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Full Reports

Transvaginal Radiofrequency Ablation of Myomas: Technique, Outcomes, and Complications

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Abstract

Objectives: The aim was to study technique, complications, and outcomes of transvaginal ultrasound-guided AU2 ▶ radiofrequency myolysis (TRFAM) of uterine myomas.
Materials and Methods: A prospective observational study of 205 patients with metrorrhagia secondary to type II/III submucosal or intramural cavity-distorting myomas undergoing outpatient TRFAM under sedation between September 2015 and February 2017.
Main Outcome Measures: Intraoperative and postoperative complications, correction of metrorrhagia, patient AU3 ▶ satisfaction, mean volume of myoma, and hemoglobin level at 1, 3, 6, and 12 months after the procedure.
Results: The mean age of the patients was 38.7 years (range 26–49). The mean operating time was 17 minutes (range 11–44). The mean postoperative time to discharge home was 2.3 hours (range 1.6–3.2). There were 2 (1.46%) patients with type III-b complications (Clavien–Dindo classification). The mean (standard deviation [SD]) preoperative myoma volume was 122.4 [182.5] cm^3. There was a significant reduction in the mean volume at 1 (85.2 [147.9] cm^3; $P = .001$), 3 (67.3 [138.0] cm^3; $P = .001$), 6 (59.3 [135.3] cm^3; $P = .001$), and 12 months (49.6 [121.4] cm^3; $P = .001$). The mean volume reduction at 12 months was 60% when compared with preoperative volume. All patients had normal menstruation at a mean follow-up of 3 months (range 1.5–6).
Conclusion: TRFAM is an effective and safe technique in selected patients for the treatment of metrorrhagia secondary to myomas.

AU4 ▶ **Keywords:** uterine myoma, radiofrequency ablation, myolysis, transvaginal approach, minimal invasive surgery

Introduction

AU6 ▶ AU5 ▶ Approximately 25% of women with myomas have abnormal bleeding, most commonly in the form of metrorrhagia.[1] In recent years, there has been a trend toward efficient and safe conservative treatments to avoid hysterectomy in patients desiring fertility. Ablation therapy using thermal energy sources has been the focus of interest as a minimally invasive strategy for patients with abnormal bleeding due to myomas.[2,3] Advantages of myolysis over surgical resection include reduced morbidity (operating time, blood loss, and length of hospital stay), preservation of the endometrial cavity, real-time imaging guidance, and outpatient procedure.[3] While several studies have demonstrated the safety and efficacy of myolysis through the laparoscopic route with resolution or improvement of symptoms and significant volume reduction,[4–9] there is little experience using a transvaginal approach with only a total of 189 patients reported from five series.[10–14]

This study was designed to describe the surgical technique and to evaluate the complications and outcomes of transvaginal ultrasound-guided radiofrequency myolysis (TRFAM) in patients with metrorrhagia due to myomas.

Materials and Methods

Study design and participants

A prospective observational study was conducted in 205 women with symptomatic type II/III uterine submucosal or intramural cavity-distorting myomas undergoing radiofrequency at the CAREMUJER Clinic between September 2015 and February 2017. All patients were operated by the ◀ AU7 same surgeon, under i.v. sedation, and on an outpatient basis. Inclusion criteria were patients with metrorrhagia due to one to three fibroids of any size, unresponsive to medical therapy, and unable to be easily removed by hysteroscopy or laparoscopy. Exclusion criteria were the presence of four or more myomas >5 cm, malignancy or precancerous conditions, coagulopathy, pregnancy, pelvic inflammatory disease, and comorbidities preventing sedation. All patients were extensively counseled on the potential risks and benefits of the procedure,

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and on possible alternative treatments. The study was approved by the Ethics Committee of CAREMUJER institution and conducted according to the ethical principles of the Declaration of Helsinki (seventh revision). Written informed consent was obtained from all patients.

Surgical procedure

Pretreatment evaluation included a transvaginal ultrasound to assess the number, volume, and location of the myomas, and hemoglobin level. Myolysis was performed under sedation using i.v. propofol sodium. Ceftriaxone 2 g was administered intravenously before the procedure. The patients were in the semilithotomy position and prepped with povidone-iodine vaginal cleanser. A Tru-Cut needle (18G, 30 cm) (Mermaid Medical Iberica, S.L., Toledo, Spain) biopsy of each fibroid was performed before myolysis for permanent histological examination to diagnose a potential malignancy. A radiofrequency needle was introduced transcervically or through the anterior or posterior fornix under transvaginal ultrasound guidance. A monopolar device was used for bleeding control of the needle tracks. The radiofrequency ablation (RFA) delivery system consists of VIVA RF System Generator (STARmed Co., Ltd, JJP Hospitalaria S.L., Seville, Spain) with a coagulation electrode star RF Fixed (reference 17–35 s30F) (17G, 35 cm long, 1 cm sharp tip). A coolant circulation system of the electrode maintains suitable impedance at its surface. The radiofrequency generator operates at 480 kHz with a maximum power of 200 W at a temperature ranging from 5°C to 95°C. The power of the generator during the procedure was set to a maximum of 100 W. The generator displays the temperature of the electrode tip, as well as tissue impedance characteristics and ablation time. After centralization of the needle in a specific myoma, myolysis was performed. A single-needle ablation pulse achieved a necrosis volume of $\sim 1\,cm^3$ after 5–10 seconds. As charring is not desirable, the generator indicates the end time when it detects increased tissue impedance at the tip of the electrode. The ablation points followed a line inside of the myoma, starting distally and finishing proximally, with superimposition of the points. The core of the target myoma was ablated when the echo-enhanced area reached 80%–90% of the myoma cross-section in real-time ultrasound. Absence of vascularization was confirmed at the end by contrast-enhanced ultrasound using SonoVue® (Bracco Diagnostics, ROVI S.A., Madrid, Spain).

The patients were monitored for 2–3 hours after the procedure and discharged home if awake, tolerating fluids and food, and without undue pain. Prescribed postoperative medications included nonsteroidal anti-inflammatory drugs and antibiotics for 5 days to prevent infection of the necrotic myoma tissue.

Pelvic ultrasound and symptom assessment were performed at 1, 3, 6, and 12 months. Complications were defined according to the Clavien–Dindo classification. Recorded data included ultrasound measurements of the volume of the myomas, assuming an ellipsoid shape, hemoglobin level, symptoms, and patient satisfaction with the procedure (categorized as yes or no).

Statistical analysis

Descriptive statistics included frequencies and percentages for categorical variables, and mean and range with 95% confidence intervals (CIs) for quantitative variables. Continuous variables were compared with Student's *t*-test for paired samples. The relationship between volume of myoma at baseline and at 6 months after radiofrequency myolysis was analyzed with Pearson's product–moment correlation coefficient. Statistical significance was set at $P < .05$. The Statistical Analysis Systems (SAS) (SAS Institute, Cary, NC) version 9.4 was used for analysis.

Results

A total of 205 patients with symptomatic uterine type II/III submucosal myoma and intramural cavity-distorting myoma were included in the study. The mean age (SD) of the patients was 38.7 (8.5) years (range 26–49). All patients had metrorrhagia secondary to myomas. Preoperatively, the mean (SD) volume of the myomas was 122.4 (182.5) cm^3 (95% CI 82.1–162.8), and the mean (SD) hemoglobin level was 9.3 g/dL (range 7.2–10.5). The mean operative time was 17 minutes (range 11–44).

There were no intraoperative complications. All patients were discharged on the same day with reduced activity for the first 2 days and avoidance of strenuous activity for 1 week. Two patients (1.46%) had a type III-b complication according to the Clavien–Dindo classification. In both instances, a hysteroscopy was necessary 30 and 45 days, respectively, to remove an intracavitary free myoma.

The subsequent reduction of the myomas volume is depicted in Table 1. There was a significant reduction in the mean volume of the myomas at 1 (85.2 [147.9] cm^3; $P = .001$) and 3 months (67.3 [138] cm^3; $P = .001$), but not between 3 and 6 months (59.3 [135.3] cm^3; $P = .855$). There was also a significant reduction at 12 months (mean myoma volume 49.6 [121.4] cm^3; $P = .001$). ◀T1

The mean volume reduction of myomas was 51.55% at 6 months and 60% at 12 months. There was a significant correlation between the initial volume of myomas, and the mean volume at 6 ($r = 0.58$, $P < .0001$) and 12 months ($r = 60$, $P < .0001$).

There was a significant difference between the mean volume reduction of the first 40 cases (52%) compared with the entire sample (60%) ($P = .001$). If the first 40 cases are excluded, the mean reduction of myomas at 12 months was 71%.

Thirty patients (15%) had a myoma $\leq 39\,cm^3$, and their mean volume reduction was 81.34%. There were 24 patients with a complete disappearance of the myoma at 6 months of follow-up.

All patients had normal menstruation at a mean follow-up of 3 months (range 1.5–6) and at 12 months. The mean hemoglobin level improved significantly ($P < .0001$) from 9.3 g/dL (range 7.2–10.5) preoperatively to 11.2 g/dL (range 10.7–12.1) at 3 months.

Two hundred one of 205 patients (98.04%) were satisfied with the procedure. Dissatisfied patients indicated that they wished their myomas would have been removed.

Discussion

The optimal treatment for metrorrhagia secondary to myomas in patients desiring fertility should reduce the amount of bleeding, reduce the myoma size, and be minimally invasive and safe.[10] Conservative treatments have been developed using minimally invasive techniques to avoid invasive operations for myomas. Among those are uterine artery embolization,

Table 1. Reduction of the Volume of Myoma After 1, 3, 6, and 12 Months of Transvaginal RFA as Compared with Baseline

	Myoma volume, cm^3			
Before/after RFA months	*Mean (SD)*	*95% confidence interval*	*Crude difference mean (SD)*	P
Baseline (pretreatment)	122.4 (182.5)	82.1–162.8		
After RFA				
1	85.2 (147.9)	52.5–117.9	−37.2 (77.9)	<.0001
3	67.3 (138.0)	36.3–98.2	−55.1 (83.1)	<.0001
6	59.3 (135.3)	20.9–89.6	−63,1 (89.1)	<.0001
12	49.6 (121.4)	18.5–77.1	−72.8 (93.2)	
1 versus 12			−17.9 (27.2)	.0001

RFA, radiofrequency ablation.

high-intensity focused ultrasound (HIFU), and myolysis. Different energy sources for myolysis, such as Nd:YAG laser, bipolar/monopolar, cryoprobes, and radiofrequency, have been reported.[15–17]

Radiofrequency is the application of electromagnetic waves in a tissue rising its temperature. In 1980, it was shown that radiofrequency produced coagulative necrosis in tumors. In 1990 and 2000, radiofrequency was applied for the first time to treat a liver tumor and a metastatic bone lesion, respectively.[15] Transabdominal radiofrequency myolysis of uterine myomas was started in the 1990s to avoid major surgery.[3] Because of some instances of uterine rupture during pregnancy and the development of minimally invasive surgery, transabdominal myolysis was abandoned. It was concluded that multiple needle punctures through myometrium were the cause of the uterine weakness in pregnancy.[3,16]

The feasibility of laparoscopic radiofrequency myolysis was first evaluated by Bergamini et al.[5] in 2005. In a pilot study of 18 women with symptomatic intramural myomas, the median volume reduction of the myomas was 41.5%, 59%, and 77% at 1, 3, and 6 months, respectively. A significant improvement in symptom score and quality of life was also reported. A review of phase II and phase III studies of laparoscopic myolysis of 206 patients collected from the literature indicated a significant reduction in uterine size, elimination of myoma symptoms, and significant improvement in quality of life.[18] These results have been duplicated in subsequent studies.[7,19–21]

TRFAM has been recently suggested to be the optimal technique because it is an outpatient, safe, and fast procedure with a rapid recovery, quick return to normal menstruation, major reduction of myoma volume, and correction of anemia.[10–14,22] It is preferable to other minimally invasive techniques such as cryotherapy or HIFU, myolysis because of its reliability, lower cost, and shorter operating time.[10] It is also preferable to laparoscopic myomectomy due to reduced median blood loss (20 mL [range 0–30] versus 35 mL [range 10–300]) and the ability to treat a higher percentage of myomas (98.6% versus 80.3%).[20]

This study provides additional evidence of the feasibility and safety of TRFAM. It is short, incisionless, performed under sedation on an outpatient basis, and with a high level of satisfaction and return to normal menstruation and normal hemoglobin levels in all patients.

Salient features of published studies are summarized in Table 2. The rate of myoma volume decrease shown in our study is lower than that in others (60% versus 83%). The difference may be due to a higher number of patients (205 patients versus 83 patients) and a higher initial myoma volume (122.4 cm^3 versus 67.4 cm^3).

Table 2. Results of Ultrasound-Guided RFA Through the Transvaginal Route in Patients with Symptomatic Uterine Myomas

Author, year[Ref.]	*Study design*	*No. of patients*	*Myoma volume, cm^3, mean (SD)*		*Reduction rate (%)*	*Follow-up months*	*Complications*
			Preoperative	*Postoperative*			
Cho, 2008[11]	Prospective	24	65.12	19.3[a]	73	18	Increased vaginal discharge 14.5% Reoperation 1 case (4.3%)
Kim, 2011[10]	Prospective	69	304.6 (229.1)	79.1 (81.7)[a]	74	12	None
Jiang, 2014[13]	Prospective	46	67.4 (51.1)	11.34 (8.93)[a]	83	12	Vaginal discharge 15.2% Reoperation 4 patients (8.7%)
Brölmann, 2016[14]	Prospective	50	18.3 (9.5)	6.8 (1.2)[a]	73.3	12	Reoperation 4 patients (8%)
Rey, 2017 (present study)	Prospective	205	122.4 (182.5)	49.6 (121.4)[a]	60	12	Hysteroscopic resection of intracavitary free myoma (0.97%)

[a]Statistically significant differences versus baseline.
RFA, radiofrequency ablation; HRQL, health-related quality of life; SS, symptom severity subscale; UFS, uterine fibroid symptoms.

The technique and the types of myomas treated are addressed only in one study. Brölmann[14] reported a multicentric study using a vaginal radiofrequency technique with incorporated ultrasound (Sonata System®) at 150 W with different sections of the myoma treated simultaneously for 4–7 minutes. Myomas type II/III/IV were treated. Their transvaginal sonography improves the visualization of the uterine serosa, thereby preventing bladder and bowel injuries. When compared with our study, their radiofrequency was higher (150 W versus 100 W), their initial myoma volume was lower (18.3 cm^3 versus 122.4 cm^3), and their reintervention was higher (8% versus 1.46%).

Reintervention rates are reported ranging from 4.3% to 8.7%.[11,13,14] The causes for reintervention were described in only one study. Four of 50 patients required additional treatment due to persisted metrorrhagia, involving hysterectomy (1), hysteroscopic myomectomy (2), and endometrial ablation (3). We had 2 patients who required hysteroscopic removal of free intracavitary myomas (1.46%). This may be due to surgeon experience with >1000 transvaginal punctures and extensive practice in an animal model.

The learning curve to achieve similar myoma volume reductions is about 40 procedures. The mean volume reduction was 52% among the first 40 cases compared with 60% for the entire sample ($P = .0001$). If the first 40 cases are excluded, the mean reduction of myoma at 12 months was 71%. Factors in the learning curve include the precision of transvaginal puncture, the use of tridimensional imaging, and the myoma volume. We advise against treating myomas of a volume of 500 cm^3. During the learning curve since it may result in incomplete myolysis.

The optimal myoma volume for TRFAM is $\leq 39\ cm^3$ with an expected volume reduction of 80% and disappearance in half of the cases.

We recognize that a larger number of patients are needed to substantiate the present results, and that a longer follow-up is needed to determine the length of the myolysis success. This objective is the basis of an ongoing study with this cohort of patients and will constitute a subsequent publication. A comparison of the prospective randomized multicenter study with other systems of transvaginal radiofrequency myolysis would be helpful to identify the optimal technology.

In conclusion, transvaginal radiofrequency myolysis for type II/III submucosal and intramural cavity-distorting myomas is a safe, fast, minimally invasive, and effective technique to treat metrorrhagia and reduce myoma volume. Optimal patients are those with a myoma volume $\leq 39\ cm^3$.

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Authors' Contributions

V.E.R.: performance of the technique, study design, data collection and analysis, writing of the article; R.L.: review of the literature, data collection, and care of the patients; M.F.: selection of patients and data collection; J.L.G.: review of the literature, data collection, and critical review of the article.

Disclosure Statement

No competing financial interests exist.

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