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Ultrasound-guided transvaginal radiofrequency ablation of uterine fibroids assisted by virtual needle tracking system: a preliminary study

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ABSTRACT

Purpose: The purpose of this study was to assess the feasibility and outcome of transvaginal ultrasound (US)-guided radiofrequency ablation of uterine fibroids assisted by a real-time virtual needle tracking (VT) system.

Methods: Between January 2017 and February 2018, 19 patients (age 45 ± 8 y, range 36–53 y) with 25 symptomatic uterine fibroids underwent transvaginal radiofrequency ablation (RFA) at a single center. Mean number of fibroids for patient was 1.7 (min, max: 1–3). Patients with more than one fibroid were 10 (52.6%). Uterine fibroids (mean volume: 13.6 mL; range: 5.3–41.9 mL) were treated with a dedicated internally cooled 17 G 35 cm RF needle with 1 cm or variable active tip and the moving shot technique. An electromagnetic system was used for showing a virtual needle during the procedure. Contrast-enhanced ultrasound evaluation was performed before and immediately at the end of procedure. Feasibility of the procedure, technical success rate, volume percentage reduction at 1, 3 and 6 months, clinical outcome (QOL score) and complications were analyzed.

Results: Procedure was feasible in 19/19 patients (100%). Technical success was achieved in 100% of 25 treated fibroids. Mean fibroids volume decreased from 13.6 ml at baseline to 5.9 ml at 6 month (reduction rate 62.7%, range 48.5–76.9; $p < .05$). No major immediate or late complications occurred. Minor complications occurred in two patients. QOL score significantly improved from 68 ± 36 at baseline to 97 ± 16 at six-months follow-up ($p < .05$).

Conclusion: Transvaginal US-guided RFA assisted by a real-time VT system is a feasible, safe and effective technique for the treatment of uterine fibroids.

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Uterine fibroid; transvaginal myolysis; radiofrequency ablation; virtual needle tracking; minimally invasive surgery

Introduction

Uterine fibroids are the most frequent pelvic benign solid tumors in woman of reproductive age and the leading benign indication for hysterectomy [1]. Fibroids have been reported to occur at a rate of 2.0–9.2 per 1000 woman-years and the incidence increases with age until menopause [2,3].

While often asymptomatic, fibroids can determine symptoms such as abnormal uterine bleeding, pelvic pressure, pain, subfertility, dyspareunia and others [1]. Heavy menstrual bleeding may be caused by submucous and intramural fibroids [4,5]; subserosal fibroids are more often asymptomatic until they are sufficiently large so as to induce bulk symptoms. Transmural fibroids have submucous and subserosal components.

When symptomatic, uterine fibroids cause a significant reduction in health-related quality of life (HRQOL) as determined by the uterine fibroid symptom and quality of life questionnaire (UFS-QOL), a validated fibroid-specific survey tool [6].

The traditional treatments for symptomatic fibroids are represented by major surgery, such as hysterectomy and myomectomy, both of which are associated with significant

complications and considerable morbidity [7]. Moreover, hysterectomy don't preserve the uterus and fertility, so, in woman who want future pregnancies or who wish to retain their uterus for other reasons, the traditional surgical treatment is myomectomy, which may be performed via laparotomy, laparoscopy, hysteroscopy or transvaginal, but it isn't a definitive therapy in many cases.

In the last years, some alternative minimally invasive treatments have been proposed to treat symptomatic uterine fibroids in order to avoid major surgery and to preserve potential fertility [8,9].

Uterine artery embolization (UAE) has been demonstrated to be safe and effective on hypervascular fibroids [10], but fertility-related issues are still debated [11]. Today, uterine artery embolization is not recommended for women who want to preserve fertility and fibroid recurrence is possible, with approximately 20% of patients subsequently requiring hysterectomy [12].

In the last decades, some new mini-invasive techniques are adopted in the treatment of uterine fibroids and determine an improvement in woman's quality of life. These

procedures use various forms of energy to heat and ablate uterine fibroids, include radiofrequency energy, focused ultrasound and microwaves [13–15].

Radiofrequency ablation (RFA) is a widespread modality to achieve the local control of fibroids and creates a thermal fixation and coagulation necrosis within fibroids that result in reductions of volume, also reducing or eliminating symptoms related to uterine fibroid.

Imaging guidance is very important for radiofrequency (RF) electrode placement and procedure outcome is connected to accurate probe placement and repositioning [16]. US guidance allows for accurate real-time visualization of the RF electrode and is currently considered the main guidance for such procedures [17,18]. However, uterine fibroids may be located in challenging positions and gas bubbles released during thermal ablation can reduce the visibility of the whole procedure, increasing the risk of complications [19]. In this setting, virtual needle tracking (VT) systems, which tracks the position of the RF electrode through a small sensor on the shaft, could be helpful in improving monitoring of the RF electrode tip during ablation [17].

Finally, in some challenging cases, virtual tracking system could be combined with fusion imaging, which enables ultrasound-guided ablation procedures enhanced by a 'map' furnished by a superimposed diagnostic magnetic resonance imaging (MRI) [20].

Virtual needle tracking has been described as a useful guidance system for RF ablation of liver nodules [21] and for RF ablation of benign thyroid nodules [22]; however, as far as we know, it has never been used as guidance for RF ablation procedures of uterine fibroids.

The purpose of this study was to assess the feasibility and outcome of transvaginal ultrasound (US)-guided radiofrequency ablation of uterine fibroids assisted by a real-time virtual needle tracking (VT) system.

Methods

Institutional review board approval was obtained. Informed consent for RF ablation and to participate to our study was obtained from all patients before each procedure. All patients were informed on the potential risks and benefits of the RFA and on the possible alternative surgical treatments.

Patients

Between January 2017 and February 2018, 19 premenopausal women with 25 symptomatic uterine fibroids (diameter ranging from 2.2–4.6 cm) underwent transvaginal US-guided RFA assisted by a real-time VT system. The mean age \pm standard deviation was (age 45 ± 8 y, range: 36–53 y). Full demographics data are reported in Table 1. A flow diagram of the study is presented in Figure 1. The inclusion criteria were: 1) presence of symptomatic uterine fibroids; 2) refusal of hysterectomy or myomectomy; 3) completion of childbearing and 4) biopsy proven benign fibroid. The exclusion criteria were: 1) gynecological malignant pathology in the past five years; 2) current pregnancy; 3) previous treatment with

Table 1. Patient's characteristics at baseline.

Demographics	
Patients (n)	19
Age, mean (min, max)	45 (36–53)
Fibroids	
N. fibroids	25
N. for patient mean (min, max)	1.7 (1–3)
Patients with more than one fibroid, n (%)	10 (52.6%)
Disability	
Disability, mean (min, max)	4.8 (0–10)
In patients with one fibroid	3.5 (0–10)
In patients with more than one fibroid	5.8 (5–10)
Symptoms	
Symptomatic patients, n (%)	18 (89.5%)
Menorrhagia, n (%)	10 (52.6%)
Dysmenorrhea, n (%)	8 (42.1%)
Pollakiuria, n (%)	2 (10.5%)
Dyspareunia, n (%)	1 (5.3%)

gonadotropin-releasing hormone agonist and 4) uncontrolled coagulation disorders.

Eighteen patients were symptomatic (89.5%): 10 women complained menorrhagia (52.6%), eight patients presented dysmenorrhea (42.1%), two pollakiuria (10.5%) and one dyspareunia (5.3%, Table 1).

Pre-treatment evaluation

Pre-treatment evaluation was performed in all patients with conventional transabdominal ultrasound and transvaginal ultrasound (TV), using a high-end ultrasound machine (Logiq E9, GE Healthcare, Milwaukee, WI), equipped with a 3–5 MHz convex probe and a 1–6 MHz transvaginal probe. All evaluations were performed within a week before treatment, to obtain a complete pre-ablation assessment including the number, dimensions and location of the uterine fibroids and to establish the appropriate approach route for the RF electrode.

Contrast-enhanced ultrasound (CEUS) evaluation was also performed in all patients after the intra-venous injection of SonoVue micro-bubbles contrast (4.8 ml; Bracco, Milan) to evaluate the vascularity and to confirm the number of fibroids (Figure 2(A,B)), [23].

Immediately before ablation all patients underwent a US-guided core-needle biopsy of all fibroids to be treated [24,25].

Procedure

Ablation technique was performed with intravenous moderate sedation (induction with 1.0 mg midazolam, 0.05 ng fentanyl and 1.5–2 mg/kg propofol; maintenance with 100–200 μ g/kg/min propofol) and prophylactic antibiotics were used during the ablation. Women were placed in dorsal position, with empty bladder and were monitored with electrocardiogram and pulse oximeter. Standard sterile techniques and preparation were adopted during the procedure.

All ablation procedures were performed by a physician (G.T.) with more than 16 y of experience in interventional US.

Before ablation, transvaginal US was performed and VT track system prepared. The VT system (VirtuTRAX, CIVCO Medical Solutions, Coralville, IA) was used together with the volume navigation system (V-Nav, LOGIQ E9, GE Healthcare, Milwaukee, WI; Figure 2(C)). This platform has GPS tracking

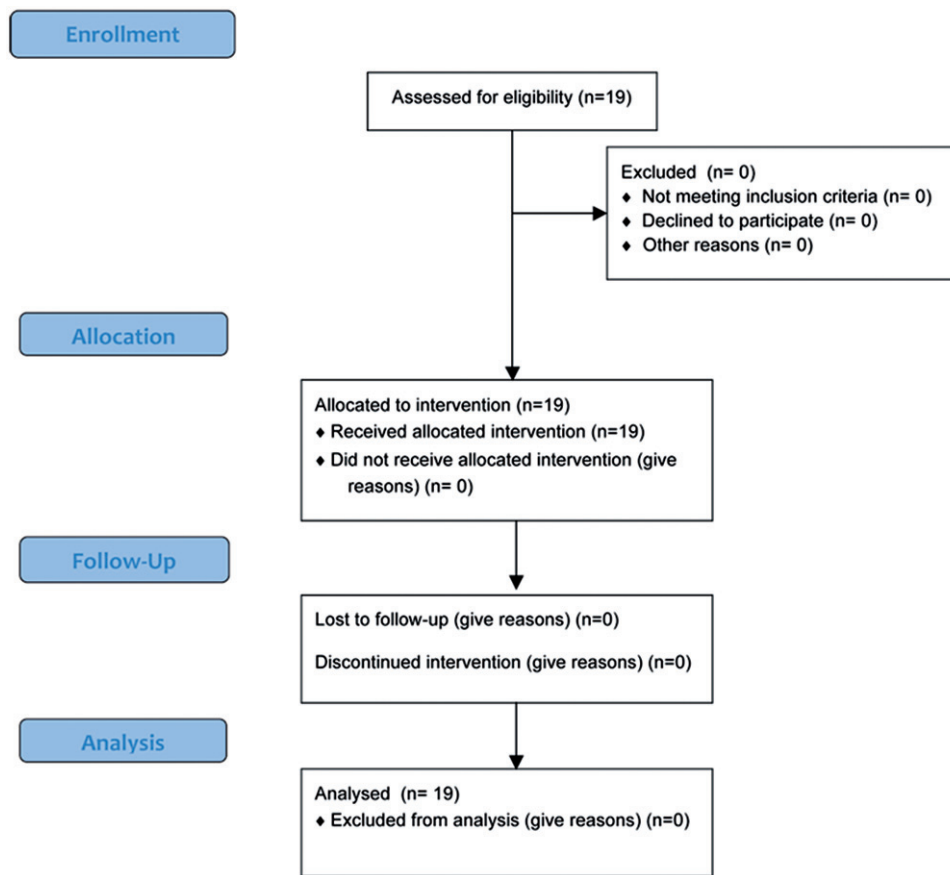


Figure 1. Consort flow diagram of the study showing no patients dropout at six-months follow-up.

capability to generate a 3-D operating volume around the patient. Two electromagnetic position sensors connected to a position-sensing unit were attached to the probe (GE Healthcare) through a bracket (Figure 2(A)). For RF electrode tracking, a similar sensor was secured on the shaft of the 17-gauge, 350-mm, fixed RF electrode (STARmed, Gyeonggi-Do, Korea; Figures 2(B) and 4(A)). The 10-mm active tip was then synchronized with the tracking device by a manual input of the RF electrode length, thus locating the exact position of the RF electrode and projecting its path on the US monitor during the procedure. Therefore, the expected RF electrode path is graphically superimposed on the B-mode image, with the color of the line dependent on the orientation with the imaging plane. When the expected RF electrode path lies fully in the imaging plane (in-plane approach), a green line appears on the B-mode scan depending on the angulation and advancement of the RF electrode and its active tip is located with a green V (Figure 4(B)). The path travelled by the RF electrode is represented by a dashed line, whereas the prospective RF electrode path is represented by a dotted line. When the RF electrode is inserted with an out of plane approach, the virtual path is projected and represented in red or blue and the location where the RF electrode will intersect the image plane is displayed in real time as a green circle. The projection of the active tip on the US scan plane is marked as a square, which becomes smaller as the RF electrode approaches the US scan plane.

The ablation system included a RF generator (STARmed, VIVA RF generator VRS01), an electric pump and the Cool-tip RF electrode (STARmed Gyeonggi-Do, Korea). The electrode was connected to the RF generator, which displays the temperature of the electrode tip, the tissue impedance characteristics, the ablation power and the time.

A 35 cm long 17G internally cooled electrode with an exposed tip of 10 mm or a variable exposed tip was used. A dedicated needle guide attached to the transvaginal ultrasound probe was used to perform VT (Figure 3(A)). Once the safest path to the target fibroid was identified with transvaginal ultrasound, the electrode was appropriately placed into of target fibroid under US real time guidance and VT. Ablation was performed with fixed needle or with the 'moving and stepping shot' technique [18], whereby the RF electrode is inserted in the distal part of the nodule and then moved 10 mm backward and upward in steps of 5–10 s.

The RF generator operated at 480 kHz with a maximum power of 200 W and at temperature ranging from 40 to 99 °C [26]. The time needed to obtain an appropriate volume of coagulation depends on both temperature and tissue impedance. The selected temperature to reach within the tissue was 85 °C and the RF generator automatically adjust the power to maintain the selected temperature. To avoid a temperature rise in the electrode, the carbonization of the surrounding tissue and the increase of electrode impedance, electrode cooling with a rapid flow ice water was used during ablation.

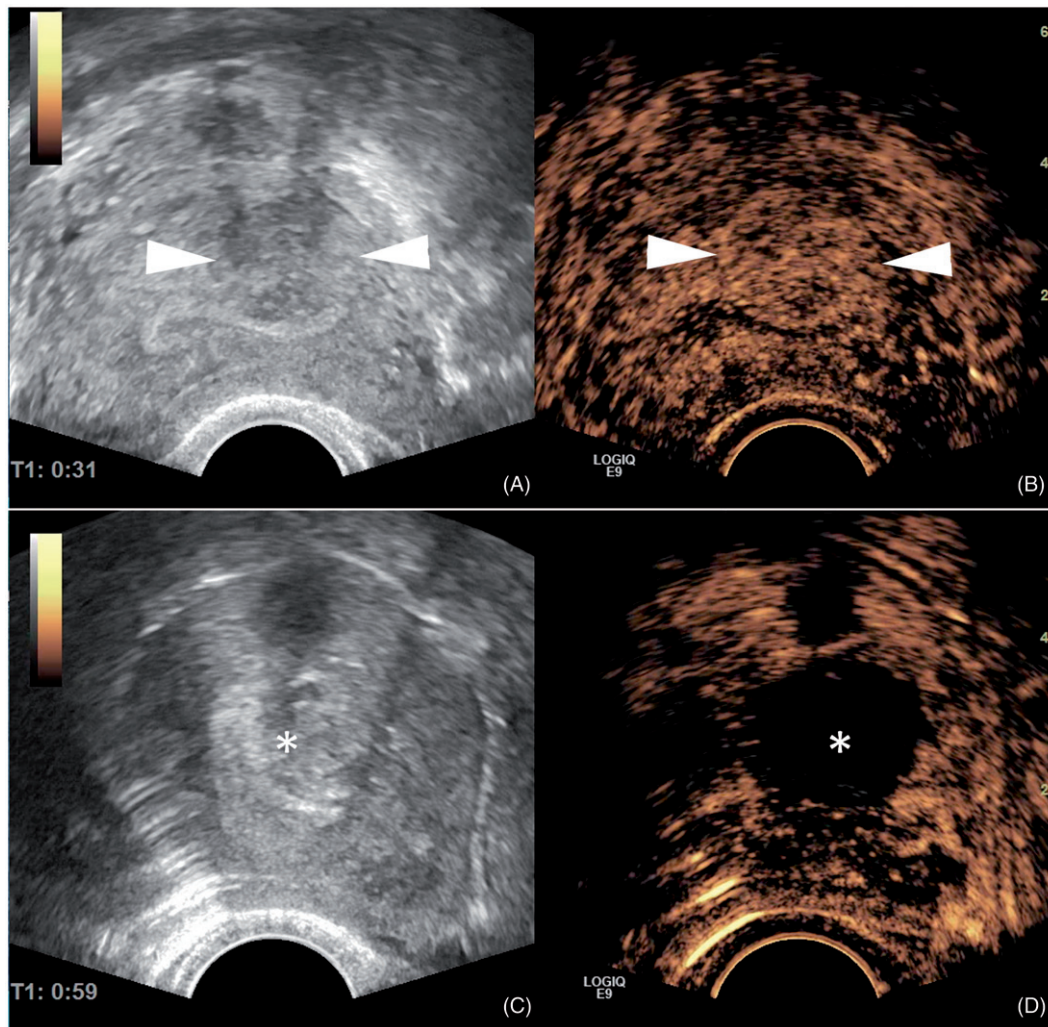


Figure 2. Contrast-enhanced ultrasound (CEUS) evaluation prior (A, B) and post (C, D) radiofrequency (RF) ablation of a submucosal fibroid (arrowheads). Note that no residual contrast enhancement could be detected after ablation procedure (asterisk).

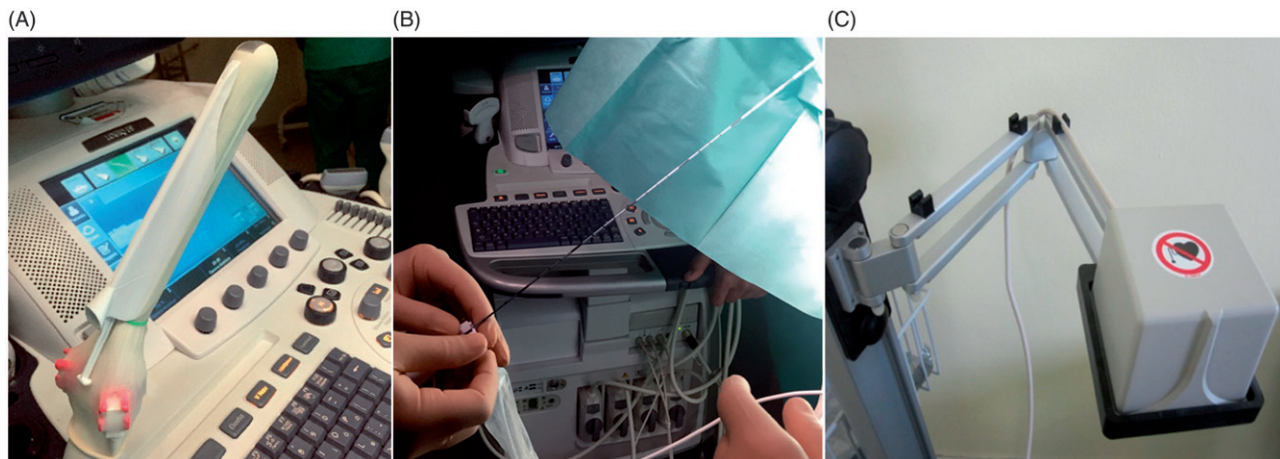


Figure 3. (A) Two small movable electromagnetic sensors are attached to the 1–6 MHz transvaginal probe (TV) with a bracket. Then, the probe and the sensors are covered with a sterile probe-cover and a sterile disposable needle-guide is applied. (B) 17-gauge, 350-mm, fixed radiofrequency (RF) electrode with electromagnetic sensor secured on its shaft (C) low-field magnetic generator for volume navigation and virtual needle tracking.

During ablation, continuous transvaginal US was used to monitor the procedure (Figure 4(B)). The total time of ablation was determined based on increased echogenicity in the fibroid. The target fibroid was ablated until the echo-enhanced area by ablation reached 80–90% of the whole

fibroid. Five to ten minutes from the end of ablation CEUS was performed in order to detect any eventual residual area on enhancement (Figure 2(C,D)).

Postprocedural pain management was started on need basis by administrating 2 g of paracetamol intravenously.

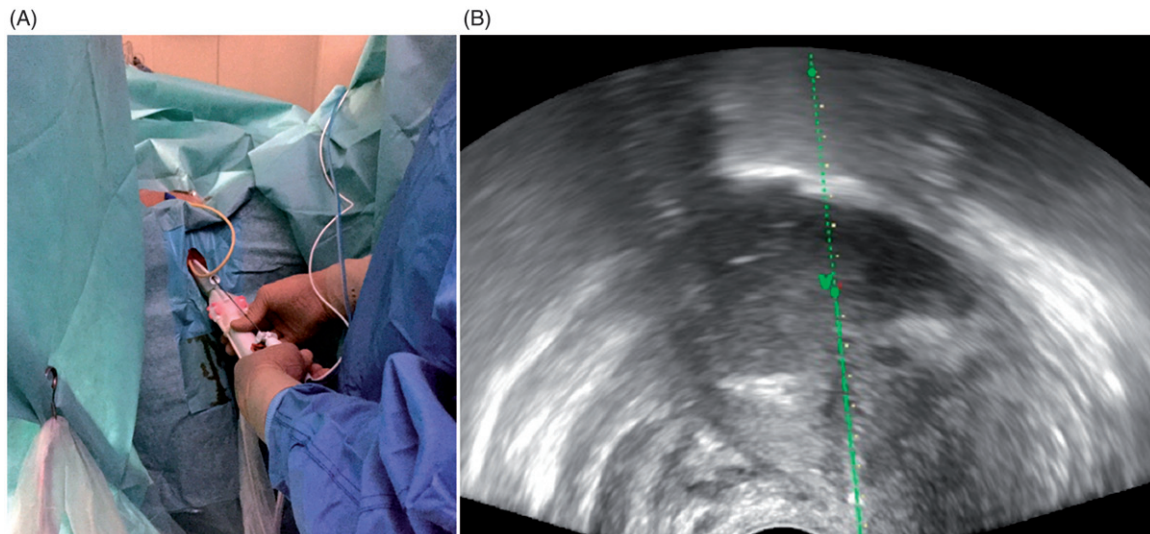


Figure 4. (A) Positions of the operator and patient. (B) Display configuration with an in-plane approach. The prospective RF electrode path is represented by the dotted line, whereas the dashed line represents the path travelled by the RF electrode. The RF electrode active tip is graphically displayed as a green 'V'.

After the procedure the patients were monitored for half day and then, if no complications were present, they were discharged.

Variables and follow-up

Feasibility of the procedure, technical success rate, complications, volume percentage reduction and clinical outcome at 1, 3 and 6 months were analyzed.

Feasibility of the procedure was defined as capability of performing the treatment as preoperatively planned.

Technical success was defined as the treatment of the fibroid according to predetermined protocol and was assessed at postprocedural CEUS following the indications of Ahmed et al. [27].

Complications were recorded and classified according to Systemic inflammatory response syndrome criteria [28].

Volume of the fibroids was calculated through transvaginal US using the formula of the ellipsoid ($V = 4/3\pi H(\text{height})W(\text{width})L(\text{length})$). Percentage volume reduction was calculated at six months from treatment as follow: $(\text{initial volume} - \text{final volume}) \times 100/\text{initial volume}$.

Symptoms improvement at six months was evaluated with the uterine fibroids symptom (UFS) and quality of life (QOL) questionnaire [6] with scores ranging from 0–100, were higher QOL scores mean a better health-related QOL.

At the six-month follow-up, patients were also asked about their overall satisfaction with the treatment, compared with baseline, using a subjective semi-quantitative scale (poor, good or excellent).

Statistical analysis

Anonymous data were entered into a database (Microsoft Excel 2010, Redmond, WA) and then analysed with SPSS Version 22.0 for Windows (IBM, Armonk, NY). Continuous variables were expressed as mean \pm SD, categorical variables were displayed as frequencies.

Nodule volume at baseline was compared with that at the six-month follow-up using the Wilcoxon test. A p value of .05 was considered to indicate significance.

UFS QOL scores were compared at different timepoints with nonparametric methods (Kruskal-Wallis rank sum test). A p value of .05 was considered to indicate significance.

Results

Transvaginal US-guided RFA assisted by a real-time VT system was feasible in 19/19 patients (100%). Technical success was achieved in all 25 fibroids (100%).

RF ablation procedures lasted between 16–43 min (mean time 28 min) depending on the size and number of treated fibroids.

Mean fibroids volume decreased from 13.6 ml (range: 5.3–41.9 ml) at baseline to 8.1 ml at one month (reduction rate 40.4%, range 19.9–60.8; ($p < .05$)), to 6.9 ml (reduction rate 49.3%, range 33.6–64.9; ($p < .05$)) and to 5.1 ml at six month (reduction rate 62.7%, range 48.5–76.9; $p < .05$; Table 2).

With volume reduction, we observed a significant symptom reduction and mean QOL scores improvement at three and six-months follow-up ($p < .05$), with a single patient complaining persistent menorrhagia (5.3%; Table 2).

No major immediate or late complications such as penetrations/burn injuries of the bowel or bladder, sepsis or peritonitis were reported. Minor complications, such as low fever, lower abdominal pain and fluid in pelvic pouches on the US examination, occurred in two patients: one patient presented low fever and abdominal pain (5.3%), while another one showed, on ultrasound evaluation, fluid in pelvic pouch (5.3%). All this findings spontaneously resolved in the first week after treatment.

Overall satisfaction at the six-month follow-up was rated by patients as positive in 18 cases (89.5%). Excellent in 15/19 patients, good in 3/19 patients and poor in only one case (5.3%).

Table 2. Longitudinal analysis ($n = 25$ fibroids).

	Median at baseline (IQR)	% Mean reduction (95% CI)		
		1 month	3 month	6 month
Volume (ml)	13.6 (5.3–41.9)	40.4% (19.9–60.8; $p < .05$)	49.3% (33.6–64.9) ($p < .05$)	62.7% (48.5–76.9) ($p < .05$)
Diameter (cm)	3.0 (2.2–4.6)	23.2% (12.9–33.7)	28.7% (20.0–37.4)	36.8% (28.7–45.0)
Clinical outcome (UFS QOL score)	68 ± 36	70 ± 40 (NS)	84 ± 22 ($p < .05$)	97 ± 16 ($p < .05$)

Discussion

The results of our study confirm that RF ablation is an effective treatment modality for uterine fibroids. The VT system was used successfully in all procedures, providing guidance that allowed all procedures, even in challenging cases, to be performed with a single puncture. At the six-month follow-up, we observed a significant mean volume reduction and clinical outcome improvement without any recurrence requiring an additional RF ablation session.

These findings are also confirmed by a recent systematic review of the literature [29] reporting high effectiveness of minimally invasive uterine fibroids treatments. Moreover RF ablation showed higher performances if compared to UAE [10] and also a lower re-intervention rate compared to MRg-FUS [30].

The main innovation of the present study consists in the application of a VT system to track the RF electrode during the ablation session. This setting has great potential to provide more accurate and radical RF ablation in several situations.

First, extreme precision is required when the RF electrode active tip is obscured by the bubbles produced during the ablation procedure as well as when the RF electrode active tip is in the proximity of the fibroid margins, where multiple fibroid punctures can cause serosal injury, adhesions and potential myometrial disruption during a future pregnancy.

Therefore, the use of a virtual guidance is extremely helpful for inexperienced operators, who may take advantage of the more reliable localization of the RF electrode active tip, allowing a shorter learning curve [31]. Moreover, when dealing with fibroids located in challenging positions, also 'out-of-plane approaches', could be required; virtual needle guidance could work-out the problem of the extremely poor visualization of the RF electrode, so the fibroid can be reached and treated [22].

As previously described for the liver [21], we found some technical problems that need to be solved to use this technique in the clinical setting. If the RF electrode is advanced without bowing on the same path of the virtual tract, the tip of the RF electrode coincides exactly with the target. When dealing with hard fibroids, the RF electrode could bend considerably, producing inaccuracies between the virtual tract and the RF electrode and also increasing the risk of breaking the Teflon coating of the electrode. This problem may be solved using a RF electrode more rigid than those used in this study and also moving gently inside the fibroid.

Moreover, we experienced some RF artefacts on the lower part of the US image during RF ablation procedures. Conversely, these RF artefacts do not influence the GPS-enhanced VT system, which becomes extremely useful when the native US image is not completely clear. However, this problem needs to be solved by US manufacturers to enhance the role of US guidance of RF ablation procedures.

No major complications occurred in our series, resulting in a complication rate equal or lower to those reported in literature [32]. In this setting, we could speculate that the use of virtual needle guidance could be helpful in reducing complications related to the poor visualization of the RF electrode active tip, especially during ablation of fibroids closer to sensitive structures.

Moreover, when dealing with submucosal fibroids, the induction of artificial ascites with injection of a small amount of saline solution (salinoma) [24] outside the uterine wall could be helpful in order to reduce the risk of damage due to heat to the surrounding bowel, vessels and bladder [33].

Good to excellent overall satisfaction was reported by a majority of the patients who underwent the procedure. This confirms that the procedure is positively accepted by patients, because of the good results with better quality of life, the preservation of uterus and fertility, short duration of the procedure and rapid return to daily activities.

The main limitations of the present study are two. First, the absence of a control group, as we meant to perform a feasibility study, proving that the VT system could be useful guidance for RF ablation of uterine fibroids.

The second limitation is the quite short follow-up; however, several articles have reported that a six-month follow-up is sufficient to evaluate the outcome of the RF ablation procedure [17,19]. On the other hand, other studies with very long follow-up [34] suggest that incompletely treated nodules may start to enlarge 1–2y after ablation. Indeed, we cannot be sure about the radicality of our treatment, but we can speculate that a more confident and precise ablation may be related to reduction of recurrences. Obviously, further double-blind studies with longer follow-ups are required to confirm this observation.

Conclusion

Image-guided percutaneous ablation appear to be effective in obtaining volume reduction of uterine fibroids and in providing significant symptoms improvement. Moreover, this technique was demonstrated to be effective also in the treatment of several benign and malignant diseases around the human body [35–38]. Thanks also to the wider application of advanced techniques, such as CEUS [39–41] and virtual navigation, with fusion imaging [20,42,43], US-guided RF myolysis represent an effective alternative to conventional surgery for the treatment of uterine fibroids. The VT system provides effective guidance in RF ablation of uterine fibroids. Virtual needle tracking system allows a safe and effective ablation of uterine fibroids, allowing a constant view of the RF needle to recognize the real tip despite ablation artifacts and reducing complications. CEUS vascularity assessment helps to evaluate

the technical success of the procedure and to highlight areas of residual enhancement.

If confirmed by further prospective randomized trials, this technique may improve the accuracy and outcome of RF ablation while reducing the complication rate and shortening the learning curve for this procedure.

Disclosure statement

Giovanni Mauri is consultant for Elesta SrL. All other authors report no conflict of interest.

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