

TWO YEARS EXPERIENCE OF INTRA-DETRUSOR BOTULINUM A TOXIN FOR IDIOPATHIC DETRUSOR OVERACTIVITY: DURATION OF ACTION, QUALITY OF LIFE AND FREQUENCY/VOLUME MEASUREMENTS

Hypothesis / aims of study

Treatment options for overactive bladder (OAB) are limited when behavioural modification and anti-cholinergic drugs have failed. Few patients' symptoms are severe enough to require clam ileocystoplasty (with its potential complications) and neuromodulation is expensive and not widely available.

Botulinum toxin A injections have been used in patients with OAB of neurological origin and there are small-scale studies of its use in idiopathic OAB^{1,2,3}. This prospective study reports the results, complications and duration of benefit following intra-detrusor injection of Botulinum A toxin.

Study design, materials and methods

Patients with urodynamically proven refractory OAB who had previously failed to respond to at least two anti-cholinergic medications at adequate dose or had experienced significant side effects, were offered treatment with intra-detrusor Botulinum toxin.

Five hundred IU of Botulinum toxin A (Dysport, Ipsen) were injected into the detrusor at 20 sites in a grid-shaped pattern, using a flexible cystoscope and the Olympus Injector system. Patients were usually awake during the procedure. All patients kept a voiding diary and completed the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI) to record the effect of their OAB on their quality of life. These parameters were measured before treatment and at two months. All patients were followed up until treatment benefit had worn off.

Results

Sixty one patients underwent treatment. 55 were female (mean age 60.74, range 17-86 years) and 5 were male (mean age 59.33, range 32-70). The table below shows pre-treatment parameters for the group:

Symptom score	
IIQ	14.08
UDI	10.56
Frequency/volume parameters	
Frequency	9.26
Nocturia	1.188
Max capacity by day	348.5
Average capacity by day	173.6

39/61 patients followed up to date have shown clinically significant improvement in frequency, nocturia and in IIQ/UDI symptom scores. Patients with no improvement or a response lasting less than 2 months were classed as non-responders (22/61).

The table below illustrates pre- and post-procedure variables and mean changes in these values for Responders only. There were no significant changes in non-responders. All data are means.

	Pre-treatment	Post-treatment	Mean improvement
Symptom score			
IIQ	14.25	3.37	11.05
UDI	10.89	3.68	7.04
Frequency/volume parameters			
Frequency	8.97	5.91	3.60
Nocturia	1.92	1.17	0.83
Max capacity by day	321.20	439.44	100.48
Average capacity by day	164.60	263.26	97.37

The procedure was generally well tolerated, although 10 patients found the procedure uncomfortable. Two patients required general anaesthesia and 5 requested intravenous sedation. Complications experienced included transient

urinary retention (3/61) and urinary tract infections (3/48). 3 patients suffered from post-procedural discomfort lasting for up to 2 weeks. 5 patients required intermittent self-catheterisation for a maximum of 2 months.

Effects were found to last a median of 8 months (range 2-14 months). To date, 25 patients have undergone second injections and 2 have undergone third and 1 a fourth.

Interpretation of results

This series shows that intra-detrusor injection of Botulinum A toxin is a safe and effective treatment for OAB. Improvements in both quality of life parameters and frequency/volume measurements are shown to last for up to 14 months. It is generally well tolerated. A significant number of patients have accepted and responded to subsequent injections.

Concluding message

This pilot study showed that the intradetrusor injection of Botulinum Toxin A seems to be an effective and safe treatment of refractory overactive bladder.

References:

- 1 BJU Int. 2005 Oct;96(6):848-52.
- 2 J Urol. 2005 Sep;174(3):984-9
- 3 J Urol. 2005 Nov;174(5):1873-7

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HUMAN SUBJECTS: This study did not need ethical approval because prospective study but followed the Declaration of Helsinki Informed consent was obtained from the patients.