

A New Radiofrequency-assisted Therapeutic Approach for Management of Vaginismus: A Pilot Experimental Study

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ABSTRACT

Background: Vaginismus is a sexual dysfunction presented as pain and fear during sexual intercourse. According to various potential etiologies, a multidimensional approach should be considered for treatment of vaginismus. We introduce a new radiofrequency-assisted therapeutic method with combination of reassurance to patients for the first time in Iranian female patients with vaginismus. **Patients and methods:** In this quasi-experimental within subject study, we applied non-invasive radiofrequency to perineal area and vagina in patients with vaginismus. Patients received intervention in two 40-minute sessions with a one-week interval. The outcome measures were Questionnaire of Cognitive Schema Activation in Sexual Context (QCSASC) and Vaginismus Diagnosis and Severity Questionnaire which were administered to patients before and two weeks after intervention. **Results:** Finally, 20 female patients with a mean age of 29.1 ± 5.42 years (minimum 21 and maximum 38 years) underwent analysis. Mean duration of marriage was 5.21 ± 3.71 years in our study individuals with the minimum length of 6 months and maximum length of 12 years. Mean Cognitive Schema Activation in Sexual Context (QCSASC) score was 74.3 ± 15.39 before and 58.95 ± 13.11 after the intervention ($p < 0.001$). Statistical analysis showed that most (13 out of 17) questions of Vaginismus Diagnosis and Severity Questionnaire were significantly improved after intervention. **Conclusion:** we found that a two-session non-invasive radiofrequency of perineal area and vagina, in combination with reassurance, improves sexual function two weeks after the final therapeutic session.

Keywords: Sexual dysfunction, Vaginismus, Radiofrequency, Dyspareunia, Penetration disorder

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INTRODUCTION

Vaginismus is a sexual dysfunction presented as pain and fear during sexual intercourse which is caused by intermittent and unintentional spasms of the outer one-third muscles of the vagina, (1). Negative attitude toward sex and history of sexual abuse are the predisposing factors for vaginismus which is a culture-dependent disorder (2, 3). A wide range of factors from fear of pain, bleeding and panic attack to family history and valuing the hymen are among the culture-dependent agents (4).

According to various potential etiologies, a multidimensional approach should be considered for treatment of vaginismus. Caregivers should take psychological, biological, emotional and relational factors of women and their partners into account. So far, plenty of psychological, sexual and pharmacological interventions as well as cognitive and behavioral therapy, relaxation therapy, bibliotherapy and hypnotherapy have been applied for management of vaginismus which had positive effects to some extent (5). Radiofrequency has been being applied since decades for vaginal rejuvenation and previous researches have proven the efficacy of

energy-based minimally invasive radiofrequency devices for vaginal tightening (6). In addition, this method might offer benefits for women with genitourinary syndrome including female sexual dysfunction (FSD) and stress urinary incontinence (SUI); however, there seems to be a need for robust data and high-quality evidence (7). A recent study has confirmed the positive effects of temperature controlled dual-mode radiofrequency for management of vaginal laxity and improvement of pelvic floor muscles as well as female sexual function.

In the present study, we introduce a new radiofrequency-assisted therapeutic method with combination of reassurance therapy for the first time in Iranian female patients with vaginismus.

PATIENTS AND METHODS

This quasi-experimental within subjects study was conducted between March and July 2022 on patients attending to our private gynecological office in Isfahan, Iran with complaints of inability for, fear of or painful intercourse. The protocol of the study was

registered to the institutional review board of Isfahan University of Medical Sciences, Isfahan, Iran. Patients were selected using availability sampling method underwent a comprehensive history taking and the diagnosis of vaginismus was confirmed using standard Persian questionnaire for vaginismus diagnosis and severity developed by Raeisi et al. (8) as well as physical examination by ruling out obstructive vaginal or hymen disorders. We assessed female patients within reproductive age and duration of marriage or relationship of more than 6 months for eligibility. Patients with psychiatric disorders, not available for follow-up or those no willing to take part in the study were excluded.

In the first session, all the patients received a comprehensive explanation upon the duration and process of therapy. Therapist (gynecologist) reassured patients about the efficacy of therapy and positive results which are usually achieved after two consecutive sessions of therapy. All the patients were advised to have no sexual intercourse until the last therapeutic and final consulting session. Patients with intact hymen underwent hymenectomy by local analgesia or general anesthesia in the operation room. In the next stage, patients underwent radiofrequency exposure in the labia major and perineum area, using a disposable grounding pad measuring 10 cm, for 40 minutes. We used HIGGS (medaria co., Tehran, Iran) radiofrequency system and the setting was adjusted on endothermy, power of 40 watts, TC effect of 100% and TC frequency of 0 Hz.

Patients were visited again 7 days after the first session and underwent radiofrequency intervention with the same setting of the previous session for 30 minutes. Then, patients were asked to have a collaboration with the operator and help her with inserting the applicator inside their vaginal canal slowly and within 10 minutes. We rarely used Lidocaine-Prilocaine gel for vestibular analgesia in case of severe pain. This stage is painful for a large proportion of patients and reassuring the patients will help with the process. Following passing the first one third of the vagina, the operator used to feel a click and the penetration got easier. When the applicator was inside the vagina, patients felt some degree of pain which was mostly relieved by reassurance. This stage took about 40 minutes. After the final therapeutic session, gynecologist asked patients to augment their sexual desire and arousal by watching movies, reading books and sexual fantasy in a way that they extremely desire sexual intercourse. Patients were advised to have their first sexual intercourse during the follicular phase of the menstrual cycle according to higher lubrication of vagina.

Demographic information as well as data on duration of marriage was recorded in a predesigned checklist. Patients filled The Questionnaire of Cognitive Schema Activation in Sexual Context (QCSASC) (9) and Vaginismus Diagnosis and Severity Questionnaire (including 17 questions which have been mentioned in appendix 1) before the first and two weeks after the final therapeutic session.

Data were analyzed using Statistical Package for Social Sciences (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Descriptive analysis was performed using mean and standard deviation as well as percentages and frequencies. Shapiro-Wilk test was used to check the normal

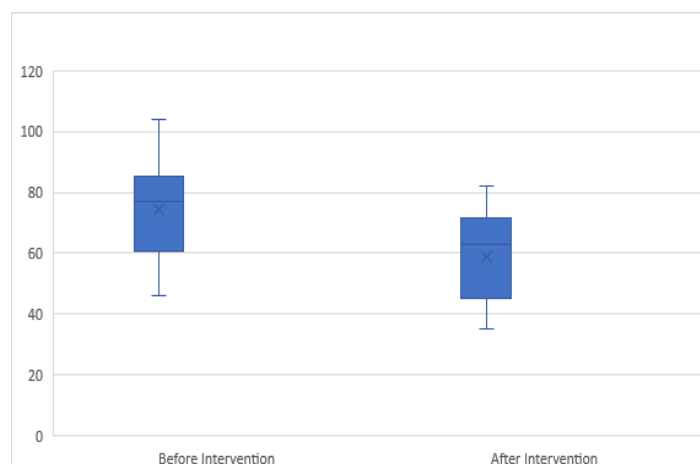


Figure 1. The mean QCSASC score before and after intervention.

distribution of data. Paired t-test was used to compare the changes within the groups. Chi square was performed to assess the changes in QCSASC results. A p-value of less than 0.05 was considered as statistically significant.

RESULTS

Finally, 20 female patients with a mean age of 29.1 ± 5.42 years (minimum 21 and maximum 38 years) underwent analysis. Mean duration of marriage was 5.21 ± 3.71 years in our study individuals with the minimum length of 6 months and maximum length of 12 years.

Mean Cognitive Schema Activation in Sexual Context (QCSASC) score was 74.3 ± 15.39 before and 58.95 ± 13.11 after the intervention ($p < 0.001$, figure 1). Statistical analysis showed that most (13 out of 17) questions of Vaginismus Diagnosis and Severity Questionnaire were significantly improved after intervention (Table1).

DISCUSSION

We found that a two-session combination therapy of radiofrequency and reassurance about the effectiveness of intervention, can efficiently improve vaginismus two weeks after the final therapeutic session. In the present study all the patients showed a decrease in Cognitive Schema Activation in Sexual Context (QCSASC) score in comparison with prior to intervention. Assessing answers to Vaginismus Diagnosis and Severity Questionnaire which was developed by Raeisi et al., we found that there is a significant improvement in symptoms of vaginismus in nearly all the 17 questions. Only answers to questions number 4, 8, 11 and 14 were not significantly improved which are more related to psychological aspects of the vaginismus which were not the main target of therapy in the present study.

Considering the need for unpleasant physical examination, there are no epidemiologic studies assessing the prevalence of vaginismus worldwide. As a result, various estimations have been presented for prevalence of this sexual dysfunction with some assuming vaginismus a rare condition, and others believing it as the most prevalent female sexual problem(10).

A proper diagnosis is the main step for choosing appropriate therapeutic approach. Unfortunately, there are lots of controver-

sies in vaginismus diagnosis as there are no precise definition or diagnostic criteria. Differentiating vaginismus from superficial dyspareunia is challenging, and on the other hand vaginal muscle spasm is not a comprehensive diagnostic criteria as a majority of patients complaint with fear of pain or penetration and vulvar pain(10). Combining dyspareunia and vaginismus as a genito-pelvic penetration disorder, Binik has proposed a diagnostic criterion which emphasizes on persistent or recurrent difficulties in sexual intercourse for at least 6 months with one or more of these conditions(11); a) Inability to have vaginal intercourse/penetration on at least 50% of attempts, b) Marked genito–pelvic pain during at least

50% of vaginal intercourse/penetration attempts. C) Marked fear of vaginal intercourse/penetration or of genito–pelvic pain during intercourse/penetration on at least 50% of vaginal intercourse/penetration attempts, and d) Marked tensing or tightening of the pelvic floor muscles during attempted vaginal intercourse/penetration on at least 50% of occasions. In our opinion, although defining a united criteria for vaginismus may be of use, but the inter-cultural varieties should be also considered in defining these criteria.

Dysfunction of pelvic floor muscles including reduced muscle control and hypertonicity, has been proposed as a predisposing factor for developing vaginismus(12). This is the reason why physio-

Table 1. Answers to Vaginismus Diagnosis and Severity Questionnaire Before and After the Intervention

Question	Before					After					p value
	Never	Relatively low	low	Relatively high	high	Never	Relatively low	low	Relatively high	high	
1	19 (95%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	2 (10%)	12 (60%)	6 (30%)	<0.001
2	4 (20%)	2 (10%)	5 (25%)	4 (20%)	5 (25%)	16 (80%)	2 (10%)	2 (10%)	0 (0%)	0 (0%)	<0.001
3	1 (5%)	0 (0%)	0 (0%)	3 (15%)	16 (80%)	9 (45%)	8 (40%)	3 (15%)	0 (0%)	0 (0%)	<0.001
4	0 (0%)	0 (0%)	1 (5%)	2 (10%)	17 (85%)	0 (0%)	0 (0%)	1 (5%)	2 (10%)	17 (85%)	>0.999
5	3 (15%)	7 (35%)	2 (10%)	3 (15%)	5 (25%)	0 (0%)	0 (0%)	0 (0%)	5 (25%)	15 (75%)	0.001
6	8 (40%)	2 (10%)	5 (25%)	2 (10%)	3 (15%)	16 (80%)	2 (10%)	2 (10%)	0 (0%)	0 (0%)	0.005
7	8 (40%)	1 (5%)	0 (0%)	2 (10%)	9 (45%)	17 (85%)	2 (10%)	0 (0%)	0 (0%)	1 (5%)	0.01
8	0 (0%)	0 (0%)	1 (5%)	3 (15%)	16 (80%)	0 (0%)	0 (0%)	0 (0%)	3 (15%)	17 (85%)	0.414
9	1 (5%)	0 (0%)	2 (10%)	4 (20%)	13 (65%)	9 (45%)	7 (35%)	2 (10%)	0 (0%)	2 (10%)	<0.001
10	0 (0%)	1 (5%)	0 (0%)	4 (20%)	15 (75%)	8 (40%)	10 (50%)	1 (5%)	1 (5%)	0 (0%)	<0.001
11	18 (90%)	1 (5%)	1 (5%)	0 (0%)	0 (0%)	20 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.180
12	6 (30%)	2 (10%)	2 (10%)	2 (10%)	8 (40%)	15 (75%)	3 (15%)	2 (10%)	0 (0%)	0 (0%)	0.002
13	6 (30%)	1 (5%)	1 (5%)	3 (15%)	9 (45%)	7 (35%)	5 (25%)	3 (15%)	1 (5%)	4 (20%)	0.01
14	10 (50%)	3 (15%)	1 (5%)	4 (20%)	2 (10%)	9 (45%)	5 (25%)	0 (0%)	3 (15%)	3 (15%)	>0.999
15	0 (0%)	1 (5%)	1 (5%)	3 (15%)	15 (75%)	8 (40%)	11 (55%)	1 (5%)	0 (0%)	0 (0%)	<0.001
16	1 (5%)	1 (5%)	1 (5%)	5 (25%)	12 (60%)	4 (20%)	11 (55%)	4 (20%)	1 (5%)	0 (0%)	<0.001
17	14 (70%)	2 (10%)	2 (10%)	2 (10%)	0 (0%)	19 (95%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0.026

therapy of pelvic floor has been considered as a therapeutic option. It will help with augment control of the vaginal musculature and improve mobility and function. In addition, pelvic floor muscle physiotherapy may relieve pain and help patient with overcome anxiety of vaginal penetration (13). Vaginal dilators, local tissue desensitization and pelvic floor biofeedback are among these techniques.

Dayan et al. have applied radiofrequency device for post-partum pelvic floor restoration in 50 women with a mean age of 32 years(14). Patients underwent vaginal radiofrequency treatment and showed an improvement in maximal pelvic floor contraction with no changes in pelvic muscle tone. No complications were reported following radiofrequency treatment.

In a recent systematic review by González-Gutiérrez et al., they evaluated 578 studies which had used non-invasive nor ablative radiofrequency diathermy for treating pelvic floor disorders (15). Although most of the studies had a low quality, but results suggested improvements in pelvic pain, sexual function or pelvic floor muscle strength.

In the present study we used pelvic and vaginal radiofrequency using Higgs device (mediaria co., Iran) for treatment of vaginismus in 20 consecutive patients which showed a significant improvement in QCSASC score.

The present study had some limitations. The low sample size and lack of control group may have resulted in biases. However, this was a pilot experimental study and will be followed by a randomized controlled trial.

CONCLUSION

Findings of the present study suggest that a two-session non-invasive radiofrequency of perineal area and vagina, in combination with reassurance about positive effects of intervention, improves sexual function two weeks after the final therapeutic session. Further studies are recommended with a larger sample size as well as sham groups to rule out the placebo effect of this intervention.

ETHICAL CONSIDERATIONS

All stages of the study were conducted in accordance to provisions of the Helsinki declaration. In addition, all patients participating in the study signed an informed consent form.

CONFLICT OF INTERESTS

There are no conflicts of interest in terms of the present manuscript.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and analyzed in the current study are available from the corresponding author on reasonable request.

ABBREVIATIONS

FSD; female sexual dysfunction, SUI; stress urinary incontinence.

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