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Gousse A[1], Barboglio P[1], Cohen B[1], Rodriguez D[1], Caruso D[1]
1. *University of Miami Miller School of Medicine*

THE NEED FOR INTERMITTENT CATHETERIZATION DURING REPEATED BOTOX® INJECTIONS FOR IDIOPATHIC OAB

Hypothesis / aims of study
In this prospective, IRB approved, randomized, ongoing study we evaluated the efficacy of intra-detrusor injection of BOTOX ® - *botulinum A toxin* (BTX) in patients (pts) with idiopathic overactive bladder (IOAB) resistant to antimuscarinic therapy. The aim of this study was to evaluate the post-void residual volume (PVR) throughout the study and to assess how many patients will need self intermittent catheterization (CIC).

Study design, materials and methods
A total of 44 IOAB pts were randomized to receive BTX (100U or 150U) as 10U/ml/injection "trigone and dome sparing" (10 or 15 intra-detrusor injections respectively) using a 14 Fr flexible cystoscope / 27G-4mm needle. Validated questionnaires, medical history, physical exam, 3 days voiding diaries (3xVD), urine analysis and cultures were performed in all pts before treatment (Baseline) and at 2, 6, 12 and 24 weeks post- injection. We assessed PVR by bladder scanner at every visit. We compared each time-point PVR against baseline PVR. We use ANOVA and Bonferroni test for significant difference. Significance was established at $p<0.002$. Urinary retention was defined as symptomatic PVR>200ml or any patient with PVR>300ml regardless of symptoms. Only symptomatic patients with pain or discomfort, inability to urinate, urinary tract infection or hydronephrosis on renal ultrasound were advised to start CIC.

Results
44 pts with IOAB were injected. Table 1 illustrates the number of BTX injections that pts have received with the PVR at each measured time point. Figure 1 shows that PVR was statistically higher than baseline in numerous occasions, however, the PVR always returned to baseline levels by 24 weeks post-injection.

Graphic. PVR in 6 BTX Repeated Injections

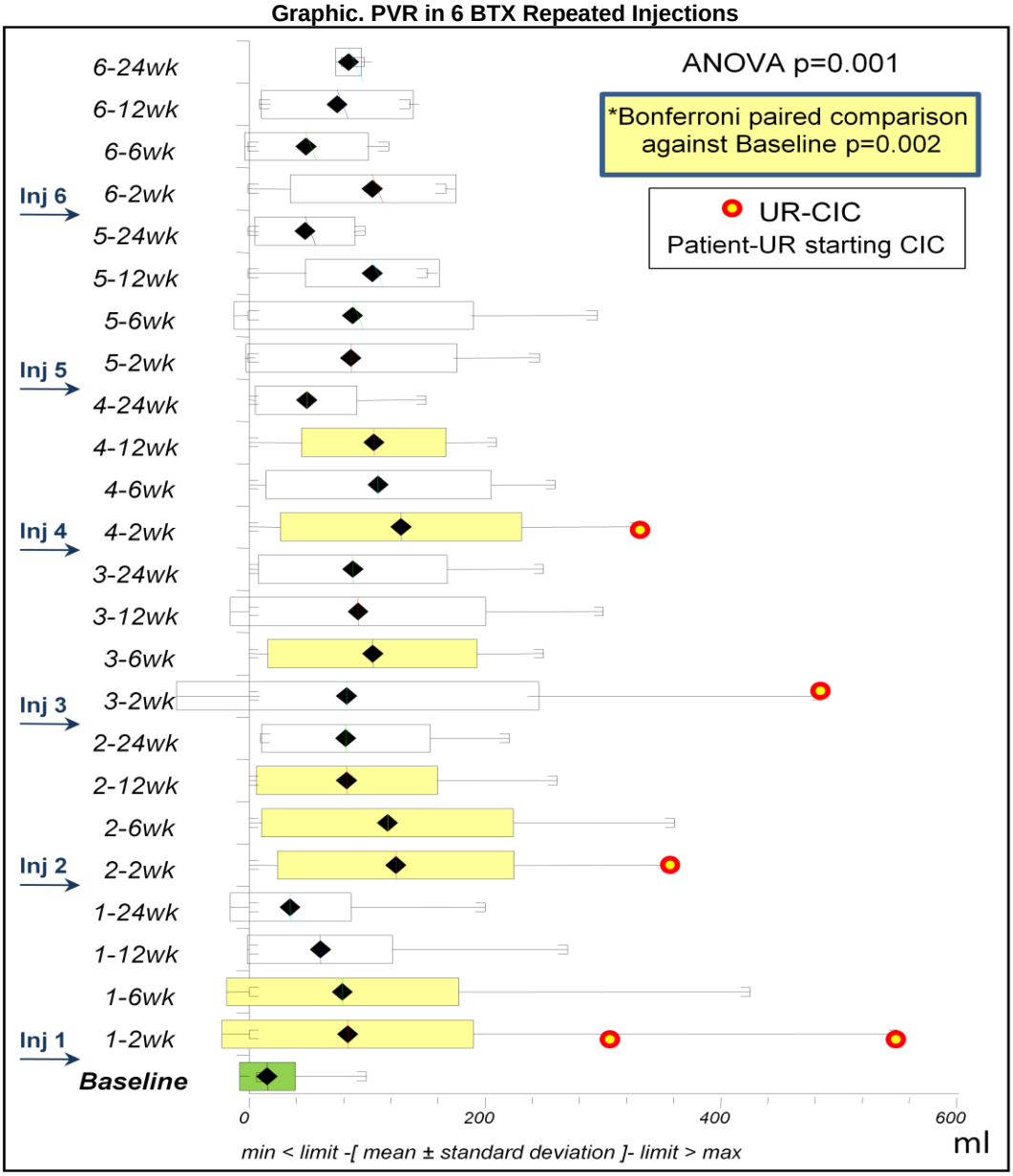

Table. PVR Comparison against Baseline

Period	N=	Mean	SD+/-	Bonferroni
Baseline	44	15	24	P value
1-2wk	44	83	107	0.003
1-6wk	44	79	98	0.002
1-12wk	44	60	62	0.034
1-24wk	44	35	51	0.348
2-2wk	24	124	100	<0.0001
2-6wk	24	117	106	<0.0001
2-12wk	24	80	77	0.0026
2-24wk	24	82	72	0.0069
3-2wk	15	105	220	0.0289
3-6wk	15	99	91	0.0017
3-12wk	15	92	109	0.005
3-24wk	15	88	80	0.0137
4-2wk	10	129	102	0.001
4-6wk	10	110	96	0.0035
4-12wk	10	106	62	0.0022
4-24wk	10	49	43	0.2545
5-2wk	10	87	90	0.0271
5-6wk	10	90	101	0.0155
5-12wk	10	107	57	0.0126
5-24wk	10	49	42	0.445
6-2wk	6	113	79	0.021
6-6wk	6	50	52	0.378
6-12wk	6	76	64	0.223
6-24wk	6	86	11	0.1541

**Bonferroni was significant at p=0.002 for 24 comparison.*

Interpretation of results

5 Pts (11%) needed to start CIC. Two patients who started CIC after the 1st BTX injection were able to stop by 16wks. These 2 patients subsequently withdrew from the study. The other 3 patients started CIC respectively after the 2nd, 3rd, and 4th BTX injection. None of these pts required CIC on subsequent injections. Two pts stopped CIC before 12wks and the other at 20wks. Hydronephrosis was never found in these pts. 4/5 pts who needed CIC received BTX 150 U and 1/5 received a 100 U.

Concluding message

BTX injection increases PVR within 2 weeks. Not all patients with PVR>200ml will need to start CIC if there is no hydronephrosis, no urinary tract infection, and no discomfort, pain or inability to urinate. The need for CIC after the initial BTX injection does not necessarily imply that this therapy will be needed in subsequent injections.

Specify source of funding or grant	**Allergan contribuited with some fundind 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 # 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**