

Title: Same Day Discharge Following Holmium Laser Enucleation in Patients Assessed to have Large Gland Prostates (≥ 175 mL)

Running Title: Same Day Discharge for Large Gland HoLEP

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Introduction:

Holmium laser enucleation of the prostate (HoLEP) is a highly effective and durable minimally invasive surgery for benign prostatic hyperplasia¹⁻². Alternative treatments (open or robotic assisted simple prostatectomy(RASP)) for large glands ($\geq 175\text{mL}$) are associated with prolonged length of stay (LOS) and postoperative catheterization³. Despite technology (robotic platform) and technique advances (retropubic, transvesical, single-port) in the management of large gland simple prostatectomy, the majority remain overnight with average LOS ranging 1.05-5 days and catheterization 3.5-8.1 days⁴⁻⁷.

The safety of transitioning HoLEP management to day-surgery was first published in 2003 by Larner *et al.* in 38 men with gland size $< 60\text{mL}$ ⁸. Since then, a small number of studies have examined same day discharge in selective patients, typically with smaller glands⁹⁻¹⁴. Abdul-Muhsin H. *et al.* (2020) attempted to find objective measures to predict safe same day discharge cases, however the major barrier identified was degree of hematuria. At our center, advances in pulsed modulated laser technology for improved hemostasis, combined with surgical technique optimization within a health system familiar with perioperative HoLEP care have demonstrated early evidence for same day discharge and same day trial of void (TOV)^(9, 15). Locally, we transition towards same day discharge consideration for initially select HoLEP cases in 2019 with provider education and care pathway handouts provided to our post-anesthetic care units (PACU). As our center optimized our care pathway and gained confidence in our outcomes, we expanded patient eligibility for same day discharge. Anecdotally, with the use of the Moses 2.0 optimized for BPH we have minimal hematuria concerns immediately postoperatively, irrespective of gland size. We look to examine contemporary same day discharge outcomes specifically in patients assessed to have large glands defined as $\geq 175\text{mL}$.

Materials & Methods:

After Institutional Review Board (IRB) approval, we queried our Electronic Medical Record (EMR) and retrospective clinical registry for specifically large gland prostates ($\geq 175\text{mL}$) that underwent HoLEP with consideration for same day discharge from December 10, 2019 to September 29, 2020. Prior to the study period, our three endourologists adopted a practice of considering all HoLEP patients for same day discharge

and same day catheter removal⁹. Preoperative reasons to exclude same day discharge consideration included lack of a caregiver or significant comorbidities (including American Society of Anesthesiology (ASA) ≥ 4 , inability to hold therapeutic anticoagulation, or dual antiplatelet therapy)¹⁶.

Per our revised local practice, the entire surgical care team and PACU received education and are familiar with our post-HoLEP procedures including avoidance/limiting post-induction narcotics⁹. It is important to acknowledge that we have over 20 years of HoLEP care at our center which results in a system familiar with the perioperative course. Our HoLEP technique has evolved over the last decade with the investigation and adoption of high-power laser technology (550um D/F/L fiber with Moses 2.0 optimized for BPH – Lumenis Ltd., Yokneam, Israel). Bi- or trilobar enucleation depends on the presence or absence of a median lobe with a bottom-up technique. Laser settings for enucleation include 2J & 40-60Hz on primary and 1J & 20Hz on secondary foot-pedal for intermittent vessel hemostasis. We previously showed Moses 2.0 improves hemostasis versus conventional techniques¹⁵. We adapted our previously published technique by moving away from predominately peeling (blunt scope dissection) toward an increased use of non-contact lasering with Moses facilitated bubble dissection. The Piranha Wolf morcellator was used in all cases.

Postoperatively, 3L continuous bladder irrigation(CBI) using normal saline (NS) solution was ran via 20-22F 3-way foley catheter with 40-60mL sterile water in the balloon. At the completion of 3L, the PACU team clamps CBI and assess hematuria. If the urine output (to the tubing) was ketchup colored (by visual hematuria scale^{9,14}) or blood clots block the tubing, an additional 3L bag was run full speed. If the urine was not ketchup colored upon initial clamping, then the nursing teams monitored outputs over 30 minutes with ambulating. If the urine remained less than ketchup colored, and the patient met day surgery discharge criteria then they were sent home from PACU. If the urine remained ketchup colored after a 2nd 3L NS bag, the urology service assessed the patient. Although we implemented the use of an objective visual scale for hematuria there remains a subjective component to evaluating these patients postoperatively. For any borderline

cases, the urology team was contacted at which point the decision for admission versus discharge was made by the surgeons.

All patients who failed same day TOV receive 18F Coude-tip catheter overnight with a repeat TOV on postoperative day 1 (POD1). Patients admitted to hospital had a TOV on POD1 at 06:00. All HoLEP patients receive PROs surveys (AUASS, BPH Index, MISI, SHIM, GAD-7, EjD) preoperative and prior to their 3-month follow up. We have a preference for in person 3-month follow up appointments, however, due to the COVID-19 pandemic some of our patient follow ups were conducted via virtual visit.

Baseline demographics, medical history, past urological surgeries, intraoperative and postoperative variables along with follow up and Clavien-Dindo complications were acquired. All comorbid patients or those on dual antiplatelet therapy or therapeutic anticoagulation received medical clearance with medication recommendations perioperatively. None of our patients required therapeutic anticoagulation bridging. Our primary outcomes of interest were hospital LOS (recorded in minutes from surgical procedure conclusion to patient discharge) and postoperative duration of catheterization (recorded in minutes from surgical procedure conclusion to the TOV).

Statistical analysis was performed using IBM SPSS software (version 25, Armonk, NY). Continuous variables were expressed as mean and range while proportions were used for categorical variables. Statistical analysis included two-tailed homoscedastic & heteroscedastic T-Tests as well as Chi-Squared or Fishers Exact (when individual group sizes <10) with significance set at $p < 0.05$.

Results:

There were 55 patients with preoperative prostate size ≥ 175 mL (39 CT, 12 MRI, 4 TRUS) scheduled for HoLEP between December 10, 2019 and September 29, 2020. There were 45/55 (82%) patients scheduled for same day discharge, while 10 patients were scheduled for overnight admission based on comorbidities. Patient and perioperative demographics is outlined in Table 1. Of patients undergoing concurrent stone surgeries, 2/8 (25%) had an unplanned hospital admission (versus 5/37 (14%) unplanned admission for HoLEP without concurrent stone surgery, $p=0.59$). 5 (9%) patients had prostate surgery

prior to their HoLEP consult (2 transurethral resection of the prostate (TURP), 2 Greenlight laser vaporization of the prostate (GLVP), 1 Rezum) with one patient undergoing 2 separate GLVP prior to consultation. Of the 10 patients planned for admission, 2(20%) utilized antiplatelet or anticoagulation medications beyond ASA 81mg daily (1 Clopidogrel, 1 Rivaroxaban). Of the 45 patients planned for same day discharge, 8(18%) utilized antiplatelet or anticoagulation beyond ASA 81mg daily (1 ASA 325mg, 1 Clopidogrel, 2 Coumadin, 2 Apixaban, 2 Rivaroxaban).

Mean preop prostate size was 229.9mL (range 175-535mL) obtained by CT, MRI or TRUS imaging modalities (Table 2). Mean rate of tissue enucleation was 2.34g/min (range 1.11-4.55g/min), and morcellation was 8.56g/min (range 3.41-22.5g/min). 1 patient required a perineal urethrostomy (preoperative prostate size 535mL) to reach the prostate.

A comparison of preoperative and 3-month postoperative follow up investigations and patient reported outcomes (PROs) is outlined in Table 3. Overall, mean preop PSA was 8.58ng/mL (range 2.70-15.66ng/mL), AUA Symptom Score 22.3 (range 2-35), and Qmax 8.8mL/s (range 2.7-19.5mL/s). At 3 months postop follow up the mean AUASS improved to 6.7(2-12), PSA 0.87ng/mL (0.082-3.25ng/mL) and Qmax 20.4mL/s (10.9-29.9mL/s) (all $p<0.05$).

All coming same day discharge rate was 70% (38/55). Of patients planned for same day discharge 38/45 (84%) were successful. Average LOS for all large gland patients (N=55) was 11.8h with catheterization of 21.2h (Figure 1). Looking specifically at patients planned for same day discharge (N=45), average LOS and catheter duration was 8.8h and 17.0h while LOS and catheter duration for patients planned for admission (N=10) was 25.7h and 39.4h, respectively (LOS $p=0.0052$. Catheterization $p=0.23$) (Figure 2). The average LOS and catheterization for patients actually discharge on the same day as their HoLEP (N=38) was 2.7h and 16.7h, respectively.

Reasons for unplanned admission in our 7 patients included 4 genitourinary (GU) reasons (postop hematuria) and 3 non-GU system reasons (1 – atrial fibrillation requiring

cardiology, 1 – bradycardia requiring cardiology, 1 – vocal cord mass on intubation requiring intraoperative laryngoscopy/biopsy and postop observation).

Postoperatively, unplanned medication encounters occurred in 3/55 (5.5%) patients prior to their 3-month follow up (2 Emergency Department, 1 Urology Office). The 2 patients presenting to the ED after discharge had infectious complications (1 UTI – Clavien-Dindo II, 1 Urosepsis with AKI requiring temporary (<14day) dialysis – Clavien-Dindo IVa). Overall complication rate was 13/55 (23.6%) with only 1/55 patient having a Clavien-Dindo grade 3 or higher complication (Grade: I(5), II(7), III(0), IV(1), V(0)). The single IVa complication was a 74year old man with preop urinary retention and indwelling catheter who underwent same day discharge and TOV with success (PVR = 20mL) followed by increased hematuria/clots and fever starting >24hours postoperatively. He subsequently presented to ED with clot retention, fever and urosepsis (Sequential Organ Failure Assessment (SOFA) score ≥ 2) leading to a transient AKI requiring short term dialysis (<14days). Following antibiotic therapy his 3-month follow up renal function was at baseline with complete emptying. No patients had bladder neck contractures or required subsequent genitourinary tract surgery.

Discussion:

We report the safety and efficacy of same day discharge considerations in specifically large gland prostates undergoing HoLEP. The overall average LOS was 11.8h with catheter duration of 21.2h. When compared to large gland outcomes at our center in 2010, our current LOS represents a 220% reduction¹⁷. For all large gland patients, we achieved >70% rate of same day discharge with a 3.6% re-presentation to ED and <2% readmission rate prior to scheduled follow up. For patients specifically planned for same day discharge our success rate was 84%. Transitioning to same day discharge consideration and same day TOV has not compromised clinical outcomes. Compared to the current literature, we included a wider range of patients who were eligible for same day discharge and provide evidence to support the inclusion of large glands.

As one of the recurring barriers for same day discharge in large gland HoLEPs is the immediate postoperative degree of hematuria, the utilization of Moses 2.0 technology has proven valuable in its improved hemostasis along with adopting a surgical technique that

uses less blunt dissection as well as implementing a system for monitoring patient's eligibility for discharge postoperatively¹⁴⁻¹⁵. As technologies and techniques have improved, morcellation efficiency has also improved when comparing to our own centers rates reported 10 years ago¹⁷. We feel that transitioning to the Wolf Piranha morcellator as well as the use of Lumenis Moses 2.0 and subsequent improved hemostatic surgical technique all play a factor in allowing continuous morcellation due to improved visualization.

There is minimal difference in length of catheterization compared to large gland HoLEPs performed at our center 10 years ago or between sub-cohorts in our study¹⁷. This catheter duration (<24h) remains significantly shorter than either robotic or open simple prostatectomy for large gland BPH management⁴⁻⁷. Factors contributing to the unchanged catheter duration include access to our urology clinic for same day TOV occurring later in the day or provider comfort. Ultimately, we believe that if having the TOV successfully passed the following morning allows for >70% of large gland HoLEPs to be safely performed as same day discharge then this is a positive outcome in the setting of transitioning large glands to same day discharge.

Examining the unplanned admission cohort (Figure 2) is interesting as the duration of their catheterization is not different than the entire cohort, planned same day cohort or actually discharged same day cohort. This finding points towards the non-urologic etiology of unplanned admissions and shows that ongoing hematuria, CBI or failed TOV is likely not contributing to their longer LOS (>24h) as most had successful TOVs in the morning of POD1.

In our study 14.5% of patients had concurrent urolithiasis intervention without a significant difference in LOS, catheter duration, or unplanned admission. Our results support the previous few studies that examined same day discharge feasibility in patients that utilize antiplatelet/anticoagulation medications^{12,14}. Changing our operative technique to improve hemostasis is reflected in our lower rate of unplanned admissions for hematuria (6.7%) compared to other literature for same day discharge (31.9%)¹⁴. Our findings that large gland size itself is not a contraindication to same day discharge is supported by Abdul-Muhsin H *et al.* who showed successful same day discharge was associated with larger glands (88.4 vs 69.0mL p=0.033), however primarily due to degree

of postoperative hematuria they concluded that it would be safer to consider admitting these patients¹⁴.

Only 3.6% presented to the ED postoperatively with 1 requiring readmission. This is lower than the current literature on same day discharge post-HoLEP which reports a range of ED presentation 28-36.7 and 3.4-28.9% readmission^{8,10-12,14}. We believe this difference is a combination of the improved operative hemostasis, thorough discussion with patients regarding healing expectations and a strong clinic support staff who have worked within a system familiar with perioperative HoLEP care for over 20 years at our center. It is important to acknowledge one patient had a grade IVa complication and was fortunate to return to his baseline. It is unclear if his clinical course would have changed by admitting overnight or POD1 TOV, as the onset of hematuria/clots and fever occurred >24hours after surgery. Even for the 10 comorbid high-risk patients planned for admission, half were discharged within 24hours and may have had the same resultant post-discharge complication. Despite ongoing efforts to minimize infectious complications with preop urine cultures and targeted preop antibiotics we consent all patients that we are unable to completely remove infectious complications from surgical intervention of the urinary tract.

There are few specific situations (ex. bladder diverticula) where RASP may be advantageous; however, HoLEP has shorter operative time, less transfusions, catheterization and LOS¹⁸⁻¹⁹. Transitioning to same day discharge and TOV further adds to the advantages of HoLEP. GLVP for prostates >100mL show increased conversion to electrocautery TURP (7.3-16%) for hemostasis along with increased retreatment (1.2-16% at 12-36months)²⁰⁻²². Similarly, novel use of transurethral bipolar plasmakinetic enucleation/resection is associated with longer LOS and catheterization versus HoLEP²²⁻²³. Further prospective randomized studies are required to identify the role of alternative treatments compared to safe and durable large gland HoLEP outcomes.

A limitation is the generalizability of our surgical outcomes and implementation of a same day discharge protocol within this large gland prostate cohort, particularly for low volume centers or surgeons starting to perform HoLEP. The challenge of the HoLEP learning curve have been well documented and the effect of surgeon expertise on successful management in these large gland prostates and ability to safely transition to

same day discharge is very important²⁴. Also, as our high-volume center has provided HoLEP for over 20 years our patients interact with a system (operative team, nursing, PACU, anesthesia) that is familiar with the typical perioperative course.

Conclusions:

We report the first outcomes of same day discharge for HoLEP in specifically large glands (≥ 175 mL). A combination of technologic advances and technique optimization at our high-volume center have allowed for a safe adoption of same day discharge, providing additional advantages over alternative large gland treatments.

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Abbreviations:

ASA = American Society of Anesthesiology

AUASS = American Urological Association Symptom Score

BPH = Benign Prostatic Hyperplasia

CT = Computerized Tomography

EjD = Male Sexual Health Questionnaire Ejaculatory Function Short Form

GAD-7 = Generalized Anxiety Disorder-7

HoLEP = Holmium Laser Enucleation of the Prostate

MISI = Michigan Incontinence Symptoms Index

MRI = Magnetic Resonance Imaging

N = Number of Patients

PSA = Prostate Specific Antigen

PVR = Post Void Residual

Qavg = Average Flow Rate

Qmax = Maximum Flow Rate

QOL = Quality of Life

SHIM = Sexual Health Inventory for Men

TRUS = Transrectal Ultrasound

Table 1: Patient and Perioperative Demographics for All Holmium Laser Enucleation of the Prostate in Glands $\geq 175\text{mL}$ Following Transition to Same Day Discharge Consideration

Variable	Mean	Range
Age (years)	73.8	56-91
ASA Score	2.6	2-4
Enucleation time (min)	72.5	23-133
Morcellation time (min)	23.3	2-113
Total procedure time including ancillary procedures (min)	121.6	37-243
Energy Used (kJ)	190.09	65.57-369.57
Intraoperative pathology specimen weight (g)	165.1	45-385
	N	%
Moses 2.0	39	70.9%
Perineal Urethrostomy	1	1.8%
Concurrent Urolithiasis Surgery	8	14.5%
- Unilateral Ureteroscopy	2	3.6%
- Bilateral Ureteroscopy	2	3.6%
- Cystolitholopaxy	4	7.3%
Urinary Retention at Time of HoLEP	36	65.5%
- Indwelling Urethral Catheter	32	58.2
- Clean Intermittent Catheterization	4	7.3%
History of Urinary Retention	43	78.2%

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Prostate Cancer Detected on Pathology	1	1.8%
Gleason Grade Group I	1	1.8%

ASA = American Society of Anesthesiology Score; N = number of patients; HoLEP = Holmium Laser Enucleation of the Prostate.

Table 2: Comparison of Preoperative Prostate Size Estimation (CT, MRI or TRUS) to Intraoperative Specimen and Postoperative Pathologic Dry Weight

Preoperative Prostate Size Imaging Modality	Number of Patients	Baseline Preoperative Assessment (mL) Mean/(Range)	Intraoperative Specimen Obtained (g) Mean/(Range)	Pathologic Dry Weight (g) Mean/(Range)
All Modalities	55	230 (175-535)	165 (45-385)	147 (45-305)
CT	39	227 (175-431)	162 (45-385)	145 (45-274)
MRI	12	218 (175-280)	160 (95-230)	137 (54-230)
TRUS	4	290 (175-535)	214 (175-308)	185 (125-305)

CT = Computerized Tomography; MRI = Magnetic Resonance Imaging; TRUS = Transrectal Ultrasound

Table 3: Comparison of preoperative Serum PSA, Validated Symptom Scores (AUASS, QOL, BPH Index, SHIM, MISI, GAD-7, EjD), Post Void Residuals and Urinary Flow to 3 Month Follow Up

Variable	Baseline	3 months	% Change	P Value
	Preoperative Mean/(Range)	Postoperative Mean/(Range)		
Serum PSA, ng/mL	8.58 (2.70-15.66)	0.87 (0.082-3.25)	89.9	<0.001
Serum Hemoglobin, g/dL	13.45 (8.3-16.9)	12.32 (7.0-15.5)	8.4	0.10
Serum Creatinine, umol/L	1.27 (0.76-4.57)	0.99 (0.70-1.39)	22.0	0.014
AUA Symptom Score	22.3 (2-35)	6.7 (2-12)	70.0	<0.001
QOL Score	4.9 (2-6)	1.3 (0-2)	73.5	<0.001
BPH Index	7.3 (1-12)	2.5 (0-7)	65.8	<0.001
MISI	6.9 (0-19)	6.0 (0-16)	13.0	0.63
SHIM	10.1 (0-25)	13.8 (1-25)	36.6	0.26
GAD-7	2.9 (0-14)	1.2 (0-5)	58.6	0.14
EjD	7.7 (0-20)	6.7 (0-16)	13.0	0.65
Post Void Residual (mL)	172 (37-600)	25 (0-109)	85.5	0.0033
Qmax (mL/s)	8.8 (2.7-19.5)	20.4 (10.9-29.9)	131.1	0.032
Qavg (mL/s)	4.3 (1.4-7.3)	15.5 (10.9-20.1)	260.5	0.045

PSA = Prostate Specific Antigen; AUASS = American Urological Association Symptom Score; BPH = Benign Prostatic Hyperplasia; MISI = ; SHIM = Sexual Health Inventory for Men ;

GAD-7 = Generalized Anxiety Disorder-7; EjD = ; Qmax = Peak urinary flow; Qavg = Average urinary flow.

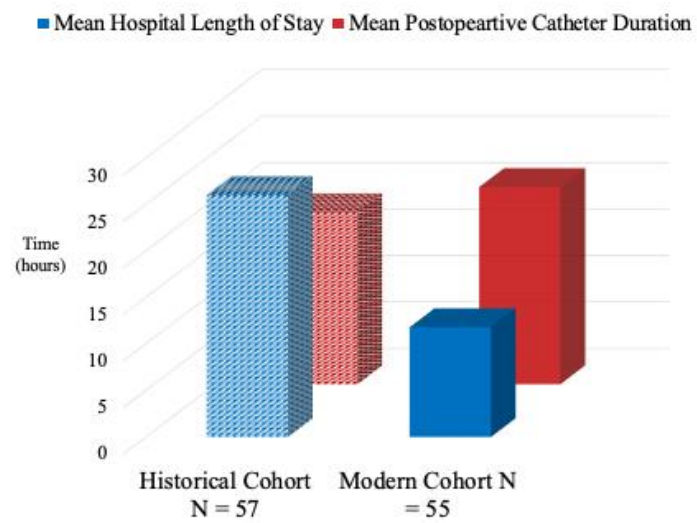


Figure 1: Comparison of Mean Length of Stay and Postoperative Catheter Duration for Patients Assessed to have Large Gland Prostates ($\geq 175\text{mL}$) Undergoing Holmium Laser Enucleation of the Prostate between Historical Cohort¹⁷ (Krambeck *et al.* 2010) and Modern Cohort Following Adoption of Same Day Discharge Consideration.

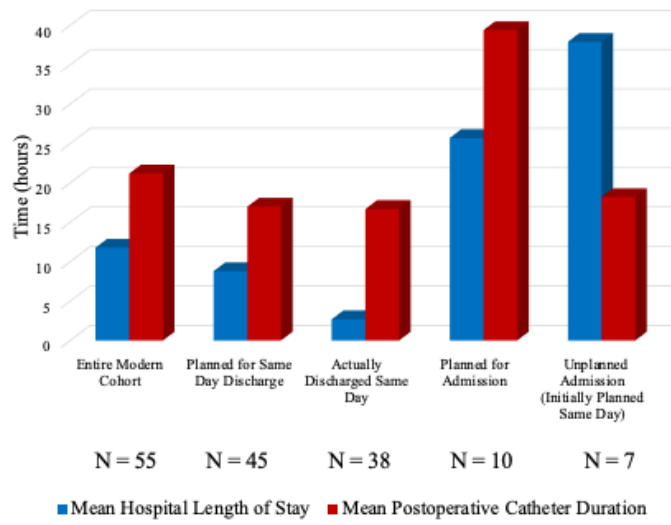


Figure 2: Length of Stay and Postoperative Catheter Duration for Patients Assessed to have Large Gland Prostates ($\geq 175\text{mL}$) Undergoing HoLEP with Consideration for Same Day Discharge Broken Down by Clinical Course