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COMPARATIVE STUDY OF INTRAVESICAL ONABOTULINUMTOXINA INJECTION FOR INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME – BLADDER BODY VERSUS TRIGONAL INJECTION

Hypothesis / aims of study
Intravesical onabotulinumtoxinA (BoNT-A) injection can relieve the symptoms of interstitial cystitis/bladder pain syndrome (IC/BPS). However, the therapeutic efficacy of different injection sites is not well known. In this clinical trial, we compared the therapeutic efficacy and the changes of urodynamic study between bladder body and trigonal BoNT-A injection.

Study design, materials and methods
We conducted a prospective randomized clinical trial of bladder body versus trigonal BoNT-A injection for patients with refractory IC/BPS. Under sedation, 100 U of BoNT-A in 10ml saline were injected into 20 bladder body sites or 10 trigonal sites. We evaluated the patients at 4th week and 8th week after the injection. The primary endpoint of this study was the changes of Visual Analog Scale (VAS) for Pain, at the 8th week after the injection. Secondary endpoint included the changes of Global Response Assessment (GRA), urinary frequency, O'Leary-Sant score and Problem Index (ICSI, ICPI, OSS), quality of life index (QoL-I), and urodynamic study at the 8th week after the injection.

Results
Twenty patients (bladder body, N=10; trigone, N=10) with refractory IC/BPS was included in this study. Patients in both group had significant improvement in VAS, ICSI, ICPI, OSS and FBC (functional bladder capacity) after the injection. The changes of ICSI (9.5±4.7 vs 5.7±4.3, p= 0.043) and OSS (18.6±8.6 vs 11.3±5.9, p= 0.047) at 8th week after the injection had significant difference between two groups, which trigonal injection had more improvement. There was no significant difference in the changed of urinary frequency (day/night), voiding volume, post-void residual volume (PVR) and cystometric bladder capacity (CBC) from baseline to second month after BoNT-A injection at either bladder body or trigone (Table 1). Seventy percent (N=7) patients in bladder body group and 50% (N=5) patients in trigone group had decrease of VAS more than 2 points after the injection. Twenty percent (N=2) patients who received bladder body injection and 40% (N=4) patients who received trigonal injection had excellent improvement of the symptoms (GRA≥2) (Table 2). The adverse effects showed no significant difference between two groups (Table 3). However, there was more patients experience dysuria after the treatment in the bladder body group.

Interpretation of results
Compared the primary and secondary endpoints between two group, most of the urodynamic parameters showed no significant difference.

Concluding message
Bladder body and trigonal BoNT-A injection had similar therapeutic effect and adverse effects on relieving IC/BPS symptoms.

Table 1. Changes of measured parameters after treatment

	Bladder (N=10)	Trigone (N=10)	P value
Age	54.8±8.7	51.9±13.1	0.512
MBC	830.8±138.7	688.2±178.1	0.028
Glomerulations	1.4±0.7	1.9±0.8	0.122
ICSI-B	13.4±3.7	11.3±4.2	0.043*
ICSI-1M	9.3±6.1	7.0±3.6	
ICSI-2M	9.5±4.7	5.7±4.3	
ICPI-B	12.6±2.9	10.9±3.5	0.084
ICPI-1M	7.1±5.4	7.0±4.1	
ICPI-2M	9.1±4.7	5.7±3.4	
OSS-B	26.0±6.2	22.2±7.1	0.047*
OSS-1M	16.4±11.0	14.0±7.3	
OSS-2M	18.6±8.6	11.3±5.9	
VAS-B	6.2±1.4	5.7±1.6	0.276
VAS-1M	3.1±2.7	3.2±1.6	
VAS-2M	3.7±1.8	2.8±1.9	
FBC-B	160.0±111.5	194.0±124.3	0.602
FBC-1M	242.2±77.9	276.0±161.1	
FBC-2M	278.2±155.9	316.7±167.6	
Frequency-B	17.3±11.3	13.8±6.5	0.844
Frequeycn-1M	13.7±8.8	12.6±6.6	
Frequeycy-2M	12.3±7.8	11.7±5.2	
Nocturia-B	3.9±1.5	3.6±1.1	0.064
Nocturia-1M	2.9±1.8	2.7±0.8	
Nocturia-2M	3.5±1.3	2.3±1.2	
Qmax-B	14.0±10.6	11.8±5.3	0.328
Qmax-1M	16.9±6.2	14.1±9.8	
Qmax-2M	13.3±8.4	20.2±8.7	
Volume-B	228.3±136.1	269.5±163.0	0.359
Volume-1M	239.9±64.6	234.8±210.6	
Volume-2M	195.4±115.3	326.8±229.5	
PVR-B	88.8±93.7	28.7±54.9	0.204
PVR-1M	114.4±141.4	35.2±50.5	
PVR-2M	84.9±81.0	30.4±27.5	
CBC-B	317.0±146.3	251.8±143.7	0.656
CBC-1M	354.3±146.3	228.2±243.5	
CBC-2M	280.3±110.8	357.2±246.2	
GRA-B	0	0	0.262
GRA-1M	1.0±1.1	1.0±0.9	
GRA-2M	0.8±0.9	1.3±1.1	

*** Significant difference between group, p< 0.05**

Table 2. The changes of VAS and GRA after treatment

	Bladder (N=10)	Trigone (N=10)	P value
VAS ≥ 2	7 (70%)	5 (50%)	0.085
VAS < 2	3 (30%)	5 (50%)	
GRA ≥ 2	2 (20%)	4 (40%)	0.264
GRA < 2	8 (80%)	6 (60%)	

Table 3. Adverse effects

	Bladder (N=10)	Trigone (N=10)	P value
None	1 (10%)	5 (50%)	0.293
Urinary tract infection (UTI)	0	1 (10%)	
Dysuria	9 (90%)	4 (40%)	
UTI and Dysuria	0	0	

Disclosures

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