Routine use of loop diuretics during morcellation does not improve holmium laser enucleation of the prostate outcomes: A prospective, double-blind, randomized controlled trial

Nick S. Dean[1,2], Perry J. Xu[1], Kyle Tsai[1], Alyssa McDonald[1], Allaa Fadl-Alla[1], Jenny N. Guo[1], Amy E. Krambeck[1]
[1]Department of Urology, Northwestern University, Chicago, IL; [2]Division of Urology, Department of Surgery, University of Alberta, Edmonton, AB, Canada

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Corresponding author: Dr. Nicholas S. Dean**,** Division of Urology, Department of Surgery, University of Alberta, Edmonton, AB, Canada; ndean@ualberta.ca

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ABSTRACT

KEY MESSAGES

- Routine administration of loop diuretics (furosemide 20mg IV) during HoLEP does not appear to improve outcomes (same-day trial of void or discharge) or decrease rates of complication
- It is our opinion that patients with capsular perforation (visualization of peri-prostatic fat), undermining of the bladder neck, and prolonged case duration (>120 minutes) can be safely offered 20 mg of IV furosemide to decrease the likelihood of clinical fluid overload.

Introduction: Loop diuretics have been administered historically during morcellation to promote urine production postoperatively and to minimize the impact of fluid absorption during holmium laser enucleation of the prostate (HoLEP) procedures. Despite the widespread use of furosemide, no prior study has examined the effects of this medication on postoperative outcomes, including same-day discharge (SDD), same-day trial of void (SDTOV), re-admission rates, or fluid overload. We sought to compare outcomes of HoLEP with and without the use of an intraoperative furosemide.

Methods: From January 2023 to June 2023, we prospectively randomized 138 patients undergoing HoLEP 1:1 to receive or not receive 20 mg of IV furosemide during morcellation (STU00217795). Our primary outcome was to compare rates of SDD between those who receive

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furosemide at time of HoLEP vs. controls. Secondary outcomes included intraoperative efficiencies and postoperative clinical outcomes.
Results: There was no difference in demographics and prostate features between patients randomized to furosemide (n=69) vs. controls (n=69). Patients receiving furosemide were less likely to undergo a SDTOV attempt (furosemide: 81.6% vs. control: 97.0%, p=0.005) and to achieve SDD (furosemide: 63.6% vs. control: 81.8%, p=0.019). There was no difference between the cohorts in the rates of failed SDTOV, mean length of stay (LOS), or mean catheterization time. No patients in either group experienced symptomatic postoperative fluid overload.
Conclusions: IV furosemide administered during HoLEP does not improve rates of SDD, SDTOV, LOS, duration of catheterization, or adverse event rates. Routine intraoperative furosemide administration does not appear to have a role within a contemporary HoLEP treatment pathway.

INTRODUCTION

Holmium laser enucleation of the prostate (HoLEP) is a benign prostatic hyperplasia (BPH) surgical treatment option recommended by North American and European BPH guidelines[1-3] Since its introduction in the 1990's by Drs. Fraundorfer and Gilling, HoLEP has become increasingly utilized due to its durability, effectiveness, and versatility.[4] When comparing HoLEP to the prior gold standard BPH surgical treatment option (transurethral resection of the prostate, TURP), HoLEP is associated with a lower risk of blood transfusion, re-treatment, and irrigation fluid absorption.[5-8]

Irrigation fluid absorption during a transurethral prostate procedure has the potential for devastating consequences.[9] TURP syndrome is a systemic condition characterized by an excessive absorption of fluid irrigation during prostate resection, leading to profound hyponatremia.[9] Although the rates of TURP syndrome have decreased with the use of isotonic irrigation fluids, patients continue to be at risk of irrigation fluid absorption during transurethral prostate surgery leading to cardiac insufficiency, lung edema, or cardiac arrest.[8] Rapid isotonic irrigation fluid absorption characteristically causes hyperchloremic metabolic acidosis, rather than hyponatremia.[8] Fortunately, the risk of irrigation fluid absorption during HoLEP is lower than that with TURP.[6,8] Loop diuretics have been historically administered during the morcellation phase of HoLEP to encourage diuresis in an attempt to negate volume expansion from irrigation fluid absorption and prevent/minimize associated clinical sequelae.[10-14] Despite a low absolute risk of clinical fluid overload following HoLEP, many surgeons continue to routinely administer prophylactic IV furosemide during morcellation in the contemporary HoLEP era with no evidence to support its use.[10-14]

In the last five years, there have been several advancements that have propelled the growth of HoLEP efficiency and utilization.[15,16] Perhaps the most important of these

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improvements has been advances in laser technology leading to improved operative efficiency and hemostasis.[15-17] Improvements in procedural hemostasis have allowed urologists to offer HoLEP as a same-day procedure with a same-day trial of void (SDTOV).[18-20] Despite optimization of peri-operative and post-operative pathways, rates of failed same-day discharge (SDD) and SDTOV range from 10-40%.[18-21] There has been a growing interest in examining predictors of failed SDD and SDTOV, to better select ambulatory HoLEP patient candidates and minimize catheter re-insertions and unplanned overnight admissions.[22] Furthermore, there has been a growing interest in examining whether medications (tranexamic acid), or instrument modifications (24French (F) vs. 28F laser resectoscope), have an effect on rates of successful SDD and SDTOV in an ambulatory HoLEP pathway.[21,23] Gross hematuria has been previously identified as the greatest predictor for failed SDD in ambulatory HoLEP patients.[24] Theoretically, intra-operative administration of furosemide during HoLEP will increase post-operative urinary production and dilute gross hematuria during a same-day voiding trial. The effect of a loop diuretic on rates of SDD and SDTOV are currently unknown.

With our study we aimed to investigate if routine diuretic administration during morcellation improves rates of SDD and SDTOV for ambulatory HoLEP patients. Furthermore, we aimed to assess if routine furosemide reduced rates of clinical complications such as fluid overload in the contemporary HoLEP era.

METHODS

This prospective double-blind, parallel design, 1:1 randomized controlled trial was performed to compare ambulatory HoLEP patient outcomes with and without the administration of intra-operative IV furosemide. Institutional review board (IRB) approval was attained (STU00217795) and the protocol registered on Clinicaltrials.gov (NCT05620784). All procedures were completed at a single academic center by a high-volume HoLEP surgeon with urology resident and endourology fellow learners using MOSES 2.0 pulse-modulated holmium laser technology and a Wolf Piranha morcellator. The primary surgeon completed each procedure with a 28F laser resectoscope, utilizing an early apical release, and a two or three-lobe enucleation technique dependent on prostate anatomy. This study was performed without external funding. Patient data was secured in a REDcap database.

Adult males (≥18 and ≤89 years old) that underwent HoLEP between January 2023 to May 2023 were candidates for enrollment. Patients with severe chronic kidney disease (eGFR by CKD-EPI <30mL/min/1.73m^2), liver failure, loop diuretic allergies or hypersensitivity, anticipated need for perineal urethrostomy (penile prosthesis), or concurrent procedures (ureteroscopy, percutaneous nephrolithotomy (PCNL), or non-urologic surgery) were excluded from the study. Patients planned for overnight admission pre-operatively were also excluded from the study.

After an informed consent process, patients were randomized 1:1 to receive (treatment) or not receive (control) 20mg of IV furosemide. Block randomization was performed by our research coordinators (AM, AF) utilizing REDcap. Patients, the surgical team, and the post-

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operative nursing teams were blinded to the randomization allocation. Only our research coordinators, the operating room nurses, and anesthesia teams were aware of whether the patient received or did not receive 20mg of IV furosemide during morcellation.

The primary outcomes included the rate of successful SDD and SDTOV between the treatment arm and the HoLEP controls. Secondary outcomes included intra-operative efficiencies, post-operative clinical outcomes, and rates of adverse events with a focus on complications associated with irrigation fluid overload. Post-operative labs were not completed routinely within our HoLEP pathway. All patients were enrolled in our SDTOV and SDD HoLEP pathway. All patients had a 22 Fr three-way foley catheter inserted at the end of the HoLEP procedure. All patients received continuous bladder irrigation (CBI) with a single five-liter bag of normal saline at the end of the HoLEP. Patients were assessed by the urology team after the completion of CBI for a SDTOV. If there were concerns regarding the degree of gross hematuria, CBI was restarted and a TOV was delayed overnight at the surgical team's discretion. Patients that failed their post-operative day 0 TOV had a foley catheter reinserted and were kept overnight for observation. Patients that had an asymptomatic elevated post-void residuals (PVRs) after SDTOV were admitted for observation for an extended voiding trial overnight. Length of stay (hours) was calculated from the time of HoLEP completion to the time of discharge from hospital. Patients were followed with a standardized telephone call at one week and an in-person follow up appointment at 3 months post-operatively.

Analysis was performed in an intention-to-treat protocol (ITT), however patients that were no longer candidates for SDD after HoLEP (incidental urethral stricture dilation requiring indwelling foley, incidental bladder tumor resection requiring indwelling foley, etc…) were excluded from the primary outcome (SDD) analysis. The study design was transitioned from a non-inferiority study to a superiority trial in consultation with senior colleagues after trial registry on clinicaltrials.gov, but prior to patient enrollment. Two-sided t-tests were performed to compare the means of continuous variables. A p-value of less than 0.05 was considered statistically significant. Data analysis was performed using SPSS (IBM SPSS Statistics for Windows v.29). Our sample size calculation was based off a SDD rate of 60%, which has been previously defined as the mean rate of SDD after ambulatory HoLEP.[21] With a power of 90% and an alpha of 0.5%, the number of patients required was 66 patients per group to detect a 25% difference in SDD. Assuming a loss to follow-up rate of 5%, 138 patients in total were recruited. Patients that were unable to reached at our standardized one-week telephone follow-up were contacted by our research coordinators.

RESULTS

Patient characteristics

Between January 2023 and June 2023, 138 patients were enrolled and underwent randomization (Furosemide n=69 (50%), Control n=69 (50%). (Figure 1). There were no statistically significant differences between the control (C) and treatment arms (F) in regards to pre-operative patient

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characteristics including age (F: 71.8 years vs. C: 69.3 years, p=0.060), American Society of Anesthesiologists score (ASA) (F: 2.5 vs. C: 2.4, p=0.115), pre-op prostate volume (F: 130.5cm^3 vs. 120.3cm^3, p=0.458), rates of pre-op indwelling foleys or intermittent catheterization (IC) (F: 18.8% vs. C: 25.0%, p=0.413), anticoagulation (F: 13% vs. C: 13%, p=1.000), or pre-op post void residual volumes (PVR) (F: 128.5mL vs. C: 121.3mL, p=0.889). (Table 1)

Perioperative findings: LOS, SDD, and SDTOV

After completion of HoLEP, 95.7% (n=66) of patients in both the control group and the treatment group were candidates for SDD and SDTOV. Three of the HoLEP procedures were completed too late in the operative day to practically allow for a post-operative same-day voiding trial. The other three patients were not permitted to undergo their planned same-day voiding trials due to a spinal anesthetic, an incidental bladder tumor requiring resection, and an incidental urethral stricture requiring urethral dilation. There was no difference in peri-operative outcomes including mean specimen weight (F: 84.3grams (g) vs. C: 84.5g, p=0.988), procedural times (defined as time from insertion of resectoscope until the time of insertion of foley catheter at procedural completion) (F: 62.9 mins vs. C: 58.1 mins, p=0.650), or rates of intra-operative complications (F: 0% vs. C: 0%, p=1.000). (Table 1)

Postoperative outcomes

Patients that received furosemide were less likely to undergo a SDTOV attempt after HoLEP (F: 81.6% vs. C: 97.0%, p=0.005). There was no difference in rates of failed SDTOV between the two groups (F: 16.0% vs. C: 12.5%, p=0.579). Patients that received furosemide were less likely be discharged on the same day of their HoLEP (F: 63.6% vs. C: 81.8%, p=0.019), however there was no difference in length of stay (LOS). Mean follow-up was 2.5 months in the furosemide cohort and 2.7 months in the control cohort (p=0.258). There was no difference between groups in post-operative catheter duration, 30-day complications, ER-rates, or re-admissions rates (all p>0.05). (Table 1) There was a single >II CD grade complication within the entire cohort. This complication involved a patient randomized to the furosemide arm that went into urinary retention after SDTOV on post-operative day zero. The patient required an operating room procedure for a foley catheter insertion after a failed attempt at a bedside flexible cystoscopy-assisted catheter placement by the overnight resident team.

Subgroup analysis: >100cm^3 prostates

Overall, 73 patients within our study had a pre-operative prostate volume greater than 100cm^3 (F: n=35, C: n=38) with volumes ranging from 100cm^3 to 444cm^3. There was no statistically significant improvement in SDD, successful SDTOV, LOS, catheter duration, fluid overload/TURP syndrome, or overall complication rates with the addition of furosemide to our ambulatory HoLEP pathway for prostates >100cm^3. More patients in the control cohort were able to undergo an attempt at SDTOV after HoLEP (F: 71.4% vs. C: 92.1%, p=0.021). (Supplementary Table 1)

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Comments

Furosemide use during morcellation has become common practice within North America with the dissemination of HoLEP to theoretically combat concerns regarding fluid absorption and fluid overload during prolonged procedures and prolonged morcellations. Prior to this study, we have administered 20mg of IV furosemide routinely during morcellation for all HoLEP procedures. With improvements in HoLEP procedural efficiency secondary to contemporary techniques and advancements in laser and morcellator technology, we aimed to see if furosemide can be removed from our ambulatory HoLEP pathway with a double-blind randomized controlled trial.

Persistent gross hematuria has been identified as one of the most common causes for failure of ambulatory SDTOV HoLEP.[24] We originally hypothesized that furosemide would dilute post-operative hematuria and benefit rates of SDD and SDTOV. We did not identify any SDTOV or SDD advantage to furosemide administration. Conversely, patients that received furosemide were found to have significantly lower rates of both SDTOV (81.6% vs. 97.0%, p=0.005) and SDD (63.6% vs. 81.8%, p=0.019). We have some difficulty believing that furosemide administration would negatively impact these patient outcomes, but the results do provide strong evidence that furosemide should not be given to ambulatory HoLEP patients in an attempt to improve rates of SDTOV or SDD. Furthermore, we did not identify any benefit to LOS, catheterization duration, or rates of 30-day re-admissions, ER presentations, or complications with the administration of furosemide.

The main motivation for the propagation of furosemide administration during HoLEP has been to theoretically maximize safety, by attempting to diurese patients to limit net fluid gain. Within our trial, we did not identify any episodes of clinical fluid overload in either cohort (0% vs. 0%, p=1.000). Fortunately, we did not identify any adverse patient reactions associated with furosemide administration either. Procedural duration has been previously identified as a risk factor for irrigation fluid absorption during transurethral BPH surgery.[8] The average procedural duration within our study was 60.5 minutes with 1.4 grams of prostate adenoma removed/minute (g/min). Only three procedures (2.2%, n=3/138) in our study had a surgical duration of longer than three hours (207min, 211min, and 219min) with 368g, 190g, and 338g of adenoma removed, respectively. It remains unclear whether a greater number of episodes of post-operative fluid overload would be identified if pre-operative prostate volumes were larger, procedural durations were more prolonged, or if procedural efficiency was greatly reduced. Patients within this cohort were not excluded based on pre-operative prostate volume, and therefore the study population demographics and pre-operative prostate characteristics are representative of patients undergoing treatment at high-volume HoLEP referral centers in the United States of America.

The findings of our study provide support against the routine administration of furosemide during morcellation for ambulatory HoLEP candidates, however it remains unclear if there are special situations in which patients may benefit. The absolute risk of developing clinical fluid overload, TUR syndrome, or electrolyte abnormalities after Laser enucleation of the

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prostate (LEP) has not been well defined, but in small studies the overall risk is approximately 0%.[6,8,10,11] Procedural duration, resection depth, prolonged procedural durations, sheath size, surgical method, intravesical pressure, and capsular perforations have been identified as risk factors for rapid irrigation fluid absorption and associated clinical sequelae.[8,9] We believe it is reasonable to administer 20mg IV furosemide when there is a capsular perforation (visualization of peri-prostatic fat) or undermining of the bladder neck early in a procedure especially in prolonged cases (>120 minutes) to decrease the likelihood of clinical fluid overload. Further research will be required to determine if furosemide has a protective role in patients at a higher risk of developing irrigation fluid overload (capsular perforation, prolonged procedures >4 hours, open vascular sinuses, or severe prostatomegaly). Developing an adequately powered study to examine the role furosemide in these patients would be difficult given the rarity of symptomatic rapid fluid irrigation absorption during contemporary HoLEP procedures.

The generalizability of our results may be limited by our high-volume HoLEP experience, high surgical efficiency, and institution SDD HoLEP pathway. Our study is limited by lack of standardized post-operative serum electrolytes to monitor for electrolyte abnormalities. Serum labs (complete blood count and basic metabolic panel) were only drawn for clinical concern including, but not limited to significant intra-operative or post-operative hematuria. Our study was further limited by the lack of a standardized objective measure for intra-operative irrigation fluid absorption. Our study relied solely on a clinical diagnosis of the clinical sequelae of irrigation fluid overload. Additionally, our study was limited by its single high-volume center design. It is possible that at a lower volume center or during a surgeon's learning curve that routine administration of furosemide may be more useful given the rate of capsular perforation would be presumably higher and procedural duration longer. Despite these limitations, this was a well-executed double-blind randomized controlled trial with excellent post-operative follow-up and similar pre-operative patient demographics and prostate characteristics between arms.

CONCLUSIONS

Intra-operative furosemide during morcellation does not improve rates of SDD or SDTOV in patients undergoing HoLEP. Furthermore, we did not identify any episodes of clinical fluid overload or TURP syndrome in either treatment arm. Despite furosemide being a low-cost and relatively benign medication, there appears to be no role for its routine administration in a contemporary ambulatory HoLEP care-pathway.

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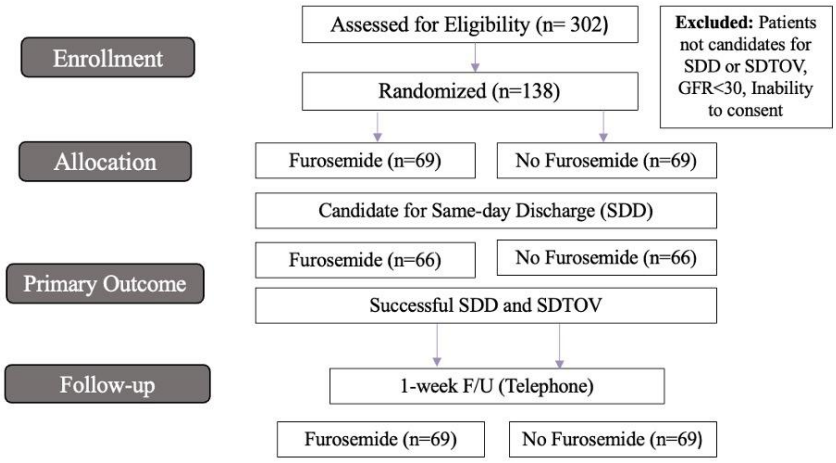
Competing interests: Dr. Dean is a consultant for Olympus. Dr. Krambeck is a consultant for Boston Scientific, Wolf, Storz, and Virtuoso Surgical. She is a data safety monitoring board member for Uriprene.

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FIGURES AND TABLES

Figure 1. Study schema.



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Table 1. Demographics and baseline characteristics, perioperative outcomes, and postoperative outcomes				
		Furosemide (n=69)	**Control (n=69)**	**p**
Baseline characteristics	Age (years) ± (SD)	71.8±7.1	69.3±6.9	0.060
	BMI (kg/m^2) ± (SD)	28.0±4.4	28.0±4.3	0.975
	American Society of Anesthesiologists Score (ASA) ± (SD)	2.5±0.5	2.4±0.5	0.115
	Preoperative prostate volume (cm^3) ± (SD)	130.5±87.7	120.3±64.2	0.458
	Indwelling Foley or CIC (%)	13 (18.8)	17 (25.0)	0.413
	Anticoagulation (%)	9 (13.0)	9 (13.0)	1.000
	Prior BPH surgery (%)	13 (19.1)	8 (11.6)	0.225
	Prior urinary retention (%)	29 (43.3)	35 (50.7)	0.675
	Prostate-specific antigen (PSA) ± (SD)	6.2±6.1	5.7±3.9	0.655
	Prior UTIs (%)	12 (17.9)	15 (21.7)	0.579
	Prostatitis (%)	4 (5.8)	3 (4.2)	0.671
	Preoperative urinary incontinence(%)	13 (19.1)	15 (22.1)	0.674
	Diabetes mellitus (%)	5 (7.3)	10 (14.5)	0.174
	Urethral stricture disease (%)	3 (4.3)	0 (0)	0.076
	Alpha-blocker (%)	55 (79.7)	52 (75.4)	0.544
	5-alpha reductase inhibitor (%)	18 (26.1)	27 (39.1)	0.104
	Anti-muscarinic (%)	5 (7.3)	6 (8.7)	0.755
	Preoperative postvoid residual (mL) ± (SD)	128.6±194.7	121.3±163.7	0.889
	AUASS total ± (SD)	20.9±6.8	22.4±7.0	0.357
	SHIM ± (SD)	13.8±8.9	10.5±8.2	0.134
	MISI incontinence total score ± (SD)	6.5±5.0	5.6±6.0	0.466
	MISI incontinence bother score ± (SD)	1.6±1.9	1.6±2.0	0.957

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Perioperative outcomes	Mean total procedure time (min) ± (SD)	62.9±39.7	58.1±24.5	0.650
	Mean enucleation time (min) ± (SD)	31.9±16.9	33.2±17.1	0.631
	Mean morcellation time (min) ± (SD)	10.3 ±13.5	10.7±12.2	0.885
	Mean specimen weight (g) ± (SD)	84.3±72.3	84.5±61.9	0.988
	Energy kJ ± (SD)	153.9±96.7	152.6±61.8	0.929
	Intraoperative complications (%)	0 (0)	0 (0)	1.000
	Same-day surgery candidates after HoLEP (%)	66 (95.7)	66 (95.7)	1.000
Postoperative outcomes	Same-day TOV (SDTOV) (%)	56 (81.6)	64 (97.0)	**0.005***
	Failed SDTOV (%)	9 (16.0)	8 (12.5)	0.579
	Same-day discharge (SDD) (%)	42 (63.6)	54 (81.8)	**0.019***
	Mean length of stay (hours) ± (SD)	14.4±15.2	11.4±17.5	0.286
	Median length of stay (hours) + range	6.0, 1.5−120	6.8, 1.5−72	N/A
	Mean catheterization length (days) ± (SD)	0.9±2.2	0.61±1.4	0.222
	ER-30 day (%)	5 (7.3)	7 (10.3)	0.532
	Re-admission 30-day (%)	3 (4.4)	3 (4.4)	1.000
	30-day complications: Total (%)	6 (8.7)	9 (13.0)	0.416
	Urinary tract infection	0 (0)	3 (4.3)	
	Urinary retention	5 (7.4)	6 (8.7)	
	Return to OR, catheter insertion	1 (1.4)	0 (0)	
	30-day complications: >II (%)	1 (1.4)	0 (0)	0.319
	Transfusions	0 (0)	0 (0)	1.000
	TURP syndrome/Fluid overload	0 (0)	0 (0)	1.000
	Followup (months) ± SD	2.5±1.2	2.7±1.2	0.258

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