



Original Article

Improvement in autonomic dysreflexia after detrusor onabotulinumtoxinA injections in patients with chronic spinal cord injuries

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ABSTRACT

Objectives: To investigate the therapeutic effects of repeated detrusor onabotulinumtoxinA (BoNT-A) injections on autonomic dysreflexia (AD) in patients with chronic spinal cord injuries (SCI).

Materials and Methods: A total of 49 patients with SCI were enrolled to receive two sets of 200 U BoNT-A injections into the detrusor at baseline and 6 months later. The primary end points were improvement in the severity of AD and net change in the grade of incontinence. Secondary end points included net changes in the scores of the Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire, and quality of life index as well as urodynamic parameters.

Results: A total of 31 men and 18 women with cervical ($n = 27$) or thoracic ($n = 22$) SCI were enrolled. They had a mean age of 41.6 years and duration of injury of 8 years. Fifteen patients did not have AD at baseline or after treatment. AD was completely resolved in three patients, and improved in 18; treatment made no difference in three patients and AD was exacerbated in 10. There were no significant differences in any urodynamic variables between patients with and without AD. A significantly greater improvement in the UDI-6 was noted in patients without AD and those in whom AD improved than in those with AD. The occurrence of AD was also not significantly associated with persistent urinary incontinence after the BoNT-A injections. There was no significant difference in the quality of life index between patients with and without AD at the end point.

Conclusion: Detrusor BoNT-A injections improved AD in 62% of SCI patients with AD at baseline.

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1. Introduction

Autonomic dysreflexia (AD) is a potentially life-threatening condition. AD occurs most often in individuals with spinal cord injuries (SCI) above the T6 level [1]. It is characterized by severe paroxysmal hypertension (episodic high blood pressure) associated with throbbing headaches, profuse sweating, nasal stuffiness, flushing of the skin above the level of the lesion, bradycardia, and apprehension and anxiety, which is sometimes accompanied by cognitive impairment [2]. Patients with chronic SCI may develop AD during bladder overdistention, stool impaction, or urinary tract infection (UTI).

Studies have shown that onabotulinumtoxinA (BoNT-A) injected into the detrusor can restore urinary continence, lower the rate of UTI, decrease intravesical pressure, and increase bladder compliance in up to 80% of SCI patients [3,4]. Although repeated injections of botulinum toxin A are necessary to achieve the desired effects, most patients tolerate the procedure in exchange for a better quality of life (QoL) [5]. Repeated injections restore renal function or halt renal deterioration in patients with SCI [6].

BoNT-A has been proven to be effective for the treatment of neurogenic detrusor overactivity (NDO) [7]. BoNT-A is one of the most powerful neurotoxins; it inhibits the release of neurotransmitters from the nerve fibers and urothelium [8,9]. BoNT-A also has an antinociceptive effect on the bladder wall. The current literature also suggests that noxious (painful) stimuli are the primary initiators of AD [10,11]. In previous studies, some patients with SCI and detrusor sphincter dyssynergia (DSD) reported resolution or improvement of AD after urethral or detrusor BoNT-A injections [10,11]. However, other patients reported exacerbation or occurrence of AD after BoNT-A injections. No previous study appears to

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have investigated the association of AD and detrusor BoNT-A injection.

In this study, we investigated the therapeutic effects of repeated detrusor BoNT-A injections on urinary incontinence and AD in patients with chronic SCI. We also investigated whether any factors could predict the resolution or exacerbation of AD after BoNT-A injections.

2. Materials and methods

Forty-nine patients with SCI and DSD were consecutively enrolled in this prospective study and received two sets of 200 U BoNT-A injections into the detrusor muscle at baseline and 6 months later. Patients were then monitored for therapeutic efficacy of the injections, which was evaluated by urinary incontinence and an increase in bladder capacity. The effects of BoNT-A on AD were also assessed at baseline and after repeat injection 6 months later.

All patients were aged 18 years or older and had a history of chronic suprasacral SCI for 1 year or more. For all patients, the diagnosis of DSD was made based on video urodynamic studies. In addition, all patients voided by reflex or abdominal stimulation with or without clean intermittent catheterization, were free of indwelling catheters and cystostomy, and were free of UTI on enrollment. All patients had been treated with antimuscarinic agents for at least 1 year, which had failed to resolve the urinary incontinence. Exclusion criteria included detrusor underactivity and large bladder compliance, proven intrinsic sphincteric deficiency, Grade 2 or higher vesicoureteral reflux, and hypersensitivity to BoNT-A or any type of botulinum toxin.

During the screening period and at each visit after BoNT-A injection, patients were asked to report AD symptoms such as hypertension, sweating, erythema in the upper extremities, headaches, and blurred vision during the last 3 months prior to the end point. The severity of AD was also classified as mild, moderate, or severe if the AD symptoms occurred occasionally, often, or frequently, respectively.

This study was approved by the Institutional Review Board and Ethics Committee of Tzu Chi General Hospital. Informed consent was obtained before screening and all patients were informed about the possible complications related to BoNT-A injections.

BoNT-A injection was performed in the operating room under light intravenous general anesthesia. A total of 200 U of BoNT-A (Allergan Co., Irvine, CA, USA) dissolved in 20 mL of normal saline was injected into 40 sites in the detrusor muscle including the lateral and posterior walls and the dome, sparing the trigone. The injection sites were widely distributed to cover the whole bladder wall. A 14F Foley catheter was routinely inserted after the BoNT-A injections, and patients were discharged with catheter removal the next morning and monitored in the outpatient clinic thereafter. All patients were instructed to continue clean intermittent catheterization or abdominal stimulation to empty their bladders. BoNT-A injections were repeated 6 months later. Before each subsequent set of BoNT-A injections, video urodynamic studies were performed, during which AD was evaluated at full bladder or when patients had a bladder reflex to void.

After BoNT-A injection, antimuscarinic agents were discontinued. Patients were monitored every 3 months for 12 months to gauge improvements in urinary incontinence and AD. The urogenital distress inventory (UDI-6) and the incontinence impact questionnaire (IIQ-7) [12] were used to assess incontinence distress and the impact of urinary incontinence on daily life, respectively. In addition, we extracted the three incontinence related scores (urgency, stress, and insensible incontinence) from the UDI-6 to score the overall incontinence grade. QoL was also evaluated using the QoL index (QoL-I) self-assessment adapted from the International Prostatic

Table 1

The changes of autonomic dysreflexia in patients with spinal cord injury at baseline and after onabotulinumtoxinA injections.

	Male SCI	Female SCI	Total
No AD	10 (32.3%)	5 (27.8%)	15 (30.6%)
Complete resolution of AD	3 (9.7%)	0 (0.0%)	3 (6.1%)
Improvement of AD >50%	8 (25.8%)	7 (38.9%)	15 (30.6%)
Improvement of AD >25%	2 (6.5%)	1 (5.6%)	3 (6.1%)
No change of AD	2 (6.5%)	1 (5.6%)	3 (6.1%)
Exacerbation of AD	6 (19.4%)	4 (22.2%)	10 (20.4%)

AD = autonomic dysreflexia; SCI = spinal cord injury.

Symptom Score [13]. The patient perception of bladder condition questionnaire, a patient-reported measure of bladder condition, was used to assess patient satisfaction with the global treatment outcome. Patient satisfaction was based on an improvement in the patient perception of bladder condition by two or more points after the second set of BoNT-A injections [14].

There were two primary end points: (1) improvement in the severity of AD from baseline to 12 months, and (2) net change in the grade of incontinence from baseline to 12 months. Secondary end points included net changes in the scores of the UDI-6, IIQ-7, and QoL-I, as well as the changes in urodynamic parameters including cystometric bladder capacity, voiding detrusor pressure at maximum flow rate (Q_{max}), postvoid residual volume, and bladder compliance from baseline to 12 months.

All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

3. Results

A total of 31 men and 18 women with cervical ($n = 27$) or thoracic ($n = 22$) SCI were enrolled. They ranged in age from 22 years to 74 years (mean, 41.6 years) and the duration of injury ranged from 1 year to 35 years (mean, 8.0 years). At baseline, AD was reported in 34 patients (21 men and 13 women). After two sets of BoNT-A injections, AD was reported in 31 patients (18 men and 13 women). There was no significant difference in the occurrence of AD between the cervical and thoracic levels or between genders.

Analysis of AD at baseline and after BoNT-A injections revealed that 15 patients did not have AD at baseline or after treatment. Complete resolution of AD was noted in three patients, improvement in AD was noted in 18, and no difference in AD was found in three patients, while exacerbation of AD occurred in 10 patients (Table 1). The main symptoms of AD in these patients at baseline and after BoNT-A injections are listed in Table 2.

Comparison of urodynamic parameters at baseline and after BoNT-A injections showed no significant difference in any urodynamic variable between patients with and without AD, except that patients with AD had a significantly lower Q_{max} and larger postvoid residual volumes (Table 3) than patients without AD. There were no significant differences in the changes in urodynamic

Table 2

The main symptom of autonomic dysreflexia at baseline and after onabotulinumtoxinA injections.

	Baseline	Post-treatment
Increase extremity reflex	8	9
Hypertension	5	4
Sweating	9	13
Flushing or erythema	4	2
Headache	6	3
Blurred vision	2	0

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