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Title	Is Self-discontinuation of a transurethral catheter following pelvic reconstructive surgery as effective as office-based discontinuation?; A Randomized Controlled Trial
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Purpose of Study:

- To determine if self-discontinuation of transurethral foley catheters in patients diagnosed with postoperative urinary retention (POUR) following inpatient pelvic organ prolapse surgery is non-inferior to office-discontinuation.
    - **Primary Aim:** To determine the incidence of POUR (as defined as the continued need for catheterization) at postoperative day 6-8 (POD6-8) following inpatient pelvic organ prolapse surgery in patients who self-discontinue their indwelling urinary catheter compared to those who present to the office for discontinuation.
    - **Secondary Aims:** To compare patient satisfaction, number of patient related encounters (emergency room, office visit, or telephone calls), incidence of postoperative urinary tract infection (UTI), post void residual volume (PVR) at 2-week postoperative visit, and total duration of catheter use between the two groups.

Hypothesis or Research Question

- We hypothesize that self-removal of indwelling urinary catheters will be non-inferior to office-removal on POD6-8 regarding ongoing symptoms of POUR following inpatient pelvic organ prolapse surgery.
- We further hypothesize that self-removal of indwelling urinary catheters will result in fewer office visits and improved patient satisfaction in the immediate postoperative period.
- In addition, we hypothesize that the duration of POUR (number of days urinary catheter use is required) will be equivalent in the self-removal group compared to that of the office-removal group.
- Lastly, we hypothesize that there will be less incidence of UTI in the self-removal group.

Background

Postoperative urinary retention (POUR) is a common issue following urogynecologic surgery, with incidence rates of 1.4-43% [1-5]. The wide range of incidence is due to the lack of a

standardized definition of POUR. Generally speaking, POUR can be characterized by any impairment in bladder emptying following surgery. While the gold standard for assessing voiding function remains measurement of a postvoid residual (PVR), there are many voiding trial (VT) methods being used across institutions [6]. In our clinical practice, rates of POUR following pelvic reconstructive surgery are approximately 54% [7]. These patients are provided an indwelling transurethral foley catheter to remain in place for approximately one week, at which time they are seen in the office for a subsequent voiding challenge. The incidence of POUR, and continued need for indwelling urinary catheter, at one-week postoperative is approximately 16% (review of prior data from pooled studies of our patients).

Historically, the most widely accepted postoperative VT for the assessment of voiding function was the backfill method. This method consists of retrograde-filling the bladder through the patients foley catheter with 300 mL sterile normal saline (or maximum capacity, if sooner), removing the indwelling urinary catheter, and allowing the patient to void. A voided volume of at least 200 mL (or two-thirds of the instilled volume) is considered passing, and correlates with adequate bladder function. An alternative assessment of voiding function is the spontaneous VT, where the indwelling catheter is removed and a patient is asked to void spontaneously when she has the urge. A PVR is then measured, either by way of ultrasound or with in-and-out catheterization.

It is controversial which of these methods are superior, and studies are conflicted. In a comparison of backfill VT versus spontaneous VT in patients undergoing outpatient urogynecologic surgery, the backfill method was superior in 'passing' rates [8]. However, a recent retrospective study of 1153 patients following urogynecologic surgery showed that backfill VT was associated with an increased rate of urinary tract infections and higher failed trial of void [9]. Furthermore, patient satisfaction does not differ between the two types of VT performed [8]. Nevertheless, both of these methods were studied in a clinical setting, and we lack information on self-discontinuation efficacy at home.

What is evident in all research is that evaluation and management of POUR can be cumbersome, and highly concerning to patients. Patients with indwelling urinary catheters often feel anxiety, embarrassment, and loss of dignity. Furthermore, it has been shown that patients would prefer to be more involved in the decisions around catheter use [10]. Managing an indwelling urinary catheter and returning to the outpatient clinic only a week after discharge from the hospital can be overwhelming for patients and their involved caregivers.

Review of the literature reveals no studies to date regarding self-removal of indwelling urinary catheters. Given the low incidence of POUR at one-week postoperative and patient dissatisfaction with urinary catheter management, home self-removal of indwelling urinary catheters is an important topic of investigation. We aim to fill this knowledge gap by determining the incidence of POUR at POD6-8 with self-removal of indwelling urinary catheters compared to office-removal in the setting of inpatient pelvic organ prolapse surgery. Furthermore, we aim to compare patient satisfaction with self-removal versus office-removal, as previous publications suggest that patients may feel empowered by being more involved in the management of their urinary catheter [10]. If self-removal proves to be non-inferior to

office-removal, this would be a new, efficient and potentially cost-effective management option for POUR.

Research Plan

- **Study Design**
  - Randomized controlled trial
  - Non-inferiority trial

- **Setting for the study**
  - Patients of Cincinnati Urogynecology Associates, TriHealth Inc, undergoing inpatient surgery for pelvic organ prolapse at Good Samaritan Hospital or Bethesda North Hospital who fail their voiding trial will be offered enrollment.
  - Those patients who choose to enroll in the study will be provided with a sealed envelope that will dictate to which group the patient has been randomized.
  - Those patients randomized to the self-removal group will be provided with a diagrammatic handout, illustrating proper removal of their catheter. They will be instructed to remove their indwelling urinary catheter at home on the morning of POD7. They will also be provided with the direct phone number of our Research Nurse and the pager number of our on-call staff, which they will use to contact the team if they are unable to void within 5 hours of catheter removal. If they are unable to void, the Research Nurse or on-call staff will arrange a clinic visit for the same day at one of three outpatient clinics (Clifton, West Chester, Kenwood) for replacement of an indwelling urinary catheter.
  - Those patients randomized to the office-removal group will schedule an office visit for POD6-8 at one of three outpatient clinics (Clifton, West Chester, Kenwood). At this visit the patient will undergo a backfill VT.
  - All patients will present to one of three outpatient clinics (Clifton, West Chester, Kenwood) at two weeks postoperative for a routine postoperative evaluation, measurement of PVR, urine dip, and completion of the patient questionnaire.
  - All patients will present to one of three outpatient clinics (Clifton, West Chester, Kenwood) at six weeks postoperative for a routine postoperative evaluation and urine dip.

- **Participants**
  - Study population: All women 18 years of age or older, who undergo vaginal vault suspension or robot-assisted laparoscopic sacrocolpopexy, with or without additional concomitant procedures by a physician at Cincinnati Urogynecology Associates, TriHealth for treatment of pelvic organ prolapse (POP) and who fail their VT prior to discharge will be approached for recruitment.
  - Inclusion/Exclusion criteria:

        - Inclusion
            - Adults 18 years of age or older
            - Undergoing vaginal vault suspension or robot-assisted laparoscopic sacrocolpopexy by a physician at Cincinnati Urogynecology Associates, TriHealth for the treatment of POP
            - Concomitant procedures such as hysterectomy, suburethral sling, anterior or posterior colporrhaphy, bilateral salpingectomy or salpingooophorectomy
            - Failed voiding trial prior to discharge
        - Exclusion
            - Unwillingness to participate in the study
            - Physical or mental impairment that would affect the subject's ability to self-remove indwelling urinary catheter, including patient's with Multiple Sclerosis, Dementia, Parkinsonism, or those who have impaired mobility or are wheelchair bound
            - Bladder injury, fistula repair or other need for prolonged catheterization
    - Sample size
        - A sample size was calculated to be 74 patients in each arm based on the following:
            - The estimated POUR requiring indwelling urinary catheter at 7 days postoperative is 16% (based on internal audit of data)
            - The non-inferiority margin was set at 15%. [11]
            - The power was set at 80%.
            - Due to estimated loss-to-follow-up rate of approximately 13%, the number of patient enrollment was set at 84 subjects in each group, 168 total.

- **Data Collection**
    - Primary outcome:
        - POUR at POD6-8 as defined by need for continued indwelling urinary catheter or intermittent self-catheterization.
        - Continued indwelling urinary catheter will be required in the following settings:
            - Self-removal group – inability to void or sense of incomplete bladder emptying after 5 hours of catheter removal
            - Office-removal group – voided volume less than two-thirds of the instilled volume or PVR greater than 100mL after backfill of up to 300mL

- Secondary outcomes
  - Scores on patient questionnaire collected at the two-week postoperative visit [12,13] (Patient Questionnaire and Visual Analog Scale)
  - Number of patient contact points (office visits, telephone calls and emergency room visits) regarding POUR or indwelling urinary catheter care up to 2 weeks postoperative.
  - PVR measurement at 2-week postoperative visit.
  - UTI diagnosed within 6 weeks postoperative (as defined by positive urine culture, or treatment with antibiotics by a provider).
  - Total duration (number of days) of urinary catheter use (including indwelling urinary catheter and intermittent self catheterization) within 6 weeks postoperative.
- General demographic data
  - Name, date of birth, age, race, weight, height, BMI, parity, tobacco use, medical comorbidities, date of surgery
- Data collection tool

- **Intervention or experimental aspect of the study**
  - Procedure
    - All patients of Cincinnati Urogynecology Associates who undergo vaginal vault suspension (VVS) or robot-assisted laparoscopic sacrocolpopexy (RSCP) will have a backfill VT on POD1 at 6am, per standard practice. The backfill VT will be performed by the nursing staff. Per protocol, up to 300ml sterile saline will be instilled into the bladder and the indwelling urinary catheter will be removed. Patients will be allotted 30 minutes to void. The instilled volume, voided volume , and PVR if needed will be recorded.
    - Failure of backfill VT is defined by inability to void two-thirds of the instilled volume or PVR greater than 100mL.
    - Patients who fail the backfill VT postoperatively will have an indwelling urinary catheter reinserted and will be taught on its use by nursing staff. They will be approached for possible study enrollment by one of the study investigators.
    - If a patient agrees to participate in the study, she will receive a sealed envelope dictating to which group she will be randomized.
    - All subjects will be provided prescriptions for pain medication, bowel regimen, and cranberry supplements, per standard practice.

- Number of contact points (office visits, emergency room visits, and phone calls to care team) will be recorded during the first two weeks postoperative.

- Self-removal group
  - They will be provided with a diagrammatic handout, illustrating proper removal of their catheter (Diagram for Self-Removal)
  - They will be instructed to remove their indwelling urinary catheter at home on the morning of POD7 at approximately 7am.
  - They will be provided with the phone number of the Research Nurse and the pager number of the on-call staff.
  - On POD6 evening or POD7 morning, the Research Nurse will contact each patient to remind patients of the plan and review proper self-catheter removal.
  - On POD7 they will discontinue their indwelling urinary catheter by way of the instructions provided.
  - If they are UNABLE to void within 5 hours of catheter removal or have feelings of incomplete bladder emptying, they will call the Research Nurse or page the on-call staff. The Research Nurse or on-call staff will arrange a clinic visit for the same day at one of three outpatient clinics (Clifton, West Chester, Kenwood) for replacement of an indwelling urinary catheter.
    - A urine dip will be performed on the urine collected via the catheter. If positive for leukocyte esterase, white blood cells, or nitrites, the urine sample will be sent to the laboratory for culture
    - All urine culture results will be reviewed and if positive, will be treated and recorded. They will return to home with an indwelling urinary catheter and represent to the office for their two-week postoperative visit.
  - If they are ABLE to void within 5 hours of self-removal, they will remain without a catheter and present for their routine two-week postoperative visit the following week.

- Office-removal group
  - They will call the office to schedule a repeat VT visit on POD6-8 (POD7 will be encouraged).
  - They will have a backfill VT (as described above).
  - If they are UNABLE to void two-thirds of the instilled volume or have a PVR greater than 100ml, they will have an indwelling urinary catheter

reinserted at that time. They will return to home with an indwelling urinary catheter and represent to the office for their routine two-week postoperative visit.

- If they are ABLE to void two-thirds of the instilled volume, they will remain without a catheter and present for their routine two-week postoperative visit the following week.
- A urine dip will be performed on the foley catheter urine sample prior to the initiation of the backfill VT. If positive for leukocyte esterase, white blood cells, or nitrites, the urine dip will be sent to the laboratory for culture. All urine culture results will be reviewed and if positive, will be treated and recorded.

- Two-week postoperative visit
  - All patients will present to the office for routine two-week postoperative visit.
  - Those patients who have an indwelling urinary catheter in place at this time will have a backfill VT performed (as described above).
    - If they are UNABLE to void two-thirds of the instilled volume or have a PVR greater than 100ml, they will either have an indwelling urinary catheter replaced or be taught intermittent self-catheterization. They will have follow-up per standard office practice.
    - If they are ABLE to void two-thirds of the instilled volume, they will remain without a catheter and present for their routine six-week postoperative visit.
  - All patients will have a PVR measured and recorded.
  - All patients will have a urine dip performed (either from a voided urine sample or foley catheter urine sample) at their two-week postoperative visit. If positive for leukocyte esterase, white blood cells, or nitrites, the urine dip will be sent to the laboratory for culture. All urine culture results will be reviewed and if positive, will be treated and recorded.
  - All patients will complete the patient satisfaction questionnaire and VAS at their two-week postoperative visit (Patient Questionnaire and Visual Analog Scale)

  - Six-week postoperative visitAll patients will present to the office for routine six-week postoperative visit.
  - All patients will have a urine dip performed at their six-week postoperative visit. If positive for leukocyte esterase, white blood cells, or

nitrites, the urine dip will be sent to the laboratory for culture. All urine culture results will be reviewed and if positive, will be treated and recorded.

- Total duration of catheter use (indwelling urinary catheter or intermittent self-catheterization) will be extracted from the patients' chart and recorded at this time.

Statistical Analysis

- Descriptive statistics will be generated for demographic information such as age, race, BMI, Parity etc. The OR and 95% CI's of OR will be utilized to compare our primary outcome, the incidence of POUR between the two groups (self-removal and office-removal). Continuous variables such as the patient satisfaction questionnaire on VAS will be analyzed using independent samples t-tests or Mann-Whitney U test for significant difference between groups. Categorical variables will be tested using the Fisher's exact or Pearson Chi-square tests.

Ethical Considerations

- **Informed consent**
  - Patients who agree to participate in the study will sign a written informed consent. They will be consented by one of the stated investigators or trained Research Nurse and they will receive a copy of the signed informed consent statements (ICS). A copy will be put in their medical file.

- **Privacy information**
  - Extensive efforts will be made to ensure and maintain participant confidentiality. All identifying information will be maintained in a secure area at all times. Source documentation will be maintained in a separate folder. When documentation has to be made available for data analysis, copies of the source (Excel spreadsheets) with only Subject ID number visible and personal information obscured will be used. All communication between staff members regarding participant data will occur via the Subject ID number only. However, identifying information will be retained in the original/source documents.
  - The participant will be logged in the Excel spreadsheet and assigned a Subject ID number. Each participant will be assigned the next available Subject ID number. Once each Subject ID number has been assigned, it will not be reassigned. The Excel spreadsheet will be stored on a password

protected, encrypted TriHealth computer for ten years following study closure, and then purged.

Cost/Budget

Item	Amount	Qty	Total
Patient stipend for visit (mileage, time for travel, questionnaire completion, etc)	$25.00	168	$4,200.00

Estimated Period of time to complete study:

Estimated Period of Time to Complete Study	
When will study begin?	1/01/2017
Protocol Development Completed	4 weeks
Admin Review Time	2 weeks
IRB Approval	6 weeks
Data collection	18 months
Data analysis	2 months
Presentation development (if applicable)	3 weeks
Manuscript Development (if applicable)	4 weeks
Journal submission process (if applicable)	2 months
Study closure	2 weeks

- **When and how will results be disseminated?**
  - We plan for the results to be disseminated in Spring 2019 at a national meeting in the form of a poster or oral presentation. We also plan for the results to be published.

References

1. Dorflinger A, Monga A. Voiding Dysfunction. *Curr Opin Obstet Gynecol* 2001;13(5):507-512.
2. Partoll LM. Efficacy of tension-free vaginal tape with other pelvic reconstruction surgery. *Am J Obstet Gynecol* 2002;186(6):1292-1298.
3. Shiotz HA. Comparison of 1 and 3 days transurethral foley catheterization after vaginal plastic surgery. *Int Urogynecol J* 1995;6:158-161.
4. Glavind K, Morup L, Madsen H, Glavind J. A prospective, randomized, controlled trial comparing 3 hour and 24 hour postoperative removal of bladder catheter and vaginal pack following vaginal prolapse surgery. *Acta Obstet Gynecol Scan* 2007;86:1122-1125.

5. Hakvoort RA, Elberink R, Vollebregt A, Ploeg T, Emanual MH. How long should urinary bladder catheterization be continued after vaginal prolapse surgery? A randomized controlled trial comparing short term versus long term catheterization after vaginal prolapse surgery. *BJOG* 2004;111:828-830.
6. Geller EJ. Prevention and management of postoperative urinary retention after urogynecologic surgery. *International Journal of Women's Health* 2014;6:829-838.
7. Crisp C
8. Foster RT Sr, Borawski KM, South MM, et al. A randomized, controlled trial evaluating 2 techniques of postoperative bladder testing after transvaginal surgery. *Am J Obstet Gynecol* 2007;197:627.
9. Jambusaria LH, Davenport AP, Hill BJ, Adam A. Urinary tract infection rates after passive and active trial of void. *Am J Obstet Gynecol* 2016: Supplement to April;49:S493.
10. Bhardwaj R, Pickard R, Carrick-Sen D, Brittain K. Patients' perspectives on timing of urinary catheter removal after surgery. *British Journal of Nursing* 2012;6(18):S4-S9.
11. Schumi, J., et al. Through the looking glass: understanding non-inferiority. *Trials* 2011;12: 106.
12. Srikrishna, S. et al. Validation of the Patient Global Impression of Improvement (PGI-I) for urogential prolapsed. *Int Urogynecol J* 2010;21 (5): 523-528.
13. Jannelli ML, Wu JM, Plunkett LW, et al. A randomized controlled trial of clean intermittent self-catheterization versus suprapubic catheterization after urogynecologic surgery. *Am J Obstet Gynecol* 2007;197;72.e1-72.e4.
14. Hakvoort R, Thijs S, Bouwmeester F, Broekman A, Ruhe I, Vernooij M, Burger M, Emanuel M, Roovers J. Comparing clean intermittent catheterization and transurethral indwelling catheterization for incomplete voiding after vaginal prolapse surgery: a multicenter randomized trial. *BJOG* 2011;118:1055-1060.