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100 VS. 150 UNITS OF INTRA-DETRUSOR BOTOX: DOSE DIFFERENCES IN OAB-WET PATIENTS?

Hypothesis / aims of study

We evaluated the efficacy of intradetrusor injections of BOTOX®- *botulinum A toxin* (BTX) in patients with idiopathic overactive bladder (IOAB) with urinary incontinence (OAB-Wet) resistant to antimuscarinic therapy. Our aim was to evaluate differences in response to urinary frequency (UF), urge urinary incontinence (UUI) and Urogenital Distress Inventory-6 (UDI-6) response between 2 different doses of BTX: 100 U and 150 U.

Study design, materials and methods

A total of 27 IOAB-Wet patients were randomized to receive BTX (100 or 150U). A 14-Fr flexible cystoscope and 27G-4mm needle were used to administer 10U/ml/injection in a trigone and dome sparing fashion. Validated questionnaires, medical history, physical exam, 3-day voiding diaries (3xVD), post-void residual volume, urine analysis and cultures were performed in all patients before treatment (Baseline) and at 2, 6, 12 and 24 weeks post- injection. Multichannel urodynamics (UDS) were performed prior to therapy and 6 weeks post-injection. UF per 24-hr period was calculated by averaging the results of the 3xVD. A student's T-test was used for determining statistical significance ($p<0.05$).

Results

Fifteen patients received 150 U and 12 received 100 U. Table 1 outlines the results for UF, UUI and UDI-6 scores for both pre- and 12 weeks post-injection.

Table 1

BTX-Dose (Pre-injection and 12 weeks post-injection)	**100U**		**150U**	
	Pre (n=12)	**Post**	**Pre (n=15)**	**Post**
UF (mean +/- SD)	13.9 +/- 5.8	8.9 +/- 3*	14.3 +/- 5.7	11.1 +/- 3.3*
UUI (mean +/- SD)	10.9 +/- 6.1	3.7 +/- 3*	7.8 +/- 6.7	0.4 +/- 0.7*
UDI-6 (mean +/- SD)	11.5 +/- 3	7.4 +/- 2.9*	11 +/- 4	4.6 +/- 3.6*

***p-value < 0.05**

Interpretation of results

UF was significantly reduced with both dosages at the 2-week and 12-week post-injection interval. A significant reduction in the episodes of UUI occurred with both dosages at 2 and 12 weeks. There was a significant improvement in the UDI-6 scores with both dosages at the 2 and 12-week evaluations. There was a statistically significant improvement in UUI when comparing 100U vs. 150U ($p=0.02$). The UF and UDI-6 scores, however, did not reach statistical significance when comparing 100U vs. 150U. There was no difference amongst the UDS results between the two dosages.

Concluding message

BTX is significantly efficacious in diminishing UF, UUI and UDI-6 scores in IOAB-wet patients ($p<0.05$). Our series supports superiority of BTX 150U over 100U in the improvement of UUI.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**20020122**
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**