Official Title: Evaluating the effect of Tamsulosin on Postoperative Urinary Retention in Women undergoing Same Day Hospital Discharge Following Pelvic Reconstructive Surgery: A Randomized Trial

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Tamsulosin to Prevent Postoperative Urinary Retention in ERAS Patients Following Pelvic Reconstructive Surgery

Wake Forest Baptist Medical Center

Evaluating the effect of Tamsulosin on Postoperative Urinary Retention in Women undergoing Same Day Hospital Discharge Following Pelvic Reconstructive Surgery: A Randomized Trial

MANUAL OF PROCEDURES/PROTOCOL

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Background

Postoperative urinary retention (POUR) is a significant postoperative complication in 14-16% of all surgeries (Kowalik) and 21-50% following female pelvic reconstructive surgery (Ripperda). POUR is associated with increased risk of urinary tract infection and healthcare costs (Hooten) as well as decreased patient satisfaction (Kenton).

The bladder neck and urethra are rich in α-adrenergic receptors. One potential mechanism by which POUR occurs following female pelvic reconstructive surgery is disruption of the local autonomic nervous system, increasing sympathetic drive to the bladder outlet and inhibiting urethral relaxation and bladder emptying. The prophylactic use of α-AR antagonists before the onset of symptoms may decrease the incidence of POUR after urologic and colorectal surgery in men (Ghuman, Akkoc, Poylin, Claney). Recently, a retrospective matched cohort study by Chapman et al. showed a significantly decrease risk of POUR with the use of tamsulosin following female pelvic reconstructive surgery. In this study, active voiding trials were performed on postoperative day 1 for the tamsulosin group. In a follow-up double-blinded randomized controlled trial, a 10-day course of tamsulosin started 3 days preoperatively vs. placebo showed a reduction in POUR from 24.6% in the placebo group to 8.7% in the tamsulosin group (Chapman). The voiding trials in this study were performed on postoperative day 1.

With enhanced recovery after surgery protocols, same-day discharge has become a common phenomenon with female pelvic reconstructive surgery. It is safe and cost effective for patients with no increase in postoperative complications as compared to an overnight stay (Schiavone, Jennings, Carter-Brooks). Same day hospital discharge with voiding trials performed on the day of procedure, however, may be associated with even higher rates of acute POUR. In our unit, at least 50% of women undergoing multicompartment native tissue vaginal repair, who are discharged on the same day, have to perform either self-catheterization or have an indwelling Foley catheter which increases patient burden and risk of UTIs. It may also decrease overall patient satisfaction.

The purpose of this double-blind, randomized controlled trial is to determine the difference in incidence of POUR following a postoperative day 0 voiding trial in patients undergoing multicompartment native tissue vaginal repair of pelvic organ prolapse, with or without concomitant mid-urethral sling, who received 0.4 mg of tamsulosin 5 days pre- and post-operatively compared to those who receive placebo. The 5-day period was determined based on the pharmacokinetics of tamsulosin. Given the recent trend in

same-day discharge, increasing the success of postoperative day 0 voiding trial would theoretically decrease the percentage of patients going home with indwelling Foley catheters, increase patient satisfaction and decrease urinary tract infection rates. Additionally, continuing tamsulosin for 5 days postoperatively to prevent decrease in steady-state blood levels may theoretically reduce the incidence of delayed urinary retention.

Specific Aims

Primary Aim(s):

(1) To compare rates of POUR following an active voiding trial on postoperative day 0 between women undergoing multicompartment, native tissue vaginal repair that received perioperative tamsulosin versus women that received placebo

Secondary Aim(s):

(1) To compare the mean total number of days of postoperative catheterization, incidence of delayed urinary retention and urinary tract infection rates up to 6 weeks post-surgery between groups

(2) To compare ED visits and serious adverse events, as classified by Clavien-Dindo, between groups

(3) To compare patient level of satisfaction with voiding function immediately prior to hospital discharge and at 1 week post-procedure.

Hypothesis

Peri-operative administration of tamsulosin decreases the incidence of POUR on postoperative day 0 in female patients who undergo multicompartment native tissue vaginal repair compared to those who receive placebo.

Keywords:
ERAS (enhanced recovery after surgery)
POUR (postoperative urinary retention)
FPRS (female pelvic reconstructive surgery)
IP (investigational product)
FPMRS (female pelvic medicine and reconstructive surgery)

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Study Design

This is a double-blind, randomized controlled trial. Both investigators and participants will remain blinded to the intervention. All surgery will be performed by FPMRS board-certified urogynecologists. The patients will be able to have a revealing of the intervention they received at 6 weeks post-surgery

Outcomes

Primary

To compare rates of POUR following an active voiding trial on postoperative day 0 between women undergoing multi-compartment native tissue vaginal repair that received preoperative tamsulosin 5 days preoperatively and continued 5 days post operatively versus a group that received placebo

Secondary:

To compare the following between the two groups:

1. Postoperative urinary tract infection rates (up to 6 weeks post-surgery)
2. Incidence of delayed urinary retention (defined as PVR > 150 ml up to 6 weeks post-surgery)
3. ED visits and serious adverse events within 30 days post procedure
4. Total number of days of catheterization
5. Patient level of satisfaction with voiding/bladder function immediately prior to hospital discharge: Very dissatisfied, moderately dissatisfied, slightly dissatisfied, neutral, slightly satisfied, moderately satisfied, very satisfied

Inclusion criteria:

1. Stage II or greater pelvic organ prolapse in > 1 vaginal compartment
2. Plan for multicompartment native tissue vaginal repair (which would include any combination of uterosacral ligament suspension, sacrospinous ligament suspension, cystocele and/or rectocele repair, with or without hysterectomy and with or without concomitant mid-urethral sling) or vaginal closure with FPMRS-trained surgeons at Wake Forest Baptist Health.
3. Participation in Enhanced-Recovery-After-Surgery protocol with plan for same-day hospital discharge
4. Willing to remain compliant with IP.

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Exclusion criteria:

1. Intraoperative complication necessitating prolonged bladder drainage or placement of a vaginal pack x 24 hours (patients would exit study after randomization and will be excluded from the per-protocol analysis)
2. Patients whose surgical plan would necessitate a voiding trial on postop day >0
3. Less than 21 years of age
4. Unable to understand English
5. Patients who are scheduled to undergo combined colorectal procedures such as rectopexy, sphincteroplasty
6. Patient with known allergy to tamsulosin or sulfa drugs
7. Patients with upcoming cataract surgery
8. Patient with orthostatic hypotension
9. History of postvoid residual (PVR>150) prior to surgery with prolapse reduction
10. Patients with hypertension on alpha-blockers
11. Single compartment prolapse repair (anterior or posterior repair only)
12. Use of mesh for prolapse repair
13. High tone pelvic floor dysfunction

Pre-Assessment –
All women scheduled to undergo multicompartment native tissue vaginal repair with plan for same day surgical discharge will be screened for their eligibility. If eligible and consenting, the following baseline data will be collected on paper forms that will then be transcribed into a secure REDCap (Research Electronic Data Capture) Database:

1. Demographic data including age, race, BMI, zip code
2. Medical and Surgical History
3. Menopausal status, including current exposure to topical vaginal estrogen
4. Type of planned surgical procedure
5. Plan for concomitant sling placement
6. Assessment of post-void residual volume (collected via bladder scan or CIC)

Randomization **-**

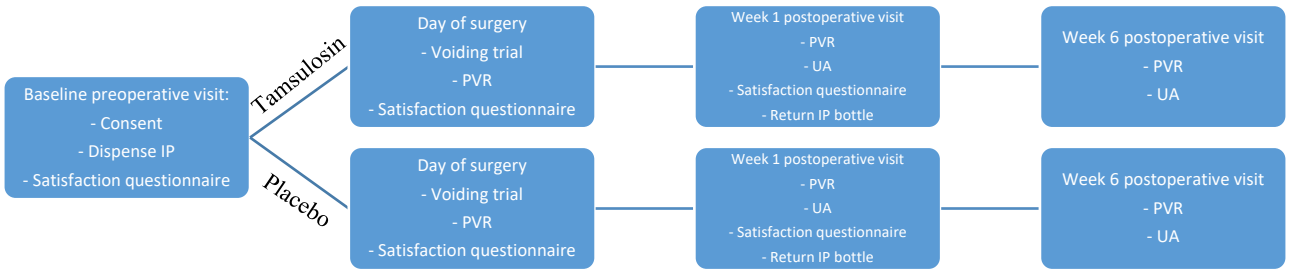
All enrolled and consented patients will undergo randomization at their pre-operative clinic visit. A study patient can be randomized into either tamsulosin IP or Placebo IP group. Randomization assignment will occur through sealedenvelope.com-generated random allocation using a randomly permutated block design (8 subjects per block). An

unblended designated person who will not participate in data collection or analysis will be responsible for providing randomization schedule. Study staff will dispense the assigned IP bottle (see below) in the urology clinic. Study patient charts will get updated with the IP ID (e.g. 01A, 02A, 01B, 02B…). Research staff administering follow-up questionnaires will also be blinded to the subject's randomization. The subject will be asked to bring back their IP bottle at the time of their postoperative visit.

Study Intervention –

10 pills of each IP and placebo will be placed in identical coded containers and stored in a locked area in the clinic. Instructions for IP usage will be provided to subjects for 10 days of usage as 0.4 mg qd by PO route starting 5 days prior to day of surgery and continued for a total 10 days. The research manager will be the only member of the study team who has the research key designating which containers are IP versus placebo.

On postoperative day 0 after recovery from anesthesia, each patient will have their bladder emptied using the indwelling Foley and their bladder will then be retrograde-filled with 300 cc of normal saline and given 30 minutes to void. A postvoid residual volume<150 cc will be considered a success of the voiding trial. If the voiding trial was considered failed, the patient will have a foley catheter reinserted and the patient will be instructed to remove the catheter at home after having a bowel movement. If they are unable to void at home within 4 hours of catheter removal, they will return to the Wake Forest Urology clinic for self-catheter teaching.



IP Accountability –

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IP and placebo bottles will be stored in a locked cabinet on the clinic premises. They will be dispensed to the patient at the time of consent collection and will be brought back by the patient at time of the 1-week postoperative visit. This will be recorded in a study log to keep track of bottles signed in and out. The bottles as well as log will be stored for long-term archiving.

Post-Surgery Assessments –
Postoperative day 0 voiding trial result
For women who fail initial trial of void, post-operative day when bladder function returned
Postoperative exam at 1 and 6 weeks
Pelvic examination at 6 weeks
Data points to be collected:
Post-void residual (PVR), urinalysis (UA), patient level of satisfaction (1-7 – very dissatisfied, moderately dissatisfied, slightly dissatisfied, neutral, slightly satisfied, moderately satisfied, very satisfied)

Power analysis

For a superiority study, if we assume 5% significance level and 80% power with internal audit rates of POUR of 24.3% for the control group and expecting 2.9% for the tamsulosin group (Chapman), then total sample size would be approximately 74 with n= 37 in each group. Accounting 20% non-compliant and dropout rate, we expect to enroll 88 patients total with 44 in each group. Power calculations done with sealedenvelope.com

Statistical analysis will be performed using IBM SPSS Statistics 24 or similar program.

Baseline and demographic data will be reported using standard descriptive methods. Scores of questionnaires (age, race, BMI, insurance, smoking y/n) and clinical evaluations (menopausal status, vaginal atrophy y/n, estrogen use, type of surgery etc.) will be calculated appropriately. Outcomes will be presented as number with proportion for categorical data and mean and standard deviation (in case of normally distributed data) or median with interquartile range (in case of not normally distributed data). Comparisons within groups will be done for numerical data using either paired t-test (in case of normally distributed data) or Wilcoxon signed rank test (in case of not normally distributed data) and Fisher exact test or Mcnemar for categorical data. Between-group comparisons will be done using either unpaired t-test (in case of normally distributed

data) or Mann-Whitney U test (in case of not normally distributed data) and Chi-square test for categorical data.

Calendar of Events

	Baseline	**Day of surgery**	**Week 1 post-operative visit**	**Week 6 postoperative visit**
Consent	**x**			
Dispense IP	**x**			
Voiding trial		**x**		
PVR	**x**	**x**	**x**	**x**
UA	**x**		**x**	**x**
Level of satisfaction with voiding function (1-7)	**x**	**x**	**x**	
Return IP bottle			**x**	

Data Collection and Management –

Data collection will occur at each visit outlined in the **Calendar of Events**. All study data will be recorded on data collection forms (CRFs: Case Report Forms) designed by the research manager (Sachin Nalin Vyas, MS, PhD), and securely maintained. Any discrepancies between data collection forms and supporting source documents such as physician's notes should be explained on the forms. Any changes made to original entries on data collection forms should be crossed through with a single line and initial and dated by the person making the correction. Do not obscure the original entry.

Data will be entered by study manger's staff into a REDCap Database (described in detail in the "STUDY SUBJECT PROTECTION" section of this protocol) that will be stored on a secure server by the study center (WF: Wake Forest University). Study data source documentation and progress notes will be monitored by the PI (principal Investigator) as outlined in the "STUDY MONITORING AND DOCUMENTATION" section. Data collected from visits should be entered into REDCap within 5 business days. Any queries to data entered into REDCap should be addressed within 5 business days.

WF site will maintain all essential study documents in original format and source documentation that support the data collected on study participants in compliance with ICH/GCP guidelines. Documents must be retained until at least 2 years have elapsed

since the formal discontinuation of the clinical investigation. Research Center WF Urology Female Pelvic Health Group PI will be responsible to ensure that these essential documents are retained and are not accidentally damaged or destroyed prior to the required elapsed time.

Study Monitoring and Documentation

Study Monitoring

The PI at the WF center will monitor the study and assess the need for amendments as the study progresses. If a protocol revision is necessary for reasons including but not limited to the rights, safety, or welfare of participants, or scientific integrity of the data, an amendment is required. IRB (Institutional Review Board) or equivalent approvals of the revised protocol—and if necessary, revised informed consent—must be obtained prior to implementation at each site.

Data Monitoring

Semi-annual data verification will be conducted by the research manager to verify that data entry into REDCap is accurate, and to assess compliance with the study protocol requirements. Study data will be source-verified for roughly 25% of overall data collection efforts. Progress notes and supporting documents will be obtained from the EPIC WakeOne within 3 days of procedure and scheduled visits. Other monitoring activities include but are not limited to reviewing informed consent/research authorization forms, adverse event documentation, and protocol deviation reports.

Protocol Deviations -

Protocol deviations will be documented in sequential order according to event of occurrence and they will be entered into REDCap.

Reporting Adverse Events:

In a study by Kaplan, AE's in women and children were abdominal pain, asthenia, constipation, dizziness, dry mouth, drowsiness, dyspepsia, headache, incontinence, nasal congestion, nausea, orthostatic hypotension, and somnolence.

The overall safety profile in women seemed to be generally consistent with the profile in men.

Patients will initially be screened for these adverse events on postoperative day 1 via telephone call.

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Adverse events (AEs) will be recorded and reported to local IRB as per regulations on Serious Adverse Event reporting guideline. Post-operative and surgical attributed AEs will be defined using the Clavien-DINDO grading

TABLE 1. Classification of Surgical Complications Clavien-DINDO Grade Definition for surgery attributed post-op events only

Grade 1	Any deviation from the normal postoperative course without the need for pharmacologic treatment. Allowed therapeutic interventions are: drugs as antiemetics, antipyretics, analgesics, physiotherapy
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III IIIA IIIB	Requiring surgical, endoscopic or radiological intervention Intervention not under general anesthesia Intervention under general anesthesia
Grade IV IVA IVB	Life-threatening complication (including CNS complications)* requiring IC/ICU management Single organ dysfunction (including dialysis) Multi-organ dysfunction
Grade V	Death

Protocol Specific Reportable AEs include those determined to be related to postoperative recovery as listed below:

Surgery or catheter-related:

Infection (UTI, Vaginal, Pelvic Abscess)
Venous Thromboembolism
Pelvic pain
Surgical bleeding (Significantly higher estimated blood loss)
Vaginal bleeding (Unexpected bleeding following sexual activity)
Excessive vaginal discharge
Fistula
New or worsening dyspareunia
Hematoma
Urgency ‘de novo’
Stress or Urgency Incontinence (New or worsening)

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Urinary retention (PVR>150) longer than 2 weeks post-surgery

Medication-related:
Orthostatic hypotension/dizziness
Postoperative atrial fibrillation
Abdominal pain
Asthenia
Constipation
Dry mouth
Drowsiness
Dyspepsia
Headache
Nasal congestion
Nausea
Somnolence

Underlying diseases are not reportable as AEs unless there is an increase of severity or frequency during the course of the study. If an AE has not resolved at the time of AE Form completion, save form as incomplete in REDCap until resolved. Once resolved, update AE form, and enter into REDCap and save form as complete.

Adverse Event Definitions:
Adverse Event: any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including abnormal laboratory finding) in subjects, whether or not related to the administration of IP versus placebo.

Serious Adverse Event: an adverse event that
Led to death
Led to serious deterioration in the health of the subject that either resulted in

- a life-threatening illness or injury
- a permanent impairment of a body structure or a body function in subject or prolonged hospitalization of existing hospitalization
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

<u>Adverse Event Severity</u>:

Mild: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

Moderate: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning.

Severe: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating.

Relationship of AE to Operative Procedures:

Unrelated: No evidence that the timing if the AE has a relationship to the administration of study drug.
Possibly Related: The AE has a timely relationship to the study drug, however a potential alternative etiology may be responsible for the AE.
Probably Related: The AE has a timely relationship to the study drug and the causative relationship can clearly be established. No potential alternative etiology is apparent.

Study Subject Protection

Protection of each subject's personal health information will be a priority in this study. One master file in Microsoft Excel Format containing subject personal information including name and medical record number will be kept in a password-protected file, on a designated protected research drive on a password-protected computer in a locked office at each respective institution. In that file, each subject will be assigned a subject identification number that will be used for the purposes of data collection.

All paper forms used for data collection will be kept in a research cabinet dedicated to this project, which will be locked at all times, in a locked office at Wake Forest Baptist Health, Urology Department, Research Office at Charlois Blvd Clinic. Identification numbers of study patients must correspond to the subjects listed in the master file.

All study data will be transferred and managed electronically using REDCap. Each subject will be entered into REDCap using the assigned identification number. REDCap is a secure, web-based application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation, audit trials, and a de-identified data export mechanism to common statistical packages. The system was developed by a multi-institutional consortium that was initiated at Vanderbilt University and includes Wake Forest Baptist Health. The database is hosted within the Clinical and Translational Research Unit at Wake Forest and is managed by the Quantitative Health Sciences Department. The system is protected by a login and

Secure Sockets Layers (SSL) encryption. Data collection is customized for each study as based on a study-specific data dictionary defined by the research team with guidance from the REDCap administrator in Quantitative Health Sciences at Wake Forest.

Project Schedule:

November-December: Protocol finalization, submission to WISER and IRB
March 2021-April 2022: Patient enrollment and date collection
April 2022 – May 2022: Data analysis/Submission

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Appendix A: Data Collection Variables

Demographics:

- Age at time of Surgery
- Race
- zip code
- Height/ Weight or BMI
- Parity
- Menopausal status
- Current estrogen use: systemic, vaginal, both, none
- Smoking status: none, past, current
- Preoperative PVR
- Preoperative anti-cholinergic use
- Preoperative UDS parameters (Qmax, Pdet at Qmax, Cough/Valsalva LPP)
- Prior Pelvic Surgery (None, Reconstructive, Anti-Incontinence, C/S, Laparoscopy, Other)
-Diabetes
- Preop POPQ Exam
- Stage of prolapse
- Leading edge of prolapse compartment (anterior, apical, posterior)

Surgery

- Month/Year of Surgery
- Hysterectomy if performed and type (vaginal, laparoscopic, open)
- Vaginal colporrhaphy if performed and type (anterior, posterior)
- Apical vaginal suspension if performed and type (Sacrospinous, uterosacral)
- Vaginal closure
- High perineorrhaphy
- Stress Incontinence Procedure: None, RP sling, single-incision sling, TOT
-
- Other concomitant procedures
- EBL

Postop parameters

- Active voiding trial PVR on POD 0
- Day of bladder function return
- UTI within 6 weeks
- Persistent urinary retention > 2 weeks
- Delayed urinary retention (PVR > 150 after passing 1st trial of void)
- Emergency Room visit/evaluation

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- Readmission within 30 days
- Reoperation for complication within 30 days
- Other (including: Delayed urinary tract injury, Delayed bowel injury, Hematoma, Transfusion, Cardiac complication, Respiratory complication)

Postoperative Follow Up
- 1 and 6 week follow up visits with PVR

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