

## ADVERSE EVENTS OF INTRAVESICAL ONABOTULINUMTOXINA INJECTION BETWEEN PATIENTS WITH OVERACTIVE BLADDER AND INTERSTITIAL CYSTITIS – DIFFERENT MECHANISM OF ACTION OF BOTOX ON BLADDER DYSFUNCTION

### Hypothesis / aims of study

Intravesical onabotulinumtoxinA (BoNT-A) injection has been proposed to treat both overactive bladder (OAB) and interstitial cystitis/bladder pain syndrome (IC/BPS) in patients with refractory conditions. We compared adverse events (AEs) after BoNT-A treatment between IC/BPS and OAB in women.

### Study design, materials and methods

IC/BPS patients who failed conventional treatments were enrolled to receive suburothelial injection of BoNT-A (100 U) followed by hydrodistention. Age matched OAB female patients refractory to antimuscarinic agents underwent BoNT-A (100 U) injection. The bladder capacity, maximum flow rate (Q<sub>max</sub>), post-void residual (PVR), and voiding efficiency (VE) at baseline, 3 and 6 months, and the post-treatment AEs were analyzed between groups.

### Results

Finally, 89 IC/BPS and 72 OAB women were included. In OAB group, the bladder capacity and PVR increased, and VE decreased significantly at 3 and 6 months after BoNT-A treatment. In IC/BPS group, the Q<sub>max</sub> increased significantly at 6 months. There were significant differences in changes of capacity, Q<sub>max</sub>, PVR and VE between the two groups. Moreover, OAB patients suffered more frequently from events of hematuria, UTI, and large PVR (>200 mL), but less frequently from event of straining to void.

### Interpretation of results

To our knowledge, this is the first study to compare the BoNT-A injection related AEs between OAB and IC/BPS patients. Our data demonstrated that by injecting 100 U of BoNT-A into the suburothelial space, the volume of bladder capacity and PVR increased, and the VE decreased significantly in women with OAB than those with IC/BPS within 6-month follow-up period. These results imply that the contractility of bladder in OAB patients might be more susceptible to BoNT-A injection than that in IC/BPS, which might reflect the different mechanism of action of BoNT-A on bladder dysfunction. Further investigations to compare the changes of sensory or motor proteins in the OAB and IC/BPS bladder at baseline and after BoNT-A treatment might provide evidence for this speculation.

### Concluding message

In conclusion, OAB women had higher PVR volume and lower VE than those in IC/BPS after BoNT-A injection. These results imply that the bladder contractility of OAB patients are more susceptible to BoNT-A, which might reflect the different mechanism of action of Botox on bladder dysfunction.

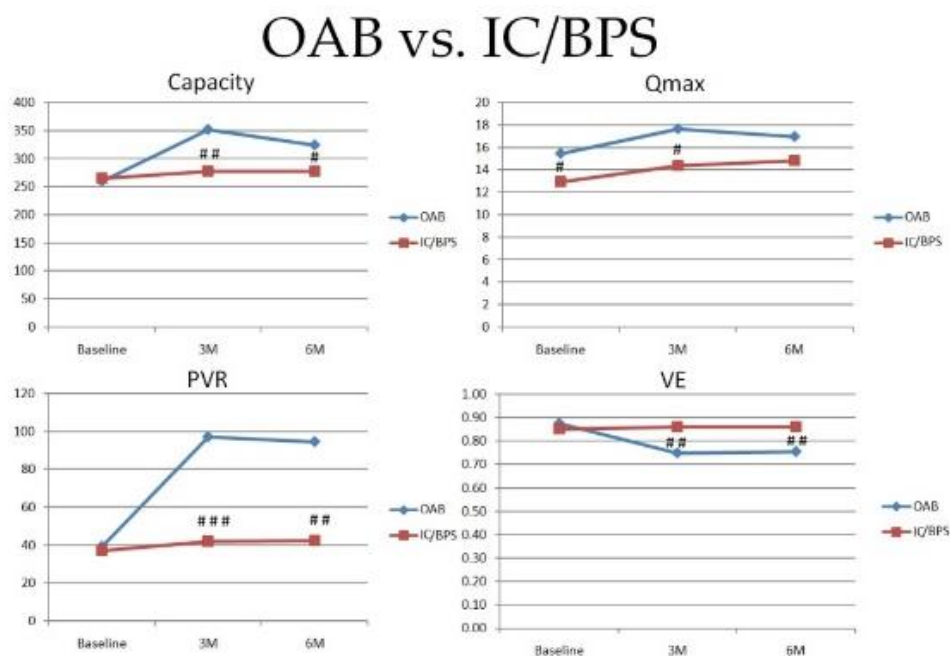


Fig. 1. The changes of bladder capacity, maximum flow rate (Q<sub>max</sub>), postvoid residual (PVR), and voiding efficiency (VE) at time-points after onabotulinumtoxinA injection between patients with overactive bladder (OAB) and interstitial cystitis/bladder pain syndrome (IC/BPS).

Table 1. Characteristics of study patients

Group	OAB (N=72)	IC/BPS (N=89)	p
Age (years)	49.15±10.85	48.81±11.81	0.777
Functional bladder capacity (mL)	351.43±135.21	124.72±76.91	0.000 <sup>1</sup>
Daytime frequency (times/day)	34.05±14.56	15.64±7.88	0.000 <sup>1</sup>
Nocturia (times/night)	8.05±2.99	4.90±4.93	0.009 <sup>1</sup>
Urgency (times/24 h)	33.00±17.87	-	
Urge urinary incontinence (times/24 h)	10.57±12.98	-	
Visual analogue scale	-	5.43±2.24	
Maximum flow rate (Qmax) (mL/s)	15.73±9.69	12.62±5.48	0.012 <sup>1</sup>
Voided volume (mL)	224.86±122.24	244.41±112.12	0.364
Postvoid residual (mL)	39.19±100.28	38.01±93.26	0.916
Total bladder capacity (mL)	260.93±143.25	266.19±117.15	0.800
Voiding efficiency	0.88±0.20	0.85±0.30	0.577
First sensation of filling (mL)	112.14±68.90	117.33±53.28	0.744
Strong desire to void (mL)	210.86±120.41	197.45±87.74	0.597
Cystometric bladder capacity (mL)	264.61±145.28	274.72±109.92	0.714
Detrusor pressure at Qmax (cmH <sub>2</sub> O)	27.49±13.60	19.19±10.65	0.000 <sup>1</sup>

<sup>1</sup>p<0.05. Independent t test.

Table 2. The adverse events in patients with overactive bladder and interstitial cystitis/bladder pain syndrome

Adverse Events	OAB (%)	IC/BPS (%)	p
Hematuria	7 (9.7)	0 (0)	0.003 <sup>1</sup>
UTI	20 (27.8)	6 (6.7)	0.000 <sup>1</sup>
Straining to void	6 (8.3)	27 (30.3)	0.001 <sup>1</sup>
PVR > 200 mL	23 (31.9)	6 (6.7)	0.000 <sup>1</sup>
AUR	1 (1.4)	0 (0)	0.265
Any	42 (58.3)	38 (42.7)	0.048 <sup>2</sup>

<sup>1</sup> Pearson Chi-square with Fisher exact correction. <sup>2</sup> Pearson Chi-square test.

UTI: urinary tract infection. PVR: postvoid residual. AUR: acute urinary retention.

#### Disclosures

**Funding:** none **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Research Ethics Committee, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation **Helsinki:** Yes **Informed Consent:** Yes