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PROSTATE BIOPSY-RELATED SEPSIS: EPIDEMIOLOGY, RISK STRATIFICATION, AND PREVENTION STRATEGIES

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ABSTRACT

Prostate biopsy remains an essential diagnostic procedure for confirming prostate cancer; however, biopsy-related infectious complications can result in emergency department visits, hospitalization, sepsis, and, rarely, septic shock. The infectious risk is particularly relevant to the transrectal approach, in which the biopsy needle traverses the rectal mucosa and can introduce enteric organisms into prostatic tissue and the bloodstream. The transition from transrectal to transperineal biopsy is the most important contemporary procedural development in infection prevention. Transperineal biopsy avoids direct traversal of the rectal mucosa and is associated with a lower infectious burden. Randomized evidence also indicates that transperineal biopsy can be performed under local anesthesia, and selected patients may undergo the procedure without antibiotic prophylaxis. When transrectal biopsy remains necessary, prevention should be based on local resistance patterns and individual risk, with consideration of rectal povidone-iodine preparation and targeted or otherwise appropriately selected antimicrobial prophylaxis. Management of suspected post-biopsy sepsis requires prompt recognition, microbiological sampling, early empiric antimicrobial therapy, assessment and treatment of organ dysfunction, appropriate fluid and vasopressor therapy when indicated, source control when necessary, and subsequent antimicrobial de-escalation according to microbiological results.

KEYWORDS

Prostate Biopsy, Sepsis, Urosepsis, Transrectal Biopsy, Transperineal Biopsy, Infectious Complications, Antibiotic Prophylaxis, Antimicrobial Resistance, Fluoroquinolone Resistance, Prostate Cancer

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Introduction

Prostate biopsy remains a central component of the diagnostic pathway for men with suspected prostate cancer. Advances in prostate-specific antigen testing, multiparametric magnetic resonance imaging, biomarkers, and risk assessment have reduced unnecessary biopsies, but histopathological confirmation remains necessary in many patients before definitive treatment. [1]

The two principal biopsy approaches are transrectal (TR) and transperineal (TP). Historically, transrectal ultrasound-guided biopsy became dominant because it is technically straightforward and can be performed under local anesthesia. However, passage of the needle through the rectal wall exposes the procedure to enteric flora and creates a route for bacterial inoculation. Increasing antimicrobial resistance has made this limitation increasingly important. [2]

Post-biopsy infectious complications range from urinary tract infection and acute bacterial prostatitis to bacteremia, sepsis, and septic shock. Although severe events are uncommon, they can lead to emergency evaluation, hospitalization, intensive care, substantial healthcare costs, and, rarely, death. [3]

Methodology

This narrative review was based on a focused search of PubMed/MEDLINE for literature addressing prostate biopsy-related infectious complications, sepsis, risk factors, antimicrobial resistance, and prevention strategies. Search terms included prostate biopsy, transrectal biopsy, transperineal biopsy, sepsis, infectious complications, antibiotic prophylaxis, fluoroquinolone resistance, rectal swab, targeted prophylaxis, povidone-iodine, fosfomycin, and antimicrobial resistance. Priority was given to systematic reviews, meta-analyses, randomized controlled trials, prospective studies, large population-based cohorts, and major guideline or position papers. Findings were synthesized narratively, with emphasis on clinically relevant outcomes, differences between biopsy approaches, patient-specific risk factors, local resistance patterns, and the strength and limitations of available preventive interventions.

Epidemiology of Prostate Biopsy-Related Infection

Overall Infectious Burden. The frequency of infectious complications following prostate biopsy varies substantially among studies. In the largest systematic review of 165 studies involving 162,577 patients, the standardized prevalence of sepsis was 0.8% after transrectal biopsy and 0.1% after transperineal biopsy; standardized hospitalization prevalence was 1.1% and 0.9%, respectively. These estimates should be interpreted in the context of substantial heterogeneity in biopsy technique, prophylaxis, outcome definitions, and study populations. [5] More recent U.S. population-level data identified 301,733 prostate biopsies performed between 2012 and 2021, of which 2,587 were followed by sepsis within 14 days. The sepsis proportion increased from 0.6% in 2012 to 1.1% in 2016 and subsequently declined to 0.7% in 2021. The authors observed that the decline occurred alongside reduced use of single-agent fluoroquinolone prophylaxis and increased use of multi-agent prophylaxis. [6] In a contemporary Swedish nationwide cohort of 31,222 men biopsied between 2020 and 2023, infection-related hospitalization occurred in 2.0% after transrectal biopsy compared with 0.6% after transperineal biopsy, further supporting a lower infectious burden with the transperineal route. [7]

Microbiology and Pathogen Spectrum. The microbiological profile of post-biopsy infection is strongly associated with the transrectal route. Enteric Gram-negative organisms, particularly *Escherichia coli*, are the predominant pathogens reported in bacteremic and severe infectious complications. In a European randomized screening cohort, *E. coli* was the predominant organism among available positive blood cultures. [8]

Fluoroquinolone-resistant rectal colonization is an important determinant of infectious risk after transrectal biopsy. In a multicenter cohort of 2,673 men, 20.5% had fluoroquinolone-resistant rectal cultures; resistant colonization was associated with post-biopsy infection (6.6% vs 1.6%) and hospitalization (4.4% vs 0.9%). [9]

The prevalence of ESBL-producing organisms varies substantially between populations and should not be represented by a single universal percentage. For example, one prospective study reported ESBL-producing organisms in 12.5% of rectal cultures, with quinolone resistance in 18%. Local surveillance is therefore more clinically useful than applying a fixed prevalence estimate to all biopsy populations. [10]

Risk Factors for Post-Biopsy Infection and Sepsis

Diabetes Mellitus. Diabetes mellitus is a repeatedly identified risk factor for post-biopsy infection. In a population-based Swedish study, diabetes was independently associated with infection after transrectal biopsy, with reported odds ratios in the range of 1.5-2.5 depending on the analysis. Earlier prospective data also identified diabetes as a risk factor for post-biopsy fever. The biological mechanisms are likely multifactorial and include impaired host defense and increased risk of urinary and rectal colonization. However, specific HbA1c thresholds for biopsy-related infection have not been validated sufficiently to define a universal high-risk cutoff. [13]

Previous Antibiotic Exposure. Recent antibiotic exposure is consistently associated with increased risk of post-biopsy infection and/or resistant rectal flora. A systematic review identified antibiotic exposure as a significant risk factor. In a clinical cohort, antibiotic use within the preceding 4 weeks was associated with a fourfold relative risk of infection requiring hospitalization. The effect is clinically relevant because antimicrobial exposure can select for organisms resistant to the prophylactic agent. [14]

Previous Urinary Tract Infection or Prostatitis. Previous urogenital infection, bacteriuria, and treatment for urinary tract infection have been identified as risk factors for post-biopsy infection. The 2024 Swedish population-based study confirmed diabetes and previous UTI as important predictors of infection after transrectal biopsy. Active symptomatic urinary infection should generally be evaluated and treated before an elective biopsy. [15]

Rectal Colonization with Resistant Bacteria. Fluoroquinolone-resistant rectal colonization is a particularly important risk factor for transrectal biopsy. Liss et al. found that resistant colonization was associated with substantially higher odds of infection and hospitalization. The prevalence of resistance varies by geography and population; therefore, local data or prebiopsy culture may be preferable to assuming a fixed prevalence. [16]

International Travel and Healthcare Exposure. Recent international travel and healthcare exposure have been associated with increased risk of post-biopsy infection, particularly when they increase the likelihood of colonization with resistant organisms. In one cohort, recent international travel and antibiotic use were independently associated with infection requiring hospitalization, with relative risks of 2.7 and 4.0, respectively. These findings support incorporating travel and recent healthcare exposure into individualized risk assessment. [17]

Indwelling Urinary Catheter and Urinary Obstruction. Indwelling catheterization and urinary dysfunction may increase the risk of infection after transrectal biopsy. In a retrospective cohort of 1,203 men, preoperative catheterization, diabetes, and higher BMI were independent risk factors for infectious complications. The magnitude of risk should be interpreted cautiously because catheterization may also reflect underlying urinary tract pathology. [18]

Obesity and Other Comorbidities. Obesity has been associated with infectious complications in some cohorts. Wu et al. reported BMI, diabetes, and preoperative catheterization as independent predictors of infection. Other factors, including immunosuppression, chronic corticosteroid therapy, chronic kidney disease, and frailty, may plausibly influence risk, but evidence specific to prostate biopsy is less consistent and does not support universally defined thresholds. [19]

Procedure-Related Risk Factors

The biopsy approach is a major procedural determinant of infection risk, with transrectal biopsy consistently showing a greater infectious burden than transperineal biopsy in large comparative datasets. Higher operator volume has also been associated with lower infection rates in U.S. population-based data; surgeons performing approximately 25 biopsies annually had lower odds of post-biopsy infection than surgeons performing one biopsy annually. Evidence linking the absolute number of cores to sepsis is less consistent, and a universal threshold such as >12 cores should not be presented as an established risk cutoff. [20,21]

Practical Risk Stratification Schema

Lower-Risk Patients. A lower-risk profile is characterized by absence of active urinary infection, no known resistant organism colonization, no recent antibiotic exposure or hospitalization, no relevant history of resistant infection, and no major uncontrolled comorbidity. Risk assessment should be individualized rather than based on a single validated score. [22,23]

Intermediate-Risk Patients. Patients with diabetes, previous UTI, recent antibiotic exposure, recurrent urinary symptoms, significant urinary dysfunction, previous biopsy, or repeated healthcare exposure may warrant additional preventive consideration, particularly if a transrectal approach is planned. [24]

High-Risk Patients. Higher-risk features include previous post-biopsy sepsis, known fluoroquinolone-resistant or ESBL-producing colonization, recent hospitalization or broad-spectrum antibiotic exposure, recurrent or complicated UTI, indwelling catheterization, and significant immunosuppression. These factors should prompt consideration of a transperineal approach and, if transrectal biopsy is unavoidable, individualized antimicrobial planning. Fixed criteria such as HbA1c >8%, CD4 <200 cells/ μ L, or a specific travel interval have not been validated as universal prostate-biopsy risk thresholds and should therefore not be treated as formal scoring criteria. [25]

Prevention Strategies

1. **Selection of Biopsy Approach: Prioritizing Transperineal Biopsy.** The strongest procedural strategy for reducing infection is avoidance of the rectal route. The EAU position paper supports transperineal biopsy because of its lower infectious risk. Contemporary randomized and population-based evidence supports this approach. [26]

The PREVENT randomized trial enrolled 658 biopsy-naïve participants and compared transperineal biopsy without antibiotic prophylaxis with transrectal biopsy using targeted prophylaxis. No infections occurred in the transperineal group, whereas four infections (1.4%) occurred in the transrectal group; cancer detection was comparable between groups. [27]

Transperineal biopsy can be performed under local anesthesia. In a series of 1,287 patients, Stefanova et al. reported a 49.8% overall cancer detection rate, 0.3% infection-suggestive lower urinary tract symptoms with only one positive urine culture, and no sepsis-related admissions. These data support feasibility, although observational series should not be interpreted as proof that sepsis is impossible. [28]

2. **Antibiotic Prophylaxis.** For transrectal biopsy, antimicrobial prophylaxis remains an important component of infection prevention. Evidence supports prophylaxis compared with no prophylaxis, but the optimal regimen depends on local resistance patterns and patient-specific risk. Prolonged or broad-spectrum prophylaxis should be avoided when a narrower effective strategy is available. [29]

Specific drug choices and doses should follow current local institutional protocols, antimicrobial susceptibility patterns, allergy history, renal function, and national regulations. A single universal regimen or fluoroquinolone-resistance threshold should not be presented as applicable to all settings.

3. **Targeted Prophylaxis Using Rectal Swab Culture.** Culture-directed prophylaxis identifies resistant rectal flora before transrectal biopsy and allows prophylaxis to be selected according to susceptibility. In a prospective study of 247 men, 41.7% carried fluoroquinolone-resistant *E. coli*; only two patients developed post-biopsy fever and none developed sepsis after culture-directed prophylaxis. A 2025 randomized multicenter study similarly found a low overall rate of acute prostatitis (1.1%) with a selective culture-based strategy, although the study population had a relatively low baseline infectious risk.

Systematic-review evidence supports targeted prophylaxis as a potential strategy, but its effectiveness varies among studies and it does not eliminate infection completely. [30]

4. **Rectal Povidone-Iodine Preparation and Antisepsis.** Rectal povidone-iodine preparation is supported by randomized trials and meta-analyses as an adjunct to antimicrobial prophylaxis for transrectal biopsy. The exact concentration, delivery method, timing, and duration vary between studies; therefore, a single universal preparation such as a 1,000-2,000 mg suppository administered 15-30 minutes before biopsy should not be presented as a standard evidence-based protocol.

5. **Augmented Prophylaxis for Selected Patients.** Augmented prophylaxis combines agents with complementary activity spectra. In a retrospective cohort, adding a dose of intramuscular gentamicin to a standard three-day regimen was associated with a reduction in infection-related hospitalization from 3.8% to 0.6%. However, these findings are context-specific and observational; broader prophylaxis increases antimicrobial exposure and selection pressure. Augmentation should therefore be guided by local resistance patterns and individual risk rather than applied universally.

6. **Fosfomycin as a Fluoroquinolone-Sparing Alternative.** Fosfomycin has been evaluated as an alternative to fluoroquinolone prophylaxis for transrectal biopsy, particularly in patients with fluoroquinolone-resistant rectal flora. A randomized study evaluated switching to fosfomycin when resistant organisms were identified. Another randomized study comparing two fosfomycin dosing schedules found no significant

difference between the regimens and reported low rates of febrile complications. Fosfomycin may therefore be considered in selected settings, but dosing should follow the validated local protocol rather than be presented as a universal 3-g regimen.

7. **Procedural and Technical Optimization.** Technical interventions include rectal antisepsis, needle disinfection, and other procedural modifications. An external validation study of an alcohol needle-washing protocol found that the intervention was associated with reduced post-biopsy sepsis, but this evidence remains observational. Povidone-iodine rectal preparation has stronger randomized evidence. Routine enemas have not consistently demonstrated the same level of benefit.

Management of Post-Biopsy Infection and Sepsis

Clinical Presentation and Recognition. Patients should receive clear safety-netting instructions to seek urgent medical assessment for fever, rigors, dysuria, urinary frequency or urgency, pelvic or perineal pain, malaise, hypotension, confusion, tachycardia, reduced urine output, or other features of systemic infection. The timing of presentation can vary, and clinicians should maintain suspicion for infection even when symptoms occur several days after biopsy.

Initial Assessment. Assessment should include vital signs, evaluation for organ dysfunction, renal function, blood count, urinalysis, urine culture, and blood cultures in patients with suspected sepsis when obtaining cultures will not delay antimicrobial therapy. Serum lactate is appropriate in patients with suspected sepsis or hypoperfusion. Imaging should be considered when there is concern for a prostatic abscess, urinary obstruction, persistent bacteremia, or failure to improve with appropriate treatment.

Empirical Antimicrobial Therapy. Empirical antimicrobial therapy should be initiated promptly in patients with suspected sepsis and should reflect local resistance patterns, recent antimicrobial exposure, previous cultures, allergy history, renal function, and the biopsy approach. Because fluoroquinolone-resistant *E. coli* is an important cause of post-transrectal biopsy infection, fluoroquinolone monotherapy should not automatically be assumed to provide adequate coverage in severe infection. For mild urinary infection or prostatitis, oral therapy may be appropriate in selected clinically stable patients; severe infection or sepsis generally requires intravenous therapy. The exact empirical regimen should be determined by local antibiograms and institutional sepsis protocols rather than by a single universal prostate-biopsy regimen. Therapy should be narrowed once culture and susceptibility results are available.

Supportive Care and Source Control. Patients with sepsis should be managed according to established sepsis principles, including appropriate crystalloid resuscitation when indicated, vasopressor support for persistent hypotension, monitoring for organ dysfunction, and timely source control. The Surviving Sepsis Campaign recommends an individualized approach to fluid administration rather than indiscriminate large-volume resuscitation in every patient. Persistent fever or bacteremia despite appropriate therapy should prompt reassessment for complications such as prostatic abscess or obstruction.

Antimicrobial Stewardship and Resistance Prevention

The evolution of prostate biopsy practice illustrates the tension between individual patient protection and population-level antimicrobial stewardship. Increasing antimicrobial resistance limits the long-term sustainability of simply broadening or prolonging prophylaxis.

The transperineal approach provides a procedural alternative by avoiding direct rectal contamination. In selected patients undergoing transperineal biopsy, randomized and meta-analytic data suggest that antibiotic prophylaxis can potentially be omitted without increasing infectious complications, although current guideline recommendations and institutional practice vary. [31]

Contemporary Guidelines and Recommendations

European Association of Urology (EAU) Recommendations. The EAU position paper recommends the transperineal route because of its lower infectious risk and supports appropriate prophylaxis and rectal antisepsis when the transrectal route is used. Recommendations should be interpreted alongside newer randomized and meta-analytic evidence, particularly regarding antibiotic omission for selected transperineal procedures.

American Urological Association (AUA) Recommendations. The AUA/SUO guideline recognizes both transperineal and transrectal biopsy techniques and emphasizes biopsy technique as part of a broader strategy to improve safety and diagnostic performance. Antibiotic selection for transrectal biopsy should follow local antimicrobial susceptibility patterns and current institutional guidance.

Emerging Strategies and Future Directions

Advanced Diagnostic Techniques. Rapid molecular detection of resistant organisms and other microbiological approaches may eventually permit more individualized prophylaxis, but these methods remain investigational and are not yet standard components of prostate biopsy pathways.

Novel Prophylactic Approaches. Fosfomycin-based strategies, selective targeted prophylaxis, procedural antisepsis, and antibiotic-sparing transperineal protocols continue to be evaluated. Future studies should prioritize standardized definitions of infection and sepsis, patient-level risk prediction, and antimicrobial stewardship outcomes.

Institutional Quality Improvement Initiatives. Healthcare systems should consider standardized prebiopsy risk assessment, local antibiogram surveillance, monitoring of post-biopsy infections and resistant organisms, transition pathways toward transperineal biopsy, and clear post-biopsy safety-netting. Continuous audit is essential because local resistance patterns and infection rates can change over time.

Conclusions

Prostate biopsy-related sepsis is an uncommon but potentially serious complication. The infectious burden is consistently higher with the transrectal approach, particularly in settings with substantial antimicrobial resistance. Important risk factors include diabetes mellitus, previous urinary infection, recent antibiotic exposure, resistant rectal colonization, recent healthcare exposure, international travel, urinary catheterization, and selected comorbidities. Risk stratification should inform the biopsy route and, when transrectal biopsy is used, the choice of prophylactic strategy.

The most important preventive development is the increasing use of transperineal biopsy, which provides comparable cancer detection with a lower infectious burden. For transrectal biopsy, targeted prophylaxis, appropriate antimicrobial selection, and rectal povidone-iodine preparation can reduce infectious complications, but no prophylactic strategy completely eliminates risk.

Management of suspected post-biopsy sepsis requires rapid recognition, microbiological sampling, prompt empiric antimicrobial treatment, appropriate hemodynamic support, and subsequent de-escalation based on culture results. Overall, contemporary practice should move toward a model centered on transperineal biopsy, individualized risk stratification, evidence-based infection prevention, antimicrobial stewardship, and rapid recognition and treatment of post-procedural sepsis.

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Conceptualisation: SK

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Formal analysis: SK

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