

## FACTORS ASSOCIATED WITH THERAPEUTIC EFFICACY OF INTRAVESICAL ONABOTULINUMTOXINA INJECTION FOR OVERACTIVE BLADDER SYNDROME

### Hypothesis / aims of study

To analyze the predictors of therapeutic efficacy after intravesical botulinum toxin A injection for overactive bladder syndrome (OAB) refractory to antimuscarinic therapy.

### Study design, materials and methods

All consecutively OAB patients, who visited the urologic outpatient clinics of a medical center and refractory to antimuscarinic treatment, were prospectively enrolled. All enrolled patients received intravesical injection of 100 U onabotulinumtoxinA (Botox). The Global Response Assessment (GRA) score  $\geq 2$  at 3 months after Botox injection was defined as a successful treatment, otherwise failed.

### Results

Overall, 89 patients received intravesical injection. Eighty patients, including 42 men and 38 women, had received follow-up at 3 months. The overall success rate was 63.8%. The global response assessment, urgency severity score, urgency, urgency urinary incontinence and frequency episodes, and functional bladder capacity improved after treatment. However, post-void residual volume (PVR) increased, and voiding efficiency (VE) decreased after treatment. Female gender (odds ratio = 3.75) was the only independent factor associated with the success. Female gender (coefficient = 0.74), low baseline overactive bladder symptoms score (coefficient = -0.12) and the presence of OAB-wet (coefficient = 0.79) were independent factors associated with therapeutic efficacy (i.e., GRA score). VE (odds ratio = 0.062) was the only predictor for a large PVR at 3 months. The optimum cutoff value of VE was <87% with the area under the ROC curve being 0.64 (sensitivity = 63.8%, specificity = 57.1%).

### Interpretation of results

This study revealed that intravesical Botox injection was significantly associated with a reduction of OABSS, USS, urgency and UUI episodes, number to void, and number of OAB-wet, but not VV, at all time-points and even at 6 months. A reduction of USS may be associated with sensory therapeutic effect, and an increase of bladder capacity may be correlated with motor therapeutic effect. Female gender, low OABSS and the presence of OAB-wet were associated better therapeutic efficacy. Low baseline VE is associated with large PVR.

### Concluding message

The therapeutic effects of Botox can persist till 6 months after treatment. Female gender, low overactive bladder symptoms score and OAB-wet are associated better therapeutic efficacy, and low baseline VE is associated with large PVR. These findings can serve as an initial guide or assist in consultation regarding the treatment of OAB patients with Botox injection.

Table 1. The follow-up data after treatment

Variables	Baseline (a)	2 weeks (b)	1 month (c)	3 months (d)	6 months (e)	‡P
Number	89	89	87	80	60	-
Age (years)	64.7±14.8	64.7±14.8	64.5±14.9	64.9±14.5	63.2±15.8	-
Gender						
Male	46	46	45	42	29	0.99
Female	43	43	40	38	31	-
GRA	0±0	1.4±1.3	1.6±1.4	1.6±1.3	1.6±1.6	<0.001
OABSS	11.7±2.4	9.3±3.2	9.3±3.3	9.1±3.4	8.4±3.4	<0.001
USS	3.8±0.6	3.1±1.0	3.1±1.1	3.3±1.1	3.1±1.1	0.001
Urgency episodes (72 h)	30.0±15.7	24.3±18.6	23.0±21.4	25.6±20.3	21.9±22.1	<0.001
UUI episodes (72 h)	8.2±11.2	4.1±8.5	5.1±10.1	5.5±12.5	5.0±12.5	<0.001
Number of void (72 h)	38.3±14.5	37.9±16.4	35.6±15.1	34.9±16.1	32.9±18.1	<0.001
VV (mL)	201±113	191±133	207±119	226±138	224±118	0.08
PVR (mL)	41±83	163±126	148±93	113±109	90±77	<0.001
TBC (mL)	242±134	354±155	354±158	309±151	319±134	<0.001
VE (%)	85±19	53±25	59±20	68±25	72±21	<0.001
OAB-wet	62	31	37	39	27	<0.001

†Values are given as mean  $\pm$  standard deviation or number. GRA= global response assessment; the other abbreviations are the same as Table 1.

‡The Skillings-Mack test

§Post hoc comparison was performed with Wilcoxon sign-rank test or McNemar test

Table 2. Univariate and multivariate logistic regression analyses of factors associated with therapeutic success at 3 months (n = 80)

Variables	Therapeutic outcome		Univariate analysis		‡Multivariate analysis	
	Success (n = 51)	Failure (n = 29)	OR (95% CI)	P	OR (95% CI)	P
Female gender	30	8	3.75 (1.40~10.06)	0.009	3.75 (1.40~10.06)	0.009
Age (years)	62.1±15.6	69.9±11.1	0.96 (0.92~0.99)	0.03	-	-
OABSS	11.7±2.4	11.5±2.5	1.05 (0.87~1.27)	0.64	-	-
USS	3.8±0.5	3.7±0.6	1.53 (0.68~3.45)	0.30	-	-
Urgency episodes (72 h)	29.0±15.8	30.1±14.4	1.00 (0.97~1.03)	0.76	-	-
UUI episodes (72 h)	8.4±9.8	7.4±13.4	1.01 (0.97~1.05)	0.70	-	-
Number of void (72 h)	37.3±14.7	38.1±13.1	1.00 (0.96~1.03)	0.80	-	-
VV (mL)	208±118	194±104	1.001 (0.997~1.005)	0.59	-	-
PVR (mL)	40±98	48±64	0.999 (0.994~1.004)	0.69	-	-
TBC (mL)	248±148	242±109	1.000 (0.997~1.004)	0.25	-	-
VE (%)	87±16	81±24	1.01 (0.99~1.04)	0.23	-	-
OAB-wet	41	16	3.84 (1.32~11.1)	0.01	-	-

†Values are given as mean ± standard deviation, number or odds ratio (95% confidence interval). CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

‡Backward stepwise multivariate logistic regression analysis was performed including all variables from the univariate analysis.

Table 3. Univariate and multivariate linear regression analyses of factors associated with the GRA score at 3 months (n = 80)

Variables	Univariate analysis		‡Multivariate analysis	
	Coefficient (95% CI)	P	Coefficient (95% CI)	P
Female gender	0.68 (0.15~1.23)	0.01	0.76 (0.25~1.27)	0.004
Age (years)	-0.02 (-0.04~-0.003)	0.09	-	-
OABSS	-0.07 (-0.18~0.05)	0.27	-0.12 (-0.24~-0.01)	0.03
USS	-0.04 (-0.56~0.47)	0.88	-	-
Urgency episodes (72 h)	-0.003 (-0.02~0.01)	0.67	-	-
UUI episodes (72 h)	0.001 (-0.02~0.02)	0.96	-	-
Number of void (72 h)	-0.01 (-0.03~0.01)	0.42	-	-
VV (mL)	0.001 (-0.001~0.004)	0.37	-	-
PVR (mL)	-0.001 (-0.004~0.002)	0.60	-	-
TBC (mL)	0.000 (-0.002~0.003)	0.68	-	-
VE (%)	0.017 (0.003~0.031)	0.02	-	-
OAB-wet	0.81 (0.24~1.38)	0.006	0.79 (0.19~1.38)	0.01

†Values are given as coefficient (95% confidence interval). Abbreviations are the same as in Table 1&2.

‡Backward stepwise multivariate linear regression analysis was performed including all variables from the univariate analysis.

#### Disclosures

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