Title: The use of a routine indwelling urinary catheter in patients receiving neuraxial anesthesia for elective total joint arthroplasty

PI: Dr. Craig Della Valle

Co-investigators:

Tad Gerlinger, MD

Denis Nam, MD

Joshua Greenspoon, MD

Jaewon Yang, BS

IRB Approval # 19123101

NCT #05428020

Document attached: Study protocol

Approved study: 2/21/2020

Approved amended protocol: 10/7/20

The use of a routine indwelling urinary catheter in patients receiving neuraxial anesthesia for elective total joint arthroplasty

Principal Investigator
Craig Della Valle M.D

Co-Investigators
Tad Gerlinger M.D
Denis Nam M.D
Joshua A. Greenspoon M.D
JaeWon Yang

Purpose:

Determine whether routine use of a short term indwelling urinary catheter decreases the rate of urinary retention in patients undergoing elective inpatient total joint replacements

Hypothesis:

We hypothesize that the routine use of a short term indwelling urinary catheter will decrease the rate of urinary retention compared to patients who do not receive a urinary catheter.

Background and Introduction:

Urinary retention is a known complication following surgical procedures, with a theoretical increased risk in patients receiving neuraxial anesthesia due to a decreased ability to sense bladder distension.[1] Urinary retention is associated with adverse events including bladder atony, increased post void residuals, and postoperative urinary tract infection. Treatment of urinary retention involves intermittent or indwelling urinary catheter placement, both of which are associated with an increased prevalence of postoperative urinary tract infection.[2]

There currently is no consensus whether the use of a urinary catheter in elective joint arthroplasty with neuraxial anesthesia decreases the risk of urinary retention. The prevalence of retention reported in the literature varies widely with reports anywhere from 0% to 75% in patients with early removal of a catheter or after procedures performed without a catheter.[3,4]

At Rush University Medical Center currently, all patients undergoing primary total joint arthroplasty receive neuraxial anesthesia preoperatively and have short term indwelling urinary catheter placed intraoperatively. The urinary catheter is removed when the patient arrives on the orthopedic floor and the Rush urinary retention protocol is followed.

The need for routine use of indwelling urinary catheters was previously investigated in a randomized controlled trial by Miller et al in 2013 in patients undergoing total hip arthroplasty.[5] They found a 2.8% rate of urinary retention in patients who received a urinary catheter and a 9.7% rate in patients who did not. Although this did not demonstrate statistical significance (P 0.07), they concluded that a routine indwelling urinary catheter is not required.[5] However, Miller et al provided a fairly large time span for urinary catheter use ("removal within 48 hours") and failed to provide any temporal data regarding duration of use. With this in mind, our study will further investigate this conclusion with a goal to identify if routine use of a urinary catheter that is removed on the same day of surgery decreases postoperative urinary retention in patients undergoing elective inpatient total joint replacement.

Study Design

Prospective, multi-surgeon, single institution, randomized controlled trial

Inclusion Criteria
Any patient >18 years of age scheduled for an inpatient primary hip or knee replacement

Exclusion Criteria

1. Patients with a known history of prostate, urological or kidney surgery
2. Patients where close monitoring of urine output are necessary during the perioperative period (renal disease, renal failure, chronic indwelling urinary catheter)
3. Patients with a history of urinary incontinence
4. Patients undergoing a revision total knee or total hip arthroplasty
5. Patients requiring indwelling continuous epidural anesthesia
6. Patients with a preexisting urinary tract infection, as diagnosed on preoperative screening.
7. Patients unable to void prior to surgery as required by anesthesia.

Treatment Groups:
Group 1 (Control): Short term urinary catheter- Patient will receive a urinary catheter at the time of the surgery. The urinary catheter will be removed upon arrival to the orthopedic floor post operatively. Patients will subsequently be monitored for urinary retention according to the Rush University Medical Center urinary retention protocol.

Group 2 (Experimental): No urinary catheter- Patients will not receive a urinary catheter at time of surgery. They will be monitored for urinary retention according to the Rush University Medical Center urinary retention protocol

Sample Size Calculation
Based on a randomized controlled trial published by Miller et al in 2013, to detect a clinically significant difference of 7%, we would need 194 patients per group, or 388 patients. Assuming a drop-out rate of 10%, a total of 432 patients will be required. An interim analysis will be performed once half of this total is enrolled.

Urinary retention protocol:

Patients will be monitored closely for urinary retention according to current Rush University Medical Center Urinary Retention Protocol. After removal of catheter (control group) or from arrival in PACU (experimental group), patients will be given 4 hours to void a volume corresponding to 30ml/hour. If the patient fails to do so, they will be bladder scanned. Bladder scan results of 450ml or greater will result in one time straight catheterization.

If bladder scan shows 150 ml to 349 ml of urine, patients will be given an additional 4 hours to void and a repeat bladder scan will be performed. If unable to void at this point and/or bladder volume is >450, patient will receive a one time straight catheterization.

If bladder scan shows 350 ml to 449 ml of urine, patients will be given an additional 2 hours to void and a repeat bladder scan performed. If unable to void at this point and/or bladder volume is >450, patient will receive a one time straight catheterization.

If patients require a straight catheterization, they will be monitored with bladder scan according to protocol and a second straight catheterization will be performed if necessary. At time of second straight catheterization, a urinalysis will be sent. If patient requires a third straight catheterization, a urology

consult will be placed according to protocol and patient will either receive an indwelling urinary catheter or intermittent straight catheterization with urology follow up.

Demographics, Patient Specifics
Age, sex, short form 12 scores, ASA score, medical co-morbidities, weight, height, length of hospitalization, BMI, history of benign prostatic hypertrophy, presence of preoperative urinary tract infection (diagnosed during preadmission testing), intravenous fluids given during surgery, operating room time, estimated blood loss, length of hospital stay, discharge destination (home versus rehabilitation facility), time to mobilization postoperatively, and length of urinary catheter usage.

At the time of enrollment in the study, patients will be given a urinary history questionnaire known as the International Prostate Symptom Score (I-PSS) and be asked about history of urinary retention, history of incontinence, and history of polyuria to screen for preexisting urinary issues. Existing pre-operative laboratory testing will be abstracted from the subjects' medical record.

Patients will receive standardized multimodal analgesic regimen that is utilized at Rush University Medical Center for patients undergoing a total joint replacement for perioperative and postoperative pain management. Modifications will be made on a case by case basis as is currently the standard practice (for example, allergy, intolerance, or medical contraindication such as acute kidney injury to NSAID use)

Outcome Measurements:

1. Episodes or urinary retention, defined as necessitating 2 straight catheterizations or placement of an indwelling urinary catheter.
2. Number of straight catheterizations and volume of urine
3. Episodes of indwelling urinary catheter placement in the postoperative course
4. Urinary tract infections
    a. Diagnosed via urinalysis at time of second straight catheterization or urinary placement
    b. Patients will be asked via questionnaire the following at time of initial follow up to screen for possible urinary tract infection. If screen positive, will order urinalysis and urine culture.[6]
        - Have you had any pain with urination?
        - Have you had an increase in urinary frequency?
        - Have you noticed any lower abdominal pressure with urination?
        - Have you noticed any changes in the color or smell of urine?
5. Patient satisfaction (HCAHPS survey) to be administered at initial follow up visit
6. Patients who receive a straight catheterization or placement of a urinary postoperatively will be asked via questionnaire a modified version of survey published by Darbyshire et al.[7]
    a. Was placement of the catheter painful?
    b. Was placement of the catheter embarrassing?
    c. Did you know why you were catheterized?
    d. Did the doctor or nurse talk you through why you were being catheterized?
7. Acute periprosthetic joint infections

Risks, Benefits
All surgical patients are at risk of developing urinary retention. To minimize adverse events associated with urinary retention, all patients will be closely monitored according to the Rush University Medical center urinary retention protocol.

Breach of confidential and/or privacy is a risk of the study. Below is a description of the procedure for maintaining confidentiality. There is no direct benefit to the participants in this study.

Procedures for maintaining confidentiality:
A breach of confidentiality and/or privacy is a risk of this study. To prevent this and protect patient identity and information, all collected data will be deidentified and stored electronically in password protected files. All information will be collected and reviewed by the research team only. Data will be maintained on a password-protected computer in the research office of Midwest Orthopedics.

References:

1. Balderi T, Carli F. Urinary retention after total hip and knee arthroplasty. Minerva Anestesiol. 2010 Feb;76(2):120-30.

2. Lo E, Nicolle L, Classen D, et al. Strategies to prevent catheter-associated urinary tract infections in acute care hospitals. Infect Control Hosp Epidemiol. 2008 Oct;29 Suppl 1:S41-50.

3.Farag E, Dilger J, Brooks P, Tetzlaff JE. Epidural analgesia improves early rehabilitation after total knee replacement. J Clin Anesth. 2005 Jun;17(4):281-5.

4.Borghi B, Agnoletti V, Ricci A, van Oven H, Montone N, Casati A. A prospective, randomized evaluation of the effects of epidural needle rotation on the distribution of epidural block. Anesth Analg. 2004 May;98(5):1473-8.

5.Miller AG, McKenzie J, Greenky M, et al. Spinal anesthesia: should everyone receive a urinary catheter?: a randomized, prospective study of patients undergoing total hip arthroplasty. J Bone Joint Surg Am. 2013;95(16):1498–1503. doi:10.2106/JBJS.K.01671

6. Anger J, Lee U, Ackerman AL, et al. Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline. J Urol. 2019;202(2):282–289. doi:10.1097/JU.0000000000000296

7. Darbyshire D, Rowbotham D, Grayson S, Taylor J, Shackley D. Surveying patients about their experience with a urinary catheter. Int J of Uro Nursing 2016;10(1):14-20.