ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Original Article

Case Series of Reproductive Outcomes after Laparoscopic Radiofrequency Ablation of Symptomatic Myomas

Jay M. Berman, MD, Abraham Shashoua, MD, Christopher Olson, MD, Sara Brucker, MD, John A. Thiel, MD, and Bala Bhagavath, MD

From the Wayne State University School of Medicine, Detroit, Michigan (Dr. Berman), Advocate Illinois Masonic Medical Center, Chicago, Illinois (Dr. Shashoua), Edward Hospital, Naperville, Illinois (Dr. Olson), University of Tübingen, Tübingen, Germany (Dr. Brucker), University of Saskatchewan, Saskatoon, Saskatchewan, Canada (Dr. Thiel), and University of Rochester Medical Center, Rochester, New York (Dr. Bhagavath).

ABSTRACT **Study Objective:** To analyze pregnancy delivery and safety outcomes after patient receipt of percutaneous, laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA) for symptomatic uterine myomas.

Design: Case series (2010−2017); evidence was obtained from 2 randomized, controlled trials (level I), 6 cohort studies (level II-2), and in commercial settings (level II-3).

Setting: Multiple sites in the United States, Canada, Europe, and Latin America (university hospitals, community hospitals, and stand-alone surgery centers). Commercial cases were United States based and followed US Food and Drug Administration clearance of Lap-RFA.

Patients: Premenopausal adult women with symptomatic uterine myoma types 1 through 6.

Interventions: The Lap-RFA procedure was conducted under general anesthesia with laparoscopic and intra-abdominal ultrasound guidance.

Measurements and Main Results: Safety unknowns included the safety of a full-term pregnancy for mother and baby, rates of spontaneous abortion, preterm delivery, postpartum hemorrhage, placental abnormalities, intrauterine growth restriction, and vaginal versus cesarean delivery. A total of 28 women (mean age = 35.0 ± 3.4 years) conceived a total of 30 times after Lap-RFA, either as part of a clinical study or in commercial settings. The number of myomas treated per patient ranged from 1 to 7. The diameter of treated myomas ranged from 0.9 to 11.0 cm. Most patients had 1 or 2 myomas, and most myomas were ≤5.5 cm in maximal diameter. The 30 pregnancies resulted in 26 full-term live births (86.7%), all healthy infants, with an equal distribution of vaginal and cesarean deliveries. Four (13.3%) spontaneous abortions occurred. No cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction were reported. One event each of placenta previa and postpartum hemorrhage were reported.

Conclusion: Conception and safe, full-term pregnancy are achievable after Lap-RFA of symptomatic myomas. Additional large, rigorous, multivariate prospective studies that adjust for confounders and report pregnancy outcomes after symptomatic myoma treatment are needed. Journal of Minimally Invasive Gynecology (2019) 00, 1−7. © 2019 AAGL. All rights reserved.

Keywords: Myomas; Laparoscopy; Leiomyoma; Pregnancy; Radiofrequency ablation; Uterine sparing

Dr. Berman reports grants, personal fees, and nonfinancial support from Acessa Health during the conduct of the study; outside the submitted work, he reports grants from Allergan, Gynesonics, and Obseva as well as personal fees from AbbVie, Bayer, Boston Scientific, Medtronic, and Merck. Dr. Shashoua reports personal fees from Acessa Health. Dr. Olson has nothing to disclose. Dr. Brucker reports grants and nonfinancial support from Acessa Health during conduct of the study. Dr. Thiel reports grants from Acessa Health during the conduct of the study; outside the submitted work, he reports grants from Allergan. Dr. Bhagavath reports grants and nonfinancial support from Acessa Health during the conduct of the study; outside the submitted work, he reports grants and nonfinancial support from Hologic, Inc.

Acessa Health, Inc. (Austin, TX) provided funding for independent third-party data collection, analysis of the data, and editorial assistance.

Presented as a poster at the American College of Obstetricians and Gynecologists 2018 Annual Clinical and Scientific Meeting, Austin, TX, April 27-30, 2018.

Corresponding author: Jay M. Berman, MD, Wayne State University School of Medicine, Department of Obstetrics and Gynecology, Hutzel Women's Hospital, 7 Brush North, 3990 John R, Detroit, MI 48201.
E-mail: jberman@med.wayne.edu

Submitted March 27, 2019, Revised May 24, 2019, Accepted for publication June 14, 2019.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ — see front matter
https://doi.org/10.1016/j.jmig.2019.06.009

Uterine myomas (leiomyomas) are the most common benign, solid tumors found in women, with a 70% to 80% cumulative incidence by age 50 [1]. Annually, ~1% of US women seek treatment for uterine myomas [2]. Symptoms can include abnormal uterine bleeding, pelvic pain, enlarged uterus or pelvic mass, and bowel and/or bladder dysfunction [3]. Myomas may make conception difficult and increase the risk of adverse pregnancy outcomes [2].

Treatment approaches include conservative medical management, hormonal therapy, minimally invasive surgical and radiologic techniques, and hysterectomy [3]. Medical therapies reduce myoma symptoms and volume over the short-term [4−6]. However, women may respond poorly over the long-term [7]. Hysterectomy is the only treatment that eliminates all risk of myoma development. Minimally and less invasive techniques are typically recommended for women who would like to conceive within 1 year of surgery [4] because they are uterine sparing, have reduced morbidity and recovery time, and may preserve fertility [3,8]. These techniques include myomectomy (laparotomy, minilaparotomy, laparoscopy, or hysteroscopy), uterine artery embolization, magnetic resonance−guided focused ultrasound surgery, and ultrasound-guided thermal ablation [3,6]. However, limited head-to-head data exist to evaluate the impact of various myoma treatments on fertility and pregnancy [4].

Percutaneous, laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA; Acessa Health, Inc., Austin, TX) is an outpatient, uterine-sparing, minimally invasive technique to treat symptomatic uterine myomas. Lap-RFA can be used to treat intramural, subserosal, submucosal, and transmural myomas. It is not recommended for pedunculated myomas with a stalk <50% of the total myoma diameter. Pedunculated myomas with a stalk >50% of the total myoma diameter can be treated with Lap-RFA at the surgeon's discretion [9]. Lap-RFA received US Food and Drug Administration (FDA) clearance in November 2012 [11], and >2500 procedures have been performed. This case series evaluates pregnancy delivery and safety outcomes after Lap-RFA for symptomatic uterine myomas.

Materials and Methods

Data on all pregnancy cases were collected from 8 clinical trials and multiple commercial settings (defined as postmarket cases after FDA clearance unrelated to a clinical trial) between December 2010 and December 2017 [9,10,12−17]. Clinical trials included 3 premarket, prospective studies (2 feasibility studies and 1 pivotal trial with a 3-year follow-up) [12−15]; 4 postmarket, prospective studies (1 surgeon training study, 2 randomized controlled trials, and 1 pilot study) [9,10,16,17]; and 1 postmarket retrospective cohort study [18]. Table 1 provides a description of the design, geographic location, key inclusion/exclusion criteria, and follow-up for all studies evaluated. Briefly, clinical trials were conducted at multiple sites in the United States, Canada, Germany, and Latin America (Mexico and Guatemala). Study settings were university hospitals, community hospitals, and stand-alone surgery centers [9,10,12−17]. All commercial cases were from the United States. The duration of follow-up for the prospective clinical trials ranged from 1 to 5 years, [9,10,12−15,17] except for the surgeon training study, which followed patients for 4 to 8 weeks [16]. No preset follow-up duration was established for the retrospective cohort study [19] or the commercial cases.

Patients treated in a clinical trial met the inclusion and exclusion criteria for their original study; for commercial patients, the attending physician established the inclusion and exclusion criteria. The prospective clinical trials enrolled premenopausal adult women with myomas ≥1 cm and ≤7 cm [12−15], ≥1 cm and ≤5 cm [17], or ≤10 cm [9,10,15] in diameter, with a total uterine volume ≤300 cm^3 [12−15,17] or the equivalent of 16 weeks' gestation [9,10,15]. Patients were also required to have a normal Papanicolaou test and no current untreated cervical dysplasia or malignancy. Exclusion criteria included contraindications for laparoscopic surgery or general anesthesia, the presence of significant intra-abdominal adhesions, and/or chronic pelvic pain not caused by myomas [9,12−16].

Women who had only pedunculated submucosal (type 0) and/or <50% intramural submucosal (type 1) myomas were not treated with Lap-RFA and were referred for hysteroscopic myomectomy; however, women who had type 1 myomas in conjunction with other myoma types [2−6] were eligible for treatment with Lap-RFA. Additionally, women who had only pedunculated subserosal (type 7) myomas were referred for laparoscopic myomectomy.

The Lap-RFA procedure has been described in detail by Chudnoff et al [14]. It is conducted under general anesthesia with laparoscopic and intra-abdominal ultrasound guidance used to locate and target each myoma. A radiofrequency handpiece tip is inserted percutaneously and introduced into the targeted myoma; laparoscopic ultrasound is used to confirm tip placement. The surgeon deploys a 7-needle electrode array from the tip to the desired ablation diameter and volume within the myoma capsule. The device generator raises the tissue temperature to 95° to 100°C over a period of seconds to minutes (based on myoma size, desired ablation volume, and/or the system's algorithm), causing coagulative necrosis and myoma cell death without compromising the surrounding healthy myometrium or endometrium. The myoma shrinks and may be absorbed over time. Lap-RFA does not require laparoscopic suturing. Six weeks of pelvic rest is recommended after the procedure.

Gynecologic surgeons who performed Lap-RFA as part of the clinical trials completed standardized data collection forms that captured patients' baseline characteristics and

Table 1

Characteristics of clinical trials of laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA) and procedures conducted in commercial settings

	Premarket Studies			Postmarket Studies					
Data Source	Feasibility Studies		Pivotal Study NCT00874029	LUSTOR Study NCT01750008	TRUST Studies NCT01563783 (Canada), NCT02163525 (US)		Pregnancy Study NCT03028610	Retrospective Study	Commercial Settings
Reference	Garza et al, 2011	Robles et al, 2013	Chudnoff et al, 2013; Berman et al, 2004	Brucker et al, 2014	Braun et al, 2016	Rattray et al, 2018	NA	Levine et al, 2017	NA
Design	Prospective, single-center, single-arm study	Prospective, single-center, single-arm study	Prospective, multicenter, single-arm study	Prospective, randomized, single-center, longitudinal, comparative study	Prospective, single-arm, multicenter, safety, surgeon training study	Prospective, randomized, multicenter, longitudinal, comparative study	Prospective, single-center, longitudinal, single-arm, pilot study	Retrospective, single-center, comparative cohort study	Real-world evidence
Setting	Mexico	Guatemala	US	Germany	US	Canada	Germany	US (IL)	US (CA, IL, TX)
Follow-up	12 months	12 months	36 months	60 months	4-8 weeks	Up to 60 months	36 months	NA	NA
Pregnancies (n)	1	1	4	4	3	3	3	5	6
Key inclusion criteria	Premenopausal, ≥25 years old, did not desire current or future childbearing, symptomatic uterine myomas (≥1 and ≤7 cm), total uterine volume ≤300 cm^3			Premenopausal, ≥18 years old, symptomatic uterine myomas (<10 cm), uterine size ≤16 gestational weeks			Premenopausal, 18−40 years old, desire pregnancy ≤2 years after Lap-RFA, symptomatic uterine myomas (≥1 and ≤5 cm), total uterine volume ≤300 cm^3	All cases of excisional removal of uterine myomas performed from 2013 to 2016	Established by attending physician
Key exclusion criteria	Contraindications for laparoscopic surgery or general anesthesia; the presence of significant intra-abdominal adhesions, cervical myomas, and/or chronic pelvic pain not caused by myomas; history of or evidence of gynecologic malignancy							NA	

NA = not applicable.

Table 2

Patient and myoma characteristics

	Full-term Live Births	Spontaneous Abortions	Overall
Total number of women	25	4*	28
Age at baseline			
Mean (SD)	34.8 (3.4)	37.3 (1.0)	35.0 (3.4)
Median (range)	35.0 (30−44)	37.5 (36−38)	35.0 (30−44)
Gravidity†			
Mean (SD)	1.4 (1.4)	2.5 (1.8)	1.4 (1.4)
Median (range)	1.0 (0−4)	2.5 (0−5)	1.0 (0−5)
Number of myomas treated			
Mean (SD)	2.4 (2.0)	3.5 (2.1)	2.6 (2.0)
Median (range)	2.0 (1−7)	3.5 (1−6)	2.0 (1−7)
Maximal diameter of the largest myoma treated (cm)‡			
Mean (SD)	4.7 (2.2)	4.4 (1.5)	4.7 (2.2)
Median (range)	4.4 (1.4−11.0)	3.9 (3.0−6.9)	4.4 (1.4−11.0)

* One woman in this group also completed a pregnancy to term.
† Data missing for 1 woman who completed a pregnancy to term
‡ Data missing for 2 women who completed pregnancies to term.

intraoperative and postoperative outcomes, including any pregnancies. For commercial cases, the manufacturer requested that surgeons document and describe outcomes of any pregnancies that occurred after Lap-RFA therapy. For data collected prospectively during pre- or postmarket clinical trials [9,10,12−16], independent biostatistics firms analyzed and validated all baseline, perioperative, and long-term outcomes, including any postprocedure pregnancies. For the retrospective study [18] and commercial cases, when a postprocedural pregnancy was identified, a clinical coordinator or consultant retrospectively entered patient data onto standardized case report forms, which were then validated and signed off by the treating surgeon after the surgeon compared the case report with the source data. These forms were subsequently reviewed by the clinical consultant for missing data, with additional follow-up as needed.

Outcomes of interest were baseline age, elapsed time from treatment to conception, length of pregnancy, any spontaneous abortion (SAB), postpartum hemorrhage (PPH), placental abnormalities, intrauterine growth restriction or uterine rupture, delivery method (cesarean or vaginal), Apgar scores of each infant, and any other complications. The study authors had access to clinical trial data and case report forms for each patient.

Before Lap-RFA treatment, all clinical study patients signed an informed consent form, which included the potential publication of their procedures and outcomes. All clinical study sites received institutional review board approval [9,12−18], and the current study was institutional review board−approved by Wayne State University, Detroit, MI (#091417M1X, September 18, 2017).

All pregnancy data were evaluated using Excel (Microsoft, Redmond, WA) and are presented descriptively as

Table 3

Pregnancy outcomes among women (N = 28 patients, N = 30 pregnancies) who underwent laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA) of symptomatic myomas

Outcome	n (%)	Mean Age at Baseline, Years (Range)	Mean Time from Procedure to Conception, Months (Range)
Pregnancies	30 (100)	35.0 ± 3.4 (30−44)	10.7 ± 9.9 (1−54)
Full-term live births	26 (86.7)	34.7 ± 3.5 (30−44)	9.1 ± 5.9 (1−28)
Vaginal deliveries	13 (50.0)	34.5 ± 4.0 (30−44)	8.5 ± 6.5 (3−28)
Cesarean sections	13 (50.0)	34.8 ± 3.0 (30−41.5)	9.2 ± 5.4 (1−23.5)
Postpartum hemorrhage*	1 (3.8)	32	5.5
Spontaneous abortion	4 (13.3)	37.3 ± 1.0 (36−38)	21.5 ± 21.9 (6.5−54)
1st trimester	3 (10.0)	37 ± 1.0 (36−38)	24.5 ± 25.8 (6.5−54)
2nd trimester	1 (3.3)	38	12.5

* Hemorrhaging occurred after cesarean delivery of a healthy infant followed by surgical disruption of a degenerative myoma.

Table 4

Reasons for women undergoing cesarean delivery after laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA) procedure

Reported Reason for Cesarean Delivery	Overall	
	n (%) of 26 Pregnancies	n (%) of 13 Cesarean Deliveries
Unknown safety outcome of Lap-RFA on vaginal delivery	4 (15.4)	4 (30.8)
Obstetric history of prior cesarean section	3 (11.5)	3 (23.1)
Placenta previa marginalis	1 (3.8)	1 (7.7)
Nuchal cord	1 (3.8)	1 (7.7)
Oligohydramnios and fetal intolerance to labor	1 (3.8)	1 (7.7)
Presence of a uterine scar from a past myomectomy	1 (3.8)	1 (7.7)
High-risk pregnancy and/or recommendation from an obstetric and gynecologic/maternal-fetal specialist	2 (7.7)	2 (15.4)

means ± standard deviations of the means, medians (range), rates, percentages, and minimum/maximum values.

Results

Over the 7-year study period, 28 women, aged 30 to 44 years at baseline (mean = 35.0 ± 3.4 years, Table 2), conceived a total of 30 times after a Lap-RFA procedure. Of the 30 pregnancies, 24 (80.0%) occurred in women who received Lap-RFA as part of a clinical study; the remaining 6 (20.0%) were reported in women who received Lap-RFA in a commercial gynecologic setting after FDA clearance of the device and procedure. Two of the women in the clinical study cohort accounted for 2 pregnancies each. The median patient gravidity was 1.0 (range, 0−5) pregnancy. Racial and ethnic demographic information was not available for all patients.

The number of myomas treated per patient ranged from 1 to 7, and the diameter of treated myomas ranged from 0.9 to 11.0 cm. Most patients had 1 or 2 myomas, and most myomas were ≤5.5 cm in maximal diameter. The most common symptom reported by patients at baseline was menorrhagia, with 1 patient requiring preprocedural blood transfusion because of low hemoglobin and hematocrit levels. Other common symptoms were pressure, pain, and sleep disturbance.

The mean time from treatment to conception was 10.7 ± 9.9 months; excluding patients who conceived twice, the mean time to conception was 8.5 ± 4.5 months. As shown in Table 3, the 30 pregnancies resulted in 26 full-term live births (86.7%), all healthy infants, with an equal distribution of vaginal and cesarean deliveries (n = 13 for each). Four (13.3%) SABs occurred: 3 early in the first trimester and 1 at 21 weeks' gestation.

Of the 26 full-term live births, the mean ± standard deviation gestational age (reported for 21 infants) was 38.5 ± 2.2 weeks, and the mean ± standard deviation infant weight (reported for 24 infants) was 3.4 ± 0.4 kg. A total of 22 infants were assessed for Apgar scores at 1 and 5 minutes; all Apgar scores were ≥7 at 1 and 5 minutes, except for 1 infant who had an Apgar score of 6 at 1 minute; however, this score increased to 9 at the 5-minute mark. Apgar scores were not recorded for 3 infants; however, these babies were full-term and described as "healthy."

No cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction were reported. One event of placenta previa marginalis was reported before a cesarean delivery of a healthy infant, and 1 event of PPH was reported after cesarean delivery of a healthy infant [16]. This occurred after 1 of the early premarket pregnancies. Hemorrhaging began during closure of the uterus and after disruption of a single large degenerative fundal transmural myoma. Forty-eight hours after delivery, the patient experienced abdominal pain and contractions followed by expulsion of the degenerative myoma tissue and approximately 1000 mL blood. She underwent curettage, was transfused with 6 units of blood, and recovered fully 1 day later with no adverse outcomes.

Multiple reasons were reported for the cesarean deliveries (Table 4). The 2 most common were obstetric history of a prior cesarean section and the unknown safety of Lap-RFA on a subsequent vaginal delivery (n = 4 for each). Other reasons for cesarean deliveries were placenta previa marginalis, breech presentation, history of infertility with a recommendation from a maternal-fetal medicine specialist, nuchal cord, oligohydramnios and fetal intolerance to labor, and the presence of a uterine scar from a past myomectomy.

Discussion

This analysis indicates that safe childbearing with full-term gestation can be achieved after Lap-RFA of symptomatic myomas. Of the 30 pregnancies evaluated, a full-term, live birth rate of 86.7% (26/30) was achieved with no cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction.

This study's cesarean delivery rate of 50% (13/26) was higher than the overall 2013 US rate of 32.7% [19]. The

management of delivery was at the discretion of the attending obstetrician. Because many patients were of advanced maternal age (mean = 35 years), the observed cesarean section rate would be expected to more closely correspond to US rates for women aged 30 to 34, 35 to 39, and 40 to 54 years (35.5%, 41.6%, and 49.6%, respectively) [19]. Based on this limited number of cases, there is insufficient evidence to suggest that cesarean deliveries are required after Lap-RFA of uterine myomas.

One study patient experienced severe PPH (blood loss ≥1000 mL) [20] after cesarean delivery of a healthy, full-term infant. The reported US PPH incidence is 2.5% in women with untreated myomas [21]. It is not known whether this patient had a history of cesarean delivery, but a prior cesarean delivery is an independent risk factor for severe PPH [22,23]. PPH incidence after Lap-RFA should be carefully monitored.

No study patients experienced uterine rupture, which is reported in 0.035% of deliveries in the general population [24] and in ≤1% after laparoscopic myomectomy [25]. Because previous uterine surgery is known to increase uterine rupture risk, this low incidence may reflect a lack of long-term data. For example, a 6-year follow-up analysis of laparoscopic myomectomy found a 10% rate of uterine rupture [24,25].

The current study's SAB rate of 13.3% is within the 11% to 22% range for the general obstetric population [26]. Cumulative SAB rates of 46.7% and 15.3% have been reported in women with submucosal and intramural myomas [21]. In a randomized controlled trial (N = 131), SAB rates after laparoscopic and abdominal myomectomy were 20.0% and 12.2% [27], whereas a literature review of 21 studies found SAB rates between 7% and 28% after laparoscopic myomectomy [25]. SAB rates after magnetic resonance−guided focused ultrasound surgery or uterine embolization have been reported at 28% and 53%, respectively [28,29].

Traditionally, surgical myomectomy by a variety of approaches has been the gold standard to treat symptomatic myomas in women who desire to preserve fertility [4]. However, abdominal myomectomy by laparotomy is associated with a 3% to 4% risk of intraoperative conversion to hysterectomy; postoperative adhesions are also common [30,31]. Compared with myomectomy by laparotomy and minilaparotomy, laparoscopic myomectomy has been associated with improved short-term outcomes and a reduced risk of minor and major complications [32]. However, laparoscopic myomectomy requires that uterine incisions be sutured, and it can be challenging to remove unfavorably located myomas because of a lack of sensitive visualization. These factors may present challenges to less experienced surgeons. Additionally, patients typically require a 2- to 4-week recovery period [9]. In contrast, Lap-RFA procedures do not require uterine suturing, and ablation procedures can treat a greater number of myomas than myomectomy [10]. Lap-RFA patients experience less blood loss compared with patients receiving laparoscopic myomectomy [10,14,33] and have 4- to 9-day average recovery times [12−14].

Several study strengths and limitations should be noted. Despite the small number of cases included, patients' geographic heterogeneity (United States, Canada, Latin America, and Europe) is indicative of real-world experience. Likewise, all pregnancies reported to the sponsor between December 2010 and December 2017 were evaluated, and patients had a range of myoma types, sizes, and locations. Because of the retrospective nature of the research, some data were not collected; in particular, patient ethnicity, some infant characteristics (Apgar scores, gestational age, and weight), and whether or not patients had sought prior fertility treatment. Additionally, pregnancies and/or SABs after Lap-RFA may be underreported because of patients transferring care or other issues. Only 1 clinical trial in this analysis specifically analyzed pregnancy outcomes [17] because the Lap-RFA device was originally designed and tested for women who were not attempting to get pregnant. Lastly, the study population was too small to adjust for confounders that could influence conception, such as patient age, size and location of treated myomas, and the presence of other gynecologic diseases or disorders.

These findings emphasize the need for large, multivariate, adjusted prospective studies that report pregnancy outcomes after symptomatic myoma treatment [33]. In 2015, the Patient-Centered Outcomes Research and the Agency for Healthcare Research and Quality established a large, multisite registry to collect and evaluate outcomes data and inform myoma treatment decision making (www.compare-uf.org) [4]. The ULTRA registry is currently enrolling up to 200 women after Lap-RFA and following for pregnancy outcomes (ClinicalTrials.gov Identifier: NCT02100904, https://fibroids.ucsf.edu/welcome-ultra). Additionally, a postmarket analysis (TRUST-USA) is being conducted to compare the safety, outcomes, and economic impact of 3 surgical procedures (Lap-RFA, abdominal or laparoscopic myomectomy, and uterine artery embolization) for myoma treatment (ClinicalTrials.gov, NCT02163525).

Conclusion

This study suggests that conception and safe, full-term pregnancy are achievable after treatment with minimally invasive percutaneous Lap-RFA. Pregnancy outcomes for women who have received Lap-RFA to treat symptomatic myomas (intramural, transmural, submucosal, or subserosal) compare favorably with laparoscopic myomectomy.

Acknowledgment

The authors thank Acessa Health for providing funds for independent third-party data collection (Janine Little), data analysis and management (Laura Kemp), and medical writing assistance (Caitlin Rothermel and Mimi Wainwright).

References

1. Baird DD, Dunson DB, Hill MC, Cousins D, Schectman JM. High cumulative incidence of uterine leiomyoma in black and white women: ultrasound evidence. *Am J Obstet Gynecol*. 2003;188: 100–107.
2. Cardozo ER, Clark AD, Banks NK, Henne MB, Stegmann BJ, Segars JH. The estimated annual cost of uterine leiomyomata in the United States. *Am J Obstet Gynecol*. 2012;206:211.e1–211.e9.
3. Khan AT, Shehmar M, Gupta JK. Uterine fibroids: current perspectives. *Int J Womens Health*. 2014;6:95–114.
4. Stewart EA. Clinical practice. Uterine fibroids. *N Engl J Med*. 2015;372:1646–1655.
5. Gupta JK, Sinha A, Lumsden MA, Hickey M. Uterine artery embolization for symptomatic uterine fibroids. *Cochrane Database Syst Rev*. 2014;12:CD005073.
6. Vilos GA, Allaire C, Laberge PY, Leyland N, Special Contributors. The management of uterine leiomyomas. *J Obstet Gynaecol Can*. 2015;37(2):157–178.
7. Sankaran S, Manyonda IT. Medical management of fibroids. *Best Pract Res Clin Obstet Gynaecol*. 2008;22:655–676.
8. Borah BJ, Nicholson WK, Bradley L, Stewart EA. The impact of uterine leiomyomas: a national survey of affected women. *Am J Obstet Gynecol*. 2013;209:319.e1–319.e20.
9. Rattray DD, Weins L, Regush LC, Bowen JM, O'Reilly D, Thiel JA. Clinical outcomes and health care utilization pre- and post-laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: a randomized trial of uterine-sparing techniques (TRUST) in Canada. *Clinicoecon Outcomes Res*. 2018;10:201–212.
10. Brucker SY, Hahn M, Kraemer D, Taran FA, Isaacson KB, Kramer B. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet*. 2014;125:261–265.
11. Food and Drug Administration. K121858 substantial equivalence determination letter. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121858.pdf. Accessed July 31, 2018.
12. Garza Leal JG, Hernandez Leon I, Castillo Saenz L, Lee BB. Laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation of symptomatic uterine leiomyomas: feasibility study using the Halt 2000 Ablation System. *J Minim Invasive Gynecol*. 2011;18:364–371.
13. Robles R, Aguirre VA, Argueta AI, Guerrero MR. Laparoscopic radiofrequency volumetric thermal ablation of uterine myomas with 12 months of follow-up. *Int J Gynaecol Obstet*. 2013;120:65–69.
14. Chudnoff SG, Berman JM, Levine DJ, Harris M, Guido RS, Banks E. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstet Gynecol*. 2013;121:1075–1082.
15. Berman JM, Guido RS, Garza Leal JG, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol*. 2014;21:767–774.
16. Braun KM, Sheridan M, Latif EZ, et al. Surgeons' early experience with the Acessa procedure: gaining proficiency with new technology. *Int J Womens Health*. 2016;8:669–675.
17. Pregnancy outcome following global fibroid ablation using the Acessa system. Available at: https://clinicaltrials.gov/ct2/show/NCT03028610. Clinicaltrials.gov website. January 23, 2017. 2018. Accessed May 20, 2019.
18. Levine EM, Shashoua A, Delfinado L, Locher S. Radiofrequency volumetric thermal ablation of uterine leiomyomata: comparison with other therapies. In: *Poster presented at Central Association of Obstetricians and Gynecologists (CAOG) 84th Annual Meeting*; October 18-21, 2017.
19. Martin JA, Hamilton BE, Osterman MJ, Curtin SC, Matthews TJ. Births: final data for 2013. *Natl Vital Stat Rep*. 2015;64:1–65.
20. Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 183: postpartum Hemorrhage. *Obstet Gynecol*. 2017;130:e168–e186.
21. Klatsky PC, Tran ND, Caughey AB, Fujimoto VY. Fibroids and reproductive outcomes: a systematic literature review from conception to delivery. *Am J Obstet Gynecol*. 2008;198:357–366.
22. Ekin A, Gezer C, Solmaz U, Taner CE, Dogan A, Ozeren M. Predictors of severity in primary postpartum hemorrhage. *Arch Gynecol Obstet*. 2015;292:1247–1254.
23. Magann EF, Evans S, Hutchinson M, Collins R, Lanneau G, Morrison JC. Postpartum hemorrhage after cesarean delivery: an analysis of risk factors. *South Med J*. 2005;98:681–685.
24. Bernardi TS, Radosa MP, Weisheit A, et al. Laparoscopic myomectomy: a 6-year follow-up single-center cohort analysis of fertility and obstetric outcome measures. *Arch Gynecol Obstet*. 2014;290:87–91.
25. Hurst BS, Matthews ML, Marshburn PB. Laparoscopic myomectomy for symptomatic uterine myomas. *Fertil Steril*. 2005;83:1–23.
26. Ammon Avalos L, Galindo C, Li DK. A systematic review to calculate background miscarriage rates using life table analysis. *Birth Defects Res A Clin Mol Teratol*. 2012;94:417–423.
27. Seracchioli R, Rossi S, Govoni F, et al. Fertility and obstetric outcome after laparoscopic myomectomy of large myomata: a randomized comparison with abdominal myomectomy. *Hum Reprod*. 2000;15:2663–2668.
28. Rabinovici J, David M, Fukunishi H, et al. Pregnancy outcome after magnetic resonance-guided focused ultrasound surgery (MRgFUS) for conservative treatment of uterine fibroids. *Fertil Steril*. 2010;93:199–209.
29. Mara M, Maskova J, Fucikova Z, Kuzel D, Belsan T, Sosna O. Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. *Cardiovasc Intervent Radiol*. 2008;31:73–85.
30. Practice Committee of American Society for Reproductive Medicine in collaboration with Society of Reproductive Surgeons. Myomas and reproductive function. *Fertil Steril*. 2008;90(Suppl): S125–S130.
31. Gliklich R, Leavy M, Velentgas P, et al. Identification of future research needs in the comparative management of uterine fibroid disease: a report on the priority-setting process, preliminary data analysis, and research plan. Report no. 31. Agency for Healthcare Research and Quality: 2011. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/uterine-fibroids-2010_research.pdf. Accessed July 26, 2018.
32. Herrmann A, De Wilde RL. Laparoscopic myomectomy - the gold standard. *Gynecol Minim Invasive Ther*. 2014;3:31–38.
33. Sundermann AC, Velez Edwards DR, Bray MJ, Jones SH, Latham SM, Hartmann KE. Leiomyomas in pregnancy and spontaneous abortion: a systematic review and meta-analysis. *Obstet Gynecol*. 2017;130:1065–1072.