

Original article

Antibiotic prophylaxis at the time of catheter removal after radical prostatectomy: A prospective randomized clinical trial

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Abstract

Objective: To evaluate the role of antibiotic prophylaxis with oral ciprofloxacin prior to urinary catheter removal after radical prostatectomy in preventing urinary tract infection (UTI).

Materials and methods: Patients undergoing radical prostatectomy were prospectively enrolled and randomized to either the antibiotic prophylaxis group (2 doses of oral ciprofloxacin prior to urinary catheter removal) or the control group (no antibiotics given prior to urinary catheter removal). Neither patients nor study providers were blinded to the group. The primary objective was to assess for development of UTI. The secondary objective was to assess for development of *Clostridium difficile* (*C diff*) enterocolitis. Continuous variables were compared using a 2-sample *t* test. Categorical variables were compared using Pearson's chi-squared test or Fisher's exact test.

Results: One hundred seventy-five patients were enrolled and randomized (90 control and 85 antibiotic prophylaxis). After randomization, 4 patients were excluded and 4 patients withdrew voluntarily. One hundred sixty-seven patients (84 control and 83 antibiotic prophylaxis) completed the study and were available for analysis. There were no significant differences in baseline characteristics, perioperative data, or complications. There was no significant difference in the rate of UTI between the control group and antibiotic prophylaxis group (5.95% vs. 6.02%, $P = 1$). There was also no significant difference in the rates of *C diff* infection between the control and the antibiotic prophylaxis groups (3.57% vs. 0%, $P = 0.21$).

Conclusions: In this prospective, randomized, controlled trial, the use of antibiotic prophylaxis with oral ciprofloxacin prior to urinary catheter removal after radical prostatectomy did not decrease the rate of UTI, and was not associated with an increased incidence of *C diff* enterocolitis. © 2018 Elsevier Inc. All rights reserved.

Keywords: Antibiotic prophylaxis; *Clostridium difficile*; Radical prostatectomy; Randomized controlled trial; Urinary catheter; Urinary tract infection

1. Introduction

Catheter-associated urinary tract infections (UTI) are among the most common nosocomial infections and are associated with increased cost, morbidity, and mortality [1–3]. Currently, the use of prophylactic antibiotics at the time of catheter removal is controversial. Studies published to date have yielded conflicting results [4–12]. Although

the use of prophylactic antibiotics at the time of catheter removal might reduce the number of symptomatic UTI, it is unclear whether the benefits outweigh the risk of patients developing adverse events (including *Clostridium difficile* [*C diff*] colitis) from antibiotic use or the promotion of antibiotic resistant UTI [4,5].

Patients undergoing radical prostatectomy require short-term use of an indwelling urinary catheter after surgery for primary healing of the vesico-urethral anastomosis. The presence of an indwelling urinary catheter increases the prevalence of bacteriuria which correlates with catheterization duration, with about a 5% increased risk of bacteriuria per day [13]. Asymptomatic bacteriuria may persist after

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catheter removal. Harding et al. demonstrated that 66% of women with asymptomatic bacteriuria while having a urinary catheter had persistent bacteriuria 2 weeks after catheter removal. Of those women with persistent bacteriuria, 25% developed a symptomatic UTI [14]. Although there is no clear evidence that the time of catheter removal is a high-risk window for the development of symptomatic UTI, manipulation of the catheter in the presence of bacteriuria during removal is often thought to contribute to subsequent development of symptomatic infections [1]. Consequently, many providers utilize antibiotic prophylaxis at the time of catheter removal in an effort to reduce symptomatic UTI. While there is consensus that asymptomatic bacteriuria during catheterization should not be treated, there is no agreement on whether prophylactic antibiotics should be administered at the time of catheter removal for the prevention of symptomatic UTI [15].

National society guidelines differ on recommendations for antibiotic prophylaxis at the time of catheter removal in patients with indwelling urinary catheters. The Infectious Diseases Society of America advises against routine use of antibiotics for UTI prevention at the time of catheter removal [16]. The American Urological Association guidelines on antibiotic prophylaxis for urologic surgery provide options to consider prophylaxis at the time of catheter removal in patients with risk factors. These risk factors include advanced age, anatomic anomalies of the urinary tract, poor nutritional status, smoking, chronic corticosteroid use, immunodeficiency, external urinary catheters, colonized endogenous/exogenous material, distant coexistent infection, and prolonged hospitalization. Current options for treatment include empiric therapy with antibiotics, or culture directed antimicrobials (with no antibiotic treatment if the urine culture is negative) [17]. There are no specific recommendations on antibiotic prophylaxis at the time of catheter removal in patients after radical prostatectomy. Current practice among urologists varies widely ranging from no antibiotic prophylaxis to a full treatment course of antibiotics at the time of catheter removal. There is currently insufficient evidence to support or refute the use of routine prophylactic antibiotics at the time of catheter removal after prostatectomy.

2. Materials and methods

2.1. Patients and randomization

This single centered, multi-location, nonblinded, randomized, controlled trial enrolled men between July, 2014 and October, 2015. Patients undergoing either open or robot-assisted laparoscopic radical prostatectomy for prostate cancer at Strong Memorial Hospital and Highland Hospital by 1 of 5 surgeons were recruited to participate in the study. This study was approved by the University of Rochester internal review board (RSRB #50607). The clinicaltrials.gov identifier for this study is [NCT02247960](https://clinicaltrials.gov/ct2/show/study/NCT02247960).

Patients were enrolled postoperatively prior to discharge from the hospital. Patients with a history of adverse reaction or allergy to ciprofloxacin or any quinolone, patients treated with tizanide, those with a history of myasthenia gravis, or those who were anuric were excluded. Enrolled patients were randomized to 1 of 2 groups using an online random number generator (www.random.org). The control group received no antibiotics prior to catheter removal. The antibiotic prophylaxis group received 2 doses of 500 mg of oral ciprofloxacin, first dose the evening before catheter removal, and a second dose the morning of catheter removal. Patients with a creatinine clearance of less than 30 ng/ml who were randomized to receive ciprofloxacin were given an adjusted dose of 250 mg of ciprofloxacin the evening before catheter removal and 250 mg the morning of catheter removal. Patients, providers, and investigators were not blinded to the randomization. Patients with major immediate postoperative complications were excluded. Predefined complications warranting exclusion were postoperative bleeding requiring intervention and known urine leak.

All patients received up to 24 hours of routine perioperative antibiotics (either Cefoxitin, or Clindamycin and Gentamicin for patients with known penicillin or cephalosporin allergy). All patients had a urinary catheter as well as an externalized drain after surgery. All patients were placed on an enhanced recovery postoperative pathway which includes early feeding, early ambulation, oral pain medication, mechanical and chemical venous thromboembolism prophylaxis and removal of the externalized drain prior to discharge. Urinary catheter removal was scheduled 7 to 14 days postoperatively without cystogram.

In addition to the usual catheter care teaching, patients were provided with verbal and written instructions on how to take the antibiotic, signs and symptoms of UTI and signs and symptoms of *C diff* infection. All patients were contacted by phone 1 week after catheter removal to query about signs and symptoms of UTI and *C diff* enterocolitis.

Demographic and clinical data including age, race, medical comorbidities, creatinine clearance, perioperative antibiotic administration, body mass index, prostate specific antigen, prostate weight, operative time, estimated blood loss, American Society of Anesthesiologists' Classification, length of stay, catheter duration, and postoperative complications and interventions were recorded.

Urine cultures were obtained preoperatively, at the time of urinary catheter removal, at the routine follow-up appointment between 3 months and 12 months postoperatively and any time patients developed symptoms of a UTI.

Patients with symptoms of enterocolitis (diarrhea, nausea, vomiting, and abdominal pain) were tested for *C diff* enterocolitis according to hospital laboratory protocol.

2.2. Outcomes

The primary endpoint of the study was the development of a symptomatic UTI up to 6 weeks after urinary catheter

removal. Symptomatic UTI was defined according to the Centers for Disease Control definition of UTI as a positive urine culture with at least 1 organism $>100,000$ cfu/ml, with the presence of at least 1 symptom, or sign compatible with UTI (dysuria, urinary frequency, urinary retention, fever, suprapubic or abdominal pain, or hematuria) [18].

The secondary endpoint of the study was development of *C diff* enterocolitis.

2.3. Statistics and sample size

Sample size was determined using a presumed rate of symptomatic UTIs of 5% in the group with antibiotic prophylaxis and 15% in the group without prophylaxis based on previously published literature. A total of 280 patients (140 per arm) achieve 80% power to detect the proposed difference with significance level of 0.05. An interim analysis was planned after enrollment of at least half of the subjects.

At the time of interim analysis, 162 subjects had been enrolled (81 in the control group and 81 in the antibiotic prophylaxis with oral ciprofloxacin group). The Jennison and Turnbull method was used to determine that the futility index was 98.22%. In order to attain an 80% power for the rates of UTI encountered in the interim analysis, a sample size of 1,200 patients in each group would be necessary [19]. Based on this analysis, enrollment in the study was discontinued.

Two-sample *t* test was used to compare the difference of mean values of continuous variables in 2 groups. Pearson's chi-squared test or Fisher's exact test was used to compare the distribution of categorical variables between 2 groups. For all comparisons, the significance level was set a 0.05. The analysis was implemented with SAS 9.4 (SAS Institute Inc., Cary, NC).

3. Results

Between July, 2014 and October, 2015, a total of 175 patients were enrolled with 167 patients included in the final analysis. Four patients were excluded after enrollment (3 for postoperative bleeding and 1 for antibiotic intolerance) and 4 withdrew voluntarily after enrollment. Of the 167 remaining patients, 84 patients were in the control group and 83 patients were in the antibiotic prophylaxis with oral ciprofloxacin group (Fig. 1).

Patient demographics, patient and disease characteristics, and perioperative outcomes were similar between the 2 groups (Table 1). Catheter duration was not statistically significantly different between the groups at 10.08 days in the control group and 9.82 days in the antibiotic prophylaxis with oral ciprofloxacin group, $P = 0.34$ (Table 1).

Overall, 8 (4.8%) patients developed a UTI within 6 weeks after urinary catheter removal. There was no statistically significant difference in the rates of UTI between the control group and the antibiotic prophylaxis with oral

ciprofloxacin group (5.95% vs. 3.57%, $P = 0.5$). Three (1.8%) patients developed *C diff* infection with no statistically significant difference between the control and the antibiotic prophylaxis with oral ciprofloxacin group (3.57% vs. 0%, $P = 0.21$). In addition, there was no statistically significant difference between the control group and the antibiotic prophylaxis with oral ciprofloxacin group in rates of empiric antibiotic treatment in symptomatic patients without confirmatory urine culture, treatment of symptomatic patients with a negative urine culture, or treatment of patients with asymptomatic bacteriuria (Table 2).

Table 3 outlines the urine culture, symptoms prompting urine culture, and time from catheter removal to development of a UTI in the patients with UTI. Differing organisms were isolated from the urine at the time of catheter removal and at the time of UTI diagnosis in 6 of the 8 patients with a concordance rate of only 25%. Lower urinary tract symptoms (LUTS) were common after urinary catheter removal (Supplementary tables 1–3). Hematuria and dysuria were the most common symptoms of UTI with only 1 patient presenting with fever. Half of the patients who developed UTI had sterile urine or mixed flora only on urine culture obtained at the time of catheter removal. There was also significant variability in the timing from catheter removal to development of UTI, ranging from 0 to 32 days (Table 3).

Preoperative urine cultures were obtained in 158 (90.3%) patients, and all were negative. The results of the urine cultures obtained at the time of catheter removal and at the follow-up visit are outlined in Fig. 2. At the time of catheter removal, 159 (95.2%) patients had a urine culture obtained. Sixty-five percent of patients in the control group had growth of at least 1 organism compared to 29% of patients in the antibiotic group (Fig. 2A). Urine cultures were obtained in 124 (74.3%) patients at the routine follow-up appointment between 3 and 12 months after surgery. Twenty-seven percent of patients in the control group had growth of at least 1 organism compared to 16.7% of patients in the antibiotic prophylaxis group (Fig. 2B).

4. Discussion

Administration of prophylactic antibiotics at the time of urinary catheter removal is a common practice, although there is little evidence to support this practice. In this prospective randomized controlled trial, we found that the use of antibiotic prophylaxis prior to catheter removal after prostatectomy did not affect the rate of UTI. Due to futility of the primary endpoint calculated on interim analysis, our study was discontinued after enrollment of 167 patients. Importantly, we found a low rate of UTI in patients after urinary catheter removal after radical prostatectomy. The findings in this study do not support the practice of antibiotic prophylaxis at the time of catheter removal for UTI prevention after radical prostatectomy.

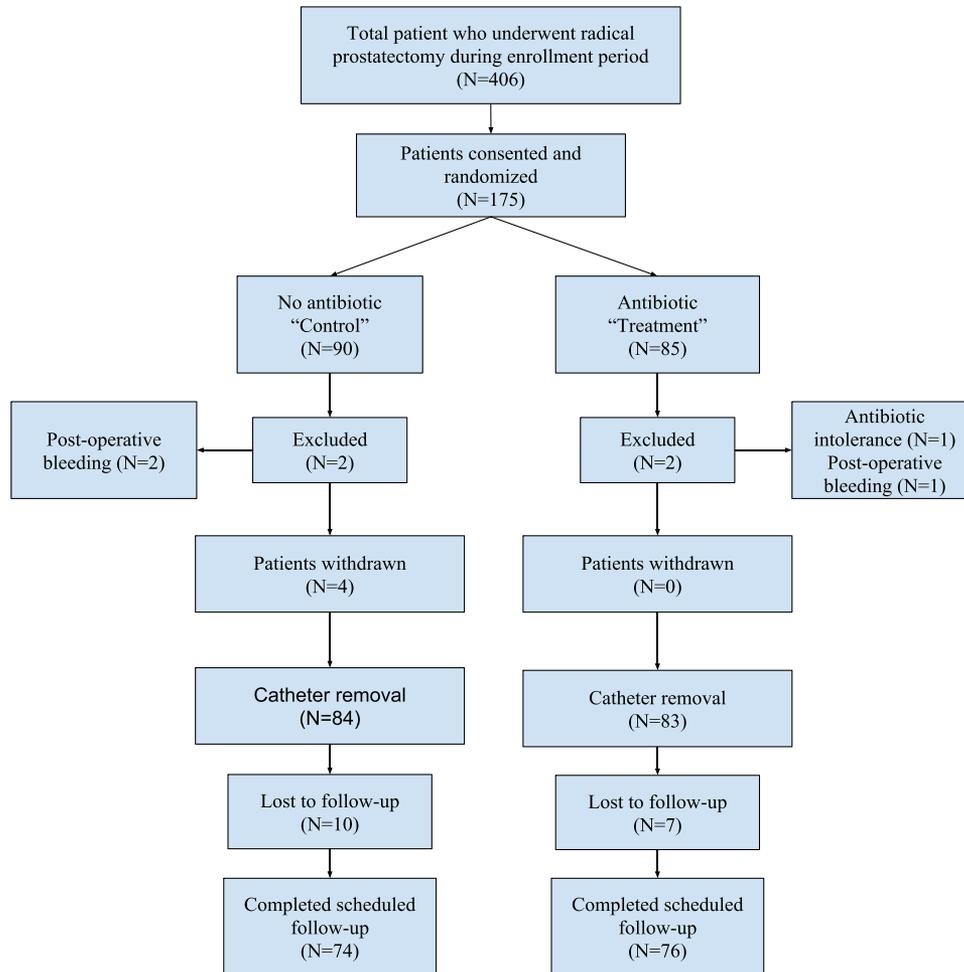


Fig. 1. Flow-chart outlining the process for patient enrollment and follow-up. One hundred seventy-five patients were consented, enrolled, and randomized with 90 patients in the control group and 85 patients in the antibiotic prophylaxis with oral ciprofloxacin group. A total of 4 patients were excluded after randomization (3 for postoperative bleeding and 1 for antibiotic intolerance). Four patients withdrew voluntarily after enrollment with 167 patients remaining in the study, 84 in the control group and 83 in the antibiotic prophylaxis group. One hundred sixty-seven patients (100%) completed intervention and were available for primary analysis while 150 patients (89.8%) were present through study completion at their follow-up appointment between 3 and 12 months following surgery.

Previous studies have demonstrated conflicting results and have variability in factors such as duration of catheterization, antibiotic choice, timing/duration of antibiotic, criteria for diagnosis of UTI, and patient population [6–8,14,15,20,21]. Pinochet et al. demonstrated a reduction in UTI with antibiotic prophylaxis at the time of catheter removal after radical prostatectomy in a retrospective cohort analysis. However, this study had multiple confounding variables including nonrandomization and direct comparison of 1 surgeon to another [7]. Pfefferkorn et al. focused on the use of antibiotic prophylaxis at the time of catheter removal for prevention of UTI in patients after abdominal surgery. They concluded that antibiotic prophylaxis reduced the number of UTI. However, this study utilized routine urine cultures 3 days after surgery to define UTI without a confirmatory urine culture at the time of symptom development. This study may have reported a higher than expected rate of UTI based on this definition of UTI [8,21].

A pilot randomized double-blind placebo-controlled trial by Wazait et al. evaluated the role of antibiotic prophylaxis prior to catheter removal in hospitalized patients. Patients with a urinary catheter >48 hours ≤7 days were randomized to receive antibiotic prophylaxis ($N=25$) or placebo ($N=23$). They found no difference in the rate of UTI in patients receiving antibiotic prophylaxis (16%) compared to patients receiving placebo (13%). This study is limited by its small sample size, and a follow-up study has not been published to date [9]. In 2011, Van Hees et al. conducted a randomized, double-blind, placebo-controlled trial evaluating the use of prophylactic antibiotics before catheter removal in surgical patients. One group received ciprofloxacin ($N=43$), a second cotrimoxazole ($N=46$) and a third placebo ($N=51$). They found no difference in the rate of UTI between the 3 groups (3% in the ciprofloxacin group, 0% in the cotrimoxazole group, and 3% in the placebo group). The power calculations for this study were based on previously reported rates of UTI of 3% with prophylaxis

Table 1
Patient characteristics, perioperative data, and complications

Clinical characteristics	No antibiotic	Antibiotic	P value
Age (years) mean ± SD	62.98 ± 6.82	62.49 ± 6.86	0.65
Race			
• White (%)	75 (89.29%)	73 (87.95%)	
• Non-White (%)	9 (10.71%)	10 (12.05%)	0.79
BMI (kg/m ²) mean ± SD	29.41 ± 5.30	28.95 ± 5.06	0.57
PSA (ng/dl) mean ± SD	7.77 ± 5.36	11.03 ± 23.31	0.22
Prostate weight (gram) mean ± SD	61.77 ± 25.79	57.31 ± 57.31	0.89
Creatinine clearance (ml/min) mean ± SD	92.53 ± 27.76	90.50 ± 29.40	0.65
ASA mean ± SD	2.32 ± 0.52	1.37 ± 0.52	0.48
HTN (%)	42 (50%)	47 (56.63%)	0.39
DM (%)	14 (16.67%)	19 (22.89%)	0.31
CAD (%)	9 (10.71%)	9 (10.84%)	0.98
Operative time (min) mean ± SD	217.24 ± 53.14	213.87 ± 49.95	0.67
Estimated blood loss (ml) mean ± SD	224.88 ± 190.18	214.81 ± 230.47	0.76
Length of stay (days) mean ± SD	1.30 ± 0.71	1.37 ± 1.27	0.63
Catheter duration (days) mean ± SD	10.08 ± 1.81	9.82 ± 1.77	0.34
Emergency room visit (%)	9 (10.71%)	3 (3.61%)	0.13
Readmission (%)	4 (4.76%)	2 (2.41%)	0.68
Complications ^a (%)	12 (14.29%)	8 (9.64%)	0.36

BMI = body mass index; PSA = prostate specific antigen; ASA = American Society of Anesthesiology physical status classification; HTN = hypertension; DM = diabetes mellitus; CAD = coronary artery disease.

^aComplications in the antibiotic group postoperative bleeding (*N* = 1), ileus (*N* = 1), pelvic lymphocele (*N* = 2), pelvic hematoma (*N* = 1), pneumonia (*N* = 1), and urinary retention (*N* = 2).

Complications in the control group *C. diff* infection (*N* = 3), dislodged urinary catheter (*N* = 2), leg swelling (*N* = 1), febrile diarrhea (not *C. diff*) (*N* = 1), ileus (*N* = 2), pelvic lymphocele (*N* = 1), wound infection (*N* = 1), and small bowel obstruction (*N* = 1).

and 17% without prophylaxis, and thus may have been underpowered based on their observed rates of infection. However, rates of UTI with and without prophylaxis in this study were low and more closely resemble the rates of infection that we observed in our study [6,14].

The main limitation of our study was lack of blinding which may have led to bias in patients and providers. Although not statistically significant, there was a trend toward increased empiric treatment without diagnostic urine culture in the control group compared to the antibiotic group (7.15% vs. 1.2%, *P* = 0.12). However, the number of patients developing symptoms after catheter

removal was similar in both groups (18 in the control group and 16 in the antibiotic group). Of those symptomatic patients in the control group, 5 had a UTI, 6 were treated empirically without a confirmatory urine culture, and 7 did not have a UTI. Of those symptomatic patients in the antibiotic group, 3 had a UTI, 1 was treated empirically without a confirmatory urine culture, and 12 did not have a UTI (Supplementary tables 1–3).

Another limitation was the inability to determine whether patients who were treated empirically had a UTI as a cause of their symptoms. LUTS are common in patients after radical prostatectomy and after urinary catheter

Table 2
Study endpoints

	No antibiotic	Antibiotic	P value
UTI	5 (5.95%)	3 (3.57%)	0.5
<i>C. diff</i>	3 (3.57%)	0 (0%)	0.24
Potential unnecessary treatment			
• Empiric treatment ^a	6 (7.14%)	1 (1.20%)	0.12
• Treatment with negative culture ^b	3 (3.57%)	5 (6.02%)	0.50
• Treatment for asymptomatic bacteriuria ^c	5 (5.95%)	1 (1.20%)	0.21

UTI = urinary tract infection; *C. diff* = *Clostridium difficile*.

^aPatients were treated with antibiotics based on urinary symptoms without obtaining a urine culture at the time that symptoms developed.

^bPatients had a urine culture obtained with development of urinary symptoms and were treated with antibiotics despite having a known negative urine culture.

^cAll patients had a urine culture obtained at the time of catheter removal per the study protocol. As a result, some patients were treated with antibiotics based on the urine culture despite having no symptoms of a UTI (asymptomatic bacteriuria).

Table 3
Urine culture results in patients diagnosed with UTI

Patient	Study group (antibiotic/no antibiotic)	Urine culture result at catheter removal ^a	Urine culture result at time of UTI	Symptoms prompting urine culture	Time from catheter removal to UTI (days)	Scheduled follow-up urine culture result ^b
1	No antibiotic	Serratia > 100,000 Citrobacter > 100,000 Enterococcus > 100,000 No growth Klebsiella oxytoca > 100,000	Klebsiella > 100,000	Hematuria and dysuria	16	Enterococcus > 100,000
2	Antibiotic	No growth	Enterobacter > 100,000	Hematuria	32	No growth
3	No antibiotic	Klebsiella oxytoca > 100,000	Klebsiella oxytoca > 100,000	Dysuria	9	No growth
4	No antibiotic	Klebsiella > 100,000 Enterobacter > 100,000 No growth	<i>E coli</i> > 100,000	Dysuria	7	Coagulase negative staph < 10,000 <i>E coli</i> > 100,000
5	Antibiotic	No growth	<i>E coli</i> > 100,000	Dysuria	24	Mixed flora
6	No antibiotic	Mixed flora	<i>E coli</i> > 100,000	Dysuria	9	Missed
7	No antibiotic	Mixed flora	Proteus > 100,000	Hematuria	6	Enterococcus 30,000
8	Antibiotic	Enterococcus > 100,000	Enterococcus > 100,000	Fever	0	

^a Refer to methods (routine urine culture).

^b Refer to methods (planned urine culture, not test of cure).

removal. As a result, it can be challenging to differentiate between symptoms from recent catheterization, recent lower urinary tract surgery, and UTI. Many patients in this study developed LUTS ($n = 19$) but had negative urine cultures (Supplementary table 3). A urine culture obtained with the onset of symptoms is crucial for proper diagnosis and treatment of UTI. Urine cultures obtained at the time of catheter removal are not useful in making the diagnosis of UTI since asymptomatic bacteriuria will resolve spontaneously in most patients.

The time from catheter removal to diagnosis of UTI ranged from 0 to 32 days (6–16 days in the control group, and 0–32 days in the antibiotic group). The current definition of catheter-associated UTI from the Infectious Diseases Society of America applies to patients who had a urinary catheter removed within 48 hours prior to the onset of symptoms. However, it is currently unknown how long after urinary catheter removal patients are at increased risk of developing a UTI, since asymptomatic bacteriuria can persist for weeks [14]. Previous similar studies have used differing time intervals for diagnosis of UTI after catheter removal, ranging from days to months [6–8,14,15,20,21]. Additional research is needed to further clarify the causal relationship between urinary catheterization and symptomatic UTI, particularly in patients with urinary catheters after genitourinary surgery.

This current study confirms that bacteriuria is common in patients with urinary catheters. However, we found poor correlation between urine culture results at the time of catheter removal and the organisms responsible for UTI. Only 2 patients (1 from the control group and 1 from the antibiotic group) with UTI had the same organism isolated at the time of catheter removal and at the time of diagnosis of UTI. The remaining patients with UTI ($n = 6$) cleared the asymptomatic bacteriuria and went on to develop a UTI with a different organism. Therefore, asymptomatic bacteriuria in patients with urinary catheters after radical prostatectomy should not be treated.

In this study, we did not find a difference in the rate of *C diff* enterocolitis between the groups. All 3 patients who developed *C diff* infection were in the control group and did not receive antibiotics at the time of catheter removal. However, each patient had multiple risk factors for development of *C diff* enterocolitis including exposure to antibiotics at the time of prostate biopsy, perioperative antibiotics, and postoperative hospitalization. Another possible explanation is that the study was underpowered to determine a difference in the rate of *C diff* infection.

5. Conclusions

In this prospective, randomized, controlled trial, the use of antibiotic prophylaxis with oral ciprofloxacin at the time of catheter removal after radical prostatectomy did not decrease the rate of UTI or affect the rate of *C diff* enterocolitis.

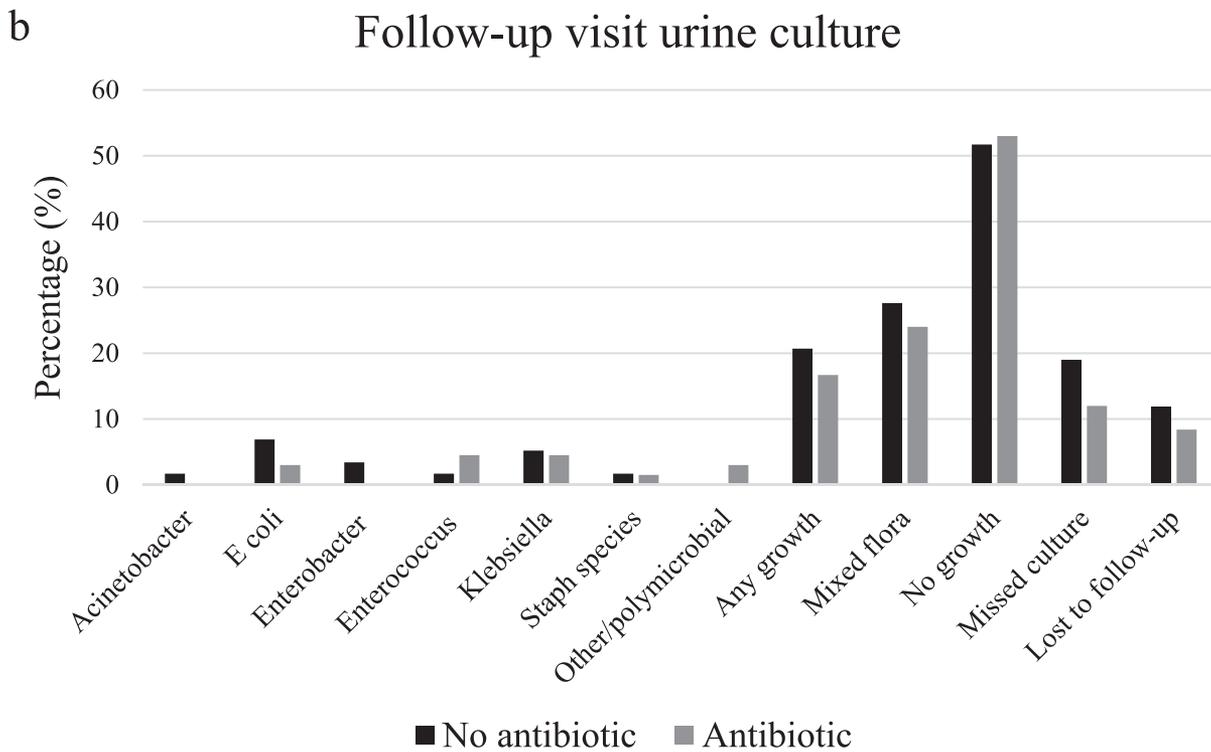
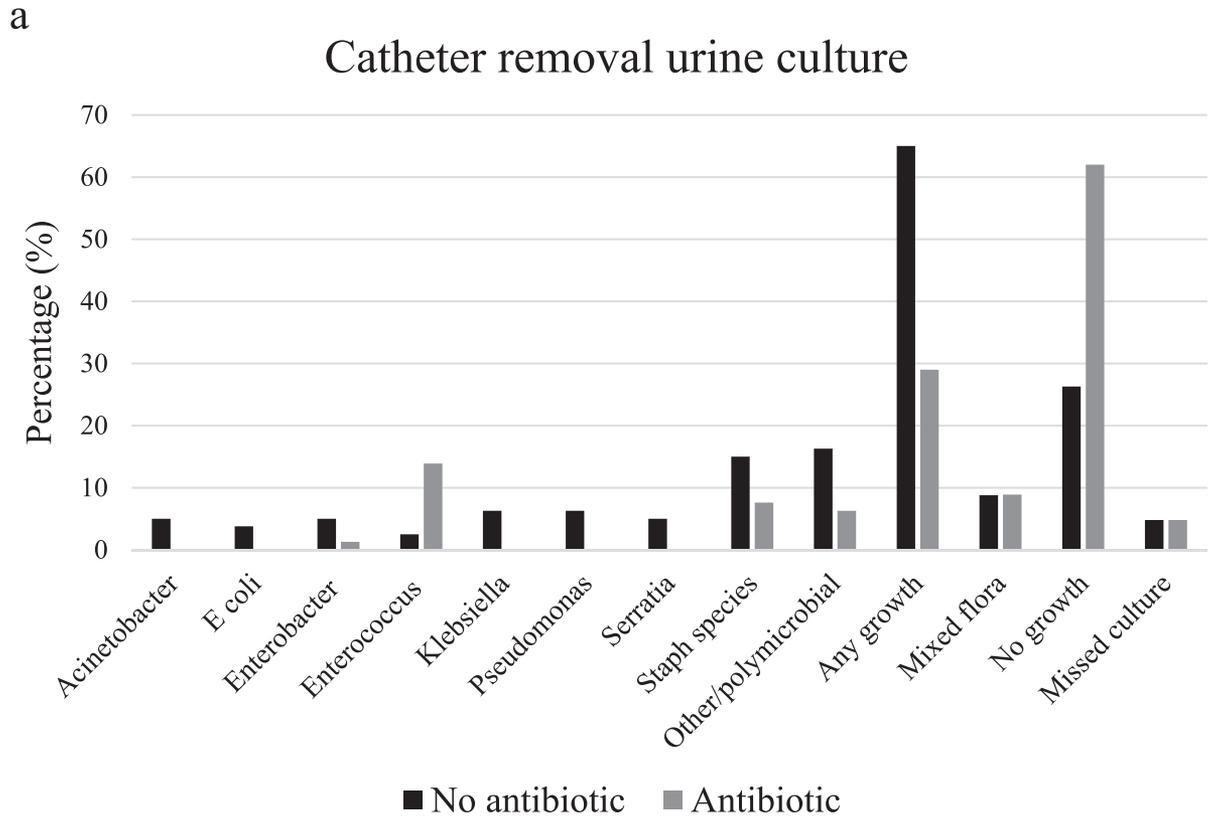


Fig. 2. Urine cultures were obtained routinely at the time of catheter removal and at the follow-up appointment 3–12 months postoperatively. Urine culture results (A) at the time of catheter removal and (B) at the routine follow-up visit.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.urolonc.2018.10.029>.

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