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Efficacy of nonablative radiofrequency on sexual function in postmenopausal women: a randomized clinical trial

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Abstract

Objective: To evaluate the efficacy of nonablative capacitive-resistive monopolar radiofrequency on sexual function and vaginal health in postmenopausal women with genitourinary syndrome of menopause.

Methods: This was a single-blind, randomized, controlled clinical trial. The participants were randomly assigned to receive six weekly sessions of capacitive-resistive monopolar radiofrequency (n = 32) or sham treatment (n = 30). Sexual function was assessed using the Female Sexual Function Index (FSFI) and vaginal health was assessed using the Vaginal Health Index (VHI). The estrogenic status was determined by vaginal cytology, which involves calculating the proportions of basal, intermediate, and superficial cells. Assessments were conducted at baseline, post-treatment, and 12-week follow-up.

Results: Compared with the control group, the intervention group showed significantly greater improvements in the Female Sexual Function Index and Vaginal Health Index at post-treatment and at the 12-week follow-up. FSFI mean changes were 5.86 versus 1.33 at posttreatment ($P < 0.001$) and 4.41 versus −0.41 at 12-week follow-up ($P = 0.011$). VHI mean changes were 4.75 versus −0.03 at post-treatment ($P < 0.001$) and 6.90 versus −0.66 at follow-up ($P < 0.001$). The effect sizes were moderate to large for the FSFI (Cohen's $d > 0.77$, 95% CI, 0.25–1.29) and large for the VHI ($d > 3.49$, 95% CI, 2.68-4.28). No significant changes were observed in estrogenic status, and no adverse events were reported.

Conclusion: Capacitive-resistive monopolar radiofrequency significantly improved sexual function and vaginal health in women with genitourinary syndrome of menopause, thereby supporting its use as a safe, nonhormone treatment option.

Key Words: Atrophic vaginitis, Diathermy, Dyspareunia, Female urogenital diseases, Sexual dysfunction.

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Menopause, defined as amenorrhea for at least 12 months, marks the beginning of a hypoestrogenic state.[1] The resulting hormonal decline leads to Genitourinary Syndrome of Menopause (GSM), a cluster of vulvovaginal and urinary symptoms affecting up to 54% of postmenopausal women and significantly impairing quality of life.[2] Common manifestations include vaginal dryness, burning, irritation, and dyspareunia,[3] which are often associated with reduced sexual desire, arousal, orgasm, and sexual satisfaction.[4]

Conventional treatments for GSM include moisturizers and lubricants, which provide symptom relief but do not reverse atrophy, and local estrogen therapy, the gold standard for restoring vaginal tissue.[5] However, owing to contraindications or personal preferences, many women avoid hormones,[6] increasing interest in regenerative

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The identified participant data, the data dictionary, and the statistical code will be available upon reasonable request to the corresponding author and under a data use agreement.

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therapies such as lasers[7] and radiofrequency.[8]

Nonablative radiofrequency is a form of electromagnetic energy that uses a high-frequency current between 0.3 MHz and 1 MHz[9] to generate controlled heating within biological tissues.

This thermal effect is achieved through the oscillation of intracellular ions and molecules, increasing the tissue temperature.[10] The resulting heat activates physiological responses such as vasodilation and activation of the inflammatory cascade, subsequently stimulating fibroblasts and promoting neocollagenesis, neoelastogenesis, and collagen remodeling.[11] These processes improve tissue elasticity, hydration, and structural remodeling. Studies have shown that temperatures ranging between 40 °C and 45 °C are sufficient to induce cellular biomodulation without causing thermal damage.[12]

There is increasing evidence that different types of radiofrequency can improve vaginal laxity,[13] urinary incontinence and sexual function,[14] vaginal dryness and dyspareunia,[15] resulting in effects comparable to those of estrogen therapy and superior to those of moisturizers,[16] and promoting neovascularization and neocollagenesis in vulvovaginal tissues.[17] However, evidence on intracavitary radiofrequency applications in menopause is limited, and none of these studies included a sham-controlled group. This absence represents a significant methodological gap, as it limits the ability to attribute observed effects specifically to the intervention. Our study addresses this gap by incorporating a sham-controlled group.

Given the significant impact of GSM on the sexual function and well-being of postmenopausal women and the limitations of conventional nonhormone therapies, exploring new therapeutic alternatives is relevant. Therefore, the objective of this study was to assess the efficacy of an intervention based on the use of nonablative capacitive-resistive monopolar radiofrequency (CRMRF) in improving sexual function and vaginal health in women with GSM compared with a sham-controlled group.

METHODS

Study design and participants

This single-blind, randomized, placebo-controlled clinical trial compared the efficacy of CRMRF (intervention group, IG) versus a control group (CG) in improving sexual function and vaginal health in postmenopausal women. The study was conducted at the Faculty of Physiotherapy and Nursing, University of Castilla-La Mancha (Toledo, Spain). This study was approved by the Ethics Committee of the Toledo Health Area (reference: 1126/2023). The study protocol and the statistical analysis plan are available at ClinicalTrials.gov (ID#: NCT06925139). Written informed consent was obtained from all participants before enrollment. The intervention and follow-up were conducted between June and December 2024. The participants were recruited via flyers and social media. The sample size was calculated to detect a between-group difference of 4.5 points in Female Sexual Function Index (FSFI) scores ($\alpha = 0.05$, power = 80%, SD = 6). A 10% attrition rate is assumed. A minimum of 31 participants per group were required. To date, no anchor-based minimal clinically important difference (MCID) has been validated for the total FSFI score in postmenopausal women. However, previous studies using nonablative radiofrequency in this population have reported mean improvements of ~4-5.5 points, which are considered clinically meaningful.[11,15]

The inclusion criteria were women aged 40-65 years with ≥1 year of amenorrhea; at least one GSM-related symptom (vaginal dryness, irritation, itching, or urinary symptoms); and dyspareunia with sexual intercourse ≥ 1/month. The exclusion criteria included active vaginal infections; neurological, neoplastic, or sexually transmitted diseases; vulvodynia or vaginismus; pelvic organ prolapse ≥ grade 2; pelviperineal hypoesthesia; pacemaker or other electronic implants; estrogen-based therapy within 3 months; history of pelvic radiotherapy; pelvic surgery within 6 months; anticoagulant therapy; prior pelvic laser or ablative vaginal rejuvenation within 6 months; or cognitive impairment.

After the screening visit, eligible women (N = 62) were randomly assigned in a 1:1 ratio to the intervention group (IG; n = 32) or sham-controlled group (CG; n = 30) via Epidat v4.2 software (Xunta de Galicia, Spain) (Fig. 1). A designated researcher (A.T.-C.) managed enrollment and group assignment via a secure randomization sequence that was inaccessible to enrollment personnel to ensure allocation concealment. The outcome assessor was blinded to group allocation. In contrast, participants were not considered fully blinded to treatment allocation, as thermal perception could not be effectively masked due to the nature of the intervention.

There was no patient or public involvement in any phase of the study design.

Therapeutic procedure

The intervention was administered using the Indiba Deep Care Elite radiofrequency device (INDIBA S.A., Barcelona, Spain), operating at 448 kHz, with a maximum output of 450 VA (capacitive mode) and 200 W (resistive mode). The participants were positioned in the lithotomy position and treated with a 20-mm resistive electrode for the external genital area to prepare the tissues and optimize conductivity, and a single-use polyamide-coated longitudinal capacitive electrode for the vaginal canal connected to the PLUMA Indiba handpiece with integrated temperature control. A passive electrode was placed over the lumbosacral region, and Indiba Proionic Intimate Cream was applied (Supplemental Fig. S1, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

In the IG, participants received six weekly sessions. Each session began and ended with five minutes of slow circular movements using the resistive electrode. The temperature was gradually increased to a comfortable level, typically rated as 4-5/10 on a subjective analog scale (0 = no thermal sensation, 10 = maximum tolerable heat).

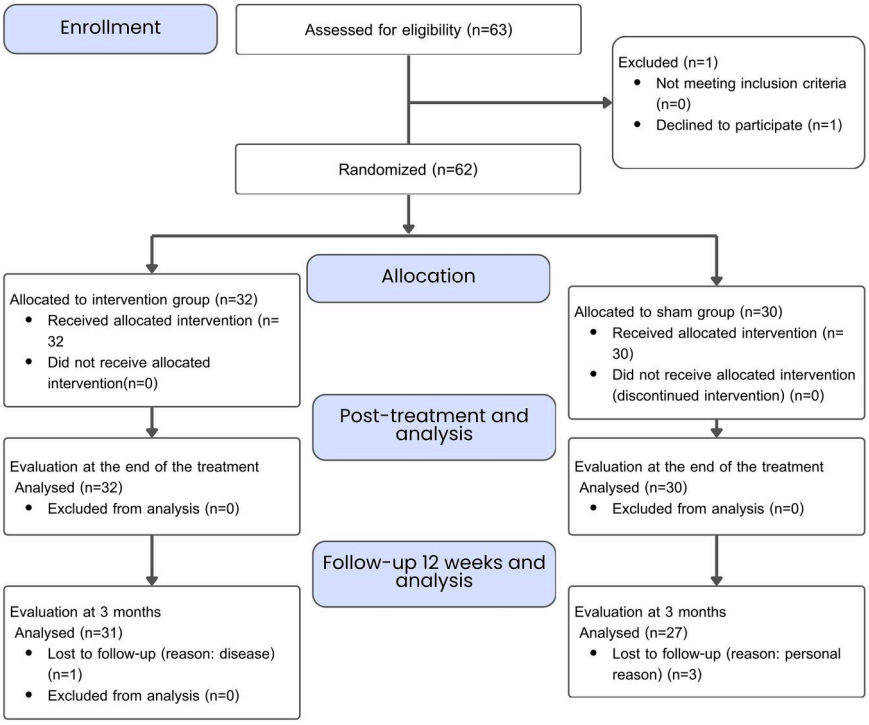


FIG. 1. CONSORT flow diagram of participant enrollment, allocation, follow-up, and analysis.

Vaginal treatment involved progressive heating with the capacitive electrode, maintaining 41-43 °C for 10 minutes, and rotating the contact point every minute clockwise.

Outcome assessments were performed at baseline (T0), posttreatment (T1, 7 wk after the first session), and at follow-up (T2, 12 wk after T1). All interventions were delivered by a physiotherapist specializing in pelvic floor dysfunctions, with more than 10 years of clinical experience in women's health. All procedures were conducted under the supervision of a gynecologist. Evaluations were conducted by a blinded assessor (A.F.-M.).

In the CG, the same protocol was followed, but without active radiofrequency emission. The device remained on without thermal emission, and the display was concealed.

Outcome measures

Sexual function (primary outcome)

Sexual function was assessed via the FSFI.[18] The 19-item FSFI evaluates six domains—desire, arousal, lubrication, orgasm, satisfaction, and pain—based on sexual activity over the past four weeks. Domain scores range from 0 to 6 (except for desire and satisfaction), with a total score ranging between 2.0 (severe dysfunction) and 36.0 (no dysfunction). A score ≤26.55 indicates sexual dysfunction.[19] The validated Spanish version was used.

Vaginal health

The Vaginal Health Index (VHI) was used to assess five parameters: elasticity, secretion (type/consistency), pH, epithelial integrity, and moisture.[20] Each parameter is scored from 1 (poor) to 5 (optimal), with scores ranging from 5 to 25 points. A total score of ≤15 indicates vaginal atrophy.[21]

Estrogenic status

The estrogenic status was estimated from the maturation index (proportion of parabasal, intermediate, and superficial cells per 100 cells obtained from a smear of the upper two-thirds of the vaginal wall) via Meisels' formula: (% intermediate cells × 0.5 + % superficial cells). Values of 0-49 indicate no or low estrogenic effects, values of 50-64 indicate moderate effects, and values of 65-100 indicate high estrogenic effects.[22] Higher values reflect greater epithelial maturation and a stronger estrogenic effect.[23]

Adverse events

Adverse events were defined as any undesirable local reactions, such as pain, burning, bleeding, or discomfort, that occurred during or after the intervention. They were assessed at each visit through direct questioning by clinical staff, and participant-reported events were recorded.

Statistical analysis

Descriptive statistics are reported as the means and standard deviations for continuous variables and as frequencies for categorical variables. Normality was analyzed via the Kolmogorov–Smirnov test and normal probability plots. Baseline group differences were

assessed via independent samples *t*-tests and χ^2 tests, whereas within-group changes from baseline to T1 and T2 were assessed via paired *t*-tests.

To improve the robustness given non-normal distributions and moderate sample sizes, nonparametric bootstrap resampling (1,000 iterations) was applied to continuous outcomes. This yielded bias-corrected and accelerated (BCa) 95% confidence intervals and *P*-values without distributional assumptions.

Pearson's correlation between the main outcome variables was examined to explore the associations between changes in sexual function and vaginal health.

Between-group differences in the FSFI, VHI, and estrogenic status were evaluated via ANCOVA, adjusting for age, time since menopause, and baseline values. Changes in the proportions of individuals with sexual dysfunction (FSFI ≤ 26.55) and vaginal atrophy (VHI ≤ 15) within groups were analyzed via McNemar's test, whereas between-group differences in these proportions were assessed via the Pearson χ^2 test.

As a complementary analysis, linear mixed-effects regression models were applied to the FSFI and VHI scores at T0, T1, and T2, including subject-specific random intercepts to account for within-subject variability. Fixed effects included group, time, and their interaction to assess treatment effects over time. Estimated marginal means were used to illustrate outcome trajectories, and significance was tested via the Welch–Satterthwaite approximation. Effect sizes (Cohen's *d*) were calculated from pooled standard deviations, with values of 0.2, 0.5, and 0.8 representing small, medium, and large effects, respectively.

Statistical analyses were performed following the intention-to-treat principle and included all randomized participants who completed at least 80% of the scheduled sessions in accordance with their assigned allocation. Missing data were handled via multiple imputation.

Analyses were conducted using SPSS v29.0 (IBM Corp., Armonk, NY) and R v4.4.2 (R Foundation for Statistical Computing, Vienna, Austria), with a two-tailed significance level of $\alpha = 0.05$.

TABLE 1. Baseline sociodemographic and clinical characteristics of participants by group

Variables	Treatment group (n = 32)	Sham group (n = 30)	*P*
Age (y), *M* (SD)	55.40 ± 4.08	56.30 ± 4.68	0.432[a]
Marital status, n (%)			
Single	2 (6.25)	4 (13.33)	0.298[b]
In a couple	26 (81.25)	25 (83.33)	
Divorced	4 (12.50)	1 (3.33)	
Education level, n (%)			
Primary	2 (6.25)	1 (3.33)	0.072[b]
Secondary	12 (37.50)	20 (66.66)	
University	18 (56.25)	9 (30.0)	
BMI, kg/m2, *M* (SD)	24.55 ± 4.15	23.98 ± 3.14	0.549[a]
< 25, n (%)	19 (59.37)	21 (70.0)	0.382[b]
≥ 25, n (%)	13 (40.63)	9 (30.0)	
Smoking status, n (%)			
Smoker/ex-smoker	3 (9.37)	3 (10.0)	0.934[b]
Nonsmoker	29 (90.63)	27 (90.0)	
Parity status, n (%)			
Nulliparous	7 (21.88)	3 (10.0)	0.438[b]
Primiparous	5 (15.63)	6 (20.0)	
Multiparous	20 (62.50)	21 (70.0)	
Comorbidity presence, n (%)	17 (53.13)	14 (46.7)	0.611[b]
Use of vaginal lubricants, n (%)			
Yes	18 (56.25)	17 (56.67)	0.974[b]
No	14 (43.75)	13 (43.33)	
Time since menopause (y), *M* (SD)	5.75 ± 3.34	6.37 ± 3.62	0.479[a]
FSFI score, *M* (SD)	20.40 ± 5.66	21.71 ± 6.20	0.380[a]
FSFI ≤ 26.55[c], n (%)	24 (75.0)	19 (63.30)	0.530[b]
VHI score, *M* (SD)	10.13 ± 2.64	10.60 ± 3.02	0.326[a]
VHI ≤ 15[d], n (%)	30 (93.80)	29 (96.70)	0.593[b]
Vaginal maturation index, n (%)			
Parabasal cells	63.91 (38.43)	64.67 (43.19)	0.942[a]
Intermediate cells	18.75 (21.93)	21.83 (28.75)	0.637[a]
Superficial cells	17.34 (28.45)	13.50 (25.02)	0.573[a]
Estrogen status, *M* (SD)	26.94 ± 32.49	26.76 ± 33.18	0.952[a]

Baseline sociodemographic and clinical characteristics are presented as mean ± standard deviation (*M* ± SD) for continuous variables or as frequency (percentage) for categorical variables. Estrogen status value calculation: (% intermediate cells × 0.5 + % superficial cells). Comorbidities considered in this study include chronic conditions such as hypertension, diabetes mellitus, thyroid disorders, and other endocrine or metabolic diseases.

BMI, body mass index; FSFI, Female Sexual Function Index; *M*, mean; n, frequency; N, total number of participants in group; SD, standard deviation; VHI, Vaginal Health Index; y, years.

[a] *P*-value calculated using Student *t* test for comparison of means.

[b] *P*-value calculated using χ^2 for comparison of frequencies.

[c] FSFI ≤ 26.55: indicates sexual dysfunction.

[d] VHI ≤ 15: indicates vaginal atrophy.

RESULTS

Participants

Sixty-two women were randomized (32 in the IG and 30 in the CG), and 58 completed the study (31 in the IG and 27 in the CG; Fig. 1).

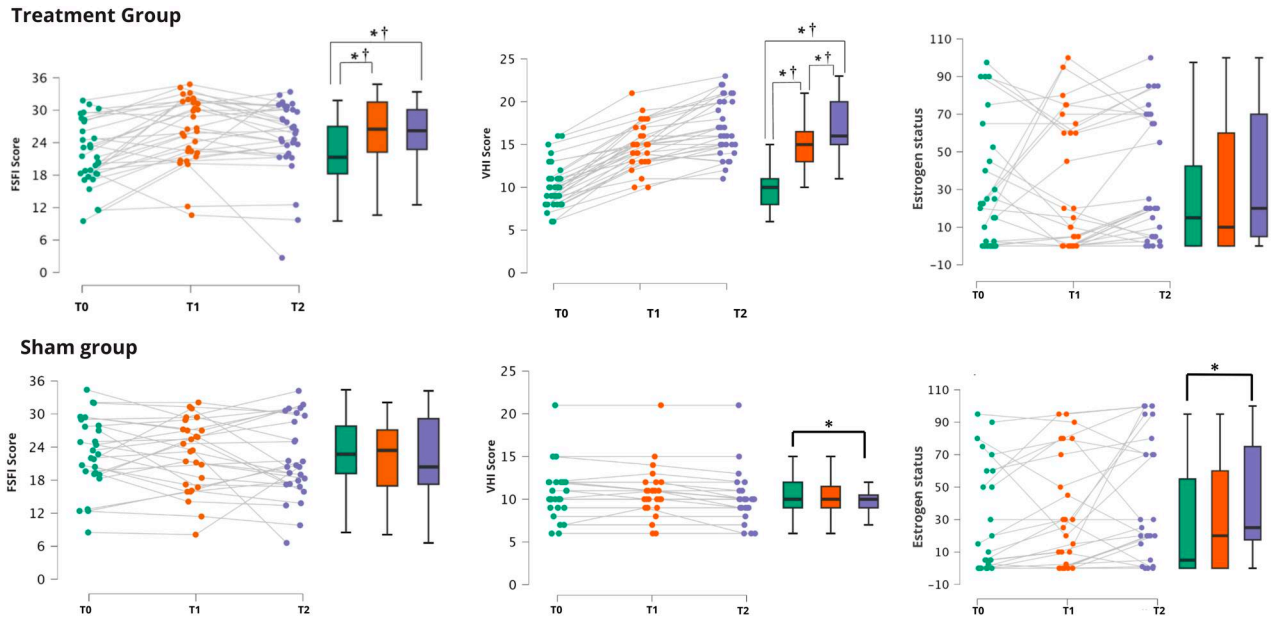
Table 1 shows the baseline characteristics of the participants. The baseline characteristics were comparable between the groups ($P > 0.05$).

Correlations

Supplementary Figure S2 (Supplemental Digital Content 1, http://links.lww.com/MENO/B482) shows the correlations between FSFI changes and both VHI and estrogenic status at T1 and T2. A positive correlation was found between improvements in FSFI and VHI. The change in the VHI from T0 to T1 correlated significantly with the FSFI score ($r = 0.40$; 95% CI, 0.17-0.59), and this association remained at T2, although it was weaker ($r = 0.33$; 95% CI, 0.09-0.53). In contrast, changes in the FSFI score and estrogenic status were negatively correlated ($r = -0.13$; 95% CI, −0.37 to 0.13 at T1 and $r = -0.33$; 95% CI, −0.54 to −0.092 at T2).

Sexual function outcomes: FSFI score and domains

Between-group analyses demonstrated that, compared with the CG, the IG achieved significantly greater improvements in overall sexual function. Adjusted ANCOVA revealed significant differences in the FSFI



		Treatment group				Sham group				Between-group comparisons	
		Mean (SD)	95% CI	*p*-value[a]	Mean (SD)	95% CI	*p*-value[a]	*p*-value[b]	Cohen´s *d*	95% CI
FSFI	T0	20.40 (5.66)	18.55 – 22.34		21.71 (6.20)	19.39–23.74				
	Mean change at T1	5.86 (4.96)	4.18–7.53	< 0.001	1.33 (4.08)	–0.32 to 2.57	0.131	< 0.001	1.021	0.49–1.55
	Mean change at T2	4.41 (5.27)	2.60–6.28	< 0.001	–0.41 (6.93)	–2.89 to 1.83	0.770	0.011	0.77	0.25–1.29
VHI	T0	10.13 (2.64)	9.16–11.03		10.60 (3.02)	9.59–11.76				
	Mean change at T1	4.75 (1.81)	4.12–5.43	< 0.001	–0.33 (0.62)	–0.25 to 0.21	0.766	< 0.001	3.49	2.68–4.28
	Mean change at T2	6.90 (2.61)	6.09–7.93	< 0.001	–0.66 (1.06)	–1.08 to -0.32	0.013	< 0.001	3.80	2.96–4.64
Estrogenic Status	T0	26.71 (31.99)	16.42–37.86		24.41 (32.23)	13.62–36.52				
	Mean change at T1	1.25 (29.28)	–8.17 to 11.74	0.829	6.33 (19.29)	–1.00 to 13.46	0.85	0.425	-0.20	–0.70 to 0.29
	Mean change at T2	7.81 (25.81)	–1.17 to 16.81	0.113	16.65 (29.69)	6.49–28.24	0.015	0.188	-0.31	–0.81 to 0.18

FIG. 2. Longitudinal changes in Female Sexual Function Index, Vaginal Health Index, and Estrogenic Status Value in the treatment and sham groups. Each outcome is plotted at three time points: T0, T1, and T2. Individual participant trajectories (lines) illustrate within-subject changes over time, and box-and-whisker plots at each time point depict the group distribution of scores (treatment vs. sham plotted separately). The treatment group shows an overall upward trend in FSFI and VHI scores over time, whereas the sham group remains relatively unchanged. Asterisk (*) indicates statistically significant within-group differences ($P < 0.05$), and cross (†) indicates statistically significant between-group differences ($P < 0.05$) at the corresponding time point. An accompanying table (inset) summarizes the mean changes from baseline to T1 and to T2 for each measure in both groups, with SD. *P*-values[a] from paired *t*-tests are provided to assess the significance of within-group changes, and *P*-values[b] from analysis of covariance (ANCOVA) adjusted for age, time since menopause and baseline values are given for between-group comparisons. *P*-holm is a *P*-value adjusted for multiple comparisons using the Holm-Bonferroni method. Notably, the treatment group demonstrates marked improvements in FSFI and VHI after treatment and at follow-up, in contrast to minimal change in sham group, while changes in the estrogenic index are modest in both groups with no significant between-group difference. Between-group effect sizes (Cohen's *d*) and 95% CI for changes in FSFI, VHI, and estrogenic status at T1 and T2, relative to T0. Cohen's *d* values reflect the magnitude of the difference in change from baseline between the treatment and sham group for each outcome. Positive values indicate greater improvement in the treatment group. Effect sizes of 0.2, 0.5, and ≥ 0.8 are interpreted as small, moderate, and large, respectively. Bias-corrected and accelerated (BCa) 95% CI are presented to indicate the precision and clinical relevance of each effect. CI, confidence intervals; FSFI, Female Sexual Function Index; SD, standard deviations; T0, baseline; T1, post-treatment, T2, 12-week follow-up; VHI, Vaginal Health Index.

total score at both T1 and T2 ($P < 0.001$ and $P = 0.011$, respectively). The IG exhibited mean increases of 5.86 points at T1 (95% CI, 4.18-7.53; $P < 0.001$) and 4.41 points at T2 (95% CI, 2.60-6.28; $P < 0.001$), whereas the control group showed minimal and non–significant changes (1.33 points at T1; 95% CI, −0.32 to 2.57; $P = 0.131$; −0.41 points at T2; 95% CI, −2.89 to 1.83; $P = 0.770$). The effect sizes indicated a large magnitude of improvement in the intervention group (Cohen's $d = 1.02$ at T1; $d = 0.77$ at T2) (Fig. 2 and Supplemental Fig. S3, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

Consistently, between-group comparisons across the domains revealed that participants in the IG experienced significantly greater improvements than those in the CG. At T1, significant differences were observed in lubrication, orgasm, and pain, with effect sizes ranging from moderate to large ($d = 0.58$-1.18). At T2, the IG maintained significant improvements in desire, arousal, lubrication and orgasm, with effect sizes also ranging from moderate to large ($d = 0.52$-0.68). Nevertheless, after applying Holm-Bonferroni correction for multiple comparisons across the six FSFI domains, the between-group differences at posttreatment (T1) remained statistically significant for the pain and orgasm domains (adjusted $P < 0.05$), whereas the improvement in lubrication showed a trend toward significance (adjusted $P = 0.052$). At follow-up (T2), no individual domain retained significance after adjustment (all adjusted $P \geq 0.16$). (Fig. 3A and Supplemental Table S1, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

In the IG, the proportion of women with sexual dysfunction (FSFI ≤ 26.55) decreased from 75% at baseline to 53.1% at both T1 and T2 ($P = 0.039$). No significant changes occurred in the CG (Fig. 4A).

Vaginal health outcomes: VHI score and domains

Between-group analyses revealed that participants in the IG experienced markedly greater improvements in vaginal health compared with those in the CG. The total VHI score increased significantly in the IG at both T1 (mean change 4.75; 95% CI, 4.12-5.43; $P < 0.001$) and T2 (6.90; 95% CI, 6.09-7.93; $P < 0.001$), whereas the CG showed no change at T1 (−0.33; 95% CI, −0.25 to 0.21; $P = 0.766$); and a significant deterioration at T2 (−0.66; 95% CI, −1.08 to −0.32; P 0.013). Between-group comparisons confirmed highly significant differences at both time points ($P < 0.001$), with large effect sizes ($d = 3.48$; 95% CI, 2.68-4.28 at T1; and $d = 3.80$, 95% CI, 2.95-4.64 at T2) (Fig. 2 and Supplemental Fig. S4, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

Consistently, the IG achieved significantly greater improvements across all domains at both T1 and T2, all of which favored the intervention ($P \leq 0.005$), whereas the CG showed deterioration over time in pH domain (−0.37 points at T2; 95% CI, −0.58 to −0.15; $P = 0.007$) and moisture (−0.33 points at T2; 95% CI, −0.58 to −0.11; $P < 0.001$). The effect sizes were uniformly large ($d > 1.13$; 95% CI, 0.59-1.66), indicating substantial and sustained improvements in vaginal health. After applying the Holm-Bonferroni correction for multiple comparisons across the five VHI domains, between-group differences at T1 and T2 remained statistically significant for all domains except elasticity at T1 (Fig. 3B and Supplemental Table S2, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

At T0, most participants in both groups had VHI ≤ 15, indicating vaginal atrophy, with no significant difference between the groups (93.8% vs. 96.7%; $P = 0.593$). At T1, this proportion decreased significantly in the IG

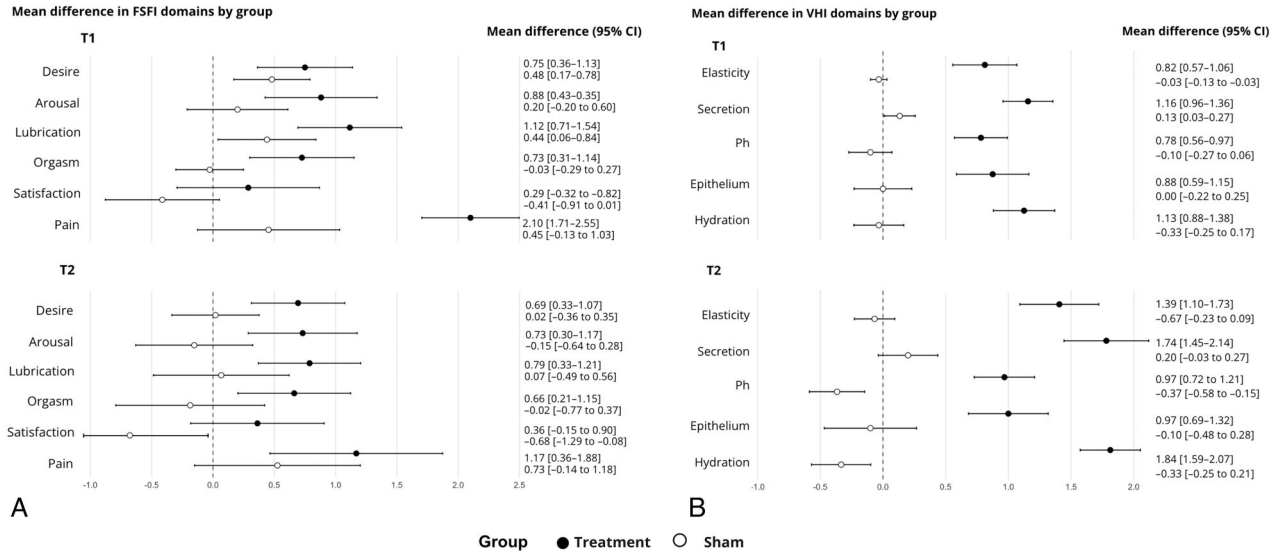


FIG. 3. Mean differences (95% confidence intervals) in **(A)** Female Sexual Function Index and **(B)** Vaginal Health Index domain scores, comparing treatment and sham groups at posttreatment and follow-up. The left panel shows FSFI domains (pain, desire, arousal, lubrication, orgasm, and satisfaction), while the right panel presents VHI domains (elasticity, fluid volume, pH, moisture, and epithelial integrity). Mean differences represent changes from baseline, with positive values indicating improvement. The 95% CI are shown to the right of each panel; CIs that do not overlap with the vertical dashed line indicate a statistically significant difference between groups. CI, confidence intervals; FSFI, Female Sexual Function Index; T0, baseline; T1, posttreatment; T2, 12-week follow-up; VHI, Vaginal Health Index.

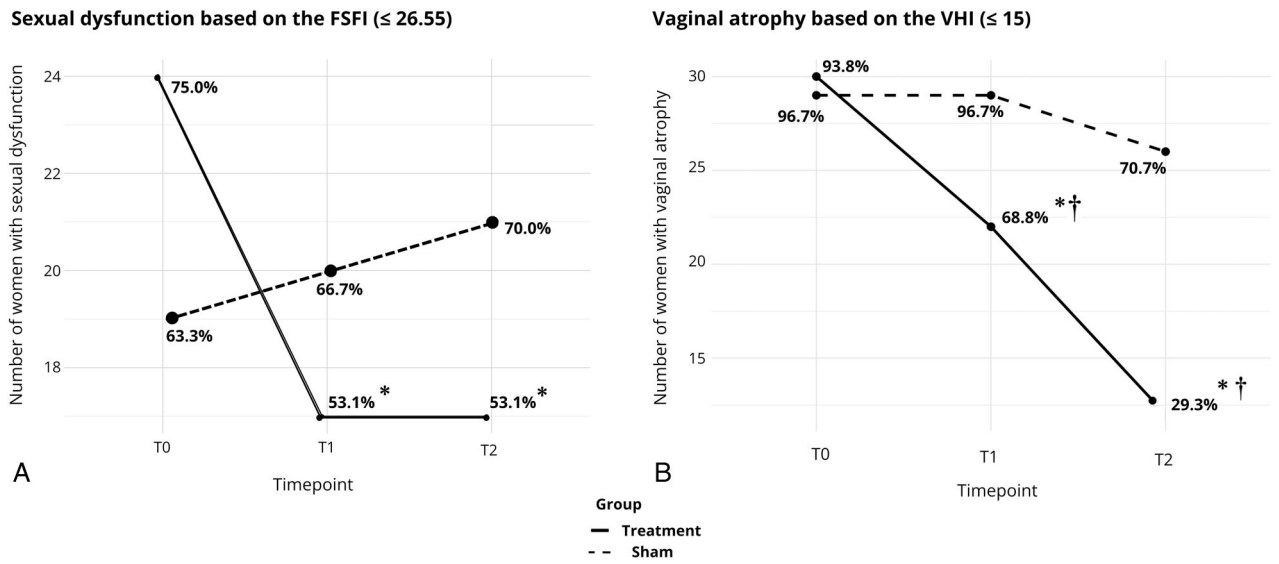


FIG. 4. Changes in the proportion of women with **(A)** sexual dysfunction and **(B)** vaginal atrophy over time in the treatment and sham groups. **(A)** Proportion of women with sexual dysfunction at each assessment time point, based on the FSFI clinical cut-off score of ≤ 26.55. Following the intervention, the treatment group (solid line) showed a notable reduction in the proportion of women with dysfunction at T1 and T2. In contrast, the sham group (dashed line) exhibited a slight increase at T1 and remained elevated at T2. These findings suggest a positive and sustained effect of the intervention on female sexual function, while no improvement was observed in the sham group. **(B)** Proportion of women with vaginal atrophy at each assessment time point, based on the VHI clinical cut-off score of ≤ 15. A progressive reduction in the number of women with vaginal atrophy was observed in the treatment group (solid line). In contrast, the sham group (dashed line) showed minimal change, with proportions remaining stable over time. These findings indicate a sustained and clinically meaningful effect of the CRMRF in reducing vaginal atrophy. Asterisk (*) indicates significant difference within the treatment group compared with baseline and cross (†) indicates significant difference between groups at the corresponding time point. CRMRF, capacitive-resistive monopolar radiofrequency; FSFI, Female Sexual Function Index; T0, baseline; T1, posttreatment; T2, 12-week follow-up; VHI, Vaginal Health Index.

(68.8%; $P = 0.008$) and further declined at T2 (29.3%; $P < 0.001$). The CG remained largely unchanged at both T1 and T2 (96.7% and 70.7%, respectively, $P = 1.00$). Between-group differences were significant at both post-treatment and follow-up points ($P < 0.01$; Fig. 4B).

Mixed-effects regression models using FSFI and VHI scores at T0, T1, and T2 revealed significant group-by-time interactions that confirmed greater improvements in the CRMRF group than in the sham group at both T1 (FSFI: $\beta = -4.74$; $P < 0.001$; VHI: $\beta = -4.78$; $P < 0.001$) and T2 (FSFI: $\beta = -4.90$; $P < 0.001$; VHI: $\beta = -7.64$; $P < 0.001$), indicating that changes in sexual function and vaginal health differed between groups (Supplemental Table S3, Supplemental Digital Content 1, http://links.lww.com/MENO/B482). Large effect sizes were observed for FSFI and VHI changes posttreatment. For the FSFI, the effects were moderate to large in the IG ($d \geq 0.77$; 95% CI, 0.25-1.29), whereas for the VHI, the effects were very large ($d \geq 3.49$; 95% CI, 2.68-4.28) (Fig. 2).

Estrogenic status

Slight posttreatment increases in estrogenic status were observed in both groups; however, values remained below 49 at all time points, indicating a low estrogenic effect according to established thresholds.[22] Adjusted analyses revealed no significant between-group differences at either T1 ($F_{1,57} = 0.646$; $P = 0.425$) or T2 ($F_{1,53} = 1.803$; $P = 0.185$) (Fig. 2 and Supplemental Fig. S5, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

For the primary variables, a sensitivity analysis using nonimputed data was conducted, and the statistical significance of the *P*-values remained consistent with the primary analysis (Supplemental Table S4, Supplemental Digital Content 1, http://links.lww.com/MENO/B482).

Adverse events

No adverse events were reported.

DISCUSSION

Main findings

This was a single-blind, randomized, sham-controlled clinical trial evaluated the efficacy of six sessions of nonablative CRMRF therapy in improving sexual function and vaginal health in postmenopausal women. Participants who received CRMRF showed significant and clinically relevant improvements in both objective (VHI) and subjective (FSFI) outcomes, supporting its use as a nonhormone option for GSM management. These

effects were sustained up to 12 weeks posttreatment and found to be independent of estrogenic status.

The positive correlation between the FSFI and VHI supports the physiological and clinical link between improved vaginal health and sexual function. Vaginal health improved significantly in the IG, with gains across all VHI domains being sustained at follow-up. These changes were both statistically and clinically meaningful, reflecting enhanced vaginal trophic status. A VHI score below 15 is commonly used instead of a minimal clinically important difference (MCID) to identify atrophic conditions.[24] In this study, the proportion of women with VHI ≤15 decreased notably, suggesting a shift toward nonatrophic conditions. No meaningful change was observed in the CG. These findings confirm VHI as a sensitive marker of treatment response and are consistent with evidence linking radiofrequency to increased perfusion, fibroblast activation, and collagen remodeling.[9,25]

Sexual function also improved markedly, particularly in the lubrication and pain domains. The proportion of women with sexual dysfunction (FSFI ≤26.5) decreased in the IG. This cut-off is widely recognized as indicative of clinically significant sexual dysfunction.[26] The mean FSFI score increased by 5.86 points posttreatment, which is the ~4-5-point threshold considered clinically meaningful in previous studies of nonablative radiofrequency in women with GSM,[11,15] with sustained improvement observed at follow-up. The mean changes in FSFI domain scores in the IG also exceeded the established MCID thresholds for desire, lubrication, orgasm and pain at T1, which aligns with previously reported values (eg, desire ≥0.7; lubrication ≥1.0).[27,28] These improvements were associated with large effect sizes, reinforcing their clinical relevance and supporting the potential of CRMRF as an effective intervention for GSM.

Our findings were consistent with those of previous studies. For example, Pinheiro et al[15] reported that the FSFI increased by ≥3 points in 54.5% of participants treated with a nonablative intracavitary radiofrequency device (temperature controlled at 41 °C) after three months of follow-up. In our study, this proportion was greater (65.6%), which may be attributed to a larger sample size or to differences in device parameters, such as frequency (1 MHz vs. 448 kHz), potentially affecting both penetration depth and thermal effects.[17]

The CG showed no meaningful changes in the FSFI or VHI, except for a transient post-treatment improvement in desire and lubrication, which was not sustained at follow-up. This is likely attributable to a placebo response, as commonly reported in sexual health trials.[29]

Overall, these results support the hypothesis that restoring vaginal health contributes to the recovery of sexual function. Consistently, FSFI improvements correlated more strongly with VHI than with cytologic changes. Although slight increases in estrogenic cytologic markers were observed in both groups, no significant between-group differences emerged, nor were these changes associated with functional outcomes. These findings suggested that treatment efficacy was independent of estrogenic status. These findings imply that symptom improvement, particularly in the IG, may be mediated by nonhormone mechanisms such as enhanced hydration, vascularization, and collagen remodeling. Vaginal biopsies may help clarify tissue-level changes in future studies.

The intervention was well tolerated, with no serious adverse events reported. Localized warmth was the most commonly reported perception during treatment, which is consistent with findings from similar studies.[30]

Strengths and limitations

One of the main strengths of this study is its rigorous methodological design, which included a sham procedure that mimicked the active treatment and a single-blind protocol, substantially reducing the risk of placebo effects and measurement bias. In addition, the concurrent use of both objective (VHI) and subjective (FSFI) validated instruments provided a comprehensive assessment of treatment efficacy, thereby enhancing the internal validity and clinical interpretability of the findings. Furthermore, the inclusion of participants regardless of their estrogenic status increases the clinical applicability of the results to a more diverse population of postmenopausal women.

Nevertheless, several limitations should be acknowledged. The FSFI is a self-reported measure of sexual function, and it may be influenced by individual, emotional, and contextual factors. Although the 12-week follow-up allowed for the assessment of sustained effects, longer-term studies are needed to assess durability and the potential need for maintenance sessions. While the sample size was sufficient for statistical power, it may limit generalizability. The absence of psychosocial or relational assessments also restricts the interpretation of the decline in sexual satisfaction despite physiological improvements.

This was a single-center study involving a relatively young age range, with recruitment carried out through flyers and social media. These factors may limit the representativeness of the sample and, consequently, its external validity. Therefore, the findings should be generalized to other populations—such as older women, those with surgical menopause, or those with different sociodemographic profiles—should be made with caution.

Despite these limitations, the present trial provides novel and robust evidence on the potential of nonablative radiofrequency as an effective intervention for improving sexual function and vaginal health in postmenopausal women. Future studies should address these aspects with larger and more diverse samples, extended follow-up, and multidimensional outcome measures to better elucidate the long-term therapeutic potential of radiofrequency in GSM management.

Interpretation and clinical implications

Our findings contribute to the growing body of evidence supporting the efficacy of nonablative radiofrequency for the management of GSM. The improve-

ments observed in terms of vaginal health and sexual function are clinically meaningful and are consistent with the proposed mechanisms of action, including enhanced perfusion, mucosal hydration, and collagen remodeling. The absence of significant effects in the control group, together with the magnitude of change observed in the intervention group, strengthens the evidence for a genuine physiological effect beyond placebo.

Although hormonal status did not appear to influence treatment response, these findings support the notion that CRMRF may benefit a broader population of postmenopausal women, including those who are unable or unwilling to use estrogen therapy. The discrepancy between improved physiological parameters and unchanged sexual satisfaction underscores the multifaceted nature of female sexual health and highlights the importance of integrative approaches that address psychosocial and relational dimensions.

Taken together, these results suggest that CRMRF represents a promising, well-tolerated, and nonhormone therapeutic option that warrants further investigation through long-term studies with multidimensional outcome assessments. From a clinical perspective, the results also support its incorporation as a complementary therapy within the comprehensive management of GSM, particularly for women with persistent symptoms despite local treatments. Further research integrating clinical and histologic endpoints may help clarify the biological mechanisms underlying its effects.

Potential clinical value

The findings from this trial indicate that capacitive-resistive monopolar radiofrequency (CRMRF) may provide a safe and effective nonhormone approach for managing genitourinary syndrome of menopause. Improvements in sexual function and vaginal health observed after treatment were maintained at follow-up, suggesting potential clinical applicability. Further studies are warranted to confirm these results and to establish long-term outcomes.

CONCLUSION

In conclusion, this study provides compelling evidence that nonablative CRMRF is a safe, well-tolerated, and effective nonhormone intervention for improving vaginal health and sexual function in postmenopausal women with GSM, with particularly notable benefits in the reduction of dyspareunia. The therapeutic effects appear to be mediated through nonestrogenic mechanisms, including enhanced mucosal hydration, increased vascularization, and collagen remodeling, offering a viable alternative for women who are contraindicated for, or reluctant to use, hormone-based therapies. Given the favorable safety profile and clinically meaningful improvements observed, CRMRF represents a promising addition to the therapeutic armamentarium for GSM. Future research should explore long-term efficacy, optimal maintenance regimens, and integration with holistic management approaches that address the psychosocial dimensions of sexual health in this population.

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