

EFFECT OF REPEAT BOTULINUM TOXIN A DETRUSOR INJECTION ON DETRUSOR OVERACTIVITY AND RENAL FUNCTION IN CHRONIC SPINAL CORD INJURED PATIENTS

Hypothesis / aims of study

Spinal cord injury (SCI) results in neurogenic voiding dysfunction and urinary symptoms. In patients with chronic suprasacral cord injury, detrusor sphincter dyssynergia (DSD) may increase intravesical pressure, cause urinary incontinence and large postvoid residual (PVR). Botulinum toxin A (BTX-A) has been shown effective in treating urinary incontinence and improve quality of life in SCI patients. This study investigated the role of repeat intravesical botulinum toxin A (BTX-A) injections on restoration of urinary continence and improvement of renal function in chronic SCI patients

Study design, materials and methods

A total of 38 patients with chronic suprasacral SCI were enrolled. All patients received videourodynamic study and ^{99m}Tc-DTPA renal scanning for glomerular filtration rate (GFR) during the screening period. Intravesical BTX-A (BOTOX) 200U injected to 40 sites of the bladder were performed every 6 months (at baseline, 6 months, 12 months and 18 months) and lasting for 2 years. Patients were kept on their present voiding management during the follow-up period. Repeat videourodynamic study and GFR test every 6 months were performed for therapeutic results. Quality of life measurement by UDI-6 and IIQ-7 and self-assessed QoL index (0-6) and the adverse events such as urinary tract infection, hematuria, difficult urination were also recorded. There were two primary end-points: (1) the net change of the bladder capacity from baseline to 24 months, and (2) the net change of the GFR from baseline to 24 months. Secondary end-point efficacy measured the net change of the cystometric bladder capacity, bladder compliance, detrusor pressure during reflex voiding, end-filling pressure or detrusor leak-point pressure and postvoid residual volume from baseline to 24 months.

Results

Among 38 patients (age 22 to 71 years), 27 completed four BTX-A injections. The mean bladder capacity increased from 207.14±111 ml at baseline to 306.39±186 ml at 6 months, 376.90±180 ml at 12 months, 371.58±131 ml at 18 months, and 424.77±165 ml at 24 months (all P<0.05). The detrusor pressure (Pdet) reduced from 39.86±21.68 at baseline to 18.77±16.83 cmH₂O at 24 months (all p<0.05). The bladder capacity increased and Pdet decreased significantly with increasing BTX-A injection number. (Fig.1.) The IIQ-7 and QoL-I all showed significantly improved after repeated BTX-A injections, but the changes were similar with increasing injection number. The GFR showed no significant change after follow-up for 24 months. After four injections, the patients could remain in an improved condition lasting for 12 to 24 months. All 27 patients were satisfactory to this treatment and wished to continue BTX-A injection when the incontinence symptoms returned.

Interpretation of results

The goals of bladder management in chronic SCI patients are intended to: (1) ensure social continence, (2) low-pressure storage and efficient bladder emptying at low detrusor pressure, (3) avoid overdistention of the bladder, (4) prevent upper urinary tract complications from high intravesical pressure, and (5) prevent urinary tract infection. This study has shown that repeat intravesical BTX-A injections can increase bladder capacity, decrease detrusor pressure, improve quality of life and preserve normal renal function for patients with chronic SCI. Repeat BTX-A injections every 6 months can also last the effective therapeutic duration for more than 12 months after cessation of treatment.

Concluding message

The results of this study showed that repeat intravesical BTX-A injections can increase bladder capacity, decrease intravesical pressure, reduce incontinence grade and preserve renal function in chronic SCI patients who have intractable urinary incontinence.

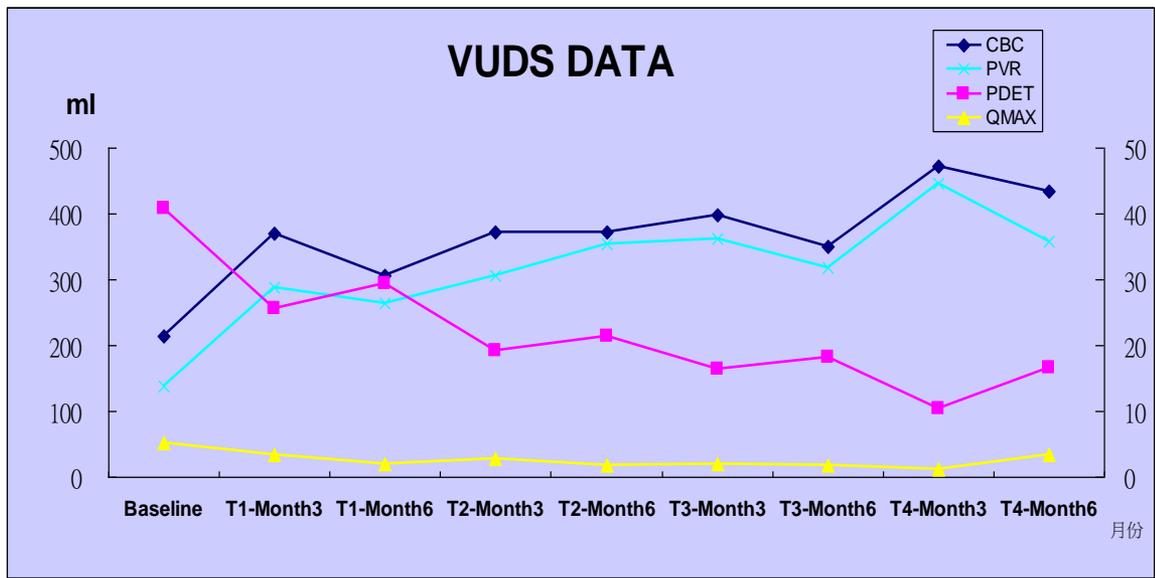


Fig.1. The changes of cystometric bladder capacity (CBC), detrusor pressure Pdet) postvoid residual (PVR) and maximum flow rate (Qmax) after repeat intravesical BTX-A injections in SCI patients.

Specify source of funding or grant	Buddhist Tzu Chi General Hospital Research Grant
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Review Board of Tzu Chi General Hospital and Tzu Chi University
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes