

## DIFFERENCE OF THE THERAPEUTIC EFFECT BETWEEN REPEATED DETRUSOR INJECTIONS OF 200 U AND 300 U BOTULINUM TOXIN A ON GLOMERULAR FILTRATION RATE IN CHRONIC SPINAL CORD INJURED PATIENTS

### Hypothesis / aims of study

To compare the difference of glomerular filtration rate (GFR) and the change of videourodynamic characteristics between the spinal cord injured (SCI) patients who received repeated detrusor botulinum toxin A (Botox) 200 U and 300 U.

### Study design, materials and methods

Sixty-eight patients with SCI and neurogenic detrusor overactivity (NDO) were enrolled in this study. The diagnosis of NDO was proved by videourodynamic study, and they were excluded if they suffered from urinary tract infection (UTI), urinary tract cancer, and other lower urinary tract disorders, such as benign prostate obstruction, urethral stricture, or intrinsic sphincter deficiency (ISD), etc. They were randomly divided into 2 subgroups receiving detrusor Botox injection of 200U and 300U Botox, respectively. The study period was 12 months. The detrusor Botox injection was performed at baseline and 6 months, and the procedure was performed by injection cystoscope under anesthesia. Before the procedure, videourodynamic study and renal DTPA scan for GFR were performed to evaluate vesicourethral function and renal function in every patient. The primary endpoint was 12 months after the first injection. The urodynamic parameters and GFR recorded at each time-point were compared between the SCI patients who received repeated detrusor Botox 200U and 300U injections.

### Results

A total of 68 patients were enrolled in this study, including 41 male and 27 female patients. Thirty-eight patients received detrusor Botox 200 U injection and 30 received Botox 300 U injections. The mean age was 41.8 years old and the mean injury duration was 8.8 years. At the end of the study, 47 patients completed the study, including 27 in 200 U group and 20 in 300U group. Seven and 6 patients drop out from the study because they could not follow the protocol and they thought the treatment is inefficient, respectively. The voiding parameters, including cystometric bladder capacity (CBC), detrusor pressure (Pdet), maximum flow rate (Qmax), postvoid residual urine (PVR) and quality of life index (QoL-I) changed significantly after treatment. There was no significant change of bladder compliance and voided volume. Overall, the GFR was 90.3±20.7 ml/min at baseline and 90.3±27.5 ml/min at the end of study ( $p>0.05$ ). When comparing the differences of voiding parameters and GFR between those patients receiving detrusor Botox 200 U and 300 U injections, there was no significant difference in the change of voiding parameters between the 2 groups (Table 1). At the end of the study, no significant difference of GFR between the two subgroups (90.5±24.2 ml/min in 200 U group, and 90.0±31.6 ml/min in 300 U group,  $p>0.05$ ) In addition, we also categorized the patients according to the injury duration in both groups. The GFR level also showed no significant difference between subgroups (Fig. 1).

### Interpretation of results

This study revealed detrusor Botox injection improved the urodynamics parameters and QoL in SCI patients either in 200 U or 300 U repeated Botox injections. There was no significant difference between the change of renal function at baseline and 12 months after Botox treatment in these 2 subgroups. When comparing the renal function according to the injury duration and therapeutic dosage, slightly improved renal function was noted in 300 U group no matter how long the injury duration was. In contrast, the renal function exacerbated in those SCI patients for more than 10 years who received Botox 200 U injections.

### Concluding message

Regardless of the injection dosage, repeated detrusor Botox injections maintained the renal function in SCI patients and improved the QoL after treatment.

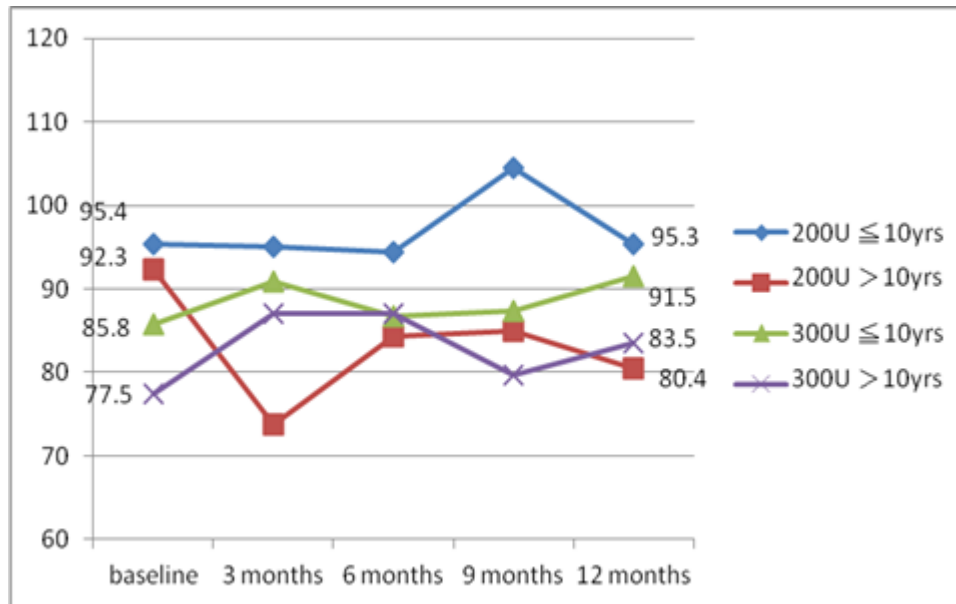
Table1. Voiding parameters, QoL index and GFR level in patients received intravesical Botox 200 U and 300 U injection

UDS parameters	Time-point	200 U	300 U
CBC (ml)	baseline	213.5±114.8	308.3±169.9
	12 months	376.9±179.7*	430.1±123.7*
Pdet (cmH <sub>2</sub> O)	baseline	40.7±21.3	36.2±23.0
	12 months	23.1±17.6*	11.9±18.8*
Qmax (ml/s)	baseline	5.18±5.69	4.47±4.78
	12 months	2.00±4.01*	3.40±10.1
Volume (ml)	baseline	75.7±97.8	80.3±98.1
	12 months	31.1±61.7*	50.1±138.0

PVR (ml)	baseline	137.8±101.6	228.0±137.1
	12 months	345.8±194.5*	380.0±163.6*
Compliance	baseline	26.9±26.8	45.9±55.0
	12 months	31.8±27.1*	25.4±16.4
QoL-I	baseline	4.51±1.37	4.17±1.24
	12 months	2.29±1.49*	2.45±1.21*
GFR	baseline	96.3±2.25	88.1±17.9
	12 months	90.5±24.2	90.0±31.6

\*:  $p < 0.05$

Fig. 1. Change of GFR level of SCI patients with different injury duration and different doses.



Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Buddhist Tzu Chi General Hospital Research Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes