Intravaginal Non-Ablative Radiofrequency In The Treatment Of Genitourinary Syndrome Of Menopausesymptoms: A Phase I Clinical Trial

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Abstract

Background: Genitourinary Syndrome of Menopause (GSM) involves vaginal dryness, dyspareunia, itching, burning, pain, and also symptoms in urinary organs. Nonablative radiofrequency (RF) is a type of current with electromagnetic waves with the thermal effect that generates an acute inflammatory process with consequent neocolagenesis and neoe lastogenesis. We aimed to describe the clinical response, cytological changes, and adverse effects of applying nonablative RF in patients with GSM and to assess sexual and urinary function after treatment.

Methods: This is a pilot study with 11 women diagnosed with GSM with established menopause. Patients with hormone replacement initiation less than six months, who used a pacemaker or had metals in the pelvic region, were excluded. Subjective measures (Visual Numerical Scale-VNS of symptoms, Vaginal Health Index-VHI) and objective measures (Vaginal Maturation Index-VMI and vaginal pH) were used. Sexual function was assessed by the FSFI, and the ICIQ-SF measured the impact on urinary function. A Likert scale measured the degree of satisfaction with the treatment. Five sessions of monopolar nonablative RF (41 °C) were performed with an interval of one week between each application. The entire evaluation was performed before treatment (T0), one month (T1), and three months (T2) after treatment. Adverse effects were assessed weekly.

Results: There was a reduction in symptoms after treatment in most patients (T1/T2, respectively): vaginal dryness 90.9%/81.8%, dyspareunia 83.3%/66.7, vaginal laxity 100%/100%, pruritus 100%/100%, burning 75%/87.5%, pain 75%/75%, and in VHI 90.9%/81.9. Most patients did not show changes in VMI (54.5%) and pH (63.6%) at T1, but there was an improvement in VMI in most patients (54.5%) at T2. Nine patients were satisfied and two were very satisfied at T1. The treatment was well tolerated and no adverse effects were observed. There was an improvement in sexual function in 72.7% and in urinary function in 66.7% in T1 and 83.3% in T2.

Conclusion: Intravaginal RF reduced the clinical signs and symptoms of GSM and women reported satisfaction with treatment. The technique showed no adverse effects and there were positive effects on sexual and urinary function.

Trial registration: This research was registered at clinicaltrial.gov (NCT03506594) and complete registration date (first date posted) April 24, 2018.

Background

Genitourinary Syndrome of Menopause (GSM) is defined as a set of signs and symptoms, involving physical and sensory changes in the external, internal genitalia and lower urinary tract region, such as loss of collagen and elastin, altered smooth muscle cell function, reduction in the number of blood vessels and an increase in connective tissue, leading to thinning of the epithelium, decreased blood flow and reduced elasticity. Women may have some or all of the signs and symptoms. The most common symptoms are dryness, dyspareunia, and urinary incontinence. It is estimated that 10–45% of these women live with some discomfort due to GSM, however, only 25% seek treatment.

The GSM treatment aims to alleviate symptoms and reverse atrophic anatomical changes. Hormonal therapy is the current gold standard treatment, which can be administered systemically or locally. Hormonal therapy also has contraindications such as a history of breast cancer, coronary artery disease, previous venous thromboembolic event or stroke, and also adverse effects, such as vaginal bleeding, endometrial hyperplasia, breast, and perineal pain, limiting its use.

Radiofrequency (RF) is a new alternative technique for GSM. It is a high-frequency current used for therapeutic purposes, based on the mechanism of heat production by conversion, that is, ionic and molecular mobilization, including from deeper tissues, favoring oxygenation, nutrition, and vasodilation of tissues. The heating of the tissues also promotes a denaturation of the collagen with a subsequent contraction of its fibers, retraction of the fibrous septa, and activation of fibroblasts. Neocolagenization and reorganization of collagen fibers may occur and subsequent tissue remodeling.

With the contraindications and limitations of standard therapy for the treatment of GSM, there is a need for the search for new therapeutic options for the management of the symptoms of the syndrome. Based on the knowledge of the physiological responses of the tissues submitted to RF, we hypothesize that menopausal women who have genitourinary changes related to GSM may benefit from this new, minimally invasive resource. Thus, intravaginal nonablative radiofrequency with controlled temperature was used for the treatment of genitourinary signs and symptoms related to GSM. This research aimed to describe the clinical response, cytological changes, and adverse effects of applying nonablative radiofrequency in patients with Genitourinary Syndrome of Menopause. Secondly, to assess sexual and urinary function after treatment.

Materials And Methods

Study design

This is a pilot study - phase 1 of a clinical trial, followed the precepts of the Declaration of Helsinki, with the approval of the ethics and research committee of the Bahiana School of Medicine and Health (EBMSP) with CAAE 72147317.9.0000.5544 and registered with clinicaltrial.gov (NCT03506594) and complete registration date (first date posted) April 24, 2018.

All patients signed an informed consent form.

Adult women with established menopause (at least 12 months after their last period and/or bilateral oophorectomy) and who had complaints of at least one of the symptoms of GSM (dryness, pain during sexual activity, vaginal laxity, itching, burning sensation, and pain in the vaginal opening). The women were referred by gynecology services and the service took place at the teaching outpatient clinic of the Physiotherapy Clinic at EBMSP. For inclusion in the study, they should have a vaginal pH of ≥5 and a negative preventive measure for malignancy and/or atypia in the last twelve months or three previous...
exams, all negative. We excluded patients with hormone replacement initiation less than six months, who used a pacemaker or had metals in the pelvic region, hemophiliacs, using vasodilators and/or anticoagulants, and those with chronic neurological degenerative diseases and/or diagnosis of current vaginal infection.

Assessment procedures

Initially, we applied a basic anamnesis questionnaire for collecting sociodemographic and clinical data. Each participant subjectively assessed their symptoms (dryness, pain during sexual activity, vaginal laxity, itching, burning sensation, and pain in the vaginal introitus) using the Numeric Rating Scale (NRS), which consists of a scale from 0 to 10 points, in which 0 means no symptoms and 10 means as many symptoms as possible.

The physical examination was to assess the Vaginal Health Index (VHI), which consists of a graduated scale from 1 to 5 for each item (vaginal elasticity, fluid volume, pH, epithelium integrity, and humidity). The sum of all items represents the vaginal health score, with 25 being the best vaginal health. The quantification of pH using a pH indicator strip between 0 and 14 (MColorPHast - pH-indicator strips) was placed directly on the right lateral vaginal wall for one minute.

The Vaginal Maturation Index (VMI) performed percentage counting of deep, intermediate, and superficial cells, in a slide of material collected from the middle third of the vagina, obtaining the VMI.

Participants answered the Female Sexual Function Index (FSFI) questionnaire to objectively assess sexual function, gathering responses in six different domains: desire, arousal, lubrication, orgasm, satisfaction, and discomfort/pain. The cutoff point $\leq 26.5$ was considered for sexual dysfunction, the increase in the score was considered an improvement. The Sexual Quotient - Female Version (QS-F) assessed women's sexual activity. This questionnaire was developed and validated in 2006, specifically for the Brazilian population. Through ten self-answering questions, the QS-F assesses all phases of the sexual response cycle with a total index ranging from 0 to 100. Higher values indicate better sexual performance/satisfaction.

To assess the impact of urinary incontinence (UI) on quality of life and characterize urinary loss, we used the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), composed of five questions that assess the frequency, severity, and impact of UI, in addition to a set of eight items of self-diagnosis, related to UI situations experienced by patients. The maximum sum of the response values indicates a score of 21 points, referring to a high impact of UI on the individual's life.

At the end of the treatment, the participant was asked about her degree of satisfaction with the treatment using a five-point Likert scale, which classified the patient's level of satisfaction as 1 - very dissatisfied; 2 - dissatisfied; 3 - unchanged; 4 - satisfied; 5 - very satisfied. To assess the clinical response, we considered as an improvement when there was the decrease in values in self-reported symptoms, verified by the numeric rating scale (NRS); the increase in the value of the Vaginal Health Index; the decrease in parabasal cells (deep) and/or increase in superficial cells evaluated by VMI; the decrease in vaginal pH; the increase in FSFI and QS-F scores; the decrease in the sum of the ICIQ-SF questions; and improved satisfaction according to the five-point Likert scale.

We used all outcome measures before, one month, and three months after the end of treatment, respectively, times T0, T1, and T2, being done by the same initial evaluators.

To test safety, we considered exist adverse effects if they had erythema, ulcers, fistulas, burns, blisters, bleeding, and/or pain. They were evaluated during the application or by the patients' self-report. We considered it high risk if it had 4 or more effects.

Therapeutic procedure

Radiofrequency (RF) was used in the form of capacitive electrical transfer, monopolar configuration (Capenergy® device, model C500), which has two electrodes: an intracavitary active, placed in the vagina with a non-lubricated condom and water-soluble gel and another electrode, dispersive, positioned in the lumbosacral region (Fig. 1). For the application, the participants were placed in the supine position and abducted lower limbs, with bent knees. The temperature was set at 41°C, with a frequency of 1MHz and power of 75kJ. When the established temperature was reached, we maintained it for 2 minutes with semicircular movements on the anterior wall of the vagina and the movement and time on the posterior vaginal wall was repeated, totaling 4 minutes of an application after reaching the established temperature (Fig. 2). Each patient underwent five RF sessions, with an interval of seven days between them.

Data analysis

For the elaboration of the database, we used the software Statistical Package for Social Sciences (SPSS), version 14.0 for Windows. The results were reported descriptively in the text or through tables and graphs; categorical variables expressed in absolute and percentage values - n (%) and continuous variables with normal distribution in mean and standard deviation (± SD), and those with asymmetric distribution, in the median and interquartile range (IQ).

Results

Sociodemographic and clinical characteristics

The sample consisted of 11 patients with Genitourinary Syndrome of Menopause, with an average age of 59.6 (± 3.93) years old, with data collected from October 2017 to August 2018. Table 1 represents the sociodemographic and clinical characteristics of the population studied. The main characteristic was vaginal dryness as they all had this symptom. Menopause duration ranged from two to seventeen years, with a median of 14 (6–15).
Table 1
Sociodemographic and clinical characteristics of 11 patients with GSM.

| Sociodemographic characteristics                  | Mean ± SD | n (%)         |
|---------------------------------------------------|-----------|---------------|
| **Age**                                           | 59.6 ± 3.93 |               |
| **Education level**                               |           |               |
| Complete higher education                         | 5 (45.5)  |               |
| Complete high school                              | 4 (36.4)  |               |
| Complete Elementary school                        | 1 (9.10)  |               |
| Illiterate                                        | 1 (9.10)  |               |
| **Marital status**                                |           |               |
| Married                                           | 4 (36.4)  |               |
| Divorced/separated                                | 3 (27.3)  |               |
| Single                                            | 2 (18.2)  |               |
| Widow                                             | 2 (18.2)  |               |
| **Self-reported skin color**                      |           |               |
| Brown                                             | 7 (63.6)  |               |
| Black                                             | 2 (18.2)  |               |
| White                                             | 2 (18.2)  |               |
| **Clinical characteristics**                      |           |               |
| **n (%)**                                         |           |               |
| **Body mass index**                               |           |               |
| Low weight                                        | 1 (9.10)  |               |
| Normal                                            | 3 (27.3)  |               |
| Overweight                                        | 6 (54.5)  |               |
| Obesity                                           | 1 (9.10)  |               |
| **Hormone replacement**                           | 5 (45.5)  |               |
| **Gynecological surgeries**                       | 9 (81.8)  |               |
| **Constipation**                                  | 4 (36.4)  |               |
| **Number of deliveries**                          |           |               |
| Nulliparous                                       | 1 (9.10)  |               |
| Primiparous                                       | 1 (9.10)  |               |
| Multiparous                                       | 9 (81.8)  |               |
| **Type of delivery**                              |           |               |
| Vaginal                                           | 5 (45.5)  |               |
| Cesarean                                          | 5 (45.5)  |               |
| **Symptoms of GSM**                               |           |               |
| Vaginal dryness                                   | 11 (100)  |               |
| Pain during sexual activity                       | 6 (54.5)  |               |
| Vaginal laxity                                    | 6 (54.5)  |               |
| Vaginal itching                                   | 6 (54.5)  |               |
| Vaginal burning                                   | 8 (72.7)  |               |
### Sociodemographic characteristics

| Symptom               | Value |
|-----------------------|-------|
| Vaginal pain          | 4 (36.4) |
| Urinary incontinence  | 6 (54.5) |
| Sexual activity       | No 6 (54.5) |
| Sexual dysfunction    | 8 (72.7) |
| Vaginal staining      | Whitish 6 (54.5) |
|                       | Normal 5 (45.5) |

### Symptoms of Genitourinary Syndrome of Menopause

We observed the clinical improvement of GSM in the values of the visual numeric scale scales (VNS) of the symptoms Vaginal dryness (VD), Pain during sexual activity (SAPain), Vaginal laxity (VL), Vaginal itching/pruritus (VI), Burning (B) and Vaginal pain expressed in Table 2, especially in the first month after treatment.

#### Table 2

- Numerical Rating Scale of the symptoms of Genitourinary Syndrome of Menopause before treatment, 1 month and 3 months after 05 radiofrequency sessions.

| Patient | PRE-TREATMENT | 1 MONTH | 3 MONTHS |
|---------|---------------|---------|----------|
|         | VD | SAPain | VL | B | Pain | VD | SAPain | VL | B | Pain | VD | SAPain | VL | B | Pain |
| 1       | 10 | 10     | 0  | 5 | 10  | 0  | 3  | 5  | 0  | 0  | 0  | 7  | 7  | 0  | 5  | 6  | 7  |
| 2       | 9  | 8      | 0  | 0 | 0   | 0  | 3  | 0  | 0  | 3  | 0  | 6  | 0  | 0  | 4  | 0  | 0  |
| 3       | 10 | 0      | 9  | 10| 7   | 0  | 6  | 9  | 10 | 6  | 5  | 0  | 2  | 9  | 10 | 2  |
| 4       | 5  | 0      | 10 | 7 | 5   | 0  | 8  | 0  | 0  | 0  | 0  | 7  | 0  | 2  | 0  |    |
| 5       | 8  | 2      | 5  | 0 | 0   | 2  | 4  | 0  | 1  | 0  | 1  | 8  | 1  | 4  | 0  | 0  |
| 6       | 7  | 7      | 0  | 0 | 0   | 0  | 1  | 1  | 0  | 0  | 0  | 1  | 0  | 0  | 0  | 1  |
| 7       | 10 | 0      | 3  | 2 | 4   | 0  | 2  | 0  | 0  | 0  | 1  | 1  | 0  | 0  | 0  | 0  |
| 8       | 10 | 0      | 2  | 0 | 4   | 0  | 1  | 0  | 0  | 0  | 2  | 0  | 1  | 8  | 0  | 2  | 0  |
| 9       | 7  | 7      | 0  | 6 | 5   | 7  | 7  | 7  | 2  | 5  | 5  | 7  | 7  | 3  | 4  | 4  | 7  |
| 10      | 9  | 8      | 5  | 5 | 8   | 8  | 1  | 0  | 0  | 0  | 0  | 1  | 0  | 0  | 0  | 0  | 0  |
| 11      | 10 | 0      | 9  | 0 | 5   | 0  | 2  | 0  | 4  | 0  | 1  | 0  | 1  | 0  | 1  | 0  | 0  |

VD = Vaginal dryness; SAPain = Pain during sexual activity; VL = Vaginal laxity; VI = Vaginal itching; B = Burning

### Vaginal Health Index (VHI)

Ten patients (90.9%) increased the VHI score in the first month, which represents an improvement, and one worsened (patient five). Regarding pre-treatment, in the third month, nine patients (81.8%) had an increase in VHI, while two (18.2%) had a reduction in this index during the initial value (Table 3).
Using non-drug and non-ablative treatment with intracavitary monopolar RF.

This is the first study to assess genitourinary symptoms and sexual function of the GSM associated with cytological analysis, and patient satisfaction after application of RF was considered safe because only one adverse effect in one patient was found up to three months after treatment. To our knowledge, this is the first study to assess genitourinary symptoms and sexual function of the GSM associated with cytological analysis, and patient satisfaction after using non-drug and non-ablative treatment with intracavitary monopolar RF.

Discussion

We found an improvement in genitourinary signs and symptoms in this pilot study that used non-ablative RF in postmenopausal women with GSM. The application of RF was considered safe because only one adverse effect in one patient was found up to three months after treatment. To our knowledge, this is the first study to assess genitourinary symptoms and sexual function of the GSM associated with cytological analysis, and patient satisfaction after using non-drug and non-ablative treatment with intracavitary monopolar RF.
Vaginal dryness was the main symptom reported by patients in this study and showed an important improvement when assessed both by self-report and by VHI. Based on the histological changes evidenced in previous studies, the process of neocolagenesis and neoelastogenesis that occurs after the exposure of controlled RF thermal energy in the vaginal tissue restores most vaginal functions such as secretion, absorption, elasticity, lubrication, and tissue consistency, which are decreased in GSM. This hypothesis is supported by previous knowledge that this high-frequency current induces collisions and movements between atoms and molecules, resulting in energy transfer to the tissue in the form of heat and a consequent controlled increase in temperature, promoting an increase in the arterial circulation, and vasodilation, improving tissue oxygenation.

VD can generate or contribute to SAPain just as abstinence from intimate relationships is involved in the decline of lubrication, often forming a cycle. Vaginal trophism is fundamental for a comfortable sexual relationship, which depends on the lubrication promoted by vasodilation of the lamina propria and the vaginal epithelium. We observed in this study that a patient who did not have dyspareunia in the pre-treatment started to report this symptom in the third month. An assumption is that the increase in the frequency of sexual activity may favor the appearance of this symptom. To confirm this hypothesis, we must include the investigation of sexual frequency before and after treatment. We are developing a randomized clinical trial where this variable has been included and, therefore, soon we may have this information. The increase in sensory perception by neurogenesis can occur after using RF, which can lead to a greater perception of the vagina and, therefore, some patients may start to report these symptoms. However, further morphometric investigations for neuronal analysis are necessary.

Other studies have also found positive results in dyspareunia. Alinsod (2015) studied RF with controlled temperature (TTCRF) with intra and extra vaginal application in six menopausal women and 10 in the peri-menopausal period with dyspareunia symptoms, demonstrating the safety and beneficial effects of the treatment. A randomized clinical trial with 20 postmenopausal women applied three sessions of intra and extra vaginal TTCRF (ThermiVa) once a month with reduced RV and dyspareunia (21). RF has also been widely used to improve collagen levels. Its diathermic effects cause the denaturation of collagen. As the temperature rises, some of the cross-links are broken, causing the structure of the triple helix to unwind. Thus, there is a consequent activation of fibroblasts, with subsequent neocolagenesis, neoeelastogenesis, and tissue remodeling. Coad et al. (2013) evaluated the histological effect of non-ablative RF on the vaginal introitus of sheep before, after seven, thirty, and ninety days. There was a significant increase in the activation of the submucosa fibroblasts and an increase in collagen when to the control group. In our study, we used NRS to grade vaginal laxity and all patients improved this complaint. Three patients who did not have the complaint initially, reported mild intensity in the reassessments, which can also be justified by the increase in sensory perception after treatment. Assessing the symptoms of GSM is challenging, due to its subjective nature. The development of a specific score with a cut-off point for the quantification of these symptoms and clinical improvement may be of great relevance to better evaluate these patients and verify the treatment effect.

Previous studies have obtained positive results with the use of monopolar RF with cryogenic surface cooling in pre-menopausal women with a history of at least one vaginal delivery and complaints of vulvovaginal atrophy/symptoms of GSM or vaginal laxity. Alinsod (2015) used the TTCRF in 23 pre-menopausal women with VL, with improvement on a seven-point scale, called the vaginal laxity questionnaire (VLQ). Krychman et al. (2017) carried out a multicenter study with 189 premenopausal women complaining of VL during sexual intercourse with significant improvements in self-report and sexual function by FSFI.

Symptoms such as itching, burning, and pain are also common complaints in GSM. Hypoestrogenia is a reduced number of epithelial layers and vessels, thinning of smooth muscles and an increase in nociceptive sensory afferents, leading to these symptoms. Also, the increase in tissue friction caused by the decrease in trophism and hydration causes greater mucosal fragility, contributing even more to the condition. In this study, there was an important improvement in these symptoms. This clinical improvement can be supported by the thermal effect of RF, which deeply affects the tissue layers. As a consequence of local peripheral vasodilation and increased blood flow, there is an improvement in trophism, oxygenation, cellular metabolism, and lubrication. High-frequency thermal therapy seems to act through the effects of analgesia, but the mechanisms by which RF controls pain are still unclear, seeming to involve the transduction of C fiber signals.

The analysis of vaginal cytology through the Vaginal Maturation Index (VMI) and the measurement of pH are well-used measures to establish diagnostic parameters of GSM but have not yet been analyzed in RF research in GSM. Brizzolara et al. (1999) carried out a study in 70 postmenopausal women determining a specific vaginal pH range that correlates with high levels of parabasal cells in the VMI, defined as at least 20%, and found a correlation between these two objective measures. We also found in this study that pH values ≥ 6.0 were compatible with a greater number of parabasal cells (≥ 20%). On the other hand, these results showed that there is no pattern of clinical/objective findings with the symptoms reported by the patients. VMI and pH, unlike NRS, remained similar in most patients (six – 54.6% and seven – 63.3%, respectively) in the first month after treatment. In the third month after treatment, most patients (six – 54.6%) had an improvement in VMI and four (36.4%) had an improvement in pH. Vaginal cytology, in part, has been inconsistent with clinical findings. A smaller-scale and more sensitive tape is recommended to detect minor variations.

GSM can have adverse effects on sexual function and general well-being. FSFI is an instrument used worldwide to assess sexual function. In this study, it had improved in most of the sample (81.8%) in the first month and the third month (72.7%). We also evaluated the patients in our study with the QS-F. It is a questionnaire specifically developed for the Brazilian population. Using the non-ablative RF technique, Lordelo et al. (2016) carried out a randomized
clinical trial with 43 women dissatisfied with the appearance of their genitalia. They applied RF to the external genitalia, with an improvement in sexual function by 3.51 points in the group treated in the evaluation by FSFI (11).

RF has been considered one of the most innovative non-surgical modalities to treat urinary incontinence (UI) and VL (36). In addition to modifying the trophism of the vaginal canal, it also targets the urethral mucosa and seems to improve not only the symptoms of GSM but also those of UI. In our study, 66.7% and 83.8% improved urinary symptoms, one and three months after treatment, respectively. Lalji & Lozanova (2017) in a pilot study carried out three treatment sessions with monopolar RF, intra, and extra cavitary, in 27 women with stress urinary incontinence (SUI). They found that 96.3% decreased the frequency of urinary loss by at least one level, 59.3% reported a decrease in the amount of loss (37). Another study with 10 patients with SUI showed improvement in the pad test one month after treatment with monopolar non-ablative RF in the urethral meatus (38). Despite different outcome measures and application forms, radiofrequency therapy appears to be a good alternative for the treatment of SUI. Histological studies have observed a reduction in collagen in the walls of the urethra in the event of loss of urethral support and/or internal sphincter dysfunction (39), which supports the use of RF in this dysfunction.

Treatment satisfaction was assessed in this study by the five-point Likert Scale, with most patients reporting satisfaction with treatment. This was reinforced by the decrease in the symptoms recorded in that research. On the other hand, we observed that, although most of the outcome measures have improved, the indication of patient satisfaction was greater, showing that the degrees of satisfaction do not always correspond to the results. Thus, satisfaction is not only linked to the therapeutic result but possibly also to the level of expectations of the people involved. It is important to consider the Hawthorne effect, which says that when individuals believe they are experiencing a form of treatment, they are more likely to respond and be satisfied with therapeutic responses (40). In this sense, we also justified to carry out a randomized clinical trial to better assess this issue.

Although part of the patients continued to show improvement in their symptoms in the third month, some symptoms were accentuated in that period. Studying the frequency of reapplication after the end of treatment to maintain clinical improvement is essential in future studies.

**Conclusions**

The treatment of the symptoms of GSM with non-ablative radiofrequency showed clinical improvement in the patients, with improvement in the self-report of the symptoms and the vaginal health index at one and three months after treatment. The cytological analysis, through the Vaginal Maturation Index, remained unchanged in most evaluations in the first month, but there was a greater improvement in the third month after treatment. There was no change in vaginal pH in most patients after radiofrequency treatment. There was no adverse effect on the eleven patients evaluated, considered a safe and well-tolerated technique. Radiofrequency had also a positive effect on sexual function and urinary function in most patients and patients reported satisfaction with treatment.

This research is a pioneer in the study of radiofrequency in women with Genitourinary Syndrome of Menopause, especially to make a comprehensive assessment of the symptoms of GSM, vaginal pH, cytology and sexual function. As it is a local non-medicated resource, it opens up a new field for the treatment of this syndrome, in addition to being a new field for Physiotherapy professionals.

**List Of Abbreviations**

B – Burning  
EBMSP – Bahiana School of Medicine and Health  
FSFI – Female Sexual Function Index  
GSM – Genitourinary Syndrome of Menopause  
ICIQ-SF – International Consultation on Incontinence Questionnaire - Short Form  
IQ – Interquartil range  
NRS – Numeric Rating Scale  
QS-F – Sexual Quotient - Female Version  
RF – Radiofrequency  
SAPain – Pain during sexual activity  
SD – Standard Deviation  
SUI – Stress Urinary Incontinence  
TTCRF – Radiofrequency with controlled temperature  
UI – Urinary incontinence
VNS – Visual Numerical Scale
VD – Vaginal dryness
VHI – Vaginal Health Index
VI – Vaginal Itchy/pruritus
VL – Vaginal laxity
VLQ – Vaginal Laxity Questionnaire
VMI – Vaginal Maturation Index

Declarations

Ethics approval and consent to participate
All patients signed an informed consent form and followed the precepts of the Declaration of Helsinki, with the approval of the ethics and research committee of the Bahiana School of Medicine and Health (EBMSP) with CAAE 72147317.9.0000.5544 and registered with clinicaltrial.gov (NCT03506594).

Consent for publication
The consent for publication was obtained from all participants, as well as consent to use the image.

Availability of data and materials
The data is available if requested the corresponding author.

Competing interests
All authors declare that there is no competition from financial and / or non-financial interests in relation to the work described.

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Authors’ contributions
C.P. and P.L. developed the project concept and wrote the main manuscript text, R.A, R.C., R.B. and T.A, collected data and A.T. and A.Q. prepared figures 1-3 and tables. All authors reviewed the manuscript.

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