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Full length article

"Combined use of Radiofrequency ablation and hysteroscopy in the treatment of uterine Myomas: An innovative approach"

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ABSTRACT

Objective: To evaluate transvaginal radiofrequency ablation (TRFA) as a preoperative strategy to facilitate hysteroscopic resection in patients with complex submucosal fibroids desiring uterine preservation.
Design: Prospective case series.
Setting: Single tertiary hospital (Puerta de Hierro University Hospital, Madrid, Spain), January 2021–June 2023.
Participants: Thirteen women with a single symptomatic fibroid containing a submucosal component, Lasmar-STEPW score ≥ 5, and no pregnancy desire for at least one year.
Interventions: TRFA was performed under general anaesthesia in an outpatient setting. Hysteroscopic myomectomy was scheduled from the sixth month onward. Outcomes included fibroid volume reduction, symptom improvement (Uterine Fibroid Symptom and Quality of Life questionnaire [UFS-QoL]), and hysteroscopic resection feasibility.
Results: Median age was 43 years. All TRFA procedures were completed successfully. At 6 months, median fibroid volume reduction was 76.8 %. UFS-QoL significantly improved (median from 32 to 14; $p = 0.004$). Complete hysteroscopic resection was achieved in 12 of 13 patients (92.3 %). One patient without fibroid regression required laparotomic myomectomy, with final diagnosis of adenomyoma. No serious complications or symptom recurrence were observed at follow-up.
Conclusion: TRFA is a safe, effective outpatient technique that significantly reduces fibroid volume and facilitates complete hysteroscopic resection in women with complex submucosal fibroids. This combined approach may expand the role of conservative vaginal surgery in selected patients.

INTRODUCTION

Leiomyomas are the most common benign solid tumors in the female pelvis. They have a cumulative incidence by 50 years of age of 70 % in Caucasian women and 80 % in African American women [1,2]. In many cases, they are asymptomatic; however, up to 25 % of women experience symptoms leading to a significant public health issue [3].

Submucosal fibroids (SM) account for approximately 10 % of all uterine fibroids, and their presence is more frequently associated with the onset of symptoms. Their gold standard treatment is hysteroscopic resection [4–7].

The SM classification helps guide the degree of difficulty and complexity of hysteroscopic myomectomy. Currently, there are two main classifications: the one described by Wansteker et al. in 1993 [8], and the Lasmar-STEPW classification published in 2005 [9].

In recent decades, several preoperative treatment alternatives for fibroids have been proposed, including pharmacological therapies [10–12] and minimally invasive procedures [13,14], with the aim of reducing fibroid size and vascularization to facilitate complete hysteroscopic resection in cases categorized as medium to high complexity.

In 2011, the Food and Drug Administration approved transvaginal radiofrequency ablation (TRFA) for the treatment of uterine fibroids.

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This technique is based on the application of a high-frequency electrical current that generates heat within the fibroid, inducing coagulative necrosis of the fibroid tissue and blood vessels. The necrotic tissue is subsequently reabsorbed by the body, achieving fibroid volume reductions [15–18].

The objective of this study was to evaluate whether TRFA could be considered a complementary option to hysteroscopy in the management of complex fibroids in women desiring uterine preservation.

MATERIALS AND METHODS

This study was designed as a prospective case series, including 13 patients selected from a total of 90 women who underwent TRFA for symptomatic uterine fibroids at Puerta de Hierro University Hospital (Madrid, Spain) between January 2021 and June 2023.

Inclusion criteria were adult women with a single symptomatic fibroid containing a submucosal component and a Lasmar-STEPW classification score of ≥ 5. Exclusion criteria were current pregnancy or desire for pregnancy within the next year, active pelvic inflammatory disease, or history of pelvic infection within the past 3 months. Patients were allowed to continue hormonal therapy or other symptomatic treatments if needed.

These 13 patients met the inclusion criteria and were enrolled for analysis. The primary outcomes evaluated were the effectiveness of the ablation procedure and the feasibility of complete hysteroscopic resection of the fibroid at six-month follow-up.

All patients participating in this study were informed in advance and provided written consent for the anonymous use of their data. Approval was obtained from the hospital's ethics committee for data processing. Each patient also signed an informed consent form for the TRFA procedure and was made aware of the limited published studies supporting its preoperative use in hysteroscopy. Informed consent for hysteroscopy was also provided and collected prior to the procedure.

Before the procedure, all patients underwent a complete gynecological examination and a two-dimensional Doppler ultrasound to classify the fibroid according to the FIGO classification [19,20] and its vascularization following the Morphological Uterus Sonographic Assessment (MUSA) classification [21]. The measurements of the three largest orthogonal diameters of each fibroid were recorded to calculate its volume using the formula $0.5233 \times a \times b \times c$, with results expressed in cubic centimeters. Clinical impact was assessed using the Uterine Fibroid Symptom and Quality of Life questionnaire (UFS-QoL) [22,23], a questionnaire used to evaluate the clinical impact associated with fibroids. The Lasmar-STEPW classification [9] was determined by an expert hysteroscopist who performed diagnostic hysteroscopy during the follicular phase of the cycle, both before and six months after TRFA.

The TRFA technique was performed under general anesthesia. The surgical scheduling was done independently of the menstrual cycle and did not require any specific prior preparation. As a prophylactic measure, 2 g of intravenous cefazolin were administered before the procedure, along with dexamethasone (8 mg) for its anti-inflammatory effect. During the procedure, the patient was positioned in the lithotomy position. As safety measures, two dispersive electrodes were placed on the inner surface of both thighs, and the generator was connected to a bag of cold saline solution, allowing continuous cooling of the electrode system. The generator used was the STARmed Co. from JJP Hospitalaria S.L. (Sevilla, Spain), set to a power of 100 W for all ablations. The needle electrode used was 35 cm in length and 17 gauge in thickness, with a 10 mm active tip (REF 17-35s10F). The ultrasound system used was a Philips Affiniti 70 W. A 15-gauge metal guide was placed over the vaginal probe. No prior biopsy was performed on the lesion. The objective of RFA is to create small areas of necrosis of approximately 1 cm^3 in the fibroid tissue, with an average ablation time of about 10 s. The procedure was considered complete when ultrasound confirmed an increase in the echogenicity of the fibroid by more than 80 % or the absence of vascularization on Doppler in the treated area.

The procedure was performed on an outpatient basis. For pain management, mild oral analgesics were prescribed as needed. No maintenance antibiotics were prescribed. Patients were advised to avoid high-impact exercise for one week following the surgery and were informed about the possibility of expelling fibroid tissue remnants through the vaginal route. Postoperative follow-up visits were scheduled at one month, six months, one year, and 18 months after the procedure. During the first postoperative visit, the patient's clinical progress was evaluated, along with their satisfaction with the procedure, the duration of analgesic use, and time off work. At the six-month follow-up, patients were asked to complete the UFS-QoL questionnaire again, a Doppler ultrasound was performed to assess the size and vascularization of the treated fibroid, and they were referred to the hysteroscopy unit for definitive resection, either in the outpatient clinic or the operating room.

Hysteroscopies were performed during the follicular phase of the menstrual cycle (between 3 and 7 days after menstruation) using a vaginoscopic approach and saline solution as the distension medium. One hour before the hysteroscopy, patients took an oral tablet of Buscopan, one 400 mg tablet of Ibuprofen, and one 5 mg tablet of Diazepam. Additionally, at the beginning of the procedure, using a speculum, 5 ml of 2 % mepivacaine were infiltrated into the vaginal fornices at the 5 and 7 o'clock positions with a 10G spinal needle. A mechanical pump was used to control the flow and intrauterine pressure. The instruments used were a Storz Bettochi hysteroscope (4.2 mm outer sheath and 3.6 mm inner sheath) with flexible forceps and a bipolar electrode, introduced through a 5 Fr operative channel of the hysteroscope, along with a fiber-optic light cable. In some cases, fibroid resection required the use of a morcellator. Samples were sent for pathological examination. Patients were discharged as soon as the procedure was completed.

Hysteroscopies that required cervical dilation were performed in the operating room under general or epidural anesthesia and two grams of cefazolin were administered as prophylaxis. Resection was carried out using a U-shaped bipolar current loop with a 4 mm section diameter, connected to a movable cannula with a hysteroscopic optical system, in our case, 12°. Saline solution was used as the distension medium. Superficial blood vessels of the fibroid were cauterized with a coagulation current of 50–70 W, and resection of the fibroid was then performed, always from the uterine fundus to the cervix for better control. Cutting power was set between 50 and 120 W. The extracted fragments were sent for subsequent pathological examination. Patients were discharged after full recovery from anesthesia.

Post-hysteroscopy clinical and ultrasound follow-up were performed at six months.

Data collected included patient and fibroid characteristics, as well as fibroid-related symptoms (assessed by the UFS-QoL questionnaire) before and 6 months after the procedure. Additionally, TRFA-specific details and hysteroscopy variables (type and resection mode) were recorded.

For descriptive analysis of data, number (and percentage) were used for categorical variables and medians for quantitative variables. The UFS-QoL values before TRFA were compared with those recorded 6 months after the procedure using the Wilcoxon signed rank test. A p-value below 0.05 was considered statistically significant. Data were analyzed using R version 4.2.2 [24].

RESULTS

Thirteen patients were referred to the fibroid unit following a diagnosis of a single fibroid with a submucosal component, identified through Doppler ultrasound, and presenting with clinical symptoms of heavy menstrual bleeding unresponsive to medical treatment. The plan was to perform TRFA to reduce fibroid's volume, followed by hysteroscopy at six months for resection.

According to the Lasmar-STEPW classification, 69.23 % (9/13) of fibroids had a score between 5 and 6, while 30.77 % (4/13) scored between 7 and 9. All patients expressed a desire for an attempt at

conservative vaginal treatment. The median age of patients at the time of TRFA was 43 years. Patient's age and baseline characteristics of the treated fibroids are shown in Table 1.

All TRFA procedures were performed on an outpatient basis. The variables directly related to the TRFA procedure are shown in Table 2. The most common minor symptoms reported were low-grade fever, asthenia, continuous vaginal bleeding, or the expulsion of necrotic tissue through the vagina. All patients were able to return to their normal activities between the first and tenth day after the procedure, with a median of two days; and needed analgesia for a median of 3 days. All but one of the patients reported being satisfied or very satisfied with the procedure.

At six months post-TRFA, all patients reported a decrease in bleeding, which had begun by the third month. The median reduction in fibroid volume was 76.81 %, and UFS-QoL scores significantly improved, decreasing from a median score of 32 [on a scale from 8 (no symptoms) to 40] before TRFA to a median score of 14 six months later (Table 3) ($p = 0.004$).

Only one of the thirteen patients did not respond adequately to TRFA; it was a 32-year-old patient who had previously undergone laparotomic myomectomy. She presented with a fundal uterine fibroid classified as FIGO type 1, with a volume of 95.9 cm^3, a maximum diameter of 7.4 cm, and MUSA type 3 vascularization. Although she reported an improvement in bleeding symptoms after TRFA, the fibroid volume remained unchanged. As a result, hysteroscopy was deemed unnecessary, and a new laparotomic myomectomy was scheduled, which ultimately confirmed a final pathological diagnosis of adenomyoma.

The remaining 12 patients underwent hysteroscopy as planned for fibroid resection. However, in two cases, the procedure was postponed until 10- and 18-month post-TRFA due to the absence of symptoms and a progressive reduction in fibroid volume, resulting in near-complete resolution in one of them (Fig. 1).

Regarding hysteroscopy after TRFA, complete fibroid resection was achieved in all patients (12/12). The resection technique was determined by an expert hysteroscopist. Ten hysteroscopies were performed in the outpatient setting, with 60 % of cases resected using a bipolar electrode and 40 % using Myosure (Table 3). In two cases, resection was carried out in the operating room due to the potential risk of severe bleeding during the procedure, although this complication did not occur, and the procedure was completed without difficulty."

The histopathological study following resection confirmed the diagnosis of a leiomyoma in all cases where TRFA and hysteroscopy were carried out. At the six-month post-resection ultrasound follow-up, no recurrence was observed.

DISCUSSION

Although submucosal fibroids account for only about 10 % of cases, they are more frequently associated with clinical manifestations, such as heavy bleeding and infertility, representing a significant public health challenge and imposing a considerable economic burden on healthcare systems [3].

Surgical excision remains the first-line treatment for this type of tumor, either through definitive management with hysterectomy or a conservative approach with myomectomy. Current trends increasingly favor conservative treatment, aiming to preserve the uterus whenever possible. When part or all the fibroid protrudes into the uterine cavity, vaginal access allows for its resection, with hysteroscopy considered the gold standard technique—enabling simultaneous diagnosis and treatment in a single procedure. Advances in hysteroscopic instrumentation have facilitated the expansion of outpatient procedures [5,6,25]. Nevertheless, hysteroscopic resection presents limitations in cases of uterine fibroids with a Lasmar-STEPW score ≥ 5 [9], as well as in fibroids with features not addressed by this classification, such as increased vascularization, greater consistency, or an unfavorable fibroid-to-cavity volume ratio.

TRFA has emerged as a non-pharmacological, outpatient, well-tolerated, and low-complexity alternative for the conservative management of uterine fibroids. It enables optimal control of clinical symptoms and contributes to a reduction in fibroid volume, while also modifying its vascularization and consistency [15–18].

TRFA seems to be especially interesting for the treatment of fibroids with a submucosal component. In these fibroids, necrosis of the capsule in contact with the myometrium may lead to detachment and protrusion into the endometrial cavity—a phenomenon known as a free intracavitary fibroid—which has been observed in 2.8 % of cases as early as two months after TRFA [18,26]. Initially, this was considered a minor complication, typically resolved through hysteroscopic intervention. However, we aimed to reframe the occurrence of a free intracavitary fibroid not as a complication, but rather as a desirable effect that simplifies subsequent hysteroscopic management. This finding typically involves a smaller fibroid, with a soft, cotton-like consistency and minimal or absent vascularization, which allows for complete resection in a single-step procedure (**Videos 1 and 2**).

The clinical symptom control, fibroid volume reduction, and complication rates observed in our study are consistent with those reported in previous studies [15,17,18]. However, it is important to note that our findings are based on a small case series, which limits the broader applicability of these results.

The transvaginal ultrasound follow-up 6 months after hysteroscopy confirmed the absence of fibroid recurrence, highlighting the effectiveness of TRFA in our series. A lack of response to TRFA appears to be associated with fibroid volumes ≥ 85 cc, as reported in other studies

Table 1
Patient and Fibroid Characteristics.

Patient Age	Fibroid Uterine Location	FIGO Classification	MUSA	Maximum Diameter	Myoma Volume	SSS Pre-TRFA	Lasmar Pre-TRFA
46	Fundal	Type 1	Type 2	5.7 cm	68.29 cc	32	7
43	Posterior	Type 2–5	Type 2	4.9 cm	47.44 cc	29	6
29	Anterior	Type 2	Type 2	3.4 cm	15.38 cc	24	6
38	Posterior	Type 2–5	Type 2	5.3 cm	48.95 cc	32	8
49	Anterior	Type 2–5	Type 2	5.2 cm	72.21 cc	29	8
46	Anterior	Type 2	Type 2	3.8 cm	19.50 cc	33	6
43	Fundal	Type 2–5	Type 2	3.9 cm	28.13 cc	35	6
45	Posterior	Type 2–5	Type 2	4.4 cm	37.78 cc	25	6
33	Anterior	Type 2–4	Type 2	4.5 cm	40.57 cc	37	5
43	Anterior	Type 2–4	Type 2	4.3 cm	35.93 cc	26	5
43	Anterior	Type 2–5	Type 2	3.8 cm	22.82 cc	33	6
35	Posterior	Type 2–4	Type 3	4.6 cm	36.03 cc	32	6
32	Anterior	Type 1	Type 3	7.4 cm	95.90 cc	34	9

Table 2
Radiofrequency Ablation Procedure characteristics.

Ablation Time per Myoma	Hospital Admission	Major Complications	Minor Complications	Satisfaction	Sick Leave Days	Analgesia Days
207 sec	No	None	Expulsion of fragments	Very satisfied	2	3
480 sec	No	None	Low-grade fever	Satisfied	2	3
300 sec	No	None	Expulsion of fragments	Satisfied	2	3
357 sec	No	None	Asthenia	Very satisfied	0	3
530 sec	No	None	Asymptomatic	Satisfied	3	3
185 sec	No	None	Asymptomatic	Very satisfied	1	3
253 sec	No	None	Asthenia	Satisfied	0	0
319 sec	No	None	Expulsion of fragments	Very satisfied	2	7
337 sec	No	None	Asymptomatic	Satisfied	1	0
605 sec	No	None	Asymptomatic	Very satisfied	10	3
154 sec	No	None	Asthenia	Very satisfied	0	2
305 sec	No	None	Asymptomatic	Very satisfied	2	2
566 sec	No	None	Expulsion of fragments	Somewhat	4	4

Table 3
Results after TRFA and Hysteroscopy.

Myoma Volume	Maximum Diameter	Volume Reduction (%)	SSS at 6 months	Lasmar at 6 months	Time to HSC (months)	Hysteroscopy	Type of HSC	Resection Mode
27.82 cc	4.1 cm	59.26	12	6	6	Yes	Surgical	Resector
17.53 cc	3.6 cm	63.04	10	5	6	Yes	Consultation	Myosure
0.05 cc	0.6 cm	99.67	12	2	18	Yes	Consultation	Electrode
4.6 cc	2.2 cm	90.60	11	5	7	Yes	Consultation	Electrode
39.04 cc	5.1 cm	45.93	10	6	6	Yes	Surgical	Resector
5.47 cc	2.5 cm	71.94	12	5	10	Yes	Consultation	Electrode
3.85 cc	2.4 cm	86.31	17	4	7	Yes	Consultation	Electrode
4.98 cc	2.4 cm	86.81	29	4	6	Yes	Consultation	Myosure
2.72 cc	1.8 cm	93.29	14	3	7	Yes	Consultation	Electrode
8.33 cc	3.1 cm	76.81	27	3	7	Yes	Consultation	Myosure
6.86 cc	2.6 cm	69.93	31	3	7	Yes	Consultation	Myosure
6.64 cc	2.4 cm	81.57	23	3	8	Yes	Consultation	Electrode
125.85 cc	7.4 cm	0	29			No		

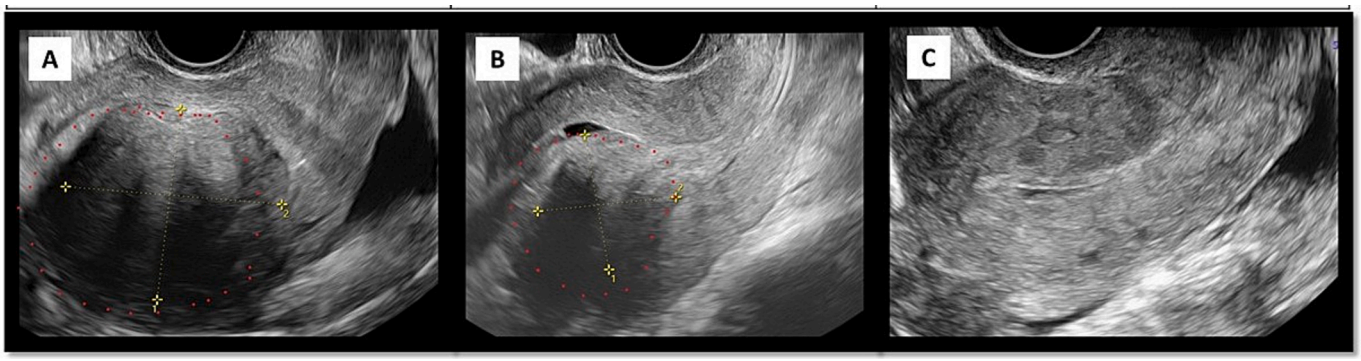

Fig. 1. A: Uterus before TRFA. **B:** Uterus 6 months after TRFA. **C:** Uterus after hysteroscopy.

[15,17,18]. In our series, the patient who did not respond adequately was later found to have an adenomyoma upon histopathological examination after laparotomic myomectomy, suggesting that the presence of adenomyomatous tissue may contribute to reduced treatment response. At present, there are no established biomarkers or imaging techniques that can reliably predict fibroid response to TRFA. Future studies should explore potential predictive markers to better tailor treatment strategies. Patients expressed high satisfaction with the procedure, which reduces hospitalizations and prolonged work absences. The slightly longer sick leave in one patient (10 days) was due to high-intensity physical activity; TRFA generally allows faster return to normal activities compared with conventional myomectomy [27]. Additionally, TRFA has been shown to be a cost-effective option compared with myomectomy, providing faster functional recovery, significant improvement in health-related quality of life and lower total costs [28].

One limitation of this study is the possible interference of TRFA in the anatomopathological diagnosis of fibroids, as samples are analyzed post-ablation and coagulative necrosis may confound the final diagnosis [29]. In addition, the small sample size precludes broader generalizability and stratified or multivariable analyses. Despite these limitations, TRFA appears to be a safe and effective preoperative option prior to hysteroscopy for medium-to-high complexity fibroids, enabling conservative vaginal management. Further research with larger cohorts is needed to confirm these findings and to investigate potential effects on pregnancy outcomes in women desiring conception, as well as long-term clinical results.

CONCLUSION

Radiofrequency ablation proved to be safe in our study of 13 patients desiring uterine preservation and minimally invasive management of uterine fibroids, as none required hospitalization, and all resumed normal activities within 0–10 days. Moreover, the technique was effective in 12 of the 13 patients, resulting in a reduction in fibroid volume and associated symptoms, as measured by the UFS-QoL scale. In the 12 patients where TRFA was effective, complete resection was achieved through subsequent hysteroscopy, with no recurrences noted in ultrasound follow-up after 6 months.

Ethics statement

The authors declare that there are no conflicts of interest related to the publication of this manuscript. No financial or personal relationships influenced the design, conduct, or reporting of this study. The research received favorable approval from the Ethics Committee of Hospital Universitario Puerta de Hierro Majadahonda (approval code PI 90/25).

CRediT authorship contribution statement

Ma. Eugenia Marín Martínez: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Gema Vaquero Argüello:** Visualization, Supervision, Conceptualization. **Tirso Pérez Medina:** Supervision, Funding acquisition. **Laura Beatriz Calles Sastre:** Methodology. **Ma. Luisa De la Cruz Conty:** Validation, Supervision. **Sara Cruz Melguizo:** Visualization, Validation, Supervision, Methodology.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [M Eugenia, Marin Martinez reports financial support was provided by Fundacion para la investigación biomedica del Puerta de Hierro University Hospital G83726968, and this funding was exclusively allocated to cover the publication expenses of the article. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.].

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Appendix A. Supplementary data

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