

# Video-urodynamic Improvement of Trigonal BTX-A Injection for Patients with Poor Bladder Compliance Secondary to Spinal Cord Injury

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**Abstract Objective:** To evaluate video-urodynamic improvement for trigonal BTX-A injection in patients with neurological poor bladder compliance. **Methods:** 68 consecutive inpatients with poor bladder compliance secondary to spinal cord injury (SCI) received trigonal injections of BTX-A (300U) into the bladder from June 2014 to February 2017. All were evaluated video-urodynamic outcome included detrusor leak point pressure (DLPP), bladder compliance (BC) and vesicoureteral reflux (VUR) at baseline and 12 weeks post-injection. **Results:** all outcomes improved significantly compared to baseline. The improvement percentage of DLPP (44.36%) and BC (77.13%). No patient developed unilateral or bilateral VUR. **Conclusions:** Trigone-including BTX-A injection is safe and effective as the treatment for low BC and does not induce VUR.

**Keywords:** video-urodynamic, bladder trigone, botulinum toxin A, low bladder compliance, spinal cord injury

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## 1. Introduction

Detrusor leak point pressure (DLPP) is characterized by the lowest value of detrusor pressure at which leakage is observed in the absence of abdominal strain or detrusor contraction [1]. Sustained DLPP is the most important risk factor for the function of upper urinary tract in patients with neuro-urological disorders, such as stroke, brain diseases and chronic spinal cord injury (SCI) [2]. Therefore, keeping the DLPP within safe limits has become a primary treatment goal for SCI patients [3].

Botulinum toxin A (Botox<sup>®</sup>, Allergan, Irvine, Calif.) is recommended as the second-line treatment for those patients who have an inadequate response to or are intolerant to anticholinergic medication [4,5]. In the past ten years, intradetrusor injection of BTX-A was performed while avoiding the trigone to prevent VUR. To our knowledge, several studies reported satisfactory clinical results about combined detrusor-trigone BTX-A injections [6-12]. However, most of these studies were small and single-center experience. Therefore, encouraged by our satisfactory clinical effects, we performed this study to evaluate the efficacy and safety of combined detrusor-trigone BTX-A injections for patients with poor bladder compliance secondary to spinal cord injury (SCI).

## 2. Materials and Methods

Consecutive SCI inpatients with poor bladder compliance (<20 ml/cmH<sub>2</sub>O) [1] were recruited in this trial from June 2014 to February 2017. Inserted A 23 gauge approximately 2 mm into the detrusor under local anesthesia or epidural anesthesia in the operating room. 300 U Botox<sup>®</sup> vials (100 U each) were reconstituted in a total of 30 ml sterile saline. Administer 24 injection sites into the bladder wall while 6 sites into the bladder trigone sparing a 5mm distance to the vicinity of the ureteral orifices and the bladder neck (Figure 1). A16 Foley catheter had been inserted for 3-5 days after injection. The outcomes were the changes in the videourodynamic test evaluated at baseline, and at 12 weeks after injection: (1) incidence of vesicoureteral reflux (VUR); (2) detrusor leak point pressure (DLPP); (3) bladder compliance (BC). The related adverse events were collected. The study was approved by the ethics committees and patients provided written informed consent before injection.

Pair Student's t-test was used for comparison of DLPP, BC and results are presented as means ± standard deviation. The chi-square test was used for categorical data. A P value of 0.05 or less was considered statistically significant. Statistical analyses were performed with SPSS 13.0 software (SPSS, Inc., Chicago, IL).

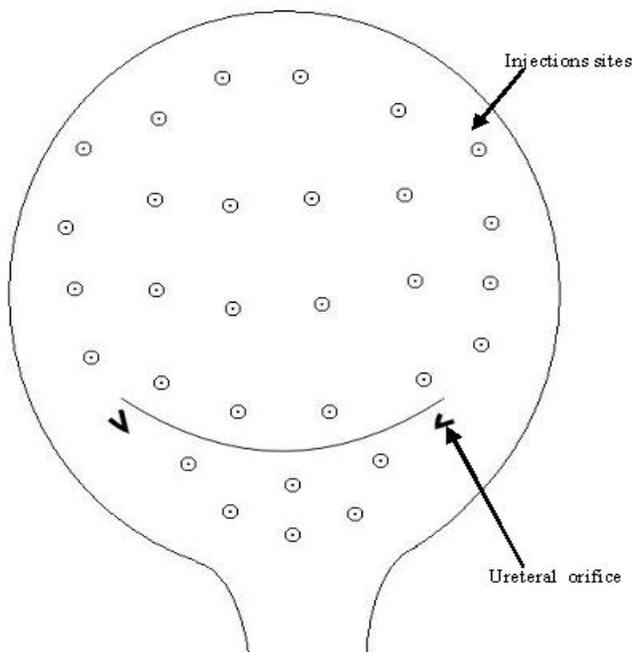


Figure 1. Location of BTX-A injection

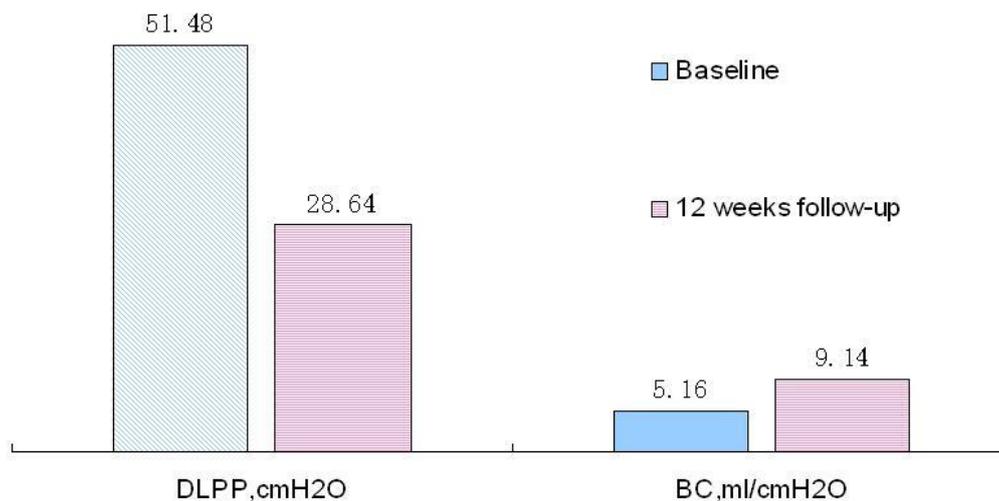


Figure 2. Videourodynamic parameters of patients at baseline and 12 weeks follow-up

## 4. Discussion

Our study demonstrates that trigonal BTX-A injection does not induce VUR during the 12 week follow-up after injection. We also noticed our results similar to the preview studies [6-12]. One study found that not one of their 24 adults with OAB refractory to anticholinergic treatment who received trigoneinjection of BTX-A developed VUR during at 6-month follow-up [6]. A similar result was obtained in 10 women 6 weeks after treatment [7]. Interestingly, Kuo [8] found that the degree of renal hydronephrosis decreased with treatment in four of the five patients with baseline hydronephrosis after injection. Another study [9] also confirmed the safety of trigone injections of BTX-A in terms of development of VUR because the only patient in their series with VUR previous to theinjection had it cured after BTX-A injection. Trigonal BTX-Ainjection has been proven effective in adults with neurological or non-neurological disorders.

## 3. Results

A total of 68 inpatients (55 male and 13 female) were enrolled in this trail. Patients' mean age, mean weight, duration of injury were 38.81y, 50.24kg, 10.19months, respectively. 59 patients were AIS grade A, and other 9 AIS grade B (Table 1).

Table 1. Baseline characteristics of the participants

Characteristic	Number of patients (N = 41)
Age, yr, mean (SD)	30.81 (16.59)
Gender, men, n (%)	55 (80.88)
Weight, kg, mean (SD)	51.24 (20.66)
Duration of injury, months, mean (SD)	10.19 (9.17)
AIS grade, A/B, n	59/9

AIS= the American social injury association.

No patient developed unilateral or bilateral VUR at week 12. Compared the baseline data, significant difference were present by week 12 for DLPP (51.48 cmH<sub>2</sub>O vs. 28.64 cm H<sub>2</sub>O, P < 0.001) and BC (5.16ml/cmH<sub>2</sub>O vs. 9.14 ml/cm H<sub>2</sub>O, P <0.001) (Figure 2). None of patients reported adverse events, such as nausea, vomiting, weakness in the respiratory.

According to the guideline, keeping the DLPP within lower limits has become a primary treatment goal for Low BC [3]. The present trial reports significant improvements in these parameters were evident with the 300-U dose of BTX-A injection. It is reported that abundant sensory nerve fibers are particularly dense in bladder trigone, and smooth muscle of bladder trigone is sensitive to small pressure changes [24]. According to these studies, combined detrusor trigone BTX-A injections may help desensitize the bladder and thereby help to decrease detrusor pressure.

No patients developed systemic or significant adverse events of treatment in this trial.

A limitation of this study is that number of patients was relatively fewer. Therefore, further studies are warranted.

## 5. Conclusions

Trigone-including BTX-A injection is safe and effective as the treatment for low BC and does not induce VUR.

## Acknowledgments

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## Conflict of Interest Statement

The authors declare no conflict of interest.

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