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PREDICTORS OF ADVERSE EVENTS AFTER ONABOTULINUMTOXINA TREATMENT FOR PATIENTS WITH OVERACTIVE BLADDER SYNDROME

Hypothesis / aims of study

Intravesical injection of onabotulinumtoxinA (BoNT-A) is effective for idiopathic detrusor overactivity (IDO) refractory to antimuscarinics. Several randomized placebo control study have proven that BoNT-A 100 U was well tolerated and significantly and clinically relevant improvements in all overactive bladder (OAB) symptoms, patient-reported benefit, and HR-QOL in patients inadequately managed by anticholinergics. Improvement of urgency severity is significantly associated with a higher success rate at 3 months and longer therapeutic duration after intravesical BoNT-A injection for IDO. Repeated BoNT-A injections for refractory OAB is safe and effective. The most common reasons for discontinuing medication were poor efficacy, adverse events and catheterization related issues. However, safety is a major concern, especially in elderly individuals. Although safety and efficacy were similar between elderly patients without frailty and younger patients, an increased risk of large PVR and a lower long-term success rate in frail elderly patients were noted after intravesical BoNT-A injection for refractory IDO.

Study design, materials and methods

A total of 290 consecutive OAB patients who received intravesical 100 U BoNT-A injection for the OAB symptoms from 2010 to 2014 were included in this retrospective analysis. All patients have been demonstrated to have urodynamic DO and were refractory to life style modification and antimuscarinic treatment. The patients received intravesical BoNT-A injection under light general anesthesia and followed up regularly at out-patient clinic at 1, 3 and 6 months after the treatment. During the follow-up visit, the maximum flow rate (Qmax), voided volume, Postvoid residual volume (PVR) and the adverse events such as acute urinary retention, large PVR and urinary tract infection (UTI) were investigated. Patients who had large PVR of over 200ml were considered having large PVR and over 350 mL as urinary retention and clean intermittent catheterization or temporarily indwelling Foley catheter were instructed. Antibiotics was routinely given to treat UTI until the urine turned clean. The patient characteristics and the occurrence of adverse events were analysed to investigate the predictive factors for adverse events.

Results

A total of 290 patients including 148 men and 142 women were included in this study. The age distribution was less than 60 years old in 79 patients, 61-75 in 104, and over 76 in 107. After BoNT-A injection, acute urinary retention developed in 24 patients (8.27%), large PVR in 68 (23.5 %) and UTI in 44 (15.2%). Male patients ($p<0.0001$), age greater than 61 years ($p=0.029$), Qmax <15 mL/s ($p=0.026$), a baseline larger than 100 mL ($p=0.005$) and a baseline voiding efficiency less than 90% ($p=0.047$) had significantly higher incidence of urinary retention. Patients older than 61 years had higher incidence of large PVR after treatment. Female patients and a baseline PVR>100 mL were associated with UTI (Table 1).

Table 1. The incidence of adverse events related to intravesical 100 U onabotulinumtoxinA injection in patients with overactive bladder syndrome

	Acute urinary retention (n= 24)	Large PVR (≥ 200 mL) at 3 M (n= 68)	Urinary tract infection (n= 44)
Gender			
Male (148)	21 (14.2%)	28 (19.6%)	13 (8.8%)
Female (142)	3 (2.1%)	40 (29.2%)	31 (21.8%)
	P< 0.0001	P= 0.061	P= 0.002
Age			
≤ 60 (79)	1 (1.3%)	11 (14.5%)	17 (21.5%)
61-75 (104)	11 (10.6%)	33 (32.7%)	16 (15.4%)
76 (107)	12 (11.2%)	24 (23.3%)	11 (19.3%)
	P= 0.029	P= 0.019	P= 0.107
Qmax			
>15 (82)	2 (2.4%)	21 (27.3%)	15 (18.3%)
10-15 (75)	7 (9.3%)	18 (24.3%)	13 (17.3%)
≤ 10 (132)	15 (11.4%)	29 (22.7%)	16 (12.1%)
	P= 0.026	P= 0.757	P= 0.398
PVR			
≤ 50 (225)	13 (5.8%)	46 (21.2%)	31 (13.8%)
51-100 (39)	5 (12.8%)	13 (35.1%)	4 (10.3%)
≥ 100 (26)	6 (23.1%)	9 (34.6%)	9 (34.6%)
	P= 0.005	P= 0.082	P= 0.013
VE			
≥ 90% (165)	8 (4.8%)	34 (21.1%)	21 (12.7%)
70-90% (73)	9 (12.3%)	17 (25.0%)	12 (16.4%)
< 70% (52)	7 (13.7%)	17 (34.0%)	11 (21.6%)
	P= 0.047	P= 0.178	P= 0.291

Interpretation of results

The results of this study revealed after intravesical onabotulinumtoxinA 100 U injection for OAB patients, AUR developed significantly more in male patients, age greater than 61 years, a baseline Qmax<15 mL/s, a baseline PVR greater than 100 mL, and a baseline VE of less than 90%. Patients older than 61 years had higher incidence of large PVR at 3 months after treatment. Female patients and a baseline PVR>100ml were associated with UTI. In selecting OAB patients for onabotulinumtoxin treatment, these predictors of AE should be cautious.

Concluding message

OAB Patients received intravesical BoNT-A injection should be carefully monitored for the occurrence of urinary retention, large PVR and UTI. Patients who are at risk of adverse events need careful counsel of the possible adverse events after treatment.

Disclosures

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