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URODYNAMIC, SYMPTOMATIC AND QUALITY OF LIFE EVALUATION OF INTRAVESICAL DYSPORT (BOTULINUM TOXIN-A) IN THE MANAGEMENT OF REFRACTORY DETRUSOR OVERACTIVITY INCONTINENCE.

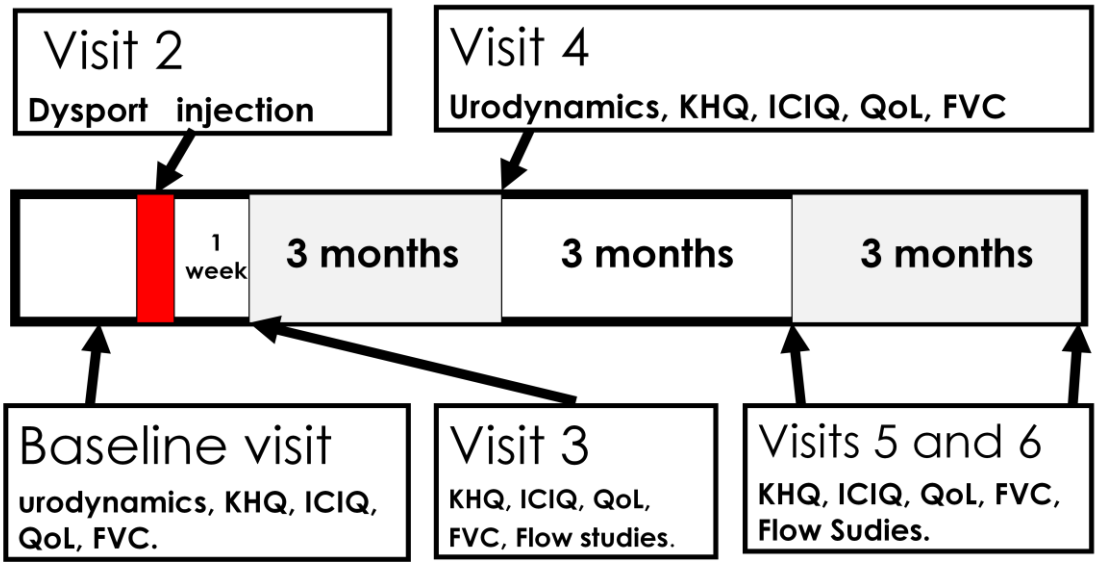
Hypothesis / aims of study

Botulinum toxin is one of the most potent naturally occurring neurotoxins known to man. There are several distinct but structurally similar types of Botulinum toxin, of which, type A and B have been most widely used. Botulinum toxin-A (BTX-A) has been used clinically in the management of several neuromuscular disorders, with increasing interest in its use in the lower urinary tract. BTX-A is commercially available in two preparations – Botox and Dysport. The majority of investigative trials reported, have used Botox, employing intravesical injections in cases of detrusor overactivity (DO), with beneficial effects. Minimal data exists on the use of newly FDA-approved Dysport. We present a study on the effects of intravesical Dysport in patients with neurogenic and idiopathic DO associated with incontinence, refractory to standard therapy.

Study design, materials and methods

This was a 9-month prospective, observational study following up patients with urodynamically proven DO (idiopathic and neurogenic) associated with DO incontinence, refractory to standard behavioral / anti-cholinergic therapy, following intravesical injections of BTX-A (Dysport). With informed consent, treatment was undertaken employing a flexible cystocope under local anaesthetic. 500 units of Dysport in 20mls normal saline was injected at 20 sites globally around the bladder (20 x 1ml aliquots), sparing the trigone. The protocol is summarized in Figure 1. Patients underwent pressure-flow urodynamics at baseline and 12 weeks post treatment. Flow rate and post void residual was assessed at each visit. Symptomatic assessment was undertaken using 3-day frequency-volume charts (FVC), Kings Health Questionnaire (KHQ), ICIQ-SF and Quality of Life and Symptoms Distress Inventory Instruments (QoL), at baseline, and 1-week, 3,6 and 9 months post-treatment.

Figure 1.



Results

53 patients (44 idiopathic DO, 9 neurogenic DO; 49 women, 4 men) were recruited into the trial. One patient withdrew after baseline, before treatment. 52 patients underwent intravesical injection of 500 units of Dysport under local anaesthetic. Two patients withdrew after treatment, before visit 4 urodynamics (one for a new diagnosis of breast cancer, one for relocation to a different area). This left 50 evaluable patients, all of which completed the trial. Significant improvement in urodynamic (Figure 2), symptomatic (Figure 2) and quality of life parameters were seen in the majority of patients with a low overall side effect profile.

Figure 2.

	Baseline	*1 week*	*3 months*	*6 months*	*9 months*
Mean Daytime Frequency	12.6	**7.8***	**5.8***	**6.3***	**7.6***
Mean Episodes Nocturia	2.4	**1.1***	**0.5***	**0.5***	**1.0***
Mean Incontinence Episodes per day	5.27	**1.0***	**0.4***	**0.4***	**1.4***
Mean max. voided volume (mls)	201	**380***	**427***	**396***	**351***
Volume to first DO (mls)	71		**200***		
Cystometric Capacity (mls)	172		**301***		
Post Void Residual (ml)	55	**110***	**156***	65	49

*** p<0.01 vs. Baseline**

Interpretation of results

Intravesical Dysport therapy for refractory detrusor overactivity has here demonstrated significant improvement in symptomatic parameters, with significant reductions in urinary frequency, nocturia and incontinence episodes out to 9 months after treatment, compared to baseline. The biggest improvements were seen in the first week after treatment, however significant further improvements were seen in the subsequent 3 months. Urodynamic parameters again demonstrated significant objective improvements. Symptomatic and quality of life instruments also demonstrated significant sustained improvements.
Apart from voiding dysfunction requiring intermittent self catheterisation (19%), and urinary tract infection (10%), no significant adverse events were noted.

Concluding message

Intravesical Dysport appears a safe and useful alternative treatment option for patients with refractory DO incontinence. There is a great need for well structured comparative randomized controlled studies to optimise this therapeutic approach.

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Gwent Healthcare NHS Trust Local Ethics Committee, MHRA (Medicines Healthcare Regulatory Authority), UK**
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	**Gwent Healthcare NHS Trust Local Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**