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REVIEW

Vaginismus: Review of Current Concepts and Treatment Using Botox Injections, Bupivacaine Injections, and Progressive Dilation with the Patient Under Anesthesia

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Abstract Vaginismus is a poorly understood condition affecting approximately 1–7% of females worldwide. This article aims to bring attention to this disorder and to review the use of Botox injections to treat these patients. Vaginismus, also known as vaginal penetration disorder, is an aversion to any form of vaginal penetration as a result of painful attempts and a fear of anticipated pain. It is involuntary and uncontrolled and functions much the same as any reflex to avoid injury. It is the most common reason for unconsummated marriages. The etiology is thought to be unknown. Numerous papers note a history of religious or strict sexual upbringing or aversion to penetration because of perceived pain and bleeding with first-time intercourse. Sexual molestation may be more prevalent in this group of patients. The Lamont classification is very helpful in stratifying these patients for treatment. Lamont grade 5 vaginismus is introduced. Vaginal Botox injections for the treatment of vaginismus has received increasing attention since the technique was first described in a 1997 case report. Plastic surgeons worldwide with their experience using Botox are well positioned to learn more about this relatively unknown entity and render treatment.

Keywords Botox treatment for vaginismus · Dyspareunia · Painful intercourse · Treatment of vaginismus · Unable to consummate · Unable to have intercourse · Vaginismus · Vestibulodynia

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"In May, 1857, I was called to see a lady aged forty-five years, who was married at twenty…. The remarkable thing in her history was the fact that she had remained a virgin notwithstanding a married state of a quarter of a century." Thus reported Sims [1] in 1861. "Her physician attempted to dilate the vagina with graduated bougies, which produced the most intolerable suffering without the least permanent improvement…. I attempted to make a vaginal examination, but failed completely."

The histories of vaginismus patients have considerable similarity. Most discover that something is wrong when they are unable to use tampons. They then realize the profound fear associated with scheduling and undergoing a gynecologic examination. Later, they report inability to consummate their marriages, often on their honeymoon night. Weeks of inability to consummate lead to months and then years of looking for a diagnosis and treatment while feeling "less than" and like "freaks" not being able to do what is normal for most women. The more severe cases are shunted from therapist to therapist, and over the ensuing years, psychologic, medical, and surgical treatments add to their failures. Divorce is imminent for many of these patients, and wife and husband often succumb to living as brother and sister or as roommates according to the description of one of my patients.

Incidence and Etiology

The incidence of vaginismus is thought to be about 1–7% worldwide, and the disorder is cross-cultural. In clinical settings, the incidence may be as high as 5–17% [2, 3]. Patients tend to be secretive about their problem and often do not discuss this with anyone else, including their

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doctors. For this reason the incidence of vaginismus may be underreported.

The current literature does not point to a definite etiology for vaginismus. Clinical and research reports indicate that women with vaginismus hold negative views about sexuality, particularly premarital sexual activity. Their background can include a strict religious or sexual upbringing as well as the belief that sex is wrong or that penetration will cause pain, injury, and bleeding. These women may fear that their vagina is too small [4, 5]. In addition, they may fear pregnancy, childbirth, or AIDS.

A history of sexual molestation at a young age has been reported by Reissing et al. [5], and this appears to be two times more common among vaginismus patients. Organic causes need to be considered such as sexually transmitted diseases, endometriosis, hymeneal and congenital abnormalities, trauma associated with genital surgery or radiotherapy, scarring from childhood trauma, vaginal atrophy, childbirth or surgery, pudendal neuralgia, pelvic inflammatory disease, pelvic organ prolapse, peripheral vascular disease, infections, vaginal lesions and tumors, and cancer [4].

Diagnosis

The ability to make a diagnosis of vaginismus can be compromised by inability to perform a satisfactory gynecologic examination, especially in the more severe vaginismus cases. For this reason, a detailed history is important. Most of my patients have diagnosed their problem by searching the Internet. Vaginismus should be part of the differential diagnosis for patients who have an aversion to vaginal penetration, be it tampon, finger, speculum, dilator, or penis, and for those who have never had pain-free intercourse.

Dyspareunia, a term of ancient Greek origin meaning "difficult mating" [6], is painful intercourse, which can range from mild to severe. A woman who has never had pain-free intercourse is considered to have vaginismus, and this too can range from mild to severe. In severe cases of vaginismus, intercourse usually is impossible, and burning pain can last for days for some patients who make the attempt. A history of never having had comfortable intercourse is important in differentiating vaginismus from dyspareunia.

A woman with primary vaginismus has never had comfortable penetration, and this is the most common reason for unconsummated marriages. A woman with secondary vaginismus has experienced normal sexual relations and often has given birth to a child, but some happening such as an infection or childbirth has triggered current pain with attempted penetration.

Vulvodynia is pain involving any part of the vulva that may or may not be associated with vaginismus. Vestibulodynia (vulvar vestibulitis) is pain in the vestibule. Provoked vestibulodynia is pain in the vestibule as a result of touching the area with a cotton-tipped applicator. It is important to ask the patient details about the pain because some patients have more of a panic reaction than pain because the tested area "is too close for comfort."

Some researchers argue that vaginismus and dyspareunia may be impossible to differentiate because vaginal penetration problems are not specific to vaginismus but frequently present as a symptom of dyspareunia [7–10]. The presence of vestibulodynia adds to the difficulty of diagnosing vaginismus in that some think vestibulodynia is the cause of inability to have intercourse.

I share Reissing's opinion that vulvodynia, if present, is specified as an associated (secondary) medical condition because vaginismus is the primary event, and that vaginal penetration disorder and dyspareunia are mutually exclusive diagnoses [11]. With dyspareunia, penetration is painful, whereas with vaginismus, penetration has never been comfortable. In severe cases of vaginismus, penetration is impossible.

Vulvodynia and vestibulodynia can be tested by both history and "Q-tip" testing [2, 12]. Sims [1] used a camel hair brush to test for vulvodynia. Associated conditions may be present such as yeast and fungal infections, lichen sclerosis, clitoral hood phimosis, and others. I have not found these conditions to have an impact on the outcome of treatment.

Lamont Classification

Before recommending treatment, it is vital to stratify the severity of vaginismus. Patients who have had many years of failed treatments may have an undiagnosed severe form of vaginismus. Lamont [13] in 1978 classified vaginismus according to the patient's history and behavior during a gynecologic examination. With the mildest form of vaginismus, grade 1, the patient is noted to have tight vaginal muscles but is able to relax enough with coaxing to have a gynecologic examination. With grade 2 vaginismus, the muscles are noted to be tight, and the patient is unable to relax, but examination can be done. The patient with grade 3 vaginismus elevates her buttocks to avoid examination. With the most severe form of vaginismus, grade 4, the patient elevates her buttocks, retracts, and adducts her thighs to avoid being examined.

Digital examination is uncomfortable in the less severe forms of vaginismus and painful or intolerable as the severity increases. A number of my patients have suggested a "grade 5" vaginismus, manifested by visceral responses

Table 1 Patient data

Classification and degree	Lamont no. of patients	Pacik no. of patients	Average duration of failed Rx (years)
Grade 1: Perineal and levator spasm: relieved with reassurance	27	6	6
Grade 2: Perineal spasm: maintained throughout pelvis	21	10	12
Grade 3: Levator spasm and elevation of buttocks	18	8	8
Grade 4: Levator and perineal spasm, elevation: adduction and retreat	10	34	7
"Grade 5" Visceral reaction manifested by any combination of crying, screaming, shaking, trembling, hyperventilating, sweating, experiencing nausea, vomiting, "going unconscious," "wanting to jump off the table," "wanting to attack the doctor"	Not described	36	8
Refused examination	4	0	

Rx, treatment

such as crying, shaking, trembling, sweating, hyperventilating, experiencing palpitations or nausea, vomiting, "going unconscious," "wanting to jump off the table," or "wanting to attack the doctor" (Table 1) [14, 15]. With the more severe forms of vaginismus, attempted gynecologic examination is impossible because of the generalized retreat, squirming, crying, and inability to cooperate. This too should trigger a diagnosis of vaginismus.

Treatment Options

The use of graduated dilators, first described by Sims [1] in his 1861 publication, is likely the most commonly used treatment plan. Milder cases of vaginismus may respond to Kegal exercises encouraging relaxation of the pelvic floor, psychotherapy, sex counseling, cognitive behavioral therapy, hypnotherapy, support groups, physical therapy to stretch the vaginal muscles, biofeedback to reduce pelvic floor tension, lubricants often containing topical anesthetics, muscle relaxants, anti-anxiety medications, antidepressants, and tranquilizers. These various methods of treatment are aimed at getting the patient to a point at which she can begin using dilators.

It is common for patients with Lamont levels 3–5 vaginismus to devote considerable time and effort to the use of dilators (they are highly motivated), and many spend more than a year making minimal progress. Often they will not even open the box of dilators. This profound aversion to any form of vaginal penetration is characteristic of patients experiencing severe levels of vaginismus. Six patients in my practice with unconsummated marriages have had vaginismus and failed treatments for more than 20 years, and three of these patients have had vaginismus for 37–38 years.

Although the treatments noted earlier often are successful with the less severe forms of vaginismus, the literature has little documentation describing a large series of patients, the protocol used, how long it took to achieve success as defined by the ability to have painless intercourse (or use a large dilator in the absence of a partner), or the success rate, and controlled studies appear to be nonexistent. More severe cases often are refractory to treatment, resulting in a great deal of frustration and upheaval in relationships and marriage.

Some patients drink themselves into a stupor or use excessive amounts of antidepressants to be able to achieve intercourse. When this results in a pregnancy, the woman is able to convince her doctor that she must have a cesarean section for delivery. Others are unable to have any form of penetration no matter what they try. Hymenectomy may be performed but vaginismus due to an intact hymen is rare. Vestibulectomy, when performed, is sometimes done as a last resort, and several of my patients have failed this treatment also.

Botox for Vaginismus Treatment

As a result of an increasing number of Internet forums, vaginismus is becoming more widely known. The use of Botox to treat vaginismus was first reported by Brin and Vapnek [16] in 1997. This reported case of secondary vaginismus was managed first with 10 units of Botox followed by 40 units of 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.

Ghazizadeh and Nikzad [17] reported on the use of botulinum toxin to treat refractory vaginismus in 24 patients. In this study, Dysport (botulinum toxin A; Ipsen Ltd, Slough, UK) 150–400 mIU was used. As a result, 23

patients were able to have vaginal examinations 1 week after the procedure, showing little or no vaginismus. One patient refused vaginal examination and did not attempt coitus. Of the 23 patients, 18 (75%) achieved satisfactory intercourse, 4 (17%) had mild pain with intercourse, and 1 was unable to have intercourse because of her husband's impotence. A second dose of Dysport was needed by one patient. No recurrences were noted during the 2- to 24-month follow-up period.

Abbott et al. [18] reported results from a double-blinded, randomized, controlled, and statistically analyzed study conducted to evaluate chronic pain and pelvic floor spasm. In this study, 60 patients were divided into two groups of 30 patients each. The one group received 80 units of botulinum toxin A (20 units/ml) injected into the pelvic floor muscles, and the other group received saline as a placebo. Pelvic floor pressures measured by vaginal manometry were noted to be significantly improved in the botulinum toxin type A group. Quality-of-life measurements were higher in the botulinum toxin group.

In a controlled study by Shafik and El-Sibai [19], eight women received Botox injections (50 IU) into the bulbospongiosus muscles for vaginismus, and five matched women were injected with saline. All the women given Botox were able to have intercourse, whereas the controls did not improve during a follow-up period of 10.2 ± 3.3 months. None of the patients given Botox required reinjection, and there was no recurrence or complication during the follow-up period.

Bertolasi et al. [20] used repeated cycles of small Dysport doses (20 mIU) injected into the levator ani under electromyographic guidance until the patient was able to achieve intercourse. Of 33 patients, 27 (82%) recovered from vaginismus and vulvar vestibular syndrome. These authors concluded that "botulinum neurotoxin type A is an effective treatment option for vaginismus secondary to vulvar vestibular syndrome refractory to standard cognitive-behavioral and medical management."

Yoon et al. [21] reported on seven patients using Botox for the treatment of vulvodynia. After the exact pain sites had been determined with a cotton tip and gentle digital palpation, injections were given into the vestibule ($n = 4$), levator ani muscle ($n = 2$), and perineal body ($n = 1$). Initially, 20 units of Botox were used, which gave relief for two patients. The remaining five patients received a second dose of 40 units 2 weeks later, with considerable improvement in their pain scores. No recurrences were noted during a 24-month follow-up period. The patients treated had varying degrees of dyspareunia due to their vulvodynia. None were noted to have vaginismus.

Pacik [22] reported on 20 patients treated under anesthesia using a combination of intravaginal Botox (100–150 units) followed by intravaginal bupivacaine (20–30 ml of 0.25% with 1:400,000 epinephrine) for the bulbocavernosus, pubococcygeus, and puborectalis muscles (Fig. 1). At the conclusion of the procedure, the patient was progressively dilated while still under anesthesia, waking up in the recovery room with an indwelling no. 5 or 6 of six possible dilators, no. 6 being the largest dilator in this series. This resulted in a cure rate exceeding 90%.

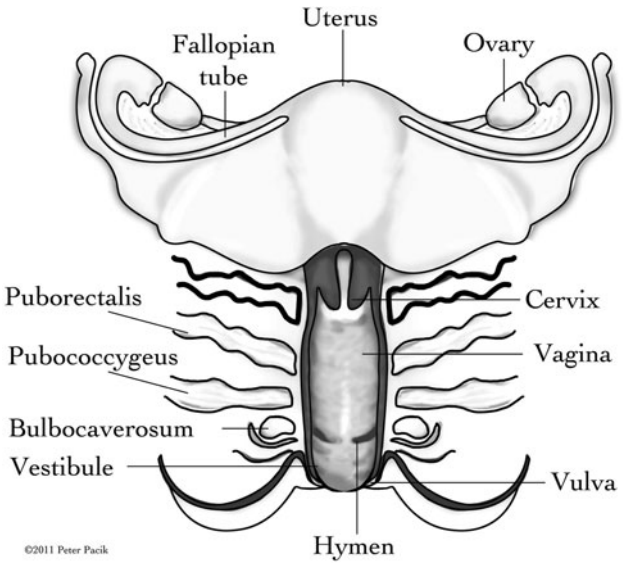

Fig. 1 Muscle anatomy

At the time of this writing (March 2011), 81 patients (unpublished) have been treated using the described technique. Our patients continue to report success rates in excess of 90%, and once these patients are able to achieve intercourse, the results appear to be permanent. To date, there have been two cases of mild stress incontinence and one case of excessive vaginal dryness. One failure will require retreatment. Once patients are achieving pain-free intercourse, repeat treatment with Botox does not appear to be needed.

After institutional review board approval, the Food and Drug Administration (FDA) approved a pilot study of 30 patients 20–40 years of age for the treatment of primary vaginismus with intravaginal Botox and progressive dilation under anesthesia (IND 109343). This study is ongoing at the time of this publication and has been registered with clinicaltrials.gov. (BTX-PV-01). Data will be analyzed for a future report.

Discussion

Nonmedical sexual pain disorders, also known as vaginal penetration disorders, are poorly understood and often misdiagnosed. Most health care professionals, including gynecologists, are not familiar with this condition.

Discussion with recent graduates of gynecology and family medicine programs indicate they had no training in this field. Some of the experts in the field feel that the default diagnosis of nonmedical sexual pain is vulvodynia or vestibulodynia, and little consideration is given to vaginismus. Although vulvodynia and vestibulodynia can coexist with vaginismus, I have found vaginismus to be the primary condition in my group of patients.

Botox is well known to the community of international plastic surgeons. Their years of general surgery and plastic surgery allow them to be comfortable treating a variety of problems involving different parts of the body. Plastic surgeons, due to the very nature of their practices, probably spend more quality time with their patients. A large number of women throughout the world are afflicted with vaginismus, and most do not have the means to travel for treatment.

Vaginismus patients require more than the usual efforts to achieve a successful outcome. Many have relationship issues, a poor self-image, and an unrelenting fear of penile penetration. Botox alone does not cure these associated problems. For these reasons, ongoing support after treatment is critical. This can be accomplished by the treating doctor or by referral to therapists well versed in vaginismus treatment such as sex counselors, psychologists, and physical therapists.

Summary

Vaginismus is a common medical problem affecting about 1–7% of the world population. It is the most common cause of unconsummated marriages. Many health care professionals are unfamiliar with the diagnosis and treatment of this condition. A variety of treatments are available, including Botox injections, for the more severe forms of vaginismus or for those patients whose condition has been refractory to other treatments. An increasing number of papers show the value of this treatment approach. Plastic surgeons worldwide with their experience using Botox are well positioned to learn more about this relatively unknown entity and to render treatment.

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