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OPEN LABEL PILOT STUDY OF URETHRAL INJECTIONS OF BOTULINUM TOXIN TO TREAT WOMEN IN URINARY RETENTION DUE TO A PRIMARY DISORDER OF URETHRAL SPHINCTER RELAXATION (FOWLER'S SYNDROME)

Hypothesis / aims of study

Urinary retention is uncommon in women, and one cause is a primary disorder of urethral sphincter relaxation, characterised by an elevated urethral pressure profile and specific findings in the urethral sphincter EMG (Fowler's Syndrome). Women may present with symptoms of obstructed voiding or complete urinary retention. Clean intermittent self-catheterisation is often painful to perform and currently, the only treatment to show benefit is sacral neuromodulation. This aim of this pilot study was to assess the efficacy, defined as improvement of flow rates by more than 50%, improvement in residual volume and scores on the IPSS questionnaire, and safety of urethral sphincter injections of botulinum toxin in women with Fowler's Syndrome.

Study design, materials and methods

In this open label pilot institutional review board approved study, ten women with mean age 40.2years (25-65) with a primary disorder of urethral sphincter relaxation (elevated urethral pressure profile (UPP), sphincter volume and abnormal EMG) presenting with obstructed voiding (n=5) or in complete urinary retention (n=5) were recruited from a single tertiary referral centre. Baseline symptoms were assessed using the IPSS questionnaire, and urinary flow and post-void residual volume were measured. After 2% lidocaine injection, 100U of onabotulinumtoxintypeA was injected into the striated urethral sphincter, divided on either side, under EMG guidance. Patients were reviewed at week 1, 4 and 10 post-treatment and symptoms were reassessed using the IPSS questionnaire, and urinary flow and post-void residual volume were measured. The UPP was repeated at week 4.

Results

An improvement in mean symptoms and bother scores on the IPSS, flow rate and post-void residual volumes were demonstrated at week 10 following botulinum toxin injections (table 1). Three out of five women showed a 50% improvement in flow rate. Four out of five women in complete retention could void spontaneously, with a mean flow rate of 11.4 mls/sec at week 10. Six patients discontinued catheterisation at week 10. The mean static UPP improved from 113 (86-139) to 92.2 (66-151) cmH_20 at baseline.

No serious side effects were reported. Three women with a history of recurrent urinary tract infections developed a urinary tract infection. None of the women developed stress incontinence. Seven out of the ten women opted to return for repeat injections.

Interpretation of results

This pilot study demonstrates an improvement in patient-reported lower urinary tract symptoms, and objective parameters such as flow rate, post-void residual volume and UPP, ten weeks following urethral sphincter injections of botulinum toxin. No serious side effects were reported. However, a larger study is required to confirm the findings of this pilot study.

Concluding message

In this open-label pilot study, Botulinum toxin injections into the striated urethral sphincter is associated with clinically meaningful improvement in voiding parameters representing a safe outpatient treatment, and a reasonable interim measure for those with retention/obstructed voiding awaiting sacral neuromodulation.

Table 1. Improvement in symptoms, urinary flow and post-void residuals 10 weeks after Botulinum injections

	Baseline	Week 10 post injection
Mean flow rate ml/sec (range)	8.1 (3.4-10)	12.6 (6.3-27.4)
Mean RV (range)	315 (40-700)	112 (0-230)
Mean IPSS (range)	20.9 (10-33)	15.3 (8-25)
Mean Bother score (range)	6.1 (4-7)	3.5 (1-7)

Disclosures
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