

**BOTULINUM TOXIN TYPE A IMPROVES BENIGN PROSTATIC HYPERPLASIA SYMPTOMS IN PATIENTS WITH SMALL PROSTATES**Hypothesis / aims of study

Botulinum toxin A (BTX-A) injection into the prostate in patients with voiding dysfunction and large prostates has been reported [1]. We expand the clinical use of BTX-A in treating patients with small prostates and symptomatic benign prostatic hyperplasia (BPH).

Study design, materials and methods

Sixteen men with symptomatic BPH, prostate volume less than 30 ml, peak flow rate less than 12 ml/sec, and refractory to at least one month of  $\alpha$  blocker treatment received BTX-A 100 U injection into the prostate transperineally under transrectal ultrasound surveillance [2]. The clinical effects were evaluated at baseline and after treatment.

Results

No significant local or systemic side effects were observed in any of the patients. All patients reported subjective improvement starting approximately one week, achieving maximal effect after one month, and maintaining at 3 months and 6 months. AT 6 to 12 months (mean 10) follow-up, no patient had recurrence of symptoms. The mean prostate volume, symptom score, quality of life index were significantly reduced by 13.3% (from 19.6 $\pm$ 1.2 ml to 17.0 $\pm$ 1.1ml), 52.6% (from 18.8 $\pm$ 1.6 to 8.9 $\pm$ 1.9), and 44.7% (from 3.8 $\pm$ 0.3 to 2.1 $\pm$ 0.3), respectively. The maximal flow rate was significantly increased by 39.8% (7.3 $\pm$ 0.7 ml/sec to 11.8 $\pm$ 0.8 ml/sec). In 2 patients who received biopsy 1 month post BTX-A injection, the TUNEL staining demonstrated increase in apoptotic activity not only in the glandular component but also in the stromal component of the prostate tissue.

Table 1. Baseline characteristics and results at 1, 3 and 6 month (M) evaluation in the 16 patients with BPH

	Baseline (N=16)	1 M follow-up (N=16)	3 M follow-up (N=16)	6 M follow-up (N=16)	Last follow-up (mean: 10 M) (N=13)
Prostate (mL)	19.6 $\pm$ 1.2	17.0 $\pm$ 1.1*	16.7 $\pm$ 1.2*	16.9 $\pm$ 1.1*	16.4 $\pm$ 2.8*
IPSS (0-35)	18.8 $\pm$ 1.6	8.9 $\pm$ 1.9*	7.9 $\pm$ 1.7*	7.4 $\pm$ 1.8*	9.0 $\pm$ 2.2*
Peak flow (mL/s)	7.3 $\pm$ 0.7	11.8 $\pm$ 0.8*	11.9 $\pm$ 1.1*	12.5 $\pm$ 1.0*	12.6 $\pm$ 0.9*
QOL (0-6)	3.8 $\pm$ 0.3	2.1 $\pm$ 0.3*	1.9 $\pm$ 0.3*	1.8 $\pm$ 0.3*	2.1 $\pm$ 0.5*
RU (mL)	67.7 $\pm$ 30.0	25.1 $\pm$ 4.0	27.3 $\pm$ 4.3	26.4 $\pm$ 4.3	26.8 $\pm$ 5.6

Values are mean  $\pm$  S. E.

\*p<0.05, in comparison with baseline

IPSS: international prostate symptom score

QOL: quality of life indices

RU: residual urine

Interpretation of results

Previously, BTX-A has been successfully applied to urethral sphincter, prostate of large volume, and bladder to reduce outlet resistance or overactive bladder [3]. We extended the clinical use of this toxin to patients with small prostates and symptomatic BPH and got good initial results. With a total dose of 100 U of BTX-A injected into the prostate, all patients who previously had low flow rate, severe lower urinary tract symptoms, and poor quality of life could have significant improvement. The effect was prompt and persistent at least for 6 months.

### Concluding message

Our preliminary results suggest that BTX-A injected into the prostate is a promising treatment for patients with small prostates and symptomatic BPH.

### References

1. Relief by botulinum toxin of voiding dysfunction due to benign prostatic hyperplasia: results of a randomized, placebo-controlled study. *Urology*, 62: 259-265, 2003.
2. Pilot study of transperineal injection of dehydrated ethanol in the treatment of prostatic obstruction. *Urology*, 61: 797-801, 2003.
3. Effect of botulinum toxin A on the autonomic nervous system of the rat lower urinary tract. *J Urol*, 169: 1896-1900, 2003.

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