The impact of post-operative voiding trial on length of stay following laparoscopic hysterectomy: a prospective, randomized control trial

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Objective: Same day discharge (SDD) is feasible following laparoscopic hysterectomy (TLH) in gynecologic oncology patients resulting in low complication and re-admission rates. Following vaginal surgery, backfill or active voiding trials have been shown to reduce hospital discharge with a catheter. The aim of this study is to determine if performing an active backfill voiding trial (AVT) vs. passive voiding trial (PVT) leads to expedited discharge following TLH. Methods: Subjects scheduled for SDD TLH were enrolled and randomized to an AVT or a PVT. The primary outcome was length of stay. Secondary outcomes include time to void, catheter replacement, admission to the extended recovery unity (ERU), post-operative pain, and complications. Results: 121 patients were randomized: 60 to an AVT and 61 to a PVT. There was a statistically significant reduction in median length of stay for patients undergoing an AVT vs. PVT (271.5 minutes vs. 329 minutes, P = 0.015). Median time to void was also decreased with an AVT vs. PVT (30 minutes vs. 289 minutes, P < 0.001). There was no difference in median pain score (2), catheter replacement, peri-operative complications, or overnight admissions between the two groups. Conclusion: There is a significant reduction in time to void and total length of stay in patients randomized to a backfill voiding trial following TLH with no increased patient discomfort. While the numbers of post-operative admissions were low and underpowered to detect a difference in admission rates, these data will help to streamline post-operative care for SDD gynecologic oncology patients.

Keywords

Same day discharge; Laparoscopic hysterectomy; Voiding trial; Perioperative outcomes

1. Introduction

Minimally invasive surgery (MIS) is associated with improved patient outcomes. Total laparoscopic hysterectomy (TLH) has been demonstrated to be safe in gynecologic oncology patients with a reduction in post-operative morbidity and length of hospital stay with no difference in cancer related outcomes in endometrial cancer [1–7]. Data have also shown

a reduction in cost of care compared to abdominal hysterectomy such that each 10% increase in MIS equates to $2.8 million in cost saving [2, 8–10]. Recent studies have evaluated strategies to streamline perioperative care and improve patient outcomes, such as same day discharge (SDD) after TLH. At the study institution, we have demonstrated that following the adoption of SDD, there was no difference in composite complication rates or readmission, which is consistent with other observational studies [11–13]. Additionally, in a study utilizing the national Perspective database, SDD was associated with a 4% reduction in cost compared to overnight admission [3].

Post-operative urinary retention (POUR), is reported to varying degrees following gynecologic surgery and is associated with increased length of stay [14–17]. Age greater than 50 and the use of opioid medications increase this risk, such that an oncologic patient population may be at higher risk for voiding dysfunction [14, 18, 19]. Active backfill voiding trials (AVT) have been described after urogynecologic surgery with a reduction in discharge with a catheter and a correlation with bladder emptying [17, 20, 21]. In a randomized study, Foster et al. noted that following transvaginal surgery performing an AVT expedited discharge by 30 minutes, although this was not statistically significant [17].

Evaluating perioperative efficiency endpoints is important to improve both quality outcomes and cost of care. There is no standard method for assuring urinary function prior to discharge following TLH. We hypothesize that performing an AVT will lead to a reduction in time to discharge. The aim of this study is to investigate the impact of AVT versus PVT on the time to discharge in patients undergoing SDD laparoscopic hysterectomy for gynecology oncology surgery.
2. Materials and methods

A prospective, randomized control trial was conducted after approval by the Brigham and Women’s Hospital Institutional Review Board on February 21, 2016 (protocol #2015P000902). Patients were randomized 1:1 to either an AVT or a PVT following TLH. Patients who were scheduled to undergo a SDD TLH were recruited beginning January 2017. This population was chosen because of the potential risk for POUR and an overall high adoption of a SDD model by high volume, minimally invasive gynecologic oncology surgeons. The protocol was retrospectively registered on Clinicaltrials.gov Trial Registration Number: NCT04487600. The study design and approval were initiated prior to the “Final Rule” regarding clinical trial registration and reporting on clinicaltrials.gov. Given the scope of the study without the use of an FDA approved or investigational agent or device, it did not meet criteria for an applicable clinical trial under 42 CFR 11.22 and thus it was not pre-registered. There were no changes to the trial design after commencement.

Patients who were scheduled to undergo SDD TLH were identified through the gynecologic oncology clinic and were assessed for eligibility to participate in this study. Participants were enrolled and consented prior to their scheduled surgery. There were no deviations to the planned surgery based on enrollment in the study. Patients were included in the study if they were over 18 years of age and were scheduled to undergo a SDD TLH by a gynecologic oncology surgeon for either benign or malignant disease. Patients were excluded if they were unable to give informed consent, had a history of significant urinary dysfunction (such as home catheterization), underwent a bilateral radical dissection (defined as bilateral ureterolysis or removal of bilateral parametria), conversion to laparotomy, or at the end of the procedure, based on the surgeons or anesthesiologists’ recommendations, were changed to inpatient status. Patients who stayed in the extended recovery unit (ERU) with planned observation for less than 24 hours were included in the final analysis.

A computer-generated blocked randomization schema was utilized with alternating block sizes to determine study groups. Voiding trial protocols for each group (AVT and PVT) as well as data collection sheets were stored in sequentially numbered, opaque, sealed envelopes which were assigned after enrollment and were opened in the operating
Fig. 2. Kaplan-Meier Curves depicting. a) time to discharge for patients randomized to active versus passive voiding trial; median 271 minutes vs. 326 minutes ($P = 0.015$); b) time to discharge for patients randomized to active versus passive voiding trial excluding patients admitted to the extended recovery unit (ERU); median 259 minutes vs. 322 minutes (146-496 minutes) ($P = 0.02$); c) the time to void for patients randomized to active versus passive voiding trial; median 30 minutes vs. 289 minutes ($P < 0.001$).

Fig. 3. Flow diagram of patient discharge following active versus passive voiding trial per study protocol.

*TOV = trial of void.
† 2 patients were discharged after voiding < 200 cc (off protocol); however, no documented re-admission or issue related to voiding dysfunction initial.

Informed, written consents were obtained from study participants as above. Supplemental Figs. 1 & 2 demonstrate the voiding trial protocols and data collection sheets for each study group. Attending surgeons were blinded to study allocation and outcome. Given the nature of the intervention, patients and nursing staff were not blinded to the allocations; however, they were blinded to the study outcomes.
Patients were randomized 1:1 to the AVT vs. PVT study groups. In the AVT group, a Foley catheter was left in place at the completion of surgery and when the patient was determined to be ambulatory by the recovery room nurse, the bladder was backfilled with 300 cc of sterile normal saline. Voiding 200 cc or (2/3) of the backfill amount was considered passing (Supplemental Fig. 1). In the PVT group, a Foley catheter was removed at the end of the operation in the operating room and patients were allowed six hours to void spontaneously, with 200 cc being considered adequate (Supplemental Fig. 2). If patients were unable to void 200 cc, a bladder scan was performed, and participants were allowed additional time if the volume on bladder scan was $<$ 500 cc. If patients demonstrated a bladder scan 500 cc or greater, a catheter was replaced. These criteria were based on current institution standards based on previously published studies [16, 17]. A pre-enrollment protocol review was conducted with both providers and perioperative nursing staff of the voiding algorithms. After arrival to the post-operative acute care unit (PACU), nursing staff followed the written protocols as outlined in the study data sheets based on randomization assignments. Data were collected on void time, bladder scan data, discharge time, perioperative narcotic use, and any discomfort with voiding using the Wong-Baker FACES Pain Rating Scale (Wong-Baker) [22].

The primary outcome was length of stay or time to discharge from the PACU following completion of the surgical procedure. To detect a 30-minute difference in discharge time with 80% power and a two-sided $\alpha$ of 0.05, 117 patients were required for enrollment [17]. Secondary outcomes include time to void, catheter replacement, discomfort with the voiding trial, and admission to the extended recovery unit (ERU). Demographic, perioperative, and follow up data were obtained from the electronic medical record. Major post-operative complications within 30 days were extracted from the medical record and defined as 1) mortality, 2) vascular morbidity, 3) wound morbidity, 4) venous thromboembolic event morbidity, 5) respiratory morbidity, 6) infectious morbidity, 7) renal morbidity, 8) re-operation, 9) 30 day readmission, or 10) post-operative blood transfusion [23]. Urinary tract infections within 30 days post-procedure were also included for secondary analysis.

### 2.1 Statistical analysis

Continuous variables were evaluated by Student’s t test or ANOVA. The Mann–Whitney U was used for ranked variables. Chi square test or Fischer Exact test was used for categorical variables. All statistical tests were 2 sided and differences were considered statistically significant at $P < 0.05$. Kaplan Meier plots of length of stay were constructed for each treatment group and compared using a log-rank test. A multivariate analysis was planned for any clinical characteristics or secondary outcomes which were statistically significant on univariate analysis. Statistical analyses were performed using GraphPad v.7.02 (San Diego, CA).

### 3. Results

A total of 134 patients were assessed for eligibility between January and August 2017. The follow up period included 30-day post-operative outcomes through October 2017. The trial was stopped upon completion of the planned enrollment. Four participants were recruited but did not meet the inclusion criteria: 1 underwent a bilateral salpingo-oophorectomy only and three had planned inpatient admissions for medical co-morbidities. One hundred and thirty patients were randomized, and ultimately, 121 women received the allocated intervention and are included in the final analysis. Fig. 1 demonstrates the Consort diagram with enrollment and intervention for the study population. Nine patients were excluded from the final analysis: two patients declined to participate post-operatively following randomization, and seven patients did not receive the study intervention in the PACU. All 121 patients who received the study intervention were included in the final analysis of which sixty patients were randomized to an active voiding trial and 61 patients were randomized to a passive voiding trial.

Table 1 demonstrates the baseline demographics and clinical characteristics for the study groups. For the entire cohort, the median age was 58 (range 28–86) and the median BMI was 30.3 (range 17.4–55.7). There was no difference in median age, BMI, race, or gravidity/parity among patients undergoing AVT vs. PVT. There was also no significant difference in other clinical factors such as distance from the hospital or baseline co-morbidities as demonstrated by Charlson Co-morbidity Index score (Table 1) [24]. One patient in the PVT group had a documented urinary tract infection (UTI) thirty days prior to surgery. The indications for surgery were also similar between the AVT and PVT groups with most patients undergoing TLH for uterine pathology [46/60 (76.7%) and 47/61 (77%) respectively] and Stage I disease [32/60, 53.3% vs. 34/61, 55.7%] (Table 1).

Regarding peri-operative outcomes, there was no difference in the length or extent of surgery (lymphadenectomy, omentectomy, ureterolysis) between groups (Table 2). The median length of surgery was 113 minutes (56–240 minutes) in the active vs. 128 minutes (61–216 minutes) in the passive voiding trial group, $P = 0.33$. Most participants in each group underwent conventional laparoscopy while 9/60 (15%) in AVT and 10/61 (16.4%) in PVT groups had robotic assisted laparoscopic surgery, $P = 0.84$. In assessing other factors which may contribute to POUR, there was no significant difference in participant history of voiding dysfunction, diabetes, or antidepressant use ($P = 0.24, 0.45$, and 0.15 respectively). Similarly, there was no difference in the use of scopolamine patch as an antiemetic, $P = 0.49$. Regarding peri-operative narcotic use, the total peri-operative dose of narcotics (oral morphine equivalents) was not significantly different for patients in the AVT group receiving 68.1 mg (12-225 mg) oral morphine equivalents vs. 64.8 mg (11-152 mg) in PVT group, $P = 0.49$. Two patients had a post-operative UTI, one in the active and one in the passive voiding trial.
Table 1. Baseline demographic and clinical characteristics for patients randomized to active vs. passive voiding trial following laparoscopic hysterectomy

|                                | Active voiding trial | Passive voiding trial |
|--------------------------------|----------------------|-----------------------|
| Number                         | 60                   | 61                    |
| Age (years)                    | 56 (28-84)           | 60 (31-86)            |
| BMI (kg/m²)                    | 30.1 (17.4-55.7)     | 32 (18.9-51.5)        |
| Race                           |                      |                       |
| White                          | 56 (93)              | 53 (87)               |
| Black                          | 0 (0)                | 0 (0)                 |
| Hispanic                       | 3 (5)                | 3 (5)                 |
| Asian                          | 1 (2)                | 5 (8)                 |
| Distance from the hospital (miles) | 30.5 (2.4-655)      | 34 (2.4-300)          |
| Gravidity (IQR)†               | 2 (1-3)              | 2 (2-3)               |
| Parity (IQR)                   | 2 (1-2)              | 2 (1-3)               |
| Disease Site                   |                      |                       |
| Ovary                          | 3 (5)                | 8 (13.1)              |
| Uterus                         | 46 (76.7)            | 47 (77.0)             |
| Cervix                         | 7 (11.7)             | 3 (4.9)               |
| Risk reducing surgery          | 4 (6.7)              | 3 (4.9)               |
| FIGO Stage‡                    |                      |                       |
| Benign                         | 7 (11.7)             | 11 (18)               |
| Pre-invasive                   | 15 (25)              | 11 (18)               |
| Stage I                        | 32 (53.3)            | 34 (55.7)             |
| Stage II                       | 2 (3.3)              | 1 (1.6)               |
| Stage III                      | 3 (5)                | 4 (6.6)               |
| Stage IV                       | 1 (1.7)              | 0 (0)                 |
| Charlson Comorbidity Index†    | 4 (0-9)              | 5 (0-14)              |

Data are reported as median (range) or n (%) unless otherwise specified.
* IQR = Interquartile range.
† FIGO = The International Federation of Gynecology and Obstetrics. Individual cancer sites were staged as per FIGO staging. Given multiple disease sites in the cohort stage was collapsed to reflect local, regional, and distant spread as classified above.
‡ Charlson Comorbidity Index was collected as per validated Charlson comorbidity index tool [26].

One patient had major post-operative complications (in the PVT group) with re-admission within 30 days for a ureteral injury requiring percutaneous nephrostomy tube placement. The total major complication rate for the entire cohort was 0.8% [23].

Table 3 demonstrates the voiding trial outcomes. There was a statistically significant reduction in length of stay for patients randomized to AVT compared to PVT (271 minutes (136-595 minutes) vs. 326 minutes (146-630 minutes), $P = 0.015$) (Fig. 2a). Similarly, there was a significant reduction in time to void in patients randomized to the AVT with patients voiding in 30 minutes (15-57 minutes) compared to 289 minutes (range 230-365 minutes) in the PVT group, $P < 0.001$ (Fig. 2c). Thirteen patients were admitted overnight to the ERU for observation, 5 (8.3%) in the AVT group and 8 (13.1%) in the PVT group, $P = 0.56$. Among patients admitted overnight, 10/13 (77%) were admitted for reasons unrelated to voiding dysfunction: three for pain control, three for post-operative nausea/vomiting (PONV), and four for respiratory/medical monitoring. Three patients were admitted for a failed voiding trial, all of whom were in the PVT group. Excluding the 13 patients admitted overnight to the ERU, there remained a statistically significant reduction in length of stay among patients undergoing an AVT compared to PVT (259 minutes (136-468 minutes) vs. 322 minutes (146-496 minutes), $P = 0.02$) (Fig. 2b). Patient reported discomfort with the voiding trial was assessed using the Wong-Baker FACES Pain Rating Scale. Pain score reporting was inconsistent, 39 patients had documented pain scores in the AVT group and 22 in the PVT group. The median pain score for each group was 2 (0-7) for the AVT group and 2 (0-8) for the PVT group. In total, six patients (5%) required catheter replacement of whom three were discharged with a catheter. There was no association between the type of voiding trial and catheter replacement, $P = 0.68$. All patients with POUR were able void at the time of outpatient repeat voiding trial with no documented ongoing voiding dysfunction at last follow-up.

The voiding trial protocols used in this study utilized parameters which were slightly relaxed compared to those previously described in the urogynecologic literature, allowing additional time to void if a bladder scan demonstrate volume
less than 500 cc. Fig. 3 outlines the flow diagram for the time point during the study protocol when participants successfully voided or “passed” the void trial for each study group. Thirty-five (58.3%) patients in the AVT group passed the initial trial of void, voiding within 30 minutes of bladder backfill compared to 41 (67.2%) in the PVT group, voiding within 6 hours of Foley catheter removal, \( P = 0.35 \). An additional 23 (38.3%) patients and 14 (23%) patients voided successfully with additional time in the active and passive voiding trial groups respectively. Eight patients had a bladder scan > 300 cc and < 500 cc and all of them voiding spontaneously with additional time without POUR.

### 4. Discussion

Overall, patients undergoing an AVT had a significant reduction in length of stay compared to patients in the PVT group. Time to void was also significantly decreased (by over four hours) in the AVT group, allowing for earlier assessment of voiding dysfunction and identification of at-risk patients. In total, 10.7% of patients with planned SDD were admitted overnight for monitoring. This is lower than previously published rates at this institution and in other studies [11, 12]. This may reflect the adoption of consistent pre-operative counseling and a multi-disciplinary approach to SDD care in this contemporary cohort. Excluding patients admitted to the ERU, the reduction in length of stay remained significant in the AVT group with a median length of stay 63 minutes shorter than the PVT group. There were no significant differences in catheter replacement, pain scores, post-operative UTIs, or major post-operative complications. Our overall complication rate (0.8%) was low compared to published rates after MIS for gynecologic malignancy (0.7-4%), further highlighting the feasibility of this model [12, 13].

Randomization resulted in similar baseline characteristics between the study groups. There were also no significant differences in perioperative outcomes on univariate analysis, such that there was no basis for performing a multivariate analysis. Most patients in this study population were obese (median BMI 30.3) up to a maximum of 55.7 mg/m² and almost 20% were elderly (age > 65), consistent with expected demographics for an oncologic population. Factors which may have contributed to voiding dysfunction based on prior studies such as intra-operative fluid volume, length of surgery or surgical complexity, or medical co-morbidities were not significantly different between the study groups [14, 18, 19].

Regarding perioperative pain management, the total opioid use was also similar. The range in perioperative narcotics use was wide in both groups such that perioperative prescribing practices is an important area of future investigation.

Prior studies have reported rates of POUR in gynecology surgery ranging up to 43% (the highest following suburethral sling placement) [14, 18]. Only 5% of patients required catheter replacement in this study. Given the small number of patients requiring catheter replacement, individ-

### Table 2. Perioperative outcomes for patients randomized to active vs. passive voiding trial following laparoscopic hysterectomy

| Active voiding trial | Passive voiding trial | \( P \) value* |
|----------------------|-----------------------|--------------|
| Number               | 60                    | 61           |
| Length of surgery (minutes) | 113 (56-240) | 128 (61-216) | 0.33  |
| Surgical start time  |                       |              |
| Prior to 11am         | 30 (50)               | 35 (57.4)   | 0.56  |
| 11am-3pm              | 28 (46.7)             | 22 (36.1)   |       |
| After 3pm             | 2 (3.3)               | 4 (6.6)     |       |
| Estimated blood loss (mL) | 25 (10-150) | 50 (10-200) | 0.93  |
| Robotic surgery       | 9 (15)                | 10 (16.4)   | 0.84  |
| Lymphadenectomy       |                       |              |
| None                 | 26 (43.3)             | 28 (45.9)   | 0.50  |
| Sentinel lymph node biopsy | 27 (45)       | 33 (54.1)   |       |
| Complete pelvic +/- para-aortic lymphadenectomy | 7 (11.7) | 0 (0) |       |
| Ureterolysis          | 5 (8.3)               | 3 (4.9)     | 0.69  |
| Omentectomy           | 8 (13.3)              | 7 (11.5)    | 0.76  |
| Total fluid balance (mL) | 1448 (125-4420) | 1405 (630-3670) | 0.86 |
| Scopolamine patch     | 15 (25)               | 12 (20)     | 0.49  |
| Total opioid use (oral morphine equivalents, mg)† | 68.1 (12-225) | 64.8 (11-152) | 0.64 |
| Reported history of voiding dysfunction | 8 (13) | 14 (23) | 0.24 |
| History of diabetes   | 10 (17)               | 7 (11)      | 0.45  |
| Pre-op antidepressant use | 19 (32)     | 12 (20)     | 0.15  |

Data are reported as median (range) or n (%) unless otherwise specified.

*P values are calculated via Chi Square or Fischer exact for categorical variables and two sample t-test (for parametric testing) or Mann Whitney test (for non-parametric testing) for continuous variables.

† Opioid equivalents were calculated to oral morphine equivalents using opioid conversion calculator [27, 28].
Table 3. Voiding trial outcomes for patients randomized to active vs. passive voiding trials following laparoscopic hysterectomy

|                                | Active voiding trial (n = 60) | Passive voiding trial (n = 61) | P value* |
|--------------------------------|------------------------------|-------------------------------|----------|
| Length of stay (minutes)       | 271.5 (136-595)              | 326 (146-630)                 | 0.015    |
| Length of stay (minutes) excluding ERU† | 259 (136-468) (n = 55) | 322 (146-496) (n = 53) | 0.02     |
| Time to void (minutes)¥        | 30 (15-57)                   | 289 (130-365)                 | < 0.001  |
| Median Pain Score (0-10)       | 2 (n = 39)                   | 2 (n = 22)                    | 0.72     |
| Catheter replaced              | 2 (3.3)                      | 4 (6.6)                       | 0.68     |
| Admission to ERU †             | 5 (8.3)                      | 8 (13.1)                      | 0.56     |

Data are reported as median (range) or n (%) unless otherwise specified.
*P values are calculated using Fischer Exact testing for categorical variables and Mann Whitney test for continuous variables.
†ERU = extended recovery unit.
¥Patients who failed the trial of void (2 in the AVT and 4 in the PVT) were excluded from the time to void analysis.

Table 3. Voiding trial outcomes for patients randomized to active vs. passive voiding trials following laparoscopic hysterectomy

In addition to streamlining peri-operative care, there may be a potential cost benefit with an AVT. While many PACU costs are fixed, there are data to suggest that PACU time can vary between $1 to $8 per minute [25, 26]. If we were to assume an average PACU cost of $4 per minute, if all patients undergoing PVT in this series instead had an AVT, this would result in a cost savings of $15,372 for the study population. While a complete cost analysis would require evaluation of fixed and variable costs within the institution which is beyond the scope of this study, the improvement of perioperative efficiency has potential cost benefits that warrant further study. Further, while patient reported outcomes were not included in this study, there was no difference in patient discomfort between study groups. An AVT allows for a more accurate and expedited assessment of voiding dysfunction. By providing an efficient measure of POUR, discharge planning may be optimized with reduced anxiety regarding risk for readmission or subsequent urinary retention.

There are limitations which must be considered when interpreting the results from the current trial. In assessing discomfort as a surrogate for patient satisfaction, pain scores were reported inconsistently, documented in 2/3 of the AVT participants and just over 1/3 in the PVT. While there was no difference in this subset, the current study does not clearly reflect patient preference. Similarly, due to regional population demographics, most women enrolled in the study were white with no black women enrolled. While prior studies have not demonstrated a difference in POUR by race, this does limit the generalizability of this study. The primary study endpoint of discharge time was chosen as a discrete and meaningful clinical outcome; however, other factors may influence length of stay aside from time to void alone. Variables which may impact discharge time were collected and accounted for with randomization; however, other unknown variables may potentially bias the results. Finally, only a small number of women in this study (less than estimated in the literature) demonstrated POUR requiring catheter replacement or overnight admission. While these were not the primary study endpoints, the current study is underpowered to detect significant differences in these outcomes based on the small number of events. While a larger series may demonstrate a difference in these outcomes, improvement in perioperative efficiency with a reduction in time to void and length of stay provides clinically meaningful incentive for practice reform.

5. Conclusions

An AVT results in a significant reduction in time to void and length of stay with no increased adverse events compared to a PVT. Performing an AVT following SDD TLH improves perioperative efficiency to optimize patient care.

Author contributions

AF and CF designed the research study. MD, KB, and RN performed the research. KE analyzed the data. MD wrote the manuscript with the contribution of KB and RN. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Trial Registration Number: NCT04487600; 7/24/2020, retrospectively registered.
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Conflict of interest
The authors declare no competing interests.

Supplementary material
Supplementary material associated with this article can be found, in the online version, at https://ejgo.imrpress.com/EN/10.31083/j.ejgo.2021.01.2293.

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