



Heat can treat: long-term follow-up results after uterine-sparing treatment of adenomyosis with radiofrequency thermal ablation in 60 hysterectomy candidate patients

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Abstract

Background Adenomyosis may induce pelvic pain, abnormal uterine bleeding or bulk symptoms. If hormonal treatment proves ineffective or contraindicated, hysterectomy may be necessary. For patients who desire to conserve the uterus despite severe symptomatology, uterine-sparing techniques have been introduced. Radiofrequency thermal ablation (RFA) consists of the local application of high temperature to eliminate diseased tissue, applied recently for adenomyosis treatment. The objective of the study was to analyze the efficacy of RFA for avoiding hysterectomy in patients with adenomyosis-related symptoms.

Methods This is a single-center, retrospective cohort study performed in a referral center for endometriosis. The study population consisted of all consecutive patients who underwent Radiofrequency thermal ablation (RFA) treatment as an alternative to hysterectomy for adenomyosis between March 2011 and June 2019 in our institution. RFA was performed using laparoscopic access. To evaluate the impact of RFA treatment on symptoms, follow-up findings were compared to preoperative symptomatology using the ten-point visual analog scale (VAS) for pain assessment.

Results Sixty patients were included in the study, 39 of them (65%), underwent a concomitant surgery for endometriosis in association to RFA. On a long-term follow-up (mean 56 months (range 10–115, SD 29), hysterectomy was performed in 8 patients (13%). The mean VAS score before vs after surgery was 7.4 vs 3.3 for dysmenorrhea, 3.7 vs 0.3 for dyschezia, 4.7 vs 0.7 for dyspareunia, and 4.0 vs 1.4 for chronic pelvic pain, being significantly reduced after RFA for all these pain components ($p < 0.0001$ in every case). Thirty-one patients (52%) suffered from AUB before RFA, this symptom persisted in 10 patients (16%) during follow-up ($p < 0.001$). Bulk symptoms were present in 16 patients (27%) and disappeared after RFA in all cases.

Conclusions RFA allows for hysterectomy avoidance in most cases. It leads to marked improvements in pain symptomatology, uterine bleeding and bulk symptoms.

Keywords Adenomyosis · Endometriosis · Hysterectomy · Radiofrequency thermal ablation · Uterine-sparing

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Abbreviations

<i>RFA</i>	Radiofrequency thermal ablation
<i>MUSA</i>	Morphological Uterus Sonographic Assessment
<i>HIFU</i>	High-intensity focused ultrasound
<i>AUB</i>	Abnormal uterine bleeding
<i>VAS</i>	Ten-point visual analog scale

Uterine adenomyosis may present a diffuse or focal disease [1, 2] and lead to different pelvic pain components [3] or bulk symptoms [4].

One-third of adenomyosis cases are asymptomatic [5]. Hormonal therapy is a first-line treatment; however, it

may prove ineffective and hysterectomy may be necessary. Patients, especially young, often prefer to conserve the uterus despite suffering severe symptomatology [6]. In the past, adenomyosis was usually associated with advancing age and parity, however, nowadays, 20% of total cases is detected in younger women [7]. Therefore, different uterine-sparing approaches have been introduced [4, 8].

Adenomyosis-related symptoms may be similar to those of endometriosis, and the two conditions coexists in 20–50% cases [9, 10]. Uterine adenomyosis may spread into the anterior compartment, infiltrating the bladder [11], or it may involve the posterior compartment, infiltrating the rectovaginal septum and/or parametrium [12–14]. These aspects must be carefully considered when surgical treatment is planned. Therefore, an adenomyosis treatment strategy that allows the visualization and targeted removal of all lesions seems to be optimal, of which laparoscopy can be considered the gold standard.

RFA is a thermal ablation treatment modality, involving the local application of high temperature to eliminate diseased tissue. It has been widely applied for the treatment of uterine fibroids [15], and thereafter for adenomyosis [16]. The mechanism of action involves inducing coagulative necrosis by ionic movement using an alternating current to heat the affected area [17]. The result of RFA is a progressive reduction in its volume, even up to 12 months after surgery [16].

Objectives

Primary objective

To assess the efficacy of RFA for avoiding hysterectomy in patients with adenomyosis-related symptoms by considering long-term follow-up data.

Secondary objective

To assess the outcome of radiofrequency thermal ablation (RFA) laparoscopic treatment of uterine adenomyosis in terms of pain scores, abnormal uterine bleeding (AUB) and bulk symptoms.

Materials and methods

This is a single-center, retrospective cohort study. Between March 2011 and June 2019, sixty patients underwent RFA treatment as an alternative to hysterectomy for adenomyosis in our institution (Department of Obstetrics and Gynecology, Gynecologic Oncology and Minimally-Invasive Pelvic Surgery, International School of Surgical Anatomy, Sacred

Heart Hospital, Negrar di Valpolicella, Verona, Italy), all of which were included in our study. Within the same time period, approximately 70,000 patients were referred to our institution for endometriosis treatment, 10,000 of which underwent surgical treatment for endometriosis. Of these 10,000 patients, 850 underwent laparoscopic hysterectomy with endometriosis being associated. Patients were eligible for inclusion in our study if they had symptomatic adenomyosis, not responsive to medical therapies and they desired to preserve their uterus.

Patients who presented concomitant uterine fibroids were not included, to avoid a possible bias related to the presence of other uterine pathology.

All patients underwent a pelvic examination and pelvic ultrasonography. Diagnosis and mapping of adenomyosis was made with the use of transvaginal ultrasound, according to Morphological Uterus Sonographic Assessment (MUSA) criteria [18]. Focal adenomyosis was diagnosed if the affected tissue was surrounded by tissue comprised of at least 25% healthy myometrium, otherwise adenomyosis was classified as diffuse. Adenomyoma was reported if focal adenomyosis was distinctly demarcated and surrounded by hypertrophic myometrium [2]. If numerous focal lesions were present, they were described separately. The localization of each lesion on the fundus, anterior, posterior, lateral right or left uterine wall, was reported.

Painful symptoms such as dysmenorrhea, dyspareunia, dyschezia, dysuria and chronic pelvic pain were evaluated at hospital admission and at each ambulatory evaluation. Pain for each component was assessed using the visual analog scale (VAS) ranging from 0 to 10 points. If hysterectomy was performed, a maximal VAS score for pain was the deciding factor for demolitive surgery. Patients were asked about their subjective evaluation of the outcome of the treatment performed, using a 5-point scale: 1 (completely disappointed), 2 (partially disappointed), 3 (uncertain), 4 (partially satisfied), and 5 (completely satisfied). Postoperative complications, if present, were classified according to Dindo–Clavien grading system for surgical complications [19, 20].

In our study, RFA was performed using the StarBurst (AngioDynamics) system, consisting of a current generator and pump (IntelliFlow Pump, AngioDynamics) allowing for the irrigation of affected tissue with a continuous flow of isotonic solution, and a RITA StarBurst Talon 14G Device (AngioDynamics) characterized by a central hook and 4 additional extractable tines, each positioned at 90° from the other, containing electrodes, thermocouple sensors, and open tips for fluid dropping. The precise ultrasonographic mapping of the lesion and the centimeter scale on the needle, allows a focused treatment of the affected tissue. The Starburst system allows for a sphere of treatment ranging from 2 to 4 cm in diameter. In cases of lesions bigger than 4 cm, the overlapping technique was applied, using repeated

needle accesses to create multiple spheres of coagulation so as to achieve complete ablation of the affected site (Supplemental Fig. 1).

The temperature and current being applied to the tissue undergoing treatment is shown in real time on a display and may be controlled by the surgeon. Throughout the procedure, the StarBurst generator keeps the operator informed about the efficiency parameters correlating with ablation quality.

In all cases the RFA treatment was performed in laparoscopic approach, which allowed to perform a careful inspection the abdominal cavity and a concomitant removal of all endometriotic lesions, if present, according to the surgical technique previously reported in our studies [11–14]. In all cases hysteroscopy was also performed during surgery to evaluate the uterine cavity.

Statistical analysis

Continuous variables were expressed as the mean and standard deviation or median and interquartile range for the asymmetric or non-normal variables. Categorical variables were expressed by their frequency distribution.

The rate of patients requiring surgical treatment for hysterectomy after RFA, as an expression of treatment failure was calculated, and the timing of hysterectomy was also reported.

For each different pain parameter (dysmenorrhea, dyspareunia, dyschezia, dysuria, chronic or pelvic pain) comparison (pre vs post-surgery) the paired Student's t-Test or the Wilcoxon Matched-Pairs Signed-Ranks Test was applied.

A p-value of less than 5% was considered to be statistically significant.

Statistical analysis was performed using STATA vers.15 (StataCorp LLC, 4905 Lakeway Drive, College Station, Texas 77,845, USA).

Ethical aspects

This study was performed according to the guidelines for observational studies and in accordance with the last revision of the Declaration of Helsinki.

The study obtained approval of a local Institutional Review Board (Prot n. 42,083).

Results

The study population comprised 60 patients with indications for hysterectomy in the treatment of adenomyosis who underwent uterine-sparing RFA laparoscopic treatment between March 2011 and June 2019 at our center, all of

them completed follow-up. The mean follow-up period was 56 months (range 10–115, SD 29).

The mean age at surgery was 43 years (range 38–50, SD 3.0). In 39/60 cases (65%), concomitant surgery for endometriosis was performed, with DE identified in 36 patients (60%). Bowel endometriosis was present in 13/60 patients (21%) and was managed with segmental resection in 6 (10%), discoid resection in 2 (3%) and rectal shaving in 5 (8%). Extension of the disease into the parametrium was observed in 26/60 patients (44%) and required unilateral or bilateral parametrectomy in 10 (17%) and 16 cases (27%) respectively. Bladder nodules necessitating bladder partial resection were found in 1 case (2%). Patient characteristics, surgical procedures and surgery duration times are reported in Table 1.

The mean intraoperative blood loss was 49 ml per patient (range 0–200, SD 46). The mean surgery duration for all 60 patients was 123 min (30–300 range, SD 59) being 139 min for patients undergoing concomitant surgery for endometriosis (range 45–300) and 93 min (range 30–150) for those not, revealing a significantly shorter surgical duration for the latter group ($p=0.0004$). The mean duration of hospitalization for all 60 patients was 4 days (range 1–9, SD 2). Among the 39 patients undergoing concomitant surgery for endometriosis, the mean time until discharge was 4 days (range 3–9), while for patients undergoing isolated adenomyosis treatment, it was 2 days (range 1–3). No intraoperative complications were reported for any patient. Early complications included one case (2%) of postoperative fever treated with antibiotics (grade I according to Dindo–Clavien grading system for surgical complications) in a patient having undergone concomitant endometriosis surgery.

Pain was present in 49/60 patients (82%), manifesting alone in 16 cases (27%) and in association with other symptoms in 33 (55%). AUB presented in 31/60 patients (52%) and bulk symptoms in 16 (27%). Symptoms which induced surgical treatment are shown in Fig. 1. The most frequently reported symptom was related to pelvic pain with concomitant AUB (27/60 patients, 45%). 22 patients (37%) had undergone previous endometriosis surgeries (mean 2 surgical treatments, range 1–5) that had failed to control symptoms, such as pelvic pain, which continued to persist. 19/60 patients (32%) presented with contraindications to medical therapy and a further 19 (32%) presented with symptoms refractory to medical treatment.

Sites of uterine adenomyosis are shown in Supplemental Fig. 2. The most frequent site was the posterior uterine wall, which presented in 35/60 cases (58%) as a single localization and in 9 cases (15%) in association with anterior wall adenomyosis. In one case (2%), a double posterior focal adenomyosis was identified. The anterior wall was a single site of adenomyosis in 9/60 patients (15%), whereas the fundus was in 6 others (10%). Adenomyosis

Table 1 Characteristics of all 60 patients included in the study along with associated surgical procedures, endometriosis sites, duration of surgery, and RFA procedure details

Age (years): mean (range), standard deviation	
	43 (38–50), SD = 3.09
Associated endometriosis	39 (65%)
I stage rASRM	0 (0%)
II stage rASRM	2 (3%)
III stage rASRM	2 (3%)
IV stage rASRM	35 (58%)
Associated surgical procedures and endometriosis sites: number (percentage)	3 (5%)
Bilateral endometriomas	8 (13%)
Monolateral endometriomas	36 (60%)
Deep infiltrating endometriosis	6 (10%)
Bowel segmental resection	2 (3%)
Bowel discoid resection	5 (8%)
Bowel shaving	16 (27%)
Bilateral parametrectomy	10 (17%)
Monolateral parametrectomy	1 (2%)
Appendectomy	1 (2%)
Salpingectomy	36 (60%)
Ureterolysis	1 (2%)
Vaginal resection	1 (2%)
Bladder resection	123 (30–300), 59
Surgery duration (minutes): mean (range), SD	139** (45–300), 64
Total study population (60 patients): minutes (range), SD	93** (30–150), 35
Associated endometriosis surgery (39 patients): minutes (range), SD	(3–45), 9.15
No associated pelvic endometriosis (21 patients): minutes (range), SD	
Duration of RFA procedure: mean minutes (range), SD	

** Although additional procedures (adhesiolysis, salpingectomy) can prolong surgery duration, the only significant difference in surgery duration was apparent between patients with and without associated endometriosis ($p = 0.0004$)

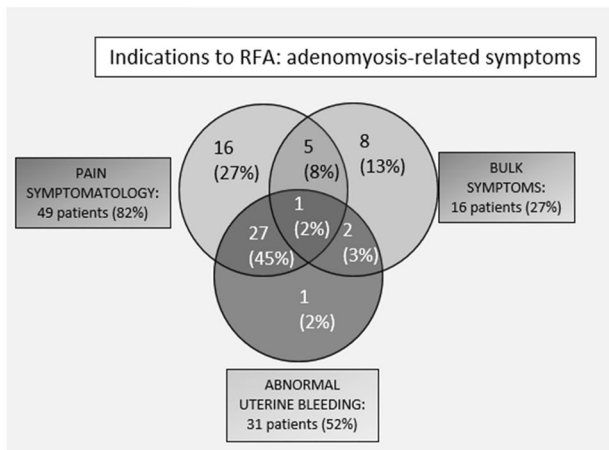


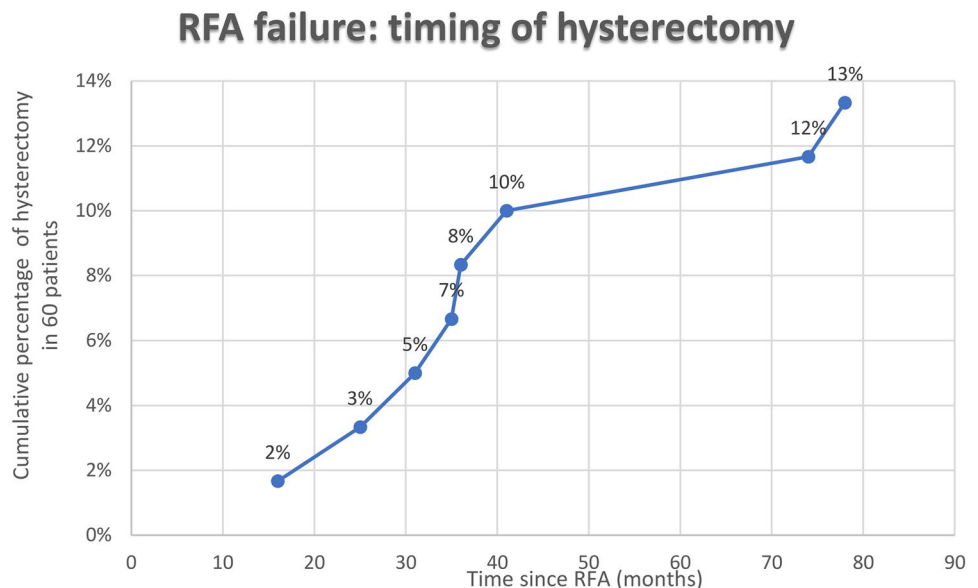
Fig. 1 Adenomyosis-related symptoms as indications for surgical treatment and their associations. The number of patients reporting each symptom and its percentage of the total study population of 60 patients is shown

was classified as focal in 33/60 cases (55%), diffuse in 13 (22%) and the presence of a distinct adenomyoma was detected in 14 patients (23%). In 10 patients (17%), we observed more than one adenomyosis site.

The mean number of applications of RFA necessary for the treatment of adenomyosis (multiple treatments are required for the overlapping technique or in cases with double adenomyosis sites) was 1.9 (range 1–5, SD 1). In 23/60 patients (38%), a single access was performed only.

8/60 patients (13%) underwent hysterectomy during follow-up (Fig. 2). Indications were related to pelvic pain (6 patients) and isolated or concomitant AUB (6 patients).

Fig. 2 Cumulative percentage of hysterectomy as RFA failure (for a total of eight in 60 patients): timing of hysterectomy during follow-up

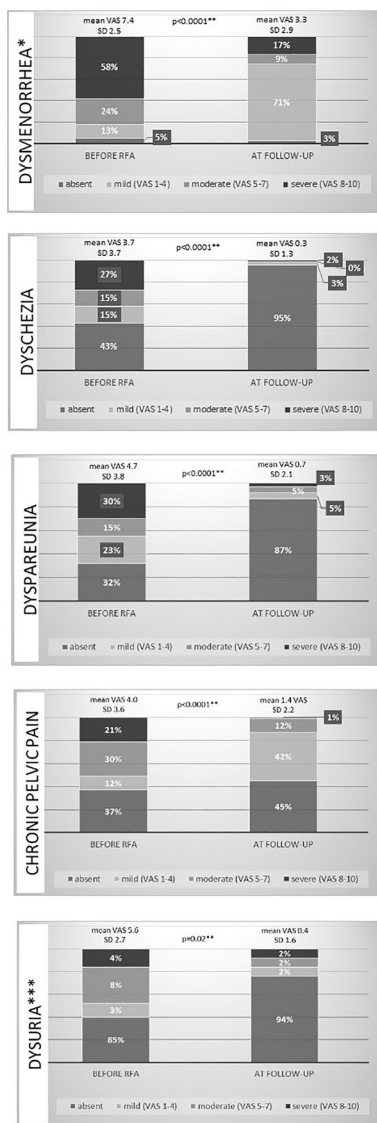


The mean time from RFA to hysterectomy was 45 months (range 16–78, SD 22).

Pain reduction after RFA was observed for all pain components. For the evaluation of dysmenorrhea, we excluded patients who had not menstruated (due to hormonal treatment) for at least 6 months before RFA or at the time of follow-up, and as such, only 32 cases were evaluated for this parameter. The mean VAS score before and after RFA was 7.4 and 3.3 respectively, with the delta score being 4.1, SD 3.5 ($p < 0.0001$). The mean VAS score before vs after surgery was 3.7 vs 0.3 for dyschezia, 4.7 vs 0.7 for dyspareunia, and 4.0 vs 1.4 for chronic pelvic pain, being significantly reduced for all three pain components ($p < 0.0001$ in every case). The percentage of patients reporting a severe VAS score (> 7) was also significantly lower ($p < 0.05$) after RFA for all pain components (Fig. 3).

Before RFA, dysuria was reported by 9/60 patients. When evaluated only in symptomatic patients, the mean preoperative VAS score was 5.6, which was reduced, after RFA, to 1.6, with the mean delta score being 4.0. Statistical analysis confirmed a significant difference between the scores ($p = 0.02$). The VAS score for all pain components before and after surgery is shown in Fig. 3.

Before RFA, 31/60 patients (52%) suffered from AUB due to hypermenorrhea or continuous bleeding. After surgery, AUB persisted in 10 patients (16%), while menstruation was normal in 22 (36%). A further 28/60 patients (47%) presented with amenorrhea, 12 (20%) induced by continuous hormonal treatment, 4 (6%) related to Asherman’s syndrome, and 12 (20%) related to ovarian inactivity. In all cases, the cessation of ovarian activity occurred in potentially menopausal patients (aged over 40 years) with a mean age of 45 years (range 40–50, SD 3.8). The mean time



* for evaluation of dysmenorrhea, patients with amenorrhea were excluded, so evaluation was performed in 32 patients

**p value is referred for the mean VAS score before treatment and during follow-up, confirmed by non-parametric tests

***for dysuria, as a less frequent symptom, the analysis included the subgroup of patients who reported dysuria before surgery. Regarding these 9 patients, the difference in the VAS score before and after RFA was statistically significant, with a mean difference of 4 points (p value=0.02

Fig. 3 Adenomyosis-related symptoms before and after surgery for all pain components: dysmenorrhea, dyschezia, dyspareunia, dysuria, and chronic pelvic pain. The mean VAS score and the percentage of patients who reported severe (VAS 8–10), moderate (VAS 5–7), mild

(VAS 1–4) or completely absent symptoms are shown. The mean differences between pre- and postoperative VAS scores for dysmenorrhea, dyschezia, dyspareunia, chronic pelvic pain, and dysuria were 4.1, 3.4, 3.8, 2.6, 4.0

from RFA to menopause onset was 1 year (range 0–4 years, SD 1.5).

Four patients presented with amenorrhea related to Asherman’s syndrome. In these cases, severe intrauterine adhesions were diagnosed upon hysteroscopy. The mean age of patients with Asherman’s syndrome was 42 years (range 39–45, SD 2.8).

Bulk symptoms were present in 16 patients (27%) and disappeared after RFA in all cases.

Last ultrasonography in expert hands was considered for the evaluation of adenomyosis during the follow-up, with the mean time from RFA to ultrasound of 49 months (range 9–115, SD 27). Adenomyosis had completely disappeared in

11 of these 56 cases (20%), had reduced in 36 others (64%), and initially diminished before recurring again in one case. It remained unchanged in 12 patients (21%).

Most patients were completely satisfied (34/60, 56%) or partially satisfied (9/60, 15%) with the results of RFA treatment. 7/60 patients (12%) were uncertain, a further 8 patients (13%) were partially disappointed, and 2 others (3%) were completely disappointed. 47/60 patients (78%) said that with hindsight they would still undertake the same treatment, and the same number would recommend the procedure to a friend suffering the same clinical condition.

Two term pregnancies occurred during follow-up, both as a result of spontaneous conception. One occurred at

36 months after RFA in a patient having had two previous first-trimester miscarriages. The delivery was performed by cesarean section at 35 gestational weeks, due to preterm contractions. The other pregnancy occurred 53 months after RFA with a vaginal delivery being performed at full term. Good maternal and fetal outcomes were reported in both cases.

A possible bias could be related to the presence of endometriosis in association to adenomyosis in 65% of patients. For this reason, a multivariate analysis was performed, excluding any influence by factors such as association of endometriosis surgery, endometriosis site, presence of DE, type of adenomyosis (diffuse or focal), severity of preoperative symptomatology, and pre- or postoperative medical therapy, on the delta value for pain regarding preoperative and postoperative VAS scores.

In the subgroup of patients with isolated adenomyosis a reduction of intensive bleeding was observed as well: metrorrhagia was present in 14 of 21 (67%) patients before and in five of them (24%) after surgery ($p = 0.005$). Among patients with isolated adenomyosis the mean VAS score for dysmenorrhea was 7.06 before surgery and 4.0 after surgery, with the delta score of 2.73 ($p < 0.01$). Dysmenorrhea was evaluated in 16 of 21 women with isolated adenomyosis, excluding women with amenorrhea induced for at least 6 months before RFA or at the time of follow-up. The percentage of patients reporting a severe VAS score (> 7) for dysmenorrhea in this subgroup was 63% (10 of 16) before surgery, and 19% (3 of 16) after surgery.

Discussion

In order to avoid hysterectomy in patients suffering from adenomyosis-related symptoms, who are unresponsive to conventional therapies, several treatment approaches may be considered [4, 8]. Specifically, we have presented the outcome of RFA treatment using a laparoscopic approach, which has the advantage, contrarily to the vaginal route, of a concomitant visualization and eradication of all endometriosis lesions, and a general exploration of the pelvic area so that other causes of pelvic pain could be ruled out.

Overall, patients affected by a complex disease of adenomyosis associated to endometriosis (39/60, 65%), and those with isolated adenomyosis (21/60, 35%) have reported good outcomes during follow-up.

In most cases (52/60, 87%), RFA treatment was effective in avoiding the need for hysterectomy. Among the 8 patients for whom RFA failed, the mean amount of time between RFA and hysterectomy was 42 months (range 16–78), suggesting at least some short-term relief from symptoms.

Our results suggest a relevant improvement in pelvic pain after RFA, with VAS scores for all components

including, dysmenorrhea, dyspareunia, dyschezia, dysuria, and chronic pelvic pain, significantly lower ($p < 0.05$) after RFA, over long-term follow-up.

In our study, most patients were completely (56%) or partially (15%) satisfied form with RFA treatment.

It has already been demonstrated that RFA leads to a marked improvement in dysmenorrhea and uterine volume [21–23]; however, our findings reveal significant relief from other symptoms such as dyspareunia, dyschezia, dysuria, and chronic pelvic pain. Further to this, the results of multivariate analysis excluded any influence of concomitant endometriosis surgery on these results. The outcome in terms of pain reduction was optimal for all types of adenomyosis, including focal and diffuse adenomyomas, suggesting that RFA treatment could be a wide-reaching therapeutic option.

In comparison to excisional techniques, RFA is less invasive. Adenomyosis, even if focal, is characterized by a lack of clear demarcation between affected and healthy tissue. As a consequence, during excision, excessive bleeding, and incomplete asportation of adenomyosis may result. Moreover, as the suture may be placed in areas infiltrated by residual adenomyotic tissue, difficulty in correct reconstruction and hemostasis during uterine closure may result.

Surgical treatment for diffuse adenomyosis is even more difficult than that of the focal one, as the disease infiltrates extensive areas of the uterus. It requires wide access to the uterine wall with a large incision into the myometrium; specialized techniques such as “H” shaped incision, have been developed for this purpose [24]. Uterine artery ligation may be helpful in reducing bleeding; however, the invasive nature of the procedure and its possible complications are significant.

RFA presents a viable alternative to such excisional techniques. Although the clear demarcation of healthy tissue from that affected by adenomyosis is often not obvious during surgery, ultrasonography is able to identify adenomyosis sites. As such, RFA treatment based on ultrasonographic mapping could spare uninvolved tissue more effectively.

Of other uterine-sparing techniques for adenomyosis treatment, HIFU has reported good outcomes in terms of symptom relief and restored uterine volume [25]; however, its efficacy seems to be reduced when adenomyosis is in the posterior uterine wall [26, 27], a commonly identified site in our study.

In relation to the reduction of AUB, we can hypothesize that the mechanism in which RFA alleviates uterine bleeding may be related to thrombosis induction in blood vessels within the treated tissue, and inactivation of estrogenic receptors in the surrounding unaffected area [22]. It may also be due to a progressive reduction of adenomyotic lesions, remodeling of uterine morphology and normalization of coordinated uterine contractions.

The strengths of the study is related to good quality of preoperative diagnosis and surgical techniques, as it was performed in a referral center for endometriosis.

A possible bias could be related to the presence of endometriosis in association to adenomyosis in 65% of patients. For this reason, a multivariate analysis was performed, excluding any influence by factors such as association of endometriosis surgery, endometriosis site, presence of DE, type of adenomyosis (diffuse or focal), severity of preoperative symptomatology, and pre- or postoperative medical therapy, on the delta value for pain regarding preoperative and postoperative VAS scores.

In conclusion, on a long-term follow-up, RFA was an optimal uterine-sparing treatment for symptomatic adenomyosis manifesting alone, or when associated with endometriosis. Complications were predominantly related to concomitant endometriosis surgery. RFA allowed for hysterectomy avoidance in most cases, leading to marked improvements in pain symptomatology, uterine bleeding and bulk symptoms.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00464-021-08984-z>.

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Declarations

Disclosures Anna K. Stepniewska declares that she has no conflict of interest and nothing to disclose. Silvia Baggio declares that she has no conflict of interest and nothing to disclose. Roberto Clarizia declares that he has no conflict of interest and nothing to disclose. Francesco Bruni declares that he has no conflict of interest and nothing to disclose. Giovanni Roviglione declares that he has no conflict of interest and nothing to disclose. Matteo Ceccarello declares that he has no conflict of interest and nothing to disclose. Maria Manzone declares that she has no conflict of interest and nothing to disclose. Massimo Guerriero declares that he has no conflict of interest and nothing to disclose. Marcello Ceccaroni declares that he has no conflict of interest and nothing to disclose.

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