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Original Article

Outpatient Multimodality Management of Large Submucosal Myomas Using Transvaginal Radiofrequency Myolysis

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ABSTRACT **Study Objective:** To evaluate the safety and efficacy of transvaginal radiofrequency myolysis (RFM) with or without combined hysteroscopy for treatment of large submucosal leiomyomas with a substantial intramural portion.
Design: Retrospective observational study (Canadian Task Force classification III).
Setting: Hospital outpatient department.
Patients: Twenty-four patients with large submucosal leiomyomas with a substantial intramural portion.
Interventions: Transvaginal RFM with or without combined hysteroscopy.
Measurements and Main Results: Twenty-four patients with large submucosal leiomyomas with a substantial intramural portion were enrolled to undergo stepwise RFM. Additional hysteroscopic myomectomy was performed in 6 patients at 3 to 6 months after RFM. Myoma volumes were measured via 3-dimensional ultrasonography before RFM and at 1, 3, 6, 12, and 24 months postoperatively. Symptom severity was assessed using the Uterine Fibroid Symptom and Quality of Life questionnaire and the Health-Related Quality of Life questionnaire. The total volume reduction rate 24 months postoperatively was 84.2%. Symptom severity and health-related quality of life scores demonstrated substantial improvements at 12 months after RFM.
Conclusions: RFM with or without hysteroscopy is an effective treatment for large myomas with deep intramural positioning, and it seems safe for use in all patients with submucosal myoma-related symptoms. Journal of Minimally Invasive Gynecology (2014) 21, 1049–1054 © 2014 AAGL. All rights reserved.

Keywords: Hysteroscopy; Radiofrequency myolysis; Submucosal myoma

Uterine myomas, generically known as fibroids, are the most common benign gynecologic tumors in women of reproductive age, reportedly occurring in 20% to 40% of this population [1,2]. Almost 50% of myomas are found incidentally without symptoms, and only about 25% are symptomatic [3]. Symptom severity and presentation patterns depend on the number, size, and location of the myomas. The most common symptoms are menorrhagia and dysmenorrhea. Further, submucosal leiomyomas commonly cause abnormal uterine bleeding, menstrual abnormalities, and subfertility, unlike the other 2 classes of leiomyomas, namely, subserosal and intramural [4,5].

Currently, surgical treatment of symptomatic leiomyomas involves total hysterectomy or myomectomy, and the most commonly recommended method of myomectomy to treat submucosal myomas is hysteroscopic myomectomy. However, not all submucosal leiomyomas can be treated using this method.

Lasmar et al [6] have suggested a classification system for submucosal leiomyomas, based on size, width of the base, location, and depth of penetration into the myometrium. They scored submucosal leiomyomas in 55 women who underwent hysteroscopic myomectomy, and recommended whether an alternative to the hysteroscopic technique was warranted based on the total score. They recommended transabdominal myomectomy rather than hysteroscopic

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myomectomy in patients with high scores for submucosal leiomyomas, to preserve the uterus [6].

Since 2004 we have performed transvaginal radiofrequency myolysis (RFM) in premenopausal post–childbearing patients with symptomatic submucosal leiomyomas who desired preservation of their uterus. RFM has several advantages: it does not require admission care, is associated with low postoperative bleeding and pain, and patients may rapidly resume daily activities within a few hours after RFM. Furthermore, after RFM, myoma cells and feeding vessels are coagulated, which ensures minimal bleeding during subsequent hysteroscopic myomectomy. In the present retrospective observational study we report our experience with a group of patients who underwent transvaginal RFM with or without concomitant hysteroscopy to treat large submucosal leiomyomas with deep intramural positioning, with an emphasis on the safety and efficacy of performing this procedure in the outpatient department.

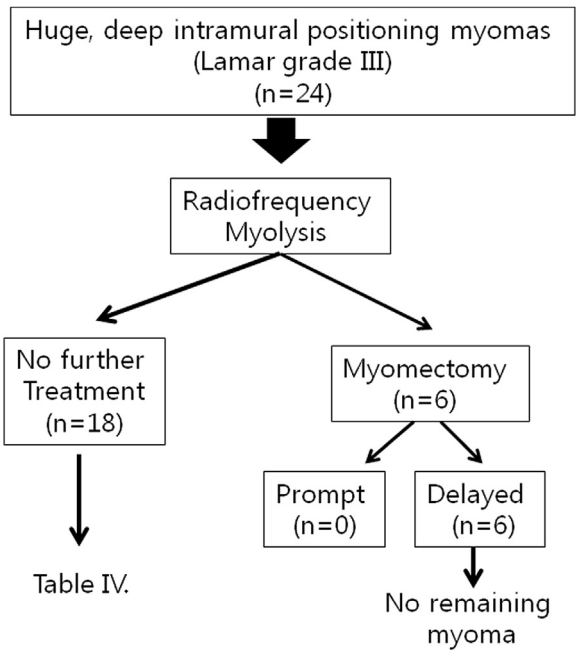
Material and Methods

Patients

Premenopausal women who visited the fibroid center of Seoul St. Mary's Hospital from March 1, 2009, to February 28, 2012, for management of large symptomatic submucosal myomas with deep intramural positioning (submucosal myoma grade III, as determined using the system of Lasmar et al [6]) were enrolled in the study (Fig. 1). All patients were counseled extensively on the potential risks and benefits of the procedure and possible alternative surgical treatments.

Fig. 1

Treatment design and steps used in the present study.



The study protocol was approved by the Ethics and Research Committee of the Catholic University of Korea. Exclusion criteria were as follows: opting out of RFM, any abnormalities detected in cancer screening tests, abnormal coagulation test results, current pregnancy, recent pelvic or endometrial inflammatory disease, and positive results of a chlamydia or gonorrhea polymerase chain reaction test.

Multimodality Steps

Myomas were scored using the Lasmar system [6] (Table 1), and the recommended RFM treatment steps were followed (Table 2). In Table 2, prompt myomectomy refers to hysteroscopic myomectomy performed after RFM in the same operative field, and delayed hysteroscopic myomectomy refers to hysteroscopic myomectomy conducted 3 to 6 months after RFM. RFM was initially performed in all patients. After 3 months, patients were reevaluated, and hysteroscopic myomectomy was performed if the myoma volume was reduced to <5 cm.

Study Procedure and Data Collection

Preoperative and postoperative myoma volume was measured using 3-dimensional ultrasonography via the Virtual Organ Computer-aided Analysis volume calculation method. Sonographic evaluation was repeated at 1, 3, 6, 12, 18, and 24 months postoperatively. The final volume regression rate was calculated as follows: 100 − [(24 months postoperative volume/preoperative volume) × 100]. To minimize interpersonal variation, the ultrasonograms were checked by a single trained gynecologist (H. H. C.). The RFM procedure and equipment used have been described previously [7].

Patient subjective myoma-related symptoms were assessed using the Uterine Fibroid Symptom and Quality of Life questionnaire [8] at the initial visit and at 12 months postoperatively. Patients were asked to rate the severity of symptoms, with higher scores indicating greater symptom severity. The health-related quality of life (HRQoL) questionnaire was also administered, and the summed scores of the subscales, namely, concerns, activities, energy/mood, control, self-consciousness, and sexual function, were calculated. Higher summed scores indicated better HRQoL.

Table 1

Submucosal scoring system of Lasmar et al [6]

Points[a]	Depth of penetration, %	Volume, cm	Width of base	Location in uterus
0	0	≤2	≤1/3	Lower third
1	≤50	2–5	>1/3–2/3	Middle third
2	>50	>5	>2/3	Upper third

[a] If the myoma was located in a lateral wall, 1 point was added to the total score.

Table 2

Comparison of treatment methods for submucosal myomas suggested by Lasmar et al [6] and RFM multimodality outpatient treatment used in the present study

Score	Group	Recommended treatment (Lasmar et al [6])	RFM multimodality treatment steps
0–4	I	Low-complexity hysteroscopic myomectomy	RFM RFM with prompt hysteroscopy
5–6	II	Complex hysteroscopic myomectomy, perhaps with preparation using a GnRH analogue and/or a 2-stage surgical procedure	RFM RFM with prompt or delayed hysteroscopy
7–9	III	Alternative non-hysteroscopic technique	RFM RFM with delayed hysteroscopy

GnRH = gonadotropin-releasing hormone; RFM = radiofrequency myolysis.

Patients were also asked to report postoperative complications such as vaginal bleeding, abdominal pain, fever/febrile sense, increased vaginal discharge, and dyspnea each time they visited for routine follow-up ultrasonography.

Statistical Analysis

Statistical analysis was performed using the χ^2 test and the Excel 2007 tutorial (Microsoft Corp., Redmond, WA).

Results

Twenty-four patients were enrolled in the present study. Patient characteristics and changes in symptom severity and the Uterine Fibroid Symptom and Quality of Life and HRQoL scores after RFM are given in Table 3. At 12 months after RFM all of these parameters were significantly improved over baseline scores.

Initial leiomyoma volumes before RFM are given in Table 4. The total volume reduction rate at 24 months after RFM was 84.2% (Fig. 2). Of the 24 patients enrolled, 6 underwent hysteroscopic myomectomy at 3 to 6 months after RFM (Figs. 2 and 3). Reoperation was not required in any patients in the study.

No serious or life-threatening complications were noted. Postoperative pain was reported by 8 patients (33.3%), but it resolved within 4 hours with use of analgesics. Mild postoperative vaginal spotting was noted in all patients, lasting 3 to 7 days. Increased vaginal discharge was noted in 5 patients (27.7%) after RFM.

Discussion

Since it was first described in 1976, hysteroscopic myomectomy has been used as the standard treatment for submucosal myomas [9]. This technique enables painless and rapid recovery and improves patient quality of life [10]. The total volume and that of the intramural portion of the submucosal myoma are the primary limiting factors for hysteroscopic resection. Many studies have reported that hysteroscopic myomectomy is not suitable for treatment of myomas larger than 5 to 6 cm [11–15]. Similarly, the success and symptom improvement rates are limited by myoma size. Fernandez et al [16] reported a symptom improvement rate of 94% for myomas <3 cm but a rate of 77% for those 3 to 5 cm, and a rate of 44% for those >5 cm. Camanni et al [17] suggested that patients with myomas >5 cm or with a Lasmar score >7 were likely to require a 2-step procedure and that recovery time was significantly longer in patients with myomas >6 cm vs those with myomas <6 cm.

In our previous study, the volume reduction rate at 18 months after RFM was 95.5% in Lasmar group I,

Table 3

Patient characteristics and changes in symptom severity and HRQoL scores before and after treatment at 12 months of huge, deep intramural submucosal myoma (relevant to Lamar group III)[a]

			Symptom severity score		HRQoL score	
No. of myomas	Patient age, yr	Parity	Baseline	12 months	Baseline	12 months
18	40.1 (6.75)	1.3 (1.0)	75.9 (9.1)	11.6 (4.4)[b]	46.1 (12.8)	90.2 (8.9)[b]

HRQoL = Health-Related Quality of Life questionnaire.
[a] Values are given as mean (SD).
[b] p = <.05 compared with baseline.

Table 4

Initial volume and volume reduction rate after RFM[a]

		Post-RFM volume, cm^3					
		Months after RFM					
No. of myomas	Initial volume, cm^3	3	6	12	18	24	Volume reduction rate, %
18	112.37 (52.9)	62.3 (20.8)	57.8 (18.8)	54.4 (20.5)	14.1 (19.4)	17.6 (13.2)	84.2

RFM = radiofrequency myolysis.
[a] Unless otherwise indicated, values are given as mean (SD).

85.6% in group II, and 91.1% in group III [7], and these rates at 24 months after operation in the present study were similar: 84.3% for group III submucosal myomas (only group III myomas were included in this study). The overall symptom improvement rates were also satisfactory. Symptom severity scores and HRQoL scores were greatly improved at 12 months after RFM (Table 3). Collectively, the results suggest that RFM is effective for treating submucosal myomas, in particular large myomas with deep intramural positioning.

Coagulation of myoma cells and feeding vessels with RFM ensures bloodless, rapid, and effective hysteroscopic myomectomy. The most important complications of hysteroscopic myomectomy are uterine perforation and intravasation of the distention medium. Uterine perforation may occur during cervical dilation and hysteroscopic insertion, and in particular during intramyometrial tissue resection [18]. Studies have demonstrated that fluid intravasation is affected by intramural extension of the myoma [19], duration of surgery [20], myoma size [21], and total inflow volume [20]. In the present study, the myomas exhibited a pale bloodless surface and low Doppler signals on ultrasound examination after RFM. These changes brought about by RFM guarantee less bleeding during subsequent hysteroscopic myomectomy.

Previously reported complications of RFM for treatment of submucosal myomas include pain ($\leq$2 hours, 75.5%; 2–24 hours, 21.1%; 1–7 days, 3.4%), vaginal spotting ($\leq$2 weeks, 29.3%; 2–4 weeks, 65.5%; 4–8 weeks, 5.1%), and increased vaginal discharge (4 weeks, 75%; 4–6 weeks, 16%; 8 weeks, 8%) [7]. However, these complications are minor, not life-threatening, and easily controlled with medication. In the present study no serious complications were observed, such as penetration and/or burn injuries of the

Fig. 2

Changes in Lasmar grade III myoma volume after radiofrequency myolysis. **(A** and **B)** Preoperative images show a Lasmar grade III submucosal myoma (5.6 × 5.1 cm). Arrowhead indicates the endometrial lining. **(C)** After 3 months, the myoma volume has decreased (4.5 × 3.8 cm). **(D)** A further decrease in myoma volume is observed after 12 months (3.4 × 2.3 cm).

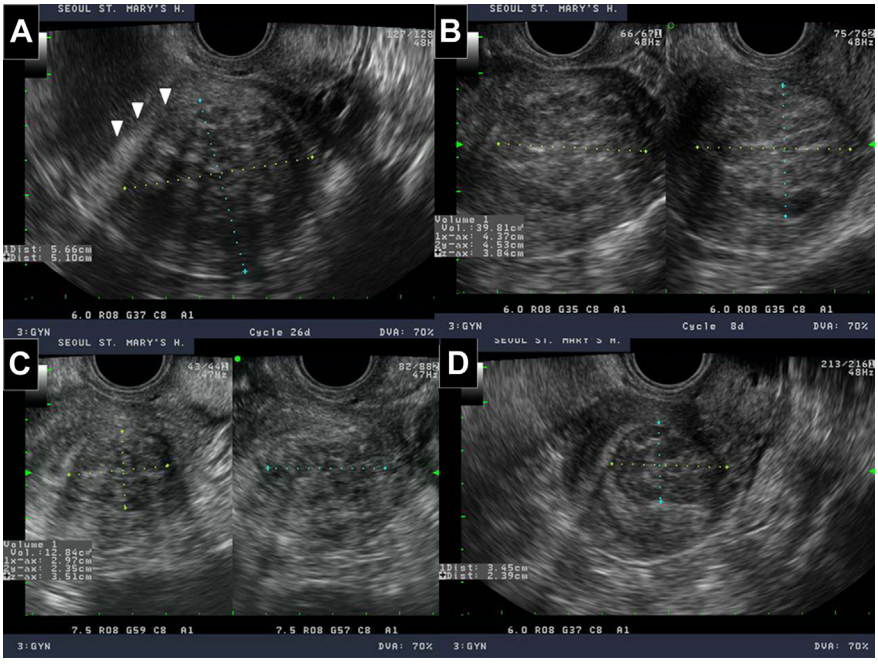
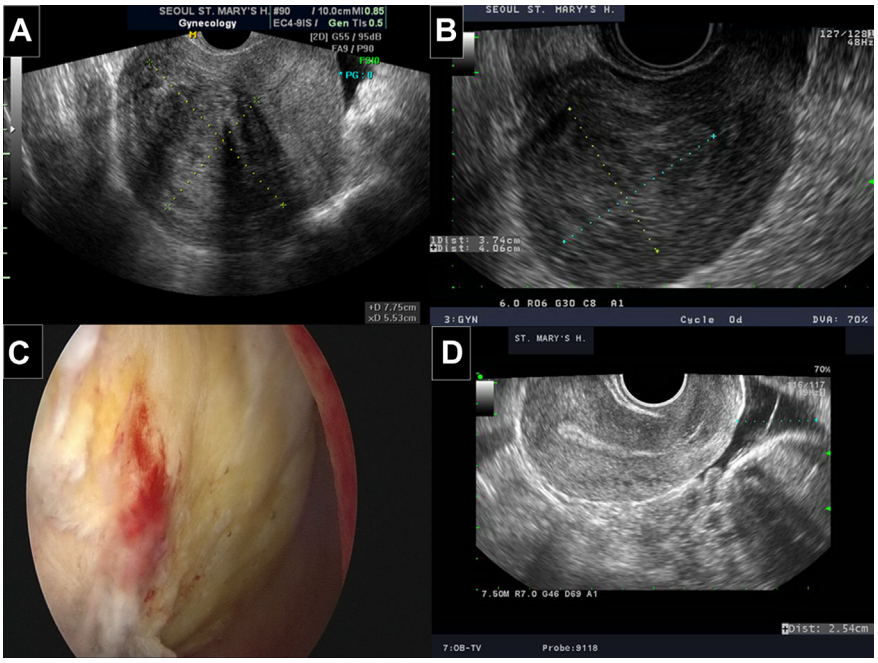


Fig. 3

Delayed hysteroscopic myomectomy after radiofrequency myolysis. **(A)** Preoperative image shows a Lamar grade III submucosal myoma (7.7 × 5.5 cm). **(B)** After 3 months, myoma volume has decreased (3.7 × 4.0 cm). **(C)** Hysteroscopic resection was performed, and the surface of the myoma was found to be pale, white, and bloodless. **(D)** Postoperative uterus.



bowel or bladder, infection, sepsis, shock, embolism, and peritonitis.

Limitations of the present study include its retrospective design and small sample size. In addition, we did not examine the effects of the treatment procedure on fertility.

In conclusion, transvaginal RFM is a promising treatment for submucosal myomas, in particular large myomas (>5 cm), with a substantial intramural portion. Furthermore, combined with RFM, hysteroscopy seems to be safe and effective in all patients with submucosal myoma–related symptoms. Neither RFM nor hysteroscopy requires hospitalization. They require only outpatient care and guarantee less pain, few complications, and early recovery.

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