Protocol Title: Effect of Indwelling Foley Placement, Immediate Post-Operative Straight Catheterization,or No Catheterization on Post-operative Urinary Retention After Transforaminal Lumbar Interbody Fusions

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Study Proposal

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Principal Investigator: Kern Singh, MD

Co-Investigator: Matthew Colman, MD

Study Coordinator: Mukesh Ahuja

1) BACKGROUND

Post-operative urinary retention (POUR) is one the most common post-operative complications after elective spine surgeries. Common causes of POUR include bladder stenosis, distension, trauma due to catheterizations, age, and prostate hyperplasia.[5] The incidence of POUR increases with age, gender, types of surgery conducted, any comorbidities such as cerebral palsy or multiple sclerosis, use of drugs such as anticholinergic agents, beta blockers, or sympathomimetics, and use of IV fluids.[5] This condition has been associated with the development of UTIs and sepsis, increased post-operative length of stay (LOS), and 90-day readmission after surgery. In the field of spine surgery, the reported incidence of POUR is highly variable, and there is no consensus on effective methods of prevention.

2) PURPOSE

To determine if indwelling Foley placement at the onset of the procedure, straight catherization at the conclusion of the procedure, or no catheterization whatsoever produces the lowest rates of POUR after transforaminal lumbar interbody fusions (TLIFs).

3) HYPOTHESIS

We hypothesize that neither intraoperative indwelling Foley placement nor immediate post-operative straight catherization will reduce the incidence of POUR in patients who undergo TLIF surgical procedures.

4) STUDY QUESTIONS

a) Is there a difference in risk of POUR or other complications when using either an indwelling Foley catheter, immediate post-operative straight catheterization, or no catheterization during TLIF spinal surgeries?

b) Is there a difference in hospital length of stay when using either an indwelling Foley catheter, immediate post-operative straight catheterization, or no catheterization during TLIF spinal surgeries?

5) METHEDOLOGY

a) Study Design

a. Prospective randomized controlled trial
b. Group 1: Indwelling Foley catheterization
    i. Placed in the operating room immediately prior to the TLIF procedure and removed the following morning
c. Group 2: Straight catheterization
    i. In-and-out straight catheterization that will take place at the conclusion of case before extubation
d. Group 3: No catheterization during TLIF surgery

b) Study Population

a. Single-level TLIF patients
    i. Patients scheduled to undergo a primary single-level TLIF procedure for degenerative conditions will be asked to participate in the study. Potential subjects will meet with a research coordinator to discuss the details of the study. Those who choose to participate will be consented accordingly.
    ii. Inclusion criteria
        1. Patients undergoing a primary single-level TLIF
            a. Diagnosis: radiculopathy, stenosis, herniated nucleus pulposus, degenerative disc disease, spondylosis, osteophytic complexes, spondylolysis, spondylolisthesis
        2. Patients able to provide informed consent

    iii. Exclusion criteria
        1. Patients with baseline urinary dysfunction requiring manual bladder emptying via intermittent straight catheterization, suprapubic catheters, or other indwelling catheters.
        2. Allergies or other contraindications to medicines in the post-operative urinary retention protocol
        3. Lack of consent
    iv. A priori analysis was conducted using the limited available data and we have established a sample size of 40 in each cohort will be sufficient in order to identify a difference between cohorts. Kiddoo et al. had study design comparing hydrophilic coated versus polyvinylchloride catheters in preventing urinary tract infections and used a sample size close to 100

patients. Of the 120 patients screens 97 were ultimately included in the study. As such, our prospective study will require a similar sample size.

c) Data collection:

a. The institution's post-operative urinary retention protocol (attached) will be followed for all patients and relevant events and values recorded in the electronic medical record as is standard institutional practice.
b. **Data Collection & Record Keeping:** Data will be recorded from electronic medical records and survey studies as previously listed. Information will be imported into an excel sheet and maintained in reports included in supplemental documentation. As stated above patient identifiable information (name, MRN, DOB, etc) will be utilized to collect data on the correct patient. Variables collected will be as listed in the study design. After all data has been collected patients will be assigned a study serial number in the excel sheet and de-identified. EPIC and NextGen will be accessed from MOR and collected directly from the patient's charts. All information regarding the nature of the proposed investigation provided to the investigator (with the exception of information required by law or regulations to be disclosed to the IRB, the subject, or the appropriate regulatory authority) will be kept in confidence by the investigator. All personal information will be treated as strictly confidential and not made publicly available. All records and appendices are stored in separate locked filling cabinets as well as a password protected computer which are accessed only by the Principal Investigator and Study Coordinators. All identifiable data will be destroyed a year after the study is complete.
c. **Data Privacy & Confidentiality:** As stated previously all data will be collected directly from the electronic medical records, survey results as previously listed. Information will be imported into an excel sheet. Once all data has been collected patients will be de-identified and provided a database serial number. This serial number will be used to merge files and ensure the data is not mixed up between patients. All data will be recorded and accessed from a password-protected computer at MOR, to which only the study personnel have access.

6) OUTCOMES

a) Primary

a. Ability to spontaneously urinate
b. Post-void (or attempted void if allotted time for spontaneous void elapsed) residual volumes as measured via bedside bladder scanner
c. Need for straight catheterization or post-operative indwelling Foley catheter placement
d. Initiation of an alpha-1 inhibitor post-operatively
e. Urologic consultations for evaluation of post-operative urinary complications
f. Number of patients who were discharged with indwelling Foley catheter or clean intermittent catheterization
g. UTI acquired post-operatively
h. Length of hospital stay

i. The number of hours of hospitalization from entering the recovery room (time zero) until patient meets discharge criteria.

b) Secondary

a. General health status
   (i) Patients will be asked to complete the Short Form-12 Survey (SF-12) for general health status questionnaire prior to surgery at their preoperative office visit or just prior to surgery in the preoperative waiting area. In the post-operative period, patients will be asked to complete the Short Form-12 Survey for general health status questionnaire at the follow up office visits.
   (ii) Pain Visual Analog Scale (VAS) questionnaire
   (iii) Oswestry Disability Index (ODI) questionnaire
   (iv) Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaire

b. Narcotic consumption
   i. The total amount of narcotic use for each subject will be recorded. Dosages of narcotics will be converted to morphine equivalents. This information will be measured during the hospitalization.

c. Post-operative complications
   i. Post-operative nausea and vomiting
      1. Any patient complaining of nausea who receives and anti-emetic will be considered to have PONV. The medication, dose and number of times administered will be obtained from the hospital record.
   ii. Venous thromboembolic events
      1. Patients with a positive venous ultrasound were considered to have a venous thromboembolism.
   iii. Ileus
      1. Any patient who requires placement of a nasogastric tube or fails to pass flatus by post-operative day three will be considered to have an ileus.
   iv. Respiratory depression/airway compromise
      1. Oxygen saturation <88%
      2. Respiratory rate <8 in medical record vital signs
      3. Post-operative re-intubation or prolonged (>48 hours intubation)
   v. Renal Insufficiency
      1. Increase in creatinine by 0.5 mg/dL from baseline
   vi. Wound Complication
      1. Surgical site infection
      2. Wound dehiscence

7) Covariates Measured

A) Demographic
   a. Age, Sex, Ethnicity, Body Mass Index (BMI), Insurance

B) Comorbidities
C) Smoking Status
D) Duration of spinal symptoms
E) Previous spinal surgery (other than lumbar spine surgery)
F) Intraoperative variables
    a. Surgeon
    b. Operative time
    c. Estimated blood loss
    d. Anesthesia used
    e. Unilateral versus bilateral instrumentation

8) Statistical Analysis

Demographic and baseline variables will be presented utilizing descriptive statistics (mean with standard deviation, median with interquartile range and proportions). Due to randomization, any differences in the study cohorts will be due to chance alone ($p<0.05$).

Normally distributed outcomes will be compared between the treatment groups utilizing an unpaired t test with ANOVA for repeated measures. Mann-Whitney test will be used for those outcome variables, which are not normally distributed. Binomial outcomes will be compared between treatment groups utilizing Chi square testing. Confidence intervals (95%) and p values will be reported where appropriate.

Sources:

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