCV) had a negative QFT and negative TST results none was reported of having previous TB infection [Table 3]. The results of sensitivity and specificity testing for QFT and TST as well as the PPV and NPV are defined in Table 4.

Table 3: Peritoneal dialysis group risk factors cross tabulation with tests

N (%)	QFT			TST		
	+ ve	–ve	*P*-value	+ ve	–ve	*P*-value
Previous TB						
Yes	0	1 (100)	N/A	1 (100)	0	N/A
No	5 (8.2)	56 (91.8)		5 (8.3)	55 (91.7)	
BCG scar						
Present	1 (2.9)	34 (97.1)	0.107	2 (5.7)	33 (94.3)	0.206
Absent	4 (14.8)	23 (85.2)		4 (15.4)	22 (86.6)	
Contact TB						
Yes	0	4 (100)	N/A	2 (50)	2 (50)	0.049*
No	5 (9.1)	50 (90.9)		4 (7.4)	50 (92.6)	
DM						
Yes	2 (6.9)	27 (93.1)	0.548	3 (10.3)	26 (89.7)	0.632
No	3 (9.4)	29 (90.6)		3 (9.7)	28 (90.3)	
HCV						
Yes	0	3 (100)	N/A	0	3 (100)	N/A
No	5 (8.3)	55 (91.7)		6 (10.7)	50 (89.3)	
IHD						
Yes	0	11 (100)	N/A	1 (9.1)	10 (90.9)	0.698
No	5 (10)	45 (90)		5 (10.2)	44 (89.8)	
Steroids						
Yes	1 (12.5)	7 (87.5)	0.582	0	8 (100)	N/A
No	4 (9.1)	90 (90.9)		6 (13.6)	38 (86.4)	

HCV = Hepatitis C virus, DM = Diabetes mellitus, IHD = Ischemic heart disease, TB = Tuberculosis, BCG = BCG = Bacillus Calmette-Guérin, QFT = QuantiFERON, TST = Tuberculosis skin test, N/A = Not available. *Numbers that do not add up to total count for group are due to missing data

Table 4: Sensitivity, specificity, TB prevalence, PPV, and NPV for QFT and TST among groups

Group	QFT test (%)	TST test (%)
HD		
Sensitivity (95% CI)	91.67 (80-97.6)	63.16 (46-78.2)
Specificity (95% CI)	71.43 (63-78.9)	95.52 (90.5-98)
PPV (95% CI)	19.5 (14-25)	51.5 (44-59)
NPV (95% CI)	91.1 (87-95)	91.1 (87-95)
PD		
Sensitivity (95% CI)	7.69 (1.3-36.1)	35.71 (13-65)
Specificity (95% CI)	91.84 (80-97.7)	97.87 (89-99.6)
PPV (95% CI)	6.6 (0-13)	55.8 (43-68)
NPV (95% CI)	92.3 (87-99.3)	93.3 (87-99.6)

HD = Hemodialysis, PD = Peritoneal dialysis, QFT = QuantiFERON, TST = Tuberculosis skin test, CI = Confidence interval, PPV = Positive predictive value, NPV = Negative predictive value. Prevalence - 7%; reference: Waness, 2011[27]

Discussion

This study aimed to detect the prevalence of LTBI using IGRAs (QFT) as compared to TSTs among dialysis patients. Positive QFT results were found to be 8.1% in PD and 45.3% in HD in the current study. Our study showed a significant correlation between QFT and TST among the HD patients. There was no correlation found between the two tests in PD patients. There was also poor agreement between the two tests in both HD and PD patients. Our findings are consistent in the literature with several published studies,[13-19] where the agreement between TST and QFT is almost always poor when the TST was cutoff to 5 mm, and moderate at best when 10 mm was used or repeat TST was performed for booster effect.[17] Our study showed 45.3% positive in QFT and17.4% positive in TST among HD patients which appeared to be within range with the other published studies resulting to 36% (range 21-46%) positive in QFT and 30% (range 13-63%) positive in TST.[13-20]

The sensitivity and specificity of QFT in the HD group were 71 and 92%, respectively. This is comparable with other studies where specificity and sensitivity among this group was found to be 67.5 and 66.7% in Saudi Arabia,[13] 89.7 and 100% in Turkey,[15] 62.1 and 100% in Taiwan,[18] respectively; and a sensitivity of 61% in USA by Redelman-Sidi and Sepkowitz.[21] This shows a wide range of variability among other studies, which may

be attributed to local prevalence of TB, BCG vaccination status, sample size, and recruitment criteria. Several systemic reviews and meta-analyses have been conducted, looking at the sensitivity and specificity of QFT in correlation with TST as well as its cost-effectiveness. Several studies was reported of having inability to accurately estimate these variables because of the limited number of studies; heterogeneity of patient populations; lack of clear recruitment; diagnostic and interpretation criteria; and diversity of objectives, measurements, and diagnostic tests applied and compared. So interpretation of these results remains extremely variable among authors. A 2010 meta-analysis[22] concluded that "IGRAs are superior, in comparison with the TST, for detecting confirmed active TB disease, especially when performed in developed countries." While another meta-analysis published in 2011[23] concluded that in low- and middle-income countries, neither TST nor IGRAs have value for active TB diagnosis in adults. This variability may be explained from an obvious difference between the meta-analyses based from the developed countries, while the other is considering the developing countries. Most studies are favorable of QFT use for its negative predictive values (NPVs),[24] which supports our findings (PPVfor QFT in HD patients was 19.5 and 6.6% in PD and NPV for QFT in HD was 91.1% and 92.3% in PD). This result conforms to the Centers for Disease Control and Prevention (CDC) released guidelines for the use IGRAs in screening for TB (CDC, 2010),[11] which states that "IGRAs generally should not be used for testing persons who have a low risk for both infection and progression."This was in conformation with two other studies by Inoue *et al*.,[25] showing PPV of 44.4% (8 of 18) and NPV of 100% (87 of 87) and Găvriluţ *et al*.,[26] indicating a PPV of 29.4% and NPV of 96.1%.

The strong point of our study is the comparison between QFT test and long follow-up of these patients for 2years. The limitation of our study is that there is no true gold standard for LTBI for the comparison of the results and can be determined only after a long follow-up.

Conclusions

With a wide variability in the positivity of QFT sensitivity in both HD and PD patients, it should not be used as the sole determinant of TB status, since the sensitivity and specificity did not reach 99%. We recommend using either TST or QFT as they have the same significance in diagnosing latent TB. We also recommend the use of IGRA for its NPV in diseased patients in conjunction with post-positive TST.

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