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Original article

Effectiveness of a transrectal prostate needle biopsy protocol with risk-tailored antimicrobials in a veterans cohort

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Abstract

Purpose: To prospectively implement a prostate biopsy protocol to identify high-risk patients for bleeding or infectious complications and use risk-tailored antimicrobials, patient education, and postbiopsy monitoring with the objective of reducing complications.

Materials and methods: Overall, 637 consecutive patients from June 2014 to August 2016 underwent prostate biopsy at our Veterans Affairs hospital. In the protocol cohort, patients were screened before biopsy and prophylaxis was tailored (high risk = ceftriaxone; low risk = ciprofloxacin). Patients were also provided additional education about bleeding and monitored for up to 1-hour. We defined complications as any deviation from normal postbiopsy activities. Comparisons were made between preprotocol/postprotocol cohorts. Logistic regression was used to identify risk factors for admissions or complications.

Results: Median age was 67 years (IQR: 64–69, $P = 0.29$) in both groups (pre $n = 334$, post $n = 303$). Preprotocol, 99% patients received ciprofloxacin; postprotocol, 86% received ciprofloxacin and 14% received ceftriaxone ($P < 0.001$). There were no deaths in either group. There were decreased 30-day complication and hospitalization rates in the postprotocol group (pre 15% vs. post 8.9%, $P = 0.025$; 3.3% vs. 1.0%, $P = 0.048$). Sepsis occurred in 2 patients preprotocol and no patients postprotocol. Postprotocol group was associated with decreased 30-day complications on multivariable logistic regression (OR = 0.58, 95% CI: 0.35–0.95, $P = 0.031$).

Conclusions: A screening protocol before prostate biopsy is a targeted approach for selecting prophylactic antimicrobials and closer monitoring postbiopsy for bleeding. Our results suggest that the protocol has a favorable effect on complication and hospitalization rates. Published by Elsevier Inc.

Keywords: Urologic surgical procedures, Male; Prostate cancer; Biopsy; Complication, Postoperative

1. Introduction

Although generally considered a safe procedure, complications following prostate biopsy can be devastating. Infectious complications, including fever, urinary tract infection (UTI), acute prostatitis, and epididymo-orchitis occur with 1% to 6% of transrectal ultrasound-guided prostate biopsies (TRUSBx) [1,2]. Life threatening sepsis is a feared complication and is estimated to occur in 0.5% to 1% of patients undergoing TRUSBx [3]. Bleeding after TRUSBx is also a significant issue with rates as high as 85% for hematuria, 45% for hematochezia, and 93% for hematospermia [4]. Fortunately, this bleeding is usually self-limited but can be bothersome, anxiety provoking, and occasionally severe enough to cause hospitalization.

As recommended by expert committees, fluoroquinolones are commonly used for antimicrobial prophylaxis before TRUSBx [4–7]. The 2008 AUA best practice policies on antimicrobial prophylaxis and 2016 AUA white paper on prevention of prostate biopsy complications both recommend the use of a fluoroquinolone or a first through third generation cephalosporin, or alternatively an aminoglycoside along with metronidazole or clindamycin, for

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24 hours or less perioperatively [6]. Fluoroquinolones are the most commonly used antimicrobial for prostate biopsy prophylaxis due to high bioavailability, wide antimicrobial spectrum covering clinical relevant pathogens, and high concentrations in prostatic tissues. Fluoroquinolones have been shown to significantly decrease infectious complications after prostate biopsy [8–12], but wide-spread use has been associated with emergence of fluoroquinolone-resistant infections after TRUSBx in North America and Europe [13–17]. The incidence of infectious complications, driven by fluoroquinolone-resistant organisms, has been rising 2- to 4-fold over the past 2 decades [18,19]. Halpern et al. [20] reported an increase in infections from 2.6% to 3.5% from 2011 to 2014 ($P = 0.02$) .

Given that an estimated 1 million prostate biopsies are performed in the United States annually, infectious complications also have significant public health implications [19]. Although rectal swab and culture has been used to assess potential antimicrobial resistance, this practice is difficult to incorporate into clinical practice with unclear cost benefit and underdevelopment of standardized microbiology practices [21]. The American Urologic Association (AUA) Quality Improvement Summit in 2014 recommended identifying high risk patients and considering augmented antibiotics to decrease the complications related to fluoroquinolone resistant organisms [21]. This prompted us to review our prophylactic antimicrobial regimen in patients undergoing prostate biopsy. In this study, we prospectively implemented a biopsy protocol at our Veterans Affairs hospital to identify high-risk patients for bleeding or infections and selectively use risk-tailored antimicrobials with the objective of reducing complications.

2. Methods

We conducted a cohort analysis of consecutive patients who underwent TRUSBx from June 1, 2014, to August 30, 2016, at the William S Middleton Memorial Veterans Hospital. This was an interventional quality improvement project with retrospective analysis of the preintervention and postintervention periods. This project was performed in accordance will institutional regulations for quality improvement projects. The VA is an integrated health system and its electronic health record (EHR) offers a comprehensive longitudinal view of a patient's diagnostic journey. Clinical and pathologic characteristics were collected via a detailed EHR review including demographic data, Charlson comorbidity index (CCI) [22], body mass index, medications including prebiopsy antimicrobials and aspirin, prior biopsy history, prebiopsy prostate specific antigen (PSA), digital rectal examination (DRE) results, prostate volume via ultrasound, pathology results, 30-day complications, and 30-day hospitalizations.

The primary endpoint of this study was the rate of postbiopsy hospitalizations and complications within 30 days. We defined complications as any deviations from normal postbiopsy activities including any unprompted calls to the phone triage by patients, outpatient medical intervention, emergency room visits, or hospitalization. Complications were categorized as infectious, bleeding, or other. Infectious complications were determined based on clinical symptoms with or without a positive urine culture. Patients were triaged over the phone or fully evaluated upon arrival. We counted patients who were treated with empiric antibiotics by providers outside of our department as having a UTI. According to the Centers for Disease Control and Prevention (CDC), a febrile UTI was defined as fever 38°C (100°F) or higher accompanied by 1 or more lower urinary tract symptoms (i.e., urgency, frequency, dysuria, or suprapubic tenderness) with or without a positive urine culture [23]. We used the CDC definition of febrile UTI. Patients with these symptoms in addition to other signs indicating systemic inflammatory response syndrome [24] such as heart rate 90 beats per minute or greater, chills, diaphoresis, general weakness, along with laboratory markers of systemic infection, were hospitalized for suspected septicemia. Sepsis was defined as systemic inflammatory response syndrome and clinical evidence of an infection; positive blood culture was not necessary for sepsis in this study.

2.1. Risk-tailored antimicrobial protocol implementation

The standard prophylactic antimicrobial regimen of the preprotocol cohort consisted of 2 doses of ciprofloxacin (500 mg, oral) 1 tablet 2 hours before TRUSBx and the other tablet 12 hours after the TRUSBx. The risk-tailored antimicrobial protocol was implemented on August 1, 2015. This protocol required the provider to document patient-reported answers to the following questions that were developed a priori based on prior literature that identified patients at higher risk for infection [21,25]:

(A) Have you been treated with antibiotics for a UTI in the past 6 months?
(B) Have you had a severe UTI (defined as febrile illness or hospitalization secondary to infection of urinary source) in the last 5 years?
(C) Have you had a prostate biopsy within 6 months?
(D) Do you use clean intermittent catheterization or have an indwelling catheter?

Patients answering yes to any of the above questions were considered to be at high infection risk with standard antimicrobial prophylaxis, and the prescriber was alerted to substitute ceftriaxone (1 gm, intramuscular) for oral ciprofloxacin (500 mg, oral, 1 tab 2 hours before the biopsy and second tab 12 hours after the biopsy). We chose to substitute with a single 1 g dose of ceftriaxone based on local antibiogram, safety profile, ease of administration, as well as the fact that this is recommended as an antimicrobial prophylaxis of choice for patients undergoing TRUSBx in