OnabotulinumtoxinA (Botox) Nerve Blocks Provide Durable Pain Relief for Men with Chronic Scrotal Pain: A Pilot Open-Label Trial

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DOI: 10.1111/jsm.12707

ABSTRACT __

Introduction. Chronic scrotal pain (CSP) is a common, often debilitating, condition affecting approximately 4.75% of men. While nerve blocks using local anesthetics usually provide temporary pain relief, there are no publications on the use of longer acting nerve blocks to provide more durable pain relief for men with CSP.

Aim. The aim of this study was to determine if onabotulinumtoxinA (Botox) cord blocks provide durable pain relief for men with CSP.

Methods. In this pilot open-label study, men with CSP who had failed medical management but experienced temporary pain relief from a standard cord block underwent a cord block with 100U Botox.

Main Outcome Measures. The outcomes measured were changes 1, 3, and 6 months post-Botox injection in (i) a 10-point visual analog scale (VAS) pain score; (ii) scrotal tenderness on a three-point scale as rated by physical examination; and (iii) the Chronic Epididymitis Symptom Index (CESI) to measure the severity and impact of scrotal pain on men. Paired *t*-tests were used to compare groups.

Results. Eighteen patients with CSP seen between April and September 2013 had Botox injected as a cord block. At the 1-month follow-up, pain reduction was reported by 72% of patients (mean VAS score: 7.36 vs. 5.61, P < 0.003), while by physical examination 44 and 34% of the men had either complete or partial resolution of scrotal tenderness. In addition, there was also a significant reduction in CESI scores (22.19 vs. 19.25, P < 0.04). At 3 months, 56% had both sustained pain reduction and reduced tenderness based on the VAS score (mean: 7.36 vs. 6.02, P < 0.05) and physical exam. The CESI score continued to be significantly lower. Unfortunately, by 6 months, most men had a return to their baseline levels of pain and tenderness.

Conclusions. Our pilot study found that Botox cord blocks provide pain reduction for 3 months or more for most men with CSP. Khambati A, Lau S, Gordon A, and Jarvi KA. OnabotulinumtoxinA (Botox) nerve blocks provide durable pain relief for men with chronic scrotal pain: A pilot open-label trial. J Sex Med 2014;11:3072–3077.

Key Words. Botox; Chronic Scrotal Pain; OnabotulinumtoxinA

Introduction

Chronic orchialgia or chronic scrotal pain (CSP) is defined as "intermittent or constant unilateral or bilateral testicular pain three months or longer in duration that significantly interferes with daily activities" [1]. This is a common condition and many will have severe disabling pain for months or years with disruption of their normal

lives. CSP can be caused by various processes including infectious (epididymitis, prostatitis), benign (hydrocele, spermatocele, varicocele), testicular malignancy, postsurgical (vasectomy, hernia repair, scrotal procedure), radiculopathy, neuropathic, or referred pain [2]. Hence, a thorough history and physical examination is essential in order to characterize, locate, and treat the underlying source of pain [3]. Unfortunately, almost 25%

of cases remain idiopathic and the therapies are often empiric [1]. Patients are usually treated in a step-wise fashion, with medical management involving antibiotics, anti-inflammatories, and analgesics being the first steps. Next course of therapy includes regional nerve blocks using a combination of local anesthetic and/or steroids, with or without ultrasound guidance [4]. Invasive options include microsurgical denervation of the spermatic cord, which is shown to be effective in up to 96% [5-7] of cases and with a 75% success rate at 20 months of follow-up [8]. Finally, epididymectomy or orchiectomy has been performed with variable success rates. Costabile et al. demonstrated that the clinical benefit of orchiectomy is uncertain, as 80% of patients continued to experience significant pain [9].

The finding of nerve blocks providing short-term relief of scrotal pain coupled with the effectiveness of denervation of the spermatic cord in reducing or eliminating scrotal pain prompted us to consider the use of a longer acting nerve blocking agent. OnabotulinumtoxinA (Botox: Allergan, Irvine, CA, USA) provides temporary but long-acting sensory fiber nerve blocks [10,11]. OnabotulinumtoxinA has been used by urologists for the treatment of painful pelvic and bladder disorders, overactive bladder syndromes, and benign prostatic hypertrophy [12,13]. In this study, we administered Botox cord blocks to assess its effectiveness in providing durable pain relief for men with non-neuropathic scrotal pain.

Aim

The aim of this study was to determine if the use of Botox as a cord block provides durable pain relief for men with CSP.

Methods

After approval from our research ethics board, 18 patients with CSP seen between April and September 2013 were enrolled in our study. Exclusion criteria included men trying to conceive with their partners in the next 6 months, history of allergic reaction to Botox and human serum albumin, history of motor neuron disease or neurogenic bladder, use of anticoagulation or blood dyscrasias, and inability to provide informed consent. They underwent a comprehensive workup with a thorough medical and psychiatric history, physical examination, and investigations including Doppler ultrasonography of the scrotum, urine, and semen

studies. No specific reversible cause was identified for the pain. All patients failed conservative management with anti-inflammatories, antibiotics, anticonvulsants, and analgesics, but experienced temporary pain relief felt to be significant by the patients from a spermatic cord block using a 10 cc solution of 0.5% Marcaine (Hospira, Montreal, Quebec, Canada) and 2% xylocaine. These patients were offered a cord block with Botox. The possible benefits of longer term relief but also the risk of complete failure, hypersensitivity reactions, generalized muscle weakness, and sensory changes were explained. After consent was obtained, we proceeded with the Botox injection. One hundred units of Botox was reconstituted in 10 cc of normal saline, and injected into the upper scrotum approximately 1-2 cm distal to the external ring, infiltrating the branches of the genitofemoral and the ilioinguinal nerves, identical to the technique described by Issa et al. [14] This technique is similar to the cord block widely used by urologists, with extra care being taken to confirm with each injection that the injection is not into any vascular structure. Before injection, the syringe is aspirated to confirm that the needle is not entering an artery or vein. All blocks were administered by the same person (K.A. Jarvi).

Main Outcome Measures

The objective measures to document changes in pain were changes following the Botox cord block in a visual analog pain score and the Chronic Epididymitis Symptom Index (CESI). The subjective measures were changes in tenderness of the scrotum by physical examination. Patients were asked to fill a 10-point visual analog pain scale (VAS) before Botox injection and, 1-month, 3-month, and 6-month following injection. In addition, they were also subjected to careful physical examination of the scrotum with their tenderness in the testis and epididymis rated on a zero- to three-point scale (this is a nonvalidated scale used at our center to grade tenderness; 0 being no tenderness and 3 being exquisitely tender) and sensory changes noted at each visit. This provided another means of assessing the degree of scrotal tenderness in patients. All physical exams were performed by the same individual (K.A Jarvi). Finally, patients also completed the CESI at each visit. Paired t-test was used to analyze the VAS score, physical tenderness rating, and CESI score before and after administration of Botox cord block.

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