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SAFETY AND TOLERABILITY OF SEDATION FREE FLEXIBLE CYSTOSCOPY FOR INTRADETRUSOR BOTULINUM TOXIN-A INJECTION IN PATIENTS WITH NEUROGENIC OR NON-NEUROGENIC DETRUSOR OVERACTIVITY.

Hypothesis / aims of study
Intradetrusor Botulinum Toxin-A (BTX-A) injection is now a widely accepted second line treatment option for patients with both neurogenic and non-neurogenic detrusor overactivity. We evaluated the safety and tolerability of administering the injection via a flexible cystoscope in an office setting in a mixed patient population.

Study design, materials and methods
We retrospectively reviewed the data of consecutive patients who underwent intradetrusor BTX-A injection for refractory overactive bladder (OAB) symptoms. Patients with neurogenic and non-neurogenic OAB symptoms were included in the analysis. The bladder was instilled with 40ml 2% lidocaine using a 14Fr foley catheter in all patients 10 minutes prior to the injection. The bladder was not drained before commencing the injection procedure. All patients underwent BTX-A injection with a 14 Fr flexible cystoscope using a 4mm 27G needle with 1050mm working length. Urinalysis and culture was performed on all patients prior to the injection. When positive cultures were documented, patients were treated and sterile urine cultures were recorded prior to injection. All patients received prophylactic antibiotics for 3 days post injection. The following parameters were studied: gross hematuria, urinary tract infection, autonomic dysreflexia, pain during and 15 mins after the procedure. Pain scores were measured using a 10cm visual analogue scale. All patients had vital signs monitored before and 30 minutes after the procedure.

Results
Mean age was 53 (range 23-83 years). There were 66 (63%) females and 38 (37%) males. There were 76 non-neurogenic patients and 28 neurogenic patients in our study. Among the neurogenic patients, 24 were spinal cord injury (level of injury- C5 – L1) patients and 4 were diagnosed with multiple sclerosis. Of the 24 patients with spinal cord injury, 10 patients had T6 and above level of injury. None of patients reported gross hematuria during the first 24 hour period after the injection. Autonomic dysreflexia was not observed in the neurogenic population. Mean pain score in female patients during the injection was 2.46 (range 0-6) and after the injection was 0.4 (range 0-2). Mean pain score in male patients during the injection was 2.52 (range 0-8) and after the injection was 0.4 (range 0-3). Among the non-neurogenic patients 8 (10%) required extended course of antibiotics for symptomatic urinary tract infections. In the neurogenic population 2 (7%) patients required extended course of antibiotics for symptomatic urinary tract infections.

Interpretation of results
None of the patients reported gross hematuria immediately after or during the first 24 hour period after the injection. Among the neurogenic patients, none of the patients developed autonomic dysreflexia during or after the injection procedure. Patients in both groups tolerated the injection procedure well. We did not observe a statistical significant difference in the pain scores between male and female patients. Urinary tract infections were found in 10% and 7% of non-neurogenic and neurogenic patients respectively.

Concluding message
Sedation free intradetrusor Botulinum toxin-A injections delivered via a flexible cystoscope is a safe procedure to be performed in an office setting. The procedure is well tolerated by both neurogenic and non-neurogenic patients.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Miami-Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**