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Intradetrusor OnabotulinumtoxinA Injections at the Time of Holmium Laser Enucleation of the Prostate for Men with Severe Storage Symptoms

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Abstract

Introduction: Intradetrusor onabotulinumtoxinA (OTA) injection is a well-established treatment option for refractory overactive bladder; however, its use at the time of holmium laser enucleation of the prostate (HoLEP) for men with bladder outlet obstruction (BOO) and severe storage symptoms has not been previously reported.

Materials and Methods: We retrospectively identified men with BOO and severe storage symptoms who underwent treatment with 200 U of intradetrusor OTA (Botox[®]) at the time of HoLEP. Patients were propensity score matched to a cohort of HoLEP-only patients based on age, Michigan Incontinence Symptom Index (M-ISI) score, preoperative urinary retention, urge incontinence, and prostate size. Perioperative, postoperative, and patient-reported outcomes were examined between groups.

Results: We identified 82 men who underwent HoLEP, including 41 patients in the OTA group and 41 patients in the control group. There was no difference in operative times (59 minutes OTA vs 55 minutes control, $p=0.2$), rates of same-day trial of void (TOV) (92% OTA vs 94% control, $p=0.7$), or rates of same-day discharge (88% OTA vs 85% control, $p=0.6$) between groups. There was no difference in temporary postoperative urinary retention (7% OTA vs 2% control, $p=0.3$) between groups. Patients who received OTA injections had a significant reduction in their incontinence scores at 3-month follow-up (M-ISI -8, interquartile range [IQR]: -13 to 0, $p<0.001$), whereas control patients did not (M-ISI -5, IQR: -8 to -1, $p=0.2$). There was no difference in rates of 90-day complications between groups (OTA 10% vs control 5%, $p=0.7$).

Conclusions: Intradetrusor OTA at the time of HoLEP is safe and is associated with improved urinary incontinence scores and AUA Symptom Score. Rates of same-day discharge and same-day TOV after HoLEP were not affected by OTA. These findings support the role of OTA as an adjunct to surgical intervention in men with incontinence in the presence of BOO.

Keywords: Botox[®], BPH, OAB, storage symptoms, HoLEP

Introduction

MEN WITH BLADDER OUTLET OBSTRUCTION (BOO) from benign prostatic hyperplasia (BPH) often present with severe storage symptoms.^{1–3} The surgical management of BPH in patients with severe storage symptoms can be challenging, as symptoms of detrusor overactivity can per-

sist after surgical relief of BOO and often contribute to residual postoperative lower urinary tract symptoms (LUTS).⁴ This can be particularly severe in patients who have urge incontinence.⁵

Although intradetrusor onabotulinumtoxinA (OTA) injections are well established and an effective treatment for overactive bladder (OAB)-related detrusor overactivity,⁶ the

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safety of its simultaneous use at the time of BOO procedure has not been well established. Clinicians may be reasonably concerned about provoking acute urinary retention in patients who may already be predisposed to retention because of their BOO.⁶ Several smaller studies have demonstrated that simultaneous bladder OTA injection at the time of transurethral resection of the prostate (TURP) can be safe and reduce postoperative LUTS.⁷

Holmium laser enucleation of the prostate (HoLEP) is one of the few guideline-recommended surgical treatment for BPH that is appropriate for all prostate sizes.^{8–10} As HoLEP has begun to establish itself as the gold standard minimally invasive BOO procedure,^{11,12} the treatment of severe storage symptoms remains an important consideration in the surgical treatment of LUTS related to BPH. To date, no studies have investigated the concurrent use of intradetrusor OTA at the time of HoLEP. In this study, we performed a retrospective study to assess the safety and efficacy of concurrent intradetrusor OTA injection and HoLEP for men with severe storage symptoms and BOO from BPH.

Materials and Methods

Study cohort

We conducted a single institution retrospective comparative cohort study between August 2021 to October 2022. After obtaining institutional review board (IRB) approval, men with severe storage symptoms were identified and consented to have simultaneous intradetrusor OTA at the time of HoLEP. Men were selected for this procedure at the discretion of the lead surgeon based on the subjective severity of their reported storage symptoms. Specifically, men with BPH and urge incontinence requiring the use of protective pads or absorbent underwear were offered OTA injection and counseled of the risks of intradetrusor OTA. These men were consented for the procedure and completed a Michigan Incontinence Symptom Index (M-ISI) and AUA Symptom Score (AUASS) as part of their initial clinic visit.

A control group was identified from our prospectively maintained HoLEP IRB-approved database. We performed propensity score matching based on preoperative M-ISI Severity score, prostate size, age, and urinary retention status at initial visit to identify a comparison control group ($n=41$) with similar preoperative characteristics to the OTA group ($n=41$).

Intraoperative technique

For the men selected and consented to undergo concurrent intradetrusor OTA and HoLEP, the OTA injection was performed at the beginning of the procedure, before urethral dilatation for HoLEP. The Wolf (Richard Wolfe Medical Instruments, Vernon Hills, IL) Aspiration/Injection system was used to administer OTA injection, which was 200 U of OTA mixed into 20 mL of 0.9% physiologic saline injected in equal 0.5 mL aliquots throughout the bladder. HoLEP was then performed as previously described with either a 28F or 24F laser resectoscope depending on the size of the prostate and ureteroscope availability with the MOSES 2.0 holmium laser.^{13,14}

Postoperative follow-up

Most of the patients underwent a same-day trial of void (TOV) and discharge pathway, whereas patients with signif-

icant comorbidities were planned for an overnight admission and postoperative day (POD) 1 TOV. Our same-day discharge pathway has been previously described.¹⁵ Men were closely followed with a telehealth visit at 1-week postoperative and an in-person visit at 3 months. An additional 6-month postoperative appointment was scheduled if patients had urinary incontinence or other urologic issues requiring close follow-up. At follow-up visits patients were asked to fill out postoperative M-ISI and AUASS questionnaires. Men were asked to self-report emergency department (ED) visits, urinary tract infections (UTIs), and any other postoperative complications. In addition, our research team performed retrospective chart reviews to capture ED visits, hospital admissions, and 90-day complications.

Statistical analysis

We performed propensity score matching using age, prostate size, baseline M-ISI Severity score, preoperative urinary retention, and reported urge incontinence to identify a control cohort. We compared baseline characteristics, perioperative complications, and patient-reported questionnaire data between our OTA and control cohorts using Wilcoxon and paired *t*-tests for continuous variables, and Fisher's exact test for categorical variables as appropriate. We used $p < 0.05$ as our cutoff for statistical significance. Statistical analysis was performed using R statistical software, version 4.2.0.

Results

The overall study cohort consisted of 82 men who all reported severe urinary urgency, 41 who underwent HoLEP with OTA and 41 who underwent HoLEP only. The cohorts were matched by age, prostate size, preoperative urinary retention, and preoperative M-ISI score (Table 1). The OTA cohort had a significantly higher proportion of men with baseline urinary incontinence requiring pads ($n=33$, 80%) compared with the control group ($n=20$, 48%) ($p=0.01$). There were no other demographic differences between the two groups (Table 1).

Perioperatively, there was no statistically significant difference in procedural time. There was no difference in enucleation time, morcellation time, overall procedural time, or tissue specimen weight between groups (Table 2). The overall rate of same-day discharge was 88% in the OTA cohort and 85% in the control cohort ($p=0.6$). A minority of patients ($n=10$, 12%) underwent a planned overnight admission. Of the patients eligible for the same-day discharge, 36 (97%) of the OTA patients underwent same-day discharge compared with 35 (100%) in the control group ($p=0.3$). The remaining five patients (12%) in the OTA group were discharged on POD1. There was no difference in the rates of same-day TOV between groups (OTA $n=34$, 92% vs control $n=33$, 94%, $p=0.7$) in patients not planned for overnight admission. All of patients in the study completed a TOV before their discharge.

At 3-month follow-up, the OTA group reported an 8-point improvement (interquartile range [IQR]: -13-point to 0-point change) in their preoperative M-ISI Severity score ($p < 0.001$) and a median 9-point improvement (IQR: -17-point to -5-point change) in total AUASS ($p < 0.001$). In the control group, there was a median 11.5-point improvement (IQR: -23-point to -5-point change) in total AUASS

TABLE 1. BASELINE PATIENT CHARACTERISTICS

Median (IQR) or N (%)	HoLEP and OTA (n=41)	HoLEP (n=41)	Total (n=82)	p
Age (years)	73 (69–78)	74 (65–77)	73 (66–77)	0.7
Prostate size (g)	102 (60–133)	110 (73–140)	109 (69–134.5)	0.4
Pre-op M-ISI severity (32 points total)	12 (9–16)	11 (8–13)	11 (8–14.5)	0.3
Pre-op total IPSS (35 points total)	21 (16–24)	19.5 (15–25)	20 (15.5–24)	0.8
Pre-op incontinence requiring pads	33 (80)	20 (48)	53 (65)	0.01
Urinary retention at baseline	12 (29)	11 (27)	23 (28)	1
Diabetes mellitus	9 (22)	7 (17)	16 (20)	0.8
Neurologic conditions ^a	2 (5)	2 (5)	4 (5)	1
Previous benign prostatic hyperplasia surgery	3 (7)	4 (10)	7 (9)	1
History of pelvic radiation	0 (0)	0 (0)	0 (0)	1
Pre-op anticholinergic/beta-agonist agent	10 (24)	5 (12)	15 (18)	0.2
Pre-op anticoagulation or antiplatelet agent	8 (20)	7 (17)	15 (18)	1

Bold values indicate statistically significant result

^aIncludes Parkinson's disease, multiple system atrophy, previous stroke, traumatic brain injury, spinal cord injury, multiple sclerosis, and cerebral palsy.

HoLEP=holmium laser enucleation of the prostate; IPSS=International Prostate Symptom Score; IQR=interquartile range; M-ISI=Michigan Incontinence Symptom Index; OTA=onabotulinumtoxinA.

($p < 0.001$), but no significant change in M-ISI Severity scores (median –5-point change, IQR: –8-point to –1-point change, $p = 0.2$) when compared with preoperative questionnaires (Figs. 1 and 2). More men in the OTA group $n = 11$ (28%) required anticholinergic therapies compared with men in the control group $n = 5$ (13%) at a mean follow-up of 4.1 months, but this difference was not statistically significant ($p = 0.1$).

The median improvement in International Prostate Symptom Score (IPSS) at 6 months was 15.5 points (IQR: –19.5-point to –11.25-point change, $p < 0.001$) in the OTA cohort and 13 points (IQR: –19-point to –8-point change, $p < 0.001$) in the control group. There was an insufficient number of

postoperative M-ISI scores obtained at 6 months to compare changes with preoperative scores. At 6 months follow-up, 2 patients (5%) in the OTA cohort required repeat administration of intradetrusor OTA injection in the office. Despite most of the patients in this study reporting preoperative incontinence requiring pads, self-reported postoperative continence was 89% ($n = 36$, mean 3.8-month follow-up) in the OTA group and 87% in the control group ($n = 31$, mean 4.5-month follow-up, $p = 0.8$).

There was no difference in 90-day complications between groups (OTA $n = 4$, 10% vs control $n = 2$, 5% $p = 0.7$). There was no grade 3 or above Clavien–Dindo complications. Transient postoperative urinary retention was observed in

TABLE 2. PERIOPERATIVE AND POSTOPERATIVE DATA

Median (IQR) or N (%)	HoLEP and OTA (n=41)	HoLEP (n=41)	Total (n=82)	p
American Society of Anesthesiologist class				0.6
I	1 (2)	1 (2)	2 (2)	
II	18 (44)	22 (54)	40 (49)	
III	20 (49)	18 (44)	38 (46)	
IV	2 (5)	0 (0)	2 (2)	
V	—	—	—	
Procedure time (minutes)	59 (45–86)	55 (42–69)	56.5 (44–79.5)	0.2
Enucleation time (minutes)	32 (25–49)	30 (22–38)	31 (23–41)	0.1
Morcellation time (minutes)	7 (4–17)	7 (4–12)	7 (4–14)	0.7
Tissue weight (g)	64.5 (42.5–103)	74 (38–101)	65 (39–101)	0.8
Intraoperative complications	0 (0)	1 ^a (2)	1 (1)	1
Transfusion required	0 (0)	0 (0)	0 (0)	1
Length of stay				0.6
Same-day discharge	36 (88)	35 (85)	71 (87)	
1 day	5 (12)	4 (10)	9 (11)	
2+ days	0 (0)	2 (5)	2 (2)	
Planned overnight admission	4 (10)	6 (15)	10 (12)	
Same-day TOV ^b	34/37 (92)	33/35 (94)	67 (93)	0.7
TOV before discharge	41 (100)	41 (100)	82 (100)	1
90-Day complications	4 (10)	2 (5)	6 (7)	0.7
Grade III or above	0 (0)	0 (0)	0 (0)	1

^aCut edge of prostate was near right ureteral orifice; did not require stent placement.

^bOf those eligible for same-day TOV and discharge.
TOV = trial of void.

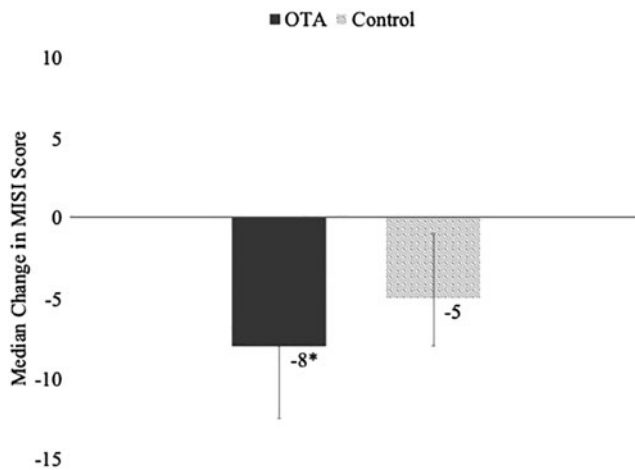


FIG. 1. Median change in Michigan Incontinence Symptom Index score postoperatively. *Indicates $p < 0.05$ when comparing postoperative with preoperative score by paired t -test.

three OTA patients (7%) compared with one control patient (2%), but this difference was not statistically significant ($p = 0.6$). All the episodes of transient urinary retention lasted < 2 days and occurred within the first postoperative week. There was one patient in the OTA group (2%) who had a delayed episode of gross hematuria on POD28 requiring overnight admission for continuous bladder irrigation in the setting of therapeutic anticoagulation. The patient was discharged without a Foley catheter and without operative intervention. There were no other 90-day complications, including blood transfusions, clot evacuations, strictures, or bladder neck contractures captured in the cohort.

Discussion

Long-standing BPH can cause anatomical and functional changes of the detrusor muscle, which often presents as severe storage symptoms.^{5,15} Although relief of BOO after TURP, HoLEP, and Thulium:YAG is associated with improvements in LUTS, correction of obstruction may not

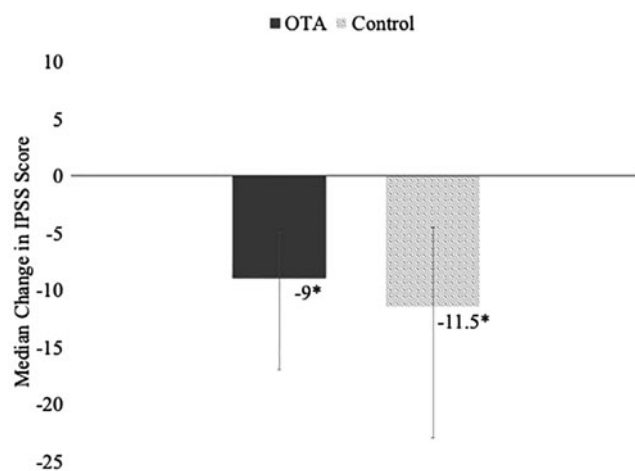


FIG. 2. Median change in AUA symptom score postoperatively. *Indicates $p < 0.05$ when comparing postoperative with preoperative score by paired t -test.

be sufficient in relieving urinary symptoms for patients with storage symptoms related to underlying remodeling of the detrusor muscle, especially in the first 3 months postoperatively.^{8,16–18} A persistence of storage symptoms after laser enucleation is associated with decreased quality of life and justifies research attempts to mitigate these symptoms postoperatively.¹⁹ Although storage symptoms can be addressed pharmacologically after the surgical treatment of BOO, this approach can result in delayed relief from bothersome urinary symptoms and undesirable side effects, including but not limited to constipation. Few studies have reported on the simultaneous surgical treatment of storage symptoms and BOO during index surgery.

There has been one prior study to our knowledge reporting the use of simultaneous intradetrusor OTA at the time of TURP.⁷ This study compared the efficacy of TURP with solifenacin vs TURP with concurrent OTA injection in reducing symptoms of detrusor overactivity in a cohort of 39 men.⁷ The authors reported significant improvement in frequency, urgency, total IPSS, and IPSS quality of life scores among both groups, with a more significant reduction in those that received concurrent bladder OTA. Of note, the study did not report on differences in adverse outcomes such as acute postoperative urinary retention. Despite these positive results, studies examining the effects of intradetrusor OTA treatment at the time of outlet obstruction are limited.

In this study, we present the first comparative study of concomitant intradetrusor OTA injection and HoLEP for men with severe storage symptoms and BOO from BPH, with a focus on the safety and patient-reported efficacy of this approach. We found that OTA at the time of HoLEP was safe and did not increase the risk of failed trials of void, extend length of stay, increase UTIs, or increase rates of acute urinary retention. The three men who did develop acute urinary retention were temporarily catheterized for not > 2 days and all had subsequent TOVs. Furthermore, we found that in addition to a 9-point improvement in AUASS scores, indicating effective relief of outlet obstruction, men who underwent concurrent OTA injections at the time of HoLEP had significant improvements in incontinence scores.

Given that the reported minimum changes in AUASS and M-ISI Severity scores that are clinically meaningful are 5.2 points and 4 points, respectively,^{20,21} our observed improvements are both statistically and clinically significant. By contrast, the standard HoLEP cohort had no significant change in M-ISI Severity score. However, we found that $\sim 90\%$ of men in both cohorts had self-reported continence at 3- to 6-month follow-up. Taken together, these findings suggest that although the vast majority of men regain continence after HoLEP, this process can take several months for men with baseline incontinence, and early OTA administration can help with urgency and regaining continence during the postoperative period.

Our study serves as an important proof of concept for the simultaneous surgical treatment of severe storage symptoms and BOO from LUTS. The results of our study suggest that not only is the approach safe but also appears to have a significant impact on patient-reported severity of urge incontinence in the postoperative course. Our study results support the further clinical utilization and investigation of concomitant intradetrusor OTA and HoLEP in men with BPH. Although concerns about causing acute urinary retention

with simultaneous OTA injection may be justified with TURP, the maximal removal of prostatic tissue and relief of outlet obstruction with HoLEP may obviate concerns about iatrogenic retention. This principle has been demonstrated in a previous study demonstrating the safety of HoLEP in men with acontractile bladders.²²

We recognize the limitations to this study, including its retrospective and single-institution design. Therefore, there may be confounders that we did not account for when identifying our comparison group. Nevertheless, we performed propensity score matching to compensate for the retrospective nature of the study, controlling for preoperative M-ISI Severity score, prostate size, age, urinary retention status, and self-reported urge incontinence. In addition, our study may have been underpowered to identify differences in outcomes such as rates of postoperative acute urinary retention. However, our findings serve as a proof of concept and justify a larger randomized controlled trial of bladder OTA at the time of HoLEP.

We also relied on patient-reported symptoms and clinician judgment as the determinant for who underwent OTA injection at the time of HoLEP, rather than more objective measures of detrusor overactivity (i.e., urodynamic evaluation). As such, it is difficult to predict which patients may have similar treatment responses to our study cohort. Hur et al. identified that patients with a history of urinary retention had less persistence of storage symptoms after laser enucleation and may be less likely to benefit from OTA injections at time of laser enucleation.²³ Using objective methods to identify patients who would benefit from OTA and measure postoperative outcomes, such as performing urodynamic studies to identify true detrusor overactivity, may have allowed for a more rigorous assessment of treatment efficacy.

However, our approach more closely approximates real-world clinical practice, in which patient-reported symptoms and questionnaires are more often the primary tools to assess treatment efficacy of BOO procedures. Finally, we recognize that other standardized questionnaires exist, such as the Overactive Bladder Symptom Score that may provide more relevant data about the symptoms in this patient population, but these questionnaires are not routinely used in our clinical practice. Despite these limitations, this study represents one of the first to identify the safety and effectiveness of intradetrusor OTA at time of HoLEP for the treatment of men with severe storage symptoms and BOO.

Conclusions

Intradetrusor OTA at the time of HoLEP is a safe and effective treatment for men with both urge incontinence and BOO from BPH. Men who underwent OTA injections at time of HoLEP experienced an improvement in incontinence scores and AUASS. The observed improvements in voiding and incontinence scores were both clinically and statistically significant. OTA administration at the time of HoLEP did not prolong operative time or decrease rates of same day TOV or discharge. There was no difference in 90-day complication rates, including transient urinary retention, bleeding complications, and UTIs, between the OTA and control patients. Our findings support further investigation and clinical utilization of simultaneous bladder OTA injection at the time of HoLEP for patients with severe storage symptoms.

Authors' Contributions

Project conception, data entry, statistical analysis, and writing by M.M.H. and A.E.K. Project conception, data entry, statistical analysis, writing, and editing by N.S.D. Project conception, data entry, writing, and editing by M.A.A. and M.S.L. Project conception and data entry by J.N.G.

Author Disclosure Statement

A.E.K. is a consultant for Boston Scientific, Wolf, Storz, and Virtuoso Surgical. She is a data safety monitoring board member of Sonomotion and Uriprene. M.S.L. is a consultant for Lumenis.

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Abbreviations Used

AUASS = AUA symptom score
BOO = bladder outlet obstruction
BPH = benign prostatic hyperplasia
ED = emergency department
HoLEP = holmium laser enucleation of the prostate
IPSS = International Prostate Symptom Score
IQR = interquartile range
IRB = institutional review board
LUTS = lower urinary tract symptoms
M-ISI = Michigan Incontinence Symptom Index
OAB = overactive bladder
OTA = onabotulinumtoxinA
POD = postoperative day
TOV = trial of void
TURP = transurethral resection of the prostate
UTIs = urinary tract infections