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BOTOX® FOR IDIOPATHIC OVERACTIVE BLADDER PATIENTS REFRACTORY TO ANTIMUSCARINIC THERAPY IN THE ABSENCE OF DETRUSOR OVERACTIVITY

Hypothesis / aims of study

The majority of publications and ongoing studies on botulinum toxin-A (BTX-A) therapy for patients with idiopathic overactive bladder (I-OAB) refractory to antimuscarinic treatment include detrusor overactivity (DO) as an inclusion criteria. I-OAB is a syndrome that requires the symptoms of urgency, frequency (UF) with or without urge incontinence (UUI) in order to establish its diagnosis. For this reason the aim of our study is to investigate whether patients with clinical symptoms of I-OAB and no evidence of DO on urodynamics (UDS) would also respond to BTX-A therapy.

Study design, materials and methods

We collected the data from our prospective, IRB approved, randomized ongoing trial, in which 50 patients have received at least one injection. All patients have I-OAB refractory to antimuscarinic therapy: 27 with UUI (OAB-wet) and 23 without UUI (OAB-dry). All patients were randomized to 100 or 150 units of intra-detrusor BTX-A. Patients' assessment included clinical history, UDS, UA, urine culture, UDI-6 questionnaire and 3 consecutive days voiding diaries (3-VD). Improvement outcome was evaluated by 3-VD. A successful outcome was determined for those who achieved a >50% reduction in UUI episodes in their 3-VD for the OAB-wet group; >40% decrease in their UF in their 3-VD for the OAB-dry group. Comparison analysis was assessed between baseline and week 12 after BTX injection. T-test was used for the paired comparison of the parametric variables and we used Kruskal-Wallis for those non-parametric.

Results

22/50 patients had no DO on UDS baseline: 14/23 were OAB-dry and 8/27 OAB-wet.
79% of the OAB-dry patients (11/14) showed more than 40% improvement by week 12 after BTX-A; their baseline average UF of 24 dropped to 14 by week 12 ($p<0.015$ N=14). 75% Of the OAB-wet group (6/8) showed more than 90% improvement by week 12; their baseline UUI episodes average of 7.9+/-6 dropped to 0+/-2.6 by week 12 ($p<0.02$ N=8). Tables 1 and 2 present the UDS results comparison at baseline and week 12 for both groups.
UDI-6 questionnaire total score were significantly decreased in both groups by week 12 ($p<0.05$).

Table 1. OAB – DRY URODYNAMICS COMPARISON BETWEEN BASELINE AND 12 WEEKS

IMP	N =	PVR	MCC	p-DetMax	p-VesMax	Vol Voided	pDetQMax	Max Flow
BASE	14	37+/-43	263+/-124	47+/-31	82+/-31	259+/-191	46+/-38	15+/-10
12wk	14	30+/-48	242+/-112	41+/-26	79+/41	176+/-54	23+/-9	10+/-5
p-val		0.77	0.657	0.699	0.884	0.127	0.128	0.212

PVR = post-void residual, MCC = maximal cystometric capacity, pVesMax = maximal vesical pressure, Vol voided = volume voided, pDetQMax = detrusor pressure at maximal flow.

Table 2. OAB – WET URODYNAMICS COMPARISON BETWEEN BASELINE AND 12 WEEKS

IMP	N =	PVR	MCC	pDetMax	p-VesMax	Vol Voided	p-DetQMax	Max Flow
BASE	8	18/-22	321+/-164	40+/-14	71+/-24	294+/-201	35+/-20	12+/-6
12wk	8	2+/-4	282+/-18	15+/-7	35+/-32	126+/-62	9+/-1.4	12+/-4
p-val		0.108	0.74	0.03	0.235	0.101	0.02	0.96

PVR = post-void residual, MCC = maximal cystometric capacity, pVesMax = maximal vesical pressure, Vol voided = volume voided, pDetQMax = detrusor pressure at maximal flow.

Interpretation of results

Patients without evidence of DO demonstrated excellent response to BTX-A therapy. 80% of those patients without UUI had a decrease of at least 40% in their UF by week 12. 75% of the OAB-wet group were able to be dry with no UUI episode by week 12. Validated questionnaires also corroborated this successful outcome by week 12 when compared to baseline. UDS showed a significantly lower detrusor pressure during voiding phase on the OAB-wet group at week 12 when compared to baseline. We found no other UDS parameters difference among the two groups.

Concluding message

BTX-A injection therapy has proved to significantly decrease the UUI episodes and UF in patients with and without UUI respectively. Research studies should also include patients with I-OAB even in the absence of DO in their baseline study (screening) in order to cover the entire OAB disease.

Specify source of funding or grant	**Allergan provided some funding and study medication**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Local IRB number# 20020122-02**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board**

Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**