Original Article

Does the setting for intradetrusor onabotulinumtoxinA injection for management of overactive bladder matter?

James H. Ross*, Megan Abrams[1], Sandip P. Vasavada[2], Jeffrey M. Mangel[1], Cecile A. Ferrando

Center for Urogynecology and Pelvic Reconstructive Surgery, Cleveland Clinic, Obstetrics, Gynecology and Women's Health Institute, [1]Division of Female Pelvic Medicine and Reconstructive Surgery, MetroHealth Medical Center, Case Western Reserve University School of Medicine, [2]Cleveland Clinic Foundation, Glickman Urological Institute, Cleveland, Ohio

*E-mail: rjames.ross@hmhn.org

ABSTRACT

Introduction: Intradetrusor onabotulinumtoxinA (Botox) injections, to treat idiopathic overactive bladder (OAB), can be performed in the office setting under local analgesia alone or in the operating room (OR) under local and/or sedation. The objective of this study was to compare the symptomatic improvement in patients with OAB who underwent treatment with intradetrusor onabotulinumtoxinA injections in an in-office versus the OR setting.

Methods: We performed a multicenter retrospective cohort study of women with the diagnosis of refractory non-neurogenic OAB who elected to undergo treatment with intradetrusor onabotulinumtoxinA injections between January 2015 and December 2020. The electronic medical records were queried for all the demographic and peri-procedural data, including the report of subjective improvement post procedure. Patients were categorized as either "in-office" versus "OR" based on the setting in which they underwent their procedure.

Results: Five hundred and thirty-nine patients met the inclusion criteria: 297 (55%) in the in-office group and 242 (45%) in the OR group. A total of 30 (5.6%) patients reported retention after their procedure and it was more common in the in-office group (8.1%) versus the OR group (2.5%), ($P = 0.003$). The rate of urinary tract infection within 6 months of the procedure was higher in the OR group (26.0% vs. 16.8%, $P = 0.009$). The overall subjective improvement rate was 77% (95% confidence interval: 73%–80%). Patients in the OR group had a higher reported improvement as compared to the in-office group (81.4% vs. 73.3%, $P = 0.03$).

Conclusions: In this cohort study of patients with OAB undergoing intradetrusor onabotulinumtoxinA injections, post procedural subjective improvement was high regardless of the setting in which the procedure was performed.

INTRODUCTION

Overactive bladder (OAB) is a common and bothersome condition in the female population. It not only creates an economic burden on the patients and the health-care system as a whole[1] but also creates an emotional distress and impacts the mental health of the affected patients.[2] First-line treatment for OAB and urge urinary incontinence (UUI) includes patient education and behavioural modifications. Second-line treatment includes the use of medications. Although an effective and common pharmacologic choice for treatment, anticholinergics are associated with a myriad of bothersome side effects that can lead to a decrease in the patient compliance and even a complete cessation of the treatment.[3-5] As many of the anticholinergics can also cross the blood–brain barrier, more and more studies are theorizing that the anticholinergics can impact the

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cognition, and there may even be an association between these medications and the development of dementia.[6,7] An alternative pharmacologic agent is the beta-3 agonist which does not have the same side effect profile, is equally effective, and may have better adherence;[8] however, it is costly and is not always covered by the insurance providers. Once the first- and the second-line therapies have failed, physicians typically proceed to the third-line treatment for OAB/UUI.

Third-line treatments for OAB/UUI include interventions such as percutaneous tibial nerve stimulation, sacral neuromodulation (SNM), or onabotulinumtoxinA injections into the detrusor muscle of the bladder. The effect of onabotulinumtoxinA injections approximately lasts for 3–12 months, and many patients require re-treatment. The greatest risk associated with this procedure is the development of urinary tract infection (UTI) or post procedural urinary retention. The reported incidence of UTI after onabotulinumtoxinA may be as high as 25%–35%,[9,10] and the retention or incomplete bladder emptying rates range from 0% to 43%.[9-11] OnabotulinumtoxinA has been shown to be efficacious. A large randomized controlled trial by the Pelvic Floor Disorders Network evaluated the efficacy of onabotulinumtoxinA in controlling the refractory episodes of UUI and compared it to SNM and found that the onabotulinumtoxinA showed a greater reduction in the mean urge incontinence episodes at 6 months as well as a greater improvement in the symptoms of bother and a higher treatment satisfaction.[9]

OnabotulinumtoxinA injections can be performed in the office setting under local analgesia applied to the urethra and the bladder. In select cases or based on the surgeon's preference, the procedure can also be performed in the operating room (OR) under IV sedation or general anesthesia. Procedural settings comparing the OR to the office have been evaluated in gynecology, but there are no studies to date (PUBMED Search 2000–2021) that have compared patient outcomes following intradetrusor bladder onabotulinumtoxinA injections performed in the office versus the OR settings. Therefore, the primary objective of this study was to compare the subjective symptomatic improvement in the OAB symptoms in patients suffering from idiopathic OAB/UUI who underwent treatment with onabotulinumtoxinA injections into the bladder in an in-office versus OR setting. We secondarily aimed to compare the adverse events and rate of repeat injections or alternative treatments between the two groups.

METHODS

This was a multicenter retrospective cohort study of women who presented with a diagnosis of non-neurogenic OAB or UUI and elected to undergo treatment with onabotulinumtoxinA injections between January 2015 and December 2020. At both the study centers, an academic urogynecologist and/or female urologist performed the onabotulinumtoxinA injections with the assistance of fellows.

Patients were identified by searching both institutions' system-wide electronic medical record (EMR) for the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) codes: OAB (N32.81), Urge Incontinence (N39.41), or Mixed Incontinence (N39.46), in addition to the current procedural terminology (CPT) code for Cystourethroscopy, with injection(s) for chemodenervation of the bladder (52,287). Patients were excluded if they had received intradetrusor onabotulinumtoxinA injections prior to January 2015, had a diagnosis of interstitial cystitis or bladder pain syndrome, or a diagnosis of neurogenic bladder or had associated neurological conditions such as multiple sclerosis, Parkinson's disease, spinal cord injury, and/or dementia. Each medical record identified by these ICD-10 and CPT codes was reviewed to ensure that each patient met the inclusion criteria and no exclusionary diagnoses were overlooked. The EMR was then queried for all the data points of interest, including patient demographics and procedural data.

Definitions of the variables to be collected in this study were determined *a priori* to the data collection. Patient variables of interest included the baseline demographic data, chronic medical conditions, prior OAB treatments, and the pre-procedural post void residual urine volume. Intra procedural or intra-operative variables included the location of the procedure, dosage of the onabotulinumtoxinA, number of intra-detrusor injections placed, and the volume of each injection. Post-procedural variables were subjective improvement, post-procedure retention or incomplete bladder emptying, UTI, re-treatment, and alternative treatments. Subjective improvement was determined by a lack of incontinence symptoms reported at the follow-up visit or by documented improvement as per the patient report. Urinary retention or incomplete bladder emptying was diagnosed based on the documented need for bladder depression within 6 months of onabotulinumtoxinA injections. For consistency, we will refer to either retention or incomplete bladder emptying as retention for the remainder of the manuscript. UTI was diagnosed based on the documentation of treatment with antibiotics or a positive urine culture within 6 months of onabotulinumtoxinA injection. Data were collected by one co-investigator at each institution (JR, MA).

This was primarily a descriptive study. Categorical variables were reported as *n* (%) and continuous variables as mean ± standard deviation or median (range). Comparisons of the outcome measures were performed via the Student's *t*-test for parametric continuous outcomes, Mann–Whitney *U*-test for nonparametric outcomes, and a Chi-square test

for all the categorical outcomes. Univariate analysis was performed on all the potential outcomes of in-office versus OR onabotulinumtoxinA. Variables that were determined to be statistically significant ($P \leq 0.05$) were entered into a regression model, which was performed to identify independent risk factors. Adjusted odds ratios, with 95% confidence intervals (CIs), were calculated for all the independent predictors. All statistical tests were two-sided, and $P \leq 0.05$ was considered statistically significant. JMP version 15.0 (SAS Institute, Cary, NC) was used for all statistical analyses. IRB approval was obtained.

RESULTS

A total of 539 patients met the inclusion criteria, of which 297 patients received the onabotulinumtoxinA injections in the office and the rest 242 in the OR. The mean age of the overall cohort was 64 (±12.8) years, and the mean body mass index was 32.4 (±8.6) kg/m^2. Four hundred and twenty-nine (79.6%) patients were postmenopausal. Table 1 shows the patient characteristics for both the groups. There was a significant difference in the race between the two groups, with the in-office group being 79% White and 17.5% Black while the OR group was 62% White and 31% Black ($P < 0.001$ and $P < 0.001$, respectively). Additionally, the rate of tobacco use (21.5% vs. 5.4%, $P < 0.001$) and the incidence of hypertension (62.4% vs. 45.8%, $P < 0.001$), and lung disease (19.4% vs. 10.7%, $P = 0.005$) were higher in the OR group. The in-office group had a higher incidence of pre-procedural recurrent UTIs (13.8% vs. 5.0%). For the entire cohort, the average number of OAB medications prescribed prior to the onabotulinumtoxinA injection was 2 (range 0–6). Patients in the in-office group were more likely to have tried a beta-3 agonist (39.1% vs. 26.1%, $P = 0.002$). A total of 70 patients had a sacral neuromodulator placed prior to their onabotulinumtoxinA injections, with no difference between the two groups.

Table 2 shows the intra-operative and post-operative variables. Of the 242 onabotulinumtoxinA injections performed in the OR, 229 (94.6%) were performed in that setting due to the surgeon's preference and 189 (78.1%) of these were performed under monitored anesthesia care. No patients were admitted overnight after their procedure was performed in the OR. In the total cohort, 97.8% of the cases received a total of 100 units of onabotulinumtoxinA. The median number of injection sites was 20 (range 5–30) and the volume per injection was 0.5 (range 0.5–2). Within 6 months of the procedure, 30 (5.6%, 95% CI: 3.9%–7.8%) patients were diagnosed with urinary retention and 113 (21.0%, 95% CI: 17.7%–26.4%) with a UTI across both the cohorts. Patients who had their onabotulinumtoxinA injected in the office were more likely to have retention (8.1% vs. 2.5%, $P = 0.003$) but were less likely to have a UTI (16.8% vs. 26.0%, $P = 0.009$). Subjective improvement in the symptoms was reported in 77% (95% CI: 73%–80%) of the whole cohort,

Table 1: Preprocedure patient characteristics

Characteristics	Total (*n*=539)	Office (*n*=297)	OR (*n*=242)	*P*
Age, mean±years	64±12.8	65.3±12.1	62.6±14.5	**0.01**
Race, *n* (%)				
White	384 (71.2)	235 (79.1)	149 (61.6)	**<0.0001**
Black	126 (23.4)	52 (17.5)	74 (30.6)	**0.0004**
Asian	4 (0.7)	2 (0.7)	2 (0.8)	0.83
Unknown	27 (5.0)	10 (3.4)	17 (7)	0.05
BMI, mean±SD (kg/m^2)	32.4±8.6	35.6±8.6	32.2±8.8	0.31
Parity	2 (0–8)	2 (0–8)	2 (0–8)	0.97
Postmenopausal, *n* (%)	429 (79.6)	241 (81.1)	188 (77.7)	0.33
Smoker, *n* (%)	68 (12.6)	16 (5.4)	52 (21.5)	**<0.0001**
Hypertension, *n* (%)	287 (53.2)	136 (45.8)	151 (62.4)	**0.0001**
Diabetes, *n* (%)	122 (22.6)	60 (20.2)	62 (25.6)	0.14
Kidney disease, *n* (%)	47 (8.7)	21 (7.1)	26 (10.7)	0.13
Lung disease, *n* (%)	79 (14.6)	32 (10.7)	47 (19.4)	**0.005**
Recurrent UTI, *n* (%)	53 (9.8)	41 (13.8)	12 (5.0)	**0.0004**
OAB dry, *n* (%)	22 (4.1)	10 (3.4)	12 (5.0)	0.35
OAB wet/UUI, *n* (%)	517 (96.0)	287 (96.6)	230 (95.0)	0.35
Trial of meds, *n* (%)	527 (97.8)	289 (97.3)	238 (98.3)	0.41
Number of meds	2 (0–6)	2 (0–6)	2 (0–5)	0.6
Anticholinergics, *n* (%)	508 (96.4)	273 (94.5)	235 (98.7)	**0.006**
Beta 3 agonists, *n* (%)	175 (33.2)	113 (39.1)	62 (26.1)	**0.002**
PFPT, *n* (%)	118 (21.9)	34 (11.4)	84 (34.7)	**<0.0001**
PTNS, *n* (%)	12 (2.4)	7 (2.4)	6 (2.5)	0.93
SNM, *n* (%)	70 (13.0)	33 (11.1)	37 (15.3)	0.15
PVR, median (range), mL	10 (0–180)	10 (0–180)	10 (0–175)	0.84
DO, *n* (%)	162 (30)	57 (19)	105 (43.4)	**<0.0001**

Data in bold indicate statistically significant. BMI=Body mass index, UTI=Urinary tract infection, PFPT=Pelvic floor physical therapy, PTNS=Percutaneous tibial nerve stimulation, SNM=Sacral neuromodulation, PVR=Postvoid residual, DO=Detrusor overactivity, OAB=Overactive bladder, UUI=Urge urinary incontinence, SD=Standard deviation, OR=Odds ratio

Table 2: Intraprocedure and postprocedure characteristics

Characteristics	Total (*n*=539)	Office (*n*=297)	OR (*n*=242)	*P*
Reason for OR				
Surgeon preference, *n* (%)			229 (94.6)	
Patient preference, *n* (%)			0	
Medical, *n* (%)			5 (2.1)	
Schedule, *n* (%)			8 (3.3)	
Local, *n* (%)			8 (3.3)	
MAC, *n* (%)			189 (78.1)	
General, *n* (%)			45 (18.6)	
Concomitant prolapse repair, *n* (%)			3 (1.2)	
Admission, *n* (%)			0	
100 U, *n* (%)	527 (97.8)	289 (97.3)	238 (98.3)	0.41
200 U, *n* (%)	9 (1.7)	7 (2.4)	2 (0.8)	0.15
Other doses, *n* (%)	3 (0.6)	1 (0.3)	2 (0.8)	0.45
Injection sites, median (range)	20 (5–30)	20 (5–30)	20 (10–20)	0.99
mL per site, median (range)	0.5 (0.5–2)	0.5 (0.5–2)	0.5 (0.5–1)	**<0.0001**
Retention, *n* (%)	30 (5.6)	24 (8.1)	6 (2.5)	**0.003**
PVR at diagnosis, median (range), mL	285 (175–1000)	282.2 (174–593)	287.5 (203–1000)	0.77
UTI, *n* (%)	113 (21.0)	50 (16.8)	63 (26.0)	**0.009**
Subjective improvement, *n* (%)	408 (77.0)	211 (73.3)	197 (81.4)	**0.03**
Second Botox, *n* (%)	300 (55.7)	183 (61.6)	117 (48.3)	**0.002**
Time to re-treatment, median (IQR), day	236 (168–392)	196 (154–287)	349 (208.5–535.5)	**<0.0001**
PTNS after, *n* (%)	4 (0.7)	2 (0.7)	2 (0.8)	0.33
SNM after, *n* (%)	48 (9.0)	23 (7.7)	25 (10.3)	0.75

Data in bold indicate statistically significant. MAC=Monitored anesthesia care, PVR=Postvoid residual, UTI=Urinary tract infection, PTNS=Percutaneous tibial nerve stimulation, SNM=Sacral neuromodulation, IQR=Interquartile range, OR=Odds ratio

with a higher number of patients in the OR group reporting an improvement (81.4% vs. 71.3%, $P = 0.03$). When potential confounders, which were determined *a priori* as variables most likely to affect the primary outcome, were controlled for, these findings remained significant [Table 3]. Larger number of patients in the in-office group returned for a second injection (61.6% vs. 41.3%, $P = 0.02$). A total of 48 patients eventually underwent sacral neuromodulator placement after their onabotulinumtoxinA with no difference between the two groups.

When looking specifically at the patients who had tried a SNM before their onabotulinumtoxinA injection, there was no difference in the reported subjective improvement between those patients who had never undergone a SNM and those who had. Also, there was no difference in postprocedure UTI or return for a second treatment. There was, however, a difference in the retention rates, as the patients with a previous SNM demonstrated higher rates of retention post onabotulinumtoxinA injection (11.4% vs. 4.7%, $P = 0.04$).

Table 3: Adjusted odds ratios for postprocedure outcomes

Characteristics	AOR	CI	*P*
Retention	0.1	0.03–0.3	**0.0001**
Postprocedure UTI	3.3	1.7–6.6	**0.0005**
Subjective improvement	2.9	1.5–5.7	**0.002**
Second Botox treatment	0.3	0.2–0.6	**<0.0001**

Data in bold indicate statistically significant. UTI=Urinary tract infection, CI=Confidence interval, AOR=Adjusted odds ratio

DISCUSSION

Intra-detrusor onabotulinumtoxinA injection is an effective treatment for OAB and UUI and can be performed as an outpatient procedure with minimal risk. Up until now, no study has evaluated the difference in the outcomes of patients who undergo the procedure in an in-office setting versus in an OR. We aimed to compare the subjective symptomatic improvement in patients presenting with OAB/UUI who underwent treatment with onabotulinumtoxinA injection in an in-office versus OR setting. We acknowledge that we found a large difference in the practice patterns and patient characteristics between the cohorts. This difference was not anticipated at the onset of the study, and we wish to be transparent in this acknowledgment and in the discussion of our findings. We found that overall, 77% of the patients reported an improvement in the symptoms and the rate of reported improvement was slightly higher in patients in the OR group. The patients who underwent the procedure in the OR were 3 times more likely to have a UTI but were 10 times less likely to have retention after the procedure.

As this study is first of its kind, there is a lack of available data to compare our outcomes with, however, several studies have reported on the outcomes following outpatient procedures performed in different settings. In the gynecologic literature, one systematic review and meta-analysis found no difference in the treatment success, adverse events, and patient satisfaction following hysteroscopy (including therapeutic interventions, such as polypectomy and hysteroscopic myomectomy) in the office compared to the OR.[12] Further, Munro *et al*., in an economic modelling study, found that the

in-office hysteroscopy was associated with reduced costs.[13] In the non-gynecologic literature, the question of setting for the procedures has also been evaluated, with some of the most robust data coming from the pulmonary and the otolaryngology literature.[14-17] Based on the previous studies in both gynecologic and non-gynecologic literature, it was reasonable to investigate the injection of intra-detrusor onabotulinumtoxinA in two settings, and like the prior studies, we also found that in-office onabotulinumtoxinA is as safe and effective as the in-OR injections. Our overall subjective improvement rate of 77% is consistent with the previously reported rates.[11]

In this study, the overall incidence of urinary retention was 5.6% and reflects what has already been published in the other studies reporting on the retention rates following onabotulinumtoxinA.[9,10] The ROSETTA trial was a multicenter randomized control trial that evaluated urge incontinence episodes after treatment with SNM or onabotulinumtoxinA. In this trial, the authors reported the post onabotulinumtoxinA retention rates of 8% and 2% at 1 and 6 months following the procedure. Our overall retention rate was 5.6%, which is consistent with these data, but of note, the ROSETTA used 200 U while a majority of our patients received 100 U. However, we did find a difference in the retention rate when we compared the two settings for onabotulinumtoxinA injection, and the retention rate (2.5%) in the OR group was much closer to the lower end of the rates reported in the ROSETTA trial, while the in-office rate (8.1%) was much closer to the upper limit reported in the trial. This finding is unexpected given the fact that anesthesia is also a risk factor for urinary retention,[17] and one might expect that the patients undergoing onabotulinumtoxinA in the OR may have a higher rate of post-procedural retention as a result of the anesthetic administered.

The majority of the providers performing in-office onabotulinumtoxinA administer a lidocaine bladder instillation prior to the procedure, as a part of the standardized care pathway. It is possible that compared to the OR cases, this instillation contributed to a higher rate of retention following onabotulinumtoxinA injection. It is also possible that the retention rates differed because of the provider preference regarding a predetermined "cutoff" for defining the retention and the need for catheterization. If the provider performing onabotulinumtoxinA in the OR had a higher threshold to define retention, it is possible that the rate of documented retention was lower. Conversely, if the in-office providers had a lower threshold, the in-office rate may have been higher. It is also possible that patients in the OR group received better pain management in the recovery which led to a lower incidence of retention,[18] but this would need to be evaluated in future. Nevertheless, the rate of retention in both the groups fell within the "expected" range of risk of retention after onabotulinumtoxinA, and while knowing this difference between the settings may help in counselling the patients prior to the procedure, it appears that both the settings are appropriate to perform onabotulinumtoxinA as far as the risk of urinary retention is concerned.

We also found a difference in the risk of post-procedural UTI. The published UTI rates after onabotulinumtoxinA have varied widely with rates reported up to 50%.[19] Our overall UTI incidence of 21% is well within this range and was below the 35% incidence found in the ROSETTA trial. However, we did find a significant difference between the two groups, with the OR group having a 3-fold higher rate compared to the in-office group. While the data on the incidence of UTI following gynecologic procedures performed in different settings is limited, the urology literature can provide some insight. One study by Doersch *et al*. looked at the outcomes of OR versus office-based ureteral stenting and found no difference in the UTI rate,[20] and another study also reported a similar UTI rate when comparing bladder biopsies performed in the office without antibiotics to those performed in the OR with antibiotics.[21] In our study, we found that the OR setting was associated with a higher rate of UTI. There can be several explanations for this. First, it is possible that the different antibiotic prophylaxis before the procedure as well as variability in the duration of the treatment (one-time dose vs. 3- or 5-day course) could have contributed to this difference, although a recent study from Martin *et al*. found that a multi-day antibiotic regimen had similar incidence of UTI as compared to a single day in patients undergoing in-office Botox injections.[22] Practice variability in empirically treating the symptoms suggestive of infection versus obtaining a urine culture could have also affected this outcome. Again, the overall UTI rate in this study is acceptable compared to the rates reported in the urogynecologic literature, and our reported differences may simply be attributed to provider practice patterns. Due to this, we are unable to make any recommendations regarding antibiotic prophylaxis in different settings.

To date, ours is the only study that compares outcomes including subjective improvement as well as urinary retention and UTI in patients undergoing intra-detrusor onabotulinumtoxinA injections in the in-office versus OR. The strengths of this study include our multicenter study design which allowed for a wide range of physicians including both Ob/Gyn and urology-trained urogynecologists as well as a variety of patient populations from both a tertiary medical center and a county-funded medical center. Both factors make our results more generalizable. Another strength of our study includes abstraction of the data from individual reliable EMR by designated co-investigators. A significant limitation of this study is its retrospective design which only allowed us to rely on the data available in our EMR. Our primary outcome was a subjective report from the patient,

and did not include a validated scale, and information and measurement biases are possible. This was mitigated by the reliability of the way the symptoms are documented in both the EMR systems but still should be acknowledged as a major limitation. Additionally, due to our study design, we were unable to stratify our post-operative retention and infection from being immediate versus farther out from the procedure, potentially limiting some of our conclusions. A final limitation, and perhaps the most important, is the one previously mentioned. While a multicenter study has many strengths, varying practice patterns between the institutions can be a major limitation as well. In our study, there was variability in some of the practices and inherent characteristics of the patient cohorts that could have affected our outcomes, and it was not possible to control for all of these factors. That said, our overall goal was to compare the patient improvement in two different settings, and we were able to determine that improvement was high across the entire cohort.

CONCLUSION

In this cohort study of patients with OAB undergoing intra-detrusor onabotulinumtoxinA injections, post-procedural subjective improvement was high regardless of the setting in which the procedure was performed. Patients undergoing injections in the OR reported higher subjective improvement and had less post-procedural urinary retention but were more likely to experience a UTI. Due to the retrospective nature of these data, one should interpret the post-procedure outcomes with caution, but in general, physicians can be reassured that either location of their procedure will result in an improved outcome for their patients.

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