

Laparoscopic Ultrasound-Guided Radiofrequency Ablation of Uterine Fibroids

Andrea Milic,¹ Murray R. Asch,² Peter A. Hawrylyshyn,³ Lisa M. Allen,³ Terence J. Colgan,⁴ John R. Kachura,⁵ Eran B. Hajeems⁶

¹Department of Medical Imaging, University of Toronto, 657 University Avenue, Mulock Larkin Wing, Room 1-042, Toronto, Ontario M5G 2C4, Canada

²Department of Diagnostic Radiology, Lakeridge Health Corporation, 1 Hospital Court, Oshawa, Ontario L1G 2B9, Canada

³Department of Obstetrics and Gynecology, Mount Sinai Hospital, 600 University Avenue, Toronto, Ontario M5G 1X5, Canada

⁴Department of Pathology, Mount Sinai Hospital, 600 University Avenue, Toronto, Ontario M5G 1X5, Canada

⁵Department of Diagnostic Imaging, Toronto General Hospital, Eaton South 1-454d, 200 Elizabeth Street, Toronto, Ontario M5G 2C4, Canada

⁶Department of Diagnostic Imaging, Mount Sinai Hospital, 600 University Avenue, Toronto, Ontario M5G 1X5, Canada

Abstract

Four patients with symptomatic uterine fibroids measuring less than 6 cm underwent laparoscopic ultrasound-guided radiofrequency ablation (RFA) using multiprobe-array electrodes. Follow-up of the treated fibroids was performed with gadolinium-enhanced magnetic resonance imaging (MRI) and patients' symptoms were assessed by telephone interviews. The procedure was initially technically successful in 3 of the 4 patients and MRI studies at 1 month demonstrated complete fibroid ablation. Symptom improvement, including a decrease in menstrual bleeding and pain, was achieved in 2 patients at 3 months. At 7 months, 1 of these 2 patients experienced symptom worsening which correlated with recurrent fibroid on MRI. The third, initially technically successfully treated patient did not experience any symptom relief after the procedure and was ultimately diagnosed with adenomyosis. Our preliminary results suggest that RFA is a technically feasible treatment for symptomatic uterine fibroids in appropriately selected patients.

Key words: Fibroid—Radiofrequency ablation (RFA)—Uterus

Uterine fibroids affect up to 65% of women by the time of menopause, and are associated with disabling symptoms including abnormal bleeding, pain, and infertility [1]. For women who do not desire further pregnancies, the established treatment is abdominal hysterectomy. Although relief of symptoms can be expected in 85–90% of women, abdominal hysterectomy generally involves a hospital stay of 3–5 days and a recovery time of several weeks. Fifteen percent of women experience significant morbidity [2]. Recently, less invasive alternatives to hysterectomy have been introduced, including laparoscopic myomectomy, laparoscopic-directed thermal ablation, cryotherapy, and uterine fibroid embolization (UFE), with post-treatment satisfaction rates of up to 96% [for review, see 3].

Laparoscopic-guided radiofrequency ablation (RFA) of the fibroids has been performed with both monopolar and bipolar single electrocautery needles since the early 1990s [1]. Newer RFA probes with multiple hooked arrays have been increasingly used by interventional radiologists to ablate larger areas than are possible with conventional radiofrequency single-needle electrodes. In an *in vivo* porcine liver model, LeVein achieved spherical regions of coagulation necrosis measuring 3.5 cm using a 12-hook array radiofrequency electrode [4]. Multiprobe-array RFA is well tolerated in patients with liver, lung, kidney, and bone tumors, with local tumor control in up to 95% [5, 6]. We present our initial experience with laparoscopic-guided RFA using LeVein Needle Electrodes (Boston Scientific, Natick, MA) to evaluate the role of RFA for treatment of small, symptomatic uterine fibroids.

Case Report

Four women with symptomatic uterine fibroids (menorrhagia 100%, dysmenorrhea 100%) were included in a prospective study. Institutional Review Board approval was obtained. The patients ranged in age from 31 to 47 years (mean 41 years). The exclusion criteria were: (1) inability to undergo laparoscopy, (2) desire to maintain future fertility, (3) more than five fibroid tumors, (4) fibroids greater than 6 cm in diameter, and (5) clinical suspicion of uterine or ovarian malignancy. Fibroid tumor size, location, and number were confirmed with ultrasound 1 month prior to the RFA procedure. The patients completed a self-administered questionnaire assessing symptoms (pain and bleeding) and quality of life prior to the procedure using a quantitative scale [1–10]. This questionnaire has been used at our institution previously to evaluate symptoms in patients undergoing UFE.

Laparoscopic surgery was performed by gynecologists with the patient under general anesthesia, and RFA was performed by interventional radiologists. Multiprobe-array, 15 cm long LeVein Needle Electrodes (Boston Scientific, Natick, MA) were used for fibroid ablation. Probes of 2–4 cm diameter were chosen according to fibroid size. Multiple RFA probe positions were necessary for complete fibroid ablation when the fibroid size exceeded the maximum available RFA electrode diameter. The RF 3000 generator system (Boston Scientific, Natick, MA) was used to perform ablations according to the manufacturer's suggested standard soft-tissue algorithm. Briefly, the RFA electrode was inserted into the fibroid and the tines were deployed in the lesion under laparoscopic ultrasound guidance.

Table 1. Characteristics of patients undergoing RFA for treatment of symptomatic fibroids

Patient no.	Treated fibroid location	No. of successfully treated fibroids	Treated fibroid maximum diameter (cm)	RFA probe size (cm)	No. of probe positions	Follow-up MRI	Clinical outcome
1	Intramural posterolateral	1	2.1	3.5	1	No enhancement	Significant decrease in symptoms
2	Submucosal central	1	4.7	4.0	2	No enhancement at 3 months; New 1.2 cm focus of enhancement at 7 months with overall decrease in fibroid size	Moderate decrease in symptoms at 3 months, gradual worsening of symptoms at 9 months
3	Submucosal central	1	1.3	2.0	1	No enhancement of treated lesion	Hysterectomy
4	Submucosal postero-inferior	0	4.9	4.0	1	Two residual fibroids N/A	Hysterectomy

RFA = radio frequency ablation; MRI = Magnetic resonance imaging

Two heating cycles were used for each probe position. The maximum power used ranged from 50 to 180 W (mean 93.1 W). An abrupt rise in the impedance, or the “roll-off,” determined the completion of the heating cycle. The mean duration of a single heating cycle was 4.4 min (range 1.1–11.1 min). A rapid echogenic effect representing microbubbles was demonstrated by laparoscopic ultrasound throughout the area of the fibroid. The electrode was removed from the uterus while the RF current was still being applied, in order to cauterize the tract and minimize the risk of bleeding.

Postoperatively, the patients were observed for 6 hr and discharged home the same day. Pain was assessed prior to discharge on a scale of 1 to 10 and nonsteroidal anti-inflammatory drugs (NSAIDs) or opioid medication prescribed accordingly. Follow-up consisted of both gadolinium-enhanced MRI and telephone interviews to assess patient symptoms. MRI was performed at 1–3 months after the procedure and again at 6 months following fibroid ablation. Telephone interviews were conducted at 2 weeks after the procedure and after the follow-up MRI examination to evaluate patient pain, bleeding, and quality of life.

Ultrasound examination prior to the RFA procedure identified multiple fibroids in 2 patients and a single fibroid in the remaining 2 patients, giving a total of 9 fibroids. When multiple fibroids were present, a single fibroid was selected for RFA on the basis of its location (submucosal) and/or size. Four fibroids (1 intramural, 3 submucosal) ranging from 1.3 to 4.9 cm (average 3.2 cm) in maximum diameter were targeted for RFA (Table 1).

In 3 patients, the laparoscopic-guided fibroid RFA was initially technically successful. In the fourth patient (patient 4), it was not possible to position the electrode into the lower uterine segment, posterior submucosal fibroid because the firmness and mobility of the uterine and fibroid tissue resulted in bending of the electrode tip. The patient was treated with hysterectomy at a later date.

All patients were discharged home within 6 hr following the RFA procedure. No major complications were encountered, but severe pain was reported by all patients in the first 2 days after the procedure, ranging from 7 to 9 on a 10-point pain scale (mean score 8/10). Patients required analgesia for 5–10 days (mean 7 days) and returned to work in 4–14 days (mean 7.7 days).

Symptom improvement was achieved in 2 of 3 women following fibroid ablation. At 3 months after the procedure, menstrual bleeding in the first patient decreased from 15 days to 4 days in duration, and from 10 pads/day to 3 pads/day. In the second patient bleeding decreased from 20 days to 12 days in duration and she required 10 pads/day compared with 30 pads/day prior to the procedure. Pain decreased from 6/10 to 1/10 in the first patient and from 10/10 to 6/10 in the second patient, enabling them to continue working. These patients reported improved quality of life, and overall satisfaction with the procedure. In the patient (patient 3) who did not obtain symptomatic pain relief following RFA, diffuse adenomyosis was identified on the 3 month follow-up MRI examination. This patient subsequently underwent a hysterectomy 5 months after RFA. The hysterectomy specimen demonstrated a small 6 mm necrotic nodule with a surrounding scar in the treated submucosal area of the uterus (Fig. 1). There was no fibroid tissue visualized adjacent to the necrotic nodule.

The 3-month follow-up MRI examination demonstrated lack of fibroid tissue enhancement in all of the 3 treated patients, suggesting initial successful ablation (Fig. 2A). There was also evidence of fibroid infarction demonstrated by high signal on T1-weighted images (Fig. 2B). At 7 months, a new 1.2 cm focus of enhancement was demonstrated within the treated fibroid in 1 patient (patient 2). This represents either recurrence of a new myoma or interval growth of microscopic residual viable tissue not appreciated on the initial 3 month follow-up MRI examination (Fig. 2C). The patient experienced increased menstrual bleeding and pain at 9 months after the procedure compared with the 3 month follow-up.

Discussion

RFA of uterine fibroids with multiprobe-array RF electrodes has not been reported in the literature to date. Of 4 patients who en-

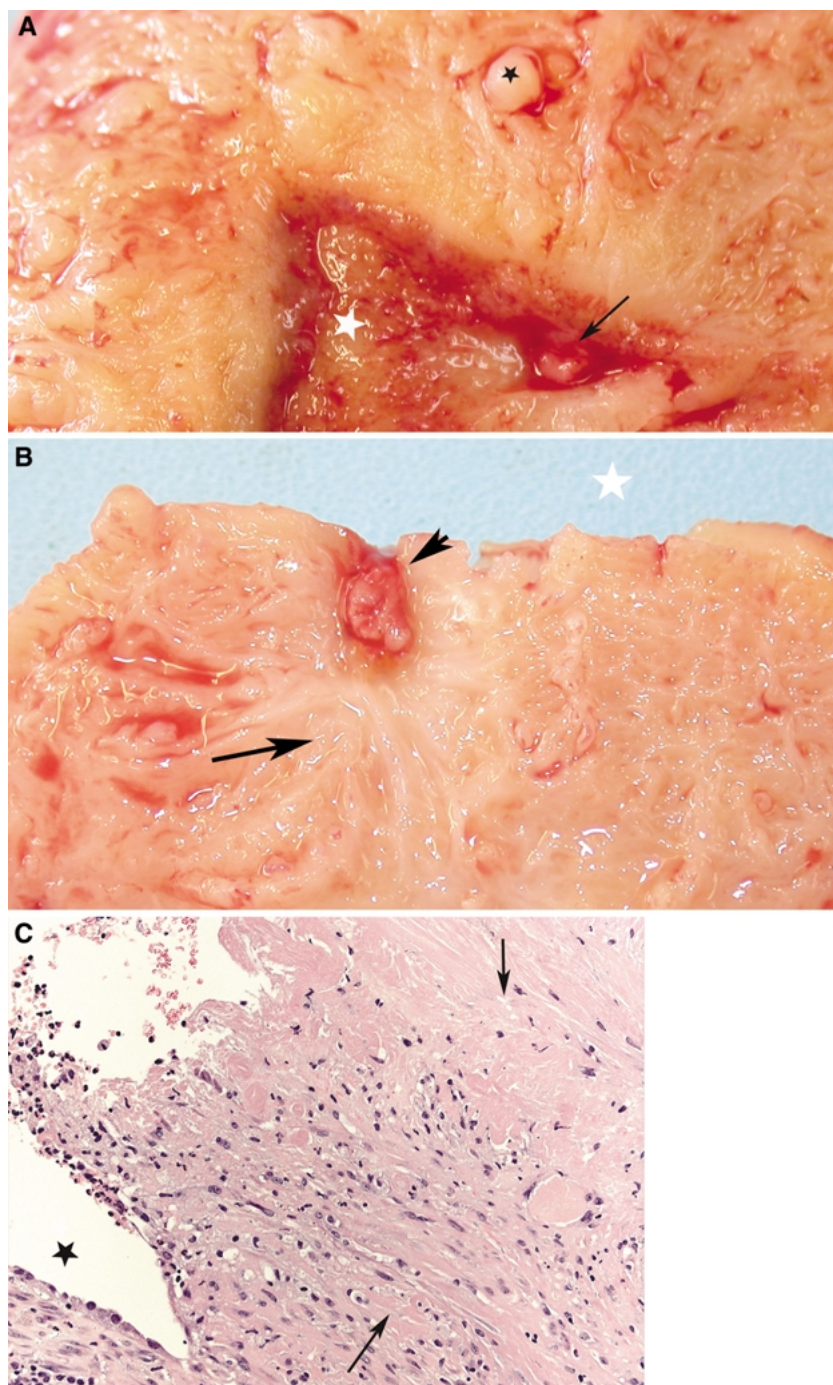


Fig. 1A–C. Hysterectomy specimen in a 41-year-old woman (patient 3) with adenomyosis following RFA treatment of a submucosal fibroid. **A** Gross hysterectomy specimen demonstrating a necrotic nodule (arrow) at the endometrial surface (white asterisk) representing the radiofrequency-treated area. An additional, nontreated fibroid can be seen in the uterine wall (black asterisk). Diffuse adenomyosis of the myometrium is present. **B** A section through the necrotic nodule (arrowhead) demonstrating its proximity to the endometrial cavity and the surrounding stellate scar (arrow). **C** Hematoxylin and eosin stain adjacent to the endometrial cavity (asterisk) demonstrating necrotic smooth muscle cells (upper arrow) and scarring depicted by fibroblasts and scanty inflammatory cells (lower arrow).

tered the study, only 1 achieved symptom relief at 3 months. Although the treatment outcome was successful in only 1 patient, our data provide valuable information which may help guide the management of uterine fibroids and the design of future fibroid RFA studies.

RFA may be most beneficial to patients with small fibroids. Therefore, careful patient selection is needed prior to fibroid ablation. Only patient 1 with a small fibroid achieved full symptom relief. Patient 2 with the largest fibroid lesion in this series required two probe positions and developed fibroid recurrence at 7 months. It has been shown that recurrence rates for liver lesions are higher for larger

lesions, primarily because multiple probe positions are required for complete ablation [7]. The echogenic microbubble artifact created by the first heating cycle obscures the lesion, making probe repositioning under ultrasound guidance more difficult.

Patient preselection should enable exclusion of patients with multiple fibroids. It is difficult to predict which of the multiple fibroids in a particular patient is the most symptomatic and therefore should be targeted for RFA. Patients with multiple fibroids should be referred for another procedure, such as UFE.

Our data demonstrate that fibroids in a posterior location are difficult to access with current RFA probes, and may be best

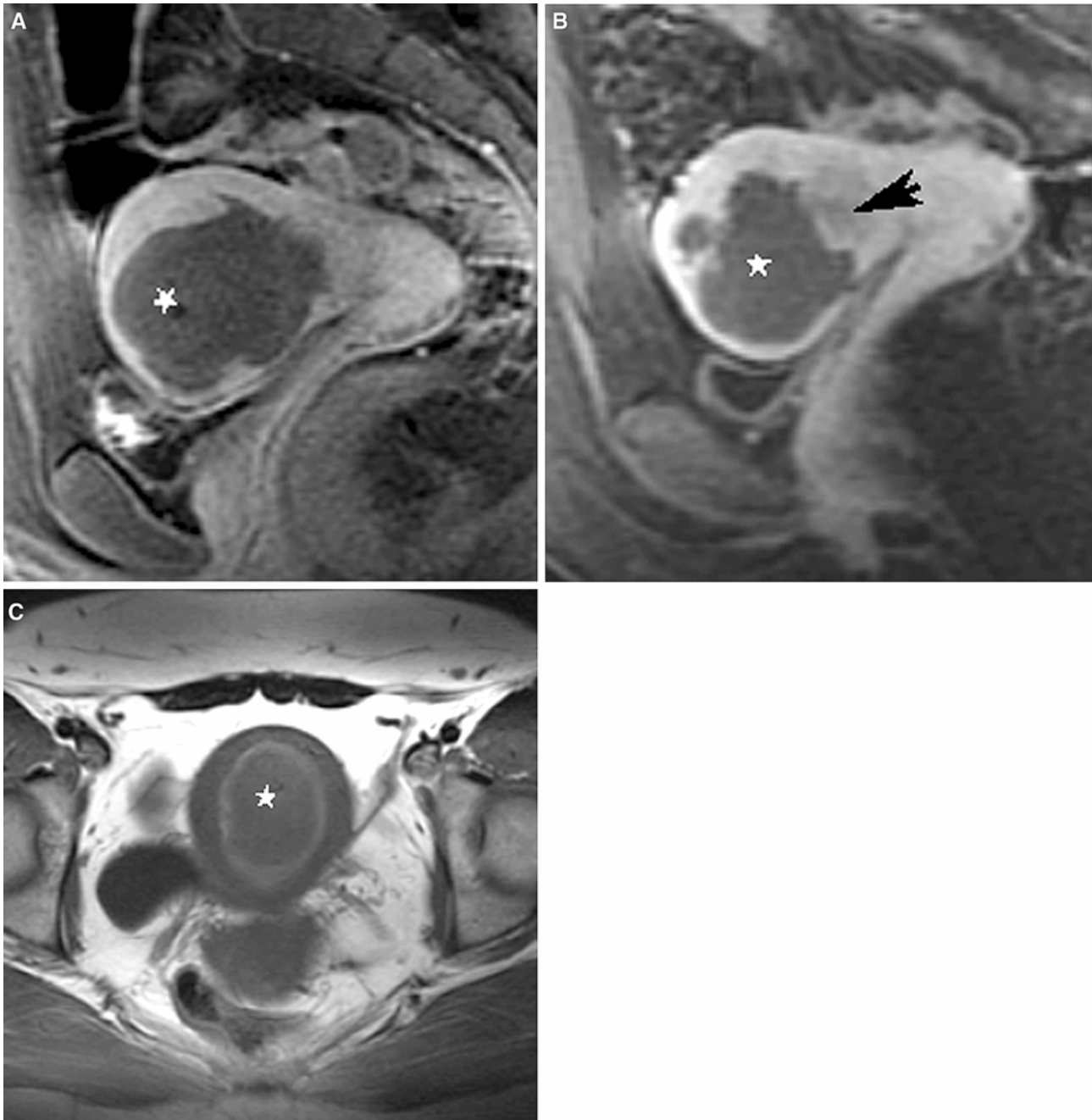


Fig. 2A–C. A 31-year-old woman (patient 2) with fibroid recurrence at 7 months after RFA. The fibroid is marked (asterisk) on each image. **A** Sagittal T1-weighted contrast-enhanced gradient-echo MR image demonstrating complete infarction of the fibroid at 1 month. **B** Sagittal T1-weighted contrast-enhanced gradient-echo MR image 7

months following RFA demonstrating a decrease in the central nonenhancing zone, and a new enhancing area posteriorly within the fibroid (arrow). **C** Axial T1-weighted MR image at 1 month demonstrating a rim of high T1 signal surrounding the periphery of the treated fibroid.

treated with an alternate procedure. The firmness of the fibroid tissue and the difficulty of stabilizing the uterus prevented precise electrode placement in patient 4 with a low, posterior fibroid. Other authors reported difficulty accessing posterior fibroids by bipolar electrodes [8] or laser fibers [9].

Preprocedural MRI should be performed for fibroid mapping, exclusion of other potential pelvic pathology contributing to a patient's symptoms, and for baseline comparison against postprocedural MRI. We used ultrasound to document fibroid location and

size prior to RFA because MRI was not readily available at our institution for the purpose of preprocedural planning in patients with fibroids. In patient 3 adenomyosis was not detected prior to RFA. Had preprocedural MRI been performed instead, this patient would have been excluded from our study and unnecessary surgery would have been prevented. MRI has a high accuracy in differentiating between fibroids and other uterine diseases such as adenomyosis [10], and has been shown to have an important role in preprocedural planning for UFE [11].

The MRI appearance of fibroids following ablation with radiofrequency electrodes has not been previously described. We showed that treated fibroids lack enhancement and a high T1 signal remains even at 7 months after RFA. These findings are consistent with the fibroid appearance after uterine artery embolization [10], and correlate with areas of infarction [12].

RFA was performed as an outpatient procedure and the patients returned to work within several days, demonstrating an advantage over hysterectomy and myomectomy which are associated with higher morbidity, longer hospital stays, and longer recovery time [2]. In addition, laparoscopic ultrasound-guided RFA offers precise targeting of abnormal fibroid tissue. Potential complications following fibroid RFA include bleeding, infection, visceral injury, and grounding pad burns [13], but none of these were encountered in our patients. We attempted to reduce the risk of bleeding by applying the RF current while withdrawing the electrode from the uterus to cauterize the tract, as described by other groups [13].

In conclusion, RFA of symptomatic uterine fibroids using multiprobe-array electrodes appears to be technically feasible for small, anterior, and fundal fibroids. Further prospective studies currently in progress with a larger, select patient population will provide reliable data on the safety and efficacy of RFA with multiprobe-array electrodes.

Acknowledgments. The grant support for this study was provided by Boston Scientific. In addition, M.R.A. is a paid consultant for Boston Scientific.

References

1. Goldfarb HA (2000) Myoma coagulation (myolysis). *Obstet Gynecol Clin North Am* 27:421–430
2. Iverson RE Jr, Chelmow D, Strohbehn K, et al. (1996) Relative morbidity of abdominal hysterectomy and myomectomy for management of uterine leiomyomas. *Obstet Gynecol* 88:415–419
3. Olive DL (2000) Review of evidence for treatment of leiomyomata. *Environ Health Perspect* 108:841–843
4. LeVeen RF (1997) Laser hyperthermia and radiofrequency ablation of hepatic lesions. *Semin Interv Radiol* 14:313–324
5. Chan RP, Asch M, Kachura J, et al. (2002) Radiofrequency ablation of malignant hepatic neoplasms. *Can Assoc Radiol J* 53:272–278
6. Dupuy DE, Goldberg SN (2001) Image-guided radiofrequency tumor ablation: Challenges and opportunities. Part II. *J Vasc Interv Radiol* 12:1135–1148
7. Kosari K, Gomes M, Hunter D, et al. (2002) Local, intrahepatic, and systemic recurrence patterns after radiofrequency ablation of hepatic malignancies. *J Gastrointest Surg* 6:255–263
8. Goldfarb HA (1995) Bipolar laparoscopic needles for myoma coagulation. *J Am Assoc Gynecol Laparosc* 2:175–179
9. Nisolle M, Smets M, Gillerot S (1993) Laparoscopic myolysis with the Nd:YAG laser. *J Gynecol Surg* 9:95–99
10. Pelage JP, Guaou NG, Jha RC, et al. (2004) Uterine fibroid tumors: Long-term MR imaging outcome after embolization. *Radiology* 230:803–809
11. Omary RA, Vasireddy S, Chrisman HB, et al. (2002) The effect of pelvic MR imaging on the diagnosis and treatment of women with presumed symptomatic uterine fibroids. *J Vasc Interv Radiol* 13:1149–1153
12. Colgan TJ, Pron G, Mocarski EJ, et al. (2003) Pathologic features of uteri and leiomyomas following uterine artery embolization for leiomyomas. *Am J Surg Pathol* 27:177–177
13. Rhim H, Dodd GD 3rd, Chintapalli KN, et al. (2004) Radiofrequency thermal ablation of abdominal tumors: Lessons learned from complications. *Radiographics* 24:41–52