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PITFALLS IN THE TREATMENT OF BOTOX THERAPY OF PATIENTS WITH OVERACTIVE BLADDER SYNDROME REFRACTORY TO ANTICHOLINERGICS

Hypothesis / aims of study

The treatment of women suffering from overactive bladder syndrome (OAB) refractory to anticholinergics, caused by neurogenic or idiopathic detrusor overactivity, with injection of Botulinum toxin A (BTX-A) in the bladder wall has shown to be effective and has gained acceptance [1, 2]. The aim of this observational study was to analyze efficacy and side effects of BTX-A in clinical practice for patients with OAB refractory to anticholinergics and to identify risk factors for non-responders.

Study design, materials and methods

We performed a retrospective analysis of women treated in our department for OAB refractory to anticholinergics. Preoperatively, all women had a complete urodynamic examination. After hydrodistension, 100 IE Botox were injected in the detrusor muscle at 20 sites under cystoscopic guidance, sparing the trigone. Post void residual urine volume was measured 2-3 weeks postoperatively to exclude urinary retention, and urodynamic assessment was repeated 6-8 weeks after operation. We analyzed urodynamic parameters, subjective improvement of OAB symptoms, and additional medical diagnosis. Statistic evaluation was undertaken by means of Student t test or Fisher's exact test, as appropriate. P values <0.05 were considered to indicate statistical significance (two-sided).

Results

Starting December 2004 until January 2008, we treated 70 women. 3 cases were excluded because of incomplete follow up. Of these remaining 67, 7 were re-injections, performed after an average of 17 months (range 12-25). The 60 patients with first injection were analyzed. 52 suffered from OAB wet and 8 from OAB dry. Mean age was 62.7 years (20.9-88.6). 9 had psychiatric and 4 neurologic disorders, 6 suffered from diabetes, whereof 2 had poor metabolic control. Postoperatively, 29 patients (48.3%) reported absence of OAB, 10 (16.7%) a significant and 14 (23.3%) a mild improvement. 7 (11.7%) reported no change. Overall, volume at first desire to void, maximum bladder capacity and post void residual urine volume increased from 171 to 209ml (P=0.017), from 307 to 401ml (P<0.001) and from 32 to 57ml, respectively. 14 patients were treated for urinary tract infection with antibiotics. 4 of the 7 non-responders had a preexistent psychiatric disorder (P=0.007) such as depression/agoraphobia (3) and schizophrenia (1). 2 of these 4 non-responders additionally had diabetes with poor metabolic control and needed catheterization for half a year due to urinary retention, beginning 2-3 weeks postoperatively.

Table 1: Clinical and urodynamic findings before and after BTX-A treatment.

Parameter	*Before BTX-A*	*After BTX-A*	*P*
Age (years)	62.7 (20.9 – 88.6)		n.s.[#]
Responder		62.6 (20.9 – 88.6)	
Non-responder		63.4 (27.3 – 82.4)	
OAB wet	52		n.s.[‡]
Responder		46	
Non-responder		6	
OAB dry	8		
Responder		7	
Non-responder		1	
Volume at first desire to void (ml)	171 (30 – 435)	209 (94 – 444)	0.017[#]
Responder	174 (30 – 435)	215 (94 - 444)	0.02[#]
Non-responder	150 (118 – 197)	146 (139 – 152)	n.s.[#]
Maximum bladder capacity (ml)	307 (50 – 580)	401 (196 – 589)	<0.0001[#]
Responder	314 (50 – 580)	410 (196 589)	0.0001[#]
Non-responder	260 (118 – 424)	310 (253 - 370)	n.s.[#]
Post void residual urine volume (ml)	32 (0 – 170)	57 (0 - 257)	n.s.[#]
Responder	32 (0 – 170)	55 (0 - 165)	0.019[#]
Non-responder	29 (2 – 55)	74 (5 - 257)	n.s.[#]
Psychiatric disorders	9		0.007[‡]
Responder		5	
Non-responder		4	
Diabetes mellitus	6		n.s.[‡]
Responder		4	
Non-responder		2*	
Neurologic disorders	4		n.s.[‡]
Responder		3	
Non-responder		1	

n.s., non significant.
Data are expressed as means (range), or number of patients.
*Diabetes mellitus with poor metabolic control
[#]student t test.
[‡]Fisher's exact test.

Interpretation of results

Our retrospective analysis demonstrates that BTX-A is an effective treatment for OAB wet or dry, refractory to anticholinergics, with a re-injection rate of 10%. Of the 7 non-responders, 4 suffered from pre-existent psychiatric disorders. The only cases with

postoperative urinary retention were the two patients suffering from diabetes mellitus with poor metabolic control. Urinary retention was diagnosed at the first follow-up 2-3 weeks postoperatively, when Botox approaches its maximum effect. As the effect of Botox decreases, the urinary retention was resolved in both patients.

Concluding message

We consider psychiatric disorders as risk factors for treatment failure, while diabetes with poor metabolic control seems to be a risk factor for urinary retention with need of catheterization. The effect of Botox is subsiding after 6 months, so that the detrusor is recovering. Our experience shows no long term complications.

References

[1] J Urol 2000;164(3):692-97.
[2] J Urol 2006;176(1):177-185.

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**retrospective observational study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**