

Botox injection for treatment of refractory vaginismus in Egyptian Women

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Abstract: Background: Vaginismus is associated with negative psychological, reproductive, sexual and marital impacts. It is a poorly understood condition, often misdiagnosed and represents a therapeutic challenge. Botox, a drug derived from a botulinum toxin, interferes with the transmission of acetylcholine that is responsible for muscle activation. Intravaginal injections of Botox appears to be a promising treatment for vaginismus. **Methods:** This is a cohort study on 42 Egyptian married women with vaginismus grade 3 or more who underwent an intravaginal injections of Botox and bupivacaine, followed by progressive dilation. The primary end point was the ability to achieve painless intercourse after treatment. Treated patients were followed for a minimum of 1 year. Female sexual function index (FSFI) scores were compared before and after treatment. Adverse effects were monitored throughout the study and recorded. **Results:** After treatment, 37 patients (88.1%) achieved painless intercourse, which was achieved at a mean of 5.3 weeks as noted by personal communications and FSFI scores. The average increase in FSFI scores from the baseline measurement to after treatment was statistically significant (9.6, P <0.001). **Conclusion:** Botox appears to be safe and effective in the treatment of vaginismus.

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1. Introduction

Vaginismus, also called vaginism, is a condition that is defined by inability of woman to any form of vaginal penetration, either sexual intercourse, digital penetration, insertion of tampons or any vaginal preparation, as well as any penetration involved in gynecological examinations (such as pv. And pap tests) due to an involuntary vaginal muscle spasm, which makes any kind of vaginal penetration painful or impossible [1]. While there is a lack of evidence to definitively identify which muscle is responsible for the spasm, the bulbocavernosus thought to be the main muscle involved in vaginismus. Other muscles such as levator ani, and perivaginal muscles have been suggested [2].

Vaginismus affects from 5% to 17% of women worldwide, and it is believed to be one of the most prevalent female sexual dysfunctions [3]. Particularly in conservative Egyptian community, patients of vaginismus, tend to be confidential and shy about this problem and often do not discuss this with anyone else, including their doctors. For this reason the incidence of vaginismus may be underestimated [4]. From other hand, vaginismus is a poorly understood condition and often misdiagnosed. Most health care professionals, including gynecologists, are not familiar with this condition [4]. Despite its description more than a century ago, vaginismus is rarely taught in medical school, residency training, and medical meetings [5].

Vaginismus is classified as primary, in which the woman has never experienced painless intercourse, or secondary, in which the woman has previously experienced painless intercourse but subsequently experiences dyspareunia [6]. Secondary vaginismus may be due to physical causes such as vaginitis or trauma during childbirth, while in some cases it may be due to psychological causes, or to a combination of causes. The treatment for secondary vaginismus is the same as for primary vaginismus [7].

Vaginismus has been classified by Lamont [8] according to its severity into four degrees or grades. In first degree (also known as grade 1 vaginismus), the patient has spasm of the pelvic floor that can be relieved with reassurance. In second degree, the spasm is present throughout the pelvis even with reassurance. In third degree, the patient elevates her buttocks to avoid being examined. In fourth degree vaginismus the most severe form of vaginismus, the patient elevates the buttocks, retreats and tightly closes her thighs to avoid examination. Pacik expanded the Lamont classification to include grade 5, in which the patient experiences a visceral reaction such as sweating, palpitations, hyperventilation, anxiety, trembling, nausea, vomiting, loss of consciousness, trying to jump off the table, or attacking the doctor [7]. The Lamont classification continues to be used to the present and allows for a common language among physicians and researchers.

Vaginismus is associated with many negative psychological, reproductive, sexual and marital impacts. These include traumatic sexual experiences, sexual abuse, infertility, conflict with strict religious and/or strict sexual upbringing, fear and/or anxiety issues, [2,5]. Vaginismus frequently leads to marital problems, depression, feelings of isolation and it is a major cause of unconsummated marriages. Vaginismus causes inability of the woman to tolerate gynecological examinations, transvaginal ultrasound, Pap Smears, cervicovaginal swaps, application of any vaginal preparations, catheterization and enema [9].

Conservative therapy may be effective in milder cases, consisting of Kegel exercises, topical anesthetics, lubricants, muscle relaxants, sex counseling, psychotherapy, sedatives, physical therapy, and therapy with vaginal dilators. These conservative measures usually take years for the patient to achieve the aim of having painless intercourse. However, severe cases are refractory to these measures, resulting in depression with marked deterioration in the psychological, familial and marital status [10].

Botox, (onabotulinumtoxin A) a drug derived from a Botulinum toxin, interferes with the chemical transmitter, acetylcholine, that is responsible for muscle contraction or spasm. Botox has proven to be as safe as aspirin. It has been used for decades to weaken over-active muscles and glands in patients with conditions such as cerebral palsy, stroke, hyperhidrosis, and migraines, as well as for cosmetic purposes [7].

The use of Botox to treat vaginismus was first reported by Brin and Vapnek [11] in 1997. They reported a case of secondary vaginismus was managed by Botox. The patient was able to have intercourse for the first time in 8 years. The results persisted during the 24 months of follow-up evaluation. Botox injections appear to be a promising treatment for vaginismus based on prior evidence from small trials and can be used for both mild and severe cases of vaginismus [4]. This study aimed at evaluating the role of Botox Injections in treatment of vaginismus in Egyptian women.

2. Patients and Methods

This is a cohort study that carried out between February 2014 and January 2017 on 42 Egyptian married women whose attended or referred to our outpatient clinics with vaginismus grade 3 or more and previous failed treatments for at least one of therapeutic modalities used for vaginismus treatment. The diagnosis of vaginismus was made after a comprehensive evaluation of medical and psychosexual questionnaire developed in this practice, review of previous diagnoses of sexual pain; previous

treatments for vaginismus; discussion with the patient and referring clinicians when possible. The penetration history in conjunction with pelvic examination responses determined the severity of the vaginismus according to Lamont classification. It was noted throughout the study that women had considerable difficulty with pelvic examinations that was impossible in all cases. Abdominal ultrasound assessment for the pelvis was performed for all patients to exclude any pelvic lesion. Women whose husbands have an erectile dysfunction, women with grad 1 or 2 vaginismus and women who didn't try any treatment before, were excluded from the study. Treated patients were followed for at least one year. Any adverse effect was monitored and recorded throughout the study. The primary end point was the ability to achieve painless intercourse after accomplished treatment course. Female Sexual Function Index (FSFI) before treatment and within 1 year after treatment was assessed for all patients. The FSFI is a 19-item questionnaire assessing sexual function during the previous 4 weeks. The questionnaire covers six domains including desire, arousal, lubrication, orgasm, satisfaction and pain. Each question is answered on a five-point Likert scale, with varying response choices and anchors. Each response is scored on a scale of 0 to 5 [9]. The minimum total score is 2 and the maximum score is 36 (table 1). All patients signed a detailed informed consent. The Student t-test was used for statistical analysis for patients who could tolerate digital examination, the vagina was examined for spasm and p value < 0.05 was considered significant.

Midazolam 1-2 mg was given intravenously as needed to calm the patient in the OR and recovery room. Small titrated doses of propofol were given during the procedure. The procedure was initiated with sterilization of valvular area with antiseptic solution then digital examination to assess the spasm of introitus and vaginal walls under lowest possible doses (as higher doses may mask the spasm) then increasing the doses to allow for intravaginal injection of Botox under full sedation. We adopted Pacik technique for Botox Injection in the vagina [5]. The Botox (onabotulinumtoxin A; Allergan, Mayo, Ireland) was kept on ice until ready for injection. One vial of frozen Botox 100 U was diluted with 2 mL saline, without foaming or shaking the vial, giving a concentration of 2.5 U/0.05 mL (Botox 50 U per 1-mL syringe). Using a small sized speculum and after bending the needle to 30° to facilitate injection into submucosal area, 1 mL (50 U) of Botox was injected into the right bulbocavernosus then similar dose was injected into the left side. Before injection, the needle is inserted into the lateral submucosal areas of the introitus, marked by the hymeneal remnants, at 7 to 9'clock on

the patient's right and 3 to 5 o'clock on her left (Figure 1). Intramuscular injections were found to be unnecessary and caused more bleeding. (Botox is known to diffuse approximately 1 cm from the injection site). When other areas of spasm or tightness of the levator ani were identified, an additional 1mL was injected in similar divided doses submucosally into the affected muscles. After the Botox injections, using 3-mL syringes, the patient received separate injections of 0.25% bupivacaine 18 mL with 1:400,000 epinephrine divided into 1-mL increments

along the length of the right and left submucosal lateral vaginal walls (9 mL per side) from the level of the cervix to the introitus. No injections were delivered anteriorly or posteriorly to avoid urinary and rectal injury. The procedure was ended with bimanual examination and insertion of a #5 or #6 indwelling dilator which further coated with a topical anesthetic. All these measures allow the patient to wake up in the recovery room with the dilator in place and no discomfort. This procedure results in a small amount of bleeding that can be controlled with pressure.

Table 1. Female sexual function index scoring

Domain	Questions	Score Range	Factor	Minimum Score	Maximum Score	Score
Desire	1, 2	1 – 5	0.6	1.2	6.0	
Arousal	3, 4, 5, 6	0 – 5	0.3	0	6.0	
Lubrication	7, 8, 9, 10	0 – 5	0.3	0	6.0	
Orgasm	11, 12, 13	0 – 5	0.4	0	6.0	
Satisfaction	14, 15, 16	0 (or 1) – 5	0.4	0.8	6.0	
Pain	17, 18, 19	0 – 5	0.4	0	6.0	
Full Scale Score Range				2.0	36.0	

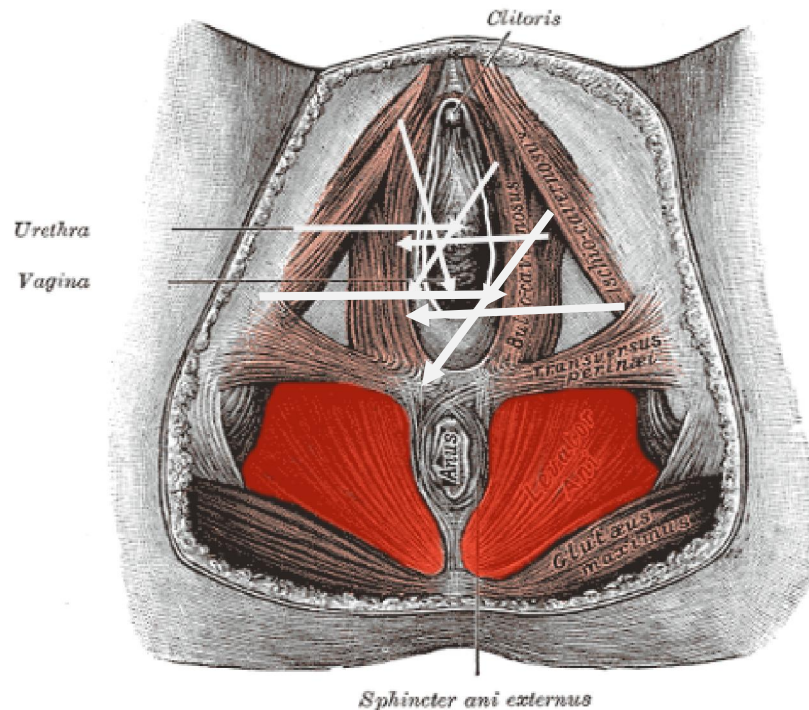


Figure 1. Submucosal injections of Botox to the bulbocavernosus, on each side, using hymeneal remnants as a landmark. The arrows point to the injection sites on each side.

The patient was then gradually dilated with the #4 dilator (3-inch circumference), the #5 dilator (4-inch circumference), and then, when possible, the #6

dilator (5-inch circumference) and reassessed with digital examination in the follow up visits. This supervised dilation continues for two to three months

as following. In the first month after procedure, dilate 2 hours a day, (1 hour in the morning and 1 hour in the evening or 2 hours at any one sitting) and advance to larger dilators as possible until the #5 or #6 dilator becomes comfortable. In the second month, decrease dilation to 1 hour a day and advance to larger sizes. In the third month, decrease dilatation to 15 - 30 minutes a day. The husbands were instructed to assist with dilation to help transition to intercourse physically and psychologically. Post procedure counseling for the couples includes a discussion of the following instructions. Attempts at intercourse should be delayed until at least the #5 dilator can be inserted easily and comfortably. For husbands who have larger penises, #7 (6-inch circumference) and #8 (7-inch circumference) dilators were used before initiating intercourse. During the first attempts at intercourse, patients and their husbands are taught to penetrate with no more than the penile tip because women with severe vaginismus are fragile at this juncture and often have considerable fear. Everything possible is done to help remove the pressure of this moment. Once penile tip penetration is achieved comfortably, the couple can advance to full penetration gently and slowly using some lubricant gels prescribed. Thrusting is discouraged because this can be a setback for the woman. Women might note "leg lock," the involuntary closure of the thighs in anticipation of penetration. The "spooning position" with entry from behind has been found to be helpful in overcoming leg

lock. Women are encouraged to try different positions during their dilation and attempts at coitus to find their comfort zone.

3. Results

This study concluded 42 married Egyptian women ranging from 16 to 55 years old with vaginismus severity from 3 to 5 grades. Basic characteristics of patients are shown in table 2. After treatment, 37 patients (88.1%) achieved painless intercourse, which was achieved at a mean of 5.3 weeks as noted by personal communications and FSFI scores. Three patients (7.1%) could not achieve intercourse within a 1-year period, despite the ability to use the #5 or #6 dilators and two patients (4.7%) failed to use the #5 dilator presumably due to uncontrolled anxiety relating to vaginal penetration.

The mean FSFI for patients before treatment was 15.3 ± 6.1 of a possible score of 36, indicating compromised sexual function. One Year after treatment FSFI mean increased to 24.9 ± 5.7 . The average change in FSFI scores from the baseline measurement to after treatment was statistically significant ($9.6, P < 0.001$).

Minor adverse effects occurred in 4 patients who suffered vaginal dryness and 2 patients developed mild temporary stress incontinence for two months. All adverse effects were cured 3 months after treatment. There were no major or permanent adverse effects.

Table 2. Basic characteristics of patients

Characteristic	Number (%), Range or Mean \pm SD
Age (years)	26 ± 5.3 (16-55)
BMI (kg/m ²)	24.6 ± 6.7
Education beyond high school	19 (45.2%)
Parity	0.5 ± 0.07 (0-3)
Duration of vaginismus (months)	19 ± 7.2 (1-52)
Type of vaginismus	
Primary	33 (78.6%)
secondary	9 (21.4%)
Lamont-Pacik level of severity (3-5)	4.3 ± 0.9
Number of prior therapeutic modalities	3.5 ± 0.4 (1-9)

Table 3. Female sexual function index before and after treatment

FSFI domain	Before treatment	After treatment	P value
Desire	4.3 ± 0.9	4.9 ± 1.1	0.08
Arousal	4.2 ± 0.8	4.7 ± 1.3	0.09
Lubrication	3.3 ± 0.7	4.6 ± 0.9	<0.01
Orgasm	2.9 ± 0.8	4.9 ± 1.2	<0.01
Satisfaction	2.7 ± 0.5	5.2 ± 1.3	<0.001
Pain	0.3 ± 0.1	5.3 ± 1.1	< 0.001
Total score	15.3 ± 6.1	24.9 ± 5.7	< 0.001

Data are presented as mean \pm SD.

4. Discussion

In this study 88.% of patients with grades 3 to 5 vaginismus had cured with intravaginal injection of botox with significant increase in FSFI scores from the baseline measurement to after treatment. Vaginismus is not a surgical problem. Hymenectomy and episiotomy are inappropriate treatments for this condition because the problem is related to the reflex spasm of perivagial and pelvic muscles [5]. Botox inhibits both alpha-motor neurone transmission to the striated musculature and gamma- neurone transmission governing this reflex contraction leading to temporary paralysis of muscles contributing to vaginismus [5]. The paralytic effect of Botox starts after approximately 2 to 7 days after injection and lasts for approximately 4 months [5] but it allows women to progressively dilate more comfortably and overcome their fear of penetration giving them confidence of their vaginae which already have dilated [7]. Women are not aware when the Botox is no longer active. Waking up of the patient in the recovery room while the dilator was in place and no discomfort, represented the initial breakthrough that allows the patient to realize that painless penetration is possible and that her anatomy is normal and gave her a psychological motivation to continue supervised dilatation and follow up [12].

Our results are consistent with many other studies. Ghazizadeh and Nikzad in 2004 used botulinum toxin to treat refractory vaginismus in 24 patients with Lamont grade 3 and 4 refractory. In this study, 75% of women achieved satisfactory intercourse, 17% had mild pain with intercourse and no recurrences were observed 24-month follow-up period [13]. Abbott reported results from a double-blinded, randomized, case controlled study that 80 units of botulinum toxin A (20 units/ml) injected into the pelvic floor muscles. Pelvic floor pressures measured by vaginal manometry showed significant improvement in group received Botulinum. Quality-of-life measurements were higher in the botulinum toxin group [14]. In a controlled study by El-Sibai, patients with vaginismus received 50 IU of botulinum toxin into the bulbocavernosus muscles; the women given Botox were able to have intercourse. None of the patients given Botox required second injection, and there was no recurrence or complication during the follow-up period [15]. Bertolasi used repeated cycles of small botulinum toxin with doses of 20 mIU injected into the levator ani under electromyographic guidance until the patient was able to achieve intercourse. 82% of patients recovered from vaginismus and vulvar vestibular syndrome [16].

Recently, Pacik and Geletta treated 241 women with vaginismus and reported 71% pain-free

intercourse at a mean of 5.1 weeks and average increase in FSFI scores by 8.8 from the baseline measurement to after treatment was statistically significant [9]. Most patients in Pacik and Geletta study, had severe vaginismus as noted by the Lamont and Pacik classifications, had an average of five failed treatments, and had the condition for a mean of 7 years that may explain the limited variations with our results.

An important limitation in this study was the lack of comparison treatment such as in placebo controlled trials. This was not possible in this cohort study for many reasons. First, the difficulty in finding out these cases which usually overlooked and kept hidden in our conservative Egyptian community. Secondly, these cases have already tried more than one therapeutic modality and lastly the relatively long period of follow-up also, most patients showed widespread geographic distribution. To overcome this problem, we selected cases of grade 3 or more vaginismus and excluded mild cases which could be affected by placebo. Another limitation is the relatively small sample size of population for reason that described above which could be solved by implementation of widespread sexual culture and screening programs to disclose and treat more hidden cases of vaginismus in Egyptian woman. Future studies of using Botox in a larger randomized controlled trials and comparative studies are warranted.

Conclusion

Botox appears to be safe and effective in the treatment of vaginismus as noted by the improvement of FSFI scores, patient communications, and ability to progress to painless intercourse.

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