Postoperative Bladder Filling After Outpatient Laparoscopic Hysterectomy and Time to Discharge: A Randomized Controlled Trial

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**Study Protocol**

We will be evaluating the effects of backfilling the bladder on time to void and time to discharge from the post-anesthesia care unit (PACU) in patients undergoing laparoscopic hysterectomy.
A randomization scheme using a block size of four will be generated. Sealed randomization envelopes will be opened for each subject after anesthesia is initiated in the operating suite. This study will be single-blinded to the participant. After group allocation, the surgeon will be informed of whether or not the bladder will be backfilled at the completion of the surgery prior to Foley catheter removal. If the patient is assigned to group A, 200 mL of room temperature, sterile normal saline will be instilled retrograde into the bladder at the completion of surgery prior to Foley catheter removal and the Foley subsequently removed intraoperatively. If the patients is assigned to group B, the Foley catheter will be removed intraoperatively at completion of the procedure. Our standard protocol is to use a 16F Foley catheter for gynecologic laparoscopy cases and patients from both groups will receive the same size catheter. Two hundred mL of sterile saline will be chosen as the amount to backfill to prevent postoperative overdistension as the patient will continue to naturally produce urine while in the recovery room awaking from anesthesia.
We used historical controls to determine our time to discharge and then calculated an adequate sample size for our primary outcome, time to discharge, with a clinically relevant 30-minute difference.
Information will be collected about narcotics receiving during the surgical procedure, as this may affect urinary retention rates. In addition, the following information will be collected: patient demographics, such as age, race, ethnicity, insurance status, BMI; health history: medical comorbidities, surgical history, preoperative medications, history of bladder problems, history of neurologic problems, history of chronic pain, and tobacco use; procedure: indication for procedure, benign/malignant pathology, time to discharge, time to void, urine output, need to go home with foley catheter, intraoperative urinary tract injury, intraoperative narcotics administration, surgical complications, estimated blood loss, intraoperative/postoperative IV fluids, postoperative opioid use, and postoperative UTI.
If a subject is unable to void, they will be admitted overnight and observed for repeat trial of voiding.
Adverse events will be monitored and collected through the Day 30 visit, to include the following categories: Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Required Intervention to Prevent Impairment or Damage (Devices), Other systems, with specific focus on bladder irritation or discomfort.

**Statistical Analysis Plan**

We have estimated a necessary sample size of 56 participants per group (112 total) with an anticipated effect size of 0.52 based on expected means of 172 minutes to discharge for the experimental arm (SD 58 minutes) and 202 minutes to discharge for the control arm (SD 58 minutes), accounting for expected loss to follow up of 10%. Patients will be randomized using 14 block groups of size 8 each.
We will provide a table of demographic and clinical characteristics by assigned group. For continuous variables, we will provide means and standard deviations per group, applying a t-test

for comparison of independent means. For categorical variables, we will provide counts and percentages, applying chi-square test for comparison of proportions.
We will develop a time-to-event analysis for time to discharge including Kaplan-Meier curves by assigned group and multivariable Cox proportional hazard models.