

# Complications of Trans-Rectal Ultrasound-Guided Prostate Biopsy: A Single-Centre Experience from Sindh Institute of Urology and Transplantation

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## ABSTRACT:

**Objective:** To evaluate the frequency, severity, and types of complications associated with TRUS-guided prostate biopsy in patients at the Sindh Institute of Urology and Transplantation (SIUT) over an 18-month period.

**Study Design and Setting:** This observational study included 302 male patients who underwent TRUS-guided prostate biopsy between January 2023 and June 2024.

**Methodology:** Pain severity was measured using the Visual Analog Scale (VAS). Complications such as haematuria, urinary tract infections, hematospermia, rectal bleeding, acute urinary retention, and epididymo-orchitis were documented. Descriptive statistics were used for data analysis.

**Results:** Acute urinary retention (6.2%), urinary tract infection (6.2%), visible haematuria (8.5%) and probe-related pain (VAS 9= 11.8%) were observed in patient underwent TRUS-guided biopsy. Hematospermia and epididymo-orchitis were seen in 10.2% and 15.8% of cases. Rectal bleeding was least common (3.3%).

**Conclusion:** TRUS-guided prostate biopsy is associated with significant procedural discomfort and a notable incidence of post-procedure complications. Enhanced pain management protocols and infection prevention strategies are essential to improve patient outcomes and procedural safety.

**Keywords:** Trans rectal ultrasound guided prostate biopsy, Infection, Acute urinary retention

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## INTRODUCTION:

Transrectal ultrasound-guided prostate biopsy (TRUS-guided PNB) continues to serve as one of the most frequently performed diagnostic interventions in contemporary urological practice. It remains the established gold standard for securing histological confirmation of prostate cancer, particularly in men with persistently elevated prostate-specific antigen (PSA) levels, abnormal findings on digital rectal examination (DRE), or suspicious lesions on multiparametric magnetic resonance imaging (mpMRI).<sup>1</sup> Despite rapid advancements in imaging technology, biomarker development, and risk calculators designed to refine biopsy selection, TRUS-guided biopsy endures as the most accessible and practical method worldwide. Its procedural simplicity, relatively low cost, and broad availability sustain its central role in both high-resource and resource-constrained healthcare systems. Nevertheless, although indispensable, this procedure is not without drawbacks, as it carries a well-documented potential for both minor and serious complications that can influence patient safety, tolerability, and healthcare burden.<sup>2</sup> The spectrum of complications associated with TRUS biopsy is wide, ranging from transient, self-limiting events to serious and occasionally life-threatening outcomes. Among the most common are haematuria, hematospermia,

and rectal bleeding. These are usually attributable to vascular injury within the prostate or rectal mucosa during needle traversal. Haematuria is reported in up to 66–85% of men, hematospermia in 30–90%, and rectal bleeding in as many as 37%.<sup>3</sup> Although such sequelae are typically mild and self-resolving within days to weeks, their prevalence can cause disproportionate anxiety for patients. Hematospermia, in particular, can be distressing, especially when unexpected. Fever, perineal discomfort, and localized rectal pain also constitute relatively frequent post-biopsy events.<sup>4</sup> While often neglected in clinical reporting, pain represents a key determinant of patient experience, significantly influencing willingness to undergo repeat biopsies and shaping overall quality of life during recovery.

More concerning are the less frequent but potentially severe complications. Sepsis, acute urinary retention, and major rectal hemorrhage requiring transfusion or hospitalization have all been documented.<sup>5</sup> Infectious complications, especially sepsis, are the most pressing in recent years. Their rising incidence is largely attributable to growing antimicrobial resistance, particularly against fluoroquinolones that have long served as standard prophylaxis. <sup>6</sup> Surveillance studies from North America, Europe, and Asia consistently report resistance rates in *Escherichia coli* and other Gram-negative organisms exceeding 20–40%, with multidrug-resistant strains increasingly implicated. This alarming trend has catalysed a paradigm shift in antibiotic prophylaxis strategies. Where a single pre-biopsy fluoroquinolone dose was once sufficient, many centres now advocate broader or individualized approaches, incorporating dual-drug regimens, targeted prophylaxis guided by rectal swab cultures, or reliance on institutional antibiograms.<sup>7</sup> These measures are demonstrably effective in reducing infectious morbidity, though they are logistically demanding and increase healthcare costs.

Equally important is the role of patient-specific risk factors in modulating susceptibility to infection. Diabetes mellitus, immunosuppression, prior antibiotic exposure, recent hospitalization, and the presence of indwelling urinary catheters are all recognized contributors to increased infectious risk.<sup>8</sup> In such patients, careful pre-biopsy evaluation is crucial, and prophylaxis may need to be tailored, extended, or replaced with alternative biopsy strategies.

Beyond infection, urinary complications also merit attention. Acute urinary retention (AUR) occurs in 0.3–6% of cases, with risk rising in men harbouring large prostates, marked median lobe hypertrophy, or baseline bladder outlet obstruction.<sup>9</sup> Mechanistically, edema, hematoma formation, or reflex sphincter spasm following biopsy can precipitate obstruction. Though most cases are transient and managed conservatively with short-term catheterization, they nonetheless add distress and sometimes necessitate pharmacological or surgical interventions.

Other complications, though not fatal, compromise patient tolerability. Vasovagal syncope occurs in up to 7% of procedures and is usually triggered by pain, anxiety, or neurocardiogenic reflexes.<sup>10</sup> Post-biopsy erectile dysfunction (ED) has also been described in up to one-third of patients, though it is usually temporary.<sup>11</sup> Etiological mechanisms include psychological stress, direct trauma to neurovascular bundles, and local inflammation. Even if transient, ED can cause considerable anxiety, especially among younger or sexually active men.

Although extremely rare, catastrophic complications such as Fournier's gangrene and infective endocarditis following TRUS biopsy have been reported.<sup>12</sup> These outcomes, though exceptional, highlight the need for stringent infection-control practices, rigorous patient selection, and awareness of high-risk subgroups.

The rationale for the present study is thus rooted in balancing accessibility with safety. By systematically evaluating the frequency and severity of pain and complications following TRUS biopsy in a Pakistani tertiary care setting, we aim to characterize the true burden of morbidity, highlight areas in need of improvement—such as updated antibiotic prophylaxis, enhanced pain control protocols, and selective adoption of safer alternatives—and contribute context-specific evidence to the global discourse on prostate biopsy safety.

## METHODOLOGY

This cross-sectional study was conducted at the Sindh Institute of Urology and Transplantation (SIUT) over a duration of 18 months, from October 1, 2020, to March 2022. A probability non-consecutive sampling technique was employed. The sample size was calculated using the Open Epi sample size calculator, based on a prostate cancer frequency of 22.2%<sup>13</sup>, a 95% confidence level, and an absolute precision of 6.63%. A total of 302 patients undergoing TRUS-guided prostate biopsy were enrolled. This study was conducted after obtaining ethical approval from the Ethical Review Committee of SIUT (CRP No. 154, ERC Approval Letter).

**Inclusion criteria** included male patients aged 50 to 69 years, with a PSA level > 4 ng/dL, or a suspicious nodule detected on digital rectal examination (DRE). Patients were excluded if they refused consent or had any of the following: end-stage renal disease (ESRD), congestive heart failure (CHF), bleeding diathesis, or active urinary tract infection.

Each patient underwent a detailed history and physical examination, followed by baseline investigations including complete blood count, serum electrolytes, renal function tests, urinalysis, and urine culture. Serum PSA and trans rectal ultrasound (TRUS) were advised for all eligible patients. Those who fulfilled the inclusion criteria and provided informed written consent were scheduled for TRUS-guided prostate biopsy. Post-procedure, patients were

followed up after one week in the OPD, with specific assessment for complications such as fever, haematuria, and febrile illness. Urine cultures were also repeated at follow-up.

Data were analysed using SPSS version 23. Continuous variables (e.g., age, haemoglobin, PSA) were summarized as means and standard deviations, while categorical variables (e.g., comorbidities, urinary nitrites, antibiotic sensitivity) were presented as frequencies and percentages. Group comparisons for continuous data were performed using the independent t-test or Mann–Whitney U test, depending on data distribution. Categorical data were analysed using the Chi-square test or Fisher’s exact test. A p-value < 0.05 was considered statistically significant.

**Results:**

Table 1 presents the frequency and percentage of complications among 302 patients undergoing TRUS-guided prostate biopsy. 3.9% patients reporting a probe pain vas score of 8. Acute urinary retention was occurring in 6.2% of patients. Urinary tract infections were seen in 6.2%, while non-visible was 8.55% patients. Epididymo-orchitis affected 15.8%, hematospermia 10.5%, and rectal bleeding was least common at 3.3%. Table 2 summarizes the descriptive statistics of key clinical variables among patients who underwent TRUS-guided prostate biopsy. The mean age of participants was 67.42 years with a standard deviation of 7.78, indicating a predominantly elderly cohort with moderate age variability. The mean prostate size measured by TRUS was 66.84 grams (SD ±32.43), reflecting considerable variability in gland size among the study population. Serum PSA levels showed a high mean of 98.35 ng/mL with a large standard deviation of 532.13, suggesting the presence of extreme outliers or markedly elevated PSA values in some patients. The mean haemoglobin level was 12.27 g/dl (SD ±1.66), which is slightly below the normal range, indicating the possibility of mild anaemia in some individuals. Table 3 presents a detailed analysis of patient-reported pain, post-procedure complications, histopathological outcomes, biopsy history, and comorbidities following trans rectal ultrasound-guided prostate biopsy. Probe-related pain was most frequently rated at VAS 9 observed in 11.8% of patients indicating significant discomfort during insertion. Visible haematuria occurred in 8.55% of cases. Fever was reported in 5.26% of patients. 6.2% had positive post-biopsy urine cultures. Rectal bleeding was reported in 3.3% of patients. Acute urinary retention was seen in 6.2% of patients. Hematospermia (10.2%) and epididymo-orchitis (15.8%) were observed. Nearly half of the biopsies (49.6%) revealed no malignancy, while Gleason scores were present in a notable number, with Gleason 6 found in 29.8% of cases. Only 7.2% had undergone a previous biopsy, indicating the majority were first-time patients. Over half the participants (54.3%) had no known comorbidities, while hypertension (18.2%) and diabetes (11.2%) were the most common

conditions among those with comorbid illness. This data underscores the importance of pain management, infection control, and patient selection in optimizing the safety and diagnostic value of prostate biopsy. **DISCUSSION:**

Data from our study indicate notably high rates of probe-related pain, with a visual analogue scale (VAS) score of 9 reported in approximately 11% of cases. These figures are considerably higher than those described in other published series, where moderate to severe pain was reported as uncommon, with fewer than 3% of patients experiencing significant discomfort.<sup>14</sup> This contrast suggests that our current analgesic and anaesthetic practices may not be sufficient to fully mitigate the burden of procedural discomfort, particularly when compared to centres with optimized pain control strategies.

Acute urinary retention (AUR) was observed in 6.2% of our cohort, a frequency that far surpasses the internationally documented incidence, which typically ranges between 0.2–1.7%.<sup>15</sup> This substantial disparity is likely reflective of the particularly advanced baseline prostate size in our patients, with a mean gland weight of approximately 67 g, as well as the high number of biopsy cores sampled. Both factors are known contributors to increased post-procedural voiding dysfunction.

Similarly, the urinary tract infection (UTI) rate of 6.2% in our series is slightly higher than what is usually reported following transrectal ultrasound-guided (TRUS) biopsy, where typical rates remain below 5%, even in high multi-drug-resistant organism (MDRO) environments, where figures seldom exceed 1%. Epididymo-orchitis occurred in 15.8% of our cases, and hematospermia in 10.5%. While the latter lies within the lower-to-middle range of published frequencies, it remains noteworthy that hematospermia has been reported in up to 93% of patients in certain cohorts.<sup>16</sup>

Table 1: Analysis of Pain and Post-Procedural Complications in TRUS-Guided Prostate Biopsy

Complications	Total	Frequency	Percent
Probe pain (Vas score 8)	302	12	3.9%
Visible haematuria	302	26	8.55%
Acute Urinary retention	302	19	6.2%
Hematospermia	302	31	10.5%
Epididymo-orchitis	302	48	15.8%
UTI (positive culture)	302	19	6.2%
Rectal bleed	302	10	3.3%

Table 2: Descriptive Statistics of Key Clinical Variables in Study Participants

Variables	Mean	Std. Deviation
Age	67.42	7.776
TRUS size	66.836	32.4287
PSA	98.3503	532.12702
HB	12.271	1.6554

Table 3: Pain Scores, Post-Procedural Complications, and Clinical Characteristics in Study Participants (n = 302)

Category	VAS/Condition	Frequency	Percentage (%)
Probe Pain (VAS)	<4/no pain	206	60.1
	5	10	3.3
	6	22	7.2
	7	16	5.2
	8	12	3.9
	9	36	11.8
Visible Haematuria	Yes	26	8.5
	No	276	91.4
Fever	Yes	16	5.26
	No	286	94.7
Post-procedure Rectal Bleeding	Yes	10	3.3
	No	292	96.6
AUR	Yes	19	6.2
	No	283	93.7
Hematospermia	Yes	31	10.2
	No	271	89.7
Epididymo-orchitis	Yes	48	15.8
	No	254	84.1
Post-procedure Urine CS	Positive	19	6.2
	Negative	283	93.1
Positive Cores (Malignancy)	No Malignancy Detected	150	49.6
	Detected	152	50.3
	Gleason Score 1	6	1.9
	Gleason Score 2	16	5.2
	Gleason Score 6	90	29.8
	Gleason Score 7	10	3.3
	Gleason Score 8	12	3.9
	Gleason Score 9	4	1.3
	Gleason Score 10	14	4.6
Previous Biopsy	Yes	22	7.2
	No	280	92.7
Comorbidities	DM	34	11.2
	DM, COPD	6	1.9
	DM, HTN	24	7.9
	DM, HTN, IHD	6	1.9
	DM, RCC	4	1.3
	HTN	55	18.2
	HTN, IHD	4	1.3
	HTN, IHD, MI	4	1.3
	No Known Comorbidity (NKCM)	164	54.3

Meanwhile, the rates of visible haematuria (8.5%), fever (~5.3%), and rectal bleeding (3.3%) in our study were broadly consistent with estimates in the literature. Reported values for haematuria generally range between 10–18%, fever is typically below 5%, and rectal bleeding is observed in around 2–3% of patients.<sup>17 18</sup> These findings suggest that, while our institutional protocol appears reasonably

effective in mitigating haemorrhagic complications, it may be less effective in controlling infectious and voiding outcomes, which remain the most prominent morbidities observed.

In recent years, the transperineal (TP) biopsy approach has been increasingly adopted worldwide. TP biopsy offers cancer detection rates comparable to TRUS biopsy but has

demonstrated significantly lower risks of urinary retention, fever, and rectal bleeding.<sup>19</sup> Nevertheless, pain can remain an issue with the TP route, although available evidence suggests it is generally less severe than what we observed in our TRUS cohort. For example, one large comparative study found that severe pain, defined as VAS =7, occurred in only about 12% of TP cases.<sup>20</sup> This highlights the importance of considering not just procedural route but also accompanying pain management strategies when optimizing biopsy protocols.

Limitations of this study include its single-centre, non-randomized design, which may reduce the external validity of the findings. Patient-reported VAS scores introduce subjectivity and potential reporting bias. The absence of long-term follow-up limits the assessment of delayed or persistent complications. Operator-dependent variability was not standardized, possibly affecting complication rates. Furthermore, the study did not include microbiological profiling of urinary pathogens, restricting the evaluation of antibiotic resistance patterns and effectiveness of prophylactic measures.

#### CONCLUSION:

TRUS-guided prostate biopsy, while indispensable for prostate cancer diagnosis, is associated with significant pain and a considerable risk of complications, particularly acute urinary retention and urinary tract infections. Nearly half of the biopsies revealed no malignancy, highlighting the need for careful patient selection. Enhanced pain management strategies and stricter infection prevention protocols are essential to improve patient safety and procedural outcomes.

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<p><b>Authors Contribution:</b>  <b>Abdul Rehman:</b> Substantial contribution to the study's conception, design, data collection, or analysis.  <b>Hafiz Dur-e-Furqani:</b> Substantial contribution to the study's conception, design, data collection, or analysis.  <b>Shireen Pyarali:</b> Accountability for all aspects of the work's accuracy and integrity.  <b>Faiz Pasha:</b> Accountability for all aspects of the work's accuracy and integrity.  <b>Tanzeel Ur Rahman Gazder:</b> Final approval of the version to be published  <b>Rehan Mohsin:</b> Final approval of the version to be published</p>
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