



Journal of Integrative and Complementary Medicine: <http://mc.manuscriptcentral.com/jaltcompmed>

EFFECTIVENESS OF RADIOFREQUENCY IN PRIMARY DYSMENORRHEA: A RANDOMIZED CONTROLLED TRIAL

Journal:	<i>Journal of Integrative and Complementary Medicine</i>
Manuscript ID	Draft
Manuscript Type:	Original Article
Date Submitted by the Author:	n/a
Complete List of Authors:	García García, Beatriz; Complutense University of Madrid, Radiology, Rehabilitation and Physiotherapy Díaz-Arribas, María José; Complutense University of Madrid, Radiology, Rehabilitation and Physiotherapy; Instituto de Investigación Sanitaria del Hospital Clínico San Carlos Urraca Gesto, María Alicia; Hospital Universitario Fundación Alcorcón, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos - Campus de Alcorcón, Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine Valera Calero, Juan Antonio; Complutense University of Madrid, Radiology, Rehabilitation and Physiotherapy; Instituto de Investigación Sanitaria del Hospital Clínico San Carlos Ortiz Gutiérrez, Rosa María; Complutense University of Madrid, Radiology, Rehabilitation and Physiotherapy; Instituto de Investigación Sanitaria del Hospital Clínico San Carlos Plaza Manzano, Gustavo; Complutense University of Madrid, Radiology, Rehabilitation and Physiotherapy; Instituto de Investigación Sanitaria del Hospital Clínico San Carlos
Keywords:	physical therapy, randomized clinical trials, women's health, therapeutics
Manuscript Keywords (Search Terms):	Diathermy, Physiotherapy modalities, Primary dysmenorrhea, Radiofrequency
Abstract:	Introduction: Non-invasive, non-ablative Transfer Electrical Capacitive and Resistive (TECAR) radiofrequency has emerged as a therapeutic tool for managing pelvic pain conditions. However, research on its efficacy in pelvic floor dysfunctions remains limited. This study aimed to assess the effectiveness of TECAR radiofrequency therapy in primary

	dysmenorrhea. Methods: A randomized, single-blind controlled trial was conducted. Forty-five nulliparous women with a medical diagnosis of primary dysmenorrhea were included. Participants were randomly assigned to a transabdominal radiofrequency group, an intracavitary radiofrequency group, or a control group. The intervention groups received nine 20-minute sessions, with three sessions per week over three weeks between menstrual cycles. Pain intensity, menstrual quality of life, general quality of life, and pain pressure thresholds were assessed before the intervention, immediately after, and one-month post-intervention. Results: Both transabdominal and intracavitary radiofrequency significantly reduced pain intensity compared to the control group ($p<0.001$). Intracavitary radiofrequency achieved a greater reduction than transabdominal, though the difference was not statistically significant ($p=0.311$). Mechanical sensitivity showed no significant differences between groups ($p>0.05$) across all pressure points. Regarding quality of life, intracavitary radiofrequency significantly improved menstrual quality of life compared to the control group ($p=0.023$), while transabdominal radiofrequency did not ($p=0.176$). Differences in general quality of life were not statistically significant in any group ($p>0.05$). Conclusion: Adding transabdominal and intracavitary radiofrequency to prescribed medical treatment leads to short-term improvements in pain intensity in patients with primary dysmenorrhea, with no significant differences between the two approaches. This allows for personalized treatment based on patient comfort and preference.

SCHOLARONE™
Manuscripts

EFFECTIVENESS OF RADIOFREQUENCY IN PRIMARY DYSMENORRHEA: A RANDOMIZED CONTROLLED TRIAL

Beatriz García-García^a, María José Díaz-Arribas^{b,*}, María Alicia Urraca-Gesto^{c,d}, Juan Antonio Valera-Calero^{a,b}, Rosa María Ortiz-Gutiérrez^{a,b}, Gustavo Plaza-Manzano^{a,b}

^a*Department of Radiology, Rehabilitation and Physiotherapy, Faculty of Nursing, Physiotherapy and Podiatry, Universidad Complutense de Madrid (UCM), Madrid, Spain.*

^b*Grupo InPhysio, Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC), 28040 Madrid, Spain.*

^c*Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Alcorcon, Madrid, Spain.*

^d*Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Mostoles, Madrid, Spain.*

* Correspondence to:

María José Díaz-Arribas

Department of Radiology, Rehabilitation and Physiotherapy.

Universidad Complutense de Madrid (UCM), Madrid, Spain.

Plaza Ramón y Cajal nº 3, Ciudad Universitaria, 28040 Madrid, SPAIN

Telephone number: + 34 91 394 15 45

Email address: mjdiazar@ucm.es

Word account: 2.658 words

Number of figures: 3

Number of tables: 3

What does this study add to the clinical work: Transabdominal or intracavitary radiofrequency results in significant reductions in pain intensity for primary dysmenorrhea.

Author's ORCID: María José Díaz-Arribas (0000-0002-6231-107X); Juan Antonio Valera-Calero (0000-0002-3379-8392); Rosa María Ortiz-Gutiérrez (0000-0002-1808-0526); Gustavo Plaza-Manzano (0000-0003-1596-5027).

**EFFECTIVENESS OF RADIOFREQUENCY IN PRIMARY
DYSMENORRHEA: A RANDOMIZED CONTROLLED TRIAL**

ABSTRACT

Introduction: Non-invasive, non-ablative Transfer Electrical Capacitive and Resistive (TECAR) radiofrequency has emerged as a therapeutic tool for managing pelvic pain conditions. However, research on its efficacy in pelvic floor dysfunctions remains limited. This study aimed to assess the effectiveness of TECAR radiofrequency therapy in primary dysmenorrhea.

Methods: A randomized, single-blind controlled trial was conducted. Forty-five nulliparous women with a medical diagnosis of primary dysmenorrhea were included. Participants were randomly assigned to a transabdominal radiofrequency group, an intracavitary radiofrequency group, or a control group. The intervention groups received nine 20-minute sessions, with three sessions per week over three weeks between menstrual cycles. Pain intensity, menstrual quality of life, general quality of life, and pain pressure thresholds were assessed before the intervention, immediately after, and one-month post-intervention.

Results: Both transabdominal and intracavitary radiofrequency significantly reduced pain intensity compared to the control group ($p<0.001$). Intracavitary radiofrequency achieved a greater reduction than transabdominal, though the difference was not statistically significant ($p=0.311$). Mechanical sensitivity showed no significant differences between groups ($p>0.05$) across all pressure points. Regarding quality of life, intracavitary radiofrequency significantly improved menstrual quality of life compared to the control group ($p=0.023$), while

transabdominal radiofrequency did not ($p=0.176$). Differences in general quality of life were not statistically significant in any group ($p>0.05$).

Conclusion: Adding transabdominal and intracavitary radiofrequency to prescribed medical treatment leads to short-term improvements in pain intensity in patients with primary dysmenorrhea, with no significant differences between the two approaches. This allows for personalized treatment based on patient comfort and preference.

Keywords: Diathermy; Physiotherapy modalities; Primary dysmenorrhea; Radiofrequency.

Article Type: Research report

Trial Registration number: NCT06200506 (Date: 8 August 2024)

**EFFECTIVENESS OF RADIOFREQUENCY IN PRIMARY DYSMENORRHEA: A
RANDOMIZED CONTROLLED TRIAL**

INTRODUCTION

Primary dysmenorrhea is a gynecological condition characterized by menstrual pain [1] in the absence of organic pathology (Fernández-Martínez et al, 2022; Fernández-Martínez, Onieva-Zafra, and Parra-Fernández, 2018; Karout et al, 2021). The main symptom is pelvic and/or abdominal pain, which may radiate to the lumbar region or lower extremities [5]. This condition negatively impacts quality of life, academic or work performance, and social well-being [1, 4, 6]. The global prevalence of primary dysmenorrhea ranges from 13% and 95% [4–6] with 2-29% of women experiencing severe pain.

Diagnosis is made by excluding other pathologies that could cause menstrual pain. However, a significant number of women do not seek gynaecological consultation for appropriate diagnosis and treatment, [4, 6] often resorting to self-medication [7].

Currently, menstrual pain is primarily managed pharmacologically. Due to increasing demand from women seeking alternatives, interest in non-pharmacological treatments has grown [3]. Various clinical trials [1, 5, 8–14] have analyzed the efficacy of non-pharmacological interventions in primary dysmenorrhea [15–18].

One emerging technique in clinical practice is non-ablative radiofrequency or diathermy. Transfer Electrical Capacitive and Resistive (TECAR) radiofrequency therapy generates high-frequency waves, typically ranging from 0.8 to 1.5 MHz (Kumaran & Watson, 2015; Rodríguez Sanz et al., 2022). Although its applications in different body regions have been tested (Beltrame et al, 2020; Carralero-Martínez et al, 2022; González-Gutiérrez et al, 2022; Li et al, 2024), no

studies have specifically evaluated its effectiveness in primary dysmenorrhea. Therefore, this study aims to determine the efficacy of radiofrequency in the treatment of primary dysmenorrhea.

MATERIALS AND METHODS

Study design

A randomized and single-blinded controlled clinical trial was conducted to compare the effects of nine sessions of transabdominal radiofrequency, intracavitary radiofrequency or “wait and see” in patients with primary dysmenorrhea. This clinical Trial was conducted in the Physiotherapy wards of the Faculty of Nursing, Physiotherapy, and Podiatry at the Complutense University of Madrid between January and July 2024. The study was evaluated and approved by the Ethics Committee of the San Carlos Clinical Hospital with internal code 22/006-EC_P and was registered in Clinical Trials with registration number NCT06200506. The clinical trial was carried out following the guidelines of the CONSolidated Standards Of Reporting Trials (CONSORT) 2010 statement [25] and the Enhancing the QUALity and Transparency Of health Research (EQUATOR) guidelines for improving the quality and transparency of health research.[26]

Participants

Fifty-two women diagnosed with primary dysmenorrhea who had experienced menstrual pain in most cycles over the past year were recruited. Eligibility criteria included being 18-35 years old, nulliparous, and having regular menstrual cycles, [27] with pain during menstruation or the 48 hours preceding it.

Exclusion criteria included the use of hormonal intrauterine devices, recent abdominal or pelvic surgery, secondary dysmenorrhea, pregnancy, recent physiotherapy treatment for menstrual

1
2
3 74 pain, or contraindications to diathermy (e.g., metallic implants, uncontrolled cancer, active
4
5 75 infections, fever, or skin wounds).
6

7
8 76 Data collection started on 20 May 2024 and was completed on 20 July 2024. Participants
9
10 77 were not involved in the design, conduct, reporting or dissemination plans of our research.
11
12

13
14 78 Randomization and masking
15

16 79 Participants were randomly assigned to transabdominal radiofrequency, intracavitary
17
18 80 radiofrequency or control group using a pre-generated randomization table developed specifically
19
20 81 for this study(Kim and Shin, 2014). Allocation was concealed using sequentially numbered,
21
22 82 opaque sealed envelopes. One researcher, not involved in evaluation or intervention, conducted
23
24 83 the random assignment. Patients were blinded to their assigned intervention.
25
26
27
28

29 84 Interventions
30
31

32 85 Each group continued with their prescribed medical-pharmacological regimen provided by
33
34 86 their family physician. Intervention groups (transabdominal and intracavitary modalities) received
35
36 87 9 sessions of 20 minutes each, three times per week over three weeks between menstrual cycles
37
38 88 while the control group followed standard medical management. A TECAR therapy device
39
40 89 (Capenergy Urogyne CM500, by capener medical, S.L.) designed for Uro-Gynecological
41
42 90 Physiotherapy was used.
43
44

45 91 The transabdominal radiofrequency group received treatment with an active electrode
46
47 92 placed over the suprapubic and infraumbilical area (**Figure 1 A**), and a passive plate positioned at
48
49 93 the sacral level. Both plates were secured with a standard strap. The intracavitary radiofrequency
50
51 94 group received vaginal RF application using a probe manipulated by the physiotherapist (**Figure**
52
53 95 **1B**), with the passive plate at the sacral level.
54
55
56
57
58
59
60

[Figure 1A and Figure 1B]

Outcomes

Assessments were conducted at baseline, immediately post-intervention, and one-month post-intervention. The baseline assessment took place after the end of menstrual bleeding. The first post-intervention assessment was performed immediately after the completion of treatment and the first subsequent menstrual bleeding, while the second post-intervention assessment followed the second menstrual bleeding. Each of the three assessments was carried out by an investigator blinded to the intervention and patient randomization.

Prior to the follow-up assessments, patients were contacted by phone. If they confirmed their willingness to participate, they were scheduled for an in-person interview at the physiotherapy rooms of the Department in the days following the end of their menstrual bleeding. During this interview, participants were provided with a physical copy of the information sheet, informed consent form, and confidentiality/privacy agreement.

At baseline, a standardized medical history was collected, including sociodemographic data and prescribed pharmacological treatments. Additionally, pain intensity, menstrual quality of life, general quality of life, and pain pressure thresholds in the pelvic region were measured.

Pain was considered the primary outcome variable. The Numeric Pain Rating Scale (NPRS) was utilized to subjectively assess pain intensity, as supported by several systematic reviews for clinical and research settings [29, 30]. Women were asked to graphically indicate their pain intensity during menstruation on a segmented, numbered scale from 1 to 10, where “0” represented no pain and “10” indicated the worst possible pain (Farrar et al, 2001). Scores below 3.4 were classified as mild pain, scores between 3.5 and 6.4 as moderate pain, and scores above 6.5 as severe pain [32].

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Secondary outcome variables included quality of life during menstruation, general quality of life and pelvic pressure pain thresholds.

Menstrual quality of life was assessed using the previously validated Spanish version of the CVM-22 questionnaire. This questionnaire scores between 0 and 66 points, with higher scores indicating worse menstrual quality of life [33]. On the other hand, general quality of life was evaluated using the SF-12 health questionnaire.[34].

To assess deep muscular tissue sensitivity, pressure pain thresholds (PPTs) were measured. This test determines the amount of pressure applied to a specific area at which a steadily increasing, non-painful pressure stimulus turns into a painful sensation. A varying pressure of 0.5 to 1 kg/sec was applied perpendicularly to the muscle. Assessments were conducted at three points in the typical painful locations described in a previous study[35, 36]: one in the suprapubic area and two at the reference points of the right and left internal oblique muscles, located one centimetre inward from the right and left anterosuperior iliac spine. These measurements were recorded using a digital algometer Commander by Jtech Medical.

Sample size calculation

To estimate the effect size for the sample size calculation, a pilot trial was conducted with 15 participants (5 per group). Following the completion of the pilot study, the minimum sample size required for this study was calculated using G*POWER software (version 3.1.9.7).

For this calculation, a repeat measure MANOVA was employed. In the a priori analysis, we specified 3 groups and 3 measurements, an effect size of $f(V)=0.4$, a two-tailed significance level (α) of 0.05, and a desired power level of 80% ($\beta = 0.20$). This analysis indicated that a total sample size of 40 participants would be necessary. To account for potential attrition

141 due to the longitudinal nature of the study, an additional 10% was added to the sample size to
142 mitigate participant dropouts.

143 Statistical analysis

144 All statistical analyses were conducted using the Statistical Package for the Social Sciences
145 (SPSS) version 25 (IBM Corporation, Armonk, NY, USA), with a significance level set at $p < 0.05$.
146 Data normality was verified prior to analysis, and descriptive statistics were used to summarize
147 the data. Normally distributed data were presented as means, standard deviations (SD), and 95%
148 confidence intervals (CI). Between-group comparability at baseline was assessed using a
149 multivariate lineal general model for continuous variables.

150 Since an analysis of covariance (ANCOVA) using baseline values as covariates has been
151 shown to be more powerful than repeated-measures analysis of variance (RM ANOVA) when
152 random group assignment is used[37], a general linear model was employed for evaluating the
153 effects of the interventions. A 3×3 mixed-design ANOVA was applied, with time (pre-
154 intervention, post-intervention, and follow-up) as the within-subjects factor and group (control
155 group, transabdominal radiofrequency group and intracavitary radiofrequency group) as the
156 between-subjects factor. Interaction effects (group*time) were assessed to determine if the groups
157 changed differently over time.

158 Given the presence of multiple primary outcomes, a Bonferroni correction was applied to
159 adjust the significance level. For group comparisons, the significance threshold was set at $p < 0.016$
160 ($0.05/3$), and for time effects at $p < 0.016$ ($0.05/3$). The group-by-time interaction was adjusted
161 to $p < 0.0083$ ($0.05/6$). Post-hoc pairwise comparisons were conducted to explore specific
162 differences between and within groups when interaction effects were significant [38].

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Effect sizes were calculated using partial eta squared (η^2) to quantify the magnitude of differences. Values of $\eta^2=0.01$ were interpreted as small, $\eta^2=0.06$ as medium, and $\eta^2=0.14$ as large [39].

RESULTS

Initially, 52 individuals were assessed for eligibility. Of these, 7 were excluded (6 for not meeting the selection criteria and 1 for declining participation). No additional reasons for exclusion were reported. This resulted in 45 participants being randomized into one of three groups, with 15 participants assigned to each. There were no losses to follow-up, no intervention interruptions, and no participants excluded from the analysis. **Figure 2** illustrates the process of participant selection, randomization, and analysis of the three study groups.

[Figure 2]

Baseline sociodemographic and clinical characteristics of the three groups (**Table 1**) showed no significant differences, supporting their comparability in sociodemographic terms. Similarly, no significant differences were observed in clinical characteristics at baseline (all, $p>0.016$).

[Table 1]

Tables 2 and 3 present the results of the general linear model analysis for pain intensity, pressure pain thresholds, menstrual quality of life, and general quality of life as measured by the SF-12 physical and mental domains, summarizing the ANOVA interaction effects (**Table 2**) and providing pairwise comparisons between the three groups post-intervention and at follow-up (**Table 3**).

[Table 2 and Table 3]

Regarding pain intensity, a significant group-by-time interaction effect was found ($p < 0.001$), indicating that pain intensity evolved differently across groups over time. Pairwise comparisons revealed significant post-intervention reductions in pain for the transabdominal radiofrequency group compared to the control group ($p = 0.011$) and for the intracavitary radiofrequency group compared to the control ($p < 0.001$). At follow-up, both the transabdominal ($p < 0.001$) and intracavitary radiofrequency groups ($p < 0.001$) maintained significantly lower pain levels than the control, demonstrating sustained pain reduction in both radiofrequency groups.

For pressure pain thresholds, no significant group-by-time interaction effects were detected after adjusting the significance level to 0.0083. The interaction effect for PPT1 was non-significant ($p = 0.959$), indicating consistent PPT1 values across all groups. Pairwise comparisons showed no significant differences between groups post-intervention or at follow-up ($p > 0.05$) for PPT SP, PPT IO-R ($p = 0.950$), and PPT IO-L ($p = 0.886$), with similar results across all time points.

Regarding menstrual quality of life, there was a trend toward a group-by-time interaction effect ($p = 0.026$), though it did not reach the adjusted significance threshold of 0.0083. However, pairwise comparisons at follow-up revealed a significant improvement in the intracavitary radiofrequency group compared to the control ($p = 0.023$), suggesting greater enhancement in menstrual quality of life for this group.

For general quality of life as measured by the SF-12 physical domain, the group-by-time interaction effect was not significant ($p = 0.941$), indicating no substantial differences in physical quality of life changes among the groups over time. Pairwise comparisons showed no significant differences post-intervention or at follow-up. Similarly, for the SF-12 mental domain, neither the group-by-time interaction ($p = 0.543$) nor the pairwise comparisons ($p > 0.05$) revealed significant differences between groups over time.

208 **DISCUSSION**

209 This trial is the first to evaluate the efficacy of radiofrequency therapy for menstrual pain.
210 To date, only one clinical trial has examined the use of radiofrequency for chronic pelvic pain
211 syndrome, yielding favourable results similar to ours [23]. Following the intervention, both groups
212 experienced a 2.7-point decrease in NPRS scores. One month later, the transabdominal group
213 showed a 3.7-point reduction, while the intracavitary group exhibited a more pronounced decrease
214 of 4.3 points from baseline.

215 The most relevant results obtained in this study need to be analyze separately, first
216 discussing the TECAR effectiveness versus prescribed medical-pharmacological regimen for
217 improving pain intensity, mechanical sensitivity, and quality of life and secondly comparing the
218 efficacy of transabdominal and intracavitary modalities.

219 Regarding pain reduction, both radiofrequency techniques demonstrated significant
220 improvements compared to the control group. However, intracavitary radiofrequency resulted in a
221 more pronounced and sustained decrease in pain over time compared to the transabdominal
222 approach. In terms of mechanical sensitivity, changes were less consistent across the different
223 pressure points assessed. While there were trends of improvement in the intervention groups, these
224 did not always reach statistical significance when compared to the control group. Concerning
225 quality of life, both radiofrequency methods led to improvements in the evaluated indicators, with
226 a more notable impact on certain functional and emotional aspects compared to the control group.

227 When comparing the efficacy of intracavitary versus transabdominal radiofrequency, the
228 intracavitary approach tended to provide greater benefits in pain reduction and some aspects of
229 quality of life. However, the differences between the two techniques were not always significant

230 across all analyzed variables, suggesting that both methods can be effective, with potential
231 advantages depending on the type of application.

232 Since limited evidence is available analyzing the TECAR effectiveness for this clinical
233 condition, a direct comparison between our results with previous research is not possible.
234 However, an indirect comparison of pain intensity, mechanical sensitivity, and quality of life
235 effects with previous research for other pelvic floor disorders may be of interest. For instance, the
236 latest systematic review on radiofrequency [24] includes only two studies where pain intensity was
237 the primary symptom: one on postpartum perineal pain [40] and another on dyspareunia [41].
238 Unlike our findings, these studies did not report significant improvements in pain intensity with
239 radiofrequency treatment. However, the same review includes a prospective study on pelvic pain
240 that documented a 3.52-point improvement on the VAS scale [42]

241 Limitations

242 Although the findings of this study are promising for the application of radiofrequency in
243 primary dysmenorrhea, certain limitations should be acknowledged. First, the nature of the
244 treatment does not allow for double-blinded masking. Second, primary dysmenorrhea has a
245 multifactorial aetiology influenced by numerous lifestyle factors that are difficult to control within
246 the study framework. Finally, only short-term follow-up was conducted. Future research is needed
247 to determine whether the observed short-term benefits persist over time and whether
248 radiofrequency therapy could contribute to a reduction in the use of analgesic and anti-
249 inflammatory medications.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

250 **CONCLUSION**

251 The findings of our study suggest that incorporating either transabdominal or intracavitary
252 radiofrequency for the treatment of primary dysmenorrhea results in significant short-term
253 reductions in pain intensity, with no notable differences between the two interventions. Regarding
254 menstrual quality of life, only the intracavitary group showed a significant improvement. However,
255 no differences were observed between groups in general quality of life or pelvic region pain
256 pressure thresholds.

257
258
259 **Authors' Contributions:** *Beatriz García-García:* Protocol/project development. Data collection
260 or management. *María José Díaz-Arribas:* Protocol/project development. Manuscript
261 writing/editing. *María Alicia Urraca-Gesto:* Protocol/project development. Data collection or
262 management. *Juan Antonio Valera-Calero:* Data analysis. Validation. *Rosa María Ortiz-*
263 *Gutiérrez:* Data analysis. Supervision. *Gustavo Plaza-Manzano:* Protocol/project development.
264 Manuscript writing/editing.

265 REFERENCES

- 266 1. López-Liria R, Torres-álamo L, Vega-Ramírez FA, et al (2021) Efficacy of physiotherapy
267 treatment in primary dysmenorrhea: A systematic review and meta-analysis. *Int J Environ*
268 *Res Public Health* 18:. <https://doi.org/10.3390/ijerph18157832>
- 269 2. Fernández-Martínez E, Onieva-Zafra MD, Parra-Fernández ML (2018) Lifestyle and
270 prevalence of dysmenorrhea among Spanish female university students. *PLoS One* 13:.
271 <https://doi.org/10.1371/journal.pone.0201894>
- 272 3. Fernández-Martínez E, Pérez-Corrales J, Palacios-Ceña D, et al (2022) Pain management
273 and coping strategies for primary dysmenorrhea: A qualitative study among female
274 nursing students. *Nurs Open* 9:637–645. <https://doi.org/10.1002/nop2.1111>
- 275 4. Karout S, Soubra L, Rahme D, et al (2021) Prevalence, risk factors, and management
276 practices of primary dysmenorrhea among young females. *BMC Womens Health* 21:.
277 <https://doi.org/10.1186/s12905-021-01532-w>
- 278 5. Manisha U, Anuradha L (2021) Effect of high frequency transcutaneous electrical nerve
279 stimulation at root level menstrual pain in primary dysmenorrhea. *J Bodyw Mov Ther*
280 26:108–112. <https://doi.org/10.1016/j.jbmt.2020.12.025>
- 281 6. Ramos-Pichardo JD, Ortega-Galán ÁM, Iglesias-López MT, et al (2020) Why do some
282 Spanish nursing students with menstrual pain fail to consult healthcare professionals? *Int J*
283 *Environ Res Public Health* 17:1–14. <https://doi.org/10.3390/ijerph17218173>
- 284 7. Barcikowska Z, Rajkowska-Labon E, Grzybowska ME, et al (2020) Inflammatory
285 markers in dysmenorrhea and therapeutic options. *Int J Environ Res Public Health* 17

1
2
3 286 8. Abd A, Thabet EM, Elsodany AM, et al (2017) High-intensity laser therapy versus pulsed
4
5 287 electromagnetic field in the treatment of primary dysmenorrhea. J Phys Ther Sci 29:1742–
6
7 288 1748. <https://doi.org/10.1589/JPTS.29.1742>
8
9
10
11 289 9. Perez-Machado AF, Rodrigues-Perracini M, Rampazo ÉP, et al (2019) Effects of
12
13 290 thermotherapy and transcutaneous electrical nerve stimulation on patients with primary
14
15 291 dysmenorrhea: A randomized, placebo-controlled, double-blind clinical trial. Complement
16
17 292 Ther Med 47:. <https://doi.org/10.1016/j.ctim.2019.08.022>
18
19
20
21 293 10. Özgül S, Üzelpasaci E, Orhan C, et al (2018) Short-term effects of connective tissue
22
23 294 manipulation in women with primary dysmenorrhea: A randomized controlled trial.
24
25 295 Complement Ther Clin Pract 33:1–6. <https://doi.org/10.1016/j.ctcp.2018.07.007>
26
27
28 296 11. Celenay ST, Kavalci B, Karakus A, Alkan A (2020) Effects of kinesio tape application on
29
30 297 pain, anxiety, and menstrual complaints in women with primary dysmenorrhea: A
31
32 298 randomized sham-controlled trial. Complement Ther Clin Pract 39:.
33
34 299 <https://doi.org/10.1016/j.ctcp.2020.101148>
35
36
37
38 300 12. McLagan B, Dexheimer J, Strock N, et al (2024) The role of transcutaneous electrical
39
40 301 nerve stimulation for menstrual pain relief: A randomized control trial. Womens Health
41
42 302 (Lond) 20:. <https://doi.org/10.1177/17455057241266455>
43
44
45 303 13. Guy M, Foucher C, Juhel C, et al (2022) Transcutaneous electrical neurostimulation
46
47 304 relieves primary dysmenorrhea: A randomized, double-blind clinical study versus placebo.
48
49 305 Progres en Urologie 32:487–497. <https://doi.org/10.1016/j.purol.2022.01.005>
50
51
52
53
54
55
56
57
58
59
60

14. Özgül S, Çinar GN, Gürşen C, et al (2023) The Effects of Connective Tissue Manipulation in Primary Dysmenorrhea: a Randomized Placebo-Controlled Study. *Reproductive Sciences* 30:181–191. <https://doi.org/10.1007/s43032-022-00964-5>
15. Sharma S, Ali K, Narula H, et al (2023) Exercise Therapy and Electrotherapy as an Intervention for Primary Dysmenorrhea: A Systematic Review and Meta-Analysis. *J Lifestyle Med* 13:16–26. <https://doi.org/10.15280/jlm.2023.13.1.16>
16. Šabec L, Golob I, Kozinc Ž (2024) The effects of taping in the management of primary dysmenorrhoea: A systematic review with meta-analysis. *European Journal of Obstetrics and Gynecology and Reproductive Biology* 296:148–157
17. Han S, Park KS, Lee H, et al (2024) Transcutaneous electrical nerve stimulation (TENS) for pain control in women with primary dysmenorrhoea. *Cochrane Database Syst Rev* 7:CD013331. <https://doi.org/10.1002/14651858.CD013331.pub2>
18. Abaraogu UO, Igwe SE, Tabansi-Ochiogu CS, Duru DO (2017) A Systematic Review and Meta-Analysis of the Efficacy of Manipulative Therapy in Women with Primary Dysmenorrhea. *Explore* 13:386–392
19. Kumaran B, Watson T (2015) Thermal build-up, decay and retention responses to local therapeutic application of 448 kHz capacitive resistive monopolar radiofrequency: A prospective randomised crossover study in healthy adults. *International Journal of Hyperthermia* 31:883–895
20. Rodríguez Sanz J, López-de-Celis C, Hidalgo-García C, et al (2022) Efectos de la terapia Tecar en lesiones deportivas de la extremidad inferior: Estudios en cadáver. In: II Congrés internacional de Fisioterapia. Group SBD

1
2
3 328 21. Beltrame R, Ronconi G, Ferrara PE, et al (2020) Capacitive and resistive electric transfer
4
5 329 therapy in rehabilitation: a systematic review. International Journal of Rehabilitation
6
7 330 Research 43:291–298
8
9
10
11 331 22. Li D, Li M, Wu G, et al (2024) Evaluating the Effectiveness of Radiofrequency Therapy
12
13 332 and Manual Pelvic Fascial Release in Treating Myofascial Pelvic Pain. Int Urogynecol J
14
15 333 35:1219–1225. <https://doi.org/10.1007/s00192-024-05763-x>
16
17
18 334 23. Carralero-Martínez A, Muñoz-Pérez MA, Kauffmann S, et al (2022) Efficacy of
19
20 335 capacitive resistive monopolar radiofrequency in the physiotherapeutic treatment of
21
22 336 chronic pelvic pain syndrome: A randomized controlled trial. Neurourol Urodyn 41:962–
23
24 337 972. <https://doi.org/10.1002/nau.24903>
25
26
27
28 338 24. González-Gutiérrez MD, López-Garrido Á, Cortés-Pérez I, et al (2022) Effects of Non-
29
30 339 Invasive Radiofrequency Diathermy in Pelvic Floor Disorders: A Systematic Review.
31
32 340 Medicina (Lithuania) 58
33
34
35
36 341 25. Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 Statement: updated guidelines
37
38 342 for reporting parallel group randomised trials. BMJ 340:. <https://doi.org/10.1136/bmj.c332>
39
40
41 343 26. Faggion CM (2020) EQUATOR reporting guidelines should also be used by clinicians. J
42
43 344 Clin Epidemiol 117:149–150
44
45
46 345 27. Marnach ML, Laughlin-Tommaso SK (2019) Evaluation and Management of Abnormal
47
48 346 Uterine Bleeding. Mayo Clin Proc 94:326–335
49
50
51 347 28. Kim J, Shin W (2014) How to do random allocation (randomization). Clin Orthop Surg
52
53 348 6:103–109. <https://doi.org/10.4055/CIOS.2014.6.1.103>
54
55
56
57
58
59
60

- 349 29. Karcioglu O, Topacoglu H, Dikme O, Dikme O (2018) A systematic review of the pain
350 scales in adults: Which to use? *American Journal of Emergency Medicine* 36:707–714
- 351 30. Hjermstad MJ, Fayers PM, Haugen DF, et al (2011) Studies comparing numerical rating
352 scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in
353 adults: A systematic literature review. *J Pain Symptom Manage* 41:1073–1093
- 354 31. Farrar JT, Young JP, Lamoreaux L, et al (2001) Clinical importance of changes in chronic
355 pain intensity measured on an 11-point numerical pain rating scale. *Pain* 92:149–158.
356 [https://doi.org/10.1016/S0304-3959\(01\)00349-9](https://doi.org/10.1016/S0304-3959(01)00349-9)
- 357 32. Walk D, Poliak-Tunis M (2016) Chronic Pain Management: An Overview of Taxonomy,
358 Conditions Commonly Encountered, and Assessment. *Medical Clinics of North America*
359 100:1–16. <https://doi.org/10.1016/J.MCNA.2015.09.005>
- 360 33. Torres-Pascual C, Torrell-Vallespín S, Mateos-Pedreño E, García-Serra J (2019)
361 Desarrollo y validación del cuestionario específico de calidad de vida relacionada con la
362 menstruación CVM-22. *Revista Cubana de Obstetricia y Ginecología* 45:
- 363 34. Geraerds AJLM, Richardson A, Haagsma J, et al (2020) A systematic review of studies
364 measuring health-related quality of life of general injury populations: update 2010–2018.
365 *Health Qual Life Outcomes* 18:160. <https://doi.org/10.1186/S12955-020-01412-1>
- 366 35. Machado AFP, Perracini MR, Rampazo ÉP, et al (2019) Effects of thermotherapy and
367 transcutaneous electrical nerve stimulation on patients with primary dysmenorrhea: A
368 randomized, placebo-controlled, double-blind clinical trial. *Complement Ther Med* 47:.
369 <https://doi.org/10.1016/j.ctim.2019.08.022>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

36. Deodato M, Grosso G, Drago A, et al (2023) Efficacy of manual therapy and pelvic floor exercises for pain reduction in primary dysmenorrhea: A prospective observational study. *J Bodyw Mov Ther* 36:185–191. <https://doi.org/10.1016/j.jbmt.2023.07.002>

37. Van Breukelen GJP (2006) ANCOVA versus change from baseline: more power in randomized studies, more bias in nonrandomized studies [corrected]. *J Clin Epidemiol* 59:920–925. <https://doi.org/10.1016/J.JCLINEPI.2006.02.007>

38. Liqueur B, Riou J (2013) Correction of the significance level when attempting multiple transformations of an explanatory variable in generalized linear models. *BMC Med Res Methodol* 13:. <https://doi.org/10.1186/1471-2288-13-75>

39. Morris PE, Fritz CO (2013) Effect sizes in memory research. *Memory* 21:832–842. <https://doi.org/10.1080/09658211.2013.763984>

40. Bretelle F, Fabre C, Golka M, et al (2020) Capacitive-resistive radiofrequency therapy to treat postpartum perineal pain: A randomized study. *PLoS One* 15:. <https://doi.org/10.1371/journal.pone.0231869>

41. Leibaschoff G, Gonzalez-Izasa P, Cardona JL, et al (2016) Transcutaneous Temperature Controlled Radiofrequency (TTCRF) for the Treatment of Menopausal Vaginal/Genitourinary Symptoms - PubMed. *Surg Technol Int* 149–159

42. Fernández-Cuadros ME, Kazlauskas SG, Albaladejo-Florin MJ, et al (2020) [Effectiveness of multimodal rehabilitation (biofeedback plus capacitive-resistive radiofrequency) on chronic pelvic pain and dyspareunia: prospective study and literature review]. *Rehabilitacion (Madr)* 54:154–161. <https://doi.org/10.1016/J.RH.2020.02.005>

DISCLOSURES

Funding: The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

Competing interest: The authors have no relevant financial or non-financial interests to disclose.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by Research Ethics Committee of San Carlos Clinical Hospital with (ID: 22/006-EC_P).

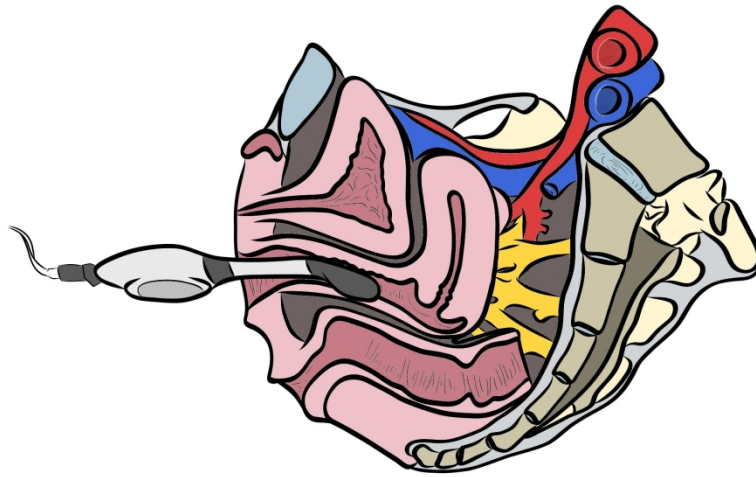
Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data availability: The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Patient and Public Involvement Statement: Participants were not involved in the design, conduct, reporting or dissemination plans of our research.



Transabdominal radiofrequency application
1276x848mm (72 x 72 DPI)



B

Intracavitary vaginal radiofrequency application

963x722mm (72 x 72 DPI)

Figure 2. Flow Chart showing study design.

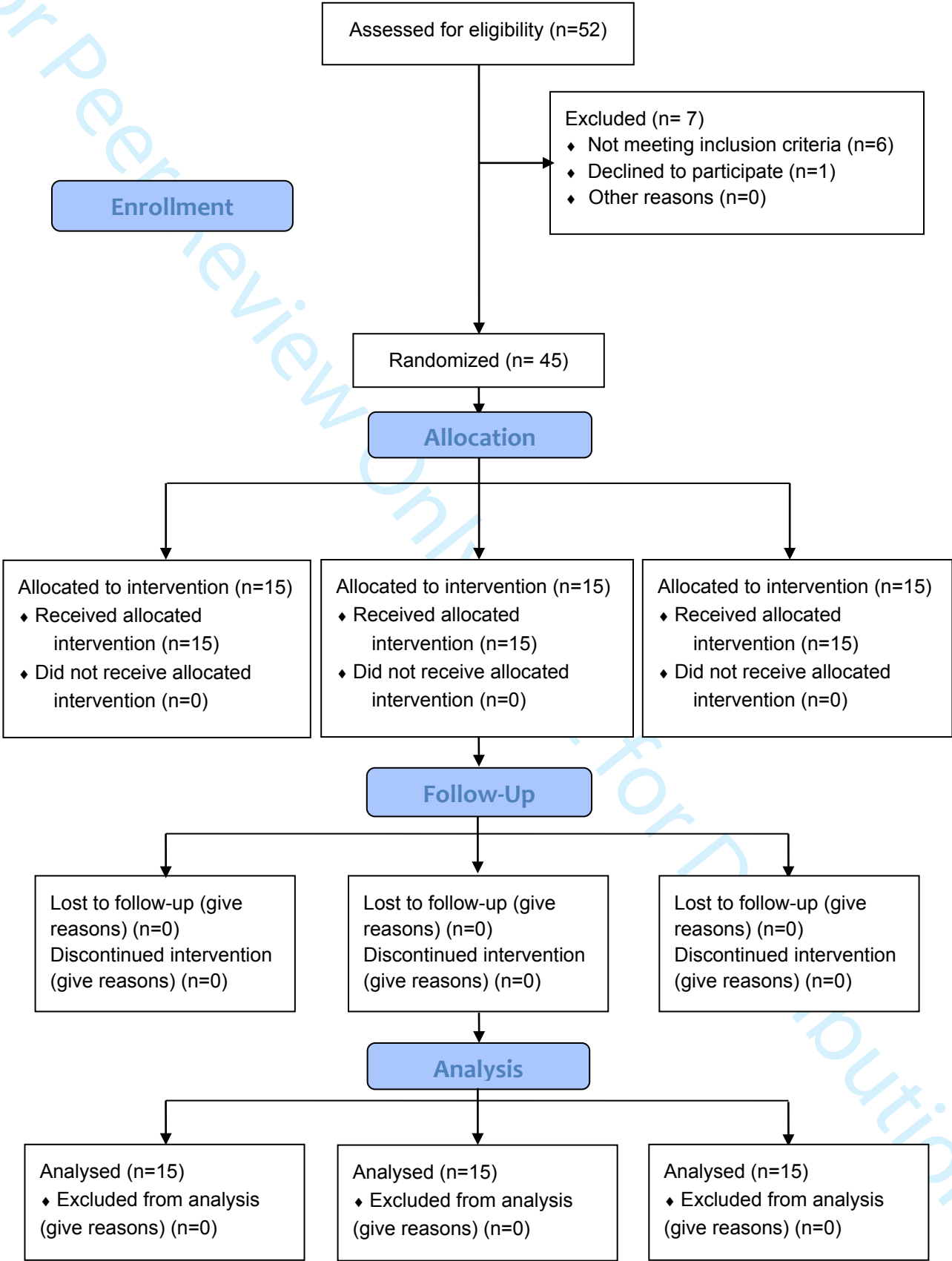


Figure captions

- Figure 1A: Transabdominal radiofrequency application.
- Figure 1B: Intracavitary vaginal radiofrequency application.
- Figure 2. Flow Chart showing study design.

Table 1. Baseline sociodemographic characteristics of the sample described by intervention groups.

	Control Group (n=15)	Transabdominal Radiofrequency (n=15)	Intracavitary Radiofrequency (n=15)	Between-Group Differences
Demographic Characteristics				
Age	28.0 ± 5.8	22.6 ± 4.4	25.8 ± 5.5	F=3.945; P=0.027
Height	1.67 ± 0.07	1.63 ± 0.06	1.64 ± 0.07	F=0.901; P=0.414
Weight	57.2 ± 6.5	57.1 ± 5.9	58.0 ± 8.0	F=0.082; P=0.922
BMI	20.5 ± 2.4	21.3 ± 2.2	21.3 ± 2.1	F=0.626; P=0.540
Clinical Characteristics				
NPRS (0-10)	7.2 ± 1.5	7.6 ± 1.4	6.9 ± 1.4	F=0.726; P=0.490
PPT SP (kg/cm²)	22.2 ± 5.8	22.9 ± 5.1	22.4 ± 7.1	F=0.053; P=0.945
PPT IO-R (kg/cm²)	24.2 ± 7.8	25.3 ± 6.1	24.3 ± 10.6	F=0.077; P=0.926
PPT IO-L (kg/cm²)	22.6 ± 5.7	26.7 ± 6.2	21.6 ± 7.7	F=0.369; P=0.694
CVM	39.1 ± 8.4	44.0 ± 5.6	40.6 ± 7.0	F=1.887; P=0.164
SF-12 PD	48.8 ± 8.4	50.4 ± 5.4	50.3 ± 5.5	F=0.268; P=0.766
SF-12 MD	47.3 ± 7.7	44.5 ± 8.8	46.6 ± 10.8	F=0.395; P=0.676

Abbreviations: BMI: Body Mass Index; NPRS: Numerical Pain Rating Scale; PPT SP: Pressure Pain Threshold Supra Pubic; PPT IO-R: Pressure Pain Threshold Internal Oblique-Right; PPT IO-L: Pressure Pain Threshold Internal Oblique-Left; CVM: Quality of Live in Menstruation; SF-12 PD: SF-12 Physical Dimension; SF-12 MD: SF-12 Mental Dimension.

Table 2. Differential analyses between groups for pain intensity, quality of life and mechanosensitivity.

	Control Group (n=15)			Transabdominal Radiofrequency (n=15)			Intracavitary Radiofrequency (n=15)			Between-Group Differences		
	Baseline	Post-intervention	Follow-up	Baseline	Post-intervention	Follow-up	Baseline	Post-intervention	Follow-up	Group*Time	Group	Time
<i>Pain Intensity</i>												
NPRS (0-10)	7.2 ± 1.5	7.2 ± 1.3	7.1 ± 1.8	7.6 ± 1.4	4.9 ± 2.3	3.9 ± 2.1	6.9 ± 1.4	4.2 ± 2.3	2.6 ± 1.9	F=6.227 $\eta_p^2=0.290$ P<0.001	F=23.676 $\eta_p^2=0.276$ P<0.001	F=25.372 $\eta_p^2=0.290$ P<0.001
<i>PPT</i>												
PPT SP (kg/cm ²)	22.2 ± 5.8	22.4 ± 5.6	21.8 ± 5.2	22.9 ± 5.1	25.4 ± 6.2	24.6 ± 4.9	22.4 ± 7.1	23.5 ± 7.5	22.8 ± 7.3	F=0.157 $\eta_p^2=0.005$ P=0.959	F=1.378 $\eta_p^2=0.022$ P=0.256	F=0.468 $\eta_p^2=0.007$ P=0.627
PPT IO-R (kg/cm ²)	24.2 ± 7.8	23.9 ± 7.8	24.5 ± 7.4	25.3 ± 6.1	28.3 ± 7.8	28.4 ± 7.3	24.3 ± 10.6	26.3 ± 10.2	26.7 ± 8.6	F=0.176 $\eta_p^2=0.006$ P=0.950	F=1.547 $\eta_p^2=0.024$ P=0.217	F=0.661 $\eta_p^2=0.011$ P=0.518
PPT IO-L (kg/cm ²)	22.6 ± 5.7	22.6 ± 5.8	22.3 ± 5.1	26.7 ± 6.2	27.0 ± 9.6	26.2 ± 6.6	21.6 ± 7.7	23.1 ± 7.8	23.6 ± 7.5	F=0.287 $\eta_p^2=0.009$ P=0.886	F=2.889 $\eta_p^2=0.045$ P=0.059	F=0.683 $\eta_p^2=0.011$ P=0.507
<i>Quality of life</i>												
CVM	39.1 ± 8.4	36.6 ± 7.8	35.7 ± 7.5	44.0 ± 5.6	32.1 ± 5.2	31.1 ± 5.6	40.6 ± 7.0	31.6 ± 5.7	29.1 ± 6.1	F=2.864 $\eta_p^2=0.085$ P=0.026	F=25.372 $\eta_p^2=0.290$ P<0.001	F=24.975 $\eta_p^2=0.287$ P<0.001
SF-12 PD	48.8 ± 8.4	49.0 ± 5.8	48.9 ± 7.7	50.4 ± 5.4	51.9 ± 6.7	52.5 ± 5.0	50.3 ± 5.5	50.6 ± 6.3	51.5 ± 6.2	F=0.194 $\eta_p^2=0.006$ P=0.941	F=2.630 $\eta_p^2=0.041$ P=0.076	F=0.764 $\eta_p^2=0.012$ P=0.468
SF-12 MD	47.3 ± 7.7	45.3 ± 9.0	49.0 ± 6.0	44.5 ± 8.8	49.6 ± 10.6	51.0 ± 7.2	46.6 ± 10.8	49.9 ± 7.2	50.9 ± 7.2	F=0.775 $\eta_p^2=0.024$ P=0.543	F=0.612 $\eta_p^2=0.010$ P=0.544	F=2.710 $\eta_p^2=0.042$ P=0.070

Abbreviations: NPRS: Numerical Pain Rating Scale; PPT SP: Pressure Pain Threshold Supra Pubic; PPT IO-R: Pressure Pain Threshold Internal Oblique-Right; PPT IO-L: Pressure Pain Threshold Internal Oblique-Left; CVM: Quality of Live in Menstruation; SF-12 PD: SF-12 Physical Dimension; SF-12 MD: SF-12 Mental Dimension.

Table 3. Multiple Comparisons: Pairwise comparisons.

	Post-intervention			Follow-up		
	Transabdominal Radiofrequency vs Control Group	Intracavitary Radiofrequency vs Control Group	Intracavitary Radiofrequency vs Transabdominal Radiofrequency	Transabdominal Radiofrequency vs Control Group	Intracavitary Radiofrequency vs Control Group	Intracavitary Radiofrequency vs Transabdominal Radiofrequency
<i>Pain Intensity</i>						
NPRS (0-10)	2.3 (0.4;4.2) p=0.011	3.0 (1.15;4.8) p<0.001	0.7 (-1.2;2.6) p=1.000	3.2 (1.5;5.1) P<0.001	4.5 (2.7;6.2) P<0.001	1.2 (-0.6;3.0) P=0.311
<i>PPT</i>						
PPT SP (kg/cm²)	3.0 (-3.0;9.0) P=0.667	1.1 (-4.8;7.1) P=1.000	1.9 (-4.2;7.9) P=1.000	2.8 (-2.7;8.3) P=0.647	1.0 (-4.4;6.4) P=1.000	1.8 (-3.7;7.3) p=1.000
PPT IO-R (kg/cm²)	4.3 (-3.8;12.4) P=0.566	2.3 (-5.6;10.3) P=1.000	2.0 (-6.1;10.0) P=1.000	3.9 (-3.3;11.2) P=0.550	2.2 (-4.9;9.3) P=1.000	1.7 (-5.5;9.0) P=1.000
PPT IO-L (kg/cm²)	4.4 (-2.8;11.7) P=0.404	0.5 (-6.6;7.6) P=1.000	3.9 (-3.3;11.2) P=0.550	3.9 (-2.1;10.0) P=0.340	1.3 (-4.6;7.2) P=1.000	2.6 (-3.4;8.7) P=0.858
<i>Quality of life</i>						
CVM	4.5 (-1.3;10.4) P=0.183	5.0 (-0.7;10.7) P=0.109	0.5 (-5.4;6.3) P=1.000	4.7 (-1.3;10.7) P=0.176	6.6 (0.7;12.5) P=0.023	1.9 (-4.0;7.9) P=1.000
SF-12 PD	2.9 (-3.1;8.8) P=0.708	2.0 (-3.8;7.9) P=1.000	0.8 (-5.1;6.7) P=1.000	4.2 (-1.4;9.8) P=0.201	3.7 (-1.8;9.1) P=0.308	0.5 (-5.0;6.1) p=1.000
SF-12 MD	4.4 (-3.9;12.7) P=0.596	4.6 (-3.6;12.8) P=0.513	0.2 (-8.1;8.5) P=1.000	2.0 (-4.2;8.3) P=1.000	2.0 (-4.2;8.1) P=1.000	0.1 (-6.2;6.3) 0.2 P=1.000

Abbreviations: NPRS: Numerical Pain Rating Scale; PPT SP: Pressure Pain Threshold Supra Pubic; PPT IO-R: Pressure Pain Threshold Internal Oblique-Right; PPT IO-L: Pressure Pain Threshold Internal Oblique-Left; CVM: Quality of Live in Menstruation; SF-12 PD: SF-12 Physical Dimension; SF-12 MD: SF-12 Mental Dimension.