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Medium term outcomes and safety profile of OnabotulinumtoxinA intra-vesical injections in men with idiopathic detrusor overactivity

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Introduction

- Overactive bladder (OAB) symptoms are prevalent even in men affecting 10.8% vs 12.8% in women [1].
- When bothersome OAB symptoms remain despite conservative measures, behavioural therapy, anti-muscarinic and beta-3 agonist medication, intravesical Onabotulinum toxin A (BoNT-A) injections have been shown in several randomised controlled trials to reduce incontinence episodes and improve quality of life (QoL) outcome measures when compared to placebo[2-6].
- The main adverse events are de novo use of intermittent self-catheterisation (ISC) and urinary tract infection (UTI).
- The phase III trials contained very few male patients (between 0 and 11.9%)[4-7].
- One study reported long term success in only 25% of men where success was defined as symptoms free or still having repeated BoNT-A injections [8].
- Given this paucity of data on men, we assessed the clinical effectiveness and safety profile for BoNT-A for men with IDO and compared them against the outcomes in females.

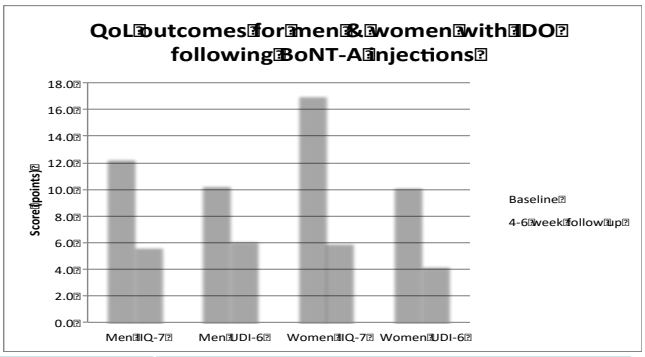
Methods

- Men with IDO who had had intra-vesical BoNT-A since 2004 were identified from our institution's prospectively maintained database.
- Subjects were over 18 years of age with confirmed detrusor overactivity on urodynamic studies.
- Patients with neurogenic detrusor overactivity, and patients with OAB symptoms without detrusor overactivity on their urodynamics were excluded.
- The study was registered as a clinical audit within the local trust. The data for women with IDO was also extracted for comparison.
- Information regarding adverse events including UTI and de novo CISC was added retrospectively by review of patients follow up documentation.
- UTI was defined as symptoms of UTI requiring antibiotic treatment.
- QoL scores were recorded using the urogenital distress inventory six (UDI-6) and the incontinence impact questionnaire seven (IIQ-7) at baseline and at four to six week follow up.
- Statistical analysis and production of figures was done using Microsoft Excel Version 2011. Matched and unmatched t-tests were used for continuous variables and results considered statistically significant if $p<0.05$.

Demographics	Men	Women	p
Total injections for IDO	134 (26.3%)	376 (73.7%)	-
Age at injection (years)	57.1 (SD 13.0)	53.5 (SD 11.2)	0.02

BoNT-A doses	90 U	100 U	150 U	200 U	250 U	300 U	Not known	Total
n	1	57	12	44	12	3	4	**133**
%	0.8	44.2	9.3	34.1	9.3	2.3	3	**100**

Results



	QoL Outcomes		
	Men	**Women**	**p**
Baseline UDI-6	10.3	10.2	0.87
4-6 week FU UDI-6	6.1	4.2	0.00
Δ Symptom score	**-4.2**	**-6.0**	0.01
p (paired t)	0.00	0.00	
Baseline IIQ-7	12.3	17.0	0.00
4-6 week FU IIQ-7	5.7	5.9	0.78
Δ Symptom score	**-6.6**	**-11.1**	0.00
p (paired t)	0.00	0.00	

	Safety profile		
	Men	**Women**	**p**
ISC			
Follow up	123 (92.5%)	139 (37.2%)	-
Already using ISC	15 (12.2%)	14 (10.1%)	0.59
New ISC (all doses)	45/108 (41.7%)	30/125 (24%)	0.00
UTI			
Follow up	124 (93.2%)	141 (37.7%)	-
UTI (all doses)	36 (29.0%)	29 (20.6%)	0.11

Conclusions

- Men with IDO experienced a statistically significant improvement in UDI6 and IIQ7 scores after BoNT-A injections.
- This improvement was statistically less than for women.
- The UTI rates and need for new ISC were greater for men than for women.

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