

DOSE FINDING PROSPECTIVE RANDOMIZED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF BOTULINUM-A TOXIN FOR REFRACTORY NON-NEUROGENIC OVERACTIVE BLADDER

[1124]

Angelo E Gousse*, Hari Siva Gurunadha Rao Tunuguntla, Dinorah Bateman, Darcy Velazquez, Miami, FL

INTRODUCTION AND OBJECTIVE: The optimal dosage of Botulinum Toxin-A (BTA) for refractory non-neurogenic Overactive Bladder (OAB) remains to be established. Several investigators have reported satisfactory outcome using 200 to 300 Units. We report the results of a *dose-finding prospective randomized study* comparing 100 vs. 150 Units using validated instruments to evaluate the efficacy and safety of “Low-Dose” BTA in the management of non-neurogenic OAB.

METHODS: Twenty patients (14 female, 6 male) 26 to 75 years of age (mean 52.6 ± 13.4) with refractory non-neurogenic OAB were prospectively evaluated & randomized to 100 Units (N=10) vs. 150 Units BTA (N=10). BTA was injected under IV sedation. Study patients were re-injected Q 6 months. *Student’s t test* measured: 1) Age and gender vs. pre and post BTA variables [t-VV, 24-hr urinary frequency, improvement in QOL, UDI-6, and PVR] 2) differences in same variables before and after BTA.

RESULTS: Follow-up included 6 to 24 months (mean 14 months). There was no association between BTA injection outcome measures and age (<50 vs. ≥ 50), gender, and dosage (100 Units vs. 150 Units). t-VV, frequency, QOL significantly improved following BTA at both dosage. *Spearman* correlation was noted between 1) percent improvement QOL and pre-Botox QOL, (p =0.006), 2) percent global QOL improvement and post BTA t-VV (p= 0.023), and 3) pre and post BTA QOL (p = 0.025). Increased t-VV was observed with increasing number of BTA sessions. (258.8 ± 176.1 versus 538.2 ± 294.4 ml for single vs. > 2 sessions: p=0.016). One female patient (transiently PVR rise) developed bacterial cystitis in the 150 Units group.

**Paired t-test (2-tailed) **Chi-square test*

CONCLUSIONS: In non-neurogenic OAB patients Intravesical Botulinum toxin A injections are effective at both dosage, 100 and 150 Units. Tidal voided volume is increased and correlates with improvements in Global QOL and reduction in urinary frequency at both dosage. Repeat sessions improve voided volume more than the first BTA session. PVR is not statistically increased at both dosage used. Lower dosage i.e., 100 Units may be as effective as the higher dosage which have been previously used. Further studies should investigate even lower dosage.

Variable	100 Units Botox	150 Units Botox	p value
Tidal voided volume (pre-Botox)	79.5 ± 31.5744	73.5 ± 15.4650	0.606*
Tidal voided volume (post-Botox)	323.5 ± 253.6845	417.6 ± 278.7269	0.459*
Urinary frequency (pre-Botox)	14.9 ± 5.5066	19.4 ± 15.1379	0.456*
Urinary frequency (post-Botox)	8.6 ± 3.7178	7.4 ± 3.0623	0.432*
UDI-6 (pre-Botox) (maximum score, 18)	17.5556 ± 26.7587	9.2222 ± 4.4659	0.408*
UDI-6 (post-Botox) (maximum score, 18)	5.6 ± 5.1683	5.9 ± 3.7253	0.853*
Postvoid residual (ml) (pre-Botox)	43.4 ± 23.2245	51.7 ± 44.5248	0.635*
Postvoid residual (ml) (post-Botox)	51.7 ± 44.0733	81.0 ± 127.4746	0.527*
Patient perceived percent global symptom (QOL) improvement (%)	59.5 ± 14.2302	53.0 ± 28.3039	1.000**