Published in final edited form as:

Female Pelvic Med Reconstr Surg. 2021 February 01; 27(2): 121–125. doi:10.1097/SPV.0000000000000753.

Does a Recent Urinary Tract Infection Increase the Risk of Post-procedure Urinary Tract Infection after Onabotulinum Toxin A?

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Abstract

Objectives: To evaluate the risk of post-procedure urinary tract infection after injection of onabotulinumtoxin A in women who had a urinary tract infection within 30 days prior to procedure.

Methods: This was a retrospective cohort study of women who underwent their first injection of onabotulinumtoxin A from 2010 to 2016. Two cohorts were identified: 1) recent urinary tract infection (within 30 days prior to injection); and 2) no recent urinary tract infection. Our primary outcome was urinary tract infection within 90 days after onabotulinumtoxin A. Continuous variables were analyzed using the Wilcoxon rank sum test and categorical variables were analyzed using Fisher's exact or χ^2 tests.

Results: One hundred sixty-six women underwent their first onabotulinumtoxin A injection. Twenty-five (15%) had a recent urinary tract infection and 141 (85%) did not. Women with a recent urinary tract infection were more likely to have a subsequent infection (52% vs. 26%, $p < 0.01$). However, in a logistic regression model, controlling for history of recurrent urinary tract infection, age, history of diabetes mellitus, perioperative antibiotics, and urinary retention

requiring catheterization, the association between having a recent urinary tract infection and a subsequent urinary tract infection was no longer significant (adjusted OR 1.98; 95% CI = 0.60, 6.50; $p=0.26$).

Conclusions: Performing a first injection of onabotulinumtoxin A within 30 days of a urinary tract infection does not increase the odds of post-procedure urinary tract infection. Therefore, onabotulinumtoxin A therapy does not need to be delayed after a recent urinary tract infection.

Keywords

Urinary Tract Infections; onabotulinumtoxinA; Botulinum Toxins; Type A; Female

Introduction

Intra-detrusor injection of onabotulinum toxin A (BTX-A) is an effective treatment for refractory overactive bladder (OAB).¹⁻⁴ Urinary tract infection (UTI) is a common adverse event after BTX-A procedure. Randomized controlled trials report post-procedure UTI risk to be as high as 35% despite antibiotic prophylaxis.¹⁻⁴ Therefore, there is a need to identify modifiable risk factors to aid in decreasing the risk of UTI after BTX-A injection.

In general, there are known risk factors for UTI such as urinary tract anomalies, indwelling catheters, older age, diabetes mellitus, female gender, and elevated post void residual (PVR).⁵⁻⁹ Another risk factor is cystoscopy with manipulation, where the American Urologic Association recommends antibiotic prophylaxis. This recommendation is based on decreased risk of infection after transurethral resection of the prostate with prophylactic antibiotics which has been extrapolated to other procedures like BTX-A procedure.^{8,10} The BOTOX® product information and medication guide advises against injection at the time of an active bladder infection.¹¹

However, for women who have had a recent infection it is unclear if there should be a prolonged waiting period prior to injection. Preoperative UTI is a risk factor for postoperative infection after open and laparoscopic urologic procedures.^{9, 12, 13} We hypothesized that women with a recent UTI would have a higher risk of post-procedure UTI after BTX-A. Thus, we sought to determine whether UTI within 1 month of a BTX-A injection increases the risk of UTI after BTX-A injection.

Materials and Methods

After receiving institutional review board approval, a retrospective cohort study was performed of women who underwent first injection of BTX-A from January 1, 2010 through July 19, 2016 at one academic institution. We included all women 18 years or older undergoing their first BTX-A injection for either idiopathic OAB or neurogenic OAB regardless of dose. Data were only collected from the first injection; subsequent injections were not evaluated. We excluded those with prior bladder reconstructive surgery, planned suprapubic tube drainage, and history of bladder cancer. Two cohorts were compared: 1) recent UTI defined as a positive urine culture or UTI symptoms with antibiotic treatment within 30 days prior to injection of BTX-A; and 2) no recent UTI. This study population

included women with idiopathic OAB who were previously enrolled in two randomized controlled trials where data had been collected in a standard fashion.^{2, 3} Medical records were reviewed and data regarding demographics, medical history, and pre- and post-injection information were collected. The primary outcome was a clinical diagnosis of post-procedure UTI, defined as either symptoms of UTI with positive urine culture/urinalysis or empiric treatment for UTI symptoms, within 90 days after BTX-A injection. This definition was chosen as it closely aligns with a clinical referral-based practice.

Antibiotic prophylaxis was prescribed before and/or after injection according to physician's preference or study protocol (for patients enrolled in a randomized trial). Ciprofloxacin, nitrofurantoin, or sulfamethoxazole/trimethoprim were used as prophylaxis. Patients who were in a research study were screened for UTI on the day of injection and those with a positive urine dipstick as determined by the parent study protocol (urine dipstick resulting with positive nitrites and/or leukocytes 1+ or greater) were not injected and had their urine sent for culture. Patients who were not in a research study still underwent urinalysis, but the decision to proceed with the injection was at the discretion of their treating physician. In some instances, those with a suspicious urine dipstick were still injected. For these individuals, if the urine culture returned positive, they were considered to be in the recent UTI group. There was no predefined waiting period after UTI treatment before the injection procedure was performed in those with a recent UTI. Those with post void residual (PVR) volume > 300 ml regardless of symptoms or PVR > 150 ml plus the bothersome symptom of incomplete bladder emptying after injection were instructed to perform clean intermittent self catheterization (CISC). Patients enrolled in randomized clinical trials were routinely contacted by research staff to assess their symptoms post-procedure. Women receiving injections outside of clinical trials were instructed to call and report incomplete emptying symptoms as part of post-procedure standard clinical practice. Antibiotic prophylaxis during CISC was prescribed at the discretion of the treating physician.

Data were analyzed with SAS 9.4 (SAS Inc. Cary, NC). To compare the difference of each variable between recent and no recent UTI groups, Wilcoxon rank sum tests, Fisher's exact, or chi-square tests were used as appropriate. Multivariable logistic regression analysis was performed to test the effect of history of recent UTI on post-procedure UTI after BTX-A with adjustment of potential confounders. Known risk factors for UTI and significantly different baseline characteristics between our two cohorts were included as potential confounders. A subanalysis was performed in those with idiopathic OAB while excluding neurogenic OAB and patients who catheterized at baseline. In the sub-analysis, we also restricted our outcome to only those with symptomatic culture-proven UTI, based on the European Association of Urology guidelines for UTI diagnosis.

It was assumed that post-procedure UTI would be 15% in women without a recent UTI and a clinically significant difference between our two cohorts would be a threefold difference, or 45% experiencing UTI. Thus, using a 2:1 ratio of those without a recent UTI to those with a recent UTI, at least 75 women (50 without a recent UTI and 25 with a recent UTI) were needed to detect a difference between 15% and 45% UTI with a significance level of 0.05 and power of 80%.

Results

A total of 166 women underwent a first BTX-A injection during the study period (Figure 1). Median age was 66 [55, 73] years, 137 (83%) patients were white, median BMI was 30 [25, 35] kg/m². The majority of women, 104 (63%), received 100 units and 62 (37%) received 200 units. There were 25/166 (15%) with a recent UTI and 141/166 (85%) with no recent UTI. Women in the recent UTI cohort were more likely to have a history of recurrent UTI, to receive antibiotic prophylaxis prior to the injection, to perform catheterization at baseline, to have urinary retention requiring catheterization after injection, and have neurogenic OAB compared to women who did not have a recent UTI prior to BTX-A (Table 1). At baseline, 5 (3.5%) women without a recent UTI and 6 (24%) women with a recent UTI performed clean intermittent catheterization ($p<0.01$). After injection, 21 (14%) additional people without a recent UTI and 4 (16%) in the recent UTI group had to initiate CISC due to retention after BTX-A injection.

The twenty-five women with a recent UTI all had urine cultures performed. The pre-injection UTI organisms were: 15/25 (60%) *Escherichia coli*, 5/25 (20%) *Klebsiella pneumonia*, 2/25 (8%) *Proteus mirabilis*, 2/25 (8%) *Enterococcus faecalis*, and 1/25 (4%) *Staphylococcus aureus*.

Forty-nine (29.5%) women experienced a post-procedure UTI. Thirty-nine women were diagnosed with UTI by presence of symptoms with a positive urine culture while 10 were empirically treated based on symptoms only. *Escherichia coli* was the most common organism on urine culture and was present on 37% of positive post-procedure cultures. The other most common organisms were *Klebsiella pneumonia* (19%) and *Enterococcus faecalis* (19%).

In this study, the mean time from recent UTI diagnosis to injection was 6 days (median 3 days, [0, 6]). Eleven women had positive urine cultures from urine sent on the day of BTX-A injection. Of those women, all were treated with antibiotics after the urine culture returned. Of these, 4 did not have subsequent UTI, while 7 went on to have another infection.

When evaluating the primary outcome, women with a recent UTI were more likely to have a post-procedure UTI than those without a recent UTI (13/25 (52%) vs. 36/141 (26%), $p < 0.01$). However, in a logistic regression model controlling for age, history of recurrent UTI, history of diabetes mellitus, antibiotics prior to the procedure, and urinary retention requiring catheterization after BTX-A, the association between having a recent UTI and developing a post-procedure UTI was no longer significant (adjusted OR 1.98; 95% CI = 0.60, 6.50; $p=0.26$). Nevertheless, in the same model, age, history of recurrent UTI, diabetes mellitus, and urinary retention requiring catheterization after BTX-A were significantly associated with subsequent UTI (Table 2).

In the sub-analysis of women with idiopathic OAB, there were 138 women. As noted above, in this sub-analysis the outcome of UTI was defined as having symptomatic, culture-proven infection. There were 16/138 (12%) with a recent UTI and 122/138 (88%) with no recent UTI. Those in the recent UTI group were similar to those without a recent UTI except they

were more likely to have a history of recurrent UTI and received antibiotics prior to the procedure instead of only after the procedure (Table 3). In this population with idiopathic OAB, risk of post-procedure UTI was not significantly different in women with recent UTI compared to those without recent UTI (5/16 (31%) vs. 25/122 (21%), OR = 1.76; 95% CI = 0.56, 5.54; $p = 0.33$). In a logistic regression model controlling for age, history of recurrent UTI, history of diabetes mellitus, antibiotics prior to the procedure, and urinary retention requiring catheterization after BTX-A, the association between having a recent UTI and developing a post-injection UTI was also not significant (adjusted OR 1.94; 95% CI = 0.35, 10.8; $p=0.45$). However, in the same model, age, history of recurrent UTI, diabetes mellitus, antibiotics prior to procedure, and urinary retention requiring catheterization after BTX-A were significantly associated with subsequent UTI (Table 4).

Discussion

In this retrospective cohort study, a UTI within 30 days of BTX-A injection did not increase the risk of a post-procedure UTI (within the 90 days after injection) when controlling for potentially confounding variables. Variables associated with UTI after injection are also known risk factors for UTI, including age, history of recurrent UTI, diabetes mellitus, and urinary retention requiring catheterization after BTX-A, even when analyzing only those with idiopathic OAB.

The strengths of our study are the presence of detailed pre- and post-procedure data, along with medical comorbidity information that was obtained from the electronic medical record. Given that BTX-A injections were performed in both the urology and urogynecology clinics at our institution, we believe that our findings are generalizable to others who perform BTX-A injections.

Our study is limited by its retrospective design. Although all injections were performed at a single institution, there were practice pattern differences in periprocedural antibiotic usage and CISC implementation. However, we attempted to control for some of these potentially confounding variables by performing a logistic regression analysis. In addition, our data could have follow-up bias as women may have been treated outside of our institution for UTI. However, many local institutions including the two other major health systems in our region share reporting with our electronic medical record; thus, we believe this bias to be minimal.

Also, we do not believe that this potential bias would differentially affect one comparison group over another. Finally, our study is limited in that we were not able to ascertain if and when patients received antibiotics for other non-urologic clinical indications during the study period.

While many other studies have reported UTI as an adverse event after BTX-A therapy, few studies have evaluated a recent UTI as a risk for another UTI after the procedure. Leitner et al. examined asymptomatic bacteriuria as a risk for UTI after BTX-A for neurogenic detrusor overactivity (NDO) without antibiotic prophylaxis. In that study, post-procedure UTI was low (5% - 7%) and not significantly different based on presence or absence of

asymptomatic bacteriuria prior to BTX-A injection.¹⁴ The authors concluded that the use of peri-procedural antibiotic prophylaxis needs to be critically reconsidered. However, their study population is different from our study population in all subjects had the diagnosis of NDO, most subjects were male (62%), and the overall proportion of subjects diagnosed with post-injection UTI was substantially lower than those reported in most studies. Another study reported a decrease in UTI after BTX-A injection; however, the study population was again focused on NDO,¹⁵ and thus different than the population studied here. Given the differences in post-procedure UTI for NDO patients, we performed a sub-analysis to exclude neurogenic OAB patients. We also followed the European Association of Urology guidelines for UTI diagnostic criteria in the subanalysis since UTI definitions have been inconsistent among studies.¹⁶ Another group assessing men and women undergoing their first intravesical BTX-A injection for refractory idiopathic detrusor overactivity found that women were more likely to have a UTI after injection.¹⁷ However, as women are at higher risk for UTI at baseline, it is unclear whether recent UTIs (prior to injection) played an additional role in their study.

In our study, *Escherichia coli* was the most common organism to cause UTI before and after BTX-A. However, there were fewer *Escherichia coli* infections after BTX-A (37%) compared to before BTX-A (60%). Interestingly, the number of *Enterococcus faecalis* infections increased from 8% before BTX-A to 19% after BTX-A.

There are currently no recommendations regarding when to inject BTX-A after a recent UTI. Thus, the question of timing BTX-A injection in relation to a recent UTI is very clinically relevant. There were 25 women (15%) with a recent UTI in this study, and the mean time from recent UTI to injection was 6 days (median 3 days). As a recently treated UTI did not increase the risk for a post-injection UTI, it appears safe to schedule a BTX-A injection after UTI treatment with antibiotics without the need for a waiting period. In this study, 11 women were found to have a UTI on the day of injection. Of those women, 7 (64%) had a subsequent UTI after the procedure. This highlights the importance of ensuring the absence of UTI at the time of injection and considering pre-procedure urine culture for those at increased risk for UTI to allow for treatment prior to injection. Women found to have a UTI on the day of injection were included as part of the recent UTI group for the analysis. These women have an even higher risk of post-procedure UTI than others; even with their inclusion, the recent UTI group did not exhibit an increased risk of post-procedure UTI when controlling for confounding factors.

Of all the factors in our study that were associated with post-procedure UTI, the only modifiable risk factor is urinary retention requiring catheterization in those without a prior need to perform CISC. While post-procedure elevations in PVR continue to occur in 5% - 16%¹⁻⁴ of patients who receive BTX-A, the need for catheterization in these patients has been questioned. In the time period when our study was conducted, CISC was initiated when the PVR was greater than 300 ml or if patients were symptomatic with a PVR greater than 150 ml. Elevated PVR after BTX-A has not been shown to cause upper tract injury or increase UTI, but performing CISC does increase the risk of UTI.¹⁸ Thus, in the absence of irritative voiding symptoms, higher PVRs are now tolerated after BTX-A without initiating CISC,¹⁹ and surveillance is the treatment of choice in patients with low risk, asymptomatic

urinary retention.²⁰ By limiting initiation of CISC to those instances when it is really needed, UTI risk might be further modified in those undergoing BTX-A injection.

In multiple studies, the risk of UTI after BTX-A remains high regardless of dosage used^{1–4}. Our study indicates that most of the risk factors for UTI are non-modifiable. Adjunctive medications to minimize UTI such as vaginal estrogen, oral vitamin supplements, and probiotics have not been studied in the context of BTX-A injections. Since most associated factors for UTI are non-modifiable, identifying methods of minimizing UTI after BTX-A injection should be a goal of future research. Furthermore, it is important to have an informed discussion about UTI risk prior to BTX-A injection as age, history of recurrent UTI, diabetes mellitus, and urinary retention requiring catheterization increase the risks of post-procedure UTI.

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Figure 1.
Flow diagram of study patients
UTI, urinary tract infection
BTX-A, onabotulinum toxin A

Table 1.**Patient Demographics**

	No Recent UTI N=141	Recent UTI N=25	P value
Median Age (years)	66 [56, 73]	65 [55, 71]	0.74 ¹
Median BMI	30 [24,35]	31 [26, 34]	0.80 ¹
White Race	116 (82%)	21 (84%)	1.00 ²
History of Recurrent UTI	22 (16%)	15 (60%)	<0.01 ³
Diabetes Mellitus	25 (18%)	5 (20%)	0.79 ³
Charlson Comorbidity Index score	3.0 [2.0, 4.0]	3.0 [2.0, 4.0]	0.97 ¹
Baseline Post Void Residual (mL)	20.0 [10.0, 55.0]	40.0 [20.0, 60.0]	0.11 ¹
Neurogenic indication	19 (14%)	8 (32%)	0.02 ³
Antibiotic prophylaxis prior to procedure	54 (41%)	18 (78%)	<0.01 ³
Performs catheterization at baseline	5 (3.5%)	6 (24.0%)	<0.01 ²
Urinary retention after injection requiring catheterization	26 (18%)	10 (40%)	0.02 ³

Data are displayed as n (%) or median [Q1, Q3]

P values from:

¹Wilcoxon

²Fisher Exact

³Chi-Square

UTI, urinary tract infection

BMI, body mass index, kg/m²

mL, milliliter

Table 2.

Multivariable Logistic Regression

	Adjusted OR (95% CI)	P value
Recent UTI	1.98 (0.6, 6.5)	0.26
Age	1.05 (1.01, 1.09)	0.01
History of Recurrent UTI	3.34 (1.21, 9.21)	0.02
Diabetes	3.26 (1.18, 8.96)	0.02
Antibiotic prophylaxis prior to procedure	0.44 (0.18, 1.08)	0.07
Urinary retention after injection requiring catheterization	7.23 (2.57, 20.39)	<0.01

UTI, urinary tract infection

Table 3:

Patient demographics for the sub-analysis of Idiopathic Overactive Bladder

	No Recent UTI N=122	Recent UTI N=16	Total N = 138	P value
Median Age (years)	66.5 [56, 74]	69.5 [64.5, 74]	67 [56, 74]	0.63 ¹
Median BMI	30.6 [25, 35.2]	33.2 [28, 34.7]	30.7 [25.1, 35.2]	0.49 ¹
White Race	101 (83%)	16 (100%)	117 (85%)	0.13 ²
History of Recurrent UTI	15 (12%)	9 (56%)	24 (17%)	<0.01 ³
Diabetes Mellitus	24 (20%)	4 (25%)	28 (20%)	0.62 ³
Charlson Comorbidity Index score	3.0 [2.0, 4.0]	3.0 [3.0, 3.5]	3.0 [2.0, 4.0]	0.78
Baseline Post Void Residual (mL)	20.0 [5.0, 43.0]	40.0 [10.0, 52.0]	20.0 [10.0, 50.0]	0.38
Antibiotic prophylaxis prior to procedure	45 (39%)	11 (73%)	56 (43%)	0.01 ³
Urinary retention after injection requiring catheterization	21 (17%)	3 (19%)	24 (17%)	0.88 ³

Data are displayed as n (%) or median [Q1, Q3]

P values from:

¹Wilcoxon²Fisher Exact³Chi-Square

UTI, urinary tract infection

BMI, body mass index, kg/m²

mL, milliliter

Table 4.

Multivariable Logistic Regression for the sub-analysis of Idiopathic Overactive Bladder

	Adjusted OR (95% CI)	P value
Recent UTI	1.94 (0.35, 10.8)	0.45
Age	1.09 (1.02, 1.15)	0.006
History of Recurrent UTI	7.55 (1.88, 30.4)	0.005
Diabetes	4.97 (1.31, 18.9)	0.02
Antibiotic prophylaxis prior to procedure	0.07 (0.02, 0.34)	0.001
Urinary retention after injection requiring catheterization	21.6 (4.87, 95.4)	<0.0001

UTI, urinary tract infection