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ORIGINAL RESEARCH

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

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Darrien D Rattray[1]
Laura Weins[2]
Lexy C Regush[2]
James M Bowen[3,4]
Daria O'Reilly[3,4]
John A Thiel[1,2]

[1]Department of Gynecology, Regina General Hospital, Regina, SK, Canada; [2]Department of Obstetrics, Gynecology and Reproductive Sciences, University of Saskatchewan, Regina, SK, Canada; [3]Department of Health Research Methods, Evidence and Impact, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada; [4]Programs for Assessment of Technology in Health (PATH), Research Institute of St Joe's Hamilton, Hamilton, ON, Canada

Objective: The objective of this study was to compare laparoscopic ultrasound-guided radiofrequency ablation of fibroids (Lap-RFA) and laparoscopic myomectomy in terms of 1) health care utilization and 2) serious complication rates. The secondary objectives were comparison of subject responses to validated symptom and quality-of-life questionnaires. We hypothesized that Lap-RFA health care utilization and clinical outcomes would not be worse than those of laparoscopic myomectomy in the aggregate.

Patients and methods: Post-market, randomized, prospective, multicenter, longitudinal, non-inferiority interventional comparative evaluation of health care utilization and clinical outcomes in premenopausal women with symptomatic uterine fibroids who desired uterine conservation was conducted. Both procedures were planned as outpatient day surgeries. Health care resource utilization was measured during the procedure day and at 1 week, 1 and 3 months post-surgery. Symptom severity and quality of life were based on patients' responses to the Uterine Fibroid Symptom Severity and Quality-of-Life Questionnaire, EuroQol-5D-visual analog scale general health status and menstrual impact questionnaires, and time from work.

Results: Forty-five participants provided written informed consent and were enrolled (Lap-RFA, n=23; myomectomy, n=22) in Canada. Hospitalization time (primary endpoint) was 6.7±3.0 hours for the Lap-RFA group and 9.9±10.7 hours for the myomectomy group (Wilcoxon, p=0.0004). Intraoperative blood loss was lesser for Lap-RFA subjects: 25.2±21.6 versus 82.4±62.5 mL (p=0.0002). Lap-RFA procedures took lesser time than myomectomy procedures: 70.0 versus 86.5 minutes (p=0.018), and Lap-RFA required −34.9% (130 fewer) units of surgical equipment. At 3 months, both cohorts reported the same significant symptom severity reduction (−44.8%; p<0.0001). Lap-RFA subjects also took lesser time from work: 11.1±7.6 versus 18.5±10.6 days (p=0.0193). One myomectomy subject was hospitalized overnight after experiencing a 20-second asystole during the procedure. One Lap-RFA subject underwent a reintervention. The combined per patient direct and indirect costs of the two procedures were comparable: Lap-RFA (CAD $5,224.96) and myomectomy (CAD $5,321.96).

Conclusion: Compared to myomectomy, Lap-RFA is associated with significantly lesser intraoperative blood loss, shorter procedure and hospitalization times, lesser consumption/use of disposable and reusable surgery equipment, reduced health care resource utilization, and faster return to work through 3 months posttreatment. Direct and indirect costs of Lap-RFA and myomectomy are comparable.

Keywords: Acessa, radiofrequency ablation, fibroids, laparoscopy, myomectomy, ultrasound

Correspondence: John A Thiel
Medical Professional Corporation,
100-2631 28th Avenue, Regina,
Saskatchewan S4S6X3, Canada
Tel +1 306 586 1800
Fax +1 306 586 3511
Email drjthiel@aol.com

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Introduction

Uterine fibroids account for ~35% of all hysterectomies in Canada, with significant rates of morbidity and mortality in Canadian women as well as significant economic impact throughout the health care system.[1–3] Although women with fibroids are often asymptomatic, 20%–50% of patients with uterine fibroids present with abnormal uterine bleeding, pelvic pain and pressure, bowel and bladder symptoms, and/or problems related to fertility.[4,5] For those women desiring uterine and reproductive conservation and who are candidates for surgical intervention, myomectomy and laparoscopic ultrasound-guided radiofrequency ablation (Lap-RFA, Acessa™; Acessa Health, Inc., Austin, TX, USA) are available and increasingly used alternatives, depending on patient objectives and physician expertise.

A pivotal study of Lap-RFA was conducted in the USA and Latin America in a heterogeneous population of women with symptomatic uterine fibroids to determine the efficacy and safety of the procedure as studied over a 3-year follow-up period. The 3-month efficacy and safety outcomes were predictive of outcomes observed at 3 years.[6]

Following the pivotal study, Brucker et al reported operative and perioperative outcomes and 30 days post-procedure complications rates from a randomized controlled trial of ultrasound-guided laparoscopic myomectomy and Lap-RFA conducted in Germany.[7] The authors reported equivalent safety outcomes for the two procedures. They also reported shorter operative and postoperative experiences for the Lap-RFA patients with lesser intraoperative blood loss and treatment of more fibroids than for the laparoscopic myomectomy patients. However, the patient populations in the German study were ethnically homogeneous and did not represent the diversity of populations of patients with uterine fibroids seen in North America. Also, the authors did not compare health care utilization by the patient groups pre- and post-procedure for the two procedures. Consequently, a randomized controlled trial that would compare Lap-RFA and two other standard uterine-preserving treatments (myomectomy and uterine artery embolization [UAE]) in terms of clinical outcomes and health care utilization among a heterogeneous patient population through the critical 3 months post-procedure visit was warranted.

The objectives of this randomized study were twofold. The primary objectives were 1) the evaluation of health care utilization 12 months prior to treatment through the 3 months follow-up period and 2) serious complication rates of all three procedures. The secondary objectives included a comparison of responses to the validated uterine fibroid symptom and quality-of-life (UFS-QOL) questionnaire,[8] the EuroQol visual analog scale (EQ-VAS) self-assessment of current general health state,[9] the patient satisfaction and overall treatment evaluation (OTE) questionnaire,[10] the menstrual impact questionnaire (MIQ),[11] and reinterventions for fibroid-related symptoms. Our hypothesis is that the health care utilization and clinical outcomes after Lap-RFA within 3 months posttreatment are not inferior to those of laparoscopic myomectomy.

Patients and methods

Design

This post-market, randomized, prospective, multicenter, longitudinal, non-inferiority interventional comparative study was designed for the evaluation of health care utilization and clinical outcomes in premenopausal women with symptomatic uterine fibroids who desired uterine conservation (ClinicalTrials.gov Identifier: NCT015663783). Procedures under evaluation included Lap-RFA, myomectomy (laparoscopic or abdominal), and UAE. After the investigators received Research Ethics Board approval (Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board [REB-12-350], Regina Qu'Appelle Health Region Research Ethics Board [REB-12-40]) and approval from the University of British Columbia Research Ethics Board (REB A2-136), potential subjects were recruited from clinics, hospitals, and investigators' practices in British Columbia, Saskatchewan, and Ontario, Canada. All study participants were informed of the purpose of the study and its testing requirements, interventions, assessments, duration of the follow-up period, and potential risks and benefits to participation. The consent process included the participant's willingness to be randomized (1:1) to one of two groups as follows: Group 1 offered randomization to either Lap-RFA or myomectomy, whereas Group 2 offered randomization to either Lap-RFA or UAE. The investigational centers were allowed to participate in either or both groups. The investigating surgeons had sufficient education and proctoring in Lap-RFA to participate in and conduct the randomized controlled trial.

Participants, enrollment criteria, and interventions

Participants were enrolled if they satisfied defined inclusion and exclusion criteria. The inclusion criteria were as follows: premenopausal, menstruating females ≥18 years of age having symptomatic uterine fibroids with no fibroid diameter ≥10 cm as measured by transvaginal ultrasound; having a uterine size of ≤16 gestational weeks; having

had no untreated cervical malignancy or dysplasia in the 36 months prior to enrollment; desiring uterine conservation and childbearing potential; and willing to comply with all study tests, procedures, and assessment tools. The exclusion criteria included those women who were unwilling to be randomized, were contraindicated for laparoscopic surgery or general anesthesia, were at high risk for or known to have significant intra-abdominal adhesions, required major elective concomitant procedures that would confound the results, were pregnant or lactating, had taken any depot gonadotropin releasing hormone agonist within 3 months prior to screening, had chronic pelvic pain not due to fibroids, had known or suspected endometriosis or adenomyosis, had a history of or active pelvic inflammatory disease, had a non-uterine pelvic mass >3 cm in any diameter, had a cervical myoma, or had one or more completely intracavitary myomas (Type 0) or only Type 0/1 submucous myomas that could be treated at hysteroscopy. All data were collected on standardized case report forms at the treatment sites by independent, third-party study monitors and were sent to an independent biostatistics firm (Innovative Analytics, Kalamazoo, MI, USA) for analysis of clinical results.

Lap-RFA has been well described in the literature.[12,13] Briefly, the system comprises an electrosurgical radiofrequency generator and accessories that are designed to deliver monopolar radiofrequency energy to tissue through a percutaneous handheld disposable electrosurgical probe with a deployable seven-needle electrode array. Mapping of the uterus and targeting and ablation of the uterine fibroids are accomplished under laparoscopic direct ultrasound guidance. The volume of treated tissue is determined by an ablation algorithm, which dictates the length of the array deployment and the treatment time. The ablation zone extends 0.5–1 cm beyond the ends of the needle array; thus, each fibroid capsule is treated as the array tips typically are placed within 1 cm of the fibroid capsule. Of note, Lap-RFA should not be confused with myolysis or cryoablation, which are technologically and procedurally different. Myolysis and cryoablation were completed without ultrasound guidance. Lap-RFA allows the precise placement of the treatment array to within 1 cm of the fibroid capsule; placement is confirmed in three dimensions, thus preventing any significant thermal spread beyond the capsule and preventing damage to normal myometrium.[14]

Gynecologic surgeons experienced in laparoscopy performed the myomectomies. Unless there was problematic intraoperative bleeding, all myomectomies were performed laparoscopically with the patient in the lithotomy position. The port placement, equipment, and suture for closure varied among the investigating surgeons; however, in each case, hemostasis was aided by intramyometrial injection of dilute vasopressin. The overlying capsule was entered using monopolar energy and the fibroids were removed with a combination of blunt dissection and electrosurgery. All myometrial defects were reapproximated in layers using delayed absorbable suture. All participants enrolled into Group 2 who were randomized to UAE were referred to the radiologist for the procedure.

Regardless of the assigned intervention, there were no intraoperative exclusions. If adhesions were found, they could be lysed as appropriate. If pedunculated serosal fibroids with thin stalks (<50% of the myoma diameter) were found intraoperatively, they could be surgically excised. Also, any endometriosis and/or adenomyosis could be treated/excised if found intraoperatively.

Following discharge from the post-anesthesia recovery unit, patients were readmitted to the day surgery unit. The decision to discharge the patient was made by the responsible nurse in that unit, based on the patient meeting the standard day surgery discharge criteria. The responsible surgeon was not contacted prior to discharge.

Analyzed outcomes were the comparative clinical efficacy and safety of the treatment alternatives and associated factors that influence health care utilization costs in Canadian dollar (CAD) including the procedure day and the first 3 months post-procedure. Clinical efficacy was measured in terms of mean UFS-QOL scores, subjects' perceptions of their general health status (EQ-VAS) and the impact on their activities of their menstrual bleeding over time (MIQ), subjects' satisfaction with their treatment, days until return to work, complications, and fibroid-related reinterventions.

Average resource costs per patient were estimated for Lap-RFA and myomectomy patients based on resource use data collected during the study. Unit costs were applied to the average number of resources consumed in each treatment group. Assessed operative costs included those related to disposable equipment used for each procedure and inpatient stays resulting from each procedure. Three-month postoperative costs included hospitalizations for fibroid symptoms, reinterventions, emergency room visits, gynecologist visits, and general practitioner (family doctor) visits. Productivity costs were based on the average number of days off work for patients in each group. Total hours of work were calculated assuming an 8-hour workday and multiplied by the average Canadian hourly wage for females as of December 2017.[15] The unit costs applied to the various resources are shown in Table 1. Equipment unit costs were obtained from Regina

Table 1 Unit costs of disposable procedural equipment, other health care resources, and patient productivity

Item	Unit cost (CAD)
Procedural equipment[a]	
RF handpiece	$2,635.00
Dispersive electrode pads (pair)	$82.00
10–12 mm trocar and sheaths	$60.00
Foley catheter/drainage bag	$12.00
Insufflation tubing	$16.00
Veress needle	$67.00
Open-sided speculum	n/a
5 mm suction irrigator	$31.00
5 mm trocar	$65.00
Adhesion barriers	$56.00
Morcellator	$761.00
Laproscopic large claw	n/a
Endo mini shears	$116.00
Kronner uterine manipulator injector	$33.00
Laparoscopic coagulation/cutting device	$475.00
Ultrasound cutting instrument	$595.00
Other medical resources	
Family doctor visit[b]	$35.00
Gynecologist visit[b]	$41.90
Emergency room visit[c]	$148.00
Hospitalization for fibroids[d]	$3,173.00
Day procedure for reintervention[e]	$1,577.00
Productivity	
Average hourly wage[f]	$24.65

Notes: All costs are expressed in Canadian dollar (CAD). [a]Obtained from Regina General Hospital, Saskatoon, SK, Canada. [b]Medical Services Branch, Ministry of Health.[17] [c]Dawson and Zinck.[18] [d]Canadian Institute Health Information.[16] [e]Ontario Ministry of Health and Long-term Care.[19] [f]Statistics Canada.[15]
Abbreviation: n/a, not available.

General Hospital (Saskatoon, SK, Canada). The cost per inpatient stay was obtained from the Canadian Institute Health Information patient cost calculator (CMG 521),[16] and the costs per gynecologist (partial consultation) and family doctor visit (partial assessment) were based on the Saskatchewan Payment Schedule For Insured Services Provided by a Physician.[17] The cost of each emergency room visit was based on a Canadian Institute Health Information survey,[18] and the cost of the reintervention was obtained from the Ontario Case Costing Initiative for a total laparoscopic hysterectomy.[19]

Sample size, randomization, and statistical methods

The estimated sample size was based on the length of hospital stay as a surrogate for the direct cost of treatment. Originally, the study sample size was based on data from Nash et al,[20] Al-Fozan et al,[21] and Brucker et al,[7] as three procedures were being compared (Lap-RFA, UAE, and myomectomy) and the mean lengths of stay for patients receiving these procedures were 8, 19, and 23 hours, respectively. The pooled SD of the difference in length of stay between Lap-RFA and either of the other two procedures was 12 hours. The Lap-RFA and UAE procedures were compared using a one-sided test of non-inferiority of the Lap-RFA length of stay. The null hypothesis was that the length of stay for subjects receiving Lap-RFA was >10% worse, setting the alpha level to 0.0125 for each of the two comparisons (Lap-RFA versus UAE, Lap-RFA versus myomectomy). Under these assumptions, the sample size needed was 22 in total or 11 in each of the Lap-RFA and myomectomy treatment groups for each comparison to achieve a power of 0.80. The *p*-value for non-inferiority was 0.025.

An independent, third-party biostatistician (Innovative Analytics) randomized subjects in each site based on their group assignment in a 1:1 ratio in blocks of either four or six. A unique subject number was allocated to each randomization assignment, and the enrolled subjects were randomized to the lowest available subject number at each investigative site. Neither study participants nor surgeons were blinded to the randomization assignments.

Descriptive statistics for continuous variables are presented and include the mean, SD, median, and minimum and maximum. For selected continuous variables, 95% CIs are also presented. For categorical variables, frequencies and percentages of each outcome are presented. Selected operating room, post-anesthesia recovery, and day surgery/hospitalization time variables are compared using a Wilcoxon rank sum test. Intraoperative blood loss during the two procedures is compared using a two-sample *t*-test. Changes within each procedure group in terms of UFS-QOL health-related quality-of-life scores, UFS-QOL symptom severity scores, and EQ-VAS scores are compared using a paired *t*-test, and changes between procedures are compared using a two-sample *t*-test. *p*-values of <0.05 are considered significant to describe differences between groups in terms of intraoperative blood loss, UFS-QOL health-related quality-of-life scores, UFS-QOL symptom severity scores, and EQ-VAS scores. All statistical analyses were conducted using SAS version 9.3 (SAS Institute, Inc., Cary, NC, USA).

Results

A total of 51 subjects provided written informed consent and enrolled between October 2012 and June 2017. Three subjects withdrew consent prior to treatment and opted for a hysterectomy. The investigator withdrew one subject due to a finding of adenomyosis without any fibroids found during laparoscopic ultrasound. Only two subjects were recruited into Group 2 (Lap-RFA: n=1; UAE: n=1). Therefore, the analysis was confined to Group 1 participants only, with a

total of 45 subjects enrolled into Group 1 (Lap-RFA: n=23; myomectomy: n=22). Baseline demographics are provided in Table 2. Lap-RFA subjects were of similar mean age as the myomectomy subjects. Most participants were Caucasian (69.6% and 81.8%, respectively), or Black comprising 13.0% and 9.1% of the respective cohorts. The laparoscopic approach was intended for the 22 subjects randomized to myomectomy. However, one myomectomy subject was converted to the abdominal approach, so the surgeon could excise a total of seven subserosal and intramural fibroids ranging in largest diameter from 1.5 to 7.0 cm. All 23 Lap-RFA subjects were treated without conversion to an open approach. Mean intraoperative blood loss was significantly lesser for the subjects undergoing Lap-RFA than for those undergoing myomectomy: 25.2±21.6 versus 82.4±62.5 mL, respectively (p=0.0002). The total and mean numbers of fibroids treated and excised, respectively, were 79 (mean: 3.4±2.4 for Lap-RFA) and 61 (mean: 2.8±2.4 for myomectomy).

Health care resource utilization and productivity costs

In the 12 months prior to enrollment, 61% of participants in the Lap-RFA group and 68% in the myomectomy group had visits to a family doctor, whereas 22% and 14% had at least one emergency department visit related to their fibroid symptoms, respectively. However, >90% of the Lap-RFA group had at least one visit to a gynecologist in the year prior to study enrollment, compared to 64% in the myomectomy group (Table 3).

Details regarding health care resource utilization related to hospital stay and procedure time are outlined in Table 4. The mean hospitalization time was 6.7±3.0 hours (median, 6.0 hours; range, 3.6–18.7 hours) for the Lap-RFA group and 9.9±10.7 hours (median, 7.1 hours; range, 5.1–55.6 hours) for the myomectomy group. Thus, the p-value for the test of non-inferiority of Lap-RFA relative to myomectomy regarding total hospitalization was statistically significant (p=0.0004; Wilcoxon test). For those individuals who were discharged home from the day surgery unit, a similar finding was observed: mean hospitalization times of 6.2 versus 7.18 hours (p=0.002). Most (89%) of the procedures were completed as day surgery cases, with only one (4.3%) subject admitted to the hospital after Lap-RFA and three (13.6%) subjects admitted following myomectomy.

Details of equipment and materials use during the Lap-RFA and myomectomy procedures are tabulated in Table 5. In the Lap-RFA group, each of the 23 cases used one or more sets of dispersive electrodes for a total of 26 sets and 1 RF handpiece for a total of 23 RF handpieces; neither piece of

Table 2 Baseline subject demographics

Variable	Lap-RFA (n=23)	Myomectomy (n=22)	p-value
Age, years			0.2263
Mean (SD)	39.4 (7.3)	42.0 (6.95)	
Median (min.–max.)	38.0 (29–53)	42.0 (26–52)	
Body mass index, kg/m^2			0.2995
Mean (SD)	27.5 (6.5)	25.6 (5.1)	
Median (min.–max.)	26.8 (15.9–44.7)	25.5 (17.9–39.6)	
Ethnicity,[a] n (%)			
Caucasian	16 (69.6)	18 (81.8)	
Black	3 (13.0)	2 (9.1)	
Chinese	0 (0.0)	0 (0.0)	
Korean	0 (0.0)	0 (0.0)	
Japanese	0 (0.0)	0 (0.0)	
Latin American	0 (0.0)	0 (0.0)	
Filipino	1 (4.3)	0 (0.0)	
Aboriginal	0 (0.0)	1 (4.5)	
South Asian	1 (4.3)	1 (4.5)	
Southeast Asian	0 (0.0)	0 (0.0)	
West Asian	1 (4.3)	0 (0.0)	
Other[b]	1 (4.3)	0 (0.0)	

Notes: [a]According to the Canadian Employment Equity Act. [b]One subject, who did not identify with any of the listed ethnicities, identified herself as "other".
Abbreviation: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation.

Table 3 Health care resource utilization for fibroid symptoms in the 12 months prior to enrollment

Health care resource	Lap-RFA (n=23)	Myomectomy (n=22)
Family doctor visits		
Subjects with a visit, n (%)	14 (60.9)	15 (68.2)
Total visits, n	31	22
Number of visits for all subjects, mean±SD (min.–max.)	1.3±1.6 (0–6)	1.0±1.1 (0–4)
Number of visits for subjects seeing family doctor, mean±SD (min.–max.)	2.2±1.48 (1–6)	1.5±1.06 (1–4)
Gynecologist visits		
Subjects with a visit, n (%)	21 (91.3)	14 (63.6)
Total visits, n	49	30
Number of visits for all subjects, mean±SD (min.–max.)	2.1±1.7 (0–8)	1.4±1.8 (0–8)
Number of visits for subjects seeing gynecologist, mean±SD (min.–max.)	2.3±1.65 (1–8)	2.1±1.92 (1–8)
Emergency department visits		
Subjects with a visit, n (%)	5 (21.7)	3 (13.6)
Total visits, n	9	4
Number of visits for all subjects, mean±SD (min.–max.)	0.4±0.9 (0–4)	0.2±0.5 (0–2)
Number of visits for subjects to emergency department, mean±SD (min.–max.)	1.8±1.3 (1–4)	1.3±0.58 (1–2)

Abbreviations: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation; min, minimum; max, maximum.

Table 4 Operating room, PAR, and day surgery/hospitalization times

Variable	Lap-RFA (n=23)	Myomectomy (n=22)	Difference between medians	*p*-value[a]
Induction of anesthesia to leaving operating room, minutes				
Mean±SD	101.1±24.9	112.6[b] (35.6)[b]	8	0.012
Median (min.–max.)	97.0 (65–170)	105 (56–185)		
Procedural time, minutes				
Mean±SD	73.3±26.2	84.6±33.7	16.5	0.018
Median (min.–max.)	70.0 (40–142)	86.5 (25–154)		
PAR, minutes				
Mean±SD	80.5±28.4	86.8±21.4	7.5	0.029
Median (min.–max.)	76.0 (40–148)	83.5 (42–134)		
PAR discharge to hospital discharge, minutes				
Mean±SD	221.6±161.4	395.5±619.6	55.5	0.002
Median (min.–max.)	182.0 (45–865)	237.5 (135–3055)		
PAR discharge to hospital discharge from day surgery unit, minutes[c]				
Mean±SD	192.3±81.8	237.6±92.1	36.5	0.011
Median (min.–max.)	178.5 (45–355)	215.0 (135–470)		
Total hospitalization for those transferred from PAR to day surgery unit, hours[c]				
Mean±SD	6.20±1.59	7.18±1.62	1.08	0.002
Median (range)	5.88 (3.6–9.2)	6.95 (5.1–10.5)		
Total hospitalization, hours[d]				
Mean±SD	6.74±3.03	9.94±10.67	1.17	0.0004[d]
Median (min.–max.)	5.97 (3.6–18.7)	7.14 (5.1–55.6)		
Number of subjects with postoperative complications prior to discharge, n	0	2		
Total number of subjects hospitalized post-procedure, n	1	3		
Mean length of stay for hospitalized subjects, d±SD (min.–max.)	0.78 (0.8–0.8)	1.14±1.056 (0.3–2.3)		

Notes: [a]Wilcoxon test of median time for non-inferiority, alpha=0.025. [b]This includes a mean time of 9±14 minutes (min.–max., 2–30) to treat adhesions in four subjects in the myomectomy group. [c]These subjects were discharged from the day surgery unit and were not hospitalized (Lap-RFA, n=22; myomectomy, n=18). [d]Primary endpoint of the study.

Abbreviations: d, day; Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation; min, minimum; max, maximum; PAR, post-anesthesia recovery.

Table 5 Equipment and materials used during Lap-RFA and myomectomy procedures

Equipment/material	Lap-RFA (n=23)		Myomectomy (n=22)	
	Disposable	Reusable	Disposable	Reusable
Dispersive electrodes (pads), n	26	0	0	0
Procedures, n (%)	23 (100)			
Mean number per procedure	1.13			
RF handpiece, n	23	0	0	0
Procedures, n (%)	23 (100)			
Mean number per procedure	1.0			
10–12 mm trocar and sheaths, n	41	2	45	1
Procedures, n (%)	21 (91.3)	2 (8.7)	21 (95.5)	1 (4.5)
Mean number per procedure	1.78	0.09	2.05	0.05
Foley catheter/drainage bag, n	23	0	22	0
Procedures, n (%)	23 (100)		22 (100)	
Mean number per procedure	1.0		1.0	
Insufflation tubing, n	7	16	5	17
Procedures, n (%)	7 (30.4)	16 (69.6)	5 (22.7)	17 (77.3)
Mean number per procedure	0.30	0.70	0.23	0.77
Veress needle, n	18	5	17	6
Procedures, n (%)	18 (78.3)	5 (21.7)	17 (77.3)	5 (22.7)
Mean number per procedure	0.78	0.22	0.77	0.27

(*Continued*)

Table 5 (*Continued*)

Equipment/material	Lap-RFA (n=23)		Myomectomy (n=22)	
	Disposable	Reusable	Disposable	Reusable
5 mm suction irrigator, n	4	2	19	3
Procedures, n (%)	4 (17.4)	2 (8.7)	19 (86.4)	3 (13.6)
Mean number per procedure	0.17	0.09	0.86	0.14
5 mm trocar, n	2	2	41	6
Procedures, n (%)	2 (8.7)	2 (8.7)	20 (90.9)	2 (9.1)
Mean number per procedure	0.09	0.09	1.86	0.27
Adhesion barriers, n	0	0	20	0
Procedures, n (%)			14 (63.6)	
Mean number per procedure			0.91	
Morcellator, n	0	0	19	1
Procedures, n (%)			19 (86.4)	1 (4.5)
Mean number per procedure			0.86	0.05
Endo mini shears, n	0	0	11	5
Procedures, n (%)			11 (50)	5 (22.7)
Mean number per procedure			0.50	0.23
Kronner uterine manipulator injector, n	0	0	12	2
Procedures, n (%)			12 (54.5)	2 (9.1)
Mean number per procedure			0.55	0.09
Laparoscopic coagulation/cutting device, n	0	0	3	2
Procedures, n (%)			3 (13.6)	2 (9.1)
Mean number per procedure			0.14	0.09
Ultrasound cutting instrument, n	0	0	1	0
Procedures, n (%)			1 (4.5)	
Mean number per procedure			0.05	
Laparoscopic tray, n	0	23	0	22
Procedures, n (%)		23 (100)		22 (100)
Mean number per procedure		1.0		1.05
Single-tooth tenaculum, n	0	23	0	11
Procedures, n (%)		23 (100)		11 (50)
Mean number per procedure		1.0		0.50
Open-sided speculum	0	21	1	2
Procedures, n (%)		21 (91.3)	1 (4.5)	2 (9.1)
Mean number per procedure		0.91	0.05	0.09
Storz lap needle driver, n	0	0	0	21
Procedures, n (%)				20 (90.9)
Mean number per procedure				0.95
Gleisch suture passer, n	0	0	0	18
Procedures, n (%)				18 (81.8)
Mean number per procedure				0.82
Laproscopic large claw, n	0	0	2	15
Procedures, n (%)			2 (9.1)	15 (68.2)
Mean number per procedure			0.09	0.68
Laparoscopic single-tooth tenaculum, n	0	0	0	3
Procedures, n (%)				2 (9.1)
Mean number per procedure				0.14
Laparoscopic knot pusher, n	0	0	0	2
Procedures, n (%)				2 (9.1
Mean number per procedure				0.09
Lahey tenaculum clamp, n	0	0	0	1
Procedures, n (%)				1 (4.5)
Mean number per procedure				0.05
Total equipment pieces used	154	94	218	148

Abbreviation: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation.

equipment was used during the myomectomy procedures. All of the procedures in the Lap-RFA group used reusable single-tooth tenaculums, whereas only half of the myomectomy procedures required the use of reusable single-tooth tenaculums. The greatest difference in operative equipment and materials was the use of 5 mm trocars: whereas only four 5 mm trocars (2 disposable and 2 reusable) were used during the Lap-RFA procedures, forty-seven 5 mm trocars (41 disposable and 6 reusable) were used during the myomectomy procedures. In addition, the myomectomy procedures required the use of 13 additional types of equipment to complete the surgeries than were required for the Lap-RFA procedures. Overall, Lap-RFA required −34.9% (130 fewer) units of disposable and consumable units of equipment during the study, with Lap-RFA consuming −29.4% (66 fewer) disposables and using −36.5% (54 fewer) consumables than did myomectomy.

In the 3 months following the intervention to treat uterine fibroid symptoms, there was nominal use of health care resources by both groups (Table 6), with <10% of subjects visiting a family doctor or a gynecologist.

The majority of women who participated in the study were employed: 78.3% in the Lap-RFA group and 86.4% in the myomectomy group (Table 7). In the 3 months prior to their procedures, a similar proportion of women stated that they took time off work because of fibroid symptoms (Lap-RFA: 47.8%, n=11 and myomectomy: 40.9%, n=9). Of those subjects who were employed, the mean number of missed workdays during the 3 months prior to their Lap-RFA procedure was 5.5±2.7 days; this compares with 7.4±6.4 days for those who would undergo myomectomy. During the 3 months following treatment, 9% of individuals in each group reported missing work secondary to fibroid-related symptoms. After the procedure, physicians recommended patients not to return to work for ~4 weeks, up to a maximum of 6 weeks. Including the procedure day, the average number of days that employed subjects stayed home from work was significantly lesser in the Lap-RFA group (11.1±7.6 days) compared to the myomectomy group (18.5±10.6 days; p=0.0193)

Table 6 Health care resource utilization for fibroid symptoms: post-discharge to 3 months

Health care resource	Lap-RFA (n=23)	Myomectomy (n=22)
Family doctor visits		
Patients with a family doctor visit, n (%)	1 (4.3)	0
Number of visits, mean±SD	1.0	0
Total visits, n	1	0
Gynecologist visits		
Patients with a gynecologist visit, n (%)	1 (4.3)	2 (9.1)
Number of visits, mean±SD	1.0	1.0±0.0
Total visits, n	1	2
Emergency department visits		
Patients with a visit, n (%)	0	2 (9.1)
Number of visits, mean±SD	0	2.0±0.0
Total visits, n	0	4
Hospital utilization		
Hospitalizations for fibroid symptoms, n	0	1
Reinterventions, n	1	0

Abbreviation: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation.

The average per patient health care utilization and patient productivity costs of the two procedures were comparable (Table 8): Lap-RFA cost CAD $97.00 lesser than myomectomy (CAD $5,224.96 versus CAD $5,321.96), when productivity costs were considered. Lap-RFA was associated with higher procedural costs, but lower post-procedural costs as well as lower productivity costs from lost workdays.

Clinical outcomes: subject responses to validated questionnaires

Subjects in both groups responded to questions posed in the validated UFS-QOL questionnaire (at baseline and at 3 months post-procedure) regarding the extent of their symptom severity and health-related quality of life (Table 9). Those women randomized to Lap-RFA reported both greater (worse) symptom severity and lower (worse) quality of life at baseline than did those randomized to myomectomy (symptom severity: 61.55±19.8 versus 58.4±18.8; quality of life: 39.8±25.5 versus 47.9±23.9). At their 3 months follow-up, women from both cohorts reported the same significant reduction (−44.8%) in symptom severity from their baseline scores: Lap-RFA: 95% CI: −39.9, −16.6 (p<0.0001) and myomectomy: 95% CI: −37.2, −15.0 (p<0.0001). The Lap-RFA group reported a greater percentage improvement over baseline in their health-related quality of life than did the myomectomy group: 62.2% versus 45.8%, respectively. However, improvement over baseline in both groups was statistically significant (p=0.0009 and p=0.0001, respectively).

Mean health-state (EQ-VAS) scores (the higher the score, the better the health state) for the Lap-RFA group improved by 31.8% from a baseline level of 58.9±22.8 to 77.1±20.2 (Table 9). The mean health-state score for the myomectomy subjects improved by 15.3% from a baseline value of 71.8±11.5 to 82.7±8.1. However, the difference/improvement from baseline was statistically significant for subjects in both groups: p=0.0003 and p=0.0004, respectively.

The MIQ was given to all participants at baseline before treatment and at the 3 months follow-up visit to measure the subjects' perceptions of their bleeding and its impact on their

Table 7 Employment status and days missed from work at 3 months prior and 3 months following Lap-RFA and myomectomy

Variable	Lap-RFA (n=23)		Myomectomy (n=22)	
	3 months prior	3 months following	3 months prior	3 months following
Number of employed study subjects, n (%)	18 (78.3)	18 (78.3)	19 (86.4)	20 (90.9)
Full-time	13 (56.5)	13 (56.5)	16 (72.7)	16 (72.7)
Part-time	5 (21.7)	5 (21.7)	3 (13.6)	4 (18.2)
Number of study subjects looking for work, n (%)	0 (0.0)	1 (4.3)	1 (4.5)	1 (4.5)
Number of study subjects self-described as homemakers, n (%)	5 (21.7)	4 (17.4)	2 (9.1)	1 (4.5)
Days missed from work due to fibroid symptoms, mean±SD (min.–max.)	3.4±3.5 (0–10)	0.4±1.3 (0–5)	3.4±5.6 (0–21)	0.3±1.0 (0–4)
Number of employed subjects who missed work due to fibroid symptoms, n (%)	11 (47.8)	2 (8.7)	9 (40.9)	2 (9.1)
Missed workdays for those who took time off due to fibroid symptoms, mean±SD (min.–max.)	5.5±2.7 (1–10)	3.5±2.1 (2–5)	7.4±6.4 (2–21)	3.0±1.4 (2–4)
Days surgeon recommended taking off work due to procedure, mean±SD (min.–max.)		30.2±16.5 (0–42)		31.3±14.8 (0–42)
Days missed from work due to and following the procedure, mean±SD (min.–max.)		11.1±7.6 (3–30)		18.5±10.6[a] (4–38)

Notes: [a]The difference in the mean number of days missed from work due to and following the procedure was statistically significant (p=0.0193).
Abbreviations: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation; min, minimum; max, maximum.

Table 8 Per patient average cost of Lap-RFA and myomectomy through 3 months post-procedure

Variable	RFA (n=23)	Myomectomy (n=22)	Difference: Lap-RFA minus myomectomy
Procedure day health care costs			
Equipment	$2,914.98	$1,214.13	$1,700.85
Transfer to inpatient care	$137.96	$432.68	($294.72)
Subtotal	$3,052.93	$1,646.81	$1,406.12
Post-discharge health care costs through 3 months			
Hospital for fibroid symptoms	$0.00	$144.23	($144.23)
Day procedures (reintervention)	$68.57	$0.00	$68.57
Emergency visits	$0.00	$26.91	($26.91)
Family doctor visits	$1.52	$0.00	$1.52
Gynecology visits	$1.82	$3.81	($1.99)
Subtotal	$71.91	$174.95	($103.04)
Total procedural and post-procedural health care costs	$3,124.84	$1,821.76	$1,303.08
Productivity costs			
Lost workdays	$2,100.12	$3,500.20	($1,400.08)
Total costs	$5,224.96	$5,321.96	($97.00)

Notes: All costs are expressed in Canadian dollar (CAD). Values in parenthesis are expressed as negative values.
Abbreviation: Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation.

activities and quality of life (Table 9). At baseline, 78.3% and 86.4% of subjects in the Lap-RFA and myomectomy groups, respectively, reported experiencing heavy-to-very heavy bleeding. At the 3 months follow-up visit, the percentage of respondents in each group, who reported heavy-to-very heavy bleeding, decreased to 47.4% and 40.1%, respectively. Similar decreases occurred from baseline to 3 months in terms of the extent bleeding impacted subjects' work, physical, and social, and leisure activities.

The overall treatment effect survey was given to all participants at 3 months to measure overall satisfaction with the treatment to which they were randomized. Eighty-five percent of the Lap-RFA respondents reported satisfaction with their treatment, and 90.0% of myomectomy respondents reported satisfaction. Ninety percent of both Lap-RFA and myomectomy participants would recommend the treatment to a friend with the same health problem. Seventy-five percent of the ablation group respondents found Lap-RFA "moderately" or "very effective" in eliminating symptoms; 72.7% of the myomectomy respondents found the excisional therapy "moderately" or "very effective" in eliminating symptoms.

Safety

One serious adverse event was reported in the study from a subject randomized to myomectomy. She was hospitalized overnight after having experienced a 20-second asystole

Table 9 Mean transformed uterine fibroid symptom severity and health-related quality-of-life (UFS-QOL) scores, self-assessment of general health-state (EQ-VAS) scores, and subject responses to the MIQ

Questionnaire	Baseline scores		Scores at 3 month follow-up	
	Lap-RFA (n=23)	Myomectomy (n=22)	Lap-RFA (n=20)	Myomectomy (n=22)
UFS-QOL (SD)[a]				
Symptom severity	61.55 (19.8)	58.4 (18.8)	34.8 (25.6)	32.2 (22.6)
Health-related quality of life	39.8 (25.5)	47.9 (23.9)	63.3 (31.1)	69.9 (24.1)
Concern	40.05 (34.8)	40.2 (31.2)	59.5 (34.3)	61.8 (24.3)
Activities	39.6 (29.4)	51.95 (28.7)	60.0 (32.8)	73.2 (27.0)
Energy/mood	40.4 (26.4)	49.5 (26.0)	68.2 (31.8)	70.9 (25.8)
Control	41.5 (26.4)	51.8 (29.9)	60.1 (32.9)	72.05 (29.1)
Self-consciousness	38.8 (30.4)	45.8 (28.6)	63.75 (33.1)	67.8 (29.2)
Sexual function	35.3 (27.6)	41.5 (29.7)	59.4 (37.1)	72.7 (29.8)
EQ-VAS (SD)[a]	58.9 (22.8)	71.8 (11.5)	77.1 (20.2)	82.7 (8.1)
MIQ, n (%)[b]				
Blood loss				
Light	2 (8.7)	0 (0.0)	1 (5.3)	3 (13.6)
Moderate	3 (13.0)	3 (13.6)	9 (47.4)	10 (45.5)
Heavy	8 (34.8)	6 (27.3)	5 (26.3)	8 (36.4)
Very heavy	10 (43.5)	13 (59.1)	4 (21.1)	1 (4.5)
Not applicable/missing	0	0	1	0
How much your bleeding limited work outside home? n (%)				
Not at all	3 (13.0)	5 (22.7)	5 (26.3)	4 (18.2)
Slightly	2 (8.7)	3 (13.6)	5 (26.3)	4 (18.2)
Moderately	8 (34.8)	8 (36.4)	5 (26.3)	5 (22.7)
Quite a bit	6 (26.1)	5 (22.7)	2 (10.5)	2 (9.1)
Extremely	4 (17.4)	1 (4.5)	2 (10.5)	0 (0.0)
Not applicable/missing	0	0	1	0
How much your bleeding limited physical activities? n (%)				
Not at all	1 (4.3)	3 (13.6)	5 (26.3)	11 (50.0)
Slightly	4 (17.4)	5 (22.7)	4 (21.1)	5 (22.7)
Moderately	7 (30.4)	4 (18.2)	5 (26.3)	4 (18.2)
Quite a bit	5 (21.7)	9 (40.9)	2 (10.5)	2 (9.1)
Extremely	6 (26.1)	1 (4.5)	3 (15.8)	0 (0.0)
Not applicable/missing	0	0	1	0
How much your bleeding limited social or leisure activities? n (%)				
Not at all	3 (13.0)	6 (27.3)	6 (31.6)	9 (40.9)
Slightly	3 (13.0)	5 (22.7)	6 (31.6)	8 (36.4)
Moderately	5 (21.7)	3 (13.6)	3 (15.8)	4 (18.2)
Quite a bit	6 (26.1)	6 (27.3)	2 (10.5)	1 (4.5)
Extremely	6 (26.1)	2 (9.1)	2 (10.5)	0 (0.0)
Not applicable/missing	0	0	1	0

Notes: [a]All scores are expressed on a scale of 1–100. Decreasing symptom severity scores indicates a decrease in the severity of fibroid symptoms experienced by the subjects. Increasing health-related quality-of-life scores and health-state scores indicates improvement in fibroid-related quality of life and general health state, respectively. [b]Percentages are based on non-missing responses.

Abbreviations: EQ-VAS, EuroQol visual analog scale; Lap-RFA, laparoscopic ultrasound-guided radiofrequency ablation; MIQ, menstrual impact questionnaire; UFS-QOL, uterine fibroid symptom and quality of life.

during the procedure and subsequent to intramyometrial injection of dilute vasopressin.

One reintervention, a total laparoscopic hysterectomy, was reported for one subject in the Lap-RFA group who complained of heavy menstrual bleeding at baseline and for 2 months post-procedure. She was very anxious for relief of her bleeding and was booked for Novasure endometrial ablation. However, the device could not be engaged and the subject subsequently underwent a hysterectomy.

No pregnancies were reported in either group by the 3 months visit.

Discussion

Results from this Canadian-based randomized controlled trial of Lap-RFA and myomectomy for the treatment of symptomatic uterine fibroids indicated that Lap-RFA procedures can be completed more quickly and required fewer operative resources than myomectomy procedures; the average overall

direct and indirect costs through 3 months of follow-up were comparable for the two cohorts. The primary endpoint of the study was the mean total hospitalization time for subjects in each treatment group. Mean total hospitalization was ~3 hours shorter for the Lap-RFA group compared to the myomectomy group, and the difference was statistically significant. This is similar to a finding from a German single-center study, which reported a significantly shorter mean hospitalization time of 10.0±5.5 hours for the Lap-RFA group versus 29.9±14.2 hours for the laparoscopic myomectomy group.[7] Our results and those from the German study demonstrate that hospitalization time for Lap-RFA appears not to depend on the health care system where the procedure is performed. In addition, three subjects from the current study in the myomectomy group were admitted overnight compared to one subject in the Lap-RFA group.

The overall results of this trial support the rejection of our null hypothesis: Lap-RFA was not worse than myomectomy with respect to health care resource utilization and clinical and safety outcomes. The shorter hospitalization, reduced overall equipment and material needs, comparable direct and indirect costs, and comparable-to-improved patient-reported health outcomes – including shorter time to return to work – for the subjects in the Lap-RFA group could result in overall reduced health care costs in non-single payer health care markets, such as in the USA. Indeed, Havryliuk et al, in their recent systematic review and meta-analysis of the literature (2006–2016), described surgical and radiological treatments of symptomatic fibroids and reported a trend toward minimally invasive, outpatient, uterine-sparing options.[22]

As the health care systems accelerate toward a consumer- and value-oriented payment model, considerations of health care utilization, the ability of patients to return to work soon after treatment, and improved clinical outcomes increasingly become important considerations. Women who underwent Lap-RFA were able to return to work ~1 week sooner than those women in the myomectomy group (11.1 versus 18.5 days). Our results provide similar evidence for a more rapid return to work as those reported by Hahn et al (women in the Lap-RFA group missed 10.0 workdays compared to 17.0 workdays for women in the myomectomy group).[23] The study results are of significant value, as providers and payers develop new models, such as bundled payment arrangements, which focus on lowering health care resource consumption within a defined episode of care.

Last – and not an endpoint of the study, but certainly a worthwhile observation – is the difference in environmental impact from the two surgical methods. Twenty-two cases of myomectomy consumed 66 more units of disposable equipment than 23 cases of Lap-RFA. All units of disposable surgical equipment must be processed and transported to a landfill and – with hundreds of thousands of myomectomies performed annually throughout the world – the mass of the related surgical garbage is significant. Whether one is an economist, a surgeon, or a professor, consideration of the environmental impact of a surgical procedure may become more and more germane to the preferred surgical approach.

Limitations

The preprocedure health care resource utilization information was based on participant recall, which is subject to recall bias. Costs were collected and analyzed ad hoc retrospectively rather than prospectively, which may have led to unknown reporting errors. Only disposable equipment costs from one center were evaluated; the capital costs of the reusable equipment were not analyzed nor were the procedural costs such as operating room time and anesthesia. The lack of long-term data is a limitation; the data are based on outcomes to 3 months post-intervention and, therefore, the durability of the symptom improvement and pregnancy outcomes could not be evaluated for either procedure. However, multiple studies of Lap-RFA indicate the durability of 3-month outcomes over 1, 2, and 3 years.[6,22,24,25] Finally, the laparoscopic myomectomies in the current study were performed without robotic assistance. In many global markets, robotic-assisted procedures represent approximately one-third of all laparoendoscopic gynecologic procedures for benign disease.[26] Thus, the findings of direct procedural supply costs reported may not be generalizable to other markets where procedural supply costs would be significantly higher for the myomectomy group on average.

Conclusion

Lap-RFA provides a safe alternative to myomectomy for the treatment of uterine fibroids. Compared to myomectomy, Lap-RFA is associated with significantly lesser intraoperative blood loss, shorter procedure and hospitalization times, lesser consumption/use of disposable and reusable surgical equipment, comparable direct and indirect costs, and faster return to work through 3 months posttreatment.

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