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ORIGINAL ARTICLE

An antimicrobial prophylaxis protocol using rectal swab cultures for transrectal prostate biopsy

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Abstract
Purpose To evaluate the benefit of an antimicrobial prophylaxis protocol using rectal swab cultures in patients undergoing transrectal ultrasound (TRUS)-guided prostate biopsy in our Veterans Affairs population.
Methods Between June 1, 2013, and June 1, 2014, we implemented an antimicrobial prophylaxis protocol using rectal swab cultures on selective media containing ciprofloxacin for all men scheduled for TRUS-guided prostate biopsy. Data from 2759 patients from Jan 1, 2006 to May 31, 2013, before protocol implementation served as historical controls. Patients with fluoroquinolone (FQ)-susceptible organisms received FQ monotherapy, while those with FQ-resistant organisms received targeted prophylaxis. Our objective was to compare the rate of infectious complications 30 days after prostate biopsy before and after implementation of our antimicrobial protocol.
Results One hundred and sixty-seven patients received rectal swab cultures using our protocol. Seventeen (14 %) patients had FQ-resistant positive cultures. Patients with positive FQ-resistant culture results were more likely to have had a history of previous prostate biopsy and a positive urine culture in the last 12 months ($p = 0.032$, $p = 0.018$, respectively). The average annual infectious complication rate within 30 days of biopsy was reduced from 2.8 to 0.6 % before and after implementation of our antimicrobial prophylaxis protocol using rectal swab cultures, although this difference was not statistically significant ($p = 0.13$).
Conclusion An antimicrobial prophylaxis protocol using rectal culture swabs is a viable option for prevention of TRUS-guided prostate biopsy infectious complications. After implementation of an antimicrobial prophylaxis protocol, we observed a nonsignificant decrease in the rate of post-biopsy infectious complications when compared to historical controls.

Keywords Antibiotic prophylaxis/methods · Biopsy/methods · Postoperative complications/prevention and control · Prostate/pathology · Prostate/ultrasonography · Rectum/microbiology

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Introduction

Prostate adenocarcinoma is the most commonly diagnosed malignancy in American men with an estimated 210,000 cases reported in 2011 alone [1]. Appropriate diagnosis requires histological evaluation through prostate biopsy. Several biopsy approaches have been utilized, but the most common method in the USA is transrectal ultrasound (TRUS)-guided needle biopsy. TRUS-guided needle biopsy

of the prostate is an extremely common procedure in the USA with nearly 1 million procedures performed annually.

Recognized postoperative complications associated with transrectal prostate biopsy include infectious complications such as urinary tract infection, epididymo-orchitis, acute prostatitis, bacteremia, sepsis, and death [2]. Antimicrobial prophylaxis with a fluoroquinolone (FQ) or first-, second-, or third-generation cephalosporin has shown to reduce the risk of these complications and is a current guideline recommendation [3, 4]. Currently, FQs are the most used antimicrobial prophylaxis for prostate biopsy. However, antibiotic resistance is a growing concern because as many as 11–24 % of men are colonized with FQ-resistant organisms [5–11]. FQ and other multidrug-resistant organisms have been associated with the increasing rate of post-biopsy infectious complications, reported in as many as 2.8–6.9 % of patients [12–16]. In a study of 75,190 Canadian men undergoing TRUS-guided prostate biopsy between 1996 and 2005, Nam et al. [14] observed a significant increase in the rates of 30-day hospital admissions following biopsy with infectious complications accounting for 72 % (1.0 % in 1996 to 4.1 % in 2005). Similarly, Loeb et al. [13] found hospital admission rates were 2.65-fold higher within 30 days of prostate biopsy when compared to the control population using Surveillance, Epidemiology, and End Results (SEER) data. The analysis found that infectious complications requiring hospitalization became more common over time, from 1991 to 2007, in men who underwent prostate biopsy versus randomly selected controls.

Targeted antimicrobial prophylaxis based on rectal swab culture for men undergoing TRUS-guided prostate biopsy has been proposed as an effective method to reduce post-biopsy infectious complications. However, the results of targeted antimicrobial prophylaxis in comparison with standard empiric prophylaxis are conflicted [10, 11, 17, 18]. The benefit of targeted antimicrobial prophylaxis and impact on post-biopsy infectious complications is still uncertain.

We prospectively evaluated the benefit of an antimicrobial prophylaxis protocol using rectal swab cultures in all patients undergoing TRUS-guided prostate biopsy in our Veterans Affairs (VA) population. We hypothesized that our antimicrobial prophylaxis protocol would reduce the rates of post-biopsy infectious complications in comparison with standard empiric prophylaxis among historical controls.

Methods

Study population

We completed a prospective study at the George Wahlen VA Medical Center in Salt Lake City, Utah. Adult men scheduled for TRUS prostate biopsy between June 1, 2013, and June 1, 2014, were enrolled following informed consent. Institutional review board approval was obtained before the study was initiated. Adult men of any age undergoing TRUS-guided prostate biopsy for any reason who received rectal swab culture were included.

Study procedures

Enrolled patients scheduled to undergo TRUS-guided prostate biopsy underwent a rectal screening culture as previously described 1–4 weeks before their biopsy [19]. Briefly, swabs were vortexed in transport medium (E-swab©, Copan, Murrieta, CA) and ~ 50 µl was plated on MacConkey agar with 10 µg/ml ciprofloxacin (Mac-C©, Hardy Diagnostics, Santa Maria, CA). Each colony type from Mac-C was identified, and susceptibilities were performed using an automated microbiology instrument (Phoenix© NMIC/ID-126, BD Diagnostics, Sparks, MD) or MALDI-TOF MS (Biotyper©, Bruker, Billerica, MA) coupled with broth microdilution and/or disk diffusion. Patients did not undergo any bowel preparation prior to biopsy. Most men with FQ-susceptible rectal swab cultures received a dose of ciprofloxacin 500 mg 1 h prior to procedure, and 500 mg twice daily for 3 days following the procedure. Antimicrobial prophylaxis in FQ-resistant men was at the direction of the clinician in accordance with AUA guidelines and local resistance patterns [3]. Most often antimicrobial prophylaxis in FQ-resistant men was sulfamethoxazole/trimethoprim.

Demographic and clinical data collection

Basic demographic and clinical data were collected for prospectively enrolled patients ("intervention cohort") undergoing TRUS biopsy. Age, BMI, calculated Charlson comorbidity score, post-void residual, prostate-specific antigen, estimated prostate volume, biopsy results and Gleason score were collected. Antibiotic susceptibilities from the rectal swab culture and prescribed targeted prophylaxis were documented. We additionally collected information on risk factors for increased risk of post-biopsy infection including diabetes, immunosuppression, prior antibiotic use within previous 6 months, and previous prostate biopsy [20]. Any reported infectious complications within 30 days of biopsy requiring treatment were documented. Infectious complications included bacterial cystitis (positive urine culture and irritative voiding), pyelonephritis (positive urine culture, flank pain, and nausea), bacteremia (two positive blood cultures with urinary pathogen), and/or sepsis (meeting previously established criteria [21]). Historical control patients ("historical controls"), who previously underwent TRUS-guided prostate biopsy before

our targeted antibiotic prophylaxis intervention, were identified through medical record review. The rate of previously defined infectious complications within 30 days of prostate biopsy and FQ resistance status among men with infectious complications between January 2006 and May 2013 ($n = 2759$) was collected. Although empiric prophylaxis varied between providers, most patients received FQ monotherapy for 1–3 days.

Primary and secondary outcomes

The primary outcome of this study was to compare the rate of infectious complications 30 days after prostate biopsy before and after implementation of our antimicrobial prophylaxis protocol using rectal swab cultures. Our secondary outcomes included identifying demographic and clinical factors, which may predict FQ resistance.

Statistical analysis

Demographic and clinical variables were summarized as count (%), mean (standard deviation, SD), or median (inter-quartile range, IQR) for the intervention cohort ($n = 167$), men who received a rectal culture swab and subsequent biopsy; and for men who received a rectal culture swab ($n = 185$) stratified by FQ culture result (FQ resistant vs. FQ susceptible). A two-sample t test was used for continuous variables if the distribution was approximately normal, and a Wilcoxon rank-sum test was used otherwise. A Chi-squared test was used for categorical variables unless the expected cell counts were <5, in which case a Fisher's exact test was used. Missing data were excluded from our analyses. All analyses were conducted in R v.3.0.3 (http://cran.us.r-project.org/) using two-sided tests with a 0.05 significance level.

Results

Of the 185 patients prospectively enrolled in this study between June 2013 and June 2014, 167 patients subsequently received prostate biopsy. Nineteen patients enrolled in this study underwent a rectal swab but did not undergo subsequent biopsy. Additionally, 2759 patients who received prostate biopsy between January 2006 and May 2013 served as historical controls. The demographic and clinical characteristics of the intervention cohort, men who received rectal swab culture and subsequent prostate biopsy ($n = 167$), are summarized in Table 1. Mean age and BMI were 64.8 years and 29.5 kg/m^2, respectively. This was a repeat biopsy for 121 patients and the first biopsy for 45 patients in the intervention cohort. Additionally, 13 patients had a positive urine culture in the last 12 months and 48 patients had an antibiotic exposure in the last 6 months. Seventeen (14 %) patients had cultures positive for FQ-resistant organisms.

Table 1 Demographic and clinical characteristics of intervention cohort ($n = 166$)

Variable[a]	Summary
Age—mean (SD)	64.8 (6.3)
BMI—mean (SD)	29.5 (5)
PSA—median (IQR)	5.4 (4.2, 8.2)
Prostate size—mean (SD)	49 (25.9)
Number of biopsies—*n* (%)	
1	45 (56 %)
2	20 (25 %)
3	9 (11 %)
4	4 (5 %)
5	1 (1 %)
6	1 (1 %)
BPH/LUTS symptoms—*n* (%)	74 (40 %)
Positive UCx in last 12 months—*n* (%)	13 (7 %)
Antibiotic exposure in last 6 months—*n* (%)	48 (27 %)
Positive biopsy result Positive—*n* (%)	65 (40 %)
Gleason score—*n* (%)	
1, (3 + 3) = 6	34 (52 %)
2, (3 + 4) = 7	16 (25 %)
3, (4 + 3) = 7	3 (5 %)
4, (4 + 4) = 8	7 (11 %)
5, (4 + 5) = 9	4 (6 %)
6, (5 + 4) = 9	1 (2 %)
Charlson comorbidity score—*n* (%)	
0	59 (32 %)
1	37 (20 %)
2	50 (27 %)
3	20 (11 %)
4	8 (4 %)
5	3 (2 %)
6	6 (3 %)
7	1 (1 %)
10	1 (1 %)

BMI body mass index, *PVR* post-void residual, *PSA* prostate-specific antigen, *BPH/LUTS* benign prostatic hyperplasia/lower urinary tract symptoms, *UCx* urine culture

[a] Missing values: PSA = 2, prostate size = 9, number of biopsies = 105, antibiotic exposure in last 6 months = 5, positive biopsy result = 23, Gleason score = 120

Table 2 compares demographic and clinical factors between patients with or without FQ-resistant culture results after implementation of our protocol. There was no significant difference in mean age, mean BMI, mean prostate size, Charlson comorbidity index, and frequency of antibiotic exposure in the previous 6 months between patients with

Table 2 Demographic and clinical characteristics summarized by fluoroquinolone culture result

Variable	FQ+ ($N = 25$)	FQ− ($N = 160$)	p value*
Age—mean (SD)	66.1 (6.4)	64.6 (6.3)	0.27
BMI—mean (SD)	29.2 (6)	29.5 (4.8)	0.77
PSA—median (IQR)	4.9 (4, 6.9)	5.6 (4.2, 8.5)	0.37
Prostate size—mean (SD)	45.7 (23.5)	49.6 (26.3)	0.46
Number of biopsies—*n* (%)			
1	5 (45 %)	40 (58 %)	**0.032**
2	1 (9 %)	19 (28 %)	–
3	2 (18 %)	7 (10 %)	–
4	2 (18 %)	2 (3 %)	–
5	1 (9 %)	0 (0 %)	–
6	0 (0 %)	1 (1 %)	–
BPH symptoms—*n* (%)	9 (36 %)	65 (41 %)	0.66
Positive UCx in last 12 months—*n* (%)	5 (20 %)	8 (5 %)	**0.018**
Antibiotic exposure in last 6 months—*n* (%)	9 (38 %)	39 (25 %)	0.2
Positive biopsy result—*n* (%)	7 (35 %)	58 (41 %)	0.62
Gleason score—*n* (%)			
$(3 + 3) = 6$	3 (43 %)	31 (53 %)	0.69
$(3 + 4) = 7$	2 (29 %)	14 (24 %)	–
$(4 + 3) = 7$	0 (0 %)	3 (5 %)	–
$(4 + 4) = 8$	1 (14 %)	6 (10 %)	–
$(4 + 5) = 9$	1 (14 %)	3 (5 %)	–
$(5 + 4) = 9$	0 (0 %)	1 (2 %)	–
Charlson comorbidity score—*n* (%)			
0	8 (32 %)	51 (32 %)	0.31
1	5 (20 %)	32 (20 %)	–
2	8 (32 %)	42 (26 %)	–
3	0 (0 %)	20 (12 %)	–
4	3 (12 %)	5 (3 %)	–
5	0 (0 %)	3 (2 %)	–
6	1 (4 %)	5 (3 %)	–
7	0 (0 %)	1 (1 %)	–
10	0 (0 %)	1 (1 %)	–

FQ fluoroquinolone, *BMI* body mass index, *PSA* prostate-specific antigen, *BPH/LUTS* benign prostatic hyperplasia/lower urinary tract symptoms, *UCx* urine culture

Bold values indicate significant p values ($p < 0.05$)

* p values for continuous variables were calculated using a t test if the distribution was approximately normal or a Wilcoxon rank-sum test otherwise; for categorical variables, a Chi-squared test was used if the expected cell counts were ≥5, or a Fisher's exact test otherwise

or without FQ-resistant culture results. Patients with positive FQ-resistant culture results were more likely to have had a history of previous prostate biopsy and a positive urine culture in the last 12 months ($p = 0.032$, $p = 0.018$, respectively). One hundred and forty patients (88 %) who had negative FQ-resistant cultures received ciprofloxacin prophylaxis. Patients with positive FQ-resistant cultures most commonly received sulfamethoxazole/trimethoprim (28 %). Supplementary Table 1 summarizes the antibiotic prophylaxis prescribed to patients in the intervention cohort based on FQ resistance culture results.

The annual rate of infectious complications post-biopsy from 2006 to 2014 at our institution is illustrated in Supplementary Fig. 1. There was a general increase in the annual complication rate in the historical controls cohort and immediately prior to implementation of our intervention. The average annual infectious complication rate within 30 days of biopsy was reduced from 2.8 to 0.6 % (supplementary Table 2) before and after implementation of an antimicrobial prophylaxis protocol using rectal swab cultures, although this difference was not statistically significant ($p = 0.13$). A single infectious complication

occurred in the intervention cohort, requiring intensive care hospitalization for FQ-sensitive *Escherichia coli* sepsis. This patient had a FQ-sensitive rectal swab culture prior to biopsy and received FQ prophylaxis prior to prostate biopsy. Additionally, there was a decreasing trend in the number of prostate biopsies performed annually from 2006 to 2014: 488 biopsies were performed in 2009 (peak) versus only 167 performed in 2013–2014 during our intervention (trough) (Supplementary Fig. 1).

Discussion

With the increasing rates of drug-resistant post-biopsy infectious complications, many approaches have been evaluated to reduce the risk of these complications in men undergoing TRUS-guided prostate biopsy, including changing standardized empiric antibiotic prophylaxis and using augmented or targeted antimicrobial prophylaxis. Augmented prophylaxis [standard empiric prophylaxis with administration of additional antimicrobial agents(s)] has shown a reduction in hospitalization rates in several studies [22, 23]. However, the rising rates of extended-spectrum β-lactamase (ESBL)-producing organisms is a concern for this specific practice. Up to 19–41 % of men undergoing rectal swab, harbored ESBL-producing organisms and 20.5–35 % of men with post-biopsy infectious complications had positive urine or blood cultures for ESBL-producing organisms [20, 23–26]. Augmented empiric antimicrobial prophylaxis, in light of the rising rates of ESBL-producing organisms, encourages overtreatment of a significant percentage of men undergoing TRUS-guided prostate biopsy sensitive to FQ (86 % of patients in our study) and promotes poor antibiotic stewardship.

Antimicrobial prophylaxis using rectal swab culture is promising and offers several advantages. Targeted prophylaxis enables pre-biopsy screening to identify patients with FQ-resistant rectal flora, so an individualized antibiotic prophylaxis regimen may be prescribed. Additionally, Taylor et al. reported that targeted prophylaxis resulted in a cost savings of $4,499 per post-biopsy infectious complication avoided. According to this analysis, 38 men would require rectal swab culture before prostate biopsy to prevent a single infectious complication [17]. Disadvantages of targeted prophylaxis with rectal swab culture include the need for an additional outpatient visit. However, in our study population, the first visit served as the consultation visit with discussion of prostate biopsy, rectal swab, informed consent process, and research consent. The second visit was more efficient with the patient undergoing prostate biopsy. This two-visit procedure was well received by most patients considering TRUS-guided prostate biopsy. Also, the additional cost and decreased productivity for microbiologists culturing the rectal swabs is a concern when compared to empiric prophylaxis. Alternative approaches to reducing post-biopsy infectious complications such as multiagent empiric antimicrobial prophylaxis, disinfectant enemas, and trans-perineal biopsies have been proposed but have recognized advantages and disadvantages [4, 27–30].

In this prospective evaluation of an antimicrobial prophylaxis protocol using rectal swab cultures for TRUS-guided prostate biopsy in the VA population, we observed a decrease in the rate of post-biopsy infectious complications when compared to historical controls, although this difference was not statistically significant. Additionally, 14 % of patients had positive rectal cultures for FQ-resistant organisms in the intervention cohort. Our results are consistent with several previous studies regarding targeted antimicrobial prophylaxis for TRUS-guided prostate biopsy [10, 11, 17, 18]. In a study conducted at the Naval Hospital San Diego, Duplessis et al. [10] obtained 235 rectal swabs from men scheduled to undergo subsequent prostate biopsy between May 2010 and March 2011 to develop a targeted antibiotic prophylaxis regimen. No infectious complications were identified in this cohort up to 7 days post-biopsy. Although there was no control group in this study, the authors anecdotally report three patients with septic complications among 103 biopsies in the 4 months immediately prior to this intervention. Taylor et al. [17] evaluated the benefit of targeted antimicrobial prophylaxis in 112 men who received rectal swab culture and 345 men who received standard empirical prophylaxis. Nearly 20 % of men who received rectal swabs harbored FQ-resistant organisms. Although there was no infectious complication 30 days after biopsy, when compared to men receiving empiric antibiotic prophylaxis (2.6 % post-biopsy infectious complication rate), this difference was nonsignificant. Suwantarat et al. [18] reported results from a targeted antimicrobial prophylaxis regimen using rectal culture, similar to the intervention conducted in the present study, at the Cleveland VA. Over a period of one year, 364 patients were recruited of whom 202 (61 %) received rectal swab culture and targeted prophylaxis. Eleven percent of men with rectal swab cultures were colonized with FQ-resistant organisms. The authors observed a significant difference in the incidence of post-biopsy infectious complications between the two groups after 1 year (0.5 vs. 9 %). Additionally, there was a significant reduction in infectious complications with FQ-resistant organisms during the 18-month period after versus before the intervention (1.6 vs. 4.3 %). Most recently, Dai et al. [11] retrospectively examined FQ-resistant organisms colonization and the 30 day post-biopsy infectious complication rate in 487 patients: 314 who received rectal swab cultures and targeted prophylaxis and 173 who received standard empiric prophylaxis. The rate of FQ-resistant organisms was 12.1 % among the 314 patients

who received rectal culture. Patients who received targeted prophylaxis had fewer infectious complications (1.9 vs. 2.9 % $p > 0.05$) and decreased odds of infection (OR 0.70; 95 % CI 0.2–2.5) on multivariate analysis, although the results did not achieve statistical significance.

A major limitation of previous studies assessing the benefit of antimicrobial prophylaxis using rectal swab culture is the nonrandomized design and impact of selection bias. Although a randomized controlled trial would be optimal, our present study attempts to minimize selection bias by prospectively implementing a standardized targeted prophylaxis protocol for all men undergoing TRUS-guided prostate biopsy at our institution. Furthermore, we used historical controls to evaluate differences in post-biopsy infectious complication rates before and after our intervention.

However, there are several limitations to the present study. The use of historical controls introduces a temporal bias since patients treated in the past may have exhibited different patterns of antimicrobial resistance and prophylactic response. Additionally, available data from these historical controls were limited to infectious complications post-biopsy; there were limited clinical or demographic data that may have been helpful to identify or control for risk factors for infectious complications. Residual confounding factors not captured in our study may influence complications and antimicrobial prophylaxis. A large, prospective, randomized control trial is needed evaluate the impact of targeted antimicrobial prophylaxis with rectal swab culture on infectious complications after TRUS-guided prostate biopsy.

Conclusion

The increase in infectious complications associated with TRUS-guided prostate biopsy has been linked with the growing rates of FQ-resistant organisms. In this prospective evaluation of rectal swab cultures for TRUS-guided prostate biopsy in the VA population, 14 % of patients had positive cultures for FQ-resistant organisms in the intervention cohort. We found patients with positive FQ-resistant culture results were more likely to have had a history of previous prostate biopsy and a positive urine culture in the last 12 months. After implementation of an antimicrobial prophylaxis protocol using rectal swab culture, we observed a decrease in the rate of post-biopsy infectious complications when compared to historical controls, although this difference was not statistically significant. Randomized controlled trials are needed to evaluate the efficacy and efficiency of this approach.

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard This clinical study was approved by the institutional review board, and all patients provided informed consent prior to participation. All study procedures have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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