

The Impact of Higgs Radiofrequency on Pelvic Organ Prolapse and Sexual Function Among Women Suffering from Vaginal Laxity

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ABSTRACT

Background & Objective: Vaginal laxity is a prevalent disorder that influences woman's sexual satisfaction and quality of life. This study aimed to evaluate the impact of Higgs radiofrequency on pelvic organ prolapse and sexual function among women suffering from vaginal laxity.

Materials & Methods: This was a pre- and post-intervention study. Twenty-two subjects who suffered from vaginal laxity referring to a pelvic floor clinic affiliated with Tehran University of Medical Sciences were studied. Higgs radiofrequency was administered at six sessions with a two-week interval. Women were evaluated by an urogynecologist for pelvic organ prolapse quantification (POP-Q) twice: before and three months after intervention. Also, women responded to the Female Sexual Function Index (FSFI-19) at baseline and three months follow-up assessment. Data were analyzed by descriptive statistics and paired samples t-test.

Results: The mean age of participants was 40.30 (SD = 8.01) years. The mean number of gravidities was 2.45 (SD = 1.29). Seventeen women (77.3 %) suffered from severe or moderate vaginal laxity. After intervention, the point Ba ($P=0.02$), perineal body-point PB ($P=0.058$) and total vaginal length (0.014) significantly improved. Also, female sexual function and its six domains improved ($P<0.001$).

Conclusion: The findings indicated that Higgs radiofrequency was a safe and noninvasive technique that improved some pelvic organ prolapse quantification and sexual function among women suffering from vaginal laxity.

Keywords: Higgs radiofrequency, Pelvic organ prolapse, Sexual function, Vaginal laxity



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Introduction

Vaginal laxity or looseness is a relatively prevalent disorder that influences woman's sexual satisfaction and quality of life. It has been reported that 24 to 38% of women suffer from vaginal laxity. It has been associated with parity, symptoms of prolapse, stress urinary incontinence, overactive bladder, reduced vaginal sensation during intercourse, and worse general sex life (1, 2).

Pelvic Organ Prolapse (POP) is known as the intra-pelvic organs descending due to weakness in the supporting structures. It is a common condition among

up to 20% of women under the age of 45 and has been reported as high as 39.8% among elderly woman (3). Pelvic organ prolapse may decline quality of life as well as sexual satisfaction (4).

The radiofrequency technology has been used to improve vaginal laxity, and pelvic organ prolapse, sexual function, lubrication, genito-pelvic sensation, and considered widely safe and effective (5, 6). Vicariotto *et al.* showed that radiofrequency was a safe treatment with a rapid and persistent consequence on vaginal laxity and sexual satisfaction for 12 months

follow up. Also, Millheiser *et al.* found that radiofrequency was effective on subjective improvement in self-reported vaginal tightness, sexual function and decreased sexual distress (7).

In another study among women suffering from vaginal laxity after vaginal childbirth, a 30-minute office procedure using radiofrequency, improved the sexual satisfaction as well as decreasing the sexual distress for 12 months (8).

Radiofrequency has varied types, such as monopolar radiofrequency and Dynamic quadripolar radiofrequency. We used Higgs radiofrequency made by Danesh Bonyan Maya Slim Aria Company.

This study aimed to evaluate the impact of Higgs radiofrequency on pelvic organ prolapse and sexual function among women suffering from vaginal laxity.

Materials and Methods

Study Design and Participants

This was a pre- and post-intervention study design on a sample of women who referred to a pelvic floor clinic affiliated with Tehran University of Medical Sciences in Tehran, Iran, during December 2017 to July 2018. All women, who had sexual dissatisfaction suffering from vaginal laxity were assessed. The inclusion criteria were having signed informed consent, being married, aged 18 up to 50, having normal pop smear in recent three years. The exclusion criteria were suffering from immune suppressive diseases, having the Intra Uterine Devices, having cardiac pace maker, being pregnant or in lactation, a history of diabetes or increased blood pressure and skin diseases. All participants were asked to respond the study questionnaire twice: at baseline (before intervention) and three months follow-up evaluation. Also, an urogynecologist examined participants in terms of pelvic organ prolapse before and three months after intervention. All participants evaluated in dorsal lithotomy position after emptying their bladders.

Measurements

1. Demographic and medical history: A self-designed questionnaire was used to collect data on patients' demographic information such as age, medical history including number of gravidities and vaginal or cesarean section delivery, weight, height and score of vaginal laxity.

2. Pelvic Organ Prolapse Quantification (POP-Q): This contains six points (Aa, Ba, C, D, Ap, Bp). The POP-Q was used to report the level of descent or prolapse of the anterior vaginal wall (Aa, Ba), vaginal apex (C, D), and posterior wall (Ap, Bp). The locations of these points are evaluated through maximal Valsalva or cough in relation to the hymen. If the point descends to the hymen, it is measured as 0 cm, if it remains above the hymen, it is described as negative numbers and if it descends outside the hymen, it is measured as positive

numbers. Also, there are other measurements, which are documented independent of the hymen (point of genital hiatus GH, point of perineal body PB, and point of total vaginal length at rest TVL) (9).

3. Female Sexual Function Index (FSFI-19): The 19-item FSFI assesses the dimensions of females' sexual function among both clinical and community populations. FSFI includes six subscales consisting desire, arousal, lubrication, orgasm, satisfaction and pain. All subscale scores ranged Likert type from 0 to 5. Higher scores indicate better sexual functioning. Total score were obtained summing the subscale scores (10). Scores of 28 or lower were identified as the cutoff for sexual dysfunction. The Iranian version of the FSFI is a valid and reliable tool (11).

Intervention Protocol

We used Higgs device made by Danesh Bonyan Maya Slim Company. The protocol was performed of two packages including 6 sessions. Package 1: included 3 sessions weekly. After 15 days, package 2 was started weekly. One disposable applicator (IQA: Intra Quadratic Applicator) assigned to each patient for each treatment. For standard therapy, we used two programs: endothermy and endogym. Endothermy program generates homogeneous heat inside body between applicator and grounding pad thus increasing blood circulation in that area. This program endures 15 minutes. The second program started which is endogym. This program stimulates aerobic exercises that endures 30 minutes.

In both packages, at first session, grounding pad was attached on patient's body in front of pubic area; at second session, it was attached under the buttock; and at third session was attached on patient's body in front of pubic area.

1. Protocol of therapy sessions for mild laxity:
 - Session 1: endothermy, warm endogym
 - Session 2: endothermy, aerobic endogym
 - Session 3: endothermy, warm endogym
2. Protocol of therapy sessions for severe laxity:
 - Session 1: endothermy, aerobic endogym.
 - Session 2: endothermy, cold endogym
 - Session 3: endothermy, aerobic endogym

Statistical Analysis

We used the SPSS version 23 (SPSS Inc., Chicago, Ill., USA) for data analyzing. Descriptive statistics and the paired samples t-test were used for exploring the data and comparing before and after radiofrequency implication. The significant level was set at P-value < 0.05.

Results

Participants' Characteristics

Descriptive data of women are reported in [Table 1](#). The mean age of participants was 40.30 (SD = 8.01)

years. The mean number of gravidities was 2.45(SD = 1.29). Fourteen (63.6%) subjects had 2 to 4 vaginal delivery history. Eight participants (36.4 %) suffered from severe vaginal laxity and nine (40.9 %) had moderate vaginal laxity. Nineteen (86.3%) women were over weighted (63.6%) or obese (22.7%).

Pelvic Organ Prolapse Quantification

The results gained for pelvic organ prolapse quantification are shown in [Table 2](#). Regarding to six points (Aa, Ba, C, D, Ap, Bp) status that were between -1 to +1, all participants were on stage II (staging of the prolapse at baseline). After intervention, point Ba ($P=0.02$) and total vaginal length (0.014) significantly improved. Also, perineal body-point PB showed just

significantly improvement ($P=0.058$). However, status of point Aa, Ap and Bp improved slightly but not significantly.

Female Sexual Function Index

The results showed that female sexual function and six domains improved significantly after radiofrequency intervention ($P<0.001$). The mean of female sexual function was below cut of point at baseline (22.1, SD=6.5). After treatment the mean of sexual function increased to 30.2 (SD=3.1) during a 3 months follow up. The results obtained by the paired sample t-test are expressed in [Table 3](#).

Table 1. The characteristics of study sample

	Mean (SD)	No (%)
Age	40.45(5.27)	
Gravidity	2.45(1.29)	
Normal Vaginal Delivery	1.7(0.97)	
0		2(9.1)
1		6(27.3)
2		10(45.5)
3		3(13.6)
4		1(4.5)
Cesarean Section	0.27(0.4)	6(27.3)
Vaginal Laxity		
Severe		8(36.4)
Moderate		9(40.9)
Mild		4(18.2)
Not too loose and not too tight		1(4.5)
Body Mass Index	27.47(2.87)	
Normal (18.5-24.9)		3(13.6)
Over weight (25-29.9)		14(63.6)
Obese (≥ 30)		5(22.7)

Table 2. Pelvic Organ Prolapse Quantification

	Baseline	Follow up	P
	Mean (SD)	Mean (SD)	
Point Aa	-0.85(0.72)	-1.14(0.72)	0.1
Point Ba	-0.4286(0.67)	-0.90(0.76)	0.02
Point C	-4.95(1.32)	-4.57(1.39)	0.2
Point D	-6.85(1.15)	-6.47(1.20)	0.1
Point Ap	-0.90(0.83)	-0.95(0.74)	0.8
Point Bp	-0.57(0.92)	-0.90(0.76)	0.1
Genital hiatus point GH	4.02(0.97)	4.05(1.39)	0.9
Perineal body-point PB	3.75(0.91)	4.20(1.15)	0.058*
Total vaginal length (TVL)	9.35(0.67)	9.85(0.36)	0.014

*Just significant

Table 3. Sexual functioning score

	Baseline	Follow up	P
	Mean (SD)	Mean (SD)	
Desire	3.6 (1.1)	4.5 (0.84)	<0.001
Arousal	3.16 (1.30)	4.65 (0.73)	<0.005

	Baseline	Follow up	
Lubrication	3.84 (1.26)	5.37 (0.53)	<0.001
Orgasm	3.29 (1.6)	4.90 (0.72)	<0.001
Satisfaction	3.32 (1.4)	5.10 (0.65)	<0.009
Pain	4.87 (1.4)	5.67 (0.61)	0.001
Total score	22.1 (6.5)	30.2 (3.1)	<0.001

Discussion

The study results indicated that some pelvic organ prolapse quantification changed to a better status particularly about anterior vaginal wall, total vaginal length and perineal body. This is comparable with previous studies that showed radiofrequency could improve stress urinary incontinence and vulvo-vaginal laxity (12) or be used for vulvovaginal rejuvenation (13, 14).

On the other hand, some studies have shown that correlations between pelvic floor symptoms and anatomic organ prolapse severity have been weak (15, 16, 17).

Moreover, studies have shown that total vaginal length correlates with increased female sexual function. But, the female sexual function did not show correlation with genital hiatus (18). However, a study reported that there was no correlation between vaginal measurements with sexual function (19). Perhaps for improving the pelvic organ prolapse quantification there might be need for more therapeutic session.

The findings showed that Higgs radiofrequency can improve female sexual function and all its dimensions including sexual desire, arousal, lubrication, orgasm, satisfaction and pain. Similarly, previous studies found that radiofrequency was effective in improving sexual function (7, 20, 21). Higgs radiofrequency technology using the warm endogym provokes the vaginal mucus which might result in lubricant improving. Also, using the cold endogym or aerobic helps with contraction or relaxing of pelvic floor muscles if needed within intercourse.

The study results showed that the majority of women suffered from over weighting or obesity. This was in parallel with previous studies (22, 23, 24). Over weighting can increase pelvic floor prolapse resulting in

intra-abdominal pressure (25). Thus, managing the life style and weight controlling might decrease vaginal laxity and its side effects.

Strengths and Limitations

This study had some strengths. To the best of our knowledge, it is the first study that assesses the impact of Higgs radiofrequency on pelvic organ prolapse quantification and sexual function simultaneously among women suffering from vaginal laxity in Iran. Also, Higgs radiofrequency is a new variation of radiofrequency that uses a novel technology which is a modulation of electromagnetic waves and called contractile radiofrequency. The study limitations were: first, we used convenience sampling among women attending an educational pelvic floor clinic which limits the generalizability of the findings. Secondly, we did not evaluate other interfering variables such as partner relationship or mental status of participants.

Conclusion

The findings indicated that Higgs radiofrequency was a safe and noninvasive technique that improved some pelvic organ prolapse quantification and sexual function among women suffering from vaginal laxity.

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Conflict of Interest

The authors have no conflict of interests.

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