

CAN WE PREDICT WHO WILL RESPOND TO BOTULINUM TOXIN-A INJECTIONS FOR IDIOPATHIC OVERACTIVE BLADDER?

Hypothesis / aims of study

Patients who are refractory to antimuscarinic treatment for idiopathic overactive bladder (I-OAB) are often offered intra-detrusor injection of botulinum toxin-A (BTX-A) for symptom relief. There exists very little data addressing factors that predict responsiveness to BTX-A therapy.

The aim of this study was to evaluate demographic and urodynamic (UDS) variables that may help predict which I-OAB patients will respond to BTX-A therapy.

Study design, materials and methods

20 patients with OAB-Dry (urgency and frequency without urge urinary incontinence (UUI)) and 27 patients with OAB-Wet (those with urgency, frequency, and UUI) refractory to oral antimuscarinic therapy were enrolled in a randomized prospective trial to assess response to 100 and 150 units of intra-detrusor BTX-A. Univariate and multivariate analysis were performed to assess various demographic data and UDS parameters that may affect one's response to BTX-A.

Results

Table 1. OAB – DRY URODYNAMICS COMPARISON BETWEEN RESPONDERS AND NON-RESPONDERS

IMP	N =	PVR	MCC	p-DetMax	p-VesMax	Vol Voided	pDetQMax	Max Flow
< 40%	5	29+/-36	263+/-124	34+/-18	51+/-12	226+/-174	43+/-48	13+/-11
> 40%	15	24+/-36	242+/-112	40+/-17	62+/-27	279+/-148	24+/-12	14+/-6
p=val		0.758	0.657	0.470	0.384	0.507	0.58	0.913

IMP	N =	DO	Dose 150 U	Dose 100 U	Age	Sex=Male
< 40%	5	1/5	1	4	59+/-13	0
> 40%	15	5/15	9	6	48+/-15	5
p=val		0.578	0.147		0.105	0.197

IMP = improvement, PVR = post-void residual, MCC = maximal cystometric capacity, pVesMax = maximal vesical pressure, vol voided = volume voided, pDetQMax = detrusor pressure at maximal flow, DO = presence of detrusor overactivity

Table 2. OAB – WET URODYNAMICS COMPARISON BETWEEN RESPONDERS AND NON-RESPONDERS

IMP	N =	PVR	MCC	pDetMax	p-VesMax	Vol Voided	p-DetQMax	Max Flow
< 50%	10	24+/-33	227+/-100	29+/-16	60+/-30	171+/-97	23+/-20	14+/-7
> 50%	17	24+/-25	248+/-147	49+/-24	74+/-32	223+/-155	35+/-20	15+/-11
p=val		0.929	0.707	0.058	0.235	0.240	0.232	0.996

IMP	N =	NI Compl	DO	Dose 200 U	Dose 150 U	Dose 100 U	Age	Sex=Male
< 50%	10	9/10	8/10	1	9	8	68+/-13	0
> 50%	17	9/17	12/17	2	3	4	55+/-15	1
p=val		0.980	0.999	0.774			0.03	0.892

IMP = improvement, PVR = post-void residual, MCC = maximal cystometric capacity, pVesMax = maximal vesical pressure, vol voided = volume voided, pDetQMax = detrusor pressure at maximal flow, DO = presence of detrusor overactivity, NI Compl = normal compliance

Interpretation of results

All OAB-Dry patients had normally compliant bladders, and none of the demographic or UDS variables that were assessed were found to be significant predictors of response to therapy ($p > 0.05$ for all variables). (Table 1) For the 27 patients with OAB-Wet, younger age was a statistically significant predictor of a successful response to therapy. Additionally, patients with higher maximal detrusor pressures (pDetMax) tended to respond more frequently than those with lower pDetMax. (Table 2) When these variables were placed in a logistic regression model for multivariate analysis, neither were significantly associated with response to BTX-A intra-detrusor injection response. ($p = 0.14$ for pDetMax and $p = 0.13$ for age)

Concluding message

Pre-BTX-A injection urodynamics in patients with I-OAB-Dry is not useful for predicting which patients may respond to BTX-A therapy. Additionally, younger patients with I-OAB-Wet responded to therapy better than older patients, and those with higher pDetMax tended to respond better as well. However, neither variable was a significant predictor in a multivariate analysis. Future

studies should continue to search for factors that may predict success to BTX-A therapy so that this expensive treatment option is used resourcefully.

<i>Specify source of funding or grant</i>	Allergan provided some funding and study medication
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	Local IRB# 20020122-02
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Institutional review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes