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ORIGINAL ARTICLE

Randomized controlled trial of silver-alloy-impregnated suprapubic catheters versus standard suprapubic catheters in assessing urinary tract infection rates in urogynecology patients

Ruchira Singh[1] · Erik D. Hokenstad[2] · Sheila R. Wiest[2] · Shunaha Kim-Fine[3] · Amy L. Weaver[4] · Michaela E. McGree[4] · Christopher J. Klingele[2] · Emanuel C. Trabuco[2] · John B. Gebhart[2]

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Abstract

Introduction and hypothesis Catheter-associated urinary tract infections (UTI) are the most common health-care-related infections. We aimed to compare the UTI rate among women undergoing urogynecological procedures with a silver-alloy suprapubic catheter (SPC) and a standard SPC, and identify the risk factors predisposing patients to UTI.

Methods Patients who were to undergo placement of an SPC as part of pelvic organ prolapse surgery were enrolled between 1 August 2011 and 30 August 2017, and randomized to either standard SPC or silver-alloy SPC. Follow-up was performed at a postoperative visit or via a phone call at 6 weeks. The primary outcome was UTI.

Results Of the 288 patients who were randomized, 127 with standard SPC and 137 with silver-alloy SPC were included in the analysis. Twenty-nine out of 123 women with standard SPC (23.6%) and 24 out of 131 (18.3%) with silver-alloy SPC were diagnosed with UTI within 6 weeks postoperatively ($p = 0.30$). In univariate analysis, non-white race (odds ratio [OR] 5.36, 95% CI 1.16–24.73) and diabetes (OR 2.80, 95% CI 1.26–6.23) were associated with increased risk of UTI. On multivariate analysis, only diabetes remained an independent risk factor. Comparisons between groups were evaluated using two-sample *t* test for age, Chi-squared tests for diabetes, and Wilcoxon rank sum test for all other variables.

Conclusion There was only a 5% difference in 6-week UTI rates between those who received standard vs silver-alloy SPC; the study was not powered to detect such a small difference. Diabetes was identified as a risk factor for SPC-associated UTI in women undergoing pelvic reconstructive surgeries.

Keywords Silver-alloy suprapubic catheter · Urinary tract infection · Randomized trial · Prolapse surgery

Introduction

Urinary catheters are one of the most widely used medical devices, with 96 million indwelling urethral catheters sold annually worldwide; 24 million of which are sold in the USA [1]. Catheter-associated urinary tract infections (UTIs) are among the most common healthcare-associated infections (HAIs), accounting for 21–45% of all HAIs and bacteriuria in up to 4% of cases [2]. The incidence of bacteremia is estimated to be 3–10% per day of catheterization, with up to 70% involvement with 14 days of indwelling catheterization [3, 4]. Catheter-associated UTIs are associated with an increased length of stay, morbidity, mortality, and hospital cost [5, 6]. The cost of HAIs has been progressively increasing, with the cost burden related to catheter-associated UTIs ranging from $1,200 to $2,700 per case [2, 6]. In view of the significant prevalence and morbidity associated with UTI, many

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✉ Ruchira Singh
ruchira.26@gmail.com

[1] Department of Obstetrics and Gynecology, University of Florida, 653-1 W. 8th Street, Jacksonville, FL 32209, USA

[2] Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN, USA

[3] Department of Obstetrics and Gynecology, University of Calgary, Calgary, AB, Canada

[4] Department of Health Sciences Research, Mayo Clinic, Rochester, MN, USA

strategies have been suggested aimed at reducing the risk of catheter-associated UTIs. These include reduction in the duration of catheterization, use of an antiseptic technique for catheter insertion, use of antibiotic prophylaxis in high-risk groups, maintenance of a sterile closed drainage system, and the development of different types of catheters [6, 7]. Specialized urethral catheters have been developed, either by coating the outer surface and/or the lumen, or impregnating the catheter material with antiseptics or antimicrobials [8]. The most common antiseptic agent that has been used is silver, which has been shown to have antimicrobial activity against multiple uropathogens [9]. Based on multiple systematic reviews, the silver-alloy impregnated transurethral catheters have been shown to decrease the risk of both bacteriuria and/or catheter-associated UTIs compared with the standard catheters in hospitalized patients requiring catheterization [7–10]. On the contrary, a large three-arm multicenter randomized trial revealed no benefit of silver-alloy catheters in the prevention of symptomatic UTIs when used for short-term catheterization in hospitalized patients [11].

Women undergoing pelvic reconstructive procedures for prolapse often require bladder drainage in the postoperative period, which is achieved by using either a transurethral catheter or a suprapubic catheter (SPC). Although considered more invasive, SPC is used by many surgeons for the following reasons: increased patient satisfaction compared with the chronic indwelling urethral catheters, less discomfort [12], avoidance of urethritis [12], maintained ability to void spontaneously, easier nursing care [13, 14], and shorter hospital stay [13]. UTI is the most common complication after pelvic reconstructive surgery with the risk of UTI in this population ranging from 9 to 31% [15–18]. Hence, a decrease in the rates of UTI in this cohort will lead to a significant decrease in overall infectious morbidity.

Although there is some evidence that demonstrates encouraging results suggesting a decrease in the risk of UTI using silver-alloy catheters, the studies have varied with regard to the patient population, clinical indication, and definition of the outcomes. There is also a paucity of evidence evaluating the effectiveness of the silver-alloy-impregnated catheters for suprapubic use after pelvic reconstructive surgery. Therefore, we conducted a randomized controlled trial comparing silver-alloy SPC and standard SPC on postoperative UTI rates in women undergoing pelvic reconstructive surgeries.

The aims of this study were:

1. To compare the rates of 6-week UTI in women undergoing suprapubic catheterization following surgical repair for pelvic organ prolapse (POP) when randomized to the standard latex catheter or the silver-alloy-impregnated catheter
2. To assess the risk factors predisposing women with SPC to 6-week postoperative UTI

Materials and methods

This manuscript was written based on the "Revised CONSORT Statement for Reporting Randomized Trials" [19]. This randomized trial was approved by the Institutional Review Board at Mayo Clinic, Rochester, MN, USA. Women scheduled to undergo surgical procedures that would entail placement of a suprapubic catheter, such as surgical management of symptomatic POP of the anterior or apical compartment, with or without a concomitant procedure for stress urinary incontinence, were eligible for recruitment. Procedures included vaginal reconstructive procedures or abdominal sacrocolpopexy with or without a concomitant mid-urethral sling or Burch urethropexy.

Exclusion criteria were the presence of a UTI at the time of surgery, latex allergy, inability to provide informed consent, use of chronic self-intermittent catheterization, use of chronic antibiotics, menstrual period, presence of a fistula involving the urogenital tract, history of recurrent UTI on antibiotic suppression, immunosuppressed state, or chronic use of steroids.

Subjects were enrolled between 1 August 2011 and 30 August 2017 at a single institution. Suprapubic catheters are routinely placed after vaginal reconstructive surgeries for pelvic organ prolapse and Burch urethropexy by some surgeons at our institution. Once the patient was enrolled, they were randomized to either the standard latex catheter or the silver-alloy impregnated catheter. The participants were subjected to routine perioperative and postoperative care as per the institution protocol.

The suprapubic catheter was placed at the end of the procedure. With the patient in the Trendelenburg position, a suprapubic cystotomy was performed under direct cystoscopic guidance and the suprapubic catheter was placed. All the patients received preoperative prophylactic antibiotics as per the institution protocol, but did not receive any prophylactic antibiotics postoperatively. The institutional protocol for preoperative antibiotic prophylaxis involved the administration of parenteral cefazolin or clindamycin and gentamycin (for patients with a penicillin allergy) before the incision. The decision not to give prophylactic antibiotics for the prevention of postoperative UTI was based on the CDC guidelines, that suggested limited benefit of antimicrobial prophylaxis for the prevention of catheter-associated UTI in patients undergoing short-term and long-term catheterization [20].

The removal of the catheter was performed based on the standard postoperative catheter care guidelines (adequate urinary output [500 ml or more] over 24 h, lack of gross hematuria, and ability to void voluntarily). A post-void residual of 150 ml or less was defined as a criterion for SPC removal. None of the patients underwent self-intermittent catheterization or indwelling Foley catheterization after removal of SPC. The participants were instructed to contact their provider if they had any signs or symptoms of a UTI. If a participant

was treated for UTI at a different institution, they were instructed to contact the study team. The participants were evaluated at 6 weeks in the clinic during a postoperative visit. For women who were unable to return for a postoperative visit, a follow-up questionnaire was completed via a phone call from a study team member. The SPC was not removed if a UTI was diagnosed during 6-week postoperative period. At 6 weeks after surgery, if the SPC was still in place, a urine sample was obtained via a transurethral catheter and sent for urinalysis, bacterial Gram stain, and culture at the time of the postoperative visit. Prolonged catheterization was defined as the presence of an indwelling catheter for more than 10 days postoperatively. Routine collection of urine sample for culture was only done for the trial participants.

In this current study, we tested the hypothesis that there is no difference in the rates of postoperative UTI in the cohort of women who were randomized to either the standard SPC versus the silver-alloy impregnated SPC following surgical repair of POP. The primary outcome was the presence of UTI [21], as defined by one of the following criteria during the 6-week postoperative period: Presence of any symptoms suggestive of UTI with no other identified source such as fever >38 °C, suprapubic tenderness, costovertebral angle tenderness, or otherwise unexplained systemic symptoms, such as altered mental status, hypotension, or evidence for a systemic inflammatory response syndrome requiring antibiotic treatment, urine culture with $>10^5$ cfu/mL, urine culture with $>10^3$ cfu/mL, and evidence for pyuria (dipstick positive for leukocyte esterase and/or nitrites, microscopic pyuria) or the presence of microbes seen on Gram stain of unspun urine. For the analysis of the primary outcome, a patient was considered to have sufficient follow-up if they had met the UTI criteria mentioned above within 6 weeks postoperatively or if they had a postoperative follow-up visit either in the clinic or a postoperative follow-up phone call completed by a member of the study personnel that confirmed the absence of UTI 6 weeks following surgery.

Baseline data were collected for the subjects including demographic data, medical and surgical history, and physical examination, including height, weight, and a preoperative urine culture. The details of the operative procedures performed, estimated blood loss, duration of surgery, duration of indwelling catheter in the postoperative period, and details of postoperative complications as per the expanded Accordion grading system were noted [22]. If a patient was treated for UTI, the diagnostic criteria and the details of treatment were noted.

Randomization

After receiving signed consent, patients were randomly assigned to either the standard SPC or the silver-alloy impregnated SPC using a dynamic allocation approach based on the Pocock–Simon method to ensure balance between the treatment groups based on the following stratification factors: diabetes (yes versus no), body mass index (BMI < 30 kg/m^2, ≥30 kg/m^2), presence of UTI in the past year (yes versus no), and menopausal/hormone replacement status (postmenopausal not on hormone replacement therapy [HRT] versus all others). Patients taking both oral and vaginal routes were included in the HRT group, but they were not categorized based on the type of HRT intake (oral or vaginal). The study coordinator(s) obtained the randomization assignment for each patient by entering the patient's stratification levels into a web-based computer application prepared by the study statistician. Patients were blinded to the type of SPC. The suprapubic catheters can be differentiated by appearance; hence, the providers could not be blinded to treatment allocation.

Calculation of sample size

Previous studies of transurethral latex catheters have demonstrated a percentage reduction in UTI incidence of ranging from 27 to 73% [23, 24] with the use of silver-alloy-impregnated catheters compared with the standard latex Foley catheters. Additionally, previously published data from our center reported a UTI rate of 19% [25] with use of the standard latex Foley catheters used for SPC in a postoperative urogynecology population. Therefore, as there are to our knowledge no previous studies evaluating the UTI rate with use of the silver-alloy-impregnated SPC, a conservative estimate of a 10% reduction was used in our sample size calculation. The study was designed with 80% power to enroll a total of 222 patients per treatment to detect a 10% difference (20% vs 10%) in the UTI rate between treatment arms assuming a 10% dropout rate. This calculation was based on a two-sided Chi-squared test with a type I error level of 0.05. However, because of the lower than anticipated enrollment the study was closed to enrollment after 288 patients instead of the targeted 444 patients.

Statistical analysis

Statistical analysis was by intention to treat and was performed using the SAS version 9.3 software package. Data are summarized using standard descriptive statistics. The baseline and intraoperative patient characteristics of the two treatment arms were compared using the two-sample *t* test for age and BMI, the Wilcoxon rank-sum test for parity, Charlson index, duration of surgery, estimated blood loss, and days from surgery to SPC removal, and the Chi-squared test or Fisher's exact test for the remaining categorical variables. These characteristics were evaluated for an association with having a postoperative UTI within 6 weeks of surgery based on fitting univariate logistic regression models. A multivariate

model was fitted that included known risk factors from the literature and factors identified on univariate analysis. Associations are summarized using odds ratios (ORs) and corresponding 95% confidence intervals (CIs). All calculated p values were two-sided and p values less than 0.05 were considered statistically significant.

Results

The trial enrolled 288 women from 1 August 2011 to 30 August 2017, of whom 127 women received the standard SPC and 137 women received the silver-alloy SPC. A total of 24 women did not receive the allocated treatment for the reasons listed in Fig. 1. Of the remaining 264 women, the SPC catheter fell out prematurely for one patient and another patient underwent replacement of the silver-alloy SPC with a regular SPC 1 week after the surgery. These two patients were included in the intention-to-treat analysis.

Details of the demographic characteristics of both groups are reported in Table 1. Overall, there was no difference between the two groups in the tabled baseline demographic and clinical characteristics or parity or Charlson comorbidity index (data not shown). More women in the silver-alloy SPC group underwent hysterectomy ($n = 108$, 78.8% in the silver-alloy SPC group vs $n = 85$, 66.9% in the standard SPC group, $p = 0.03$) and adnexal surgery ($n = 114$, 83.2% in the silver-alloy SPC group vs $n = 91$, 71.7% in the standard SPC group, $p = 0.02$) compared with the standard SPC group. The groups did not differ with respect to the concomitant mid-urethral sling procedures performed ($n = 33$, 26.0% in the standard SPC group vs $n = 37$, 27.0% in the silver-alloy SPC group, $p = 0.85$). Twelve women (6 with standard SPC and 6 with silver-alloy SPC) had their catheter still in place after 6 weeks. There was no difference in the postoperative complications (based on the expanded Accordion classification) between the two groups up to 6 weeks (Table 2).

Of the 264 women, 254 had sufficient follow-up and 53 women (20.9%) were diagnosed with UTI within 6 weeks of surgery. There was no difference in the 6-week UTI rate for the standard SPC group (29 out of 123, 23.6%) and the silver-alloy SPC group (24 out of 131, 18.3%; $p = 0.30$, 95% CI for difference in the rates −7.1 to 23.0%). Of the 53 patients with a UTI within 6 weeks, 40 (75.5%) were diagnosed before SPC

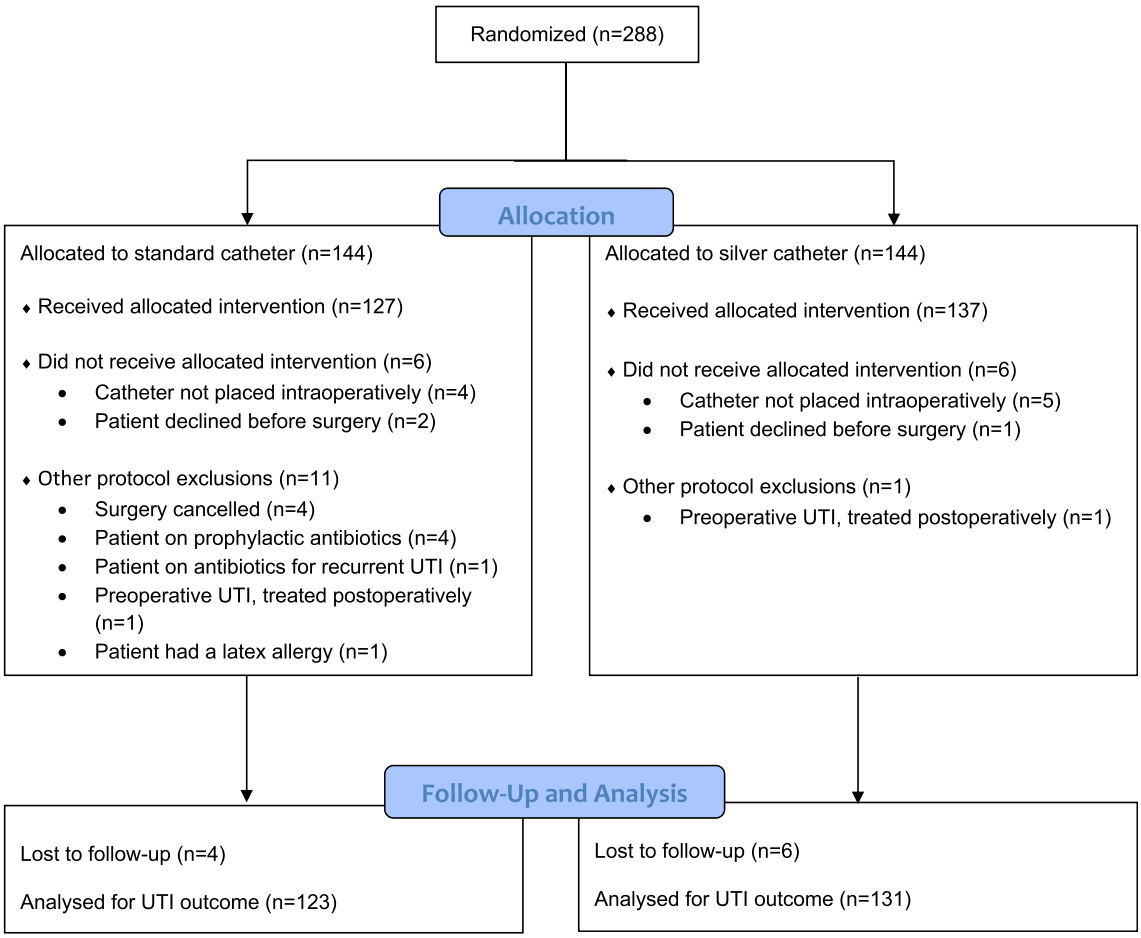

Fig. 1 Consolidated Standards of Reporting Trials flow diagram

Table 1 Comparison of baseline demographics between the two treatment arms

Characteristic	Standard SPC $N = 127$	Silver-alloy SPC $N = 137$	p*
Demographic and medical history			
Age at surgery (years), mean (SD)	66.3 (10.4)	64.7 (10.5)	0.23
BMI (kg/m^2), mean (SD)	27.8 (5.2)	27.6 (5.0)	0.80
BMI ≥30 kg/m^2, *n* (%)	31 (24.4)	31 (22.6)	0.73
Race, *n* (%)			0.72
Non-white	2 (1.6)	5 (3.6)	
White	124 (97.6)	131 (95.6)	
Unknown	1 (0.8)	1 (0.7)	
Postmenopausal not on HRT, *n* (%)	97 (76.4)	90 (65.7)	0.06
Current smoker, *n* (%)	2 (1.6)	5 (3.6)	0.45
Diabetes, *n* (%)	16 (12.6)	15 (10.9)	0.68
Corticosteroid use, *n* (%)	1 (0.8)	1 (0.7)	0.99
ASA score ≥ 3, *n* (%)	23 (18.1)	17 (12.4)	0.20
Intraoperative			
Hysterectomy, *n* (%)	85 (66.9)	108 (78.8)	0.03
Adnexal surgery, *n* (%)	91 (71.7)	114 (83.2)	0.02
Open abdominal surgery, *n* (%)	8 (6.3)	8 (5.8)	0.88
Apical suspension[b]	113 (89.0)	125 (91.2)	0.54
Anterior vaginal repair, *n* (%)	117 (92.1)	127 (92.7)	0.86
Posterior vaginal repair, *n* (%)	118 (92.9)	127 (92.7)	0.95
Sacrocolpopexy, *n* (%)	8 (6.3)	7 (5.1)	0.68
Anti-incontinence procedure, *n* (%)[a]	35 (27.6)	40 (29.2)	0.77
Ureteral stent placement, *n* (%)			0.20
No	122 (96.1)	125 (91.2)	
Yes	5 (3.9)	11 (8.0)	
Unknown	–	1 (0.7)	
Urinary tract injury, *n* (%)	2 (1.6)	4 (2.9)	0.69
Duration of surgery (min), median (IQR)	127 (108, 158)	136 (110, 169)	0.31
Estimated blood loss (mL), median (IQR)	200 (200, 300)	250 (200, 300)	0.38
Days from surgery to SPC removal, median (IQR)	13 (9, 18)	13 (9, 17)	0.55
Prolonged catheterization (>10 days), *n* (%)	85 (66.9)	92 (67.2)	0.97

ASA American Society of Anesthesiologists, *BMI* body mass index, *CVA* cerebrovascular accident, *HRT* hormone replacement therapy, *IQR* interquartile range, *SD* standard deviation, *SPC* suprapubic catheter

*Comparisons between the two treatment arms were evaluated using the two-sample *t* test for age and BMI, the Wilcoxon rank-sum test for parity, Charlson index, duration of surgery, estimated blood loss, and days from surgery to SPC removal and the Chi-squared test or Fisher's exact test for the remaining categorical variables

[a] Includes 70 midurethral sling, 4 Burch retropubic urethropexy, and 1 urethral bulking procedure

[b] Intraperitoneal colpopexy utilizing Modified McCall's culdoplasty

removal (median time to UTI was 10 days, range 5–41 days; median duration of SPC use was 10 days, range 5–42 days). The remaining 13 women (24.5%) were diagnosed with UTI after removal of the SPC (median time to UTI was 24 days, range 13–34 days; median duration of SPC use was 11 days, range 5–22 days). UTI was diagnosed by a positive urine culture >10^5 cfu/ml in 30 women and by a positive urine culture >10^3 cfu/ml with evidence for pyuria in one woman. Of the remaining 22 women, UTI was diagnosed based on a combination of symptoms and/or urine testing in 16 women and unknown in 6 women. The most common organism that was present on culture was Enterococcus, followed by Staphylococcus, *E. coli*, Acinetobacter, Proteus, Pseudomonas, and Serratia. Focusing on the UTI's diagnosed by a positive urine culture, the 6-week UTI rates were 13.0% (16 out of 123) and 11.5% (15 out of 131) for the standard SPC group and the silver-alloy SPC group respectively.

Univariate analysis showed that nonwhite women (odds ratio 5.36, 95% CI 1.16–24.73) and women with diabetes (OR 2.80, 95% CI 1.26–6.23) were more likely to have 6-

Table 2 Comparison of the two treatment arms with regard to Accordion-graded complications within 6 weeks following surgery

Characteristic	Standard SPC $N = 127$	Silver-alloy SPC $N = 137$	p*
Expanded Accordion Classification			0.79
No complications	84 (66.1)	91 (66.4)	
Mild	9 (7.1)	15 (10.9)	
Moderate	31 (24.4)	28 (20.4)	
Severe: invasive procedure/no GA	1 (0.8)	1 (0.7)	
Severe: invasive procedure under GA or single organ system failure[a]	2 (1.6)	2 (1.5)	
Severe: organ system failure and invasive procedure under GA or multisystem organ failure	–	–	
Deaths	–	–	

GA general anesthesia

*The complication grades of the two treatment arms were compared using the Wilcoxon rank-sum test

[a] Severe complications in the standard SPC group included reoperation for a vaginal constriction ring, and readmission for pulmonary embolism and ureteral stent placement. Severe complications in the silver SPC group included readmission for chest pain, reoperation of urinary retention, and hematuria

week postoperative UTI (Table 3). However, women with prolonged catheterization, defined as removal after more than 10 days, were less likely to have a 6-week postoperative UTI (OR 0.54, 95% CI 0.29, 0.99). There was no association between 6-week postoperative UTI and age, BMI, smoking status, corticosteroid use, Charlson comorbidity index, American Society of Anesthesiologists (ASA) score, and the type of surgery performed, concomitant anti-incontinence procedure, duration of surgery, estimated blood loss, and the type of catheter used. A multivariate model including diabetes (adjusted OR 2.82, 95% CI 1.24–6.40), nonwhite race (adjusted OR 4.96, 95% CI 0.99–24.94), concomitant anti-incontinence procedure (adjusted OR 0.76, 95% CI 0.35–1.64), and duration of surgery (adjusted OR per 60-min increase 1.11, 95% CI 0.76–1.60) only identified diabetes as being independently associated with UTI in the 6-week postoperative period. The direction of the association between prolonged catheterization and postoperative UTI was in the opposite direction; hence, we did not include it in the multivariate analysis.

Discussion

The UTI rates in the 6-week postoperative period after pelvic reconstructive surgery for prolapse were 23.6% in women with the standard SPC and 18.3% in the silver-alloy SPC group; the observed difference was not clinically meaningful and the study was not powered to detect such a small difference as statistically significant. The rates of UTI in women undergoing reconstructive surgery for POP with/without a concomitant anti-incontinence procedure have been reported to range from 9 to 31% [15–18]. The rates of UTI in women undergoing suprapubic catheterization after a pelvic reconstructive surgery have been shown to vary from 6 to 24% [17, 26, 27]. The variability in the rates of UTI may be explained by the different criteria used to define and treat symptomatic UTI, and the use of prophylactic antibiotics with an indwelling catheter. As per our institution protocol, the women did not receive prophylactic antibiotics with an indwelling SPC, which is congruent to the standard practice recommendations [20].

Our data did not reveal an association between the risk of UTI within the 6-week postoperative period and age, BMI ≥30 kg/ m^2, postmenopausal status, and smoking; which is comparable with the pre-existing evidence on women undergoing pelvic reconstructive surgery [17, 18, 28]. Women with a history of recurrent UTI were not included in this study as they are at an increased risk of having postoperative UTI, and may not represent all women undergoing pelvic reconstructive surgery [18, 28]. We did not find an association between the duration of suprapubic catheterization and UTI, a finding noted in a previous trial involving SPC after prolapse surgery [17]. However, the need for prolonged transurethral catheterization (>10 days) and self-intermittent catheterization has been shown to increase the risk for postoperative UTI [17, 18, 28–30]. In contrast to the pre-existing data, a concomitant anti-incontinence procedure or an intraoperative urinary tract injury did not increase the risk of UTI [18, 26, 29]. Diabetes was the only factor associated with an increased risk for UTI in the 6-week postoperative period.

The pre-existing literature is unclear on the effect of transurethral silver-alloy catheters on the reduction of asymptomatic bacteriuria and/or symptomatic catheter-associated UTI in hospitalized patients in both acute and chronic settings. The women in the silver-alloy SPC cohort did not show a statistically significant difference in UTI rate compared with the standard SPC cohort. Similarly, a three-arm multicenter randomized trial did not observe any improvement in symptomatic catheter-associated UTI/bacteriuria with the use of silver-

Table 3 Summary of factors evaluated for an association with urinary tract infection (UTI) within weeks following surgery

Characteristic[a]	No UTI within 6 weeks $N = 201$	UTI within 6 weeks $N = 53$	OR (95% CI)[d]	p
Age at surgery (years)	65.4 (10.4)	66.2 (11.4)	1.08 (0.81, 1.45)	0.59
BMI ≥30 kg/m^2	42 (20.9)	16 (30.2)	1.64 (0.83, 3.23)	0.15
White race	197/200 (98.5)	49 (92.5)	0.19 (0.04, 0.86)	0.03
Parity				0.53
0	2 (1.0)	1 (1.9)	Reference	
1	13 (6.5)	3 (5.7)	0.46 (0.03, 6.93)	
2	82 (40.8)	16 (30.2)	0.39 (0.03, 4.57)	
3	56 (27.9)	15 (28.3)	0.54 (0.05, 6.32)	
4+	48 (23.9)	18 (34.0)	0.75 (0.06, 8.79)	
Postmenopausal = not on HRT	144 (71.6)	36 (67.9)	0.84 (0.44, 1.61)	0.60
Current smoker	6 (3.0)	0 (0.0)	0.28 (0.01, 6.38)[e]	0.43
Diabetes	19 (9.5)	12 (22.6)	2.80 (1.26, 6.23)	0.01
Radiation history	5 (2.5)	0 (0.0)	0.33 (0.01, 8.08) [e]	0.50
Corticosteroid use	1 (0.5)	0 (0.0)	1.25 (0.01, 116.58) [e]	0.92
History of CVA	6 (3.0)	0 (0.0)	0.28 (0.01, 6.38) [e]	0.43
Charlson comorbidity index (severity weighted sum of diseases)				0.26
0	121 (60.2)	26 (49.1)	Reference	
1	39 (19.4)	17 (32.1)	2.03 (1.00, 4.13)	
2	26 (12.9)	7 (13.2)	1.25 (0.49, 3.20)	
3+	15 (7.5)	3 (5.7)	0.93 (0.25, 3.45)	
Charlson comorbidity index (age and severity weighted sum of diseases)				0.27
0	12 (6.0)	4 (7.5)	Reference	
1	33 (16.4)	11 (20.8)	1.00 (0.27, 3.75)	
2	60 (29.9)	7 (13.2)	0.35 (0.09, 1.39)	
3	39 (19.4)	13 (24.5)	1.00 (0.27, 3.65)	
4	22 (10.9)	9 (17.0)	1.23 (0.31, 4.84)	
5+	35 (17.4)	9 (17.0)	0.77 (0.20, 2.97)	
ASA score ≥ 3	29 (14.4)	11 (20.8)	1.55 (0.72, 3.36)	0.26
Intraoperative				
Hysterectomy	144 (71.6)	42 (79.2)	1.51 (0.73, 3.14)	0.27
Adnexal surgery	154 (76.6)	42 (79.2)	1.17 (0.56, 2.44)	0.69
Open abdominal surgery	13 (6.5)	2 (3.8)	0.57 (0.12, 2.59)	0.46
Anterior vaginal repair	184 (91.5)	50 (94.3)	1.54 (0.43, 5.46)	0.50
Posterior vaginal repair	185 (92.0)	51 (96.2)	2.21 (0.49, 9.91)	0.30
Sacrocolpopexy	12 (6.0)	3 (5.7)	0.95 (0.26, 3.48)	0.93
Anti-incontinence procedure[b]	59 (29.4)	15 (28.3)	0.95 (0.49, 1.86)	0.88
Intraoperative ureteral stent placement	11/200 (5.5)	5 (9.4)	1.79 (0.59, 5.40)	0.30
Intraoperative urinary tract injury	4 (2.0)	2 (3.8)	1.93 (0.34, 10.84)	0.45
Duration of surgery (min)	131 (108, 166)	134 (119, 166)	1.10 (0.80, 1.53)	0.56
Estimated blood loss (mL)	200 (200, 300)	250 (200, 300)	1.25 (0.85, 1.83)	0.26
Days to catheter removal, truncated at UTI date if removed after UTI	12 (9, 17)	10 (8, 16)	0.99 (0.96, 1.03)	0.58
Standard SPC (versus silver-alloy)	94 (46.8)	29 (54.7)	1.38 (0.75, 2.53)	0.30
Prolonged catheterization (>10 days)[c]	129 (64.2)	26 (49.1)	0.54 (0.29, 0.99)	0.046

[a] n and % reported for categorical variables, mean and standard deviation reported for age, and median and interquartile range reported for duration of surgery, estimated blood loss, and days to catheter removal

[b] Includes midurethral sling, Burch retropubic urethropexy, and urethral bulking procedure

[c] Truncated at UTI date if removed after UTI

[d] Odds ratio per 10-year increase in age, per 60-min increase in duration of surgery, per 100-mL increase in estimated blood loss, and per 1-day increase in days to catheter removal

[e] Firth bias correction applied owing to zero cell issue

alloy-coated catheters in hospitalized patients requiring short-term catheterization [11]. Clinical strategies have been evaluated to minimize the risk of catheter-associated UTI in women undergoing pelvic reconstructive surgeries. A randomized trial evaluating the use of prophylactic antibiotics in women with SPC after pelvic reconstructive surgery noted a decrease

in the rates of UTI in the antibiotic group compared with placebo [17]. On the contrary, Dieter et al. randomized women (with either indwelling transurethral catheter or self-intermittent catheterization) after reconstructive procedures to prophylactic antibiotics or placebo and did not note a difference in UTI rates [15]. We are not aware of any published studies evaluating the use of the silver-alloy catheter for UTI prevention in women undergoing pelvic reconstructive surgeries. This is a randomized control trial that compared the risk for catheter-associated UTI related to the silver-alloy catheter and the standard catheter when used for suprapubic drainage after a pelvic reconstructive procedure that has not been done before. The study was performed at a single institution, and hence the surgical procedures and postoperative management were standardized.

The study was designed to enroll a total of 444 patients to be sufficiently powered to detect a 10% difference in UTI rates between the two groups. Although the study was closed to enrollment after 288 patients owing to lower than anticipated enrollment, only a 5% difference in rates was observed. This increases the risk for a type II error and is a major limitation of the study. Another limitation of the study is that not all patients were able to return for in-person postoperative evaluation. However, study personnel were able to communicate with those women who could not come for a follow-up. Also, as some of the women were evaluated for symptoms of UTI at other institutions, they were treated based on clinical suspicion only, without evidence for culture-proven UTI. However, our criteria of defining symptomatic UTI based on a combination of clinical suspicion and/or positive cultures improves the generalizability of our results, as it reflects usual clinical practice. This definition has been successfully used by various other trials [15, 18, 29]. However, this may have led to overestimation of the rate of UTI in the study.

Conclusion

We conclude that there was no clinically meaningful difference in the rates of UTI in the 6-week postoperative period among women with the silver-alloy suprapubic catheters compared with the standard suprapubic catheters after pelvic reconstructive surgery for prolapse. However, the risk for postoperative UTI was increased for diabetic women.

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Compliance with ethical standards

Conflicts of interest John B. Gebhart: royalties from UpToDate and Elsevier. All the other authors declare that they have no conflicts of interest.

References

1. Saint S, Veenstra DL, Sullivan SD, Chenoweth C, Fendrick AM. The potential clinical and economic benefits of silver alloy urinary catheters in preventing urinary tract infection. Arch Intern Med. 2000;160:2670–5.
2. Umscheid CA, Mitchell MD, Doshi JA, Agarwal R, Williams K, Brennan PJ. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol. 2011;32:101–14.
3. Warren JW, Platt R, Thomas RJ, Rosner B, Kass EH. Antibiotic irrigation and catheter-associated urinary-tract infections. N Engl J Med. 1978;299:570–3.
4. Haley RW, Hooton TM, Culver DH, Stanley RC, Emori TG, Hardison CD, et al. Nosocomial infections in US hospitals, 1975–1976: estimated frequency by selected characteristics of patients. Am J Med. 1981;70:947–59.
5. Tambyah PA, Knasinski V, Maki DG. The direct costs of nosocomial catheter-associated urinary tract infection in the era of managed care. Infect Control Hosp Epidemiol. 2002;23:27–31.
6. Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA, Healthcare Infection Control Practices Advisory Committee. Guideline for prevention of catheter-associated urinary tract infections 2009. Infect Control Hosp Epidemiol. 2010;31(4):319–26.
7. Lam TB, Omar MI, Fisher E, Gillies K, MacLennan S. Types of indwelling urethral catheters for short-term catheterisation in hospitalised adults. Cochrane Database Syst Rev. https://doi.org/10.1002/14651858.CD004013.pub4.
8. Saint S, Elmore JG, Sullivan SD, Emerson SS, Koepsell TD. The efficacy of silver alloy-coated urinary catheters in preventing urinary tract infection: a meta-analysis. Am J Med. 1998;105:236–41.
9. Johnson JR, Delavari P, Azar M. Activities of a nitrofurazone-containing urinary catheter and a silver hydrogel catheter against multidrug-resistant bacteria characteristic of catheter-associated urinary tract infection. Antimicrob Agents Chemother. 1999;43:2990–5.
10. Johnson JR, Kuskowski MA, Wilt TJ. Systematic review: antimicrobial urinary catheters to prevent catheter-associated urinary tract infection in hospitalized patients antimicrobial urinary catheters. Ann Intern Med. 2006;144:116–26.
11. Pickard R, Lam T, MacLennan G, Starr K, Kilonzo M, McPherson G, et al. Antimicrobial catheters for reduction of symptomatic urinary tract infection in adults requiring short-term catheterisation in hospital: a multicentre randomised controlled trial. Lancet. 2012;380:1927–35.
12. Branagan GW, Moran BJ. Published evidence favors the use of suprapubic catheters in pelvic colorectal surgery. Dis Colon Rectum. 2002;45:1104–8.
13. Feiks A, Kosain K, Gruber W. Suprapubic bladder drainage versus a transurethral catheter in patients following anterior colporrhaphy. Wien Klin Wochenschr. 1987;99:268–72.
14. Krisman AM, Henderson RB. Suprapubic bladder drainage following anterior vaginal wall repair. Can Med Assoc J. 1969;101:164–6.
15. Dieter AA, Amundsen CL, Edenfield AL, Kawasaki A, Levin PJ, Visco AG, et al. Oral antibiotics to prevent postoperative urinary tract infection: a randomized controlled trial. Obstet Gynecol. 2014;123:96–103. https://doi.org/10.1097/AOG.0000000000000024.
16. Chung CP, Kuehl TJ, Harris SK, McBride MM, Larsen WI, Yandell PM, et al. Incidence and risk factors of postoperative urinary tract infection after uterosacral ligament suspension. Int Urogynecol J. 2012;23:947–50.
17. Rogers RG, Kammerer-Doak D, Olsen A, Thompson PK, Walters MD, Lukacz E, et al. A randomized, double-blind, placebo-controlled comparison of the effect of nitrofurantoin monohydrate macrocrystals on the development of urinary tract infections after

surgery for pelvic organ prolapse and/or stress urinary incontinence with suprapubic catheterization. Obstet Gynecol. 2004;191:182–7.
18. Nygaard I, Brubaker L, Chai TC, Markland AD, Menefee SA, Sirls L, et al. Risk factors for urinary tract infection following incontinence surgery. Int Urogynecol J. 2011;22:1255–65.
19. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med. 2001;134:663–94.
20. Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA, Healthcare Infection Control Practices Advisory Committee. Guideline for prevention of catheter-associated urinary tract infections 2009. Infect Control Hosp Epidemiol. 2010;31:319–26. https://doi.org/10.1086/651091.
21. Hooton TM, Bradley SF, Cardenas DD, Colgan R, Geerlings SE, Rice JC, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 international clinical practice guidelines from the Infectious Diseases Society of America. Clin Infect Dis. 2010;50:625–63.
22. Strasberg SM, Linehan DC, Hawkins WG. The accordion severity grading system of surgical complications. Ann Surg. 2009;250:177–86. https://doi.org/10.1097/SLA.0b013e3181afde41.
23. Liedberg H, Lundeberg T. Silver alloy coated catheters reduce catheter-associated bacteriuria. BJU Int. 1990;65:379–81.
24. Karchmer TB, Giannetta ET, Muto CA, Strain BA, Farr BM. A randomized crossover study of silver-coated urinary catheters in hospitalized patients. Arch Intern Med. 2000;160:3294–8.
25. Gebhart JB, Dixon DA, Trabuco EC, Klingele CJ, Bagniewski SM, Weaver AL. Three-year outcomes of uretex urethral support system for treatment of stress urinary incontinence. Int Urogynecol J. 2008;19:1075–9.
26. Stekkinger E, van der Linden PJ. A comparison of suprapubic and transurethral catheterization on postoperative urinary retention after vaginal prolapse repair: a randomized controlled trial. Gynecol Obstet Investig. 2011;72:109–16. https://doi.org/10.1159/000323827.
27. Anand M, Weaver AL, Fruth KM, Borah BJ, Klingele CJ, Gebhart JB. Perioperative complications and cost of vaginal, open abdominal, and robotic surgery for apical vaginal vault prolapse. Female Pelvic Med Reconstr Surg. 2017;23:27–35. https://doi.org/10.1097/SPV.0000000000000345.
28. Sutkin G, Alperin M, Meyn L, Wiesenfeld HC, Ellison R, Zyczynski HM. Symptomatic urinary tract infections after surgery for prolapse and/or incontinence. Int Urogynecol J. 2010;21:955–61.
29. Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med. 2007;356:2143–55.
30. Karp NE, Kobernik EK, Kamdar NS, Fore AM, Morgan DM. Length of catheter use after hysterectomy as a risk factor for urinary tract infection. Female Pelvic Med Reconstr Surg. 2017; https://doi.org/10.1097/SPV.0000000000000486.