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# **Original Article**

# **Retrograde Bladder Filling after Laparoscopic Gynecologic Surgery: A Double-blind Randomized Controlled Trial**

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**ABSTRACT** Study Objective: To evaluate whether retrofilling the bladder on completion of elective laparoscopic gynecologic surgery for benign indications has an effect on the timing of the first postoperative void and the timing of discharge from the hospital.

Design: Double-blind randomized controlled trial.

Setting: Single academic surgical day hospital.

**Patients:** Patients undergoing outpatient laparoscopic gynecologic surgery, excluding hysterectomy or pelvic reconstructive surgery.

**Interventions:** On completion of surgery, patients were randomized to either retrograde filling of the bladder with 200 mL of saline before catheter removal or standard care (immediate catheter removal). Patients and postanesthesia care unit nurses (outcome assessors) were both blinded.

**Measurements and Main Results:** The primary outcome was the time to first void. The secondary outcomes were time to hospital discharge, postoperative urinary tract infection, and patient satisfaction. Over a 3-month period, 47 patients were approached on the day of surgery, 42 consented and were randomized (21 to intervention and 21 to control). There were no significant differences in baseline demographics between the groups. The median time to first void was significantly shorter for patients in the intervention arm than controls ( $104 \pm 75$  minutes vs  $162 \pm 76$  minutes, p <.001). Patients who had retro-filled bladders were discharged faster from post-anesthesia care unit compared to controls ( $155.0 \pm 74$  minutes vs  $227 \pm 58$  minutes, p = .001). There were no urinary tract infections in either group, and the proportion of satisfied or very satisfied patients was high (93.8% vs 88.2%, p = .512).

**Conclusion:** Retrograde filling of the bladder after outpatient laparoscopic gynecologic surgery is a safe, effective method that significantly reduces the length of hospital stay. Journal of Minimally Invasive Gynecology (2020) 00, 1-7. © 2020 Published by Elsevier Inc. on behalf of AAGL.

*Keywords:* Laparoscopy; Retrofill; Voiding

Postoperative urinary retention after routine gynecologic surgery ranges from 0% to 21%, with even higher rates seen with pelvic reconstructive procedures [1–3]. Although

predicting postoperative urinary retention is challenging, there are many recognized risk factors including incontinence/prolapse surgery, bladder dissection, excision of

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Andrew Zakhari reports honoraria from Hologic, outside the submitted work. Ally Murji sits on the speaker bureau and the advisory board for Abbvie, Allergan, Bayer, and Hologic and the advisory board for Pfizer, outside the submitted work. The other authors declare that they have no conflict of interest.

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Institutional review board approval (#2019-0110-E) was obtained on December 12, 2019.

Data are available at https://data.mendeley.com/datasets/w8b9ph9srx/1 (DOI 10.17632/w8b9ph9srx.1).

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deeply infiltrating endometriosis, prolonged operative time, and perioperative narcotic use [4-7].

Early identification of urinary retention dictates that patients must void before discharge after an uncomplicated day surgery. This may lead to increased time in the postanesthesia care unit (PACU) and delayed discharge because patients typically awake to an empty bladder, having been catheterized throughout their procedure. Ensuring a safe and efficient discharge from the PACU not only minimizes the unnecessary use of valuable healthcare resources but also reduces patient exposure to the healthcare setting, which can be of particular importance in the context of social distancing during the coronavirus disease 2019 pandemic.

Retrograde bladder filling in the operating room before urinary catheter removal is a simple and safe intervention, which has been shown to decrease the time to first void postoperatively and the time to discharge from the PACU after laparoscopic hysterectomy [8]. However, the benefit of this intervention in patients undergoing other laparoscopic procedures in gynecology has not been investigated. Evidence of the efficacy and safety of this proposed intervention could significantly affect patient flow and optimize healthcare resource use.

Our objective was to evaluate whether retrofilling the bladder on completion of elective laparoscopic gynecologic surgery for benign indications had an effect on the timing of the first postoperative void and the timing of discharge from the hospital.

### **Materials and Methods**

#### Setting

We performed a double-blind randomized controlled trial between January 10, 2020 and April 27, 2020 at a single academic outpatient hospital in Toronto, Canada. All procedures were performed by 1 of 6 fellowship-trained gynecologic surgeons, with the assistance of a fellow in advanced gynecologic surgery. Institutional review board approval was granted (Women's College Hospital Research Ethics Board), and the trial protocol was registered online at clinicaltrials.gov (NCT04198285). Eligible patients were approached by 1 of 3 fellows on the day of surgery, and their written informed consent was obtained.

#### Participants and Randomization

We included women scheduled to undergo elective outpatient gynecologic laparoscopy who were able to provide informed consent. Exclusion criteria were scheduled pelvic reconstructive procedures (e.g., prolapse, incontinence, or vaginal reconstructive surgery), hysterectomy, laparoscopic nerve detrapments, pregnancy, history of neuromuscular disorders (e.g., multiple sclerosis), known voiding dysfunction, urinary incontinence, recurrent urinary tract infections (UTIs), genitourinary malformations, and patients taking anticholinergic medications. Finally, patients who experienced an intraoperative bladder injury were also excluded, given the need for an indwelling urinary catheter postoperatively.

Block randomization in groups of 4 was performed using a computer-generated random number generator. Sequentially numbered, opaque envelopes were used to assign patients to either the intervention or control arm and were only opened on completion of the surgery in the operating room but before extubation and transfer to the PACU.

## **Demographics and Data Collection**

Baseline characteristics were collected for all patients including age, ethnicity, smoking status, and underlying medical comorbidities such as cardiovascular disease, respiratory disease, and previous surgical interventions. Total perioperative narcotic and benzodiazepine use was collected for all patients, as well as total operative time and total intraoperative intravenous fluid volume received.

#### Intervention

All patients undergoing gynecologic laparoscopy at our center are routinely catheterized with a Foley catheter left to straight drainage for the duration of surgery. In the intervention group, on completion of the procedure and before patient extubation, 200 mL of normal saline was retrograde-instilled into the bladder through the Foley catheter before catheter removal by the surgical team in the operating room. This volume of saline was chosen because previous reports have indicated that the normal sensation to void occurs around 200 mL [9,10]. In the control group, the Foley catheter was removed on completion of the procedure, as is our routine practice. Both the patients and the outcome assessors (PACU nursing team) were blinded to the intervention, as was the statistician analyzing the results.

#### **Outcomes**

The primary outcome was the time to first void, calculated from the time of arrival to the PACU to the first successful void. A successful void was defined as any voided volume greater than 100 mL. If a void was less than 100 mL, then a bladder scan was performed. If it showed a residual volume of less than 100 mL remaining in the bladder, this also constituted a successful void. A failed voiding trial was defined as when a patient voided less than 100 mL and had greater than 100 mL residual on a bladder scan. The voiding algorithm is presented in greater detail in Supplemental Appendix 1.

Time and volume of the first void was recorded, as was voiding success, failure, and additional interventions determined by a predefined custom voiding algorithm (Supplemental Appendix 1). The secondary outcomes were total time spent in the PACU (calculated from arrival to the PACU to discharge), postoperative complications including unexpected medical visits, UTIs within the first postoperative week, and overall patient satisfaction. The PACU nursing team, who were blinded to the intervention, were solely responsible for reporting the primary outcome and determining discharge from the PACU. The nursing team at our ambulatory surgical center consists of a relatively small and consistent group who were readily engaged in this study's postoperative voiding protocol as an adjunct to the standard recovery orders.

Patients were contacted by phone by a blinded team member 1 week postoperatively to ensure that no unexpected complications arose within the first postoperative week such as UTIs or unplanned returns to the hospital or the emergency department. Screening for a UTI was done by asking symptom-related questions and whether medical attention was sought out for these symptoms, followed by an investigation of the urine analysis/culture if available. Patient satisfaction with the experience in the PACU was also measured over the phone using a 5-point Likert scale.

#### Statistical Analysis

Based on the existing literature, we calculated that with 20 subjects per arm, we would be able to detect a 10% difference between the groups in the time to first void with 99% power and a 5% type I error rate [8]. Descriptive data were reported as proportions for categoric data and medians with interquartile ranges or means with standard deviations for continuous variables. Comparisons between the 2 groups were completed with *t* tests for normally distributed continuous variables and Wilcoxon rank sum tests for skewed data. Chi-square and Fisher exact tests were used for categoric variables. A time-to-event analysis was performed for the first void and the PACU discharge. Significance was set at p < .05. An intention-to-treat analysis of the data was performed.

#### Funding

Financial support was provided through a hospital grant, Mount Sinai Hospital (Toronto, Canada) Department of Obstetrics & Gynaecology Generalist Practice Plan and the Comprehensive Research Experience for Medical Students, which is available to support ongoing research at this institution. No external peer review process was required, and there was no involvement by any party outside of the listed authors in the study design, data collection/analysis/interpretation, drafting, or submission for publication.

#### Results

#### Patient Characteristics

A total of 47 eligible patients were approached during the study period (January–March 2020), 42 of whom consented to participate (Fig. 1). After randomization, an equal number of patients were allocated to the intervention (n = 21) and control (n = 21) groups. There were no significant differences in baseline patient characteristics between the 2 groups. Surgical characteristics were also similar, with the most common procedure being laparoscopic oophorectomy. Intraoperative administration of narcotics, benzodiazepines, and intravenous fluids were similar between groups, as were total operative time and postoperative narcotic consumption. Table 1 shows patient and surgical characteristics for both intervention and control arms.

## **Outcomes**

The median time to first void was significantly shorter for patients in the intervention arm than those in the control arm (104  $\pm$  75 minutes vs 162  $\pm$  76 minutes, p <.001; Table 2). Patients who had retrofilled bladders spent significantly less time in the PACU than the controls (155.0  $\pm$  74 minutes vs 227  $\pm$  58 minutes, p = .001) and voided a larger amount of urine on the first void (median  $\pm$  interquartile range: 200  $\pm$  116.3 mL vs 60.0  $\pm$  141.3 mL, p = .008). Most patients in both groups had a successful first void (19 of 21 [90.5%] vs 18 of 21 [85.7%], p = 1.0). Differences in the time to first void and the time to discharge in the PACU are displayed in Kaplan-Meier curves in Fig. 2, showing a significant divergence between groups (p <.001 and p=.008, respectively). In the postoperative setting, there were no differences between the 2 groups in total narcotic use.

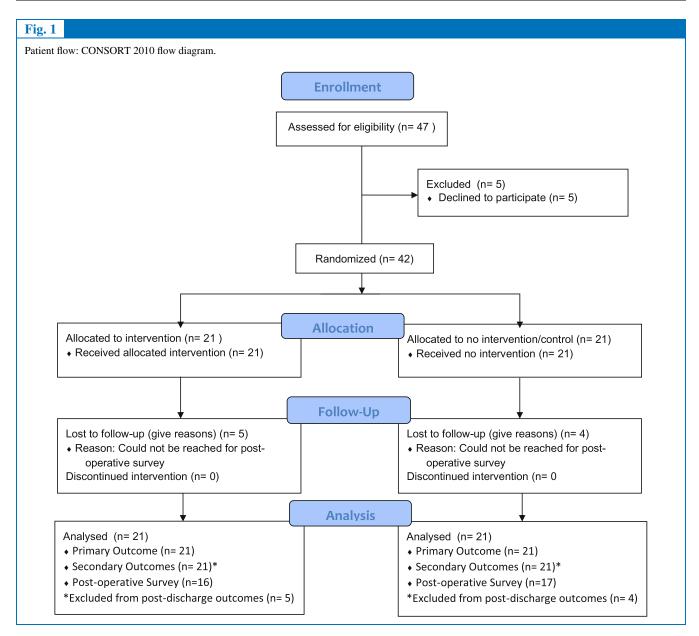
A total of 5 patients failed to void entirely, 2 in the intervention group and 3 in the control group, detailed in Table 3. Among these 5, 2 were discharged home with a Foley catheter and passed an outpatient trial of void on postoperative day 1 (1 patient with a retrofilled bladder and 1 patient in the control group). Two patients were in violation of protocol and were sent home without a Foley catheter; they were given careful instructions to return if unable to void (both patients in the control group) and recovered without complication when assessed at time of routine postoperative visit. One patient was catheterized, remained admitted in the hospital for social reasons (patient with a retrofilled bladder), and passed a trial of void the following morning.

Completion rates for postoperative follow-up surveys were similar between the 2 groups (retrofill 76% [16 of 21] and control 81% [17 of 21]). There were 2 patients who had unexpected hospital visits, 1 from each arm, both of whom presented for abdominal pain that self-resolved. There were no reported UTIs in either group. Overall, most of the patients reported that they were either satisfied or very satisfied with their experience in the PACU (93.8% vs 88.2%, p = .512).

## Discussion

## Main Findings

In this randomized controlled trial, retrofilling the bladder in the operating room with 200 mL of normal saline before urinary catheter removal after laparoscopic gynecologic surgery



was associated with a significantly shorter time to first void in the PACU and an earlier discharge from hospital, with a median difference of 58 minutes and 72 minutes, respectively. There were no differences in perioperative complications or readmission, and both groups reported high patient satisfaction. Delays in discharge because of an inability to void after outpatient laparoscopy may be avoided with this simple intervention. Earlier discharge from the hospital can also result in improved patient flow, contributing to a reduction in the use of healthcare resources and subsequent cost savings.

## Strengths and Limitations

Strengths of our study included its randomized nature and the consistent blinding of not only the patients but also the outcome assessors. We encountered minimal loss to follow-up and few protocol violations. The 2 groups were comparable in baseline characteristics, and although most of the patients were white (approximately 60%), there was nonetheless diverse ethnic representation in the groups. The study was conducted at a single institution, and all procedures were performed by a small group of similarly trained subspecialists in gynecologic surgery, ensuring a generally comparable surgical exposure to patients. Standardization of postoperative surgical care at the ambulatory hospital by a core group of nursing staff also ensured that both groups received similar PACU care.

However, these findings must be interpreted within the context of the study design. There were multiple exclusion criteria established to eliminate potentially confounding variables, which resulted in a homogeneous study population who were at low risk of urinary retention. Consequently, our results may not be generalizable to a more medically and

## Table 1

#### Patient & surgical characteristics

Characteristics	Retrofilln = 21	Controln = 21	p-value
Age, yrs, mean (SD)	37.9 (10)	41.3 (9.7)	.258
Ethnicity, n (%)	57.5 (10)	41.5 (5.7)	.256
African American	1 (4.8)	1 (4.8)	.946
Asian	4 (19)	2 (9.5)	.940
White	12 (57.1)	13 (61.9)	
Hispanic/Latino	1 (4.8)	1 (4.8)	
Southeast Asian	1 (14.3)	4 (19)	
Current smoker, n (%)	1 (4.8)	2 (9.5)	1.0
Comorbidities, n (%)	1 (1.0)	2 (9.3)	1.0
Cardiovascular disease	1 (4.8)	0(0)	1.0
Diabetes	0 (0)	0(0)	NA
Respiratory disease	0(0)	1 (4.8)	1.0
Thyroid dysfunction	3 (14.3)	5 (23.8)	.697
Neuropathy	0(0)	0 (0)	NA
Surgical history, n (%)	0(0)	0(0)	1474
Previous cesarean section	3 (14.3)	2 (9.5)	1.0
Previous laparotomy	4 (19)	4 (19)	1.0
Previous laparoscopy	9 (42.9)	6 (28.6)	.520
Operative time, min, median (IQR)	62.0 (49.0, 123.0)	62.0 (54.0, 97.0)	.930
Procedure, n (%)	0210 (1910, 12010)	0210 (0 110, 9 110)	.644
Salpingectomy*	3 (14.3)	3 (14.3)	1011
Oophorectomy <sup>†</sup>	7 (33.3)	8 (38.1)	
Cystectomy	1 (4.8)	4 (19.0)	
Endometriosis	5 (23.8)	4 (19.0)	
Myomectomy	1 (4.8)	1 (4.8)	
Other <sup>‡</sup>	4 (19.0)	1 (4.8)	
Patients receiving intraoperative narcotics/benzodiazapines, n (%)	. (1910)	1 (110)	
Fentanyl	19 (9.5)	18 (85.7)	1.0
Hydromorphone	13 (61.9)	15 (71.4)	.743
Midazolam	6 (28.6)	7 (33.3)	1.0
Total intraoperative narcotics MME <sup>§</sup> , mean (SD)	53.7 (22.1)	53.1 (26.6)	.937
Total intraoperative intravenous fluids, mL, median (IOR)	800 (625, 900)	900 (600, 1000)	.318
Total postoperative narcotics MME*, mean (SD)	11.4 (17.6)	14.9 (17.0)	.521
Patients receiving postoperative narcotics n (%)		, ( ,	
Fentanyl	4 (19.0)	10 (47.6)	.102
Hydromorphone (PO)	3 (14.3)	1 (4.8)	.606
Oxycodone	7 (33.3)	9 (42.9)	.751
IOD – interconstile reason MME – membine millionem equivalents DO – reason SD	standard desire		

IQR = interquartile range; MME = morphine milligram equivalent; PO = per os; SD = standard deviation.

\* Salpingectomy includes unilateral and bilateral salpingectomy.

<sup>†</sup> Oophorectomy includes unilateral and bilateral oophorectomy, with or without salpingectomy.

 $^{\ddagger}$  Other: Diagnostic laparoscopy with or without tubal dye test, cervico-isthmic cerclage.

<sup>§</sup> Owing to the inherent complexity of converting remifentanil to MME, this narcotic was excluded from total MME comparison.

### Table 2

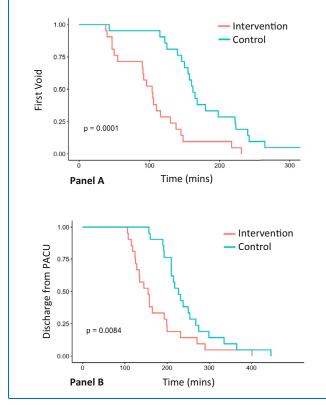
Voiding and PACU discharge times

Category	Retrofill $n = 21$	Control $n = 21$	p-value
Time to first void, min, median (IQR)	104.0 (75)	162.0 (76)	<.001
Time in PACU, min, median (IQR)	155.0 (74)	227.0 (58)	.001
Volume of first void, mL, median (IQR)	20.0 (116.3)	6.0 (141.3)	.008
Postoperative complications, n (%)	n = 16	n = 17	
Unplanned hospital visit	1 (6.2)	1 (5.9)	1.00
UTI	0 (0)	0 (0)	N/A
Satisfied/Very satisfied	16 (100)	17 (100)	N/A

IQR = interquartile range; N/A = not applicable; PACU = postanesthesia care unit; UTI = urinary tract infection.

## **Fig. 2**

Kaplan-Meier time to event curves. (A) Time to first void, comparison of intervention and control. (B) Time to discharge from PACU, comparison of intervention and control. PACU = postanesthesia care unit.



surgically diverse patient demographic. There was no formal testing of bladder function preoperatively to detect occult voiding dysfunction or to evaluate bladder capacity. Although this information would have been valuable, it would be unlikely for any significant voiding dysfunction to exist without the patient's knowledge, and differences between groups were unlikely due to randomization.

#### Interpretation

These findings are consistent with previously published studies that have investigated the effect of retrograde bladder filling after various procedures and subsequent voiding patterns. Moawad et al [8] explored backfilling with 150 mL of normal saline after minimally invasive benign hysterectomy and found significantly earlier first voids (64.9 minutes, p = .015) and sooner discharge in the intervention arm (64 minutes, p = .006) compared with controls with unfilled bladders. This significant difference between the 2 groups equates to more than \$400 in healthcare savings per patient (p = .006) and is consistent with the findings of our current study in voiding and discharge times. For patients undergoing pelvic reconstructive and incontinence surgeries, retrofilling the bladder significantly improved success rates of postoperative trial of void and more accurately predicted voiding dysfunction compared with spontaneous voiding, with similar levels of patient satisfaction rates [11]. Our study adds to the growing body of existing literature all with similar results in varying patient populations and highlights the safety and efficacy of this simple intervention in optimizing patient flow in the postoperative setting.

Given the efficacy and safety of retrograde bladder filling after outpatient gynecologic surgery, consistent with other results in the literature, this intervention can be safely recommended as part of routine postoperative care in most settings. Future studies should investigate the effects of retrofilling the bladder in a more heterogeneous and diverse surgical population to expand the generalizability of the benefits of this intervention. Furthermore, identifying which patients require a trial of void after surgery remains largely unknown and often left to surgeon judgment. A retrospective cohort study of nearly 5000 patients undergoing various same-day gynecologic surgeries found no difference in readmission rates and postoperative urinary retention in patients with and without an order to void before discharge [12]. However, the fact that they did not account for procedure type was a key limitation. For instance, the combination of laparoscopic and vaginal surgeries (including pelvic reconstructive procedures) and cancer surgeries (in which extensive lymphadenectomy or aggressive dissections may have occurred) may directly affect postoperative voiding dysfunction. Further study aimed at evaluating which patients (based on patient and surgical characteristics) could be safely discharged without a trial of void after surgery is required.

Table 3						
Patient characteristics after failing TOV						
Patient	Age, yrs	Randomization	Procedure	Outcome	TOV	
Patient 1	32	Control	Right salpingo-oophorectomy	Home with Foley catheter	Passed on POD 1	
Patient 2	38	Retrofill	Bilateral oophorectomy	Admitted for social reasons	Passed on POD 1	
Patient 3	31	Retrofill	Cervicoisthmic cerclage	Home with Foley catheter	Passed on POD 1	
Patient 4	34	Control	Ovarian cystectomy	Discharged home without Foley catheter	N/A	
Patient 5	47	Control	Bilateral salpingo-oophorectomy	Discharged home without Foley catheter	N/A	

N/A = not applicable; POD = postoperative day; TOV = trial of void.

#### Conclusion

Patients undergoing elective outpatient gynecologic laparoscopy (excluding hysterectomy and pelvic reconstructive surgery) who undergo bladder retrofilling in the operating room are able to void quicker and are discharged from the hospital faster than those undergoing the current standard of care. Retrograde bladder filling should be considered a safe addition to recovery protocols that can enhance recovery after surgery.

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# **Supplemental Appendix 1**

# Voiding protocol

- Once patient sufficiently recovered from anesthesia and feels urge to void, have patient void into voiding hat record time & volume of first void (V1)
- If patient voids 100 mL or more, consider as successful voiding trial
- If patient voids < 100 mL, perform Post-Void Residual bladder scan (PVR)
  - If <u>PVR</u> is LESS THAN OR EQUAL to 100 mL, consider as successful voiding trial
  - $_{\odot}$  If <u>PVR</u> is GREATER THAN 100 mL, consider as failed voiding trial

- If failed voiding trial, re-attempt voiding within 30 to 60 minutes
- Record time & volume of second void (V2)
- If patient voids 100 mL or more, consider as successful voiding trial
- If patient voids < 100 mL, perform Post-Void Residual bladder scan (PVR)
  - If <u>PVR</u> is LESS THAN OR EQUAL to 100 mL, consider as successful voiding trial
  - If <u>PVR</u> is GREATER THAN 100 mL, consider as failed voiding trial
- If patient fails both voiding trials, notify MD and insert foley catheter