Can Intraprostatic Injection of OnabotulinumtoxinA be Beneficial to Treat Premature Ejaculation? Results of a Prospective Study

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Introduction

Premature ejaculation (PE) is the most common sexual dysfunction in males and has been reported in 5% to 40% of sexually active men according to their age. Premature ejaculation is more prevalent in sexually naive males, particularly adolescents and young adults²⁰.

Although the pathophysiology of PE is still not completely understood, PE has been suggested to have both somatic and psychological basis, and it...
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criteria for PE for ≥ 6 months\textsuperscript{[12]}, reported intravaginal ejaculation latency time (IELT) of ≤ 2 minutes in ≥ 75% of coital attempts at a 4-week baseline assessment period, and indicated at least moderate PE-related personal distress or interpersonal difficulty.

Exclusion Criteria
History of serious medical, psychiatric or mental disorders, erectile or other sexual dysfunctions, partner’s sexual dysfunction, serious marital relational problems, very low intercourse frequency and patients with urinary tract infections were excluded.

Evaluation
The tools used for patient’s evaluation included stopwatch-measured ILETS, and patient-reported outcome measures\textsuperscript{[13]} combining premature ejaculation profile (PEP) and global impression of change (PGI) questionnaires at different study time points (Table 1). Intravaginal ejaculation latency time was measured by a stopwatch held by the partner as the time elapsing between starting vaginal penetration and starting intravaginal ejaculation. Premature ejaculation profile is a validated self-reported 4-domain 4-questionnaire. Each question scales 0–4 points with a total score of 0–16 points. Although PEP lacks validated cutoff scores, higher scores indicate better ejaculatory functions. PGI questionnaire describes the overall PE condition compared to baseline in a seven-point scale ranging from -3 to +3 points (“much worse” to “much better”, respectively)\textsuperscript{[13]}.

The patients were initially evaluated at a 4-week baseline period as they were required to report the IELT of their coital attempts as measured by stopwatch and to complete PEP questionnaire as well. Follow up assessment was done at 1-, 3- and 6-month post-injections to evaluate IELT, PEP, and PGI. Urine analysis and urine culture were done pre-injections, 1-months post injections, and thereafter as required. The patients were instructed not to receive any other therapy for PE ahead of the baseline period and throughout study duration.

Outcome Measurements
The primary endpoint was change of IELT at 3-month follow up, as compared to baseline. Secondary endpoints included changes in PEP and PGI at different
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follow up time points. Local and systemic AEs were also reported.

Procedure

The injections were performed transurethrally under general or regional anesthesia while the patient was in lithotomy position and as a day care setting. A total dose of 100 U of onaBoNT-A (BOTOX®, Allergan, Inc., Irvine, CA USA) was reconstituted in 4 ml of normal saline and divided into four fractions (1 ml, 25 U each). Prostatic tissues surrounding the ejaculatory ducts were aimed for injections using 23-gauge cystoscopic needle. Three intraprostatic injections were deeply allocated throughout floor of prostatic urethra, sparing 5 mm distance to the vicinity of bladder neck. A fourth most distal injection was allotted to the verumontanum close to ejaculatory ducts openings (Fig. 1).

Figure 1. Sites of intraprostatic injections of onabotulinumtoxinA in floor of prostatic urethra.

Statistical Analysis

GraphPad Prism for Windows, version 6.0 (GraphPad Software Inc., La Jolla, CA) was used for data analysis. Descriptive statistics were expressed as frequencies, proportions, mean (SD), and 95% confidence interval (CI). Differences over time among paired continuous data were analyzed using repeated measures ANOVA followed by Dunnett’s test for correction of multiple comparisons. Double-sided p < 0.05 was considered as significant.

Results

The study included 24 men with a mean age of 34.9 (8.9) yrs and mean IELT of 62.7 (25.9) seconds at baseline. The mean IELT has significantly increased from baseline to 79.1 (32.7), 89.0 (36.1) and 85.7 (35.4) seconds at 1-, 3- and 6-months, respectively (26.2%, 41.9%, and 36.7% increase; p < 0.0001 each). In PEP questionnaire, the score of “perceived control over ejaculation” has shown significant improvement at 3-months (p = 0.045), while at 1- and 6-months non-significant changes were reported. Additionally, the PEP data demonstrated significant changes of “satisfaction with sexual intercourse” but non-significant changes of “personal distress related to ejaculation” and “interpersonal difficulty related to ejaculation” at all follow up time points (Table 2). As for PGI, while only 2 (8.3%), 3 (12.5%), and 3 (12.5%) men reported “better” at 1-, 3- and 6-months, respectively, all other patients reported

| Measure               | Domain                              | Question                                                                 | Score                  |
|-----------------------|----------|--------------------------------------------------------------------------------|------------------------|
| PEP                   | Perceived control over ejaculation  | “Over the past month, was your control over ejaculation during sexual intercourse:” | 0: Very poor<br>1: Poor<br>2: Fair<br>3: Good<br>4: Very good |
| Satisfaction          | with sexual intercourse              | “Over the past month, was your satisfaction with sexual intercourse:”          | 0: Extremely<br>1: Quite a bit<br>2: Moderately<br>3: A little bit<br>4: Not at all |
| Personal distress     | related to ejaculation               | “How distressed are you by how fast you ejaculated during sexual intercourse?” | 0: Extremely<br>1: Quite a bit<br>2: Moderately<br>3: A little bit<br>4: Not at all |
| Interpersonal difficulty | related to ejaculation                | “To what extent does how fast you ejaculated during sexual intercourse cause difficulty in your relationship with your partner?” | 0: No change<br>1: Slightly better<br>2: Better<br>3: Much better |
| PGI                   | Compared to prior to the study       | would you describe your premature ejaculation condition as:                   | 0: No change<br>1: Slightly better<br>2: Better<br>3: Much better |

Table 1. Premature ejaculation profile and patient-reported global impression of change in premature ejaculation[19].
Table 2. Outcomes of stopwatch-measured IELT, PEP and PGI at follow up time points.

| Measure                  | Baseline | 1-mo     | 3-m      | 6-m      |
|--------------------------|----------|----------|----------|----------|
| IELT (Sec)               | Mean (SD)| 62.7 (25.9) | 79.1 (32.7) | 89.0 (36.1) | 85.7 (35.4) |
| SD (95% CI)              |            | NA       | 16.4 (12.9, 19.9) | 26.3 (20.9, 31.7) | 23.0 (18.2, 27.9) |
| % change                 | NA       | 26.2%    | 41.9%    | 36.7%    |
| P                        | 0.0001 > |          | 0.0001 > | 0.0001 > |
| PEP (Points)             | Mean (SD) | 1.29 (0.86) | 0.29 (-0.06, 0.65) | 0.33 (0.006, 0.60) | 0.21 (-0.09, 0.51) |
| Perceived control over ejaculation | p = 0.1223 | p = 0.0450 | p = 0.0032 | p = 0.2238 |
| Satisfaction with sexual intercourse | p = 0.0418 | p = 0.50 (0.16, 0.84) | p = 0.42 (0.02, 0.82) |
| Personal distress related to ejaculation | p = 0.0560 | p = 0.17 (-0.19, 0.53) | 0.042 (-0.31, 0.40) |
| Interpersonal difficulty related to ejaculation | p = 0.21 (-0.16, 0.58) | p = 0.25 (-0.16, 0.66) | p = 0.29 (-0.094, 0.68) |
| PGI, n (%)               | NA       | 13 (54.2%) | 10 (41.7%) | 10 (41.7%) | 12 (50%) |
| No change                |          | 11 (45.8%) | 10 (41.7%) | 9 (37.5%) |
| Slightly better          | 2 (8.3%) | 3 (12.5%) | 3 (12.5%) |          |
| Better                   |          |          |          |          |

IELT: Intravaginal ejaculation latency time; PEP: Premature ejaculation profile; PGI: Patient-reported global impression of change; MD: Mean difference; SD: Standard deviation; CI: Confidence interval.

“no change” or “slightly better”. Table 2 demonstrates the outcomes of PEP and PGI at follow up time points. No serious local or systemic AEs were observed. All patients demonstrated microscopic hematuria which has resolved spontaneously within one week. Transient dysuria was reported in 9 (37.5%) patients. No other ejaculatory disorders, changed erectile function, stress urinary incontinence, UTI, or sepsis were reported.

**Discussion**

There are several current therapeutic options to treat PE with variable efficacy and considerable drawbacks. Many well-designed clinical studies on selective serotonin reuptake inhibitors (SSRIs) and antidepressants support the efficacy of dapoxetine, paroxetine, sertraline, fluoxetine and clomipramine for treatment of PE\(^{14-16}\). Dapoxetine is a short-acting effective well-tolerated SSRI that can be used as ‘on-demand’ treatment for PE. It is currently the only drug approved for PE treatment\(^{14-16}\). A meta-analysis of studies of pharmacological treatments has found that paroxetine demonstrates the strongest delay of ejaculation with 8.8 fold mean IELT increase\(^{17}\). While drug treatments of PE have been demonstrated to be effective and reliable, their efficacy is often limited to the time of drug usage. In fact, the majority of men who achieved good ejaculatory control has experienced PE again after cessation of the medication\(^{14-17}\).

Antidepressant drugs may also considerably aggravate erectile dysfunction and they are strongly unadvisable for men suffering concomitant PE and erectile dysfunction\(^{17}\). Additionally, chronic SSRI treatment has been reported to cause deleterious effects on spermatogenesis and spermatozoa\(^{19}\). Topical anesthetics\(^{20}\) and herbal products\(^{21}\) have also been used in premature ejaculation of neurobiological origin due to penile hypersensitivity; although their use is not diffuse.

Based on the premises that PE has an underlying neurobiological pathophysiological basis, it has been suggested that penile and other sensory receptors play a major role in conveying sexual information to the cerebral cortex which controls and commands the cascade of events of ejaculatory reflex, and that spinal cord reflex plays a primary role in ejaculation\(^{1-3}\). Thus, any station in the route from penis to cerebral cortex (including the prostate) may be integrated in the process of PE. Nevertheless, the epididymis, vasa deferentia, seminal vesicles, prostate and bladder neck are the actual ‘executives’ of this cascade by emission of seminal fluid\(^{1-3}\). There are several additional indicators suggesting that the prostate and its innervations play an essential role in the process of ejaculation. For instance, alpha blockers - mainly tamsulosin - have been reported to induce ejaculation failure\(^{22}\). Additionally, electroejaculation has been used effectively for sperm...
retrieval in men with spinal cord injury\cite{23}. The strong association of chronic prostatitis and rapid ejaculation further suggests a prostatic role in PE\cite{24,25}.

In view of drawbacks of the existing therapies for PE, injection of botulinum-A toxin was suggested as a promising alternative PE treatment\cite{10,11,26,27}. The relatively prolonged chemical denervation reported with onaBoNT-A injection may render PE men capable to spontaneously engage in sexual activity without requiring oral medications or applying topical treatment\cite{28}. In two patent applications, Gaxiola et al.\cite{26} have proposed treating PE and prolonging ejaculation latency by injecting onaBoNT-A into the penis; or into the frenulum, prepuce, or glans penis\cite{27}. Nevertheless, the experiments based on those patent proposals have not yet been published in any peer-reviewed publication. Serefoglu et al.\cite{10} have hypothesized that inhibition of the stereo-typed rhythmic contractions of bulbospongiousus and ischiocavernosus muscles by injecting onaBoNT-A into these muscles may have a favorable effect in treatment of PE. Those investigators have reported significant prolongation of ejaculatory latency in rats, without affecting their ability to engage in sexual activity or achieving ejaculation\cite{11}. The hypothesis of Serefoglu et al., however, lacks a solid physiological foundation as the emission phase of the ejaculatory process precedes the rhythmic contractions of bulbospongiousus and ischiocavernosus muscles\cite{1-3}.

Our investigation was based on the premise that chemical denervation of the prostate and ejaculatory ducts by intraprostatic injection of onaBoNT-A might suppress the emission of seminal fluid, and consequently delay the ejaculation. Although the present study reported statistically significant changes of IELT at all follow up time points after intraprostatic injections of onaBoNT-A, these improvements were not translated into clinically meaningful changes. As for “perceived control over ejaculation”, the studied men reported barely modest improvement at 3-months, but non-significant changes at 1- and 6-months’ time points. Only 8.3%, 12.5% and 12.5% of men reported “better” in PGI questionnaire at 1-, 3- and 6-months, respectively. Nevertheless, all other men have reported “no change” or “slightly better”, and none of the men have reported “much better” at any follow up time points. These PGI findings further elucidate the marginal improvement of PE condition after intraprostatic onaBoNT-A injections. Considering the small improvement of PE condition in our study (in addition to invasiveness and cost of the procedure), this treatment did not prove itself compelling to be recommended for managment of PE.

Conclusion
Our study demonstrated statistical improvements of IELT after intraprostatic injections of onaBoNT-A, that were not clinically meaningful as the majority of men reported “no change” or “slightly better” in PGI questionnaire. Although safe, our findings of marginal improvements did not support using this procedure to remedy PE.

Acknowledgements
This project was funded by the Deanship of Scientific Research, King Abdulaziz University, Jeddah, Saudi Arabia, under grant no. (322/140/1431).

The authors, therefore, acknowledge with thanks Deanship of Scientific Research technical and financial support.

Conflict of Interests
None of the authors has any conflict of interests with any company.

The funding agency is a non-profit governmental agency, concerned with funding and supporting qualified peer-reviewed research projects. The funding agency has no influence on the results of the study.

Abbreviations and Acronyms
CI = Confidence interval
IELT = Intravaginal ejaculation latency time
MD = Mean difference
OnaBoNT-A = OnabotulinumtoxinA
PE = Premature ejaculation
PEP = Premature ejaculation profile
PGI = Patient-reported global impression of change
SD = Standard deviation
SSRIs = Selective serotonin reuptake inhibitors

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حقن مادة البوتيولينم داخل البروستاتا لعلاج سرعة القذف: دراسة مستقبلية

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المستخلص. استهدفت الدراسة ٢٤ رجلاً ممن يعانون سرعة القذف والذي تتجاوز أعمارهم ١٩ سنة، وتم حقن مادة البوتيولينم (١٠٠ وحدة) في البروستاتا نقطة النهاية الرئيسي للدراسة تحديد تأثير العلاج على التغييرات في فترة الأسنان وأثناء فترة المتابعة بعد الحقن. نتائج الدراسة الثانية تشمل النتائج المسجلة عن طريق المرضى (PEP) و (PGI). رغم التحسن الإحصائي في IELT بعد ١ و ٣ و ٦ شهور من الحقن، إلا أن PGI لم يشهد أي تحسن إحصائي. فقط ١٠٪م من المرضى سجلوا تحسن في PGI بعد ١ و ٣ و ٦ شهر. هذه النتائج الغير مؤثرة أكلينيكيًا لا تدعم استخدام حقن البوتيولينم في البروستاتا لعلاج سرعة القذف.