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Obstetric outcome after ultrasound guided transvaginal radiofrequency ablation of uterine myomas

Abstract

Purpose: The objective is to report the obstetric outcome of 8 pregnancies with uterine fibroids who conceived after RFA.

Methods: A study was conducted on 115 women with symptomatic uterine fibroids undergoing transvaginal RFA using a bipolar radiofrequency generator and an internally cooled electrode. Data on pregnancies and outcomes were collected.

Results: After the procedure, eight pregnancies occurred. Fibroid volume reduction exceeded 50% in half of the patients, with an average reduction rate of 43%. Six resulted in live births, with a cesarean section rate of 2/3, one in an ectopic pregnancy, and one in a miscarriage. Pregnancy complications were limited, and all newborns showed normal development.

Conclusion: Minimally invasive ultrasound-guided RFA is effective in shrinking the myomas and may not carry an obstetric risk. Although the number of reported cases is low, no obstetric complications specifically associated with transvaginal radiofrequency ablation of uterine fibroids have been observed.

Keywords: radiofrequency ablation, transvaginal, myomas, obstetric outcomes

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Introduction

Uterine myomas affect up to 70% of women in reproductive age.[1] Sometimes they are asymptomatic, but one third of cases experience symptoms like heavy menstrual bleeding, pain, and disorders related to the mass effect in bowel or bladder[2] and subfertility problems.[3]

Myomectomy is the standard of care in women who desire future pregnancy, although it is associated with major hemorrhage and other surgical complications like intraoperative conversion to hysterectomy, intra-uterine, and intra-abdominal adhesion formation, and subsequent pregnancy complications such as uterine rupture, placental abnormalities, and a possible need for cesarean delivery.[4]

With the intention of avoiding these risks, non-surgical alternatives have been developed to treat fibroids, such as uterine artery embolization or treatment with high-intensity focused ultrasound guided by magnetic resonance imaging (MR-HIFU) or ultrasound (US-HIFU).[5]

Hyperthermic ablation of uterine fibroids using radiofrequency energy (RFA), delivered by a laparoscopic, transvaginal, or transcervical approach using ultrasound guidance, uses the heat generated from high-frequency alternating electric current to increase the temperature and induce coagulative necrosis in targeted uterine leiomyomas. This technique has emerged as a minimally invasive treatment option, effective in reducing uterine leiomyoma volume, and has been associated with improvements in menstrual bleeding and other symptoms associated with uterine fibroids.[6]

However, very little information is available about the impact of radiofrequency ablation on pregnancy outcomes. To date, only 50 pregnancies after RFA have been reported (40 after laparoscopic RFA and 10 after transcervical RFA).[7]

Among the different approaches described, transvaginal access makes it possible to treat myomas on an outpatient basis with a minimum of discomfort and inconvenience along with a shorter recovery period for the patient.[8,9] The vaginal radiofrequency application has advantages compared to the transcervical route as it does not require cervical dilation (which reduces the associated risk of cervical injury or the creation of a false passage[10]), allowing its use in patients with cervical stenosis or cervical pathology. It enables direct access from the vaginal fornix to the fibroid, making it possible to treat any fibroid without difficulty regardless of its location or distance from the uterine cavity. So far, only anecdotal information is available about pregnancy outcomes after transvaginal ultrasound-guided RFA with a total of 5 pregnancies described in 2 publications.[11,12]

The purpose of this study is to report the perinatal outcome of 8 pregnancies with uterine fibroids who conceived after transvaginal RFA.

Methods

Between July 2018 and June 2022, 115 premenopausal women with symptomatic uterine fibroids underwent transvaginal ultrasound-guided RFA at the University Hospital Virgen de las Nieves, Granada, Spain. Data on all pregnancy cases were collected.

The study population comprised women with type 0 to type 4 symptomatic myomas according to the International Federation of Gynecology and Obstetrics (FIGO) classification[13] measuring up to 7 cm whose symptoms did not improve with medical treatment, were not candidates for other surgical treatments, the patient declined other techniques, and women in whom hysteroscopic myomectomy was not feasible (group II and III fibroids in the STEP-W Lasmar classification).[14] Pre-treatment evaluation was performed in all patients with conventional transabdominal ultrasound and transvaginal

ultrasound (TV), using a high-end ultrasound machine (Applio 550, Canon Medical, Ōtawara, Japan), 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, and included the number, size, and location of the myomas to establish the appropriate approach route for the RF electrode, in addition to the distance to the serosa of the uterus.

The exclusion criteria were more than 3 fibroids, types 5 and 6 of the FIGO classification, larger than 7 cm (according to recommendations established in previous studies[8]) if malignancy was suspected, or if they had comorbidities that contraindicated general or epidural anesthesia. Malignancy was excluded by means of endometrial biopsy in those patients referring to heavy menstrual bleeding, and MRI in those patients with compressive symptoms or fertility difficulties related to the myoma.

Ablation technique was performed with intravenous moderate sedation or spinal anesthesia. Ceftriaxone 2 g was administered intravenously before the procedure. Patients were in the semilithotomy position and were prepped with chlorhexidine vaginal cleanser. All ablation procedures were performed by a physician (A.S.) with more than 15 years of experience in interventional US.

The ablation system included a bipolar RF generator (STARmed Co., Ltd, JJP Hospitalaria S.L., Sevilla, Spain), a 35 cm long 17 G internally cooled electrode (STARmed Gyeonggi-Do, Korea) with an exposed tip of 10 mm, and an electric pump to refrigerate the system. A dedicated needle guide attached to the transvaginal ultrasound probe was used to perform the ablation. The RF generator operated at 480 kHz with a maximum power of 150 W in all procedures (although the power of the generator during the procedure was set to a maximum of 100 W), raising the internal temperature of the tissue from 60 to 90ºC.

Once the safest path to the target fibroid was identified with transvaginal ultrasound, a Tru-cut needle (Prime cut 2, PRIM 162002 16g x 200 mm, TSK, Japan) biopsy was performed before myolysis to be sure fibroids were benign. Then, the electrode was appropriately placed into the target fibroid under ultrasound real-time guidance through the anterior or posterior vaginal fornix, and then myolysis was performed.

Initially, the electrode tip was positioned in the deepest and most remote portion of the nodule (5 mm from the capsule limit), and then the generator was activated. The ablation points followed a line inside the myoma, starting distally and finishing proximally. A single-needle ablation pulse achieved a necrosis volume of 1 cm3 after 5–10 seconds, and the core of the target myoma was ablated when an echo-enhanced area reached 80%–90% of the myoma cross-section in real-time ultrasound. Tissue charring was avoided by automatic detection of increased tissue impedance at the tip of the electrode.

Data collected included age at the procedure, the main clinical symptom or indication for RFA treatment and total time of the procedure and the duration of the RFA procedure. Myoma size (volume) and type and severity of clinical status (measured by the Symptom severity score of the uterine fibroid symptom quality of life questionnaire[15]) were also collected before, 12 and 24 months after the procedure. Other information analyzed included maternal age and fibroid size at the beginning of pregnancy, elapsed time from treatment to conception, mode of conception (spontaneous or ART), length of pregnancy, spontaneous abortion, gestational age at delivery, delivery route (Cesarean or vaginal), postpartum hemorrhage, placental abnormalities, intrauterine growth restriction, uterine rupture, or any other obstetric complication, birth weight, Apgar score, and umbilical artery pH of each infant.

All patients were informed in detail about the efficacy, risks, and benefits of the radiofrequency technique, including the lack of data about pregnancy results, and all patients provided their informed consent in writing to be included in the study. Approval for this study was provided by the Biomedical Research Ethics Committee of Andalusia (Spain).

Results

Eight pregnancies were reported after RFA treatment, six resulted in live births, one resulted in an ectopic pregnancy (tubal pregnancy), and one ended in a miscarriage.

The average gestational age at delivery was 39.6 + 1.0 weeks. Pregnancy complications included one case of placenta partially accreta and a postpartum hemorrhage. Four fetuses were born by cesarean section, three of them due to fetal malposition (2 podalic, 1 transverse presentation) and one due to induction failure. No cases of low Apgar score or umbilical artery pH were reported, and all newborns showed normal development during the first months (Table 1). The patient aged 43 was a miscarriage after unintended pregnancy.

Table 1 Obstetric outcomes after transvaginal radiofrequency ablation

Case	1	2	3	4	5	6	7	8
Age (y)	38	35	35	39	43	33	35	35
Parity	0	0	0	0	0	0	0	0
Main symptom	Infertility	Infertility	Infertility Dysmenorrhea	Infertility	Infertility Heavy menstrual bleeding	Heavy menstrual bleeding	Infertility	Infertility Heavy menstrual bleeding
FIGO Type	2	4-Feb	3	3	3	4-Feb	2	4
Initial size (cm3)	16.7	22.2	169	17.5	49	29.3	48.9	46.1
Size at conception (cm3)	0	1.63	105	14.3	59.8	10	24.2	27.5
Reduction rate	100%	92,2%	38%	19%	-22%	65.50%	51.40%	40.40%
Time ablation to conception (months)	36	17	17	7	22	8	14	4

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Table 1 Continued...

Case	1	2	3	4	5	6	7	8
Mode of conception	IVF	IVF	Spontaneous	Spontaneous	Spontaneous	Spontanous	IVF	Spontaneous
Pregnancy complication	No	No	Fibroid growth	Fibroid growth	Miscarriage	No	No	Ectopic pregnancy
GA at delivery (weeks)	41.4	40.5	39.2	39.4		38.4	38	
Mode of delivery	Cesarean	Spontaneous	Cesarean	Cesarean		Spontaneous	Cesarean	
	Induction failure		fetal malposition	fetal malposition			fetal malposition	
Fetal Weight (g)	3670	2615	3950	3090		2640	3550	
Apgar score 1 and 5 minutes	9-Aug	9-Sep	9-Jul	10-Sep		10-Sep	9-Aug	
Umbilical artery pH at birth	7.31	7.22	7.18	7.32		7.32	7.18	
Postpartum complications	Placenta Accreta	No	Uterine atony	No		No	No	

Women's age at the time of treatment ranged between 35 and 43 years old. All of them were nulliparous. Mean time from ablation to conception was 15.6 months (4-36). Four patients were symptomatic (complained of heavy menstrual bleeding and dysmenorrhea). All of them desired pregnancy, and 7 of them complained of infertility. Three of them conceived after an assisted reproductive technology.

Most fibroids were intramurally located (types 2 to 4 of the FIGO classification) and had an average volume at the time of ablation of 49.8 cm3 (16-169). All patients were discharged on the day of the operation after several hours of recovery from anesthesia, without any complications related to the procedure.

Fibroids' average volume at the time of conception was 28.2 cm3 (0-105). The rate of volume reduction of the fibroid exceeded 50% in half of the patients, with a mean reduction rate of 43%. Two out of the six term deliveries underwent an increase in fibroid volume during pregnancy. Most fibroid volume reduction was achieved at 2 months in patients <40 years and at 6 months in patients older.

Discussion

Delaying pregnancy and childbirth has led to an increasing frequency of myomas in women who wish to become pregnant and, in addition to the growing desire of many patients to preserve their uterus, has favored the development of less invasive alternatives to surgery.

The goal of treatment for uterine fibroids in these patients is not only to achieve symptom relief but also to improve pregnancy outcomes. Subserosal fibroids do not seem to have an influence on fertility. The effect of intramural fibroids is unclear, although the deformation of the uterine cavity might compromise fertility leading to a decrease in the pregnancy rate.[16] Submucosal fibroids reduce the pregnancy and live birth rate by 64% and 67%.[3,17] Several hypotheses are proposed to explain why fibroids cause fertility problems, including alterations in blood flow, endometrial inflammation, an altered hormonal environment, and interfered uterine contractility needed for sperm and ovum interaction and embryo migration.[18] An increased miscarriage rate has also been reported in these patients.[19,20]

Myomectomy is usually recommended as a surgical management option for symptomatic leiomyomas in patients who desire uterine preservation or future pregnancy, although they should be counseled about the risk of recurrence.[21,22] The uterine incision and the new scar are also associated with a higher risk of uterine rupture during pregnancy and an increased likelihood of caesarean section (CS). The rate of uterine rupture associated with myomectomy at the middle and late stage of pregnancy is 0.4–1.2%, increasing the obstetric risk.[23] Additional limitations of abdominal myomectomy by laparoscopy or laparotomy are the generation of post-surgical adhesions that could hinder future surgeries, including cesarean section if required, and the possibility of requiring postoperative blood transfusion due to bleeding during myomectomy and a four to eight-week convalescence.[24,25] Although it is small, myomectomy carries a risk of hysterectomy, which would be catastrophic for women with reproductive desires.[26]

As a treatment option with fewer adverse effects, uterine artery embolization has been widely used in the treatment of uterine fibroids. There is conflicting evidence regarding the effect of uterine artery embolization on ovarian reserve, and some articles report worse obstetric outcomes in patients treated with this technique.[27] This procedure may impair the blood supply of the ovary and the function of the intima, leading to permanent infertility and increasing the rate of miscarriage and abnormal placenta.[28] Therefore, embolization is listed as a relative contraindication in some guidelines for treating patients with uterine fibroids who wish to have children.[29]

US or MR-guided HIFU treatment is a newly developed noninvasive technique in which fibroids can be precisely ablated under the guidance of ultrasound or magnetic resonance imaging using focused ultrasound energy. Although obstetric outcomes after the treatment of fibroids using HIFU-US do not seem to describe significant complications,[30] some authors[31] found that the pregnancy and live-birth rates were lower for HIFU treatments compared to myomectomy. Both HIFU and Myomectomy groups have shown a high cesarean section rate (80-82%), although a lower preterm birth rate.[18] The limited availability of this technique makes it difficult for patients to access it.

In a review of pregnancy outcomes resulting from medical, radiological, and surgical conservative treatment of uterine fibroids,[27] the live birth rate was highest after myomectomy (75.6%) and ablation (70.5%) in any of their modalities. Pregnancies after embolization had the lowest live birth rate (60.6%) and the highest rate of miscarriage (27.4%). Thus, myomectomy may be currently considered the gold-standard fertility preservation treatment for fibroids, although surgical complications can occur.

RFA, a minimally invasive procedure, can be a viable alternative to more invasive surgeries and may help preserve the uterus. It is a reasonable treatment option to consider for symptomatic uterine leiomyomas. This technique found evidence of sustained fibroid

volume reduction, significant improvements in quality of life and symptom severity,[9] in addition to a low surgical reintervention rate.[32,33]

Transvaginal access makes it possible to treat myomas of any size and location on an outpatient basis with a minimum of discomfort and inconvenience along with a shorter recovery period for the patient. Transvaginal RFA has been shown to be more reliable, to have a lower cost, the chance to be an outpatient procedure, with a shorter operating time and with a higher level of satisfaction and rapid recovery compared to HIFU.[9,10] The meta-analysis of Bradley et al.[6] also found that RFA delivery approaches were similarly effective in reducing fibroid volume and improving quality of life, and that surgical reintervention rates for fibroid-related symptoms were favorable after RFA and did not significantly differ among RFA delivery approaches.

Even though RFA is a technique that is rapidly expanding, it is important to note that RFA has not been widely studied in women who desire future fertility or who have not completed their childbearing. The studies that have been conducted have mainly focused on the effectiveness of RFA in treating fibroids evaluating reduction in heavy menstrual bleeding and fibroid volume and have not been specifically designed to evaluate the impact on pregnancy.

Although emerging case reports of pregnancies after RFA treatment show promising data for pregnancy safety and success after myoma ablation, at this time only a total of 5 pregnancies after transvaginal radiofrequency ablation of fibroids have been described in 2 studies[11,12] and no prospective studies published investigating fertility and pregnancy outcomes following RF of fibroids. Keltz et al.[34] found 20 reported cases of pregnancies following RFA, with 75% of them being delivered by cesarean section, but no reported uterine windows, abnormal placentation, uterine rupture, scarring or uterine thinning In a case-series of 30 pregnancies after laparoscopic RFA,[35] there were 26 full-term live births and four pregnancy losses (live birth rate of 86.7%). In this case series, there were no cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction. The study's cesarean delivery rate of 50% and the spontaneous abortion rate of 13.3%.

There is concern that RFA may cause infertility and increase the risk of uterine rupture in patients with myomas who desire future pregnancy. Regarding transvaginal RFA, the study of Nam[36] showed a positive effect in terms of successful pregnancies (pregnancy success rate reached 50%), carrying pregnancies to delivery, as well as symptomatic relief in women with adenomyosis treated with transvaginal RFA. RFA did not compromise the uterine muscular integrity and no wound healing time was needed after the procedure. In patients who desired pregnancy soon after receiving RFA, it was recommended to start trying to conceive 1–6 months after RFA, and the incidence of other obstetric complications, such as preterm delivery, low birth weight, and fetal malpresentation, were like those seen after other uterine-sparing surgeries. The fact that after transvaginal RFA most fibroid volume reduction is achieved a few months after the procedure is critical for patients of advanced maternal age as they may suffer from impaired ovarian function, ovulation failure, and decreased fertility.

Among the complications observed in our study, the presence of moderate placenta accreta following a vaginal delivery is noteworthy. In this case, the placenta accreta area was located on the anterior uterine wall, while the fibroid treated with radiofrequency was located on the posterior wall. We are unaware if there is any relationship between these two occurrences. We also observed a high rate of cesarean sections associated with fetal malposition. This has been frequently described in pregnant patients with fibroids.[37] A case of uterine atony was recorded that was resolved with pharmacological measures. (Carbetocin). In this case, several risk factors for uterine atony already described[38] come together, such as cesarean delivery, the presence of fibroids, and birth weight, so we do not know how previous treatment using vaginal radiofrequency may be related to uterine atony.

Since we haven't identified any obstetric complications specifically associated with the treatment of fibroids using RFA, we believe that the results in our study suggest that ultrasound-guided transvaginal RFA may offer a safe and effective alternative to existing treatments for women who desire future fertility and thus could be considered a minimally invasive treatment option for symptomatic patients who desire to preserve fertility.

We are aware that the limited number of pregnancies following vaginal radiofrequency does not allow for definitive conclusions to be drawn. However, we believe that as the first published study after the application of this technique, it begins to provide information that will need to be supported by new publications including larger case series. The rapid expansion of this technique makes it necessary to share all available information regarding obstetric and neonatal safety to detect any possible negative effects as early as possible. Although the population included in our study is indeed very small, it may provide some reassurance in this regard.

This study had several limitations. First, this report was a simple analysis of a case series. Second, only one experienced surgeon with specialization in RFA for uterine fibroids performed the procedures for the patients in this study. Third, the patients were not uniform in terms of preoperative fertility status, pre-existing disease, pregnancy methods, or the regularity and duration of follow-ups. Thus, the results of this report should be interpreted carefully until randomized, controlled studies present more reliable results.

Conclusion

This study suggests that minimally invasive transvaginal ultrasound-guided RFA is effective in shrinking the myomas and suggests that it may not carry an obstetric risk and conception, pregnancy would be safe, and a full-term pregnancy is achievable. A higher cesarean section rate has been preliminarily found. The limited number of pregnancies reported after RFA makes it difficult to draw conclusions about fertility outcomes.

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Conflicts of interest

All authors declare that they have no conflict of interests.

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