

Intradetrusor Botulinum Toxin Type A (BTX-A) for Treatment of OAB and NDO in Women: A Pilot Study of Modified Protocols



Steven Bernstein, MD

Affiliation

M Health Fairview
Fridley, MN, USA

Disclosures

Coloplast: physician
education

AbbVie: physician
education

Acknowledgment/Funding

Editorial and design services were provided by ClearView Medical Communications, LLC, and were funded by a grant from AbbVie. AbbVie had no role in the design or conduct of the research.

Background

- Approximately 15% of women in the United States suffer from overactive bladder (OAB)¹
- BTX-A treatment reduces incontinence and other symptoms of OAB and neurogenic detrusor overactivity (NDO) and improves patient quality of life²⁻⁴
- Challenges of BTX-A therapy include urinary tract infection (UTI), urinary retention, bleeding, and patient persistence with treatment
- The number of injection sites may adversely affect patient persistence and, therefore, the long-term efficacy of BTX-A therapy

Study Design

- Retrospective chart review of patients who underwent injection of BTX-A between January 2014 and September 2020 (proof-of-concept study)

Three study protocols were used for BTX-A treatment of OAB and NDO

20-site cohort

20 sites × 0.5 mL (100 U)
[standard protocol
for treating OAB¹]

3-site cohort

3 sites × 3.3 mL (100 U)
Injection sites:
**left, center, and right
posterior wall**

1-site cohort

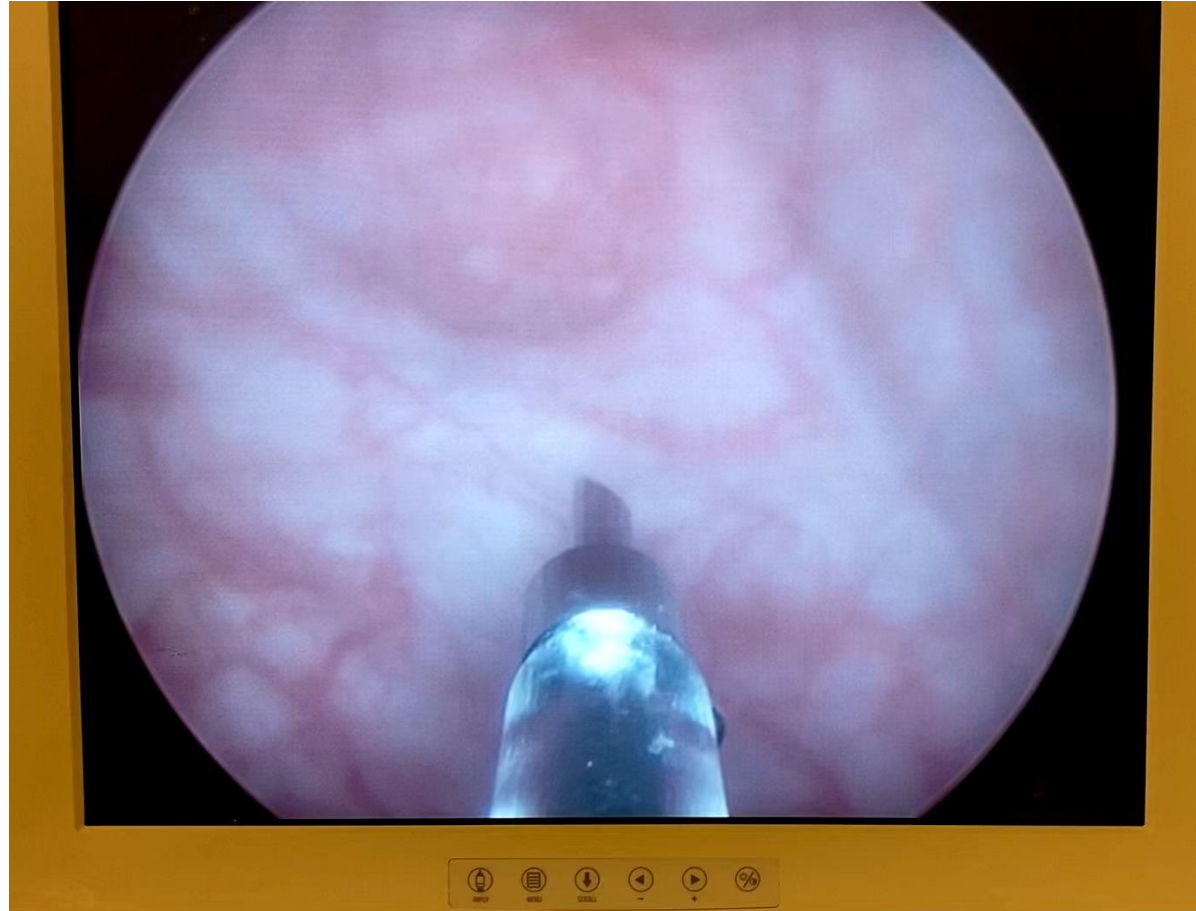
1 site × 6 mL (100 U)
Injection site:
mid posterior wall

- All patients were evaluated 2 weeks after treatment (response, PVR, UA)
- Retreatment was scheduled at 6-month intervals (adjusted if needed)

PVR, post-void residual; UA, urinalysis

1. BOTOX prescribing information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103000s5251lbl.pdf. Accessed 24 December 2020.

Video Demonstration: 1-Site Procedure



Primary Outcome Measures

Efficacy

- Success was defined as >50% improvement based on patient assessment
- Treatment interval

Safety

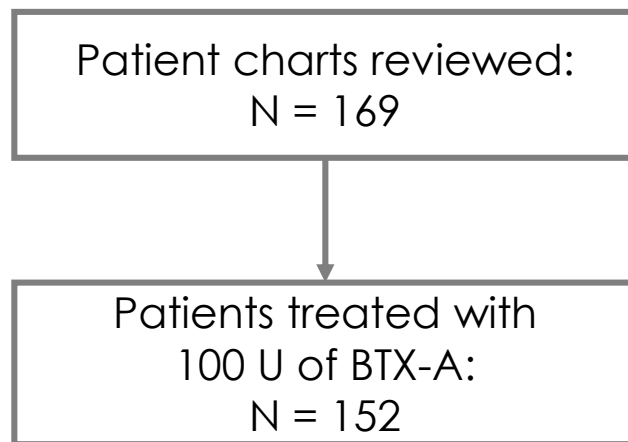
- Monitoring of adverse events
 - Urinary tract infections
 - Post-void residual volume
 - Clinically significant bleeding events

Outcomes were analyzed by number of injection sites

Patient Disposition and Background

- The study included all patients with OAB or NDO treated with 100 U of BTX-A at our center between January 2014 and September 2020

Patient disposition



Patient background

Background characteristic	Patients N = 152
Female, n (%)	152 (100)
Age, mean (SD)	64.0 (14.8)
Diagnosis, n (%)	
OAB	142 (93)
NDO	10 (7)

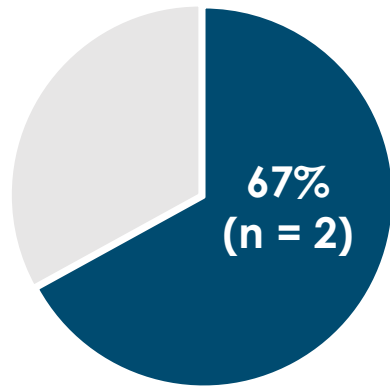
Efficacy and Treatment Interval

Parameter	20-site cohort (3 treatment sessions)	3-site cohort (320 treatment sessions)	1-site cohort (27 treatment sessions)
>50% improvement, n (%)	1 (33)	298 (93)	23 (85)
Treatment interval (month), mean \pm SD	—	6.8 \pm 0.2	7.3 \pm 0.4

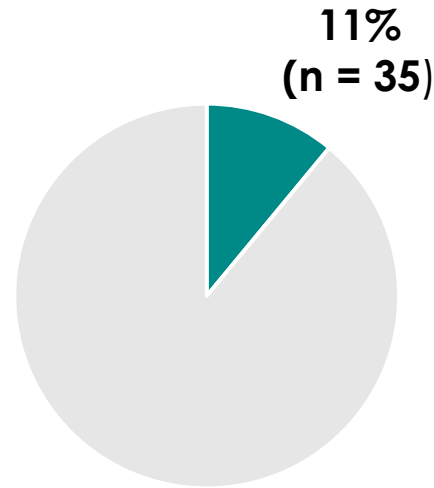
- Efficacy did not differ significantly between the modified-treatment cohorts
- Treatment interval was significantly longer in the 1-site cohort compared with the 3-site cohort ($P = .032$)
- There were no significant differences in efficacy or interval between the OAB and NDO groups

Safety

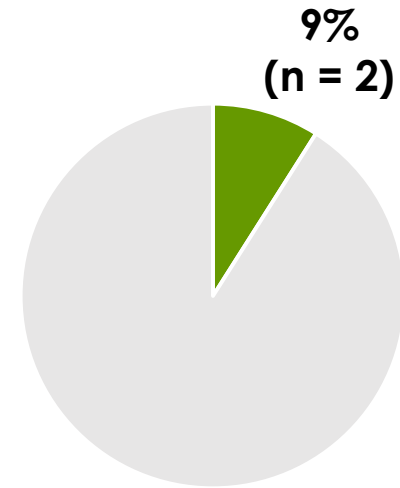
Urinary tract infections



20-site cohort
(treatment sessions, n = 3)



3-site cohort
(treatment sessions, n = 320)

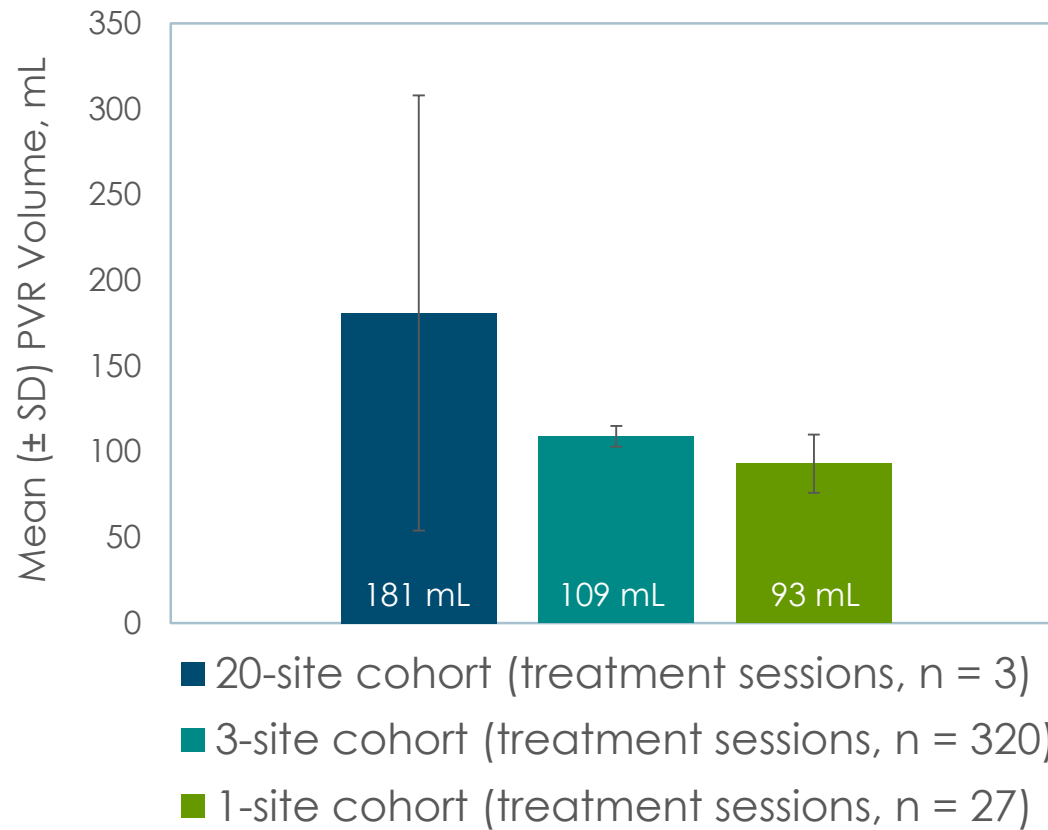


1-site cohort
(treatment sessions, n = 27)

Urinary tract infection was significantly associated with the number of injection sites ($P = .041$)

Safety [cont'd]

Post-void residual volume



Clinically significant bleeding

One patient in the 20-site cohort experienced bleeding that required catheterization and hospitalization

Conclusions

- Efficacy of BTX-A therapy was similar in the 3- and 1-site cohorts and compares favorably to that for 20-site protocols
- The UTI rate was significantly lower with fewer injection sites
- No clinically significant bleeding occurred among the 347 treatments with modified protocols
- Protocols with fewer than the standard 20 injections may improve patient persistence (fewer UTIs, lower risk of bleeding, less patient discomfort); this may improve the long-term efficacy of BTX-A treatment
- Adequately powered, randomized, controlled, multicenter studies are needed to further explore the potential benefits of modified BTX-A protocols for OAB and NDO