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ORIGINAL ARTICLE

Prevalence of Latent Tuberculosis Infection Detected by QuantiFERON-TB Gold Plus Assay in Chronic Kidney Disease Patients

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ABSTRACT

Background: *Patients with chronic kidney disease (CKD) are at increased risk of tuberculosis (TB) due to impaired cellular immunity, repeated healthcare exposure and the immunosuppressive effects of advanced kidney disease and renal replacement therapies. Accurate detection of latent tuberculosis infection (LTBI) is therefore important particularly among patients awaiting or undergoing kidney transplantation. This study evaluated the diagnostic utility of the QuantiFERON-TB Gold Plus (QFT-Plus) assay compared with the Mantoux tuberculin skin test and assessed the prevalence of TB infection across different CKD management modalities.* ***Methods & Materials:*** *A cross-sectional study was conducted among 94 patients with CKD at a tertiary care hospital in Bangladesh. Participants were evaluated using both the QFT-Plus interferon-gamma release assay and the Mantoux test. Demographic and clinical characteristics, CKD management modality, and TB-related findings were recorded. The prevalence of QFT-Plus positivity was compared with Mantoux positivity, and the distribution of latent TB infection was assessed across different treatment groups.* ***Results:*** *QFT-Plus demonstrated a substantially higher positivity rate than the Mantoux test with positivity rates of 42.6% and 14.9%, respectively. Marked discordance was observed between the two diagnostic approaches including 26 patients who were QFT-Plus positive but Mantoux negative indicating that reliance on the Mantoux test alone may miss a considerable proportion of patients with evidence of TB infection. QFT-Plus positivity was highest among kidney transplant recipients followed by patients receiving hemodialysis demonstrating a substantial burden of TB infection across advanced CKD management groups.* ***Conclusion:*** *QFT-Plus identified considerably more patients with evidence of TB infection than the Mantoux test in this CKD cohort. The* ***findings*** *support consideration of IGRA-based screening particularly among kidney transplant candidates and patients receiving hemodialysis in TB-endemic settings. Prospective multicenter studies with larger cohorts and longitudinal follow-up are warranted to establish the predictive value of QFT-Plus for subsequent active TB and to determine the clinical effectiveness of IGRA-guided preventive therapy.*

Keywords: *Chronic kidney disease, Latent tuberculosis infection, QuantiFERON-TB Gold Plus, Mantoux test; Interferon-gamma release assay.*

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INTRODUCTION

Chronic kidney disease (CKD) represents a growing global health burden with an estimated prevalence of approximately 10% worldwide [1]. Patients with CKD particularly those with advanced stages and those receiving kidney replacement therapy exhibit profound alterations in cellular immunity resulting from uremia, malnutrition, vitamin D deficiency, and other metabolic disturbances [2]. These immunological derangements predispose CKD patients to a significantly elevated risk of infectious complications among which tuberculosis (TB) remains one of the most formidable clinical challenges [3]. The association between CKD and tuberculosis has been well documented in the literature. A recent systematic review and meta-analysis by Luczynski et al. demonstrated that the pooled risk of TB disease was 57% higher in individuals with CKD stages 3–5 compared to those without CKD with the highest risk observed in stages 4–5 (incidence rate ratio: 3.63) [4]. Patients with end-stage kidney disease (ESKD) requiring dialysis face an even greater threat with estimates suggesting a 10- to 25-fold higher risk of TB reactivation compared to the general population [5]. Kidney transplant recipients constitute another uniquely vulnerable cohort as the chronic immunosuppression necessary for graft maintenance further compounds the already impaired

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immune defenses inherent to uremia[6]. A study reported active TB incidence rates of 3.92 and 4.38 per 1,000 person-years in kidney transplant and dialysis groups respectively compared to only 0.67 per 1,000 person-years in the general population [7]. The diagnosis of latent tuberculosis infection (LTBI) in CKD patients is of paramount importance as timely identification and preventive therapy can substantially reduce the risk of progression to active disease, particularly in the pre- and post-transplant settings [8]. The tuberculin skin test (TST) also known as the Mantoux test, has historically served as the primary screening tool for LTBI. However, its utility in CKD patients is severely compromised by the high prevalence of cutaneous anergy, which results from the impaired cell-mediated immunity characteristic of uremia [9]. Studies have demonstrated that TST reactivity progressively declines with advancing CKD stages with anergy rates exceeding 40% in ESKD populations [10]. Furthermore, cross-reactivity with Bacille Calmette–Guérin (BCG) vaccination further diminishes the specificity of the TST in TB-endemic regions [11]. In response to these limitations, interferon-gamma release assays (IGRAs) have emerged as a superior alternative for LTBI screening in immunocompromised populations. The QuantiFERON-TB Gold Plus (QFT-Plus) assay, a fourth-generation IGRA, measures interferon-gamma production by both CD4+ and CD8+ T cells following stimulation with Mycobacterium tuberculosis-specific antigens (ESAT-6 and CFP-10) [12]. Unlike the TST, QFT-Plus requires only a single patient visit, is unaffected by prior BCG vaccination, and does not suffer from the booster effect or reader-dependent variability. Importantly, QFT-Plus has demonstrated favorable diagnostic performance in CKD and dialysis populations, with several studies reporting higher sensitivity and better correlation with TB risk factors compared to the TST [13]. Despite the growing evidence supporting IGRA-based screening in CKD patients, data from South Asian populations, particularly from Bangladesh—a country with a high TB burden—remain limited. Furthermore, comparative data on the performance of QFT-Plus versus the Mantoux test across different CKD management modalities (conservative management, hemodialysis, peritoneal dialysis, and kidney transplantation) are scarce. This study was therefore undertaken to compare the diagnostic utility of the QuantiFERON-TB Gold Plus assay with the Mantoux test and to determine the prevalence of latent tuberculosis infection among CKD patients attending a tertiary care hospital in Dhaka, Bangladesh.

This cross-sectional study was conducted at the Department of Nephrology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from January to December 2019. Adult patients with chronic kidney disease (CKD) attending both outpatient and inpatient departments were screened for eligibility.

Inclusion criteria: Patients aged ≥18 years of either sex, with creatinine clearance <15 mL/min/1.73 m^2 (CKD stage V), receiving maintenance hemodialysis or peritoneal dialysis for more than 3 months, or who were at least 1-month post-renal transplantation were included.

Exclusion criteria: Those with a prior history of tuberculosis or a previous Mantoux test were excluded from the study.

Study procedure: Following Institutional Review Board approval and written informed consent, participants were recruited via convenience purposive sampling. The sample size (n=94) was determined using the standard formula for comparative proportions [14], assuming 58% and 48% proportions under the alternative and null hypotheses, respectively, with 80% power and 95% confidence. The QuantiFERON-TB Gold Plus (QFT-Plus) assay was performed strictly per the manufacturer's instructions (Qiagen, Germany). Concurrently, the Mantoux test was administered using 0.1 mL purified protein derivative (PPD) intradermal, with induration ≥5 mm at 72 hours interpreted as positive. When clinically indicated, additional investigations including sputum acid-fast bacilli (AFB) smear/Gene pert, ascitic and pleural fluid analysis, and lymph node biopsy were performed.

Data analysis: Statistical analyses were performed using SPSS version 23 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Group comparisons utilized the unpaired t-test and Chi-square test, with a p-value <0.05 considered statistically significant.

Ethical clearance: The study protocol received formal approval from the Institutional Review Board of BSMMU. All participants or their legal guardians provided written informed consent. Anonymity and confidentiality of personal data were strictly maintained, and participants were assured of their right to withdraw from the study at any time without any adverse consequences.

RESULTS

A total of 94 patients with chronic kidney disease (CKD) were included in the study. The mean age was higher among participants with a positive QuantiFERON-TB Gold Plus (QFT) result than among those with a negative result (44.7 ± 11.9 vs. 40.8 ± 14.3 years), although the difference was not statistically significant (p = 0.171). Among participants who had received BCG vaccination, 38 (41.8%) were QFT-positive and 53 (58.2%) were QFT-negative. Of the three participants without BCG vaccination, two-thirds (66.7%) were QFT-positive. The association between BCG vaccination status and QFT positivity was not statistically significant (p = 0.391). A history of contact with TB patients was reported by 15 participants, among whom 8 (53.3%) were QFT-positive and 7 (46.7%) were QFT-negative. Among those without a history of TB contact, 32 (40.5%) were QFT-positive and 47 (59.5%) were QFT-negative (p= 0.357). Regarding CKD management 28 (29.8%) patients were managed conservatively, 36 (38.3%) were undergoing hemodialysis, 8 (8.5%) were receiving peritoneal dialysis and 22 (23.4%) were kidney transplant recipients. Overall, 40 (42.6%) participants had a positive QFT result, indicating latent tuberculosis infection (LTBI), whereas 54 (57.4%) were QFT-negative. The prevalence of QFT positivity was 28.6% among patients receiving conservative management 44.4% among those undergoing hemodialysis, 37.5% among those receiving peritoneal dialysis, and 59.1% among kidney transplant recipients. The highest proportion of LTBI was therefore observed among kidney transplant recipients (*Table III*). Comparison of QFT and Mantoux test results demonstrated that 14 participants were positive by both methods. Among the 40 QFT-positive participants, 14 (35.0%) were Mantoux-positive, while 26 (65.0%) were Mantoux-negative. All 54 QFT-negative participants were Mantoux-negative. Overall, 14 (14.9%) participants were Mantoux-positive and 80 (85.1%) were Mantoux-negative. The distribution of Mantoux results differed significantly according to QFT status (p< 0.001) (*Table V*).

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Table I: Demographic relationship with QuantiFERON-TB Gold plus

Variables	Category	n	QuantiFERON-TB Gold Plus Positive (n=40)	Negative (n=54)	p-value
Age (years), mean ± SD	—	94	44.7 ± 11.9	40.8 ± 14.3	0.171
BCG vaccination	Yes	91	38 (41.8%)	53 (58.2%)	0.391
	No	3	3 (66.7%)	1 (33.3%)	
History of contact with TB patients	Yes	15	8 (53.3%)	7 (46.7%)	0.357
	No	79	32 (40.5%)	47 (59.5%)	

Table II: Distribution of the study population according to management pattern (*n*=94)

Mode of renal replacement	Frequency	Percentage (%)
CKD-5 on conservative management	28	29.8
Hemodialysis	36	38.3
Peritoneal dialysis	8	8.5
Kidney transplant	22	23.4
Total	94	100.0

Table III: Prevalence of latent tuberculosis infection according to the mode of renal replacement therapy

Mode of Renal Replacement Therapy	N	Latent TB Infection Present, No. (%)	Latent TB Infection Absent, No. (%)
CKD-5 on conservative management	28	8 (28.6%)	20 (71.4%)
Hemodialysis	36	16 (44.4%)	20 (55.6%)
Peritoneal dialysis	8	3 (37.5%)	5 (62.5%)
Kidney transplant	22	13 (59.1%)	9 (40.9%)
Total	94	40 (42.6%)	54 (57.4%)

Table IV: Association of demographic and TB-related factors with QuantiFERON-TB Gold Plus positivity

Variable	QFT Positive (n=40)	QFT Negative (n=54)	p-value
Age, mean ± SD	44.7 ± 11.9	40.8 ± 14.3	0.171
BCG vaccinated	38 (41.8%)	53 (58.2%)	0.391
No BCG vaccination	3 (66.7%)	1 (33.3%)	
History of TB contact	8 (53.3%)	7 (46.7%)	0.357
No history of TB contact	32 (40.5%)	47 (59.5%)	

Table V: Comparison of QuantiFERON-TB Gold Plus and Mantoux test results

Variable	Mantoux Positive	Mantoux Negative	Total
QFT Positive	14	26	40
QFT Negative	0	54	54
Total	14	80	94

Statistical significance: $p < 0.001$

DISCUSSION

The present study evaluated tuberculosis infection among patients with stage 5 chronic kidney disease (CKD) managed by different treatment modalities and compared the performance of the QuantiFERON-TB Gold Plus (QFT-Plus) assay with the Mantoux tuberculin skin test. Among the 94 participants, 40 (42.6%) were QFT-Plus positive, whereas only 14 (14.9%) were Mantoux positive. The marked difference in positivity between the two tests suggests that QFT-Plus may identify a substantially larger proportion of patients with evidence of Mycobacterium tuberculosis infection in this high-risk CKD population. The overall QFT-Plus positivity of 42.6% observed in the present study is considerable and may be explained by the increased susceptibility to tuberculosis among patients with advanced CKD. Uremia is associated with impaired cellular immunity, altered T-cell function, chronic inflammation, and nutritional abnormalities, all of which may increase vulnerability to tuberculosis infection and reactivation. Previous studies have reported a higher prevalence of latent tuberculosis infection among patients with CKD and particularly among those receiving dialysis compared with the general population [8,11]. The relatively high prevalence observed in this study may also reflect the substantial background burden of tuberculosis in Bangladesh, a country with a high incidence of tuberculosis [14,15]. A notable finding was the difference between QFT-Plus and Mantoux test results. Of the 94 participants, 40 were QFT-Plus positive, compared with only 14 who were Mantoux positive. As shown in Table V, all 14 Mantoux-positive patients were also QFT-Plus positive, while 26 patients were QFT-Plus positive but

Mantoux negative. No participant demonstrated a Mantoux-positive/QFT-negative discordant result. Thus, 27.7% of the total study population showed QFT-Plus positivity despite a negative Mantoux test. The statistically significant difference between the two testing methods ($p<0.001$) indicates substantial discordance and suggests that reliance on the Mantoux test alone could potentially miss a considerable number of patients with evidence of tuberculosis infection. The lower Mantoux positivity observed in this study may be related to the impaired cell-mediated immune response associated with advanced CKD. Uremia can result in reduced T-cell proliferation and impaired delayed-type hypersensitivity responses, potentially leading to false-negative tuberculin skin test results [7,16]. Previous investigations have similarly reported lower Mantoux reactivity among CKD and dialysis populations compared with IGRA-based testing [12,17]. In contrast, QFT-Plus measures interferon-gamma responses to M. tuberculosis-specific antigens and is less affected by previous Bacillus Calmette–Guérin (BCG) vaccination than the tuberculin skin test. These characteristics may partly explain the higher positivity observed with QFT-Plus in the present population. The demographic analysis in Table I did not demonstrate statistically significant associations between QFT-Plus positivity and age, BCG vaccination status, or previous contact with tuberculosis patients. The mean age was 44.7± 11.9 years among QFT-positive participants compared with 40.8 ± 14.3 years among QFT- negative participants ($p=0.171$). Although QFT positivity was numerically higher among participants without BCG vaccination (66.7%) than among those who had received BCG vaccination (41.8%), the difference was not statistically significant ($p=0.391$). Similarly, participants reporting previous contact with tuberculosis patients had a QFT positivity rate of 53.3%, compared with 40.5% among those without a reported contact history ($p=0.357$). These findings suggest that, within this relatively small study population, the examined demographic and exposure variables were not significantly associated with QFT-Plus positivity. However, the small number of participants in some subgroups, particularly those without BCG vaccination, limits the statistical power for detecting associations. The distribution of participants according to renal replacement modality demonstrated that hemodialysis constituted the largest management group, comprising 36 (38.3%) participants, followed by conservative management in 28 (29.8%), kidney transplantation in 22 (23.4%), and peritoneal dialysis in 8 (8.5%). The prevalence of QFT-defined tuberculosis infection varied considerably across these treatment modalities. As shown in Table III, QFT positivity was highest among kidney transplant recipients, with 13 of 22 patients (59.1%) testing positive. This was followed by hemodialysis patients, among whom 16 of 36 (44.4%) were QFT positive. QFT positivity was observed in 3 of 8 (37.5%) patients receiving peritoneal dialysis and 8 of 28 (28.6%) patients receiving conservative management. The higher frequency of QFT positivity among kidney transplant recipients is clinically important. Transplant recipients require long-term immunosuppressive therapy, which can further compromise cellular immunity and increase the risk of reactivation of previously acquired tuberculosis infection [6,15]. Previous studies have demonstrated an increased risk of tuberculosis among solid-organ transplant recipients, particularly in countries where tuberculosis is endemic [9,19]. The 59.1% QFT positivity observed in the transplant group in the present study therefore emphasizes the importance of systematic tuberculosis screening before and after transplantation. However, the cross-sectional design of this study does not allow determination of whether QFT positivity represents newly acquired infection, remote infection, or reactivation. Among dialysis patients, QFT positivity was also relatively frequent. Hemodialysis patients demonstrated a positivity rate of 44.4%, compared with 37.5% among patients receiving peritoneal dialysis. Although the difference was numerically higher in the hemodialysis group, the small number of peritoneal dialysis participants limits meaningful comparison. Previous studies have reported increased tuberculosis risk among dialysis patients and have suggested that repeated healthcare exposure, prolonged disease duration, malnutrition, and impaired cellular immunity may contribute to this increased susceptibility [8,9,18]. An important observation in the present study was the progressive increase in QFT positivity from conservative CKD management to dialysis and transplantation. QFT positivity was 28.6% among patients receiving conservative management, 44.4% among hemodialysis patients, 37.5% among peritoneal dialysis patients, and 59.1% among kidney transplant recipients. The substantially greater number of QFT-Plus-positive/Mantoux-negative results indicates that the Mantoux test alone may underestimate the burden of tuberculosis infection in this population. This is particularly relevant before kidney transplantation, when identifying patients with latent infection may provide an opportunity for preventive management before the initiation or continuation of intensive immunosuppression. Current recommendations emphasize appropriate tuberculosis screening in high-risk patients, including those undergoing transplantation [15].

LIMITATIONS

The study was conducted at a single tertiary-care center and included a relatively small sample, particularly in the peritoneal dialysis subgroup.

CONCLUSION

QFT-Plus demonstrated substantially higher positivity than the Mantoux test among patients with stage 5 CKD, with 42.6% versus 14.9% positivity, respectively. The significant discordance, particularly the 26 patients who were QFT-positive but Mantoux-negative, suggests that Mantoux testing alone may fail to identify a considerable proportion of patients with evidence of tuberculosis infection. QFT positivity was highest among kidney transplant recipients, followed by hemodialysis patients, indicating an important burden of tuberculosis infection across advanced CKD management groups. These findings support consideration of IGRA-based testing as part of latent tuberculosis screening strategies in high-risk CKD populations, particularly in tuberculosis-endemic settings such as Bangladesh. Prospective multicenter studies with larger samples and longitudinal follow-up are needed to determine the predictive value of QFT-Plus for subsequent active tuberculosis and the clinical impact of IGRA-guided preventive treatment.

RECOMMENDATION

Routine QuantiFERON-TB Gold Plus screening should be implemented for all CKD patients, especially kidney transplant candidates and those on hemodialysis. Prospective multi-center studies with long-term follow-up are recommended to evaluate clinical outcomes of IGRA-guided preventive therapy.

CONFLICT OF INTEREST

The authors declare no conflicts of interest. No funding was received for this study. The corresponding author had full access to all data and final responsibility for the decision to submit for publication.

AI DECLARATION

Artificial intelligence tools contributed marginally to manuscript preparation and development. All core scientific content was human-verified.

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