Indonesia's First: Botulinum Toxin Procedure as a Modality of Successful Vaginismus Treatment

Robbi Asri Wicaksono[1*], Merlinda Nur Annissa[2].
[1]Obstetric and Gynecology, Limijati Woman and Children Hospital, Bandung, Indonesia
[2]Dermatology and Venereology, Limijati Woman and Children Hospital, Bandung, Indonesia

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Abstract: Vaginismus is a common female sexual dysfunction, but mostly unknown among clinicians, that continues to be ignored by many medical schools, residency programs and is rarely discussed at medical meetings. Patients with vaginismus had involuntary spasm of the pelvic muscles surrounding of the vagina. Penetration such as tampons, finger, vaginal dilators, gynecological exams, and intercourse is often painful or impossible. This article aims to bring attention to the understanding and treatment of vaginismus. Vaginismus patients came to Limijati Hospital between January and December 2017. Diagnosis was made based on history taking and physical examination of vaginal spasm. The severity of vaginismus was ranked 1-5 according to Lamont-Pacik classification. Seventeen patients underwent the procedure consists of total intravenous anesthesia, botulinum toxin (botox) injections, and progressive dilation, with 100% same day successful self dilation using 4 inch silicone dilator, and 82.3% achieved sexual intercourse in average of 4,5 weeks after the procedure. Botox along with other modalities appear to be a promising result for vaginismus treatment. Awareness among clinicians about diagnosis and treatment of vaginismus is extremely needed.

1 INTRODUCTION

Vaginismus thought to be one of the most common female sexual dysfunction (Pacik, 2014). Approximately 1-7% of female worldwide suffer with this condition, and in a clinical setting has been estimated as 5% to 17% (Pacik, 2011). Vaginismus patients usually remain silent, feels taboo, rarely exposed in community nor clinicians (Pacik 2011; Pacik and Gelatta, 2017), make patients become neglected in many aspects.

Vaginismus is a physical disorder as noted by vaginal spasm (Pacik, 2010; Pacik, 2014), persistent or recurrent difficulty in allowing vaginal entry of the penis, finger, or any object, despite the woman's expressed wish to do so. It is a condition in which the muscles in the vagina spasm involuntarily preventing any vaginal penetration. Or, if penetration is possible, it can be very painful(Bertolasi *et al.*, 2009; Pacik, 2010).

The cause of vaginismus is unknown (Berek, 2007; Pacik, 2011; Pacik, 2014). Vaginismus is a very serious problem for the patients. It is poorly understood, and many physicians across a number of specialties have limited experience with this entity. It is hoped that with additional awareness, physicians will have yet another modality for the treatment of vaginismus (Pacik, 2015).

Severity of vaginismus was ranked 1-5 according to Lamont-Pacik classification(Pacik, 2011; Pacik and Gelatta, 2017). The treatment for vaginismus depends on the severity, includes education, sexual counseling, Kegel's exercises, dilation with dilators, hypnotherapy, lubricants (Pacik, 2010; Pacik, 2014), use of local anesthesia, incision of spasmodic perivaginal muscles, intravaginal botox injection (Shafik and El-Sibaik, 2000; Ghazizadeh and Nikzad, 2004; Bertolasi *et al.*, 2009; Fageeh, 2011; Pacik and Gelatta, 2017).

Botox type A is a neurotoxin produced by *Clostridium botulinum* that paralyzes muscles by the prevention of acetylcholine release and has been shown to be useful in treating conditions associated with neuromuscular dysfunction such as muscles hyperactivity and spasms (Ghazizadeh and Nikzad, 2004). There was no reporting case in Indonesia about vaginismus nor the therapy. This is the first research about botox modalities as vaginismus

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treatment in Indonesia. This procedure is adapted from a procedure developed by Peter T. Pacik, MD., FACS (Plastic Surgery Center, Manchester, NH, USA) who has received approval from the United States Food and Drug Administration (FDA) to continue studies on the use of botox to treat vaginismus.

2 METHODS

2.1 Assessment

Vaginismus patients initially contacted me without hesitation through social media which dedicated for vaginismus information, they know that they are having vaginismus, since they have experienced difficulties on penile penetration in sexual intercourse during their marriage or acitive sexually. A scheduled appointment for initial consultation and physical examination was offered to each patient. Until this paper is submitted, total 141 patients have contacted me (from all over Indonesia, including 2 patients from Malaysia, and 1 patient from Nigeria), admitting that they have penetration difficulties.

Fourty-nine patients came to my office for initial examination and consultation, to get their vaginismus and the severity confirmed, also for determining therapy options. Fourty one of them (83.6%) are candidates for the procedure (3rd to 5th degree vaginismus). Nineteen patients underwent the procedure.

Vaginismus diagnosis is based on history taking and physical examination. When a patient complains that attempted intercourse feels like it is ''hitting a wall'', suggestive of spasm at the level of the introitus, this is a symptom that helps differentiate vaginismus from dyspareunia, vulvodynia and provoked vestibulodynia (vestibulitis). A Q-tip test is performed to ruled out vulvodynia by pressing the wet Q-tip against the vestibule at the 2, 4, 6, 8, and 10 o'clock positions to determine if there is provoked pain. If Q-tip test is negative, vulvodynia is ruled out. Next, simple finger penetration attempt by examiner was perfomed to determine the vaginal spasm (Goldstein, Pukall, and Goldstein, 2009).

Patients with 3rd-5th degree was adviced to undergo the assisted dilation procedure enabling them to start the successful self dilation using silicone dilator.

Table 1: Severity of vaginismus

Grade	Description
Lamont grade 1	Patient is able to relax for pelvic examination
Lamont grade 2	Patient is unable to relax for pelvic examination
Lamont grade 3	Buttocks lift off table. Early retreat
Lamont grade 4	Generalized retreat: buttocks lift up, thighs close, patient retreats
Pacik grade 5	Generalized retreat as in level 4 plus visceral reaction, which may result in any one or more of the following: palpitations, hyperventilation, sweating, severe trembling, uncontrollable shaking, screaming, hysteria, wanting to jump off the table, a feeling of becoming unconscious, nausea, vomiting, and even a desire to attack the doctor

(references : Lamont Pacik Classification)

Once the diagnosis and severity of vaginismus had been determined, treatment options can be discussed. Basically, if a patient can tolerate finger penetration it means that they can start self dilation immediately. But when a patient cannot tolerate any kind of simple penetration, assisted dilation procedure is the most suitable option for them. Other characteristics such as age, duration of marriage or active sexually, previous treatment, and minimal progress of self dilation, are also used for procedure consideration.

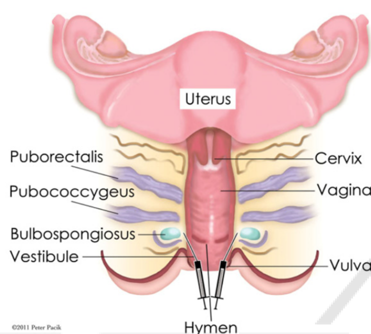
Some women choose the more traditional treatment of dilation. Dilation consists of using several dilators over time in increasing size. A dilator is inserted into the vagina to gradually stretch the vaginal muscles. Some patients become frustated with the dilation process and prefer Botox procedure so they can progress to the larger sized dilators. Other women, seek the botox procedure directly. Most women have tried dilation at home and were either unsuccesful progressing to the larger sized dilators or were too fearful to even begin treatment.

2.2 Assessment

In the operating room, patients are given total intravenous anesthesia. A pelvic exam performed to assess vaginal tightness and anatomical abnormalities, speculum is placed inside the vagina, initially for inspection of vagina and cervix. Then total of 100 units botox injected throughout the vaginal vault, 50 units of Botox injected into the

puborectalis and pubococcygeus muscles; divided into four clumns of thhree injections bilaterally. After that, 18 ml of local anesthetic (0,25% marcaine with epinephrine 1:400.000) then injected throughout the vault in a similar distribution to the previous botox injections.

The bulbocavernosus then injected in three columns; one proximal, one inferior and one distal bilaterally. A largest dilator (number 6) which had covered with xylocaine gel and natural lubricant inserted and remain in placed as the patient brought to the recovery room. This allows patients to wake up in recovery with pain-free experience for the first time while a static penetration using largest dilator happened.



Figures 1. Area of botox injection[7]

Patients transported to her room for dilation excercise. For the next 3-4 hours, patient has some rest and recover for maximum alertness. The dilator was totally removed for the first time as preparation for urinating after the procedure. After that, patient is able to successfully reinsert the dilator without any significant pain and fear. During that process, doctor supervised dilation process all the time, and also give them positive direction and encouragement as form of psychological support. Patients must do the dilation using method and movement as instructed in a certain time, such as rotating, move back forward, and changing size. At night, number 4 dilator was worn through the night while she was sleeping.

On the next day, doctor evaluate the progress of the dilation and gave patient and her spouse counseling about transition from dilation to sexual intercourse. They were discharged with a dilation program at home with typical method and movement. First follow up is one month after the procedure. Patient will undergo a simulation of several vaginal examination, such as pelvic examination, speculum examination, and transvaginal ultrasound. Patients are allowed to have direct communication to make doctor keep informed about their problem and progress.

3 RESULTS

Fourty one patients (83.6%) with 3-5 level of vaginismus are candidates for the procedure, 17 patients underwent the procedure. Seventeen patients (100%) achieved nonsexual penetration and self dilation at same day as procedure. Seventeen patients (100%) have successful vaginal ultrasound and pelvic examination in 1 month post procedure follow up. For penile penetration in sexual intercourse, 14 patients (82.3%) achieved it within average of 4,5 weeks after the procedure.

4 DISCUSSIONS

Vaginismus is a more common sexual problem than previously reported (Lamont, 1978). There is no data about vaginismus di indonesia. This is the first study about vaginismus in Indonesia.

Vaginismus is a subset of the genito-pelvic pain and penetration disorders and is currently defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) as a penetration disorder (Pacik, 2014), in accordance in ICD-10 definition as involuntary spasm of the pelvic muscles surrounding the outer third of the vagina, spesifically the perineal muscles and the levator ani muscles (Lamont, 1978; Pacik, 2014). In severe cases of vaginismus the adductors of the thighs, the rectus abdominis, and the gluteus muscles may be involved (Lamont, 1978). The diagnosis of vaginismus is made by history and physical examination (Pacik, 2014).

Patient came mostly for their unconsummated marriage and infertility. Two patients referred by dermatologists. Nineteen vaginismus patient treated with botox procedure in this study has the range of marriage duration between 6 months and 9 years. All of them never had penile penetration, they complains that attempted intercourse feels like it is ‘‘hitting a wall’’, suggestive of muscles spasm at surrounding vagina.

The first reported use of Botox to treat vaginismus was in 1997 (Ghazizadeh and Nikzad, 2004). Mechanism action of botox is the toxin enters the nerves by binding to surface protein receptors and undergoing into internalized vesicles. The light chain is released into the nerve cytosol, and the

SNARE *(soluble N-ethylmaleimide-sensitive factor attachment protein receptor)* protein complex is cleaved to inhibit exocytosis of the neurotransmitters such as acethylcholine (Goldsmith, Katz, and Gilchrest, 2012) at the neuromuscular junction (Shafik and El-Sibaik, 2000). The end result is a chemodenervation of the cholinergic neurons, either motor nerves or autonomic nerves, leading to localized absence of muscle activity (Goldsmith, Katz, and Gilchrest, 2012). Botox produces its effect by causing muscle paralysis, thus will inhibit muscles spams in vaginimus. Improvement in vaginismus is presumably due to paralysis of the bulbospongiosus muscle. The latter appears to be responsible for closure of the vaginal introitus on trial of vaginal penetration. The other pelvic floor muscles, levator ani and puborectalis muscles are apparently not involved during vaginalpenetration as the levator ani is inserted into the vaginal fornices while the puborectalis is related to the lower part of the vagina (Shafik and El-Sibaik, 2000).

Ghazizadeh and Nikzad reported the used of Botox in the treatment of refractory vaginismus in 24 patients. In this study, Dysport (150 to 400 mIU) was used. Twenty three 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 (78%) achieved satisfactory intercourse, four (17%) had mild pain, and one was unable to have intercourse because of her husband's impotence.

Botox procedure in this study consist of botox injection in bulbospongiosus muscle, dilation with the biggest dilator under anesthesia. The results were 100% patients have successful painfree penetration without muscle spasm through self dilation using 4 inch silicone dilator at the same day of the procedure, and 82,3% achieved sexual intercourse in average of 4,5 weeks after the procedure.

Dilation, in the treatment of vaginismus is a simple method buy may require long-term therapy and fail in persistent cases (Shafik and El-Sibaik, 2000). Most women have tried dilation at home and were either unsuccesful progressing to the larger sized dilators or were too fearful to even begin treatment (Pacik and Gelatta, 2017). Likewise, behavioural therapy and psychotherapy, besides being lengthy and expensive, may not succeed in cureing the condition, especially in persistent and severe degree of vaginismus. Meanwhile, botox procedure is a simple, easy, rapid, and effective treatment for vaginismus.

Side effects of botox including minor discomfort, bruising (Goldsmith, Katz, and Gilchrest, 2012), dry mouth, dysphagia, paresis extremities, or urine incontinence (Shafik and El-Sibaik, 2000). Two patients in this study report temporary mild urine incontinence, this expected gone by the time botox loses its effectiveness.

Botox is a safe drug when used according to the manufacturer's recommendations. During the past 20 years, Pacik has treated thousands of patients using botos for dynamic facial wrinkles, excessive sweating, migraine headhaches, and vaginismus, with only rare minor untowards effects mostly the result of migration of botox to nearby tissues. Around 391 vaginismus patient were treated with this botox procedure, there only few minor untoward events such as temporary mild stress incontinence (Pacik and Gelatta, 2017), same as this study. No permanent sequele were noted.

Botox has a long duration of action up to 6 months, loses its effectiveness within 4 to 6 months (Goldsmith, Katz, and Gilchrest, 2012), but another repeated botox procedure is usually not needed. At this time period, patient has made the transition from post-operative dilation to intercourse. In this study, no patient was in need of re-procedure and there was no reccurence during the follow-up period. Botox procedure effected cure in all of the vaginismus patients with no complications or recurrence.

5 CONCLUSIONS

Botox procedure appears to be safe and effective as vaginismus treatment. This procedure has helped many women to immediately start effective dilation and also end their unconsummated marriage. It is important for health care providers to know more about vaginismus. Medical school, residency program, and medical meetings are needed to spread the knowledge about vaginismus and its treatment.

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