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Botulinum Toxin Type A (BOTOX) for Refractory Myofascial Pelvic Pain

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Abstract

Objective—To assess intralevator Botulinum toxin type A (Botox) injections for refractory myofascial pelvic pain with short tight pelvic floor.

Methods—Retrospective cohort study of all women with intralevator Botox injection (100-300 Units) from 2005 through 2010 for refractory myofascial pelvic pain. Primary outcomes were self-reported pain on palpation and symptom improvement. Secondary outcomes included post-injection complications and repeat injection. Pain was assessed during digital palpation of the pelvic floor muscles using a scale of 0-10, with 10 being the worst possible pain. Follow-up occurred at <6 weeks post-injection and again at 6 weeks. Data are presented as median (interquartile range) or proportion.

Results—Thirty-one patients met eligibility criteria; 2 were lost to follow up and excluded. Median age was 55.0 years (38.0-62.0). Before Botox injection, median pain score was 9.5 (8.0-10.0). Twenty-nine patients (93.5%) returned for the first follow-up visit; 79.3% reported improvement in pain, while 20.7% reported no improvement. Median pain with levator palpation was significantly lower than before injection ($P<0.0001$). Eighteen women (58.0%) had a second follow-up visit with a median pain score that remained lower than before injection ($P<0.0001$). Fifteen (51.7%) women elected to have repeat Botox injection; the median time to repeat injection was 4.0 (3.0-7.0) months. Three (10.3%) women developed de-novo urinary retention, 2 (6.9%) reported fecal incontinence and 3 (10.3%) reported constipation and/or rectal pain; all side effects resolved spontaneously.

Conclusions—Intralevator injection of Botox demonstrates effectiveness in women with refractory myofascial pelvic pain with few, self-limiting adverse effects.

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Keywords

BOTOX; Myofascial pelvic pain; Short tight pelvic floor

INTRODUCTION

Chronic pelvic pain has been estimated to affect approximately 15% of women ages 18-50 with significant impact on the quality of life and health care costs [1, 2]. Myofascial pain as a cause of chronic pelvic pain with or without other pelvic floor pathology is well reported in the literature and causes significant morbidity for affected women [1]. It is defined as a regional condition of muscle pain and tightness characterized by the presence of myofascial trigger points, which are clinically focal hypersensitive taut bands within the muscles with an associated referred pain pattern on palpation. In myofascial pelvic pain, these trigger points are distributed over the levator muscles of the pelvic floor. Pain arising from these trigger points is believed to result from an excessive release of acetylcholine and other neurogenic inflammatory substances from the neuromuscular junction after chronic muscle contraction [1].

Management of the myofascial component of chronic pelvic pain is multidisciplinary, and treatment strategies previously described include use of steroids, non steroidal anti-inflammatory drugs, muscle relaxants, antidepressants, neuromodulators, selective serotonin reuptake inhibitors, selective norepinephrine reuptake inhibitors, pelvic floor physical therapy/exercise and trigger point injection of various substances, including local anesthetic agents, steroids and Botulinum toxin (Botox, Allergan Inc. Irvine, CA) [3]. Botox is a potent neurotoxin produced by the bacterium *Clostridium botulinum*. Its mechanism of action involves blocking cholinergic transmission and acetylcholine release at the neuromuscular junction. This blockade causes reversible flaccid paralysis of the innervated muscle and has been shown to decrease pain associated with hypertonic muscles [2]. There are several subtypes of Botox, with types A and B currently used in clinical practice after FDA approval in 1989 and 2000, respectively [4].

Use of Botox has been reported to decrease pain and improve function in cervical dystonia, limb spasticity after cerebrovascular accident and headaches. Botox also has been used in treatment of urologic disorders such as detrusor sphincter dyssynergia and overactive bladder for over a decade [5].

Although the use of Botox is reported to improve pain symptoms from muscle spasm in other parts of the body, such as head, neck and back, there currently are few reports on the effectiveness of Botox injection to the pelvic floor muscle in the treatment of myofascial pelvic pain [2]. The increasing number of potential indications, wide variation of injected doses and injection techniques, as well as non-standardized methods and outcome measures, contribute to an incomplete understanding of the ideal candidates for Botox use in the pelvic floor. This highlights the need for more studies on the use of Botox for treatment of refractory myofascial pelvic pain in the setting of hypertonic pelvic floor. We aim to report our experience on the use of intralevator Botox in a cohort with myofascial pelvic pain that has been refractory to other treatments.

MATERIALS AND METHODS

After we obtained institutional review board approval, we reviewed a retrospective cohort of all women who had at least one intralevator injection of Botox (100-300 Units) at our institution from 2005 through 2010. Patients were identified using procedure code and a

query of the billing records and electronic medical record was performed. We abstracted patient demographic data such as age, body mass index, parity, race, menopausal status, sexual activity and prior gynecologic interventions, as well as the initial and post-treatment pelvic examination and patient-reported pain and improvement. For those who opted for injections in the hospital setting, we collected surgical characteristics including length of hospitalization, estimated blood loss, and concurrent procedures, such as cystoscopy and perineoplasty.

In order to be eligible for treatment with Botox women needed to have objective evidence of pelvic floor hypertonicity with palpable contracted, cord-like muscle fibers and tenderness by assessment of pelvic floor muscles on digital examination and to have been unresponsive to previous treatments, such as multiple pain medications, intensive pelvic floor physical therapy and prior neuromodulation. Examination was performed by one of five providers at every visit. The providers consist of two Urogynecology attendings and three Urogynecology fellows. During the pre-injection examination, patients were asked to verbally quantify tenderness on digital muscle palpation using a score of 0-10, with 0 being no tenderness with pelvic floor muscle palpation and 10 being the worst possible tenderness. Patients also were asked to categorize their pain as mild, moderate or severe on palpation. At the post-injection visits, patients were asked whether they generally felt that their pain was improved, the same or worsened and were again asked to quantify their tenderness on a scale of 0-10 on palpation. These were obtained directly from the chart documentation in addition to the documented patient report of overall symptoms improvement. The pain score from the post-injection visits was categorized in order to make comparisons with the pre-injection categorical pain rating. A value of 0 was considered to be an absence of pain; values of 1-3 were categorized as mild pain, while values of 4-6 and 7-10 were categorized as moderate and severe pain, respectively. Pelvic organ prolapse quantification and post-void residual were determined as part of the pre- and post-injection examinations. Patients had the option of undergoing the procedure in the operating room with conscious sedation or in the office with oral analgesics.

The procedure was performed with the patient in the lithotomy position. One hundred to three hundred units of Botox were diluted in preservative-free saline, to achieve 10 units per milliliter concentration. A standard pudendal block kit with trumpet guide that allows for a depth of 1cm needle penetration through vaginal mucosa into the muscle fibers was used for injection. The syringe is withdrawn before each injection to avoid intravascular injection. The dose ranges were chosen based on a published study of Botox treatment for intractable symptoms of neurogenic detrusor overactivity and pelvic pain syndromes [6] and consultation with each patient based on several factors, including the number of areas to be targeted, insurance coverage and the desire to minimize potential side effects.

Digital muscle palpation was used to locate tender and contracted points along major pelvic floor muscles that required injection. The index finger was used for palpation as the 20-gauge pudendal block needle with a trumpet guide was advanced to the target site piercing through the vaginal mucosa to the intended muscle groups. Several 1cc (10 units) injections per muscle group were performed. Some patients received 2-3cc (20-30Units) injected per muscle group depending on the number of units of Botox used (100-300 Units). Targeted muscles include the coccygeus, iliococcygeus, pubococcygeus, puborectalis, obturator and pyriformis muscles. Injection locations were individualized to findings on physical examination and patient-reported tenderness at each site. Intravaginal pressure was applied for a few minutes as required for hemostasis.

The primary outcome was patient-reported tenderness on levator palpation and patient-reported symptom improvement. Secondary outcomes included time to and number of

repeat injections and complications such as hematoma, estimated blood loss, de-novo urinary retention (post-void residual >100 cc), fecal incontinence, constipation and rectal pain.

Given the wide variation in the timing of patients returning to our clinic, the follow-up visits were stratified into two time periods: <6 weeks post-injection (visit 1) and ≥6 weeks post-injection (visit 2). We compared pain and other symptoms as reported by women before the Botox injection with patient-reported pain and symptoms at visit 1 and visit 2.

All statistical tests were performed using SAS 9.3 (SAS Institute Inc., Cary NC). All tests were two sided and p values <0.05 were considered statistically significant. Data are presented as median (interquartile range) or proportion. Paired data were compared with the Wilcoxon signed-rank test or McNemar's test.

RESULTS

Thirty-one patients met the study eligibility criteria; 2 were lost to follow up and excluded from the analysis. Baseline participant characteristics are presented in Table 1. The median age was 55.0 years (38.0-62.0) and the median body mass index was 25.1 kg/m² (24.0-30.6). The majority (86.2%) of women were Caucasian, and 65.5% were post menopausal. Dyspareunia was reported by all but one (92.3%) of the 13 sexually-active women, and urinary urgency and urinary incontinence were common symptoms. The majority (79.3%) had no pelvic organ prolapse on exam, and all women had undergone pelvic floor physical therapy evaluation and treatment. Before the Botox injection the median pain score reported from tenderness on digital palpation was 9.5 (8.0-10.0).

Seventeen women (58.6%) were given Botox injections in the office, and 12 women (41.4%) received injections in the operating room under conscious sedation. Concurrent cystoscopy was performed in 5 patients (16.1%) for varied indications, and one patient (3.2%) had concurrent perineoplasty to release a previous highly scarred repair. Estimated blood loss was less than 10cc for all injections. All women went home on the same day; none required post-operative narcotics.

Of the 29 patients who returned for visit 1, Majority (20 patients (68.9%)) received 300 Units of Botox injection (20patients (68.9%)), while 4 patients 13.8%, and 5 patients 17.3% had 100Units and 200Units initial injections respectively. All the women without an overall improvement in pelvic pain symptoms at the post injection visit received 300Units of Botox injection. All the patients that received 100 or 200 Units of Botox also had a decrease in pain score from tenderness with levator muscle palpation at this follow up visit. Patient-reported pain score at the time of levator palpation at this visit was missing in the medical record for two women (6.9%); one of these women reported that in general her pain was improved and one reported no change. Therefore, among all 29 women, 23 (79.3%) reported some improvement in pain symptoms, while 6 (20.7%) reported no improvement; there were no reports of worsened pain after the Botox injection.

For the 26 women with a documented pain score before and after the Botox injection, the median pain score with levator tenderness on palpation at visit 1 was significantly lower than the pre-injection pain score ($P<0.0001$). Before the injection, all 29 women reported either moderate (10.3%) or severe (89.7%) pain from levator tenderness on palpation. At visit 1, more than half of the women (51.7%) reported no pain on digital palpation of previously tender trigger points on the levator muscles and 6 (20.7%) patients had mild pain. Two (6.9%) patients, both of whom previously reported severe pain, had moderate pain at visit 1, while 4 (13.8%) patients continued to have severe pain upon digital palpation of the tender levator muscles. Two of these four patients with persistent severe pain received

Botox injection in the operating room while the other two patients had their Botox injection in the office. Of the two women for whom a pain score was missing at visit 1, one reported moderate pain before the Botox injection and one previously reported severe pain. The prevalence of self-reported urinary incontinence reported decreased significantly from 41.4% before the injection to 13.8% at visit 1 ($p = 0.008$) [Table 2].

Eighteen (62.1%) women returned for visit 2 and had a median pain score of 3.0 (0.0-6.0), which remained lower than the pre-injection rating ($P < 0.0001$). Of these women, 66.7% reported overall improvement in pain symptoms. While 7 (38.9%) had no pain upon digital palpation of previously tender levator trigger points, 4 (22.2%) had mild pain, 3 (16.7%) had moderate pain and 4 (22.2%) had severe pain. The prevalence of self-reported urinary incontinence was lower at visit 2 than before the Botox injection ($p = 0.03$) [Table 2].

Fifteen (51.7%) of the 29 women in our cohort elected to have repeat Botox injections with a median of 1.0 (1.0-2.0) repeat injection. The median time from initial to repeat treatment was 4.0 (3.0-7.0) months. Two of the patients that reported no improvement at visit 1 and visit 2 opted to have a second injection at 3 months and 7 months after the initial injection. The remaining thirteen women that elected to undergo repeat Botox injections initially reported improvement in pain after the injection with a range of 2 to 30 months between their initial injection and the repeat injection.

Compared to baseline, the median post-void residual was higher at visits 1 and 2, but the differences were not statistically significant (both $P > 0.05$). A total of four patients met criteria for urinary retention with PVR > 100 cc after Botox injection. All four patients received 300Units of Botox injection. One of the four patients had urinary retention requiring intermittent self catheterization that preceded the Botox injection. Three of the women with de novo urinary retention required intermittent self catheterization with PVR volumes ranging from 150cc to 550cc; their urinary retention subsequently resolved at the 12 week post injection office visit. Two women (6.9%) reported fecal incontinence at visit 1 with complete resolution at 7 and 20 weeks. Both women also received 300Units of Botox injection each. Three (10.3%) women reported significant constipation and/or rectal pain after injections. These symptoms resolved by visit 2. There were no serious adverse events reported [Table 3].

DISCUSSION

Botox has been used to treat a variety of pain conditions, including focal dystonia, spasticity, myofascial pain syndrome and headaches [6]. Our objective was to evaluate the use of Botox for myofascial pelvic pain that had been refractory to other treatments. Our findings suggest that intralevator injection of Botox is at least moderately effective in women with refractory myofascial pelvic pain as evidenced by a significant decrease in patient-reported pain following Botox injection for the majority of women in our study. More than half of the patients in our study elected to have a repeat Botox injection as a result of the improvement they experienced with previous injections.

Our findings are consistent with a randomized, placebo controlled study evaluating the efficacy of Botox injection to the pelvic floor muscle in patients with chronic pelvic pain and with evidence of pelvic floor muscle spasm. This study reported a reduction in resting tension and pelvic floor muscle pressure that translated to a reduction in non menstrual pelvic pain and dyspareunia in patients injected with Botox compared to the placebo group [7]. Other studies also have reported significant improvement in patient-reported pain, quality of life and oral pain medication use for 8 to 14 weeks following Botox injections in patients with vaginismus and vestibulodynia [8-9].

Although the etiology of chronic pelvic pain is not well understood and is usually multifactorial, the management of the myofascial component can be advantageous for women with chronic pelvic pain. Jarvis et al showed evidence that Botox injection into the pelvic floor muscles resulted in a 37% reduction in resting pressure at 4 weeks and a 25% reduction maintained at 12 weeks after Botox injection, the resulting pelvic floor relaxation was reported as a factor for reducing pain sensation [2]. This same mechanical effect of Botox-induced muscle relaxation was seen in women with outlet obstruction due to failure of relaxation, or paradoxical contraction of the puborectalis muscle. Constipation and anismus improved in up to 50% of patients with long-term treatment success [10]. There also is evidence suggesting that treatment directed at the pelvic floor may improve symptoms, especially in patients with painful bladder syndrome [11-12]. Our study further supports the use of intralevator injection of Botox as a treatment option for women with refractory myofascial pelvic pain.

The use of Botox injection to the pelvic floor in our patient population resulted in only minimal and reversible side effects, such as transient de novo urinary retention, fecal incontinence, constipation and rectal pain, all of which resolved spontaneously. There were no serious long-term non-reversible adverse events reported in our study. Following injection directly into the palpated trigger points of the pelvic floor muscles, patients with refractory myofascial pelvic pain symptoms had significant reduction in their pain severity both by report and on pain scale during physical examination by digital palpation. We also found a decrease in patient-reported urinary incontinence at both post-injection visits. Although the direct effect of Botox injection to the pelvic floor on bladder function has not been studied, its use in refractory overactive bladder via injection to the bladder detrusor has been shown to be efficacious. While we cannot specify the mechanism by which Botox may improve urinary incontinence symptoms, this finding may be the result of pelvic floor relaxation and decrease in pain that can affect an irritative voiding pattern. Similarly, while it is not fully understood why injection into the levator muscle will elicit side effect of urinary retention, we observed that all the patients with urinary retention after the injection all received a higher dose (300Units) of Botox. We can also hypothesize the potential of spread after the injection of Botox into adjacent tissue including bladder detrusor which may contribute to the resulting findings of urinary retention. Although more studies will be needed in order to establish this as a potential mechanism for the urinary retention.

Our study describes one clinic's experience with intralevator Botox injection to treat a condition for which there is limited published research and has several limitations, including its relatively small sample size and retrospective design. Due to the retrospective design, the dosing and injection sites were not standardized, there was inconsistency in the timing of follow-up visits and pain data was missing for two women. In addition, we were unable to standardize the palpation technique for the myofascial trigger points. Although clinicians made an effort to be consistent in the pressure applied during the examination, the amount of pressure could have influenced patient-reported pain. We did not use a scoring system for diagnosing hypertonicity as other studies have done with the use of muscle manometry. Our general clinical approach to objective assessment of the pelvic floor muscles involves palpation for muscle attenuation or thinning as well as palpation for muscle fibers contraction and tight cord-like bands. In this retrospective study, although we did not have a scoring system for hypertonicity, it will be a consideration for future prospectively designed study with measurable effect of Botox on actual muscle tonicity. Given referral patterns to our practice it also is likely that this population of women had more advanced pathology, as evidenced by the fact that they all had prior evaluation and treatment, including pelvic floor physical therapy.

There does not appear to be a direct dose response correlation of the dose of Botox used and the pain improvement in our retrospective review. Majority of the patients received 300Units of Botox injection. Majority of the patients that received highest Botox Dose (300Units) reported improvement in post injection tenderness to digital palpation which was also evident in all the patients that receive 100 and 200Units. All the women without an overall improvement in pelvic pain symptoms and tenderness to digital palpation at the post injection visit received 300Units of Botox injection.

Our general practice approach to Botox injection is to offer the option of injection in the office or the operating room. Patients generally decide on their preference and are generally based on their ability to tolerate office pelvic examination. Other factors that are considered include the need for concomitant procedures that are not office based procedures. In our retrospective review, we found that equal number of patients in the office injection group and the operating room group continued to report severe pain at their post Botox injection follow up visit. When patients are able to tolerate the injections in the office, the same approach to injection is used and the same muscle groups are targeted.

In conclusion, our results demonstrate a significant decrease in patient-reported pain after Botox injection to the pelvic floor in our population with chronic myofascial pelvic pain. As this condition has both physical and psychological components, care of these women requires a multidisciplinary approach to both diagnosis and management. In patients who have failed conservative treatment approaches the use of intralevator Botox injection may be an effective option with minimal to no long-term adverse effects. Randomized trials using placebo comparisons are needed to fully assess the effectiveness of Botox for the treatment of chronic myofascial pelvic pain and to evaluate long-term outcomes, treatment side effects and potential long-term risks.

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Table 1

Baseline participant characteristics

Characteristic	n=29
Age (years)	55.0 (38.0-62.0)
Body mass index (kg/m ²)	25.1 (24.0-30.6)
Parity	2.0 (0.0-2.0)
Race	
Caucasian	25 (86.2)
Other	4 (13.8)
Tobacco use	5 (17.2)
Sexually active	13 (44.8)
Post-menopausal	19 (65.5)
Any prior gynecologic surgery	20 (69.0)
Pelvic organ prolapse quantification	
Stage 0	23 (79.3)
Stage 1	1 (3.5)
Stage 2	4 (13.8)
Stage 3	1 (3.5)
Levator pain score	
None	0 (0)
Mild (1-3)	0 (0)
Moderate (4-6)	3 (10.3)
Severe (7-10)	26 (89.7)
Post void residual (cc)	10.0 (0.0-30.0)
Urinary urgency	18 (62.1)
Dyspareunia *	12 (92.3)
Anesthesia	
None	17 (58.6)
Conscious sedation	12 (41.4)

Data are reported as median (interquartile range) or n (%)

* Dyspareunia reported in 12 of the 13 sexually active patients

Table 2

Comparison of pain and symptoms before and after Botox injection

	Pre-Botox compared with visit 1 (n=29)			Pre-Botox compared with visit 2 (n=18)		
	Pre-Botox	Visit 1	P	Pre-Botox	Visit 2	P
Weeks post injection	-	2.0 (2.0-3.0)			8.0 (6.0-9.0)	
Pain score	9.5 (8.0-10.0)	0.0 (0.0-3.0)	<0.0001 *	9.5 (8.0-10.0)	3.0 (0.0-6.0)	<0.0001
Pain category			<0.0001			0.002
None	0 (0.0)	15 (51.7)		0 (0.0)	7 (38.9)	
Mild	0 (0.0)	6 (20.7)		0 (0.0)	4 (22.2)	
Moderate	3 (10.3)	2 (6.9)		1 (5.6)	3 (16.7)	
Severe	26 (89.7)	4 (13.8)		17 (94.4)	4 (22.2)	
Missing	0 (0.0)	2 (6.9)		0 (0.0)	0 (0.0)	
Post-void residual	10 (0.0-30.0)	15 (0.0-68.0)	0.053	7.5 (0.0-32.0)	16.5 (3.0-62.0)	0.056
Urine retention	1 (3.5)	4 (13.8)	0.38	1 (5.6)	4 (22.2)	0.38
Urinary incontinence	12 (41.4)	4 (13.8)	0.008	8 (44.4)	2 (11.1)	0.03
Fecal incontinence	0 (0.0)	2 (6.9)	-	0 (0.0)	1 (5.6)	-

Data are presented as median (interquartile range) or n (%)

* Comparison is for 26 women who had a pain score before the injection and at visit 1.

Table 3

Summary of Findings in All 29 patients presenting for follow up.

Patient	Age	Botox Dose (Units)	Pain Score (Pre-Botox)	Pain Score (Visit #1 Post-Botox)	Pain Score (Visit #2 Post-Botox)	Injection Location	Repeat Botox	Complications
1	29	300	10	0	0	OR	Yes	-
2	61	300	10	5	2	OR	Yes	-
3	59	300	9	3	0	Office	No	Urine Retention*
4	30	300	9	3	3	OR	Yes	-
5	54	300	9	-	-	Office	No	-
6	39	300	9	9	9	OR	No	-
7	44	300	10	9	9	OR	No	Urine Retention
8	19	100	10	0	0	OR	Yes	-
9	58	100	9	0	0	Office	Yes	-
10	25	300	8	0	0	OR	No	-
11	42	200	10	4	4	Office	Yes	-
12	48	200	10	2	-	OR	No	-
13	57	100	9	3	3	Office	Yes	Fecal Incontinence
14	80	300	10	-	-	OR	No	Constipation
15	36	200	7	0	3	OR	Yes	-
16	55	200	9	0	-	OR	No	-
17	73	300	6	0	-	Office	Yes	Urine Retention
18	63	200	8	3	-	Office	No	-
19	65	300	10	2	0	OR	Yes	-
20	44	300	10	0	-	Office	Yes	-
21	37	300	6	0	0	Office	Yes	Urine Retention
22	67	100	10	0	0	Office	No	-
23	56	300	10	0	6	Office	No	Fecal Incontinence, Rectal Pain, Constipation
24	62	300	10	7	7	Office	Yes	-
25	60	300	7	0	-	Office	No	Rectal Pain, Constipation
26	30	300	8	8	8	Office	Yes	-
27	77	300	10	0	-	Office	No	-
28	69	300	9	0	-	Office	No	-
29	38	300	10	0	-	Office	Yes	-

OR – Operating Room

* Patient had pre injection urinary retention requiring intermittent self catheterization