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

Tahereh Eftekhar1, Marzieh Hajibabaei2*, Leila Pourali3, Maryam Vizheh4, Ali Montazeri5,6

1. Department of Obstetrics and Gynecology, Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran
2. Psychosomatic Medicine Research Center, Tehran University of Medical Sciences, Tehran, Iran
3. Department of Obstetrics and Gynecology, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
4. Department of Reproductive Health and Midwifery, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
5. Population Health Research Group, Health Metrics Research Center, Iranian Institute for Health Sciences Research, ACECR, Tehran, Iran
6. Faculty of Humanity Sciences, University of Science and Culture, Tehran, Iran

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<0.056) 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

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 recent three years. The exclusion criteria were suffering from immune suppressive diseases, having intrauterine 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 gravities 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) |
| 0 | 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

| Mean (SD) | Mean (SD) | P |
|----------|-----------|---|
| **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

| Mean (SD) | Mean (SD) | P |
|----------|-----------|---|
| **Desire** | 3.6 (1.1) | 4.5 (0.84) | <0.001 |
| **Arousal** | 3.16 (1.30) | 4.65 (0.73) | <0.005 |
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 lifestyle 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.

Acknowledgments

We appreciate the cooperation of all women who participated in this study.

Conflict of Interest

The authors have no conflict of interests.

References

1. Dietz HP, Stankiewicz M, Atan IK, Ferreira CW, Socha M., Vaginal laxity: what does this symptom mean?. Int Urogynecol J. 2018; 29(5):723-8. [DOI:10.1007/s00192-017-3426-0] [PMID]

2. Campbell P, Krychman M, Gray T, Vickers H, Money-Taylor J, Li W, Radley S., Self-reported vaginal laxity-prevalence, impact, and associated symptoms in women attending a urogynecology clinic. J Sex Med. 2018; 15(11):1515-7. [DOI:10.1016/j.jsxm.2018.08.015] [PMID]
3. Direkvand-Moghadam A, Ghazanfari Z, Sayehmiri K., Predictive factors for pelvic organ prolapse (POP) in Iranian women: an ordinal logistic approach. J clin Diagn Res: JCDR. 2014;8(1):96.

4. Persu C, Chapple CR, Cauni V, Gutue S, Geavlete P., Pelvic Organ Prolapse Quantification System (POP-Q)-a new era in pelvic prolapse staging. J Med Life. 2011; 4(1):75.

5. Vicariotto F, De Seta F, Faoro V, Raichi M., Dynamic quadrripolar radiofrequency treatment of vaginal laxity/ menopausal vulvo-vaginal atrophy. Minerva Ginecol. 2017; 69(4):342-9.

6. Dayan E, Ramirez H, Westfall L, Theodorou S., Role of Radiofrequency (Votiva, InMode) in Pelvic Floor Restoration. Plastic Reconstr Surg Global Open. 2019; 7(4). [DOI:10.1097/GOX.0000000000002203] [PMID] [PMCID]

7. Millheiser LS, Pauls RN, Herbst SJ, Chen BH., Radiofrequency treatment of vaginal laxity after vaginal delivery: nonsurgical vaginal tightening. J Sex Med. 2010; 7(9):3088-95. [DOI:10.1111/j.1743-6109.2010.01910.x] [PMID]

8. Sekiguchi Y, Utsugisawa Y, Azekosi Y, Kinjo M, Song M, Kubota Y et al., Laxity of the vaginal introitus after childbirth: nonsurgical outpatient procedure for vaginal tissue restoration and improved sexual satisfaction using low-energy radiofrequency thermal therapy. J Womens Health (Larchmt) 2013; 22:775-81. [DOI:10.1089/jwh.2012.4123] [PMID]

9. Madhu C, Swift S, Moloney-Geany S, Drake MJ., How to use the pelvic organ prolapse quantification (POP-Q) system?. Neuourology Urodynamics. 2018; (S6):S39-43. [DOI:10.1002/nau.23740] [PMID]

10. Rosen RC, Brown C, Heiman J, et al., The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Mar Ther 2000; 26:191-208. [DOI:10.1080/0092623002785971] [PMID]

11. Fakhri A, Pakpour AH, Burri A, Mohsedi H, Zeidi IM., The Female Sexual Function Index: translation and validation of an Iranian version. J Sex Med 2012; 9:514-523. [DOI:10.1111/j.1743-6109.2011.02553.x] [PMID]

12. Lalji S, Lozanova P., Evaluation of the safety and efficacy of a monopolar nonablative radiofrequency device for the improvement of vulvo-vaginal laxity and urinary incontinence. J Cosmet Dermatol. 2017; 16: 230-234. [DOI:10.1111/jocd.12348] [PMID]

13. Qureshi AA, Tenenbaum MM, Myckatyn TM., Nonsurgical vulvovaginal rejuvenation with radiofrequency and laser devices: a literature review and comprehensive update for aesthetic surgeons. Aesthet Surg J. 2018; 38: 302-311. [DOI:10.1093/asi/sjx138] [PMID]

14. Hashim PW, Nia JK, Zade J, Farber AS, Goldenberg G., Noninvasive vaginal rejuvenation. Cutis. 2018; 102(4):243-6.

15. Gutman RE, Ford DE, Quiroz LH, Shippey SH, Handa VL., Is there a pelvic organ prolapse threshold that predicts pelvic floor symptoms?. Am J Obstet Gynecol. 2008; 199(6):683-688. [DOI:10.1016/j.ajog.2008.07.028] [PMID] [PMCID]

16. Ghetti C, Gregory WT, Edwards SR, Otto LN, Clark AL, Pelvic organ descent and symptoms of pelvic floor disorders. Am J Obstet Gynecol. 2005; 193:53-7. [DOI:10.1016/j.ajog.2004.12.004] [PMID]

17. Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE, Correlation of symptoms with location and severity of pelvic organ prolapse. Am J Obstet Gynecol. 2001; 185:1332-7. [DOI:10.1067/mob.2001.119078] [PMID]

18. Schimpf MO, Harvie HS, Omotosho TB, Epstein LB, Jean-Michel M, Olivera CK, Rooney KE, Balgobin S, Ibeanu OA, Gala RB, Rogers RG. Does vaginal size impact sexual activity and function?. Int Urogynecol J. 2010 ; 21(4):447-52. [DOI:10.1007/s00192-009-1051-2] [PMID] [PMCID]

19. Occhino JA, Trabuco EC, Heisler CA, Klingele CJ, Gebhart JB., Changes in vaginal anatomy and sexual function after vaginal surgery. Int Urogynecol J. 2011; 22(7):799-804. [DOI:10.1007/s00192-011-1386-3] [PMID]

20. Vicariotto F, Raichi M., Technological evolution in the radiofrequency treatment of vaginal laxity and menopausal vulvo-vaginal atrophy and other genitourinary symptoms: first experiences with a novel dynamic quadrripolar device. Minerva Ginecol. 2016; 68(3):225-36.

21. Krychman M, Rowan CG, Allan BB, DeRogatis L, Durbin S, Yacoubian A, Wilkerson D. Effect of single-treatment, surface-cooled radiofrequency therapy on vaginal laxity and female sexual function: the VIVEVE I randomized controlled trial. J Sex Med. 2017; 14(2):215-25. [DOI:10.1016/j.jsxm.2016.11.322] [PMID]

22. Wasserberg N, Haney M, Petrone P, Ritter M, Emami C, Rosca J, Siegmund K, Kaufman HS. Morbid obesity adversely impacts pelvic floor function in females seeking attention for weight
loss surgery. Dis Colon Rectum. 2007; 50(12):2096-103. [DOI:10.1007/s10350-007-9058-6] [PMID]

23. Lee UJ, Kerkhof MH, Van Leijsen SA, Heesakkers JP. Obesity and pelvic organ prolapse. Current Opinion Urol. 2017; 27(5):428-34. [DOI:10.1097/MOU.0000000000000428] [PMID]

24. Giri A, Hartmann KE, Hellwege JN, Edwards DR, Edwards TL. Obesity and pelvic organ prolapse: a systematic review and meta-analysis of observational studies. Am J Obstet Gynecol. 2017; 217(1):11-26. [DOI:10.1016/j.ajog.2017.01.039] [PMID]

25. Zhu L, Lang J, Wang H, Han S, Huang J. The prevalence of and potential risk factors for female urinary incontinence in Beijing, China. Menopause. 2008; 15(3):566-9. [DOI:10.1097/gme.0b013e31816054ac] [PMID].