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Casey R[1]
1. *The Male Health Centre*

AN OPEN LABEL PILOT STUDY INVESTIGATING THE SAFETY AND EFFICACY OF BOTOX® IN 20 FEMALE PATIENTS WITH REFRACTORY SYMPTOMS OF HIGH URINARY VOIDING FREQUENCY WITHOUT INCONTINENCE

Hypothesis / aims of study

There are a number of oral pharmacologic treatments available for symptomatic overactive bladder (OAB) with or without incontinence, however most of these therapies require at least daily dosing and have significant side effects. Compliance with oral therapy is poor, and many patients chose to discontinue oral therapy. In addition, reducing the cumulative polypharmacy and anticholinergic burden is a desirable goal. Intravesical Botox® has shown promising results in the management of incontinent neurogenic and idiopathic OAB in several clinical trials. The primary objective of this study was to assess the efficacy and safety of intravesical Botox® in the management of high urinary voiding frequency in patients with overactive bladder without incontinence (dry OAB).

Study design, materials and methods

Twenty outpatient, female subjects between 18 and 75 years of age with overactive bladder for greater than 3 months without bladder pain and who have failed one or more anticholinergic medications, and not have been taking anticholinergic medications were enrolled. Patients were injected via cystoscopy with 100 IU Botox® diluted in 10 mL in a defined pattern (20 sites in the bladder, sparing the trigone) into the detrusor. Patients were assessed for urinary retention by demonstrating normal voiding in the immediate period after the procedure. Post void residual (PVR) urine measurements were performed at visit 1 (pre-treatment), weeks 2, 12 and 24. Patients received one cycle of Botox® injections and were followed for one year post-injection.

Results

Out of the 20 subjects injected with Botox®, 11 completed the trial. Out of the 9 patient who did not complete the study 1 did not receive adequate relief, 2 withdrew consent and 6 were lost to follow up after month 3 and/or 4 visit. Patients were followed up within one week after PVR to determine if further intervention was warranted. No patients presented with urinary retention. The 3 day voiding diaries collected from patients at each visit showed dramatic reduction from baseline in voiding frequency. The average number of voids over a 3 day period was reduced from 45 (prior to treatment value)to 30, after 1 month post- treatment (primary endpoint). Urinary urgency severity was measured using the four point Indevus Urgency Severity Scale (IUSS). Bowker's test of symmetry showed a reduction in the degree of urgency from 2.73 to 1.40 after 1 month post Botox® injection, on a 1 (normal) to 3 (unbearable) scale. Patients reported an improvement of 1.77 points on the bladder related quality of life questionnaire, which assessed the patients' subjective impression of their current bladder problems. Overactive Bladder Questionnaire OAB-q consisted of an 8-item symptom bother scale and 25 health-related quality of life (HRQL) items. Out of the 11 patients completing the trial 10 showed a significant improvement from 128.80 to 64.80 within the first month after treatment (secondary endpoints). The intravesicular administration of 100 IU Botox® was well tolerated, with no significant adverse events reported. There were no serious adverse events reported during the course of the trial.

Interpretation of results

The Intravesical administration of Botox® was well tolerated in this refractory dry OAB patient group. Overall, patients completing the study reported significant improvement in their OAB symptoms, with the most improvement occurring between 1 to 3 months after Botox® treatment.

Concluding message

There were no serious or significant adverse events reported, and no patients developed urinary retention after Botox® treatment. 1 patient did not complete the study due to inadequate relief within the first moth post-treatment. Our findings shows improvement in quality of life of patients treated with Botox® for high urinary frequency without incontinence, however obtaining data on more patients would be valuable.

Specify source of funding or grant	**Allergan**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinicaltrials.gov**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Trafalgar Ethics Board**

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