ESTUDO PILOTO

RADIOFREQUENCY IN THE FEMALE GENITAL LAXITY - A PILOT STUDY[a]

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Abstract

Purpose: To evaluate the effect of non-ablative radiofrequency capacitive (RF) in the treatment of sagging skin in the region of labia majora, and the influence on sexual function. Methods: The sample included 9 women with complaints of sagging skin in the labia majora, of which 7 had sexually active. The protocol consisted of 8 sessions of RF, with a temperature of 39 ° C to 41 ° C, 1x/week for up to 20 minutes. Evaluation tools, photographs taken before the first session and eight days after the last session, which were assessed by the patients themselves and by three health professionals (physiotherapist, dermatologist and gynecologist) were used. Sexual function was assessed by the FSFI questionnaire (Female Sexual Function Index). The age and BMI variables were expressed as mean and standard deviation and analyzed by Student's t test and the remaining variables were expressed as percentages and analyzed by McNemar test. Results: Regarding the clinical response of RF, all patients reported satisfaction with the treatment outcome. In assessing professionals, physiotherapists and gyecologist reported improvement in six (67%) patients and dermatologist mentioned improvement in eight (89%) of patients. With respect to sexual function, there was an increase in mean (SD) of 25.66 ± 5.7 to 27.30 ± 5.5, p = 0.38. Domains arousal and lubrication improved in 5 of 7 patients. Conclusion: RF seems to be an alternative non-invasive treatment for the treatment of skin sagging labia, however being a series of cases is necessary with a randomized evaluation of therapeutic response to long-term clinical trial.

Keywords: Pulsed Radiofrequency Treatment; Collagen; Female; Female Genitalia; Vulva.

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INTRODUCTION

In recent decades, there have been significant cultural changes regarding the role of women in the sexual behavior of humans, associated with increasing exposure of the genitals by the media. Thus, there is a search for a "perfect pussy, that makes the modern women to look for procedures that beautify the region.[1] Feminist critics are suggesting that this search for change the genital region is part of a tradition of patriarchal domination of women's bodies aiming change it to adapt to a *macho* aesthetic. However, studies have shown that women's dissatisfaction related to the appearance of their genital region may be responsible for the impact on self-esteem and performance sexual[2] Feelings of embarrassment with sexual function, such as shame about the appearance of genital and anxiety about sex, including a strong desire to improve sex, are also cited as common reasons for genital cosmetic surgeries.[3]

The anatomical and functional characteristics of the female external genitalia may interfere in the behavior of women, independent of their age and sociocultural level. When these features are out of patterns, it can cause psychological problems that influence significantly on their sexual activity and self esteem. Feelings of embarrassment with sexual function, such as shame about the appearance of genital and anxiety about sex, including a strong desire to improve sex, are also cited as common reasons for genital cosmetic surgeries.[4] According to the International Society of Plastic Surgery, in 2011, the last year assessed by the institution, Brazil is the country leader in female genital cosmetic surgery, with 9000 women operated.[5] The surgical procedure used to treat cutaneous sagging in labia majora is the labiaplasty by fill.[6] This method consists of injecting autologous fat or synthetic materials in this region, it may cause complications and the need for care in the post operative period.[6]

Currently, there is a growing interest in non-invasive interventions, aiming to rejuvenate the skin tissue with safe, in an effective way and without adverse reactions.[7] These non-surgical methods have been an attractive feature due to low risk and fast recovery.[8] The radiofrequency was initially studied in 1949 for the treatment of skin laxity with significant improvement in skin tissue appearance[8, 9] then in 1995 was used for the treatment of benign prostatic hyperplasia.[10]

Through the production of warmth to the skin layers, occurs a immediate retraction of the existing colagen and also occurs micro-remodeling over time, the radiofrequency has been employed successfully in the treatment of skin aging of the face, trunk and limbs.[8,11] There are no reports in the literature of the use of radiofrequency in the treatment of skin latixy labia.

Knowing that changes in the female external genitalia can lead to psychological problems, affecting health sexual of women, and the treatment options available are invasive methods, which have a higher risk of complications and also that there is a lack of findings in the literature as the use of radiofrequency in this region, this study aims to evaluate the response of non ablative capacitive radiofrequency in the treatment of sagging skin in the region of labia majora, and the influence on sexual function.

METHODS

This is a pilot study, a case of series, whose audience were nine women aged between 18 and 60 years and with clinical complaints of laxity in labia majora. It was done from October 2012 to January 2013. The routing was spontaneous, in wich women were invited through pamphlets and notices in gynecology and urology services, and through general communication (radio). Were excluded of the study, pregnant women, women that were in use of copper IUDs, women that presented skin lesions in the genital region.The study was conducted at the Clinical School of Bahiana School of Medicine and Public Health, at Campus of Brotas, in Salvador (Brazil-Bahia). Socio-demographic data were

collected and filled form with clinical information on previous surgeries in the genital region, use of hormones, sexual activity and obstetric history.

The treatment was composed of eight sessions of radiofrequency with an interval of seven days between them 8 weeks. The equipment of the RF used was the Tecatherap-VIP (VIP-Eletromedicina, Argentina), with bipolar method, using the handle of 2 cm and the coupling electrode which was positioned in the sacral region. For the application, the participants were positioned supine with legs in the lithotomy position, it was used hydrosoluble gel to coupling and slip of the handle on the skin. The application was performed with the electrode passing in caudal-cranial direction, with constant movement and electrode lightly pressed.

During the session, the heat level was verbally monitored and also by the infrared digital thermometer that accompanying the appliance. The intensity was gradually increased and, when the temperature reached 39-41°C values,[11] the intensity were reduced two points and the procedure was maintained for two minutes.

In all sessions photographic records for analysis of the results were performed. The photographs were taken on two occasions prior to the initial session and 15 days after completion of the sessions, and the women were in the sitting position with the legs flexed. Just one photographic machine was used (Kodak brand, 10.2 megapixels, the smart capture mode without flash), placed at a distance of 30 cm from the genital area and suspended with a tripod of 12 cm. The photographs were always taken at the same location, with the same lighting. (Figures 1 and 2)and women were always in the same position. Subjective evaluation of the photos was based on a Likert scale of three points, to evaluate the aesthetic result (appearance), with three possibilities: 1) worse, 2) unchanged, 3) improve, being established as a pattern of change tumescence and the number of wrinkles (grooves) in labia majora.

The appearance evaluation was based on the qualitative response of the patient, in addition to the opinion of a dermatologist, gynecologist and one physiotherapist. Professionals were blinded about the order of photos in relation to treatment. The satisfaction with treatment was assessed only by the patient based on the Likert scale of three points, subjectively, which ranked in the treatment: 1) unsatisfied; 2) unchanged; 3) satisfied. To assess sexual function, women with active sex life in the past four weeks answered the questionnaire FSFI (Female Sexual Function Index), translated and validated for portuguese 10. It was applied before the initial of the treatment and eight days after completion of treatment. It was considered the greater value of FSFI score as the best therapeutic response. We considered values below 26.5 for sexual dysfunction.[12]

The statistical analysis was performed using SPSS, version 14, and it was represented the numeric variables by mean and standard deviation or median and IQ. Depending of the normal distribution of the variables that was tested by the Kolmogorov test, it was used the McNemar tests to analyse the satisfaction with the treatment; and the result of treatment was evaluated using the photos, and the T test to the value of the FSFI, considering the significance of 0,05.

This study presents no conflict of interest. The project was approved by the Ethics Committee in Research of Bahia School of Medicine and Public Health at the number of CAAE: 03449212.3.0000.5544, which was approved as a randomized clinical trial which predicted a pilot study. All patients who desire and agreed to participate signed the informed consent and the study conducted in accordance with the Declaration of Helsinki as revised in 2008.

RESULTS

Clinical and socio-demographic characteristics of the 9 patients are shown in Table 1 The age ranged between 18 and 55 years, and only one patient had less than 40 years old. Being in menopause and contraceptive using were not the most frequent situations.

Table 1 - Clinical characteristics and socio-demographic

Variables	Total of patients N (%)
Age M (ffl SD)	40,7 (ffl9,7)
BMI	25,1 (ffl 3,4)
Sexual activity in the last 4 weeks	7 (78%)
Climacteric	3 (33%)
Contraceptive	2 (22%)
Surgeries	5 (56%)
Schooling	
High School	8 (89%)
Incomplete Graduation	1 (11%)
Graduated	O (O%)
Race	
White	O (O%)
Brown	3 (33%)
Black	6 (67%)

N = number of patients, M = mean, SD = standard deviation, BMI = body mass index

Analyzing the modification of the appearance of the genital area, being considered the number of folds and distension of the region, all patients reported improvement. This assessment was confirmed by the evaluation of health care professionals. The analysis of the dermatologist showed the greatest similarity to the evaluation of patients, eight of the nine evaluated reported improvement (Table 2).

Table 2 - Evaluation of genital appearance according to patients and health professionals

Opinion about the Appearance	Total of patients N (9)	(%)
Patients		
Improved	9	100
Unchanded	O	O
Worsed	O	O
Gynecologist		
Improved	6	67
Unchanded	3	33
Worsed	O	O
Physiotherapist		
Improved	6	67
Unchanded	3	33
Worsed	O	O
Dermatologist		
Improved	8	89
Unchanded	1	11
Worsed	O	O

N = number of patients

Considering patient satisfaction in relation to the proposed treatment, nine (100%) of the patients reported being satisfied with the response of the treatment (Figures 1 and 2).

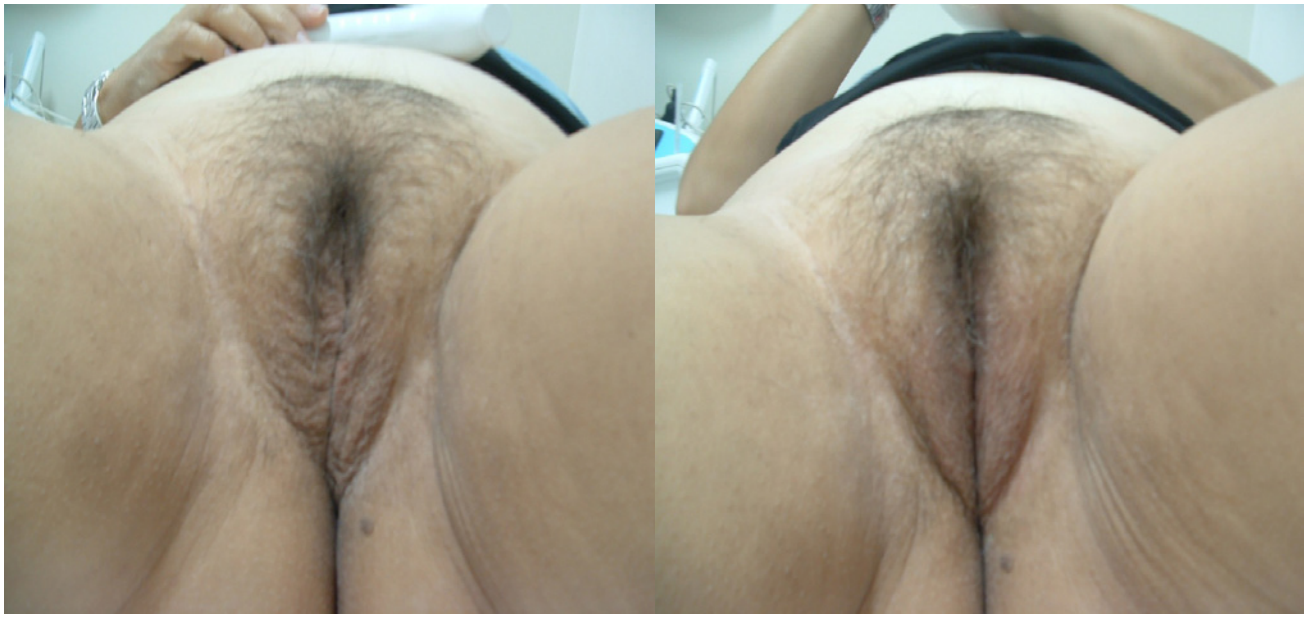

Figure 1 - Photo of the genital region of patient 1 before session RF and after 15 days of treatment RF

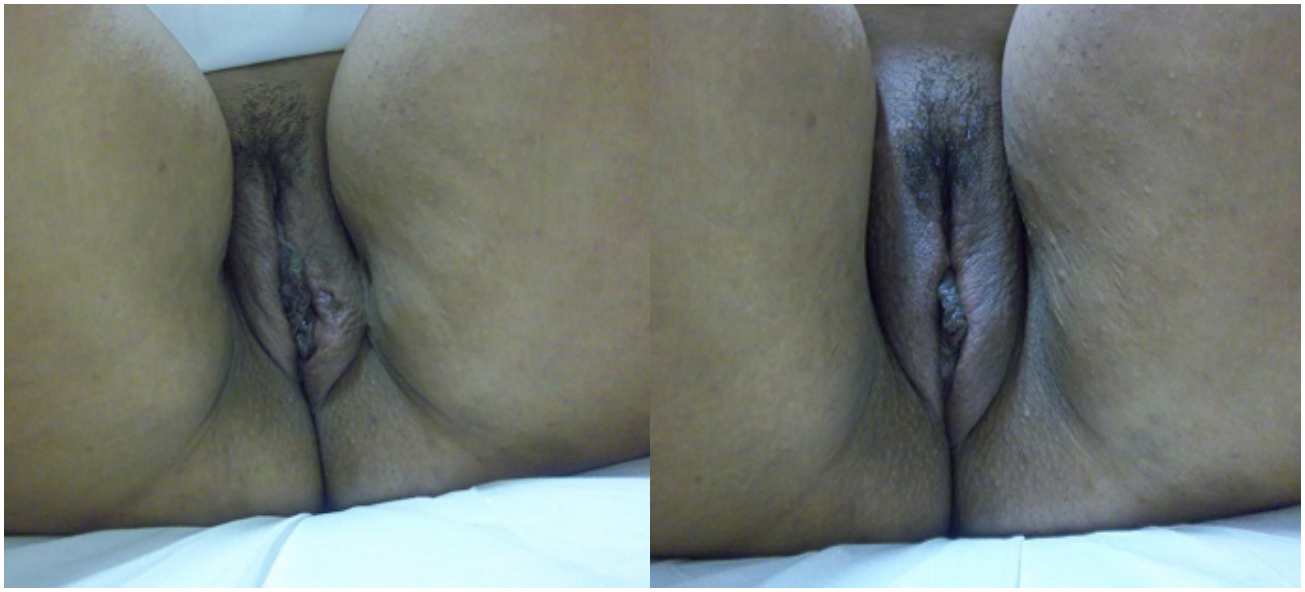

Figure 2 - Photo of the genital region of patient 2 before session RF and after 15 days of treatment RF

With respect to sexual function, there was an change in mean scores of FSFI questionnaire of 25.66 ± 5.7 to 27.30 ± 5.5, p = 0.379 (Table3). Considering the domain excitement, positive change was observed in five of the seven treated women, the same happened with lubrication (Table3). On the domain of arousal, it was observed that happened an improvement in three women and it remained unchanged in three of the seven. Four women reported sexual dysfunction before treatment, and only two remained with these dysfunctions after RF.

DISCUSSION

To our knowledgment this is the first study to assess the effects of RF in sagging skin of large genital lábia on clinical outcomes. The use of the RF to treat facial and body skin laxity also has demonstrated clinical response positive,[13,14,15,16,17,18] however, in the literature there is a lack of studies that evaluate the therapeutic response of RF in laxity tissue of the labia majora. In this study, 100% of patients reported satisfaction with the appearance of their genitalia after treatment with RF. This result can be explained by associated with decreased skin turgor folds of the labia majora. The production of new collagen and contraction of existing collagen fibers, promoted by RF, promoted a better look at the skin.[8,11,19] Furthermore, the production of elastic fibers responsible for the elasticity of the skin and reduction of sagging tissue, also contributed to a better appearance of genital labia majora.[11]

This positive change was also verified by the health professionals. The swelling of the labia majora associated with decreased skinfold thickness, determined, in the view of the evaluators, a positive response from the appearance of the genitalia. This result is due to the retraction of existing collagen, and miro-remodeling[11,13,18] over time.

Also in relation to clinical response, in the perception of raters, it appears that the dermatologist observed a better result, with 89% of responses improves, while the gynecologist and physiotherapist reported 67% improvement. A chance for a better outcome in view of the dermatologist is that this is a specialist in skin and its disorders, so he makes a careful analysis of its appearance. Already a gynecologist and physiotherapist make an inspection of the anatomy of the vulva and their disorders, the most general assessment.

Cihantimur et al (2013) in a study of women undergoing genital plastic surgeries, including 124 patients who underwent swelling of the labia majora, demonstrated by evaluation of photographs by two health professionals, an improvement of appearance in more than 95 % of women operated one year after cirurgia,[20] showing, as in the present study, the use of photographic images as a method of evaluation for aesthetic procedures in the genital region.

It is noticed that most of the work involving the RF skin, sagging verify objectively the clinical response of this feature in tissue laxity and wrinkles, through photographs for over a observador,[13,15] but there is a lack towards the genital region. Possible changes in self-esteem and sexual function can also be influenced in increased satisfaction of these women, as the average of sexual function was improved. Trichot et al (2011), reported that of 18 patients who underwent labiaplasty, 17 (94%) reported satisfaction with the appearance of their genitalia after surgery and all reported improvement in function sexual.[19] Alter (2008) in a study of women subjected to genital plastic surgery, reported that the mean degree of satisfaction of patients after surgery on a scale of 1 to 10, was 9.2 and that 93% of patients reported improved self-esteem and 71% reported improvement in sexual function.[20]

It is noticed that the participants average age of this study was 40 years, with only three women in menopause. These two variables (age and memopause) may have positively influenced the clinical response of the RF, since with aging, there is a reduction in the synthesis of collagen, with an annual loss of approximately 1% in individuals adultos.[23] Menopause also changes the appearance of skin by reducing collagen fibers, resulting in.[24]

As a series of cases, with a sample of only nine patients, that doesn't have a control group, it can be presented as limitations, but a randomized, as well as the rating of the therapeutic response to long-term clinical trial are presented as perspectives of this study, which are already being conducted by the group. Another limitation is the lack of scale for assessment of skin laxity in female genitalia, the criteria for evaluation in this research were developed by the authors of the study, based on

practical experience and in the pathophysiology of skin laxity.

During this study, while the radiofrequency was applied, women reported that happened an increase of the temperature, a sensation of warm in genital area; and they also reported that occurred an hyperemia on the same area and it lasted few days, as two or three days after the session of RF.

CONCLUSION

The RF seems to be an alternative non-invasive for treatment of laxity skin of the labia major, but as the results come from a cases series it is necessary caution on these interpretations, especially for the long-term effects. Future studies should focus on Randomized Controlled Trials with a long follow-up searching not only for benefits, but also for any possible harm.

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