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ORIGINAL ARTICLE

Intraprostatic injection of botulinum toxin-A in patients with refractory chronic pelvic pain syndrome: The transurethral vs. transrectal approach

Mohamed A. El-enen, Mohamed Abou-Farha *, Ahmed El-Abd, Hassan El-Tatawy, Ahmed Tawfik, Shawky El-Abd, Mohamed Rashed, Mahmoud El-sharaby

Urology Department, Faculty of Medicine, Tanta University, Egypt

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KEYWORDS

Chronic prostatitis;
Pelvic pain syndrome;
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ABBREVIATIONS

BTX-A, botulinum toxin type A;
CP/CPPS, chronic prostatitis associated with chronic pelvic pain syndrome;
NIH, National Institutes of Health;

Abstract ***Objective:*** To evaluate the outcome of an intraprostatic injection of botulinum toxin-A (BTX-A) in men with refractory chronic prostatitis-associated chronic pelvic-pain syndrome (CP/CPPS) and to compare the efficacy of the transurethral and transrectal routes.

Patients and methods: In an uncontrolled randomised clinical trial conducted in men with refractory CP/CPPS, the patients were classified into two groups according to the route of BTX-A injection; transurethral (group 1, 28 patients) and transrectal ultrasonography-guided (group 2, 35 patients). The chronic prostatitis symptom index (CPSI), maximum urinary flow rate (Q_{max}) and white blood cell (WBC) count in expressed prostatic secretion (EPS) were measured before and at 3, 6 and 12 months after the injection. A significant clinical improvement (SCI, defined as a reduction of 4 points or a 25% decrease in total CPSI score) was correlated with patient age, prostate volume and symptom duration.

Results: In group 1, the pain and quality-of-life domain scores improved, but statistically significantly only at 6 months. The voiding score improved at all follow-up

* Corresponding author at: Tanta Urology Hospitals, Tanta, Egypt.
E-mail address: m_farha1975@yahoo.com (M. Abou-Farha).
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CPSI, chronic prostatitis symptom index; Q_{max}, maximum urinary flow rate; WBC, white blood cell; EPS, expressed prostatic secretion; SCI, satisfactory clinical improvement; QoL, quality of life; HPF, high-power field

visits. In group 2 there was a significant improvement in all the CPSI domain scores at all follow-up visits, except for pain, which was insignificantly improved by 12 months. The SCI ratings in groups 1 and 2 were 36%, 79% and 57%, and 49%, 89% and 74% in group 2 at the three follow-up visits, respectively. The Q_{max} was significantly improved in both groups during the follow-up (except at 12 months in group 1). There was a significant reduction in the mean WBC count in the EPS in patients with inflammatory prostatitis. Both prostate volume and symptom duration were significantly associated with a lower SCI rating.

Conclusion: BTX-A is an available treatment option for patients with refractory CP/CPPS. It is more effective in patients with a small prostate and short symptom duration. The transrectal route provided better results than the transurethral route. More prospective longer term studies are needed.

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Introduction

There has been increasing research into managing the chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), defined 'as discomfort or pain in the pelvic region for $\geqslant$3 months, with sterile specimen cultures and white blood cell (WBC) counts in prostate-specific specimens, e.g., semen, expressed prostatic secretion (EPS) and urine collected after prostate massage' [1,2]. Based on previous data, CP is associated with ≈2 million outpatient visits/year in the USA (8% to urologists and 1% to primary-care physicians) with high direct costs for treatment (US$ 4000/patient/year) [3].

According to the USA National Institutes of Health (NIH) classification system, CP/CPPS is 'prostatitis category III' [1]. By definition, nonbacterial CP is an inflammatory response in the absence of any detectable causative micro-organism. The exact cause of CP/CPPS (NIH IIIB) is unknown but it might be due to psychological conditions, atypical bacterial infection, immune, neurological, endocrine dysfunction, and dyssynergic voiding [2–10]. As there is no definite cause for CP/CPPS, there is no definite or standard therapy for treatment.

Although the mechanism of action of botulinum toxin-A (BTX-A, produced by the Gram-positive anaerobic bacterium *Clostridium botulinum*) on prostatic tissues is unclear at the molecular and/or histological levels, it is supposed to affect motor, sensory or glandular function, in addition to an anti-inflammatory action through the modulation of various neurotransmitters released in different kinds of tissue. BTX-A has been assessed for managing voiding disorders due to an overactive bladder, detrusor-external sphincter dyssynergia, or BPH [11]. There are few clinical trials evaluating BTX-A for managing CP/CPPS, and unfortunately most of these trials included few patients or lacked a subjective and objective description of the outcome variables [6–9].

In the present study we aimed to evaluate the results of an intraprostatic injection with BTX-A in patients with refractory CP/CPPS (NIH-III) using clinical, urodynamic and laboratory variables, and compare the transurethral and transrectal routes of injection.

Patients and methods

The study was conducted as an uncontrolled randomised clinical trial on sexually active patients (with an International Index of Erectile Function-5, IIEF-5, score of $\geqslant$17) with CP/CPPS who were managed during the period from January 2008 to December 2013 in our department. Written consent was obtained from all participants after counselling about the nature of the study, including potential benefits and risks. The study protocol was reviewed and approved by our institutional review board.

Patients selected were those with CP/CPPS (IIIA or B), aged $<$50 years, with a symptom duration of $>$2 years and who were refractory to other medications (failed responses to antibiotics, α-blockers and anti-inflammatory agents). Patients were excluded if they had bleeding disorders, associated UTI, urolithiasis, urethral stricture, a low maximum urinary flow rate (Q_{max}, $<$10 mL/s), a postvoid residual urine volume of $>$100 mL, and/or were unfit for BTX-A, having associated neuropathy or emphysema.

The preoperative evaluation included a complete history, and clinical examination, with completion of an Arabic version of the CP symptom index (CPSI) [12]. All patients had a urine sample analysed and cultured before and after prostatic massage, and uroflowmetry. Cystoscopy was done under local anaesthesia as an outpatient procedure for patients with a Q_{max} of $<$15 mL/s, to exclude organic obstruction.

The included patients were randomised using a coin-tossing technique into two groups according to the route of BTX-A injection (Botox®, Allergan, Inc., Irvine, CA, USA). The intraprostatic injection with BTX-A was delivered under spinal anaesthesia through an endo-

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