Title: Tamsulosin and Time to Spontaneous Void Following Hysterectomy: A Randomized Controlled Trial

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Protocol

The study was a double-blinded, placebo- controlled randomized control trial that took place at two tertiary care hospital campuses in Tucson, Arizona, between June 2021 and January 2023 and involved 11 attending surgeons. Approval from the institutional review board and registration on ClinicalTrials.gov was obtained prior to enrollment.

Women 18-80 undergoing minimally invasive hysterectomy for benign indications were screened for participation. In this study, minimally invasive hysterectomy included the following procedures: total vaginal hysterectomy (TVH), total laparoscopic hysterectomy (TLH), laparoscopic assisted vaginal hysterectomy (LAVH), robotic assisted laparoscopic hysterectomy (RA-TLH), Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES), and supracervical hysterectomy. Patients were excluded from analysis if they had a planned concurrent incontinence surgery (e.g. colporrhaphy, vaginal vault suspension or sling procedure), a history of bladder cancer, or a medical contraindication to tamsulosin. Participants requiring Foley catheterization due to complications such as bladder injury were excluded. Patients were screened and consented a week prior to their scheduled surgery. The day of surgery, either 0.4mg tamsulosin or placebo was administered on average 1 hour before surgery. This timing was chosen because the peak plasma concentration of tamsulosin occurs at 4 hours, so taking into account the total operating room (OR) time (from rolling to the OR to leaving the OR suite) the medication onset coincides with the patient arriving to the PACU. Randomization was performed by the hospital investigational pharmacy, who dispensed the study medication or placebo in a blinded fashion. Both tamsulosin and placebo study medication were encapsulated and were indistinguishable from one another.

Each participant underwent a void trial post-operatively by backfilling their bladder with 200cc normal saline at the conclusion of the case and removing the foley. Demographics, medical and surgical history, surgical details, PACU discharge time, time to void, and adverse events were recorded. Adverse events included intraoperative complications, rate of readmission, and emergency department visits.

Statistical Analysis Plan

The study aimed to examine two primary objectives: (1) the time to void in the tamsulosin intervention group compared to the placebo group, and (2) the time to discharge from the PACU. A reduction of at least thirty minutes in time to void was considered a significant change that could alter the standard of care. Based on Chao et al, the time to void following a backfill void trial is 181 minutes. To determine if tamsulosin results in a 30 minute decrease in time to post-operative void, a total of 77 participants per group were needed, assuming a 5% significance level and 80% power. To account for 10% drop out or exclusion, a total of 170 patients (85 per group allocation) were consented. Wilcoxon rank-sum test was used for continuous variables and Fisher's exact test was used for categorical variables. A P value of <0.05 was considered statistically significant.