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Review Article

Radiofrequency Ablation of Uterine Myomas and Pregnancy Outcomes: An Updated Review of the Literature

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ABSTRACT **Objective:** To provide a systematic review of pregnancy outcomes after radiofrequency ablation (RFA) of uterine myomas.
Data Sources: A literature search was conducted using PubMed, Cochrane Library, Scopus, Web of Science, and Embase, from database inception to October 2021.
Methods of Study Selection: Two reviewers conducted independent literature searches. Studies that met the criteria based on title and abstract underwent full-text review. Publications were included if they reported pregnancies and obstetric outcomes after laparoscopic or transcervical RFA of myomas.
Tabulation, Integration, and Results: A total of 405 publications were initially identified and screened, 39 underwent full-text review, and 10 publications were ultimately included. There were 50 pregnancies reported among 923 RFA patients: 40 pregnancies after 559 laparoscopic RFAs and 10 pregnancies after 364 transcervical RFAs. The number of patients from these studies actively trying to conceive after RFA is unknown. Among the RFA patients who conceived, the average age at ablation was 37 years old (range, 27−46 years). Most patients had between 1 and 3 myomas ablated, and myomas size ranged from <2 cm to 12.5 cm. There were 6 spontaneous abortions (12%) and 44 full-term pregnancies (88%), of which 24 were vaginal deliveries and 20 were cesarean deliveries. There were only 2 complications among 44 deliveries: one placenta previa that underwent an uncomplicated cesarean delivery and 1 delayed postpartum hemorrhage with expulsion of a degenerated myoma, with no long-term sequelae. There were no cases of uterine rupture, uterine window, or invasive placentation and no fetal complications. The spontaneous abortion rate was comparable with the general obstetric population.
Conclusion: Almost all pregnancies after RFA of myomas were full-term deliveries with no maternal or neonatal complications. These findings add to the literature that radiofrequency myoma ablation may offer a safe and effective alternative to existing treatments for women who desire future fertility. Journal of Minimally Invasive Gynecology (2022) 29, 709−715.

Keywords: Fertility; Myoma ablation; Laparoscopic ablation; Myoma; Transcervical ablation

Uterine myomas affect a large proportion of reproductive-age women [1]. Although some are asymptomatic, others experience abnormal uterine bleeding, pelvic pain, and other symptoms that significantly disrupt daily life [2]. Although hysterectomy remains the definitive treatment, many women seek conservative management. Hormonal treatment including contraceptive pills and levonorgestrel devices can improve heavy menstrual bleeding and anemia [3], and uterine artery embolization (UAE) is a well-established nonsurgical approach. However, hormonal treatment limits patients actively trying to conceive, and fertility outcomes after UAE are mixed [4]. Currently, myomectomy is the standard of care for fertility preservation, but carries the risks of surgical complications, adhesion formation, and pregnancy complications such as uterine rupture, placental abnormalities, and possible need for cesarean delivery [5].

In recent years, myoma ablation techniques have emerged as less invasive alternatives. Radiofrequency ablation (RFA) uses an ultrasound-guided laparoscopic or transcervical handpiece to induce coagulative necrosis [6]. RFA offers targeted myoma treatment, with patients reporting significant improvement in symptoms and low reintervention rates [7].

The authors declare that they have no conflicts of interest and nothing to disclose.

A preliminary version of these findings was presented as an Open Communication abstract at the *AAGL 50th Global Congress on MIGS* in Austin, on November 15, 2021.

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Currently, RFA devices approved by the Food and Drug Administration in the United States are not approved for women who desire future fertility, and these women were largely excluded from the original clinical trials. As a result, data for pregnancy outcomes after RFA are not well established [8]. However, emerging case reports of pregnancies after RFA treatment show promising data for pregnancy safety and success after myoma ablation.

The objective of this systematic review is to synthesize the available data on pregnancy outcomes after laparoscopic or transcervical RFA of uterine myomas.

Methods

A systematic review of the literature was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The literature search was performed independently by 2 reviewers (M.P. and H.H.) using PubMed, Cochrane Library, Scopus, Web of Science, and Embase. In particular, the keywords used in various combinations included "radiofrequency fibroid ablation," "pregnancy outcomes," "fertility," "fertility outcomes," and "reproductive outcomes" (see Supplemental Appendix 1 for full search methodology). All articles that reported pregnancy outcomes after radiofrequency myoma ablation treatment were identified. Inclusion criteria were clinical studies or case reports that presented pregnancy outcomes after laparoscopic or transcervical RFA of myomas. Publications were excluded if they were clinical guidelines or literature reviews, were abstract only, were not in English, contained duplicate pregnancies reported in an already-included publication, or used an ablation technique other than RFA.

Studies were initially screened for content appropriateness based on title and abstract using the above inclusion and exclusion criteria. Studies that met criteria based on title and abstract then underwent full-text review by both authors independently to determine final eligibility. Discrepancies were resolved by discussion and consensus to determine inclusion.

The data extracted from the publications (as available) included patient age at ablation, number of myomas ablated, size and location of myomas, history of previous infertility, number of pregnancies identified, time from ablation to pregnancy, patient age at delivery, mode of delivery, and delivery complications. The data were collected and analyzed using Microsoft Excel, version 16.56 (Microsoft Corporation, Redmond, WA). For each publication, myoma characteristics, patient demographics, and pregnancy outcomes were expressed in mean, standard deviation, and/or range.

Results

The PRISMA flow diagram for publication selection is shown in Fig. 1. Initially, 405 publications were identified through the literature search, with 248 publications remaining after removal of duplicate articles. Of the remaining articles, the vast majority were excluded by screening of title and abstract, with the most frequent reasons for exclusion being a lack of reported pregnancies or pregnancy outcomes data, use of an alternative myoma ablation technique, or ineligible publication type such as clinical guideline or abstract only. Notably, 39 articles underwent full-text review, with 29 articles excluded based on reasons outlined in the PRISMA flowchart (Fig. 1). The most common reason for exclusion was the identification of a duplicate pregnancy reported in another article that was already included. Ultimately, 10 publications were included in the final literature review: Two clinical trials, 4 interim or follow-up analyses of clinical trial patients, 2 case reports, 1 case series, and 1 postmarket retrospective cohort study. These articles are displayed in Table 1 [9−18].

The publications collectively assessed 923 patients who underwent laparoscopic (n = 559) or transcervical (n = 364) RFA of uterine myomas. In total, 50 pregnancies were reported, of which 40 occurred after laparoscopic RFA and 10 occurred after transcervical RFA. The RFA method, number of pregnancies, pregnancy outcomes, and complications are reported in Table 1 [9−18].

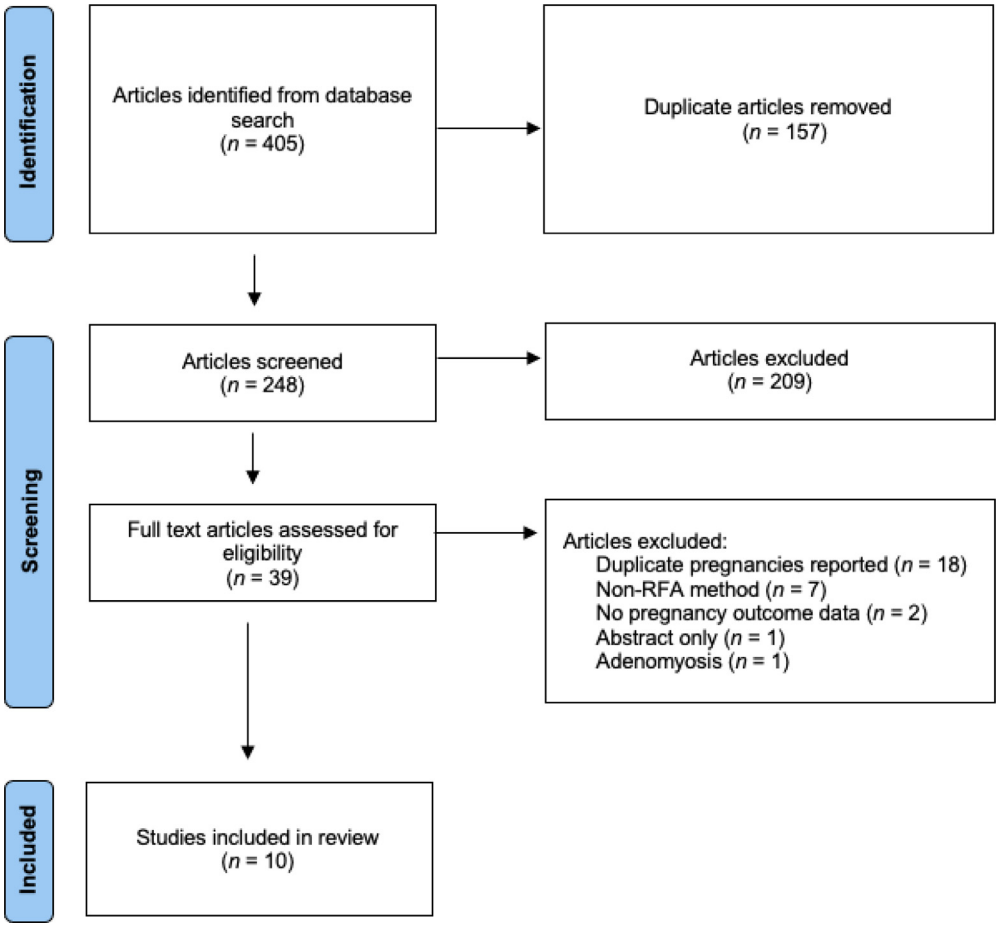
Of 50 pregnancies, there were 6 spontaneous abortions (12%) and 44 full-term pregnancies (88%), of which 24 were vaginal deliveries and 20 were cesarean deliveries. Among the 6 spontaneous abortions, 5 occurred during the first trimester of pregnancy and 1 occurred in the early second trimester. There were no reported elective terminations.

Most of the publications did not comment on the indication for cesarean delivery among their reported pregnancies. However, Berman et al [17] commented that 4 patients (15.4% of their 26 pregnancies) were recommended for cesarean delivery owing to unknown safety of labor after laparoscopic RFA, and 3 patients (11.5%) had a previous cesarean delivery. Other reasons for cesarean delivery reported by Berman et al [17] included fetal intolerance of labor and the presence of a nuchal cord. Galen et al [10], Bongers et al [12], and Lukes et al [18] each reported a pregnancy resulting in elective repeat cesarean delivery.

Among the 44 full-term pregnancies, there were no cases of uterine rupture, uterine window, invasive placentation (i.e., placenta accreta), placental abruption, or fetal growth restriction. There was 1 case of placenta previa reported by Berman et al [17], which resulted in an uncomplicated cesarean delivery. There was only 1 pregnancy associated with delivery complications, also noted in by Berman et al [17]. In this case, a large degenerating myoma was "disrupted" at the time of uterine closure during cesarean delivery. The patient had a delayed postpartum hemorrhage of 1000 mm 48 hours later with vaginal expulsion of the degenerated myoma. She ultimately recovered well and did not require reoperation; however, she did require

Fig. 1

PRISMA flow diagram for study selection. PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RFA = radiofrequency ablation.



transfusion of 6 units of packed red blood cells. Unfortunately, the authors do not offer specific details regarding the myoma disruption and we are unable to comment further on this complication. Information on the location and original type of myoma and the interval between ablation and delivery was not available in the publication.

The characteristics of the myomas ablated in each study are presented in Table 2. For the case reports, data describing the patients with pregnancies are displayed (denoted with asterisk). Most other publications did not provide specific myoma data for the patients with subsequent pregnancies, and therefore, the data for all patients in the study are displayed if it was available. Most patients had between 1 and 3 myomas ablated, and the size varied from <2 cm up to 12.5 cm.

The available information on patient age at the time of ablation and length of time from ablation to pregnancy is presented in Table 3. The average age at ablation for patients with subsequent postablation pregnancies was 37 years and ranged from 27 to 46 years. The mean time from myoma ablation to pregnancy was 16 months and ranged from 3.5 to 33 months. Most publications did not report on whether these patients had a history of infertility; however, Pschadka et al [16] did specifically mention pregnancy occurring in a woman who had previously reported primary infertility.

Discussion

RFA was Food and Drug Administration approved as a treatment for symptomatic myomas in 2012 [19] and has been shown to reduce heavy menstrual bleeding, pelvic pain, and other associated symptoms. A meta-analysis of 581 patients who underwent laparoscopic RFA showed statistically significant improvement in quality-of-life scores by mean 41.6 points (95% confidence interval, 38.9−44.3) at 12 months after ablation, and score improvement persisted at 36 months [20]. Similar improvements in quality-of-life and symptom severity scores have been seen with transcervical RFA [18,21]. In terms of need for

Table 1

Pregnancy outcomes after RFA of uterine myomas

Author	Year	Country	RFA method	Design	Number of RFA patients in study (N = 923)	Number of Pregnancies (n = 50)	Pregnancy outcomes	Complications
Kim et al [9]	2011	South Korea	Transcervical	Clinical trial	69	3	1 full-term cesarean delivery 2 full-term vaginal deliveries	None
Galen et al [10]	2014	United States Latin America	Laparoscopic	Follow-up analysis of clinical trial	204	4	2 full-term cesarean deliveries 1 full-term vaginal delivery 1 SAB	None
Jiang et al [11]	2014	China	Transcervical	Clinical trial	56	2	1 full-term cesarean delivery 1 full-term vaginal delivery	None
Bongers et al [12]	2015	Mexico United Kingdom Netherlands	Transcervical	Follow-up analysis of clinical trial	50	1	1 full-term cesarean delivery	None
Kramer et al [13]	2016	Germany	Laparoscopic	Interim safety/efficacy analysis of clinical trial	26	3	1 full-term cesarean delivery 2 full-term vaginal deliveries	None
Iversen et al [14]	2017	Denmark	Laparoscopic	Retrospective cohort study	66	3	3 full-term vaginal deliveries	None
Bends et al [15]	2018	Germany	Transcervical	Case report	1	1	1 full-term vaginal delivery	None
Pschadka et al [16]	2019	Germany	Transcervical	Case report	1	1	1 full-term vaginal delivery	None
Berman et al [17]	2020	United States EU Latin America	Laparoscopic	Case series	303	30	13 full-term cesarean deliveries 13 full-term vaginal deliveries 4 SAB	1 placenta previa, 1 PPH
Lukes et al [18]	2020	United States Mexico	Transcervical	Follow-up analysis of clinical trial	147	2	1 full-term cesarean delivery 1 SAB	None

EU = European Union; PPH = postpartum hemorrhage; RFA = radiofrequency ablation; SAB = spontaneous abortion.

Table 2

Myoma characteristics of total patients in each study

Author	Year	Number of RFA patients in each study (total N = 923)	Mean number of myomas ablated	Mean diameter of myoma (cm)	Maximum. diameter of myomas (cm)
Kim et al [9]	2011	69	2.1 ± 0.8	7.9 ± 2.0	12.5
Galen et al [10]	2014	204	3.7 ± 0.5	—	—
Jiang et al [11]	2014	56	—	4.8 ± 1.1	8.5
Bongers et al [12]	2015	50	2.4 ± 1.7	2.9 ± 1.4	6.9
Kramer et al [13]	2016	26	2.9 ± 2.6	—	—
Iversen et al [14]	2017	66	1.2 ± 0.5	—	—
Bends et al [15],*	2018	1	1	2.7	2.7
Pschadka et al [16] *	2019	1	1	3.6	3.6
Berman et al [17]	2020	303	2.4 ± 2.0	4.7 ± 2.2	11
Lukes et al [18]	2020	147	3.0 ± 2.1	—	—

RFA = radiofrequency ablation; SD = standard deviation.
Values are mean ± SD.
* Data specifically from patients with pregnancies.

reintervention, rates in the literature range from 4.4% and 11.8% [20,22,23], which is comparable with ranges seen with myomectomy and UAE [24]. Direct comparisons between RFA and myomectomy are limited; however, 2 recent studies showed similar improvement in myoma symptoms after myomectomy and RFA [25,26]. Successful pregnancies after RFA have been reported, and to the best of our knowledge, this review is the most thorough and up to date.

Of the 50 pregnancies reported in this review, 44 resulted in full-term deliveries, with only one delivery complication. Although many RFA patients underwent cesarean delivery, more than half had vaginal deliveries, which is often not advised after myomectomy owing to concerns for uterine wall integrity. No patients experienced uterine rupture or invasive placentation, which are rare but serious complications that can be seen after myomectomy. A meta-analysis of 3685 pregnancies after myomectomy showed an overall uterine rupture rate of 0.79%, with a rate of 1.2% after laparoscopic myomectomy [27]. It is difficult to determine the true risk of uterine rupture after RFA given the rarity of this complication and the limited number of pregnancies reported after RFA. However, 1 study did assess uterine wall thickness on postablation magnetic resonance imaging compared with baseline, demonstrating no significant change after transcervical RFA [6], which suggests possible preserved uterine wall integrity.

Broad conclusions on fertility success cannot be drawn from the current data, because only patients who successfully conceived after RFA are reported. Additional

Table 3

Fertility characteristics

Author	Year	Number of RFA patients in each study (N = 923)	No. of pregnancies after RFA (n = 50)	Mean age of patients at ablation (yrs)	Mean time from ablation to pregnancy (mo)
Kim et al [9]	2011	69	3	39.8 ± 6.5	—
Galen et al [10]	2014	204	4	—	—
Jiang et al [11]	2014	56	2	—	16.5 ± 2.1
Bongers et al [12]	2015	50	1	41	3.5
Kramer et al [13]	2016	26	3	—	—
Iversen et al [14]	2017	66	3	—	10.7 ± 0.6
Bends et al [15]	2018	1	1	33	33
Pschadka et al [16]	2019	1	1	38	7
Berman et al [17]	2020	303	26	35.0 ± 3.4	10.7 ± 9.9
Lukes et al [18]	2020	147	2	38 ± 2.8	30 ± 1.4

RFA = radiofrequency ablation; SD = standard deviation.
Values are mean ± SD.

information regarding how many patients were attempting to conceive without success is not available. However, we still gain some insights. Interestingly, Pschadka et al [16] reported a successful full-term pregnancy in a woman with previous primary infertility. Furthermore, there was no apparent increase in miscarriage rates after RFA. The spontaneous abortion rate in this review was 12%, which is at the lower end of the range of 11% to 22% seen in the general obstetric population [17]. In addition, although previous uterine instrumentation or surgery may create intrauterine adhesions that are potentially detrimental to fertility, 1 transcervical RFA trial noted no new adhesions on postablation hysteroscopy compared with baseline hysteroscopy [28]. Although these findings cannot be extrapolated to the conclusion that RFA improves fertility outcomes, that possibility would be consistent with data from other myoma ablation techniques not included in this review [29,30].

Studies suggest that RFA has other advantages over existing minimally invasive therapies. RFA was shown in a systematic review to have significantly greater reduction in mean myoma volume than UAE and magnetic resonance −guided focused ultrasound treatment [31]. Another major advantage of RFA over standard-of-care myomectomy is that RFA is not associated with major surgical morbidity [32,33]. The pivotal clinical trials for laparoscopic and transcervical RFA reported no intraoperative or postoperative complications [7,18], and rare complications seen in another laparoscopic RFA trial were all related to laparoscopy, with no device- or ablation-specific complications [34]. A systematic review of 38 laparoscopic and transcervical RFA studies reported no serious procedural complications, although the authors did not elaborate further on minor complications that were seen [35].

Although the current data suggest that RFA is a promising option for women seeking conservative myoma treatment, it is important to note that not all patients and myomas are ideal for RFA treatment. For example, International Federation of Gynecology and Obstetrics type VII pedunculated myomas are not advised for transcervical RFA treatment. In addition, RFA treatment is not officially approved for women seeking future fertility, because they were excluded from the original clinical trials. However, these patients may benefit most from RFA treatment. Definitive patient selection criteria are lacking and further studies are required. When deciding whether to proceed with RFA, we recommend a shared decision-making approach, taking into consideration myoma characteristics, medical and surgical risk profiles, and most importantly patient preferences.

Our literature review adds to the growing evidence that RFA is a promising treatment approach for women who desire minimally invasive myoma treatment while preserving fertility. However, the data are limited by a lack of studies specifically including women who plan to conceive, and more research is needed to understand the long-term impact and reproductive outcomes after RFA treatment.

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Supplementary materials

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