# Injection Anxiety and Pain in Men Using Intracavernosal Injection Therapy after Radical Pelvic Surgery

Christian J. Nelson, PhD,\* Wayland Hsiao, MD,† Eliana Balk, BA,\* Joseph Narus, DNP, APRN, NP-BC,‡ Raanan Tal, MD,§ Nelson E. Bennett, MD,¶ and John P. Mulhall, MD‡

\*Department of Psychiatry and Behavioral Sciences, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; 
†Department of Urology, Emory University School of Medicine, Atlanta, GA, USA; †Male Sexual & Reproductive Medicine 
Program, Urology Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; 
§Department of Urology, Tel Aviv University, Tel Aviv, Israel; \*Department of Urology, Lahey Clinic, Burlington, MA, USA

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#### ABSTRACT-

*Introduction.* Intracavernosal injection (ICI) therapy is a well-recognized treatment strategy with high success rates for men with erectile dysfunction. Despite this, injection anxiety and pain related to injection are significant barriers to its use.

Aims. This study aims to examine injection anxiety and injection pain in patients using ICI.

*Methods.* Men starting ICI therapy post radical pelvic surgery completed questionnaires at initial visit, at each of the two ICI training sessions and at a 4-month follow-up visit.

*Main Outcome Measures.* Injection Anxiety Scale, Injection Pain Scale, Injection Reaction Inventory, and the Erectile Function Domain of the International Index of Erectile Function.

**Results.** Average age of the 68 men was  $60 \pm 8$  years. At 4 months, the self-reported frequency of ICI use was: 29% <1/week, 26% 1/week, 40% 2/week, and 5% 3/week. Mean injection anxiety score at first injection was  $5.7 \pm 2.8$  (range 0–10) and significantly decreased to a  $4.1 \pm 3$  at 4 months (P < 0.001). At first injection, 65% reported high injection anxiety (≥5) and this significantly decreased to 42% (P = 0.003) at 4 months. Anxiety at first injection was negatively related to ICI frequency at 4 months (r = -0.23, P = 0.08). Mean injection pain score at first injection was low ( $2.2 \pm 1.8$ , range 0–10) and 59% rated injection pain ≤2. Injection pain remained consistent across time periods. At first injection, injection anxiety (assessed prior to injection) was related to injection pain (r = 0.21, P = 0.04) and subjects (n = 21) who reported high injection anxiety (≥5) across time points, reported an increase in injection pain scores from first injection to 4 months (2.7 vs. 3.7, P = 0.05).

Conclusions. Although injection anxiety decreased with ICI use, mean injection anxiety remained at a moderate level (4.4) and 42% of men continued to report "high" injection anxiety at 4 months. While injection pain was low, injection anxiety and pain were related. These data suggest the need for a psychological intervention to help lower injection anxiety related to ICI. Nelson CJ, Hsiao W, Balk E, Narus J, Tal R, Bennett NE, and Mulhall JP. Injection anxiety and pain in men using intracavernosal injection therapy after radical pelvic surgery. J Sex Med 2013;10:2559–2565.

Key Words. Prostate Cancer; Intracavernosal Injection; Anxiety; Pain; Erectile Dysfunction

#### Introduction

Intracavernosal injection (ICI) therapy, introduced in 1982, has become a well-established treatment for ED with a high rate of clinical efficacy [1–4]. Because of this high efficacy, ICI is often used as the cornerstone treatment of penile

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rehabilitation in men with ED following radical prostatectomy (RP) [5,6]. Although phosphodiesterase type 5 inhibitors (PDE5) are the first choice of treatment for postpelvic surgery-related ED, surgical trauma to the cavernous nerves often leads to a period of postoperative neuropraxis during which ED is recalcitrant to PDE5 treatment as only 12–17% will achieve a functional erection using PDE5 within the first 6 months

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following surgery [6]. In this setting, a second line treatment for ED, such as ICI, becomes imperative for penile rehabilitation programs. Despite the efficacy of ICI, its use has been limited by a historically high dropout rate [2,3,7,8]. Attrition rates are highest in the first year of use of penile injection therapy, with dropout rates ranging from 46% to 80% in this time period [9,10].

Many studies have evaluated the reasons for discontinuation of ICI [3,8–14]. The most frequently cited reasons have been: cost, aversion to the idea of penile injection, partner dislike of injections, loss of interest in sexual intercourse, lack of sexual spontaneity, and difficulty integrating injections into a sexual relationship. Attrition due to injection pain (needle stick) or other side effects of penile injection therapy (priapism or penile lump) is relatively low and ranges from 5% to 10% in these studies. In fact, the mean injection pain level reported by men at first injection tends to be very low. Most studies report average pain scores on a 0-10 pain rating scale to range between a score of 1 and 2 [15,16]. Despite clinical experience, which indicates that men become very anxious about penile injection therapy, anxiety is rarely assessed in these studies. Of the studies cited, two have inquired about "fear of needles." Sundaram et al. reported that 23% of men discontinued treatment because of fear of needles [8], whereas Mulhall et al. reported the fear of needles to be a relatively minor reason for dropout (5%). Clinically, many men deny a "fear of needles" yet still report moderate to high anxiety related to starting ICI treatment. As a result, rates of men reporting fear of needles may significantly underreport anxiety related to ICI. Thus, exploring anxiety related to penile injections may provide useful information that may help educate men and hopefully increase compliance and acceptance of ICI therapy.

#### **Aim**

The aim of this study was to assess the changes in injection anxiety and injection pain over time related to penile injections. We hypothesized that injection anxiety would decrease over time, and injection anxiety would be negatively related to injection frequency. We also anticipated that injection pain would be relatively low and decrease over time. We were specifically focused on the pain of the needle stick, as opposed to any pain related to the injection medication.

#### Methods

## Patient Population

Subjects were recruited consecutively as they attended our clinic. The eligibility requirements included: (i) history of radical pelvic surgery (cystectomy and prostatectomy); (ii) participation in the injection therapy program; (iii) ability to provide informed consent; and (iv) ability to converse, write, and read English. Potential subjects were excluded if they had a history of or were currently receiving radiation therapy, chemotherapy, or hormone therapy.

## Study Design

The Institutional Review Board at our center approved the study. After initial evaluation at our sexual medicine clinic, patients who were recommended to start ICI were scheduled for two ICI training sessions that included initial dosetitration. At this initial visit to the sexual medicine program, the patients are told the injections are not painful. No specific intervention is provided to reduce injection anxiety. In the first ICI training session, the nurse reviewed the injection procedure and then demonstrated the injection technique by injecting the patient. Our initial injection agent of choice has been trimix with a concentration of papaverine 30 mg/mL, phentolamine 1 mg/mL, and prostaglandin E1 10 mcg/mL. The initial dosage at the initial injection visit was 5 units (0.05 mL). The needle used was a 29 gauge, half-inch needle. Patients were instructed to inject at either the 10 o'clock or 2 o'clock position (alternating sides between injections) and instructed to hub the needle. The syringe used was either for 100 units (1 cc) or 50 units (0.5 cc), depending on the dosage being given.

In the second session, the nurse reviewed the instructions and supervised the patient (or his partner) as he performed the injection. The duration between these training sessions was optimally one week or less. The injection dose at the second session was adjusted based on the patient response to their first 5-unit injection, but generally was increased from the first test-dose. During the time between training sessions, the patients did not have a prescription for the injection medication and thus did not use the injections at home.

The subjects completed the baseline questionnaires (see below) at the visit during which ICI was recommended (before the first ICI training visit with the nurse). In both ICI training sessions, the

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