Randomized Control Trial of Silver-Alloy Impregnated Suprapubic Catheters in Urogynecology Patients

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MAYO CLINIC

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Title:
Randomized control trial of silver-alloy impregnated suprapubic catheters in urogynecology patients

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Abstract:

Worldwide, 96 million indwelling urethral catheters sold annually; 24 million of which are sold in USA.[1] 25% of hospitalized patients have a urinary catheter placed at some point during their stay[2]. Additionally, catheter-associated urinary tract infections (CAUTI) is the 2nd leading cause of nosocomial infections with 20% of hospital acquired bacteremia arising from urinary tract infection (UTI)[3]. The incidence of bacteriuria is estimated to be 3 to 10%[2, 4] per day of catheterization.

Adverse consequences of CAUTI include local and systemic morbidity, secondary bacteriuria, death, increased antimicrobial-resistance, and increased health care costs. Bacteremia complicating bacteriuria has been reported in up to 4% of patients.[5, 6] Given the significant prevalence and morbidity of CAUTI, many strategies have been suggested to reduce CAUTI. These have included irrigation of the bladder, instilling antimicrobial agents in the drainage bag and rigorously cleaning the meatus. None of these strategies have proven to be effective. [7]

Other attempts to reduce CAUTI include the development of different types of catheters. Standard indwelling catheters are made from a variety of materials including polyvinyl chlorine, plastic, plain latex, polytetrafluoroethylene, silicone elastomer, pure silicone hydrogel and polymer hydromer[8]. More recently, specialized catheters have been developed which involve coating the inner, outer or both surfaces of the catheter with antimicrobial materials[9]. These materials can be antibiotic or antiseptic with the most common antiseptic material used being silver. Silver ions are bactericidal, are used safely when applied topically to humans and used in controlling infections[10].

Previous studies of latex-based catheters have demonstrated that use of silver alloy impregnated catheters reduced the incidence of CAUTI.[11]. The magnitude of this reduction has been reported to range from 27% to 73%[12-15] in prospective randomized trials. These numbers are strengthened by a recent meta-analysis which concluded that silver alloy catheters significantly reduced bacteriuria by 3-fold compared with standard catheters[16]. Although the previous work demonstrates encouraging results in decreasing CAUTI, the studies have varied in patient population, clinical indication and definition of outcomes. Moreover, there are no previous studies evaluating the effectiveness of silver alloy impregnated catheters for suprapubic use.

Urogynecology patients undergoing pelvic reconstructive surgery require bladder drainage in the immediate post-operative period. This can be achieved by placement of either a transurethral or suprapubic catheter (SPC). Although the SPC is more invasive compared to a transurethral catheter, the SPC is used routinely in many gynecologic surgical practices because of its' many advantages. These include prevention of urethral trauma and stricture formation, decreased UTI[17, 18], increased patient satisfaction compared to chronic indwelling urethral catheters, less discomfort[19], avoidance of urethritis[20], maintained ability to void spontaneously, easier nursing care[21], and shorter hospital stay[18] . Review of literature does not demonstrate any benefit with any particular type of SPC[22].

We hypothesize that this study will show a statistically significant decrease in UTI rate among the urogynecology patients undergoing suprapubic catheterization with a silver-alloy catheter compared to the standard catheter.

Schematic Design of the Study: randomized control trial

Aims:

1) To compare the UTI rate among women undergoing urogynecological procedures with a silver-alloy suprapubic catheter compared to the standard supra-pubic catheter.
2) To identify risk factors predisposing patients to suprapubic CAUTI.

Methods

Description of Recruitment Methods:

How will subjects be identified?

Individuals who are being scheduled for a surgery which routinely requires placement of suprapubic catheter intraoperatively (i.e. abdominal sacrocolpopexy, anterior vaginal colporrhaphy, Burch colposuspension with and without mid-urethral sling), will be approached about participating in the study in the pre-operative urogynecology clinic.

How will subjects be contacted?

Subjects will be contacted in the Urogynecology clinic during the pre-operative visit. They will also be contacted during their routine 6-week follow-up post-operative visit in Urogynecology clinic. Additionally, if a patient has symptoms of a UTI or seeks medical treatment for a UTI during the 6 week post-operative period, we will ask the patient to contact the study team.

Recruitment Materials (if applicable):

n/a

Subject Population:

Number (total, each subgroup) 444 total, 222 per group

Gender:

Male	0
Female	444

Ages: 18 to 99 years

Inclusion Criteria:

- patients requiring intra-operative placement of suprapubic catheters as part of routine post-operative care for repair of anterior compartment prolapse i.e. patients undergoing anterior colporrhaphy, Burch colposuspension, with or without mid-urethral sling

Exclusion Criteria:

- Known UTI at time of surgery

- Unable to provide informed consent
- Use of chronic intermittent self-catheterization pre-operatively
- Use of chronic prophylactic antibiotics
- Use of antibiotics for any indication other than UTI during peri-operative and 6-week post-operative period
- Presence of fistula involving urogenital tract
- Use of chronic steroids or immunosuppressant
- Immunocompromised patient

Step-by-Step Schedule (include all procedures, therapies – attach a table or flow chart if there are multiple procedures or visits and indicate the window of number of days in which the participant may return for follow-up visits):

1. Informed consent obtained pre-operatively to participate in study
2. Collection of baseline information including demographics, stage of prolapse, past medical history, past surgical history, history of past UTI, laboratory studies including collection of urine for urinalysis and bacterial gram stain and culture.
3. Computer-generated randomization of subjects to either the control group (standard non-latex foley catheter) or the treatment group (silver alloy-impregnated catheter), in blocks of 4. Patients and study staff involved in outcome assessment will be blinded to type of treatment allocation.
4. Removal of catheter per standard post-operative catheter care (adequate urinary output over 24 hours, lack of gross hematuria, able to void voluntarily)
5. If a patient has symptoms of a UTI or seeks medical treatment for a UTI during the 6 week post-operative period, we will ask the patient to contact the study team.
6. Review of patient and medical records at 6 week follow-up visit for UTI and laboratory evidence, if available.
7. If suprapubic catheter still in place, sending urine sample obtained by catheter for urinalysis, bacterial gram stain and culture.

Biospecimen (types, number, volume, processing, storage): n/a

Plan for Dose Modification if Toxicity occurs (if applicable): n/a

Statistical Considerations

Endpoints

Primary: UTI rate

UTI is defined as:

(1) any symptoms (fever > 38°C, suprapubic tenderness, costovertebral angle tenderness, or otherwise unexplained systemic symptoms such as altered mental status, hypotension, or evidence of a systemic inflammatory response syndrome) requiring antibiotic treatment
(2) urine culture with > 10^5 cfu / mL
(3) urine culture with > 10^3 cfu/ mL and evidence of pyuria (dipstick positive for leukocyte esterase and/or nitrite, microscopic pyuria, or presence of microbes seen on Gram stain of unspun urine)[22]

Secondary:

Power Statement:

Previous studies of transurethral latex catheters have demonstrated a reduction in CAUTI incidence of ranging from 27% to 73%[12-15] with use of silver-impregnated catheters compared to standard latex foley catheters. Additionally, a previously published data from our center reported a CAUTI rate of 19%[23] with use of standard foley catheters used for SPC in a postoperative urogynecology population. Therefore, since there are no previous studies evaluating the CAUTI rate of silver-impregnated SPC use, a conservative estimate of 10% reduction will be used in our sample size calculation.

To obtain 80% power, with a difference in UTI rate of 10%, then the sample size per group that we hope to recruit is 400. However, we anticipate 10% drop-out so we will plan to recruit 222 per group, summing 444 total participants.

Data Analysis:

Continuous variables will be compared using a two sided t-test with alpha ≤ 0.05 considered statistically significant. Binary outcomes (UTI vs. no UTI) will be compared using Fisher's exact test. Descriptive statistics will be used to describe continuous variables for the two types of catheters. Multiple logistic regression will be used to adjust for confounders such as prior UTI, duration of catheterization, type of surgery performed, age, BMI, and comorbid conditions. Strength of association between UTI rate and confounders will be assessed by calculating odds ratios and their corresponding 95% confidence intervals.

Human Safety Aspects

Risks: The literature review does not reveal any added adverse effects of using silver-alloy catheters, above standard non-silver-alloy coated catheters. Since all patients, regardless of study participation, will have SPCs placed post-operatively as part of routine care, we do not anticipate any additional risks to participants.

Individual Subject Stopping Rules (if applicable): n/a

DSMB (if applicable):

Members:

n/a

Charter:

n/a

Stopping Rules for Efficacy and Safety (if applicable):

n/a

Questionnaires that ask about Depression (if applicable)

Included in study? Yes ☐ No ☒

If "Yes", state the plan of management for subjects with possible depression:

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