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ORIGINAL ARTICLE

Microablative radiofrequency versus pelvic floor muscle training for stress urinary incontinence: a randomized controlled trial

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Abstract

Introduction and hypothesis The efficacy of radiofrequency (RF) in stress urinary incontinence (SUI) is as yet unknown. The aim was to compare the effect of fractional microablative RF and pelvic floor muscle training (PFMT) against the combination of both therapies (RF + PFMT) in the SUI and on genitourinary syndrome (GSM).

Methods This was a three-arm randomized clinical trial including 117 climacteric women with SUI. In group 1 the treatment consisted of three monthly sessions of RF; in group 2 it was 12 weekly PFMT sessions; in group 3 it was RF + PFMT simultaneously. Assessments at baseline and 30 days after the end of therapy were conducted using validated questionnaires and scales for urinary, vaginal, and sexual functions and cytology for vaginal trophy.

Results Urinary scores improved significantly in all three groups post-treatment ($p < 0.001$) with a higher improvement in the RF + PFMT group ($p = 0.002$). One-hour pad test results were equal in the three groups. Vaginal symptoms showed an incremental improvement in RF ($p < 0.007$), and vaginal laxity showed a similar improvement in the three groups ($p = 0.323$). Vaginal Health Index score was more significant in RF and RF + PFMT groups. Sexual function improved in RF and PFMT.

Conclusions The association between RF and PFMT showed significant improvement in the SUI symptoms assessed by questionnaire. The vaginal symptoms and dryness showed greater improvement in the RF treatment and vaginal laxity showed similar improvement in the three groups. The combination of RF and PFMT in sexual function did not show benefits superior to those achieved by the therapies alone.

Keywords Female sexual function · Genitourinary syndrome of menopause · Radiofrequency · Urinary incontinence · Vulvovaginal atrophy

Introduction

The etiology of stress urinary incontinence (SUI) is multifactorial; however, aging and hypoestrogenism are the leading factors frequently associated with urogenital symptoms [1]. The first-line treatment for SUI is pelvic floor muscle training (PFMT) [2], which yields improvement rates between 56 and 70% [3]. Despite its low cost and ease of access, PFMT is associated with reduced rates of patient adherence [3, 4]. Currently, patients who continue to decline or show insufficient improvement following PFMT have no options other than surgery as an FDA-approved treatment line [5].

Radiofrequency (RF) and lasers are energy-based technologies currently being studied as potential alternative treatments for genitourinary syndrome (GSM) [6]. In contrast to lasers, which transmit energy through light, RF works through radiofrequency waves in Hertz (Hz). This energy is transformed into kinetic energy of the intracellular atoms, which

Trial registration: registered in REBEC (Registro Brasileiro de Ensaios Clínicos; Brazilian Registry of Clinical Trials) under number RBR-9v3q33.
http://www.ensaiosclinicos.gov.br/rg/RBR-9v3q33/. This study was approved by the Institutional Review Board under the number CAAE 97464918.4.0000.5405

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move and collide, generating thermal energy [5]. RF thereby increases the proportion of smooth muscle and connective tissue as a result of neocollagenesis. In addition, the thermal energy applied to the vaginal wall stimulates proliferation of the epithelium, neovascularization, collagen formation in the lamina propria, and improves natural lubrication [6, 7]. RF can be ablative, microablative, or non-ablative, depending on the action of the electromagnetic wave under the tissue. RF is ablative when the heat is capable of generating ablation and/or necrosis of the epidermis and dermis; microablative when energy fractionation produces microscopic columns of ablative thermal lesions in the epidermis and upper dermis, resulting in microscopic columns of treated tissue interspersed with areas of untreated skin [8]; and non-ablative when there is trauma only to the dermis by heating without causing ablation of the epidermis [9].

Previous studies with RF have shown benefits in urinary symptoms as secondary outcomes, such as improvement of SUI [7, 10]. One of the theories in favor of energy devices as a treatment for SUI is the strengthening of suburethral and pubocervical support, thereby decreasing urethral mobility [11]. However, no studies have assessed SUI and fractional microablative RF treatment in comparison with the first-line treatment (PFMT). Furthermore, no studies have assessed SUI symptoms following the combination of RF and PFMT treatments. Therefore, the aim of our study was to compare the effectiveness of RF, both alone and associated with PFMT, as well as PFMT therapy alone, in treating the symptoms among participants with SUI.

Materials and methods

Study design

We conducted an open-label, parallel-group, 1:1:1, randomized clinical trial among climacteric women with SUI symptoms. The study was registered in REBEC (Brazilian Registry of Clinical Trials) under No. RBR-9v3q33.

Participants

We invited women with symptoms of SUI at Women's Hospital, University of Campinas, Brazil, to participate. The inclusion criteria encompassed: women aged between 45 and 65 years, with complaints of SUI or mixed UI with stress predominance according to the International Continence Society criteria [12]. The exclusion criteria were: presence of stage III and IV genital prolapse based on Pelvic Organ Prolapse Quantification (POP-Q) [13], antecedent of previous prolapse or urinary incontinence surgery, PFMT in the last 12 months, use of vaginal estrogen in the last 6 months, systemic hormone therapy in the last 6 months, absence of pelvic floor contraction according to the Oxford Modified Scale, use of a pacemaker, decompensated heart or metabolic diseases, cognitive deficit, peripheral or central neurological disorders, presence of cancer or cervical dysplasia, and presence of an active urinary tract infection.

Study setting

The study was conducted at the Department of Obstetrics and Gynecology, Faculty of Medical Sciences, University of Campinas, Campinas, SP, Brazil, from August 2019 to May 2020. The Institutional Review Board of the university approved the study protocol (CAAE 97464918.4.0000.5405). Participants signed an informed consent form before being admitted to the study.

Procedures

Participants were allocated to one of three intervention groups (1:1:1): fractional microablative RF therapy, PFMT therapy, and both RF and PFMT therapies simultaneously (RF + PFMT). The RF treatment was performed using a microablative RF device (Wavetronic 6000 Touch Device, Megapulse HF FRAXX system, Loktal Medical Electronics, São Paulo, Brazil) monthly for 3 months. This device contains a matrix electrode with multiple micro-points. The FRAXX system releases an energy discharge managed by software that produces an ideal thermal effect by equalizing the power, controlling application time in milliseconds and analyzing the resistance that each type of fabric offers the passage of energy, called skin impedance control (SIC). It also provides random distribution control (Smart Shot), which does not allow neighboring points to heat up simultaneously, thereby inhibiting the lateral thermal effect and protecting the tissue adjacent to the micro-points. The discharge of microablative fractional electromagnetic energy causes cell evaporation and consequent protein denaturation of the tissue cells at the touched points with high precision, forming columns of dehydrated tissue, separated by slightly more than 1 mm, 200 μm in diameter, and nearly 1 mm in depth. Such precision ensures that the adjacent tissue around these dehydrated columns does not suffer a thermal effect, remaining intact and vital. The device was set at 45 W and 4 MHz to deliver the RF energy to 64 microneedles 0.2 mm in length allocated in an 8 × 8 mm area (Fig. 1). In the area where the needle penetrates and delivers the shot of energy, an ablative action occurs; however, around it there is healthy tissue—thereby defining this equipment as a fractional microablative device. Previously, the site of application was prepared with 3% lidocaine cream in vaginal hiatus, introduction of a disposable speculum, 10% lidocaine spray in the vaginal wall, vaginal cleaning with 1% aqueous chlorhexidine and 0.9% saline solution, and drying with gauze. The RF was applied under

Fig. 1 Wavetronic 6000 Touch Device, Megapulse HF FRAXXX system, Loktal Medical Electronics, and its vaginal scope

direct view along the entire vaginal wall, and a second pass was applied at the urethral meatus and anterior wall. In the first session, each RF shot was performed during 45 ms (low-mode device); during subsequent sessions each shot took 60 ms (medium-mode device; Fig. 2). The procedures were executed by a single physician.

The PFMT consisted of 12 weekly sessions. It was executed in groups and accompanied by a single experienced UI physiotherapist. Each session lasted 60 min and consisted of performing exercises to activate the pelvic floor muscles in isolation and in association with the pelvic girdle muscles. The protocol of the exercises was designed and the sequences were as follows.

Lying on the mat in supine position: three repetitions of holding the pelvic floor muscle for 10 s with the knees bent and feet flat; eight repetitions of anterior pelvic tilt with pelvic floor contraction, holding for 3 s; eight repetitions of the bridge exercises associated with pelvic floor muscle contraction for 3 s; eight repetitions of pelvic floor muscle contraction for 3 s with legs extended on the floor with external rotation from the hip; eight repetitions of pelvic floor muscle contraction for 3 s with legs in butterfly position; in lying position with knees bent and feet flat, six to ten contractions of 6 to 10 s, sustained contractions of pelvic floor muscles, 6 to 10 s of relaxing, and three pre-contractions associated with coughing (the Knack) at the end of the series.

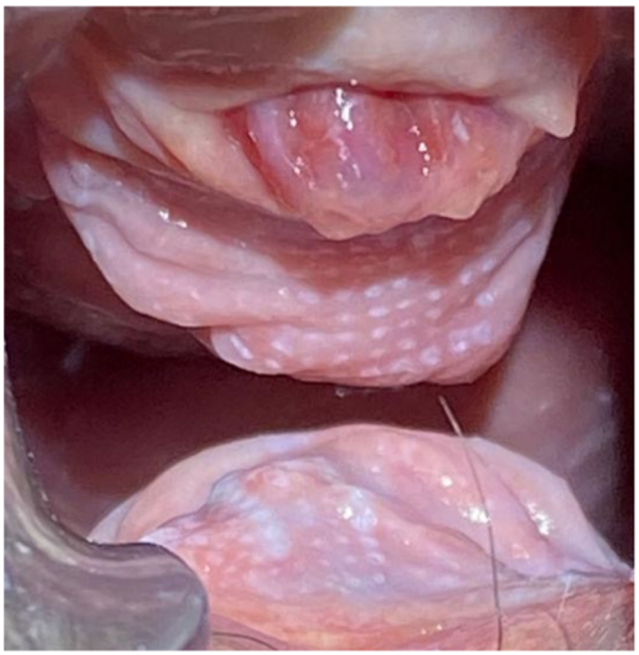

Fig. 2 Vaginal mucosa immediately after fractional microablative radiofrequency

Lying on the mat in prone position (soldier position): perform the PFMT protocol; eight repetitions of cat yoga pose exercises; three sets of 30-s "Dead Bug" core exercises; eight repetition of the pelvic floor elevator lifting the pelvic floor muscles up to three levels in a sitting position; and in a standing position with one leg on the step, performing the PFMT protocol again.

Relaxation exercises: while in the lying position, participants performed a series of stretching exercises: trunk rotation, knee to chest, hamstring stretch (holding 30 s for each exercise). In the standing position, they performed a series of mobility exercises: pelvic tilt, back extension plus forward flexion of the trunk, and trunk rotation (repeating each movement ten times).

The home exercise program was as follows. The physiotherapist had encouraged the volunteers to perform PFMT contractions at home in the same way as they did during the in-person classes (three sets of PFM contractions in supine, prone, and standing positions). The women were instructed to perform the at-home exercise program 5 days a week. If they had any problems performing the exercises alone, the physiotherapist was instructed to resolve such issues any time, either by phone or a few minutes before or after exercise classes.

The participants were evaluated prior to the treatment and 30 days after the final treatment session. The questionnaires—the International Conference on Incontinence Questionnaire Short Form (ICIQ-SF) [14], International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS) [15], Female Sexual Function Index (FSFI) [16] (validated in their native language, Marinoff Dyspareunia Scale [17], and Vaginal Dryness and Dyspareunia Visual Analogue Scale (VAS)—were self-applicable. We also applied the 1-h pad test to quantify loss of urine [18]. Vaginal examinations using a speculum were performed by the same gynecologist based on Vaginal Health Index criteria (VHI) [19].

Cytological evaluation was performed by a vaginal smear collected from the lateral vaginal wall with a spatula before and 30 days after the end of treatment; the percentage of superficial (%S), intermediary (%I), and parabasal (P%) cells were counted and the mucosa was then classified according to the Vaginal Maturation Index (VMI) of Meisel's formula

[(1.0 x %S) + (0.5 x %I) + (0.0 x %P)] as atrophic, hypotrophic, or eutrophic [20].

A self-assessment questionnaire of overall outcome and treatment satisfaction was administered. Women who missed any of the three RF sessions and/or whose attendance of the in-person physiotherapy sessions did not reach 80% were deemed to have failed to comply with the study protocol and their involvement was terminated, but they were nevertheless included in the ITT analysis.

Outcomes

The primary endpoint of this study was to evaluate the improvement of urinary symptoms at ICIQ-SF and 1-h pad test. Secondary endpoints were the assessment of changes related to vaginal epithelium at ICIQ-VS, to vaginal dryness on VAS, VMI, and VHI, and to sexual function at FSFI, the Marinoff scale, as well as dyspareunia on VAS.

Randomization

The randomization sequence was created using SAS 9.4 (SAS Institute, Cary, NC, USA) statistical software with a 1:1:1 allocation using random block sizes of 3 inches. The information about the treatment to be used was kept inside a sealed opaque envelope identified by a number. The envelope was opened after the participant had signed an informed consent form. One investigator (HS) applied the interventions. Another investigator (ALBL) was blinded to the intervention group and performed the initial and post-treatment evaluations. It was not possible for participants to be blinded to the treatment.

Statistical analysis

The sample size was calculated according to Lalji [21], who demonstrated a statistically significant difference in ICIQ-SF score following RF treatment. Considering the improvement of 1.70 ± 0.87 in pre-treatment to 30 days post-treatment and an additional 30% loss to follow-up in the sample, we calculated 117 women (39 in each group).

During statistical analysis of the data, the Kolmogorov–Smirnov testwas used to evaluate the normality of the sample. Comparative analyses between the groups were done by analysis of variance (ANOVA) or Kruskal–Wallis test. Categorical variable associations were analyzed using Chi-squared test and by Fisher's exact test. The intragroup evaluation was performed using the Wilcoxon test or Student's *t* test for paired samples for continuous variables, and by McNemar's test or Bowker's test of symmetry for categorical variables. The data were also evaluated using repeated ANOVA measures with the objective of simultaneously checking the influence of the three study groups (between-groups effect), the two evaluations (within-groups effect), and to estimate the group × time interaction effect for each of the variables. The variables were rank-transformed owing to the lack of normal distribution. Outcomes were analyzed by intention to treat (ITT). The significance level was 5%.

Results

A total of 174 women were assessed for eligibility and 117 women were randomized to the RF ($n = 39$), RF + PFMT ($n = 39$), and PFMT ($n = 39$) treatments. Fifteen women (12.8%) failed to comply with the study protocol (1 in the RF group, 2 in the RF + PFMT group, and 12 in the PFMT group) and 4 participants were lost to follow-up (2 in the RF group, 1 in the RF + PFMT group, and 1 in the PFMT group). A flowchart of the participants in our study is shown in Fig. 3.

The mean age was 54.7 ± 6.3 years old, with an average of 9.0 ± 6.5 years of menopause. All groups were comparable in terms of demographic characteristics, with no significant differences except for stable relationship status (Table 1).

Urinary incontinence

International Conference on Incontinence Questionnaire Short Form scores improved significantly in all three groups post-treatment ($p < 0.001$; Table 2). However, the improvement was significantly greater in the RF + PFMT group than in the RF and PFMT groups ($p = 0.002$). The ICIQ-SF questions 1 (frequency of loss) and 3 (interference in daily life) showed improvement of the symptoms following the treatment among the three groups ($p < 0.001$), without difference between them. Regarding ICIQ-SF question 2 (amount of urine loss), the RF + PFMT group showed the greatest reduction in the volume of urine loss (−1.23 points) compared with RF (−0.87 points) and PFMT (−0.26 points; $p = 0.002$).

Urinary loss in the 1-h pad test decreased by 7.72 g on average after treatments in this sample and significantly in all groups ($p < 0.001$), but with no differences between them ($p = 0.987$). There was a significant change from significant loss in pad test to insignificant loss in pad test among the three treatments ($p = 0.001$).

Vaginal symptoms and integrity

There was evidence that all three therapies improved vaginal symptoms, according to ICIQ-VS total scores ($p < 0.001$; Table 3). The RF group showed a more significant decrease in the symptom score (−9.3 points) compared with the RF + PFMT (−4.4) and PFMT (−3.4) groups ($p = 0.007$).

According to answers obtained from question 4 of the ICIQ-VS, vaginal laxity improved after all treatments ($p < 0.001$), with no significant differences being observed between them ($p = 0.323$; Table 3).

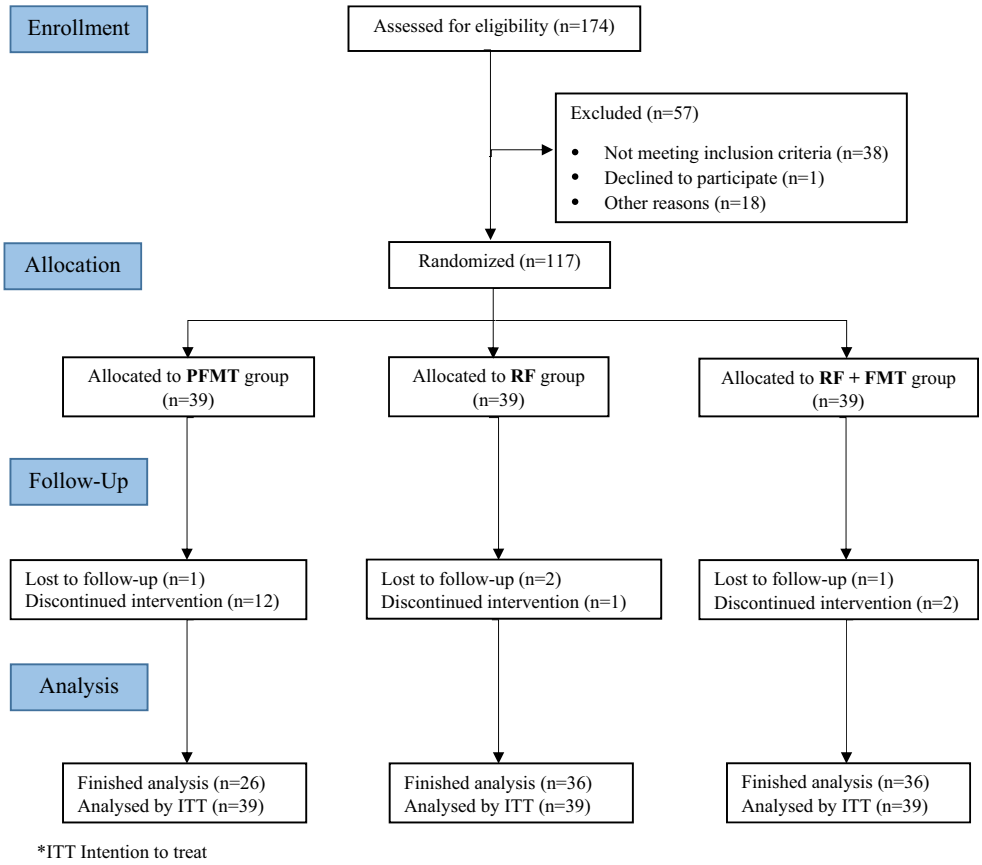

Fig. 3 Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram of the study

The sensation of vaginal dryness was evaluated according to question 7 of the ICIQ-VS questionnaire and showed improvement after RF ($p < 0.001$) and RF + PFMT ($p = 0.024$). Compared with other therapies, RF therapy was associated with the greatest shifts in sensation of vaginal dryness ($p = 0.009$; Table 3). Vaginal dryness was also evaluated according to VSA and was found to improve only after RF treatment ($p = 0.001$; Table 3).

The total post-treatment VHI scores in RF (+2.3 points) and RF + PFMT (+3.2 points) showed superior improvement over that of the PFMT group (+0.5 points; $p < 0.001$). The analyses of vaginal moisture, fluid volume, vaginal pH, and elasticity showed improvement only in the RF and RF + PFMT groups, finding no difference between them. Epithelial integrity improved in all three groups ($p = 0.187$; Table 3).

In the cytological aspect studied at MVI, only RF + PFMT group significantly reduced the percentage of parabasal cells ($p = 0.020$). No significant changes in mucosal layers were verified among the other treatments. The vaginal trophism classification showed a greater number of changes than eutrophic, but there was no statistical significance ($p = 0.572$; Table 3).

Sexual function

The FSFI total scores improved in the RF group ($p = 0.009$) and in the PFMT group ($p = 0.023$), with no differences between them ($p = 0.482$). The predominance of orgasm and desire increased only in the RF group ($p = 0.027$ and $p = 0.036$ respectively). FSFI lubrication and pain predominance improved in the RF and PFMT groups. Finally, excitement and satisfaction predominance showed no differences among any treatments (Table 4).

Dyspareunia, evaluated by the Marinoff scale, showed improvement only after RF therapy ($p = 0.037$). Dyspareunia VAS improved after RF ($p = 0.008$) and RF + PFMT therapy ($p = 0.023$; Table 4).

Treatment satisfaction

In our study, 92 % of participants reported feeling that they had been cured or that their symptoms had improved. A greater number of participants reported feeling that they had been cured in the RF and RF + PFMT groups than in the PFMT group ($p = 0.032$; Table 5). The proportion of participants who considered their symptoms to be unchanged or worse post-treatment was the same in all three groups ($p = 0.087$). Satisfied or very satisfied participants made up 86% of the sample, with no differences between groups ($p = 0.220$).

Loss of follow-up and adverse events

The PFMT group had significantly greater loss of follow-up (33.3%) than the RF (7.6%) and RF + PFMT (7.6%) groups

Table 1 Sociodemographic and sexual characteristics of the sample

Characteristics		Total sample (n=117)	PFMT (n=39)	RF (n=39)	RF+PFMT (n=39)	p value
Age (years)	Mean (SD)	54.76 (±6.3)	55.69 (±6.14)	53.56 (±6.40)	55.33 (±6.23)	0.178[a]
Ethnicity, n(%)	Median (range)	55 (50–60)	55 (53–61)	51 (48–59)	56 (51–61)	0.333[b]
	White	93 (70.4)	34 (87.1)	29 (74.3)	30 (76.9)	
	Non-white	24 (20.5)	5 (12.8)	10 (2.6)	9 (23.0)	
Education in years, n(%)	<8	18 (15.3)	4 (10.2)	9 (23.0)	5 (12.8)	0.268[c]
	8–11	36 (30.7)	14 (35.9)	7 (17.9)	15 (38.4)	
	12–15	6 (5.1)	2 (5.1)	1 (2.5)	3 (7.6)	
	>15	57 (48.7)	19 (48.7)	22 (56.4)	16 (41.0)	
Comorbidities, n (%)	Hypertension	30 (25.6)	12 (30.7)	9 (23.0)	9 (23.0)	0.153[b]
	Diabetes	3 (2.5)	0	0	3 (7.6)	
	Hypertension and diabetes	5 (4.2)	2 (5.1)	1 (2.5)	2 (5.1)	
	Others	26 (22.2)	10 (25.6)	5 (12.8)	11 (28.2)	
	None	53 (45.3)	15 (38.4)	24 (61.5)	14 (35.9)	
Smoking, n(%)	Yes	4 (3.4)	1 (2.5)	1 (2.5)	2 (5.1)	1.000[c]
	No	113 (96.5)	38 (97.4)	38 (97.4)	37 (94.8)	
BMI	Mean (SD)	28.71 (±5.0)	28.98 (±4.8)	28.95 (±4.9)	28.19 (±5.2)	0.607[a]
Sedentary, n(%)	Yes	46 (39.3)	19 (48.7)	17 (43.5)	10 (25.6)	0.091[b]
	No	71 (60.6)	20 (51.2)	22 (56.4)	29 (74.3)	
Gestations	Mean (SD)	2.40 (±1.3)	2.08 (±1.2)	2.79 (±1.5)	2.33 (±1.1)	0.077[a]
Vaginal deliveries	Mean (SD)	0.90 (±1.1)	0.79 (±1.0)	0.92 (±1.1)	0.97 (±1.2)	0.885[a]
Caesarians	Mean (SD)	1.16 (±1.0)	1.00 (±1.0)	1.34 (±1.0)	1.15 (±1.0)	0.332[a]
Abortions	Mean (SD)	0.35 (±0.8)	0.28 (±0.60)	0.53 (±1.0)	0.26 (±0.8)	0.149[a]
Hysterectomies, n (%)	Yes	14 (11.9)	3 (7.6)	6 (15.3)	5 (12.8)	0.678[c]
	No	103 (88.0)	36 (92.3)	33 (84.6)	34 (87.1)	
Prolapse, n(%)	None	61 (52.1)	20 (51.5)	19 (48.7)	22 (56.4)	0.671[b]
	Stage 1	40 (34.1)	15 (38.4)	15 (38.4)	10 (25.6)	
	Stage 2	16 (13.6)	4 (10.2)	5 (12.8)	7 (17.9)	
Menopause, n(%)	No	37 (31.6)	14 (35.9)	12 (30.7)	11 (28.2)	0.758[b]
	Yes	80 (68.3)	25 (64.1)	27 (69.2)	28 (71.7)	
Menopause age	Mean (SD)	48.79 (±4.7)	50.1 (±4.0)	47.0 (±4.5)	49.29 (±5.1)	0.043[a]
	Median	50 (46–52)	51 (48–53)	47 (43–51)	49 (46–52)	
Years of menopause, n (%)	Mean (SD)	9.0 (±6.5)	8.8 (±6.3)	9.1 (±6.6)	9.0 (+−6.7)	0.0971[a]
	Median	7.5 (4–14)	10 (7–23)	14 (8–24)	14 (8–24)	
	<5	23 (28.7)	7 (28)	7 (25.9)	9 (32.1)	0.616[b]
	5–10	32 (40)	12 (48)	12 (44.4)	8 (28.5)	
	>10	25 (31.2)	6 (24)	8 (29.6)	11 (39.2)	
Stable relationship, n (%)	No	27 (23.0)	5 (12.8)	8 (21.5)	14 (35.9)	0.048[b]
	Yes	90 (76.9)	34 (87.1)	31 (79.4)	25 (64.1)	
Sexually active, n (%)	Yes	71 (60,6)	26 (66.6)	27 (69.2)	18 (46.1)	0.073[b]
	No	46 (39,3)	13 (33.3)	12 (30.7)	21 (53.8)	
Sexual intercourse/week	Mean (SD)	1.0 (±1.1)	1.2 (±1.1)	1.1 (±0.9)	0.9 (±1.29)	0.150[a]

PFMT pelvic floor muscle training, *RF* radiofrequency, *BMI* body mass index

[a] Kruskal–Wallis test

[b] Pearson's Chi-squared test

[c] Fisher's exact test

($p = 0.02$). Only one participant (RF group) presented a complication: mild vaginal burn with spontaneous improvement of vaginal burning and mild dyspareunia after 3 months. She considered herself cured and reported being very satisfied with the treatment.

Discussion

Our study showed that women with SUI experienced objective and subjective improvement of UI with RF therapy—

Table 2 Evaluation of urinary incontinence in three groups of intervention according to validates questionnaire and 1-h pad test

Variable	Total sample	PFMT Pre	PFMT Post	PFMT *p* value[a]	RF Pre	RF Post	RF *p* value[a]	RF + PFMT Pre	RF + PFMT Post	RF + PFMT *p* value[a]	pGroup *p* value[b]	pTime *p* value[b]	pInteraction *p* value[b]
ICIQ-SF													
Total score	13.6 (±3.7)	13.1 (±4.1)	11.1 (±4.9)	<0.001	14.2(±3.1)	9.3 (±5.2)	<0.001	13.6 (±3.8)	8.2 (±5.2)	<0.001	0.566	<0.001[c]	0.002[c]
Frequency lost	3.1(±1.2)	3.0 (±1.2)	2.2 (±1.4)	<0.001	3.3 (±1.3)	1.9 (±1.4)	<0.001	3.1 (±1.2)	1.7 (±1.4)	<0.001	0.679	<0.001[d]	0.089[d]
Amount of lost	2.8(±1.2)	2.6 (±1.1)	2.4 (±1.1)	0.063	2.9 (±1.2)	2.0 (±1.1)	0.001	2.8 (±1.3)	1.6 (±1.0)	<0.001	0.396	<0.001[e]	0.002[e]
Interference in daily life	7.6(±2.3)	7.4 (±2.8)	6.5 (±3.2)	0.017	7.9 (±1.6)	5.3 (±3.6)	<0.001	7.6 (±2.3)	4.8 (±3.8)	<0.001	0.496	<0.001[f]	0.081[f]
Significant loss in 1-h pad test	90 (76.9%)	31 (79.4%)	17 (43.5%)	<0.001	31 (79.4%)	17 (43.5%)	<0.001	28 (71.7%)	16 (41.0%)	0.001	–	–	–
Grams in 1-h pad test	14.3 (±25.6)	11.1 (±17.8)	6.0 (±10.6)	<0.001	17 (±29.1)	9.3 (±22.3)	0.001	15(± 28.7)	4.5 (±11.9)	<0.001	0.647	<0.001[g]	0.987

ICIQ-SF International Conference on Incontinence Questionnaire UI short form, *pGroup* group effect or between-groups comparison, *pTime* time effect or within-groups comparison, *pInteraction* group vs time interaction effect or comparison of the deltas between groups, delta being the difference between pre- and post-treatment

[a] Wilcoxon test

[b] Repeated measures ANOVA

[c] Significant differences within groups (contrast profile test): PFMT ($p < 0.001$; Pre ≠ Post), RF ($p < 0.001$; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post); interaction effect: delta PFMT (−1.92), delta RF (−4.90), delta PMFT + RF (−5.41): PMFT ≠ PMFT + RF

[d] Significant differences within groups (contrast profile test): PFMT ($\boldsymbol{p} < 0.001$; Pre ≠ Post), RF ($p < 0.001$; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post)

[e] Significant differences within groups (contrast profile test): PFMT ($\boldsymbol{p} = 0.032$; Pre ≠ Post), RF ($\boldsymbol{p} < 0.001$; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post); Interaction effect: delta PFMT (−0.26), delta RF (−0.87), delta PFMT + RF (−1.23): PFMT ≠ RF + PFMT

[f] Significant differences within groups (contrast profile test): PFMT ($\boldsymbol{p} = 0.042$; Pre ≠ Post), RF ($\boldsymbol{p} < 0.001$; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post)

[g] Significant differences within groups (contrast profile test): PFMT ($\boldsymbol{p} < 0.001$; Pre ≠ Post), RF ($p < 0.001$; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post)

Table 3 Evaluation of vaginal symptoms and vaginal health parameters pre- and post-treatment in three intervention groups

Variable	Total sample	PFMT Pre	PFMT Post	PFMT *p* value[a]	RF Pre	RF Post	RF *p* value[a]	RF + PFMT Pre	RF + PFMT Post	RF + PFMT *p* value[a]	*p* group *p* value[b]	Ptime *p* value[b]	Pinteraction *p* value[b]
ICIQ-VS													
Total Score	17.1 (±10.6)	16.0 (±9.8)	12.6 (±10.1)	<0.001	19.7(±11.0)	10.4 (±9.7)	<0.001	15.5 (±10.7)	11.1 (±8.4)	<0.001	0.782	<0.001[d]	0.007[d]
Vaginal laxity	1.3 (±1.0)	1.4 (±1.0)	1.2 (±0.8)	0.004	1.4 (±1.1)	0.9 (±1.0)	0.004	0.9 (±1.0)	0.5 (±0.8)	0.02	0.013	<0.001[e]	0.323
Vaginal dryness	1.8 (±1.4)	1.5 (±1.3)	1.5 (±1.4)	0.928	2.1 (±1.3)	1.1 (±1.06)	<0.001	1.8 (±1.5)	1.3 (±1.2)	0.021	0.782	<0.001[f]	0.009[f]
VSA dryness scale	3.8 (±4.0)	3.3 (±3.9)	2.8 (±3.6)	0.322	4.4 (±4.1)	2.1 (±3.3)	<0.001	3.8 (±4.1)	2.7 (±3.9)	0.132	0.980	<0.001[g]	0.112
VHI total score	18.4 (±4.5)	18.8 (±4.2)	19.3 (±4.1)	0.152	18.8 (±4.5)	21.1 (±3.6)	<0.001	17.5 (±4.8)	20.7 (±4.0)	<0.001	0.511	<0.001[h]	<0.001[h]
VHI 1 (moisture)	3.9 (±1.0)	4.1 (±0.9)	4.1 (±0.8)	0.973	4.0 (±1.0)	4.5 (±0.6)	<0.001	3.7 (±0.9)	4.4 (±0.7)	<0.001	0.370	<0.001[i]	<0.001[i]
VHI 2 (fluid volume)	3.8 (±1.1)	4.0 (±0.9)	3.9 (±1.1)	0.678	4.0 (±1.1)	4.4 (±0.8)	0.020	3.5 (±1.2)	4.3 (±0.8)	<0.001	0.229	<0.001[j]	<0.001[j]
VHI 3 (vaginal ph)	2.3 (±1.4)	2.2 (±1.3)	2.4 (±1.6)	0.138	2.2 (±1.3)	3.0 (±1.7)	<0.001	2.3 (±1.5)	2.8 (±1.5)	0.004	0.757	<0.001[k]	0.054
VHI 4 (elasticity)	4.0 (±1.0)	4.2 (±0.8)	4.3 (±0.8)	0.438	4.1 (±1.0)	4.5 (±0.7)	0.009	3.8 (±1.2)	4.4 (±0.8)	<0.001	0.807	<0.001[l]	0.061
VHI 5 (epithelial integrity)	4.2 (±0.8)	4.1 (±0.8)	4.4 (±0.7)	0.016	4.3 (±0.8)	4.6 (±0.5)	0.004	4.1 (±0.9)	4.6 (±0.54)	<0.001	0.490	<0.001[m]	0.187
VMI													
Eutrophic	52 (44.4)	15 (38.4)	16 (41.0)	0.767[c]	18 (46.1)	21 (53.8)	0.172[c]	19 (48.7)	20 (51.2)	0.321[c]	–	–	–
Hypotrophic	23 (19.6)	7 (17.9)	7 (17.9)		8 (20.5)	6 (15.3)		8 (20.5)	10 (25.6)		–	–	–
Atrophic	42 (35.9)	17 (43.5)	16 (41.0)		13 (33.3)	12 (30.7)		12 (30.7)	9 (23.0)		–	–	–
Surface cells (%)	23.0	22.0	23.4	0.678	22.5	24.6	0.765	24.6	26.9	0.575	0.850	0.350	0.979
Intermediate cells (%)	50.3	48.2	46.6	0.599	52.0	51.6	0.755	50.7	55.9	0.074	0.214	0.477	0.272
Basal cells (%)	26.5	29.4	30.1	0.867	25.3	23.7	0.483	24.6	16.1	0.039	0.450	0.012[n]	0.255

ICIQ-VS International Consultation on Incontinence Questionnaire Vaginal Symptoms, *VAS* visual analog scale, *VHI* Vaginal Health Index, *VMI* Vaginal Maturation Index, *pGroup* group effect or between-groups comparison, *pTime* time effect or within-groups comparison, *pInteraction* group vs time interaction effect or comparison of the deltas between groups, delta being the difference between pre- and post-treatment

[a] Wilcoxon Test

[b] Repeated measures ANOVA

[c] Bowker's symmetry test

[d] Significant differences within groups (contrast profile test): PFMT ($p < 0.001$; Pre ≠ Post), RF ($p < 0.001$; Pre ≠ Post), RF + PFMT ($p = 0.002$; Pre ≠ Post); interaction effect: delta PFMT (−3.44), delta RF (−9.36), delta PFMT + RF (−4.44): RF ≠ (PFMT, RF + PFMT)

[e] Significant differences within groups (contrast profile test): PFMT (***p*** = 0.003; Pre ≠ Post), RF ($p = 0.003$; Pre ≠ Post), RF + PFMT ($p = 0.007$; Pre ≠ Post)

[f] Significant differences within groups (contrast profile test): PFMT ($p = 0.907$), RF (***p*** < 0.001; Pre ≠ Post), PFMT + RF ($p = 0.024$; Pre ≠ Post); interaction effect: delta PFMT (0.00), delta RF (−0.95), delta PFMT+RF (−0.51): PFMT ≠ RF[g] Significant differences within groups (contrast profile test): PFMT ($p = 0.363$), RF ($p = 0.001$; Pre ≠ Post), RF + PFMT ($p = 0.102$)

[h] Significant differences within groups (contrast profile test): PFMT (***p*** = 0.047; Pre ≠ Post), RF (***p*** < 0.001; Pre ≠ Post), RF + PFMT ($p < 0.001$, Pre ≠ Post); interaction effect: delta PFMT (0.51), delta RF (2.31), delta PFMT + RF (3.21): PFMT ≠ (RF, RF + PFMT)

[i] Significant differences within groups (contrast profile test): PFMT ($p = 0.902$), RF (***p*** = 0.001; Pre ≠ Post), RF + PFMT (***p*** < 0.001; Pre ≠ Post); interaction effect: delta PFMT (0.03), delta RF (0.54), delta PFMT + RF (0.74): PFMT ≠ (RF, RF + PFMT)[j] Significant differences within groups (contrast profile test): PFMT ($p = 0.756$), RF (***p*** = 0.018; Pre ≠ Post), RF + PFMT (***p*** < 0.001; Pre ≠ Post); interaction effect: delta PFMT (−0.08), delta RF (0.38), delta PFMT + RF (0.82): PFMT ≠ RF + PFMT[k] Significant differences within groups (contrast profile test): PFMT ($p = 0.116$), RF (***p*** < 0.001; Pre ≠ Pos), RF + PFMT (***p*** = 0.006; Pre ≠ Pos)

[l] Significant differences within groups (contrast profile test): PFMT ($p = 0.194$), RF (***p*** = **0.017**; Pre ≠ Post), RF + PFMT (***p*** < 0.001; Pre ≠ Post)

[m] Significant differences within groups (contrast profile test): PFMT ($p = 0.009$; Pre ≠ Post), RF (***p*** = 0.004; Pre ≠ Post), RF + PFMT ($p < 0.001$; Pre ≠ Post)

[n] Significant differences within groups (contrast profile test): PFMT ($p = 0.309$), RF ($p = 0.402$), PFMT + RF ($p = 0.020$; Pre ≠ Post)

Table 4 Evaluation of sexual function pre- and post-treatment in three intervention groups

Variable	Total sample	PFMT Pre	PFMT Post	PFMT *p* value[a]	RF Pre	RF Post	RF *p* value[a]	RF + PFMT Pre	RF + PFMT Post	RF + PFMT *p* value[a]	pGroup *p* value[b]	pTime *p* value[b]	pInteraction *p* value[b]
FSFI													
Total score	17.4 (±10.6)	17.9 (±10.6)	19.6 (±10.9)	0.009	19.0 (±9.7)	21.9 (±10.8)	<0.001	15.9 (±11.0)	17.6 (±11.2)	0.608	0.333	<0.001[c]	0.482
Desire	2.5 (±1.1)	2.4 (±1.0)	2.6 (±1.0)	0.061	2.5 (±1.1)	2.8 (±1.2)	0.120	2.4 (±1.0)	2.7 (±1.1)	0.175	0.919	0.001[d]	0.481
Excitement	2.5 (±1.8)	2.4 (±1.7)	2.7 (±1.7)	0.045	2.9 (±1.8)	3.2 (±2.0)	0.205	2.3 (±1.8)	2.2 (±1.8)	0.901	0.210	0.144	0.890
Lubrification	2.9 (±2.0)	3.1 (±2.0)	3.5 (±2.1)	0.009	3.2 (±1.9)	3.9 (±2.2)	0.001	2.6 (±2.1)	3.09 (±2.2)	0.303	0.336	<0.001[e]	0.474
Orgasm	3.0 (±2.1)	3.1 (±2.1)	3.4 (±2.1)	0.104	3.4 (±2.0)	3.9 (±2.2)	0.004	2.7 (±2.2)	2.8 (±2.1)	0.570	0.149	0.045[f]	0.297
Satisfaction	3.2 (±2.1)	3.3 (±2.1)	3.5 (±2.2)	0.835	3.4 (±2.0)	3.6 (±2.2)	0.133	2.9 (±2.2)	3.2 (±2.3)	0.730	0.744	0.086	0.868
Pain	3.1 (±2.2)	3.4 (±2.3)	3.8 (±2.4)	0.021	3.4 (±2.1)	3.8 (±2.3)	0.066	2.8 (±2.2)	3.2 (±2.4)	0.329	0.378	<0.001[g]	0.886
Sexual intercourse	1.0 (±1.1)	1.2(±1.1)	1.2 (±1.0)	1.000	1.1 (±0.9)	1.2 (±1.3)	0.305	0.9 (±1.2)	0.9 (±0.9)	0.996	0.200	0.224	0.722
Marinoff	1.2 (±1.1)	1.2 (±1.0)	1.1 (±0.9)	0.113	1.4 (±1.2)	1.1 (±1.1)	0.037	0.9 (±1.2)	1.0 (±1.1)	0.592	0.446	0.230	0.083
VSA dyspareunia scale	3.53(±4.1)	3.3 (±3.9)	2.4 (±3.7)	0.086	3.7 (±4.1)	2.1 (±3.6)	0.008	3.5 (±4.4)	2.0 (±3.6)	0.011	0.878	<0.001[h]	0.684

FSFI Female Sexual Function Index, *VSA* visual analog scale; *p1* between-groups effect, *p2* within-groups effect, *p3* group × group × time interaction, *pGroup* group effect or between groups comparison, *pTime* time effect or within-groups comparison, *pInteraction* group vs time interaction effect or comparison of the deltas between groups, delta being the difference between pre- and post-treatment

[a] Wilcoxon test

[b] Repeated measures ANOVA

[c] Significant differences within groups (contrast profile test): PFMT $p = 0.023$; Pre ≠ Post), RF ($p = 0.009$; Pre ≠ Post), RF + PFMT ($p = 0.197$)

[d] Significant differences within groups (contrast profile test): PFMT ($p = 0.064$), RF ($p = 0.027$; Pre ≠ Post), RF + PFMT ($p = 0.107$)

[e] Significant differences within groups (contrast profile test): PFMT ($p = 0.018$; Pre ≠ Post), RF ($\boldsymbol{p} = 0.005$; Pre ≠ Post), RF + PFMT ($p = 0.187$)

[f] Significant differences within groups (contrast profile test): PFMT ($p = 0.148$), RF ($p = 0.036$; Pre ≠ Post), RF + PFMT ($p = 0.895$)

[g] Significant differences within groups (contrast profile test): PFMT ($\boldsymbol{p} = 0.014$; Pre ≠ Post), RF ($\boldsymbol{p} = 0.043$; Pre ≠ Post), RF + PFMT ($p = 0.106$)

[h] Significant differences within groups (contrast profile test): PFMT ($p = 0.072$), RF ($p = 0.008$; Pre ≠ Post), RF + PFMT ($\boldsymbol{p} = 0.023$; Pre ≠ Post)

Table 5 Distribution of climacteric incontinence women according to subjective evaluation of treatment

Subjective evaluation	PFMT, *n* (%)	RF, *n* (%)	RF+PFMT, *n* (%)	*p* value[a]
Cured or improved	23 (88.4)	32 (88.8)	36 (100)	0.087
Equal or worse	3 (11.5)	4 (11.1)	0	
Cured	0	5 (13.8)	6 (16.6)	0.032
Improved	23 (88.4)	27 (75)	30 (83.3)	
Equal	2 (7.6)	4 (11.1)	0	
Worse	1 (3.8)	0	0	
Very satisfied or satisfied	21 (80.7)	30 (83.3)	34 (94.4)	0.220
Very unsatisfied or unsatisfied	5 (19.2)	6 (16.6)	2 (5.5)	

[a] Fisher's exact test.

whether it was associated with PFMT or not—as well as with PFMT alone. However, the improvement in UI symptom scores was greater in the RF + PFMT group. There was no difference among the three groups regarding the objective parameters in the 1-h pad test.

We observed an improvement in the general scores and in each ICIQ-SF question, regardless of treatment. Interestingly, the ICIQ-SF questionnaire general score and amount of urine loss showed significantly greater improvement in the RF + PFMT group than in the others. A previous study of 27 women with SUI and vaginal laxity who were treated with non-ablative RF showed improvement in all ICIQ-SF questions [21]. Another study also showed improvement in the ICIQ-SF score among 20 women with menopause-related SUI [22]. Furthermore, yet another study using non-ablative RF showed SUI improvement in excess of 70% through ICIQ-SF in women with SUI with a 6-month follow-up [23].

One of the first articles related to the use of RF in gynecology assessed the symptom of vaginal laxity [24]. Our study evaluated this same parameter using the ICIQ-VS questionnaire and found improvement of this symptom to be associated with all three of the treatments administered. Moreover, a previous clinical trial compared vaginal laxity symptoms in postpartum primiparous women and indicated that PFMT decreased the vaginal laxity symptoms by 45% compared with the placebo [22]. Various studies using RF have shown it to have a beneficial effect in the treatment of vaginal laxity [7, 21, 24].

Vaginal dryness and dyspareunia are considered the most common and most bothersome GSM symptoms [25]. In our study, participants complaining of vaginal dryness reported improvement after RF treatment, regardless of whether it was associated with PFMT. RF promotes the restoration of related epithelial functions such as proliferation, differentiation, glycogen synthesis, and desquamation [26].

The effect of RF on the vaginal health environment was shown in our study to improve the parameters of vaginal hydration, volume, pH, and elasticity of VHI in the RF and RF + PFMT groups, with no statistical difference found between these two treatments. Previous results described similar improvements in VHI scores after 12 weeks of RF therapy [22]. Our study described a significant decrease in parabasal cells in the RF + PFMT group, which may reflect the effect of RF on the maturation of epithelial cells. We chose to evaluate maturation using cytology in our study because it is an effective and non-invasive method. In the existing literature, two studies involving biopsy of the vaginal mucosa following RF showed maturation of the vaginal mucosa with increased epithelial layers—particularly the basal layer [22], which is in agreement with our own results.

Furthermore, regarding sexual function, there was also an improvement in the lubrication parameter in the RF and PFMT groups, but there was no difference between therapies. Total sexual function also showed no difference between the PFMT and RF groups. Previous studies have shown improvement in sexual function after RF treatment [7, 21]. The association of RF with PFMT showed no benefits to sexual function, which we tentatively attribute to the possibility that women who have undergone two simultaneous treatments may feel less comfortable and more fearful during sexual intercourse.

In our study, RF therapy improved dyspareunia as reported using the Marinoff scale or VAS. Our results are in agreement with those of a previous study that also showed an improvement in the VAS [22].

Significant concerns surround the use of energy-based devices in the treatment of SUI, and the FDA has reported several instances of adverse events based on reports and published literature [5]. Only one adverse event emerged during our study, involving a participant who presented extreme vaginal atrophy at the beginning of the study, and after the third session of RF complained of mild burning—the presence of hyperemia, abrasions, and pain during sexual intercourse. All of her symptoms improved spontaneously and the participant reported that she felt satisfied at the end of the RF treatment. We believe that RF is relatively safe, but further studies must be undertaken and published.

The use of RF increases the cost of SUI treatment in relation to PFMT, especially when the two treatments are combined. In order to determine when it is worth investing in an expensive

conservative treatment instead of surgical treatment, there is a need for further studies with long follow-ups and high rates of continued treatment comparing conservative treatments of SUI using energy devices with surgical treatment.

The greatest strength of our study is that it is, to the best of our knowledge, the first randomized controlled trial to compare RF—both associated with PFMT and alone—with the first-line treatment for SUI, that is not an industry-sponsored trial, and that has validated outcomes. More studies are needed that compare treatments in order to support clinical practice. The major limitation of our study was the short-term follow-up period; more time is needed to assess the long-term sustainability of these results. Furthermore, only one type of RF was used; it is also necessary to evaluate other types of energy equipment and assess their economic viability as alternatives to physical therapy.

Conclusions

The combination of RF and PFMT therapies showed significant improvement of SUI. Improvement of vaginal symptoms and dryness was greatest in the RF treatment group, and vaginal laxity showed similar improvement in all three groups. Compared with each therapy alone, the combination of RF and PFMT did not show benefits in sexual function.

Abbreviations FSFI, Female Sexual Function Index; GSM, Genitourinary syndrome; ICIQ-SF, International Conference on Incontinence Questionnaire Short Form; ICIQ-VS, International Consultation on Incontinence Questionnaire Vaginal Symptoms; PFMT, Pelvic floor muscle training; REBEC, Brazilian Registry of Clinical Trials; RF, Radiofrequency; RF + PFMT, Combination of radiofrequency with pelvic floor muscle training; SUI, Stress urinary incontinence; VAS, Visual analog scale; VHI, Vaginal Health Index; VMI, Vaginal Maturation Index

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Declarations

Conflicts of interest None.

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