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Title: Expanded Criteria Same Day Catheter Removal Following Holmium Laser Enucleation of the Prostate (HoLEP)

Running Title: Expanded same day catheter removal following HoLEP

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ABSTRACT

Introduction and Objectives

Holmium laser enucleation of the prostate (HoLEP) is a highly effective treatment of benign prostatic hyperplasia (BPH). Technical advances and improved hemostatic properties of Holmium lasers have allowed for increased efficiency and outcomes. Same day catheter removal following HoLEP was described at our institution in 2020 following a 30-patient pilot trial. We now present an expanded update following widespread adoption at our facility.

Methods

We reviewed patients who underwent same day catheter removal after HoLEP between 1/1/2020 and 3/21/2021. Unlike previous trials, there were no limitations to prostate size. Other changes included catheter removal in phase two of recovery when nursing was available rather than the urology clinic. Descriptive statistics are presented of preoperative, operative, and postoperative data. Univariate and multivariate analysis was performed to assess associations with failure of same day void trial.

Results

The success rate of same-day catheter removal for the 114 identified patients was 87.7%. Mean age was 69.1 $\pm$ 8.6 years and prostate volume was 109.2 $\pm$ 61.5cc, 35% were dependent on catheterization for urinary retention preoperatively and 9% were on antiplatelet/anticoagulant therapy. A total of 26.5% of patients with ASA 3 or 4 failed catheter removal compared to 3.9% of patients with ASA 1 or 2 (Likelihood ratio 9.32, p=0.002), ASA status lost significance on multivariate analysis (p=0.076). Successful catheter removal was not significantly associated with age, BMI, prostate size, catheter dependency, anticoagulation/antiplatelet therapy, AUA symptom score, prior BPH surgery, or prostate cancer in final pathology.

Conclusion

Regardless of prostate size, same day catheter removal is a safe and reliable method of post-HoLEP patient management. Patients with an ASA 3 or 4 should be counseled

regarding potential risks of temporary re-catheterization. Given ongoing nationwide shortages in hospital beds and staffing, same day discharge and catheter removal may allow for wider availability of surgical treatment for BPH.

Introduction

Holmium laser enucleation of the prostate (HoLEP) is a highly effective treatment of benign prostatic hyperplasia (BPH) and urinary obstruction. Since its first description in 1997[1], the combination of enucleative principles, hemostatic properties of the Holmium:YAG laser, and completely endoscopic nature have allowed it to become a new surgical gold standard for BPH therapy regardless of prostate size[2,3]. Over the last two decades, multiple advances have been made to improve this procedure. Technical advances have allowed for increased procedural efficiency and technological advances in laser technology have improved operative and postoperative outcomes[4-6].

Traditionally, patients required continuous bladder irrigation (CBI) overnight and urethral catheters were removed on the first postoperative day (POD1) after HoLEP. The advances in this procedure have allowed for the procedure to have reduced inpatient stays and even be moved to an outpatient procedure[7]. Newer laser technologies allowing for less blood loss are likely a major factor in this shift[6]. In patients preselected for same day discharge, success rates up to 96.7% for outpatient surgery has been reported[8-12].

Given our experience with outpatient HoLEP at our institution utilizing pulse modulated laser technology, we began removing catheters on the same day of surgery in select patients. Our initial pilot investigation had a 90% success rate with this approach[13]. We have continued this practice due to high success rate and have been offering this to an expanded patient criteria for the last year. We present our experience on an expanded patient cohort undergoing same day catheter removal at our institution.

Methods

We performed a retrospective review of two surgeons' HoLEP experience in those patients who underwent catheter removal on the same-day of HoLEP between January 1, 2020 and March 21, 2021 after obtaining Institutional Review Board approval. Based on our previous experience[13] this approach was offered to all patients who did not require overnight observation for medical reasons, this is approximately 83% of patients in our practice. Patients underwent preoperative prostate imaging for assessment of gland size and given the success of the initial series there was no specific size cut off for this

approach, but maximum size was left to surgeon discretion. In patients with an elevated PSA without prior prostate biopsy, and who otherwise meet criteria for prostate cancer screening, a standard 12 core prostate biopsy was performed in the clinic prior to offering HoLEP. To qualify for trial of same day catheter removal, patients on antiplatelet and anticoagulation medications were asked to hold these medications preoperatively, if unable to hold, the catheter was maintained until POD 1. As is our practice, we do not perform urodynamics on patients dependent on indwelling or intermittent catheterization given the known >95% success HoLEP has with rendering these patients catheter free[14], there are no changes to the void trial pathway for these patients.

Our specific approach has been published in detail[13]. Patients underwent general anesthesia with a supraglottic airway (preferably) or endotracheal intubation without neuromuscular paralysis, while we do perform HoLEP under spinal anesthesia at our institution, these patients have not yet been offered same day catheter removal. Postoperatively, patients underwent continuous bladder irrigation (CBI) with 3-6L of normal saline, if greater than 9L of CBI was required, the catheter was not removed same day. If postoperative hematuria was acceptable with CBI clamped, they were discharged from the post anesthesia care unit (PACU). Patients then went to our outpatient clinic within the same building for trial of voiding or had their catheter removed in the second phase of recovery (Phase 2). There was no prespecified amount of time required for patients to wait until catheter removal. Additionally, patients undergoing this approach typically had cases scheduled to complete by the early afternoon in order to facilitate voiding trial in clinic during business hours.

In clinic or Phase 2, patients had to ambulate, tolerate appropriate oral intake and pain control with minimal to no narcotic pain medication. Their catheters were then filled to sensation of bladder fullness (no more than 500 ml) with normal saline, this is performed to expedite bladder filling and provide an objective starting point to the void trial in order to accurately assess the degree of emptying. After voiding, a postvoid residual scan of 50% of the instilled volume was considered acceptable, which has been our successful previous practice with postoperative day one (POD 1) void trials. If patient was unable to void or serially voided low volume and/or had high postvoid residuals, an 18 Fr Coudé catheter

was inserted and patient returned on POD1 for voiding trial. Narcotics are not prescribed for this procedure as post-operative discomfort primarily consists of tolerable dysuria which is well controlled which is well controlled with non-steroidal anti-inflammatories and/or Acetaminophen. Success was defined as successfully passing a voiding trial on the same day of surgery and no episodes with retention in the first 30 days postoperatively.

Data for univariate analysis. Descriptive statistics are presented of preoperative, operative and postoperative data points. Means with standard deviations (SD) are presented for continuous variables and total number (n) with percentage are presented for nominal variables. Chi Square analysis was performed on variables to assess associations with failure of same day void trial and was analyzed with JMP 15 software. Multivariate analysis was performed using binary logistic regression with SPSS software.

Results

Through the study time period, 114 men were included in our analysis. The success rate of same-day catheter removal was 87.7%. The mean age was 69.1 $\pm$ 8.6 years, BMI was 28.2 $\pm$ 4.4 and prostate volume was 109.2 $\pm$ 61.5 ml (based on preoperative transrectal ultrasound or cross-sectional imaging). A total of 35% were dependent on either indwelling or intermittent catheterization due to urinary retention preoperatively and 4% had a known prostate cancer diagnosis (on active surveillance). There was a 75% rate of alpha blocker and 21.6% finasteride use preoperatively. With regards to antiplatelet/anticoagulant (AP/AC) medications, 9% were on AP/AC (40% clopidogrel, 20% warfarin, 40% direct oral anticoagulant) but this was held if patients were expected to participate in a same day void trial.

There were no 30-day complications in either group. One patient developed clot retention 2 months post operatively and required bladder irrigation, another patient developed a UTI 2 months post operatively which resolved with antibiotics; both patients had a successful same day catheter removal. Of the patients that passed their same day void trial, non-experienced later urinary retention episodes. Of the patients that failed same day void trial, each were subsequently able to pass a void trial within the following week and did not go on to develop retention again at a later date.

A total of 26.5% of patients with ASA 3 or 4 failed catheter removal compared to 3.9% of patients with ASA 1 or 2 (Likelihood ratio 9.32, p = 0.002). There was 1 patient with an ASA of 4, 52 with ASA of 3, 60 with an ASA of 2, and 1 patient with ASA 1. Successful catheter removal was not significantly associated with age, BMI, presence of bladder stone, amount of energy used, morcellation time, prostate size, catheter dependency, alpha blocker or 5-alpha reductase inhibitor use, anticoagulation or antiplatelet therapy, pre-operative AUA symptom score, prior history of BPH surgery, or findings of prostate cancer in pathology report. (Table 1). Though ASA categorization and PSA were significantly associated with same day void trial failure on univariate analysis, on multivariate analysis neither reached significance (p values of 0.076 and 0.230 respectively) (Table 2).

Discussion

Our findings demonstrate overall wide success of same day void trials across a diverse patient cohort of prostate sizes, previous catheter dependency, and comorbidities (as estimated by ASA). It is worth noting that many of the conditions that traditionally create concern for successful void trial after traditional bladder outlet procedures (i.e. TURP) such as age, prostate size, and current catheter dependency did not correlate with failed same day void trial following HoLEP. This is consistent with known superior catheter free rates following HoLEP established in the literature[15]. We theorize that the strong association of ASA 3 or 4 with void trial failure may be related to the overall lesser strength and conditioning among these patients which limits their ability to Valsalva void to sufficient levels immediately post-operatively, particularly following use of a general anesthetic.

The loss of ASA significance on multivariate analysis was unexpected as this held the strongest of associations on univariate analysis and had an explainable connection. It is possible that there truly is no correlation between void trial success/failure and ASA status, or that the accumulation of unmeasured confounding variables throughout the data collection underpowered the multivariate analysis which is more sensitive to data integrity. Regardless of the difference in analysis techniques, patients with an ASA 3 or 4 should be counseled regarding a trend toward increased risks of temporary re-catheterization.

The univariate significance of higher PSA being associated with void trial failure is challenging to be explained by the data as one would expect prostate size to also be significant if elevated PSA were due to increased prostate size, though this was not the case; furthermore, any relation to prostate cancer or even lack of PDE5 inhibitor use as a contributor to void trial failure with elevated PSA cannot be explained by the data as neither of these were independently associated with void trial outcomes. Given the loss of PSA significance on multivariate analysis, this initial association is believed to be coincidental, and as such would be expected to lose significance with a larger study population.

Given ongoing nationwide shortages in hospital beds and staffing, minimizing the need for inpatient stays or subsequent clinic visits for void trials will allow refocused attention of staff that may otherwise have limited capacity. Same day catheter removal and discharge can therefore allow for wider availability of surgical treatment for men with BPH. Building on our previous experience of 30 patients[13], this approach has proven to be a reliable method of post-HoLEP patient management. The success rate is not significantly different than before (87.7% now vs 90.0% prior), and the rate of complications remains low.

We attribute the sustained same day void trial success even among an expanded inclusion criteria to further refinement of our protocol and increasing familiarity and execution by participating nursing staff. Improvements, described in the methods, include patients preforming the void trial in phase 2 of PACU, rather than requiring transition to the clinic as done previously. We have also become more selective of whom we proceed with catheter removal, now requiring increased clarity of urine with CBI discontinued and that patients be fully ambulatory or at their functional baseline from the pre and post-operative setting before being offered a trial of void.

This study is not without limitations and our approach is not without potential disadvantages. Limitations include the single center nature of approach and involvement of two surgeons with specific fellowship training in HoLEP both of which may limit the reproducibility and generalizability of our findings. The ability to translate these results to non-pulse modulated laser systems may also be limited, as these have proven to be superior for hemostasis[16]. Same day catheter removal and dismissal also reduces close

post-operative observation which may increase the stress and anxiety of patients now required to care for themselves at home, though discharging without a catheter likely mitigates these concerns. It is unknown what impact same day catheter removal has on patient satisfaction and perceived level of care received.

Conclusion

In this, the largest series of same day catheter removals post-HoLEP, expanded criteria to now include all patients with any prostate size and planned same day surgery has shown to be a safe and successful option for patients desiring prompt catheter free status post operatively. By avoiding delayed void trials, this approach further lessons the dependence of already limited healthcare personal, reduces catheter dwell time, and the negatively associated attributes of catheters including discomfort, infection risk, and fall risk. Same day void trial should be offered to motivated patients at capable facilities, where possible.

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Table 1: Patient characteristics and outcomes, univariate analysis

Values are presented in mean (standard deviation) unless otherwise specified.

Variable	Successful Same Day Catheter Removal n=100	Failed Same Day Catheter Removal n=14	*P*-value
Age, y	68.5 (8.2)	73.0 (10.8)	0.925
BMI, kg/m^2	28.2 (4.44)	27.5 (3.93)	0.313
ASA 3 or 4	33.8%	81.8%	**0.004**
ASA 1 or 2	66.2%	18.2%	**0.002**
Presence of bladder stone	7.1%	14.2%	0.309
Total energy used, KJ	134.6 (59.5)	129.8 (53.6)	0.380
Enucleation time, min	50.6 (21.6)	45.1 (18.6)	0.162
Morcellation time, min	7.1 (6.0)	7.7 (7.3)	0.622
Prostate specimen weight, g	64.12 (44.4)	57.9 (36.8)	0.287
PSA, ng/mL	6.6 (4.3)	4.1 (2.2)	**0.019**
Catheter dependency	67%	50%	0.221
Alpha blocker use	74.2%	83.3%	0.490
5-alpha reductase inhibitor use	19.6%	30.8%	0.353
Anticoagulation or antiplatelet therapy	8.7%	8.3%	0.967
Pre-op AUA symptom score	18.7 (6.5)	20.8 (9.0)	0.658

Prior BPH surgery	11.3%	0%	0.201
Prostate cancer found on pathology	14.0%	0%	0.371

Table 2: Multivariate analysis via binary logistic regression

Variable	*P*-value, 95% CI
Age, y	0.425, 0.821-1.087
Specimen weight, g	0.126, 0.978-1.003
PSA, ng/dL	0.077, 0.972-1.727
ASA 1-2 or 3-4	0.100, 0.021-1.399

HoLEP - Holmium laser enucleation of the prostate

BPH - benign prostatic hyperplasia

CBI - continuous bladder irrigation

POD1 - first postoperative day

PACU - post anesthesia care unit

SD - standard deviations

AP/AC - antiplatelet/anticoagulant