

SEXUAL MEDICINE

Vaginismus Treatment: Clinical Trials Follow Up 241 Patients

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ABSTRACT

Introduction: Vaginismus is mostly unknown among clinicians and women. Vaginismus causes women to have fear, anxiety, and pain with penetration attempts.

Aim: To present a large cohort of patients based on prior published studies approved by an institutional review board and the Food and Drug Administration using a comprehensive multimodal vaginismus treatment program to treat the physical and psychologic manifestations of women with vaginismus and to record successes, failures, and untoward effects of this treatment approach.

Methods: Assessment of vaginismus included a comprehensive pretreatment questionnaire, the Female Sexual Function Index (FSFI), and consultation. All patients signed a detailed informed consent. Treatment consisted of a multimodal approach including intravaginal injections of onabotulinumtoxinA (Botox) and bupivacaine, progressive dilation under conscious sedation, indwelling dilator, follow-up and support with office visits, phone calls, e-mails, dilation logs, and FSFI reports.

Main Outcome Measures: Logs noting dilation progression, pain and anxiety scores, time to achieve intercourse, setbacks, and untoward effects. Post-treatment FSFI scores were compared with preprocedure scores.

Results: One hundred seventy-one patients (71%) reported having pain-free intercourse at a mean of 5.1 weeks (median = 2.5). Six patients (2.5%) were unable to achieve intercourse within a 1-year period after treatment and 64 patients (26.6%) were lost to follow-up. The change in the overall FSFI score measured at baseline, 3 months, 6 months, and 1 year was statistically significant at the 0.05 level. Three patients developed mild temporary stress incontinence, two patients developed a short period of temporary blurred vision, and one patient developed temporary excessive vaginal dryness. All adverse events resolved by approximately 4 months. One patient required retreatment followed by successful coitus.

Conclusion: A multimodal program that treated the physical and psychologic aspects of vaginismus enabled women to achieve pain-free intercourse as noted by patient communications and serial female sexual function studies. Further studies are indicated to better understand the individual components of this multimodal treatment program. **Pacik PT, Geletta S. Vaginismus Treatment: Clinical Trials Follow Up 241 Patients. Sex Med 2017;X:XXX–XXX.**

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Key Words: Vaginismus; Female Sexual Pain; Penetration Disorder; Genito-Pelvic Pain/Penetration Disorder; Vaginismus Treatment; Dyspareunia

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INTRODUCTION

Vaginismus is a subset of the genito-pelvic pain/penetration disorder and is currently defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* as a penetration disorder in which any form of vaginal penetration such as tampons, digit, vaginal dilators, gynecologic (GYN) examinations, and intercourse is often painful or impossible.¹ Genito-pelvic pain/penetration disorder further collapses dyspareunia and vaginismus into one entity.² Based on data that spasm is not always present in vaginismus,³ Basson et al⁴ proposed an alternative definition of persistent or recurrent difficulties in vaginal entry of

a penis, finger, or other object despite the desire to do so. Vaginismus is a psychologic disorder manifested by fear and anxiety to penetration⁵ and a physical disorder as noted by vaginal spasm^{6,7} and is distinct from other sexual pain disorders such as vulvodynia or vestibulodynia.⁷ The diagnosis of vaginismus is made by history.⁷ Women who cannot tolerate a GYN examination might have an examination under anesthesia during which any vaginal spasm disappears. Then, the patient is told that the examination was “normal.” After one such patient was hospitalized for a suicide attempt, another patient told her parents she was going to commit suicide. Symptoms of vaginismus vary according to the severity of vaginismus. Symptoms include fear, anxiety, and pain of vaginal penetration; inability to use a tampon (often noted at a young age); inability to remove a tampon that gets “stuck” (the proximal portion of the tampon swells with blood and cannot be extracted through the area of introital spasm, at times necessitating removal under anesthesia); severe pain with penetration; complaints that attempted intercourse is like “hitting a wall”; and an inability to tolerate a GYN examination. These symptoms help differentiate vaginismus from vulvodynia and provoked vestibulodynia and are suggestive of spasm at the level of the introitus.^{6–8} Vaginismus can be mild, in which different treatment approaches are effective, or severe, making treatment difficult.^{6,7} The findings of vaginal spasm support other studies that have noted active vaginal contractions in response to stimuli.^{9,10} Compared with other sexual pain disorders such as vulvodynia and vestibulodynia, the treatment of vaginismus has potential for a high rate of success.^{6–8,11,12} Stratifying the severity of vaginismus helps the clinician choose among numerous treatment options to better understand what the patient is experiencing and what she is capable of doing.^{6–8,13}

We have noted that women with milder forms of vaginismus can cooperate with different treatment suggestions, whereas women who are terrified by any attempted vaginal penetration have difficulty following treatment suggestions.^{6–8}

Reasons for sexual pain such as herpes virus, lichen sclerosis, and other medical conditions need to be ruled out as a source of sexual pain, as do vulvodynia and vestibulodynia.¹⁴ Despite its description more than a century ago,¹⁵ vaginismus is rarely taught in medical school, residency training, and medical meetings.⁷

Vaginismus can be categorized as primary, in which the patient has never experienced non-painful intercourse, or secondary, in which the patient has previously experienced non-painful intercourse but subsequently experiences pain.¹⁶

The prevalence rate of vaginismus in a clinical setting has been estimated as 5% to 17%, and it is believed to be one of the more prevalent female sexual dysfunctions.¹⁷ Different psychological factors have been associated with vaginismus, such as traumatic sexual experiences, sexual abuse, a strict religious and/or strict sexual upbringing, fear and/or anxiety issues,^{18,19} and being held down at a young age during catheterization or enemas,⁷ but it is not always associated with psychological issues and some patients give a negative history for those factors.

Women with vaginismus experience shame and embarrassment.^{7,8} A patient with 12 years of attempted and failed treatments noted how this was among the “darkest and most embarrassing periods of my life causing me to live with vaginismus in silence and shame” (personal communication). Other women have noted how they think about their vaginismus during the entire day and before they go to sleep. Vaginismus frequently leads to marital problems and depression and to feelings of isolation, is a major cause of unconsummated marriages, is an inability to tolerate GYN examinations,⁷ and is not tolerated in cultures with arranged marriages, often resulting in an annulment.

Vaginismus treatments include the widespread use of vaginal dilators, physical therapy with or without biofeedback, biofeedback, sex and relationship counseling, psychotherapy, cognitive behavioral therapy, therapist-aided exposure, hypnotherapy, and lubricants.⁷

The successful use of Botox (onabotulinumtoxinA; Allergan, Irvine, CA, USA) injections to treat secondary vaginismus was first described as a case report in 1997⁷ and later developed by different investigators.^{6–8,11,12,20–23} Abbott et al²³ using a placebo-controlled study of onabotulinumtoxinA showed that all eight women who had onabotulinumtoxinA 25 U injected into the bulbospongiosum achieved intercourse compared with none of the five women in the placebo group, with no recurrence or reinjection in the follow-up period of 8 to 14 months. Ghazizadeh and Nikzad²⁰ used Dysport (abobotulinumtoxinA; Galderma Laboratories, Fort Worth, TX, USA) to treat 23 women with Lamont grade 3 and 4 refractory vaginismus¹³ and reported a 75% success rate of pain-free intercourse in these women were followed for a mean of 12.3 months (range = 2–24).

The purpose of this report was to discuss a large cohort of women, many with failed prior treatments, who were treated using a program approved by an institutional review board (IRB) and the Food and Drug Administration (FDA) for continued research, which included a multimodal program of intravaginal injections of Botox and bupivacaine, progressive dilation under conscious sedation, use of an indwelling dilator, and post-procedure counseling, support, and follow up.^{6–8,11,12}

AIMS

1. To present a large cohort of patients based on published IRB- and FDA-approved studies for continued research^{11,12} using a comprehensive multimodal vaginismus treatment program to treat the physical and psychologic manifestations of women with vaginismus.
2. To record successes, failures, and untoward effects of this treatment approach.

METHODS

IRB and FDA Approval

IRB approval (Veritas Ethica Clinical Research, Quebec, QC, Canada) and FDA approval including investigational new drug

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