Spontaneous Void Requirements for Patients Undergoing Ambulatory Anorectal Surgery

TABLE OF CONTENTS

Objective

Urinary retention is a common complication following anorectal surgery and is thought to be multifactorial. Some researchers explain post-operative urinary retention as a consequence of long acting analgesics which dampen the ability for bladder fullness[1]. Others point to irritation to pelvic nerves that function with micturition thus blunting pain evoked reflexes[2,3]. Modifiable factors that have been found to play a role in contributing to post-operative urinary retention include the use of intravenous fluids over one liter during surgery, and administration of local analgesics. Local analgesics provide significant acute pain relief, but contribute to the theory of blunted pain reflexes. Inadequate pain control increases likelihood of urinary retention through inability of perineal relaxation. A balance must be maintained between adequate pain control and interfering with the micturition reflex. Non-modifiable risk factors include age, female sex, the presence of diabetes mellitus, and specific surgical procedure[4].

Complications of post-operative urinary retention include an increase in urinary tract infections, hospital readmission, damage to detrusor contractility, and for the elderly increased confusion and delirium[5]. The rate of urinary retention post anorectal surgery is between 16-20%. The incidence of urinary retention following high-risk ambulatory surgery is stated to be 5%. The objective of this study is to assess if not requiring patients to spontaneous void prior to discharge from the post-anesthesia care unit (PACU) will result in shorter lengths of stay in the post-anesthesia care unit without increasing hospital readmissions or emergency room visits.

Background & Research Significance

Spontaneous void is a discharge criteria from post anesthesia care units given the potential need for bladder catheterization and prolonged hospitalization for urinary retention. Research evaluating required spontaneous void following ambulatory anorectal surgery is lacking. Research has been conducted on patients requiring spinal and epidural anesthesia which demonstrated that requiring spontaneous voiding post-operation is unnecessary and delays discharge times [4]. Previous research regarding post-operative urinary management of anorectal procedures classified them as ‘high-risk’ with other procedures[5]. Researchers have sought to address potential risk factors for urinary retention and discuss restriction of pre-operative, perioperative fluid, and adequate pain control to decrease the incidence[1,2,6,7]. Determining factors that specifically guide discharge for patients undergoing anorectal surgery and the necessity of post-operative void, however, has not been previously evaluated.

Currently the protocol at The Ohio State University Hospital requires voiding spontaneously prior to discharge from the PACU, but operations performed at The Ohio State University Hospital East do not require a spontaneous void prior to discharge. A recent IRB approved study conducted by our group examined if requiring a spontaneous void prior to discharge affects emergency room visits and readmission rates. We conducted a retrospective review of ambulatory anorectal surgeries performed at the two locations. One of these locations required the ability to void spontaneously as a prerequisite for discharge after ambulatory anorectal surgeries (spontaneous void group) whereas the other location did not maintain this requirement

and patients were discharged once they were deemed ready (no void group). Our research concluded that patients can be safely discharged without voiding after anorectal procedures without increasing the risk of ED visits or readmissions. Furthermore, a requirement to spontaneously void before discharge significantly prolongs PACU stays. Thus, we propose to compare PACU discharge times between patients requiring a spontaneous void to those patients not requiring a spontaneous void.

Hypothesis:
Ability to void spontaneously after anorectal procedures does not result in reduced readmissions, emergency room visits and post op complications.

Primary Objectives:

1. To compare readmission and complications rates between patients who are required to void post anorectal surgeries to those who are sent home without voiding spontaneously.
2. To compare the rates of emergency room visit between patients who are required to void post anorectal surgeries to those who are sent home without voiding spontaneously.

Secondary Objectives:

1. To compare PACU times for patients who are required to void post anorectal surgeries to those who are sent home without voiding spontaneously.
2. To compare total hospital costs for patients who are required to void post anorectal surgeries to those who are sent home without voiding spontaneously.

Study Plan and Procedures
This study will be a prospective clinical trial, in which 100 anorectal surgery patients will be randomly assigned to a control (spontaneous void) or experimental (no void) group. Randomization will be done using the free software provided by www.randomizer.org. “Spontaneous void” group will include 50 patients who will required to void spontaneously after anorectal surgeries. On the other hand “no void” group will be 50 patients who will be discharged home from the PACU once they meet ambulatory surgery center discharge criteria per hospital guidelines. Patients requiring anorectal surgeries will be consented to take part in the study during the preoperative outpatient office visit. A post op phone call will be made by designated study personnel to participants on post-op day 30 using a study questionnaire to assess re-admission and emergency room visits.

Inclusion Criteria:

1. Age 18-80 years old
2. Patients undergoing hemorrhoidectomy, fistulotomy or anal condyloma excision.

Exclusion Criteria:

1. Age <18 yo or >80 yo
2. Prisoners
3. Pregnant Women

4. Unable or unwilling to follow the study protocol or any reason the research team believes the subject is not an appropriate candidate for this study

Measurements of Study Variables

To achieve the study goals, the following data will be collected:

Pre-operative Data:

1. Demographics: age, sex, height, weight, BMI, race
2. Insurance type
3. Past medical history
4. Diabetes history
5. Hemoglobin A1C
6. Coronary artery disease
7. Chronic obstructive pulmonary disease
8. Inflammatory bowel disease
9. Diagnosis of cancer
10. Renal dysfunction
11. Past surgical history
12. Steroid use
13. Immunosuppression
14. Smoking history
15. Substance abuse
16. Diagnosis
17. ASA class
18. Elixhauser comorbidity index
19. Hospital Cost

Post-Operative:

1. Procedure CPT
2. Where procedure took place
3. Date of procedure
4. Length of procedure
5. Estimated blood loss
6. Reoperation during index admission
7. Diagnosis of Urinary retention
8. Post-operative complications
9. Length of hospital stay in days
10. ICU admission
11. ED visit
12. Readmission
13. Interval to last follow up in days
14. Blood transfusion requirements
15. Total IV fluids received

16. Total pain medicine received
17. Hospital Cost

Post-Operative Phone Call:

1. Emergency department visit, urgent care visit, or admission outside of The Ohio State University Wexner Medical Center within 30 days post-operative
2. Reason for admission, emergency department visit, or urgent care visit

Schedule of Events

	Pre-Operative Appointment	30 Days Post-Operative
Assess Eligibility Criteria	X	
Informed Consent	X	
Pre-Op Data	X	
Post-Op Phone Call		X
Post-Op Data		X

Statistical Analysis

Data will be expressed using means +/- standard deviations in addition to sample size (n) and percentages. Further statistical analysis will include Students t test for quantitative variables and chi squared test for comparisons of qualitative variables. A p value <0.05 will be used for statistical significance.

Sample Size Calculation:

Power	N1	N2	μ1	μ2	μ1 - μ2	σ1	σ2	Alpha	Beta	
0.80000		50	50	210.0	129.1	80.9	100.0	175.0	0.050	0.20000
0.80000		75	75	210.0	144.3	65.7	100.0	175.0	0.050	0.20000
0.80000		100	100	210.0	153.2	56.8	100.0	175.0	0.050	0.20000

Report Definitions
Power is the probability of rejecting a false null hypothesis.
N1 and N2 are the number of items sampled from each population.
μ1 and μ2 are the assumed population means for power and sample size calculations.
μ1 - μ2 is the difference between population means at which power and sample size calculations are made.
σ1 and σ2 are the assumed population standard deviations for groups 1 and 2, respectively.
Alpha is the probability of rejecting a true null hypothesis.
Beta is the probability of accepting a false null hypothesis.

Summary Statements

Group sample sizes of 50 and 50 are needed to achieve 80.000% power to reject the null hypothesis of equal means when the population mean difference is μ1 - μ2 = 210.0 - 129.1 = 80.9 with standard deviations of 100.0 for group 1 and 175.0 for group 2, and with a significance level (alpha) of 0.050 using a two-sided two-sample unequal-variance t-test.

For other categorical variables, such as readmission rates, frequencies will be summarized.

Funding

A medical student has applied for a Roessler Scholarship for Summer 2018, and an additional medical student will receive college credit as an extracurricular activity for their work on this project.

Bibliography

1. Petros JG, Bradley TM. Factors influencing postoperative urinary retention in patients undergoing surgery for benign anorectal disease. *Am J Surg*. 1990;159(4):374-376. doi:10.1016/S0002-9610(05)81274-7.
2. Kunitake H, Poylin V. Complications Following Anorectal Surgery. *Clin Colon Rectal Surg*. 2016;29(1):14-21. doi:10.1055/s-0035-1568145.
3. Sutherland LM. A Systematic Review of Stapled Hemorrhoidectomy. *Arch Surg*. 2002;137(12):1395. doi:10.1001/archsurg.137.12.1395.
4. Toyonaga T, Matsushima M, Sogawa N, et al. Postoperative urinary retention after surgery for benign anorectal disease: Potential risk factors and strategy for prevention. *Int J Colorectal Dis*. 2006;21(7):676-682. doi:10.1007/s00384-005-0077-2.
5. Darrah DM, Griebling TL, Silverstein JH. Postoperative Urinary Retention. *Anesthesiol Clin*. 2009;27(3):465-484. doi:10.1016/j.anclin.2009.07.010.
6. Mulroy MF, Salinas F V, Larkin KL, Polissar NL, Ph D. Ambulatory Surgery Patients May Be Discharged before Voiding after Short-acting Spinal and Epidural Anesthesia. *Anesthesiology*. 2002;(97):315-319.
7. Pavlin DJ, Pavlin EG, Fitzgibbon DR, Koerschgen ME, Pitt TM. Management of Bladder Function after Outpatient Surgery. *Anesthesiology*. 1999;91:42-50. doi:10.1097/PRS.0000000000001335.
8. Bailey H, Ferguson J. Prevention of urinary retention by fluid restriction following anorectal operations. *Dis Colon Rectum*. 1976;19(3):250-252.
9. Baldini G, Bagry H, Aprikian A, Carli F. Post Operative Urinary Retention. *Anesthesiology*. 2009;(110):1139-1157. doi:10.1017/S0003581500073893.
10. Zaheer S, Reilly WT, Pemberton JH, Ilstrup D. Urinary retention after operations for benign anorectal diseases. *Dis Colon Rectum*. 1998;41(6):696-704.