

PREDICTIVE FACTORS OF SATISFACTORY RESPONSE TO DETRUSOR BOTULINUM TOXIN A INJECTION FOR NEUROGENIC DETRUSOR OVERACTIVITY AND DETRUSOR SPHINCTER DYSSYNERGIA IN SPINAL CORD INJURED PATIENTS

Hypothesis / aims of study

Currently, there is no clear consensus about the optimal use of this innovative treatment in clinical practice. There was no study investigating patients' demographic factors and the influence on the therapeutic results after detrusor BoNT-A injection in spinal cord injury (SCI) patients. The purpose of this study was to investigate the predictive factors affecting therapeutic results of detrusor BoNT-A treatment in SCI patients with neurogenic detrusor overactivity (NDO).

Study design, materials and methods

A total of 38 patients with chronic suprasacral SCI were enrolled for detrusor BoNT-A injections to treat urinary incontinence. All patients underwent videourodynamic studies before enrollment and all patients were proven to have urodynamic DO with or without DSD. DSD was diagnosed as the presence of increased urethral sphincter activity at uninhibited detrusor contractions or during the voiding phase. Detrusor BoNT-A injection was recommended mainly to increase the bladder capacity, decrease detrusor pressure and improve urinary incontinence in these patients. The institutional review board and ethics committee of our hospital approved this study. All patients provided informed consent before BoNT-A injection.

The patients' perceptions of lower urinary tract dysfunction were assessed using the validated Urogenital Distress Inventory 6-item short form (UDI-6) questionnaire and QOL index [7]. The UDI-6 was scored at baseline, 3 and 6 months after BoNT-A injection and the changes from baseline were assessed. The urodynamic parameters at baseline, 3 and 6 months after treatment were also compared to demonstrate the urodynamic effects of BoNT-A. In addition to UDI-6, the treatment outcomes were also assessed by the changes of the detrusor pressure at maximum flow rate (PdetQmax). Patients who had a reduction of QOL index by ≥ 2 were considered responders, otherwise, the treatment was considered to have failed.

The baseline clinical data including age, gender, level and completeness of injury, DSD grade, bladder compliance, detrusor pressure at maximal flow rate (PdetQmax) and post-void residual (PVR) were used for analyzing the predictive factors of satisfactory response. The treatment outcomes were assessed by the changes of UDI-6 and PdetQmax. Satisfactory response was defined as having a reduction of QOL score by ≥ 2 .

Results

A total of 38 patients (21 women and 17 men) with a mean age of 40.1 ± 12.4 years (ranged 20 to 72) and median duration of SCI of 10.3 years (range 1-35) were enrolled. Satisfactory response was reported in 26 (68.4%) patients. Significant improvements in the UDI-6 and QOL were reported and significant increase of cystometric bladder capacity and PVR were noted at 3 and 6 months after treatment. The PdetQmax was significantly decreased at 3 months but returned to baseline at 6 months. Patients with different clinical demographics and urodynamic parameters showed similar treatment outcome and UDI-6 scores. A baseline higher PdetQmax were correlated with more reduction of PdetQmax after treatment. In 11 patients receiving repeat 300U BoNT-A injection after failure from prior 200U injection, no significant difference of outcomes was noted between 200 and 300U.

Interpretation of results

The results of this study show that 68.4% of SCI patients had satisfactory response to detrusor BoNT-A injection for their lower urinary tract dysfunction. The urodynamic parameters improved significantly and UDI-6 scores also improved up to 6 months after detrusor BoNT-A injection. The only factor that can predict a greater reduction of detrusor pressure after BoNT-A injection is the baseline Pdet.Qmax.

The results of this study revealed that SCI patients with different type of DSD had similar therapeutic results. The age, gender, and ASIA subtype do not affect the BoNT-A treatment outcome. Because the target of treatment aimed at decrease of the incontinence degree, patients usually can accept the increased PVR and need of CIC.

Concluding message

A total of 68.4% of patients with SCI and DSD had satisfactory response to detrusor BoNT-A injection. A baseline higher PdetQmax predicts a greater reduction of detrusor pressure after BoNT-A injection, however, not affecting the improvement of UDI-6. No other factor with good correlation to the treatment results was noted.

Table 1. Changes in urodynamic parameters and quality of life indexes in patients with detrusor BoNT-A injection

	Qmax(ml/s)	PVR(ml)	CBC(ml)	PdetQmax (cmH ₂ O)	UDI-6	QOL
Baseline	5.2±5.7	138±102	214±115	40.7±21.3	11.3±3.65	4.47±1.37
3 M	3.3±4.7	293±203	375±177	26.1±17.2	7.72±4.01	2.31±1.23
6 M	2.0±2.9	263±183	306±186	29.4±25.5	8.46±4.29	2.89±1.49
<i>P</i> value						
Baseline vs 3 M	0.049	0.000	0.000	0.001	0.000	0.000
Baseline vs 6 M	0.004	0.000	0.006	0.064	0.001	0.000

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Institution Review Board of Tzu Chi General Hospital and Tzu Chi University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes