IJIMM, Volume 3, Issue 4, 2025
ISSN: 2995-5319
http://medicaljournals.eu/index.php/IJIMM

INTERNATIONAL JOURNAL OF
INTEGRATIVE AND
MODERN MEDICINE

Radiofrequency Ablation of Uterine Fibroids: A Review of Techniques, Efficacy and Outcomes

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Abstract: During the reproductive stage, uterine fibroids, which are benign smooth muscle tumors, can significantly impact a woman's quality of life. Pharmacologic treatment and surgical procedures like myomectomy and hysterectomy are included in traditional management. Radiofrequency ablation (RFA) has been a popular minimally invasive method for treating bothersome fibroids in recent years. This study covers RFA's indications, clinical efficacy, safety profiles, procedural methods, and potential future prospects in the treatment of fibroids. RFA is a good option for women looking for uterine-sparing therapy because of data from recent clinical trials and case series that demonstrate its effectiveness in symptom relief, uterine preservation, and accelerated recovery.

Keywords: uterine fibroids; leiomyoma; radiofrequency ablation; minimally invasive treatment; fertility preservation; uterine-sparing therapy; fibroid management; myolysis.

Introduction

An estimated 70% to 80% of women will develop uterine fibroids before reaching middle age, solidifying their status as the most common non-cancerous tumor found in the female pelvic region. Significantly, a substantial portion of women diagnosed with uterine fibroids, over 33%, report symptoms that negatively impact their daily routines, including discomfort from the fibroids' size and/or heavy menstrual bleeding [1,5].

Women who experience persistent symptoms from uterine fibroids may be offered a variety of surgical and interventional treatments, such as uterine artery embolization, myomectomy, and hysterectomy. However, because there is a growing need for less invasive techniques that preserve the uterus, patients may not be comfortable with these operations [1].

The initial management of fibroids with symptoms depends on a woman's plans for future pregnancy. In the US alone, over 200,000 hysterectomies are performed annually to address fibroid-related issues. There's a rising worry about the excessive use of hysterectomy as a fibroid treatment, as patients increasingly seek less invasive procedures that preserve the uterus. Myomectomy and uterine artery

embolization (UAE) are viable uterus-sparing alternatives to hysterectomy, suitable for patients who meet specific criteria [2,7].

Since radiofrequency ablation (RFA) may be administered in a minimally invasive manner, it is a safe and efficient therapy option. To cause coagulative necrosis and alleviate fibroid symptoms, RFA can be introduced into the fibroid uterus via laparoscopic, transvaginal, or transcervical means [1,14].

An incisionless transcervical ablation outpatient method guided by sonography has been developed to improve the treatment of symptomatic fibroids in women. At one year, there were clinically significant improvements in patient-reported symptom relief, no device-related complications, and a surgical reintervention rate of less than 1% in the sonography-guided transcervical ablation of uterine fibroids (SONATA) pivotal trial, which was conducted under an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) [3].

History of RFA. Initially used for liver cancer in the 1990s, radiofrequency ablation (RFA) has since expanded its use to treat various cancers across different organs. Dr. Lee pioneered its application in uterine fibroid treatment in 2002 through the Acessa technique, a minimally invasive approach utilizing laparoscopy and ultrasound guidance. This method shrinks fibroids and provides an alternative to hysterectomy, although its widespread acceptance has been less than procedures like uterine artery embolization. Although this process demonstrates potential for fertility enhancement, it currently lacks FDA authorization for fertility preservation purposes, and insurance reimbursement is frequently unclear [10].

The Transcervical Radiofrequency Ablation (TFA) technique, a minimally invasive gynecological treatment, employs a miniature ultrasound probe inserted into the uterus. Before the ablation process, a detailed ultrasound examination is conducted to pinpoint the fibroid's location and characteristics. TFA is typically performed under general anesthesia, utilizing a device with an 8.3 mm diameter and a penetration limit of 12 cm. A user-friendly interface, offering real-time visual guidance, enables the precise identification and treatment of the fibroid. Visualization of the fibroid is followed by ablation, a process that prioritizes the safety of surrounding structures like the bladder and intestines. A protective buffer zone is established to minimize the risk of thermal damage, especially crucial when dealing with fibroids that penetrate the uterine wall and are in close proximity to these organs. This careful approach ensures precise ablation of the target fibroid's volume without the need to puncture the outer uterine lining. All stages of the procedure are guided by visual imaging. The duration of the ablation procedure, ranging from one to seven minutes, is influenced by the fibroid's size. Fibroids as small as 2.0 × 1.3 cm can be treated with this method. The ablation process utilizes an electrode heated to approximately 105°C. Notably, this technique avoids thermal coagulation necrosis and the subsequent post-ablation syndrome. Expertise in vaginal endoscopic ultrasonography and experience with endoscopic fibroid procedures are advantageous, as these skills can be seamlessly integrated with TFA when necessary. Patients typically require a hospital stay of one to two days [4,17].

Methods

In one retrospective study of premenopausal women with menorrhagia and submucosal or intramural cavity-distorting fibroids was performed undergoing outpatient transvaginal ultrasound-guided Radiofrequency ablation (RFA) of uterine fibroids in the last 2 years [5].

From January 2015 to March 2021, the Sonata® System was exclusively used at Academic Hospital Cologne Weyertal to manage bleeding symptoms associated with fibroids in patients identified as high-risk due to pre-existing health conditions or complications arising after surgery. These conditions included obesity, cardiovascular and neurological issues, clotting disorders, and anemia. Fibroid detection was primarily achieved through transvaginal ultrasound imaging. A study encompassed thirty participants, within which the presence of forty-three fibroids was verified [6].

The key factors evaluated were surgical duration, patient recovery, fibroid size reduction, symptom intensity, overall well-being, and the need for further procedures. Comparisons between these outcomes were conducted using a meta-analysis approach with random effects and metaregression techniques [7,12]. Before the procedure, a comprehensive assessment was performed on all participants, involving ultrasound imaging to determine fibroid volume, maximum size, and position, along with the Visual Analogue Scale (VAS) to measure menstrual heaviness. Menstrual symptom intensity was evaluated in all participants using a pictorial scale. Prior to the procedure, blood tests were conducted to assess hemoglobin and hematocrit levels. Treatment effectiveness was determined at three, six, and twelve months following the intervention by analyzing ultrasound images, symptom ratings, and blood test results [8,21].

Results

Eligibility of the patients for RFA procedure. Participants subjects were premenopausal women aged 25–50 years with regular and regular menstrual cycles, and for whom there were clinical histories of HMB. Screening criteria allowed co-existence with a total of up to 10 fibroids in the uterine area, of types FIGO type 1, type 2, type 3, type 4, and/or 2–5 (transmural), 1 cm to 5 cm in individual fibroid size. FIGO subserosal type 5 and type 6 fibroids were not included in the number of fibroids but could be ablated at the discretion of the investigator. At least one fibroid must abut or indent the endometrial cavity, FIGO type 1, 2, 3, or type 2–5. They were excluded if they wished to conserve fertility, had type 0 fibroids ≥1.0 cm in diameter, endometrial polyps ≥1.5 cm, or greater than one polyp regardless of size.

Symptoms that could be caused by subserous fibroids, treatments that are currently in place affecting outcomes (such as endometrial ablation, uterine artery occlusion, hyperthermic ablation of fibroids, or uterine artery embolization), a uterine size of ≥1000 cm^3, sterilization implants in the tubes, and/or widespread adenomyosis were among other exclusion criteria [9].

Comparison of Lap RFA vs LM. A systematic search of PubMed, EMBASE®, and the Cochrane Library through October 2020 was conducted. Studies included were randomized controlled trials (RCTs) that compared laparoscopic radiofrequency ablation (LAP-RFA) and laparoscopic myomectomy (LM) in women with uterine leiomyomas (UL); RCTs with other comparators were excluded. Outcome measures of interest were quality of life (QOL) score differences—EQ-5D, uterine fibroid symptom QOL (UFS-QOL), and health-related QOL (HRQOL) and clinical outcomes such as mean operative blood loss (MOBL), hospital length of stay (LOS), and mean number of resected fibroids. Fixed-effects (FE) and random-effects (RE) models were used to calculate pooled effect sizes and express them as mean differences (MD) with 95% confidence intervals (CI) and p-values. All the analysis was conducted through R software (2020) [11].

579 references were found, of which 495 titles and abstracts were screened for inclusion after the removal of duplicates. Four studies were identified as meeting the criteria for qualitative review and

two studies (TRUST Canada, LUSTOR Germany) included 96 patients (47 Lap-RFA, 49 LM). QOL outcome was comparable in Lap-RFA and LM with no statistically significant difference using EQ-5D ($p=0.8750$), UFSQOL ($p=0.7019$), and HRQOL ($p=0.6220$). However, Lap-RFA experienced fewer intraoperative blood loss (MOBL) than LM (FE: MD=-43.93 ml, $p<0.001$; RE: MD=-44.64 ml, $p<0.001$). Lap-RFA also had shorter postoperative length of stay (LOS) compared to LM (FE: MD=-9.47 hours, $p<0.001$; RE: MD=-11.44 hours, $p>0.1707$). Lap-RFA also removed more fibroids compared to LM, though this failed to attain statistical significance (RE: MD=0.72, $p>0.114$).[11]

Preoperative Evaluation and Imaging. Ultrasound: The most common imaging method used in uterine fibroid diagnosis is ultrasound. Ultrasound provides an excellent view of the vascularity, site, and size of the fibroid. Ultrasound is noninvasive, safe, and a best first choice for initial diagnosis to precondition for RFA treatment [12].

MRI: Magnetic Resonance Imaging (MRI) is more detailed than ultrasound and is particularly better at determining size, location, and type of fibroid. It is particularly useful in complex situations, such as large deeply seated fibroids, where accurate localizing would be needed before RFA planning [13]. Hysteroscopy: Hysteroscopy could in some instances be used to visualize directly the submucosal fibroids that project into the uterine cavity. This will also help to ascertain the best course of treatment [14].

Anesthesia Considerations. Conscious Sedation: Most RFA treatments are done using conscious sedation, in which the patient relaxes but remains awake. Adding local anesthesia to numb the cervix and the uterus is also included. The most frequently used sedative drug is midazolam or propofol [13].

General Anesthesia: General anesthesia is the option for more complex or prolonged procedures. It renders the patient completely unconscious and painless during the procedure [12].

Regional Anesthesia: Regional anesthesia (e.g., epidural or spinal block) will be closely elected by many women, especially if they want to have a procedure that does not end the pain in the lower abdomen but allows them to remain awake or only sedated [15].

Intraoperative Procedures. The patient assumes a lithotomy posture, allowing for cervical examination using a speculum. Anesthetic is applied locally, and cervical dilation is performed when required, ensuring sufficient space for the radiofrequency electrode's insertion [12].

During a hysteroscopic or ultrasound-assisted procedure, a catheter equipped with a radiofrequency electrode is carefully positioned within the uterus via the cervix. Targeted radiofrequency energy is then applied to the fibroid, causing localized heating that results in the destruction and death of the fibroid tissue. This targeted heating and tissue destruction is repeated across multiple sites within the fibroid for complete ablation [15].

Intraoperative Monitoring: Intravenous heart rate and blood pressure are tracked. Hysteroscopy or ultrasound is performed to confirm the correct placement of the catheter and that the ablation is in progress [13]. Procedure Time: The time of procedure will generally be 30 to 60 minutes based on the quantity, size, and site of fibroids. Larger or multiple fibroids will require longer times to ablate [15].

Technical Factors: The outcome of the procedure is based on the size, location, and vascularity of the fibroid. Highly vascular fibroids will be longer to treat. Moreover, deeply placed fibroids and fibroids

adjacent to sensitive organs such as the bladder and the ovaries need to be tracked carefully so that they do not cause injury [12].

Complications: Complications which may arise are thermal injury to surrounding tissues, such as the bowel, bladder, or ovaries, and inability to ablate the fibroid. These are prevented by real-time temperature monitoring during the procedure [14].

Study of Pregnancy outcomes after RFA. ULTRA (Uterine Leiomyoma Treatment with Radiofrequency Ablation) is a prospective, multicenter cohort study evaluating pregnancy outcomes after laparoscopic radiofrequency ablation (RFA) and myomectomy in premenopausal women aged 21 years or older with symptomatic uterine leiomyomas.539 women were studied. Study population consists of women with symptomatic uterine leiomyomas, premenopausal, and aged over 21 years. There was a follow-up period longitudinal, and data were collected up to 5 years after procedures.

Participants were queried every 6 months for pregnancy and pregnancy outcomes 37 women (mean age during the first pregnancy 35.0 ± 4.7 years) conceived 43 times in total through March 2023. Of these, 22 were RFA group pregnancies and 21 were myomectomy group. Average follow-up after all procedures was 2.5 ± 1.0 years.

RFA Group (22 Pregnancies): First-Trimester Miscarriages: 9 of 22 pregnancies (40.9%, 95% CI, 20.3-61.5%) resulted in first-trimester miscarriages. Live Births: 11 pregnancies (50.0%, 95% CI, 29.1-70.9%) resulted in live births. Among the live births, 45.5% were delivered vaginally. Fetal Death: 1 pregnancy resulted in fetal death at 30 weeks of gestation. Uterine Rupture: There was one case of uterine rupture during miscarriage treatment with misoprostol 10 weeks after RFA procedure [16].

Myomectomy Group (21 Pregnancies): First-Trimester Miscarriages: 9 of 21 pregnancies (42.9%, 95% CI, 21.7-64.0%) were first-trimester miscarriages. Live Births: 12 pregnancies (57.1%, 95% CI, 36.0-78.3%) were live births. Miscarriage Rates: Both the RFA and myomectomy groups had more miscarriages than would be expected in women of this age group. The background miscarriage rate in the study population was 33.3%.

No Significant Differences: There were no differences of significance regarding rates of live birth or miscarriage between myomectomy and RFA groups, suggesting the two interventions share similar impacts on pregnancy outcomes.

Live Births and Mode of Delivery: Both groups had a rate of live births, with RFA having 45.5% vaginal deliveries out of the live births. The study did not find differences in modes of delivery between the two groups as a highlight.

The study establishes that one can experience a term pregnancy and vaginal delivery after laparoscopic radiofrequency ablation of uterine leiomyomas, like after myomectomy. Rates of miscarriage in both study groups were surprisingly high compared with the anticipated rate in the entire population for women of this age [16].

A second trial was completed Between 72 women who were treated using the Sonata System, there were 89 pregnancies and 55 deliveries, among which there were 8 women with multiple pregnancies. There were 19 vaginal deliveries, 35 Cesarean sections, 5 therapeutic abortions, 1 ectopic pregnancy, and 1 unspecified type of delivery, among a total of 62 live births. Ten of the pregnancies went to term, with a mean birthweight of 3276.7 ± 587.3 g. Ten women experienced 18 first-trimester SAb, 55.6% of

whom in two women with a history of recurrent abortion. The composite SAb rate was 22.8%, or 10.1% after excluding the outliers. There was no uterine rupture, placenta accreta, or stillbirth. This largest to-date case series shows that transcervical fibroid ablation (TFA) using the Sonata System is a safe and effective treatment in women with symptomatic uterine fibroids with regard to future pregnancy [17].

Discussion

Our experience is that Transcutaneous Radiofrequency Ablation (TRFA) is an encouraging method of treatment for the management of resistant fibroids, and it is associated with relatively minor complications, most of which are less serious than those associated with other treatments such as surgical myomectomy and uterine artery embolization. But on the basis of the limited cumulative experience and the relatively small number of treated cases, our results need to be interpreted cautiously. Confirmation in larger patient numbers in trials is suggested. Our unit reported a single instance of intestinal perforation and operation with resection of intestine in a series of 60 TRFA procedures. Other recent publications have also reported similar instances of intestinal perforation, which were treated accordingly [18].

The extensive SAGE registry, focusing on uterine fibroids and utilizing TFA treatment, anticipates collecting data from up to 2,500 patient-years. Early results from the initial 160 patients demonstrate TFA's effectiveness across various fibroid sizes and types, with an exceptionally low occurrence of complications associated with the device or procedure, at 0.6% per incident. Out of 241 fibroid cases handled, the distribution was as follows: 10% were submucous, 52% extended through the uterine wall, 28% originated within the uterine wall, and 10% were subserous; a significant proportion, exceeding one quarter, measured over 5 centimeters. Initial findings from the SAGE study support the safety, adaptability, and efficacy of TFA as a treatment for a majority of fibroid patients, demonstrating favorable real-world results and suggesting potential clinical and financial advantages [19].

Data regarding pregnancy outcomes following radiofrequency ablation (RFA) treatment remain limited. This is largely because RFA devices approved by the FDA have not yet been approved for use in women who wish to retain fertility. Moreover, the very first clinical trials actually excluded women with fertility desires from their study populations.Despite these limitations, mounting evidence from case reports and small prospective studies has begun to demonstrate promising outcomes. These early reports suggest that RFA may be an effective fertility-sparing treatment alternative, which warrants investigation in larger, well-designed studies [20].

Complications after RFA are rare, but reported that lower abdominal pain and discharge per vagina were experienced which resolved in 2 weeks. Abdominal pain, urinary tract infection and vascular injury of abdomen which were resolved without complication have also been reported. Severe ther-mal injuries and complications however can happen with RFA of uterine fibroids. There has been an interesting case of total abdominal hysterectomy following a uterine abscess which arose after myolysis. There also are many reports of severe complications after RFA in other organs, most notably fistulas such as bronchopleural, bronchobiliary and renoduodenal which were treated with massive antibiotics or surgery with resection [21].

One patient presented with headache and vomiting, which was a complication of epidural anesthesia, and both resolved spontaneously with oral treatment. Three patients experienced low back pain on postoperative days. All of them were treated by treating the pain with oral analgesics in the home

environment. Etiologies of low back pain are neurologic or muscular (20-30%) due to the lithotomy position, theoretic epidural anesthesia complication, or coagulatory necrosis of fibroid by transcatheter radiofrequency ablation (TRFA). Low back pain was observed more commonly in women with larger fibroids (37.4 cc, 94.4 cc, and 136 cc) and therefore assumed to be secondary to fibroid necrosis. But this relationship needs to be investigated with larger studies [7,22].

Evaluation of uterine patency and volume reduction post RFA. One multicenter trial of 6 centers treated 37 patients, who received treatment of 50 fibroids (mean diameter 3.4 ± 1.8 cm; range 1–8 cm) using the Sonata system. 35 were followed up and 2 withdrew. Independent reviewers rated 34 evaluable baseline and 6-week hysteroscopies, and no de novo intrauterine adhesions were observed, including in 6 patients with apposing fibroids. 1 patient was excluded from analysis due to an unevaluable video. Adhesiogenesis following post-treatment with TFA through the Sonata system is minimal, even in submucous or transmural fibroids [12,23].

Low surgical reintervention rates for heavy menstrual bleeding at 3 years occurred in the SONATA trial (9.2% binomial; 8.2% Kaplan-Meier). Important improvements in SSS (55 to 22), HRQoL (40 to 83), and EQ-5D (0.72 to 0.88) occurred and were larger than minimal clinically important differences ($p < 0.001$). 94% of the patients were satisfied at 3 years, 88% of the patients were symptom-free, work absenteeism reduced from 2.9% to 1.4%, and impairment in physical activity and work reduced significantly. No late complications were noted.Sonata-guided TFA offers long-term symptom relief, improved quality of life, and low reintervention rates at 3 years [24].

Conclusion

Radiofrequency ablation (RFA) performed transvaginally or laparoscopically is gaining recognition as a safe and effective, less invasive approach to manage uterine fibroids that cause symptoms. These procedures are relatively simple and boast outstanding safety records, making them suitable alternatives to more extensive surgical interventions. Treatment success is heavily influenced by a patient's age and the initial size of the fibroid. Smaller, non-stalked fibroids tend to respond well to treatment, especially when administered laparoscopically. A significant benefit of RFA is its ability to offer sustained symptom relief and significantly improve patients' overall well-being. Healing is typically swift, resulting in only a couple of days of missed work, and the procedure poses a very minimal chance of complications or requiring further surgery. Moreover, RFA seems to have no negative impact on fertility or the capacity to have a healthy pregnancy, making it a suitable choice for women seeking uterine-preserving treatment. RFA, whether performed transvaginally or laparoscopically, proves to be a reliable and successful method for treating uterine fibroids in suitable candidates, preserving fertility and offering lasting results with minimal impact on daily life [25,26,27].

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