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Original Article

Detecting Tuberculosis by Quantiferon TB Gold Plus Assay and its Comparison with Mantoux Test in Chronic Kidney Disease Patients

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ABSTRACT

Background: Patients with chronic kidney disease (CKD) are at increased risk of tuberculosis (TB) because of impaired cellular immunity associated with uraemia, dialysis, and immunosuppressive therapy following kidney transplantation. Conventional tuberculin skin testing using the Mantoux test may have limited sensitivity in immunocompromised patients. This study aimed to detect latent and active tuberculosis among CKD patients and compare the performance of the QuantiFERON-TB Gold Plus (QFT-Plus) assay with the Mantoux test. **Methods & Materials:** This cross-sectional study was conducted in the Department of Nephrology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from January to December 2019. A total of 103 adult CKD patients, including those receiving conservative management, hemodialysis, peritoneal dialysis, and kidney transplantation, were enrolled using purposive sampling. Demographic, clinical, and laboratory data were collected using a structured questionnaire. Participants were evaluated using QFT-Plus and the Mantoux test. Data were analyzed using SPSS version 23, and a p-value <0.05 was considered statistically significant. **Results:** Of the 103 participants, 54 (52.4%) had no evidence of TB, 40 (38.8%) had latent TB, and 9 (8.7%) had active TB disease. QFT-Plus was positive in 49 (47.6%) patients, whereas only 17 (16.5%) were Mantoux-positive. All Mantoux-positive patients were also QFT-positive; however, QFT-Plus identified an additional 32 (31.1%) patients who were Mantoux-negative (p<0.001). TB was significantly more frequent among kidney transplant recipients than among patients receiving conservative management (64.0% vs. 33.3%, p=0.023). **Conclusion:** Tuberculosis, particularly latent TB infection, was highly prevalent among patients with advanced CKD. QFT-Plus detected substantially more TB infection than the Mantoux test and may be a more useful screening tool in this immunocompromised population.

Keywords: *Chronic kidney disease, Latent tuberculosis, QuantiFERON-TB Gold Plus, Mantoux test, Renal replacement therapy.*

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INTRODUCTION

Tuberculosis (TB) remains one of the most important infectious diseases in the world. According to estimates by the World Health Organization (WHO), there were 5.7 million new cases in 2012 [1]. The pathophysiology of chronic kidney disease (CKD)- related immunodeficiency suggest that early-stage CKD could also be a risk factor for TB [2]. Immunodeficiency associated with CKD appears to be multifactorial in etiology [3]. Advanced CKD is associated with oxidative stress and inflammation, 25-hydroxyvitamin D deficiency and malnutrition with evidence of functional abnormalities in a variety of immune cells including B and T cells, neutrophils, monocytes and natural killer cells. Changes in immunity begin as early as stage 3 CKD (defined as a glomerular filtration rate <60ml/min per 1.73 m2) and worsen in later stages as kidney function deteriorates and waste products accumulate [4]. Active TB is an infectious complication that may develop and result from progression of Mycobacterium tuberculosis infection after recent exposure or reactivation of latent tuberculosis infection (LTBI). The presentation of TB in uremic patients is often quite unusual, insidious and diagnosis and management provide the treating physician with many special challenges [5]. In ESRD (End Stage Renal Disease), the diagnosis of TB disease is often difficult because of prevailing extra-pulmonary involvement and nonspecific symptoms. Extra-pulmonary TB has been reported in as many as 60% to 80% of cases, either alone or associated with pulmonary TB. The most common forms of presentation are lymphadenitis, gastrointestinal, bone, genitourinary, peritonitis, pleural effusion, pericardial effusion, miliary TB and pyrexia of unknown origin [6-8]. There is a (6.9 to 52.5) fold increase in the incidence of TB in dialysis patients compared to the general population which results from uremic immunodeficiency [9-12]. These patients have roughly (10 to 25) fold increased risk for reactivating LTBI when compared with the general population [10,13,14]. Hemodialysis itself may contribute to immune deficiency in ESRD patients through a pro-apoptotic effect due to direct blood contact with dialysis membranes that may affect the cell-mediated immune reactions [15]. Moreover, hemodialysis units themselves have been shown to be important centers for the spread of infectious TB Defects of the peritoneal immune system in patients on CAPD include a reduction of the concentration of macrophages and lymphocytes due to dilution of the intraperitoneal fluid and decreased phagocytosis and reduced cytokine production by the low pH and high lactate content of the PD fluid [15,16]. Risk in solid organ transplant recipients is estimated to be 20 to 74 times higher than the general population with a high mortality rate of up to 30%. Mortality of TB is higher in patients with disseminated disease, prior rejection and those who received anti-T cell antibody therapy [17]. The clinical presentation of TB in transplant recipients differs from the general population in that symptoms are more unusual and varied, often leading to a delay in diagnosis and poor outcomes [17,18]. The use of the tuberculin skin test (TST) remains controversial in patients with ESRD due to its high rate of false negative results. [19,20] Currently, interferon-gamma release assay (IGRA) is used as a diagnostic tool for LTBI [21]. IGRA has several advantages, including convenience

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and application in an immuno-compromised population BCG-vaccinated population and high non-tuberculous mycobacteria (NTM) prevalent area [22].

OBJECTIVES

General objective:

- To detect the presence of Tuberculosis in Chronic Kidney Disease (CKD) patients

Specific objective:

- To detect the presence of Latent Tuberculosis in CKD patients
- To detect the presence of Tuberculosis Disease in CKD patients
- To compare Quantiferon TB Gold Plus Assay with Mantoux test in CKD Patients

METHODS & MATERIALS

This was a cross-sectional study. The study was conducted in the Department of Nephrology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. The study was conducted from January 2019 to December 2019. Adult patients with chronic kidney disease (CKD) attending the outpatient and inpatient departments of the Department of Nephrology, Bangabandhu Sheikh Mujib Medical University (BSMMU), were evaluated for inclusion in the study. A convenient purposive sampling technique was used.

Inclusion Criteria

Patients were included if they met the following criteria:

- Age ≥18 years.
- Patients of either sex.
- Creatinine clearance <15 mL/min/1.73 m².
- Patients receiving maintenance hemodialysis for more than 3 months.
- Patients receiving peritoneal dialysis for more than 3 months.
- Patients who were at least 1 month after renal transplantation.

Exclusion Criteria

- Past history of tuberculosis.
- Previous Mantoux test.

Study Procedure: After obtaining approval from the Institutional Review Board (IRB), patients were recruited from the inpatient and outpatient departments of the Department of Nephrology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka. Written informed consent was obtained from all patients. Subjects were selected according to the predefined enrollment criteria, and all participants were fully informed about the study procedures.

Data Collection: Data were collected using a structured data collection form through detailed history taking, clinical examination, laboratory findings, and assessment of patient outcomes. The data were collected directly by the researcher.

Statistical Analysis: Computer-based statistical analysis was performed using appropriate statistical techniques. All data were systematically recorded in the data collection form. Quantitative variables were expressed as mean ± standard deviation (SD), whereas categorical variables were expressed as frequency and percentage. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 23 (SPSS Inc., Chicago, IL, USA). Associations between categorical variables were assessed using the Chi-square test. Comparisons of continuous variables between two groups were performed using the unpaired t-test. For all statistical tests, a p-value <0.05 was considered statistically significant.

Ethical Implications: Prior to the commencement of the study, the research protocol was approved by the Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka. The aims and objectives of the study, including the procedures, potential risks, and benefits, were explained to the patients or their legal guardians in an easily understandable local language. Written informed consent was obtained from each participant or, where applicable, from a legal guardian if the patient was incapacitated or incompetent. Participants were assured that all personal information and records would be kept confidential. The right of participants to withdraw from the study at any time during the thesis work was ensured without any adverse consequences.

RESULTS

A total of 103 patients with chronic kidney disease (CKD) were included. The findings are summarized in *Tables I–X* and *Figures 1–2*. The largest age groups were 31–40 years (n=28) and 51–60 years (n=27). The mean age was 40.8 ± 14.3 years in patients without TB, 44.7 ± 11.9 years in those with latent TB, and 45.1 ± 17.5 years in those with active TB. Of the participants, 71 (68.9%) were male and 32 (31.1%) were female. No significant association was found between sex and TB status (p=0.346). Similarly, residence was not significantly associated with TB status (p=0.403). *Figure 1* shows the distribution of TB status across BMI categories. The proportions of patients with no TB, latent TB, and active TB varied across the BMI groups. Glomerulonephritis was the most common underlying condition, affecting 45 (43.7%) patients, followed by diabetes mellitus in 38 (36.9%). Hypertension, ADPKD, and other causes accounted for 8 (7.8%), 2 (1.9%), and 10 (9.7%) patients, respectively. Hemodialysis was the most common management modality (40, 38.8%), followed by conservative management (30, 29.1%), kidney transplantation (25, 24.3%), and peritoneal dialysis (8, 7.8%). The mean age did not differ significantly between QFT-positive and QFT-negative patients (41.3 ± 13.6 vs. 39.4 ± 14.3 years; p=0.481). Neither BCG vaccination status (p=0.263) nor previous TB contact (p=0.132) was significantly associated with QFT results, although QFT positivity was higher among participants reporting previous TB contact. Overall, QFT-Plus detected TB infection more frequently than the Mantoux test. Forty-nine (47.6%) patients were QFT-positive compared with only 17 (16.5%) who were Mantoux-positive. QFT positivity was highest among kidney transplant recipients (64.0%), followed by hemodialysis patients (50.0%). Mantoux positivity was considerably lower, particularly among transplant recipients. Overall, 54 (52.4%) patients had no evidence of TB, 40 (38.8%) had latent TB, and 9 (8.7%) had active TB disease. Latent TB was most frequent among kidney transplant recipients, affecting 13 (52.0%) patients, while active TB was present in 3 (12.0%). TB prevalence was higher among hemodialysis patients than those receiving conservative management, although the difference was not significant (p=0.163). Similarly, no significant difference was observed between conservative management and peritoneal dialysis (p=0.825). In contrast, TB was significantly more common among kidney transplant recipients than among patients receiving conservative management (64.0% vs. 33.3%; p=0.023). *Figure 2* demonstrates the overall TB distribution in the study population. Latent TB represented the largest proportion of TB-related findings, followed by active TB disease. Comparison of the two diagnostic tests showed that all 17 Mantoux-positive patients were also QFT-positive. However, QFT-Plus identified an additional 32 patients who were Mantoux-negative. The difference between the two tests was statistically significant (p<0.001), indicating that QFT-Plus detected substantially more TB infection than the Mantoux test in this CKD population.

Table I
Distribution of Tuberculosis Status According to Demographic Characteristics Age Distribution.

Age group (years)	N	Normal, n (%)	Latent TB, n (%)	TB disease, n (%)	
18–30	22	15 (68.2%)	4 (18.2%)	3 (13.6%)	
31–40	28	15 (53.6%)	13 (46.4%)	0 (0.0%)	
41–50	19	10 (52.6%)	8 (42.1%)	1 (5.3%)	
51–60	27	10 (37.0%)	13 (48.1%)	4 (14.8%)	
>60	7	4 (57.1%)	2 (28.6%)	1 (14.3%)	
Mean ± SD	—	40.8 ± 14.3	44.7 ± 11.9	45.1 ± 17.5	
Sex					
Male	71	35 (49.3%)	28 (39.4%)	8 (11.3%)	0.346
Female	32	19 (59.4%)	12 (37.5%)	1 (3.1%)	
Residence					
Rural	55	31 (56.4%)	21 (38.2%)	3 (5.5%)	0.403
Urban	48	23 (47.9%)	19 (39.6%)	6 (12.5%)	

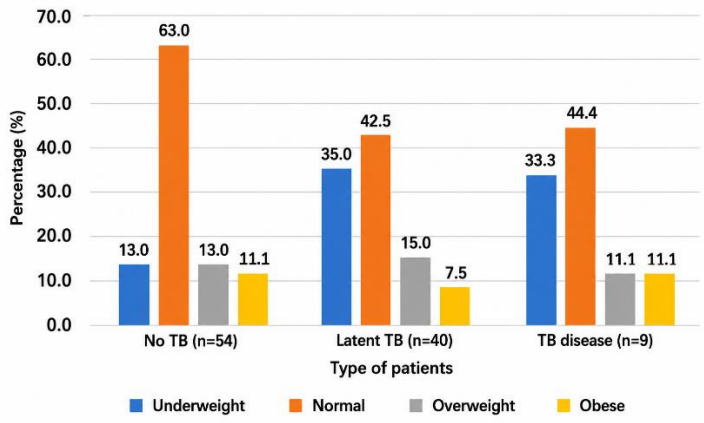


Figure 1 Tuberculosis Status According to BMI.

Table II
Distribution of Study Patients According to Etiology (*n*=103).

Comorbidities/Etiology	Frequency	Percentage (%)
Glomerulonephritis	45	43.7
Diabetes mellitus	38	36.9
Hypertension	8	7.8
ADPKD	2	1.9
Others	10	9.7
Total	103	100.0

Table III
Distribution of the Study Population According to Management Pattern (*n*=103).

Mode of Renal Replacement/Management	Frequency	Percentage (%)
CKD (V) on conservative management	30	29.1
Hemodialysis	40	38.8
Peritoneal dialysis	8	7.8
Kidney transplant	25	24.3
Total	103	100.0

Table IV
Demographic Relationship with QuantiFERON-TB Gold Plus Assay.

Variables	Category	N	QTF Positive	QTF Negative	p-value
Age (years), Mean ± SD	—	103	41.3 ± 13.6	39.4 ± 14.3	0.481
BCG vaccination	Yes	99	46 (46.5%)	53 (53.5%)	0.263
	No	4	3 (75.0%)	1 (25.0%)	
History of contact with TB patients	Yes	19	12 (63.2%)	7 (36.8%)	0.132
	No	84	37 (44.0%)	47 (56.0%)	

Table V
Comparison Between QuantiFERON-TB Gold Plus Assay and Mantoux Test Positivity According to Management Pattern (*n*=103).

Management Pattern	n	QuantiFERON Positive, n (%)	Mantoux Positive, n (%)
CKD (V) on conservative management	30	10 (33.3%)	7 (23.3%)
Hemodialysis	40	20 (50.0%)	6 (15.0%)
Peritoneal dialysis	8	3 (37.5%)	2 (25.0%)
Kidney transplant	25	16 (64.0%)	2 (8.0%)
Total	103	49 (47.6%)	17 (16.5%)

Table VI
Tuberculosis Status in the Study Population According to Management Pattern (*n*=103).

Management Pattern	n	No TB, n (%)	Latent TB, n (%)	TB Disease, n (%)
CKD (V) on conservative management	30	20 (66.7%)	8 (26.7%)	2 (6.7%)
Hemodialysis	40	20 (50.0%)	16 (40.0%)	4 (10.0%)
Peritoneal dialysis	8	5 (62.5%)	3 (37.5%)	0 (0.0%)
Kidney transplant	25	9 (36.0%)	13 (52.0%)	3 (12.0%)
Total	103	54 (52.4%)	40 (38.8%)	9 (8.7%)

Table VII
Comparison of Tuberculosis Status Between CKD (V) Conservative Management and Hemodialysis Groups (*n*=70).

Management Pattern	n	TB Present, n (%)	TB Absent, n (%)	p-value
CKD (V) on conservative management	30	10 (33.3%)	20 (66.7%)	0.163
Hemodialysis	40	20 (50.0%)	20 (50.0%)	

Table VIII
Comparison of Tuberculosis Status Between CKD (V) Conservative Management and Peritoneal Dialysis Groups (*n*=38).

Management Pattern	N	TB Present, n (%)	TB Absent, n (%)	p-value
CKD (V) on conservative management	30	10 (33.3%)	20 (66.7%)	0.825
Peritoneal dialysis	8	3 (37.5%)	5 (62.5%)	

Table IX
Comparison of Tuberculosis Status Between CKD (V) Conservative Management and Kidney Transplant Groups (*n*=55).

Management Pattern	N	TB Present, n (%)	TB Absent, n (%)	p-value
CKD (V) on conservative management	30	10 (33.3%)	20 (66.7%)	0.023*
Kidney transplant	25	16 (64.0%)	9 (36.0%)	

**Statistically significant*

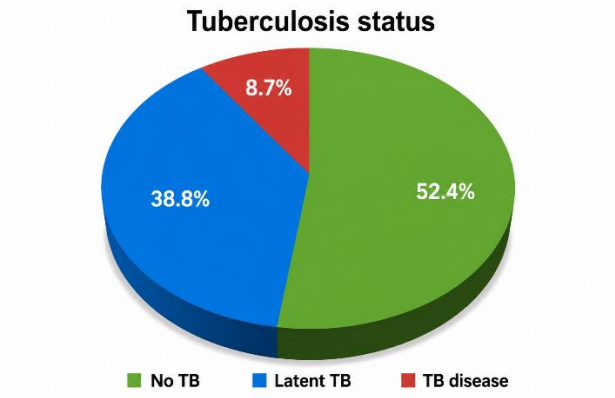


Figure 2 Tuberculosis Status in the Study Population (*n*=103).

Table X
Comparison of QuantiFERON-TB Gold Plus Assay with Mantoux Test in Detecting Tuberculosis in CKD Patients (*n*=103).

Mantoux Test	QuantiFERON Positive, n (%)	QuantiFERON Negative, n (%)	Total, n (%)	p-value
Positive	17 (16.5%)	0 (0.0%)	17 (16.5%)	
Negative	32 (31.1%)	54 (52.4%)	86 (83.5%)	<0.001*
Total	49 (47.6%)	54 (52.4%)	103 (100.0%)	

**Statistically significant.*

DISCUSSION

A total number of 103 patients were enrolled in this study of them 30 (29.1%) patients were CKD (v) on conservative management, 40 (38.8%) were CKD on maintenance hemodialysis, 8 (7.8%) were CKD on peritoneal dialysis and 25 (24.3%) were renal allograft recipient. The mean age of this study population was 40.8±14.3 years in No Tuberculosis group, 44.7±11.9 years in Latent TB group and 45.1±17.5 years in TB disease group. Tuberculosis is more common in advanced age. In our study underweight patients are more in Latent TB 14(35%) and TB disease 3 (33%) group in their study on hemodialysis patients found 27.3% patients had malnutrition which is quite similar to our study [23]. Malnutrition is associated with increased morbidity and mortality in dialysis patients. Several studies have documented malnutrition in 23% to 76% of patients on HD and in 18% to 50% of patients on peritoneal dialysis [24,25]. Total 99 (96.11%) study population were BCG vaccinated which is homogenous (97.8%) with Bangladesh demographic and health survey (2014). BCG vaccination status has no statistically significant difference on Quantiferon TB gold plus assay result in this study. Glomerulonephritis is the most common etiological factor in our study followed by Diabetes mellitus, Hypertension, ADPKD and others. In this study 54 (52.4%) patients have no Tuberculosis, 40 (38.8%) patients have latent TB, and 9(8.7%) patients suffered from TB disease in which pulmonary TB 4(3.88%) while extrapulmonary TB is (4.85%). Among extrapulmonary TB 2(40%) have pleural TB, 1(20%) Tuberculous ascites, 1(20%) bone marrow TB, 1(20%) tuberculous lymphadenopathy. Upma Narain & Arvind Gupta (2017) in their retrospective study found that the incidence of TB in nondialysis-requiring CKD group was 10.3% in which pulmonary TB was 3.9% while extrapulmonary TB was 6.4% which was similar to our findings [26]. In a study performed by Schachtner, T. and Reinke, P., 2017, in their study done on 190 hemodialysis patients from a country with an intermediate burden of TB has a high prevalence of latent TB using the QGIT (34.4%) [23]. In our study Latent TB in hemodialysis group is 16(40%) which is higher than previous study may be due to high TB burden in Bangladesh. Tuberculosis (TB) is a major public health problem in Bangladesh since long. Bangladesh ranks sixth among the 22 high TB burden countries. (Global Tuberculosis Report 2013) In this study 8(26.7%) CKD(v) on conservative management, 16(40%) of Hemodialysis patient, 3 (37.5%) of peritoneal dialysis patient and 13(52%) of Kidney transplant patients have Latent TB [1]. Chin-Chung Shu et al. (2015) in their study investigated latent tuberculosis infection (LTBI) in patient with severe CKD (estimated glomerular filtration rate <30ml/min/1.73m2) and patients undergoing dialysis found that dialysis patient (25%) have higher latent tuberculosis status then those with severe CKD (11%) [27]. This difference is more in our study may be due to high burden of TB in this country. The comparison of tuberculosis status in CKD (v) on conservative management with Kidney transplant group shows tuberculosis is more in kidney transplant group and the difference between the groups is statistically significant (p-value 0.023). Alev Atasever et al (2005) in their study they reviewed the record of 443 renal transplant recipients and found TB developed in 20 patients (4.5%) [28]. These rates are almost 10 times as high as the prevalence of TB in the general Turkish population (27 in 100 000) [29]. If the body immune mechanism is not seriously compromised, approximately 90% of the infected cases will not develop tuberculosis disease; in this case the bacilli usually remain dormant within the body. The remaining 10% of infected individuals will subsequently develop disease, half of them within 1-2 years after infection, the other half later in their life [30]. Active TB infection in transplant recipients can be due to airborne spread in the community or transmission with the transplanted organ, but the disease is believed to develop mainly because of the reactivation of an old, pre-existing focus [31]. Patients who receive kidney grafts are at an increased risk for the development of mycobacterial disease, because of uraemia and the immunosuppressants used in the post-transplant period, all of which interfere with T-cell function [32]. In our study Quantiferon TB gold plus assay and Mantoux test both are positive in 17(16.5%) patients while 54(52%) were negative for both tests. Moreover, 32 (31.1%) were Quantiferon TB gold plus assay positive but Mantoux test negative and there is no patient who are Mantoux test positive but Quantiferon TB gold plus assay negative. Difference between the results of the two groups are statistically significant (p-value- <0.001). Similar type of study was performed by G.Ates et al.(2009) found that Quantiferon TB gold assay is more useful method for screening latent TB in patients with ESRD[33]. The use of the tuberculin skin test (TST) remains controversial in patients with ESRD due to its high rate of false negative results [19,20]. Currently, interferon-gamma release assay (IGRA) is used as a diagnostic tool for LTBI [21]. IGRA has several advantages, including convenience and application in an immuno-compromised population BCG-vaccinated population and high non-tuberculous mycobacteria (NTM) prevalent area [34,35].

CONCLUSION

Presence of Latent TB and TB disease are high in both predialytic CKD, patient on dialysis and renal transplant patients. A good percentage of Mantoux test negative patient remains positive with Quantiferon TB Gold plus assay, a highly sensitive test to detect Tuberculosis in patients with CKD.

LIMITATIONS

There are some potential limitations of this study. The study was done in limited time span with a small sample size; subjects were collected from only one centre; hence it may not represent the whole population of the country.

RECOMMENDATION

Further long term multi-centered study with large sample size is to be recommended with long term follow up.

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