

Genitourinary Tuberculosis Diagnosis Using Urine GeneXpert: A Single-center Retrospective Study

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What's known on the subject? and What does the study add?

Genitourinary tuberculosis (GUTB), a significant form of extrapulmonary tuberculosis accounting for 8–15% of cases, poses diagnostic challenges owing to nonspecific symptoms such as flank pain and sterile pyuria, which mimic other urological conditions and often delay treatment. Conventional diagnostics, such as acid-fast bacilli (AFB) staining and culture, suffer from low sensitivity (10–20% and 10–90%, respectively) and slow turnaround times, whereas radiological imaging (computed tomography, intravenous pyelogram, retrograde pyelography, GUTB, ultrasonography) lacks specificity. Although histopathology is definitive, it is also invasive. The GeneXpert *Mycobacterium tuberculosis*/rifampicin assay, established for rapid pulmonary tuberculosis diagnosis with up to 88% sensitivity in sputum, has poorly characterized performance in urine for GUTB diagnosis. A study conducted in a tertiary care setting in India provides a comprehensive analysis of GUTB's clinical spectrum, diagnostic approaches, and management, demonstrating that urine GeneXpert offers a sensitivity of 52–57%, comparable to AFB culture (47–52%), supporting its role as a rapid diagnostic tool. The study also highlights the high diagnostic yield of radiological imaging (82.5%), and its complementary role with GeneXpert, alongside a notable 59% nephrectomy rate, emphasizing the need for early diagnosis to prevent complications. We advocate for multicenter studies to optimize urine-based GeneXpert protocols and refine GUTB diagnostic criteria, aiming to enhance diagnostic protocols by evaluating the sensitivity of GeneXpert against traditional AFB culture methods.

Abstract

Objective: Genitourinary tuberculosis (GUTB), a prevalent form of extrapulmonary tuberculosis, is challenging to diagnose because of non-specific symptoms, and the low sensitivity of conventional diagnostic tests. The GeneXpert *Mycobacterium tuberculosis* (MTB)/rifampicin (RIF) assay offers rapid detection, however, its performance in urine for GUTB diagnosis has not been well characterized. The objective is to evaluate the clinical spectrum, diagnostic approaches, and management of GUTB and assess the sensitivity of urine GeneXpert compared to acid-fast bacilli (AFB) culture.

Materials and Methods: We conducted a retrospective analysis of 42 GUTB cases diagnosed using South Indian Consensus criteria at a tertiary care hospital in India (March 2013–March 2019). Diagnostics included urine AFB staining, GeneXpert MTB/RIF, and culture (Löwenstein-Jensen and mycobacterial growth indicator tube). The clinical features, radiological findings (computed tomography, intravenous pyelogram, retrograde pyelography, GUTB, magnetic resonance imaging), histopathology, and treatment outcomes were evaluated for each patient. The sensitivities of GeneXpert and culture were calculated with 95% confidence intervals (CIs) for all cases.

Results: Among 42 patients (male: female ratio 1.1), 38% were in their fourth decade of life. Flank pain was predominant (52%; 22/42), and 27% had a history of tuberculosis. Urine AFB was positive in 12% (5/42) of samples, GeneXpert was positive in 57% (24/42; 95% CI: 41–72%), and culture was positive in 52% (22/42; 95% CI: 37–68%). In histopathologically confirmed cases (n=19), GeneXpert sensitivity was 52.6% (10/19; 95% CI: 29–76%) and culture sensitivity was 47.4% (9/19; 95% CI: 24–71%). Radiology suggested GUTB in 82.5% (35/42) of the cases, with renal involvement being the most common finding. Nephrectomy was performed in 59% (25/42) of the patients, and no rifampicin resistance was detected.

Conclusion: The sensitivity of GeneXpert in urine samples (52–57%) is comparable to that of AFB culture, offering a rapid diagnosis of GUTB. The integration of clinical and radiological data enhances diagnostic accuracy. Multicenter studies are needed to optimize urine-based protocols.

Keywords: Genitourinary tuberculosis, GeneXpert, AFB culture, extrapulmonary tuberculosis

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Introduction

Genitourinary tuberculosis (GUTB) accounts for 8-15% of extrapulmonary tuberculosis cases globally, second only to lymph node involvement (1). Prevalent in high-burden regions, GUTB affects the kidneys, ureters, bladder, and genital organs, often leading to severe complications such as renal failure or ureteric strictures, if undiagnosed (2). Its non-specific symptoms, such as flank pain, sterile pyuria, or hematuria, mimic urological disorders, delaying diagnosis (3). Conventional diagnostics, such as acid-fast bacilli (AFB) staining (sensitivity, 10-20%) and culture (sensitivity, 10-90%), are limited by their low sensitivity and long turnaround times (4,5). Radiological imaging techniques such as computed tomography (CT), intravenous pyelogram (IVP), retrograde pyelogram (RGP), and ultrasonography (USG) identify characteristic features such as calycectasis or putty kidney but lack specificity (6). Although histopathology is definitive, it is also invasive and resource-intensive.

The GeneXpert *Mycobacterium tuberculosis* (MTB)/rifampicin (RIF) assay, a real-time polymerase chain reaction (PCR) test, detects *Mycobacterium tuberculosis* and rifampicin resistance in <3 hours, with a sensitivity of up to 88% in sputum (7). However, its application in urine for GUTB is underexplored and potentially limited by intermittent mycobacterial shedding or urine inhibitors (8). Given the morbidity and diagnostic challenges of GUTB, the evaluation of rapid tools such as GeneXpert is critical.

Aims

To evaluate the clinical spectrum, diagnostic approaches, and management of GUTB and assess the sensitivity of urine GeneXpert compared to AFB culture.

Materials and Methods

This retrospective cohort study included 42 patients diagnosed with GUTB at a tertiary care hospital in India between March 2013 and March 2019. This study was approved by the Lokmanya Tilak Municipal Medical College and General Hospital Institutional Ethics Committee (approval number: IEC/2019/042, date: 08.06.2023). The requirement for informed consent was waived because of the retrospective nature of the study. Diagnosis adhered to the South Indian Consensus criteria (9) of requiring: one major criterion (granulomatous lesion on biopsy, an AFB in urine/tissue, or positive PCR) or two minor criteria [suggestive CT/IVP/RGP, hematuria, raised erythrocyte sedimentation rate (ESR), and prior tuberculosis history].

Data were extracted from medical records, including:

- Demographics included age and sex.

- Clinical features: Symptoms and history of tuberculosis.
- Laboratory: ESR (Westergren method).
- Urine analysis: Three early morning samples for AFB staining (Ziehl-Neelsen), GeneXpert MTB/RIF, and culture (Löwenstein-Jensen medium and mycobacterial growth indicator tube) (10).
- Imaging: CT, IVP, RGP for GUTB-specific findings (e.g., infundibular narrowing and moth-eaten ureters).
- Histopathology: Biopsy or surgical specimens of granulomatous lesions were obtained.

Patients received standard antitubercular therapy (ATT) as per the National Tuberculosis Elimination Program (11). Surgical interventions (e.g., nephrectomy and ureteric reimplantation) were also documented. Follow-up assessments were used to evaluate the treatment response and complications.

Statistical Analysis

Descriptive statistics (frequencies and percentages) were used to summarize clinical, radiological, and laboratory data. Analyses were performed using SPSS v25.0. The sensitivity of GeneXpert and AFB culture was calculated with 95% confidence intervals (CIs) using the Wilson score method for histopathologically confirmed cases of infection and all cases (clinical criteria).

Results

The cohort (22 males, 20 females; male-to-female ratio of 1.1) had a median age of 38 years (interquartile range 28-45), with 38% (16/42) in their fourth decade of life. Flank pain was the most common symptom (52%, 22/42), followed by lower urinary tract symptoms (28%, 12/42). Hematuria was rare (4.8%; 2/42). Prior tuberculosis or contact history was reported in 27% (11/42) of patients (Table 1).

Laboratory Findings

- Urine AFB staining: Positive in 12% (5/42; 95% CI 5-25).
- Urine GeneXpert: Positive in 57% (24/42; 95% CI 41-72%).
- Urine AFB culture: positive in 52% (22/42; 95% CI 37-68%).

Characteristic	n (%)
Flank pain	22 (52.4)
Lower urinary tract symptoms	12 (28.6)
Hematuria	2 (4.8)
Prior tuberculosis history	11 (26.2)
Sterile pyuria	20 (47.6)
Raised ESR (>20 mm/h)	20 (47.6)
ESR: Erythrocyte sedimentation rate	

- All AFB-positive cases (5/5) were GeneXpert-positive, showing a low mycobacterial load and no rifampicin resistance.
- ESR: Elevated (>20 mm/h) in 47.6% (20/42).

Imaging (e.g., CT/IVP/RGP/USG) suggested GUTB in 82.5% (35/42; 95% CI 68–91%), and renal involvement was noted in 71% (30/42) (Figure 1). Common findings included infundibular narrowing (45%), pipe-stem ureters (33%), and putty kidneys (21%) (Table 2).

The diagnostic performance (sensitivity) of the urine GeneXpert MTB/RIF and the AFB culture was evaluated for GUTB diagnosis (Table 3). Among 42 patients meeting the clinical criteria (South Indian Consensus), GeneXpert detected 57.1% of cases (24/42; 95% CI: 41–72%), slightly outperforming the AFB culture, which identified 52.4% (22/42; 95% CI: 37–68%). In a subset of 19 histopathologically confirmed cases, GeneXpert's sensitivity was 52.6% (10/19; 95% CI: 29–76%), whereas it was 47.4% (9/19; 95% CI: 24–71%) for AFB culture. These findings, calculated using the Wilson score method in SPSS v25.0, indicate comparable sensitivities between the two tests, with overlapping CIs suggesting no significant differences.

All patients received ATT. Nephrectomy was the most common surgery (59%; 25/42), followed by ureteric reimplantation (14%;

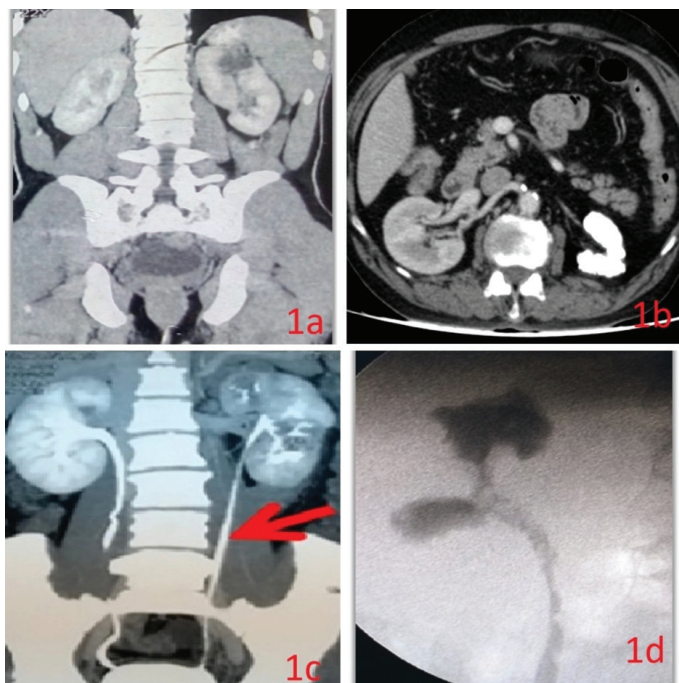


Figure 1. Imaging (CT/IVP/RGP) suggesting GUTB

1a. Left kidney showing Infundibular narrowing and calyctasis, 1b. Putty kidney, complete calcification of left kidney, 1c. Pipe stem ureter with dilated and irregular calyces with hiked up ureteric orifice, 1d. Moth eaten appearance on RGP with multiple strictures in ureter

CT: Computed tomography, IVP: Intravenous pyelography, RGP: Retrograde pyelography, Genitourinary tuberculosis

Radiological features (CT/IVP/RGP/USG)	Cases
Small contracted/thimble bladder	14
Non-functioning kidney	10
Pelvi ureteric junction narrowing	8
Pyelonephritis	5
Calyctasis	5
Infundibular stenosis	4
Urothelial thickening of pelvis and ureter	4
Vesico ureteric reflux	5
Ureteric stricture	2
Pipe stem ureter	2
Renal calcification/putty kidney	3
Adrenal calcification	2
Enlarged seminal vesicles	2

CT: Computed tomography, IVP: Intravenous pyelography, RGP: Retrograde pyelography, USG: Ultrasonography

Test	Clinical criteria (n=42) Sensitivity (95% CI)	Histopathologically (n=19) Sensitivity (95% CI)
AFB staining	11.9% (5–25%)	15.8% (4–42%)
GeneXpert	57.1% (41–72%)	52.6% (29–76%)
AFB culture	52.4% (37–68%)	47.4% (24–71%)

CI: Confidence interval, AFB: Acid-fast bacilli

6/42). A novel spiral cap augmentation technique has been used in selected cases (12). Overlapping pathologies necessitated multiple procedures in 19% (8/42) of patients.

Discussion

This study elucidates the clinical, diagnostic, and management profiles of GUTB, emphasizing the role of urine GeneXpert MTB/RIF in a high-burden setting. The predominance of flank pain (52%) aligns with Krishnamoorthy et al. (6), while Kapoor et al. (13) reported lower urinary tract symptoms as primary, reflecting GUTB's variable presentation. The low hematuria rate (4.8%) challenges its utility as a minor diagnostic criterion (9), suggesting the need to refine the diagnostic frameworks. The predominance of young adults (38% in the fourth decade) and equal sex distribution (1.1 ratio) in this cohort mirrors the patterns in endemic regions (1).

The low sensitivity (12%) of AFB staining confirms its limited role, consistent with Caviedes et al. (4). AFB culture, the gold standard, achieved 52% sensitivity within the reported 10–90% range (14); however, its 2–3-week turnaround delays treatment (4). The high yield (82.5%) of radiological imaging underscores

its diagnostic value, particularly for AFB-negative cases with renal involvement (71%) and findings such as pipe-stem ureters, consistent with prior studies (6). However, the non-specificity of imaging necessitates microbiological confirmation (15).

The sensitivity of urine GeneXpert (57% clinical, 52.6% histopathological) rivaled that of culture, supporting its use as a rapid first-line test. Its performance is comparable to that of the 50-60% reported by Koul et al. (8) in urine, but is lower than that of sputum-based studies (88%) (7). This discrepancy likely stems from intermittent mycobacterial shedding or urine inhibitors, as noted by Theron et al. (16). In our study, GeneXpert samples were obtained routinely during initial evaluation of patients. All AFB-positive cases were GeneXpert-positive, suggesting high reliability for high-burden samples. The absence of rifampicin resistance aligns with the low resistance in extrapulmonary tuberculosis (17), enhancing the therapeutic guidance of GeneXpert. However, the small sample size might have an influence on this result.

GeneXpert's rapid results (<3 hours,) enable earlier ATT initiation, potentially reducing complications such as renal loss, with a nephrectomy rate of 59%. Its integration with radiology, which detected GUTB in 82.5% of cases, forms a robust diagnostic algorithm, especially in resource-limited settings where histopathology is impractical. The South Indian Consensus criteria (9) were effective, with 45% of cases being histopathologically confirmed, validating their clinical utility.

Our GeneXpert sensitivity was lower than that of lymph node aspirate studies (76-97%) (18), reflecting the GUTB-specific challenges. The variability of culture (10.7-90%) across studies highlights the dependence on sample quality and disease stage (14). The high surgical burden, particularly nephrectomy, is consistent with that reported by Gow and Barbosa (14), emphasizing the need for early diagnosis to prevent irreversible damage. The novel spiral cap technique (12) adds a unique management perspective that may be applicable to complex cases.

GeneXpert is performed at our tertiary care public hospital facility free of cost with rapid results. This adds to the feasibility of doing such tests at an early stage, which in turn helps in early diagnosis and treatment. This helps prevent disease progression and potential long-term complications.

Study Limitations

The strengths of this study include its comprehensive evaluation of clinical, radiological, and microbiological data and the use of standardized diagnostic criteria. However, the small sample size (n=42) and single-center design are limiting factors for our study. The small sample size (n=42) limits generalization of our results to a larger population. The retrospective nature of the

study introduces potential selection bias, and the lack of a non-GUTB control group precludes a specific analysis. Variability in disease stage or organ involvement may influence sensitivity estimates, an aspect that has not yet been explored.

Multicenter studies with larger cohorts are essential to validate the performance of GeneXpert in urine samples and establish optimal sampling protocols. Our ongoing research investigates whether an increase in the number of urine samples (e.g., five vs. three) enhances the sensitivity. Comparative studies using advanced molecular assays (e.g., next-generation sequencing) could identify superior diagnostic methods. Cost-effectiveness analyses would inform the scalability of GeneXpert in low-resource settings. Integrating artificial intelligence with imaging and microbiological data may improve diagnostic precision and address the current limitations.

Conclusion

GUTB diagnosis requires a multifaceted approach that combines clinical suspicion, radiological evaluation, and microbiological confirmation. Urine GeneXpert (with 52-57% sensitivity comparable to AFB culture) offers rapid, actionable results, supporting its role as a first-line diagnostic tool. Early diagnosis with such tests can prevent potential complications occurring at a later stage of the disease, such as end-stage renal disease requiring nephrectomy. Its integration into clinical practice, along with imaging and standardized criteria, enhances diagnostic accuracy. Large-scale studies are needed to optimize urine-based protocols and reduce morbidity associated with GUTB in endemic regions.

Ethics

Ethics Committee Approval: This study was approved by the Lokmanya Tilak Municipal Medical College and General Hospital Institutional Ethics Committee (approval number: IEC/2019/042, date: 08.06.2023).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.H.S.A., S.S., V.P., A.S., P.P., A.A., S.N.K., V.B., Concept: S.S., Design: V.P., Data Collection or Processing: S.N.K., V.B., Analysis or Interpretation: A.S., P.P., Literature Search: A.A., Writing: M.H.S.A.

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