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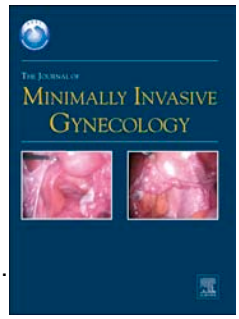

Outpatient multimodality management of large submucosal myomas using transvaginal radiofrequency myolysis

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Outpatient multimodality management of large submucosal myomas using transvaginal radiofrequency myolysis

Running title: Radiofrequency myolysis for submucosal myomas

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Abstract

BACKGROUND: Submucosal myomas are associated with subfertility and infertility, and hysteroscopic myomectomy is the most commonly recommended treatment for these tumors. However, large submucosal leiomyomas with deep intramural positioning cannot be treated by this method. In the present retrospective observational study, we report our experience with a group of patients who underwent transvaginal radiofrequency myolysis (RFM) with or without combined hysteroscopy for large submucosal leiomyomas with a substantial intramural portion, with an emphasis on the safety and efficacy of this procedure in the outpatient department.

METHODS: Twenty-four patients with for large submucosal leiomyomas with a substantial intramural portion were enrolled to undergo stepwise RFM treatment. Additional hysteroscopic myomectomy was performed in 6 patients at 3–6 months after the RFM. Myoma volumes were measured by three-dimensional ultrasonography before RFM and 1, 3, 6, 12, 24 months postoperatively. Symptoms severity was assessed using the Uterine Fibroids Symptom and Quality of Life Questionnaire and health-related quality of life (HRQoL) questionnaire.

RESULTS: The total volume reduction rate 24 months postoperatively was 84.2%. Symptom severity and HRQoL scores showed significant improvements 12 months after RFM.

CONCLUSIONS: Radiofrequency myolysis with or without hysteroscopy is an effective treatment modality for patients with large myomas with deep intramural positioning, and it seems safe for all patients with submucosal myoma-related symptoms.

Key words: submucosal myoma, radiofrequency myolysis, hysteroscopy

Introduction

Uterine myomas, generically known as fibroids, are the most common benign gynecologic tumors found in women of reproductive age, reportedly occurring in 20–40% of this population [1][2]. Almost 50% of fibroids 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 two classes of leiomyomas, namely, subserosal and intramural [4].

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

Lasmar e*t al* [6] 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 instead of hysteroscopic myomectomy for patients with high scores for submucosal leiomyomas, in order to preserve the uterus [6].

Since 2004, we have performed transvaginal radiofrequency myolysis (RFM) for premenopausal, post-childbearing patients with symptomatic submucosal leiomyoma who wanted to preserve their uteri. RFM has several advantages: It does not require admission care and is associated with low postoperative bleeding and pain, and patients may rapidly resume daily activities within a few hours of RFM. Further, 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 combined hysteroscopy for large submucosal leiomyomas with deep intramural positioning, with an emphasis on the safety and efficacy of this procedure in the outpatient department.

Patients 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 Lasmar *et al.*'s system) [6] were enrolled in this study. The exclusion criteria were as follows: opting out of RFM, any abnormalities detected in cancer screening tests, abnormal coagulation test results, current pregnancy, recent pelvic/endometrial inflammatory disease, and a positive chlamydia/gonorrhea PCR test.

Multimodality steps

The 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 conducted after RFM in the same operation field, and delayed hysteroscopic myomectomy refers to hysteroscopic myomectomy conducted 3–6 months after RFM. RFM was initially performed in all patients in the present study. After 3 months, patients were re-evaluated and hysteroscopic myomectomy was performed if the myoma size was reduced to <5 cm.

Ethics

All patients were counseled extensively on the potential risks and benefits of the procedure and possible alternative surgical treatments. The study protocol was approved by the Ethics and Research Committee of the Catholic University of Korea.

Study procedures and data collection

The pre- and postoperative myoma volume was measured using three-dimensional ultrasonography with the VOCAL 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. The RFM procedure and equipment were as described previously [7].

The patients' subjective myoma-related symptoms were assessed using the Uterine Fibroid Symptom and Quality of Life questionnaire (UFS-QOL) [8]at the initial visit and 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.

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

Statistical analysis

Statistical analysis was performed using the χ^2 test with Excel (2007).

Results

A total of 24 patients were enrolled in this study. Table 3 shows patient characteristics and changes in symptom severity and the UFS-QOL and HRQoL scores after RFM. All these parameters were significantly improved at 12 months after RFM over the baseline scores.

The initial leiomyoma volumes before RFM are shown in Table 4. The total volume reduction rate at 24 months after RFM was 84.2% (Figure 2). Of the 24 patients enrolled, 6 underwent hysteroscopic myomectomy 3–6 months after RFM (Figures 2 and 3). Reoperation was not required in any patients in this study.

No serious or life-threatening complications were noted. Postoperative pain was reported by 33.3% patients (n = 8), but it resolved within 4 h with use of analgesics. Mild postoperative vaginal spotting was noted in all cases and it lasted 3–7 days. Further, increased vaginal discharge was noted in 27.7% patients (n = 5) 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 the patients' quality of life [10]. The total size and size 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 myomas larger than 5–6 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 smaller than 3 cm but a rate of 77% for those sized 3–5 cm and a rate of 44% for those larger than 5 cm. Further, Camanni *et al*.

[17]suggested that patients with myomas larger than 5 cm or with a Lasmar score >7 were likely to require a two-step procedure and that patients with myomas larger than 6 cm needed a significantly longer recovery time than those with myomas smaller than 6 cm.

In our previous study, the volume reduction rate 18 months after RFM was found to be 95.5% in Lasmar group I, 85.6% in group II, and 91.1% in group III [7], and these rates 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 12 months after RFM (Table 3). Collectively, the results suggest that RFM is effective for treating submucosal myomas, especially 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 distension media. The former may occur during cervical dilatation and hysteroscopic insertion and occurs especially during intramyometrial tissue resection [18]. Further, studies have shown that fluid intravasation is affected by intramural extension of the myoma [19], duration of operation [20], myoma size [21], and total inflow volume [20]. In the present study, the myomas showed 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 submucosal myomas include pain (within 2 h, 75.5%; 2–24 h, 21.1%; 1–7 days, 3.4%), vaginal spotting (within 2 weeks, 29.3%; 2–4 weeks, 65.5%; 4–8 weeks, 5.1%), and increased vaginal discharge (lasting for 4 weeks, 75%; 4–6 weeks, 16%; 8 weeks, 8%) [7]. However, these complications are minor, non-life-threatening, and easily controlled with medication. In the present study as well, no serious complications were observed, such as penetration and/or burn injuries of the bowel or bladder, infection, sepsis, shock, embolism, and peritonitis.

Our study does have some limitations, namely, its retrospective design and small sample size. Additionally, we did not examine the effects of the treatment procedure on patient fertility.

In sum, transvaginal RFM is a promising treatment modality for patients with submucosal myomas, especially large myomas (>5 cm) with a substantial intramural portion. Further, combined with RFM, hysteroscopy appears to be safe and effective for 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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Figure legends

Figure 1. Treatment design and steps used in this study.

Figure 2. Changes in the size of a Lasmar grade III myoma after RFM.

A, B. Preoperative images showing a Lasmar grade III submucosal myoma (5.6 × 5.1 cm). The white arrowhead indicates the endometrial lining. C. After 3 months, the myoma size had decreased (4.5 × 3.8 cm). D. A further decrease in size was seen after 12 months (3.4 × 2.3 cm).

Figure 3. Delayed hysteroscopic myomectomy after RFM.

A. Preoperative image showing a Lamar gradeIII submucosal myoma (7.7 × 5.5 cm). B. After 3 months, the myoma size had decreased (3.7 × 4.0 cm). C. Hysteroscopic resection was performed, and the surface of the fibroid was found to be pale, white, and bloodless. D. Postoperative uterus.

Table I. Submucosal scoring system by Lasmar et al. [6]

Points	**Depth of penetration**	**Size**	**Width of base**	**Location in the uterus**
0	0	≤2 cm	≤1/3	Lower third
1	≤50%	2–5 cm	>1/3 to 2/3	Middle third
2	>50%	>5 cm	>2/3	Upper third

When the fibroid was located in a lateral wall, 1 point was added to the total score.

Table Ⅱ. Comparison of treatment methods for submucosal myomas suggested by Lasmar et al.[6] and the RFM multimodality outpatient treatment used in this report.

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 two-stage surgery	● RFM ● RFM with p/d Hysteroscopy
7–9	Ⅲ	Alternative non-hysteroscopic technique	● RFM ● RFM with delayed hysteroscopy

RFM: radiofrequency myolysis

p/d: prompt or delayed

GnRH: gonadotropin-releasing hormone

Table III. Patient characteristics and changes of symptom severity and HRQoL scores before and after treatment 12 months of huge, deep intramural positioning submucosal myoma (relevant to Lamar group III).

	Age (years)	Parity (number)	Symptom severity scores		HRQoL score	
			Baseline	12 months	Baseline	12 months
Myomas (n=18)	40.1 ± 6.75	1.3 ± 1.0	75.9 ± 9.1	11.6 ± 4.4†	46.1 ± 12.8	90.2 ± 8.9†

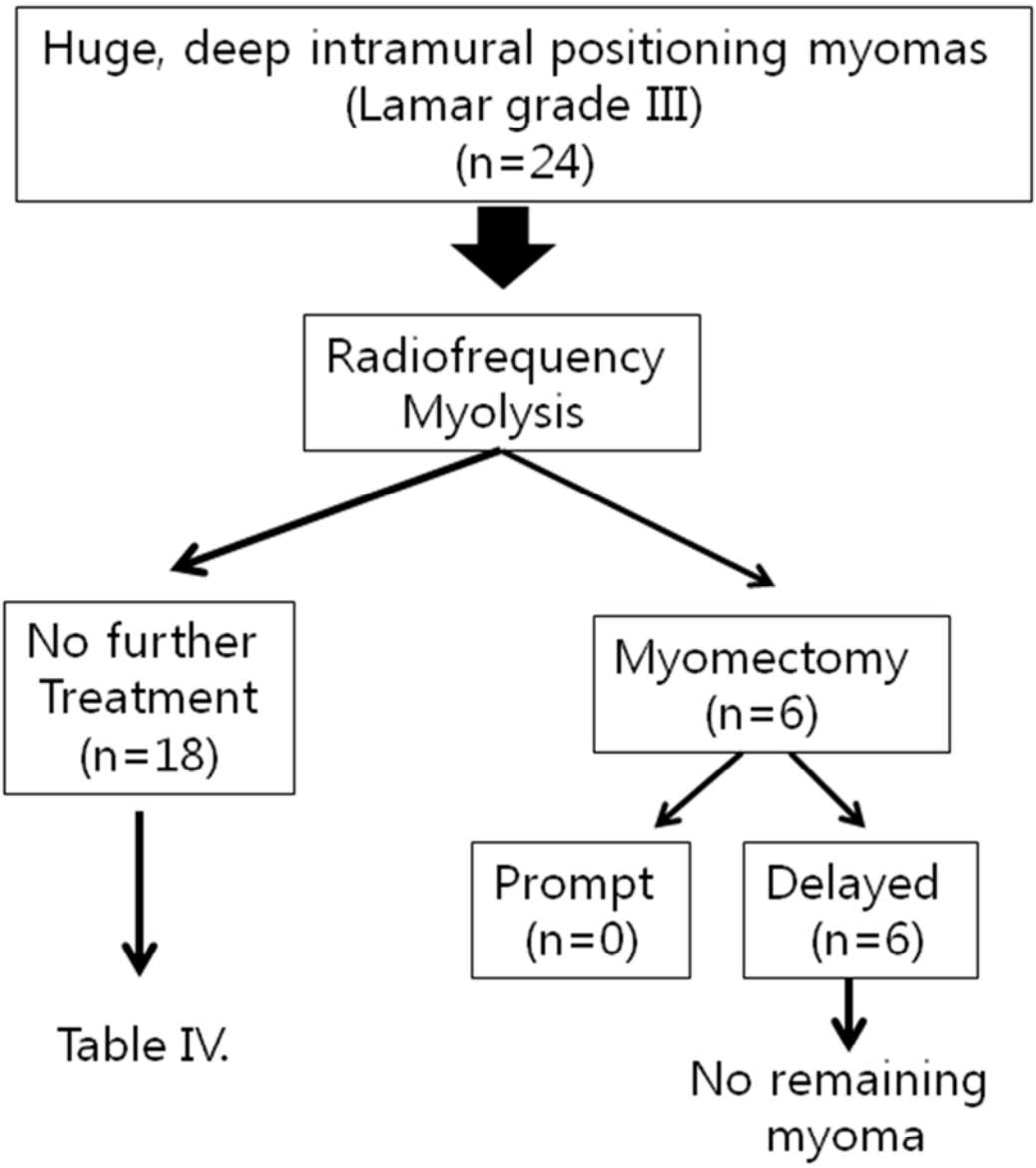
† *P*-valuen < 0.05 compared to the baseline

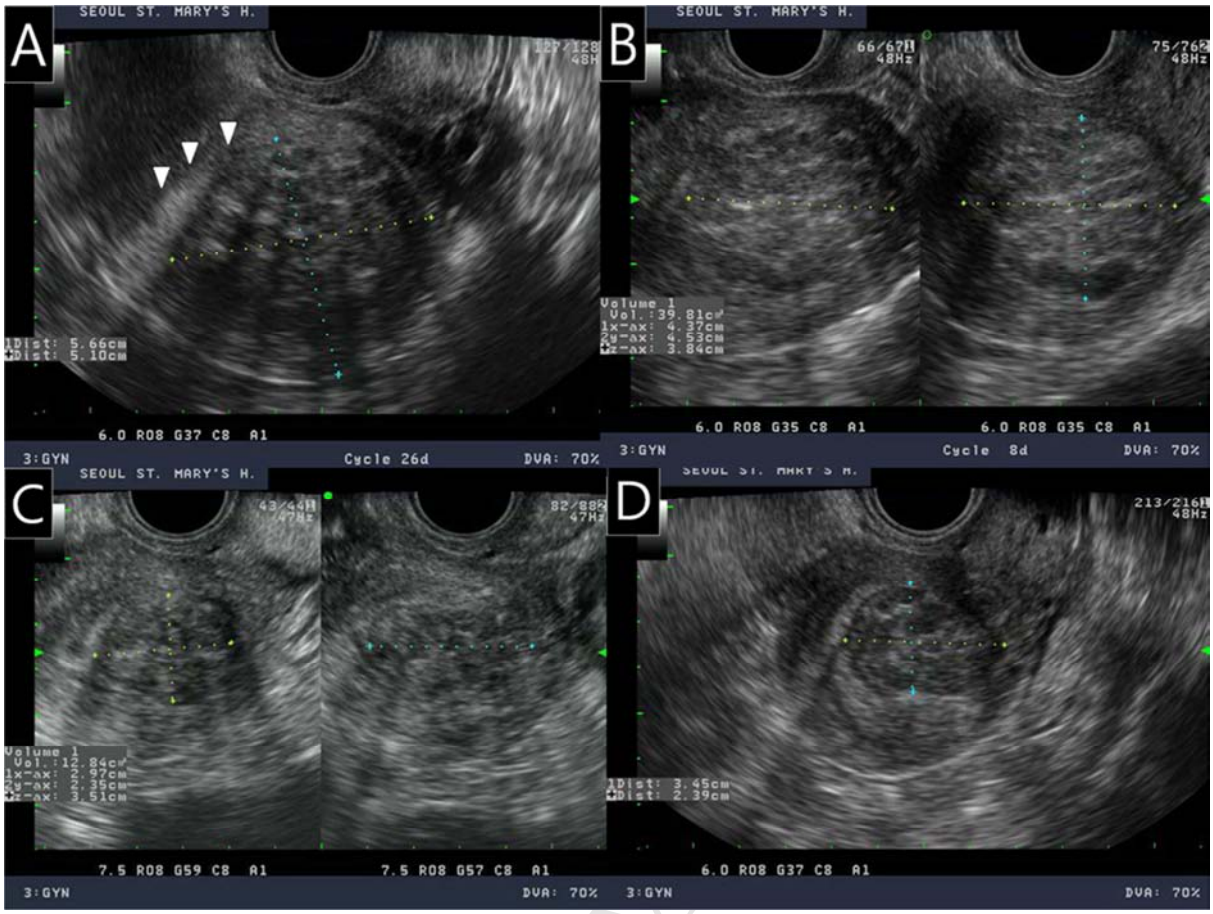
RFM: radiofrequency myolysis

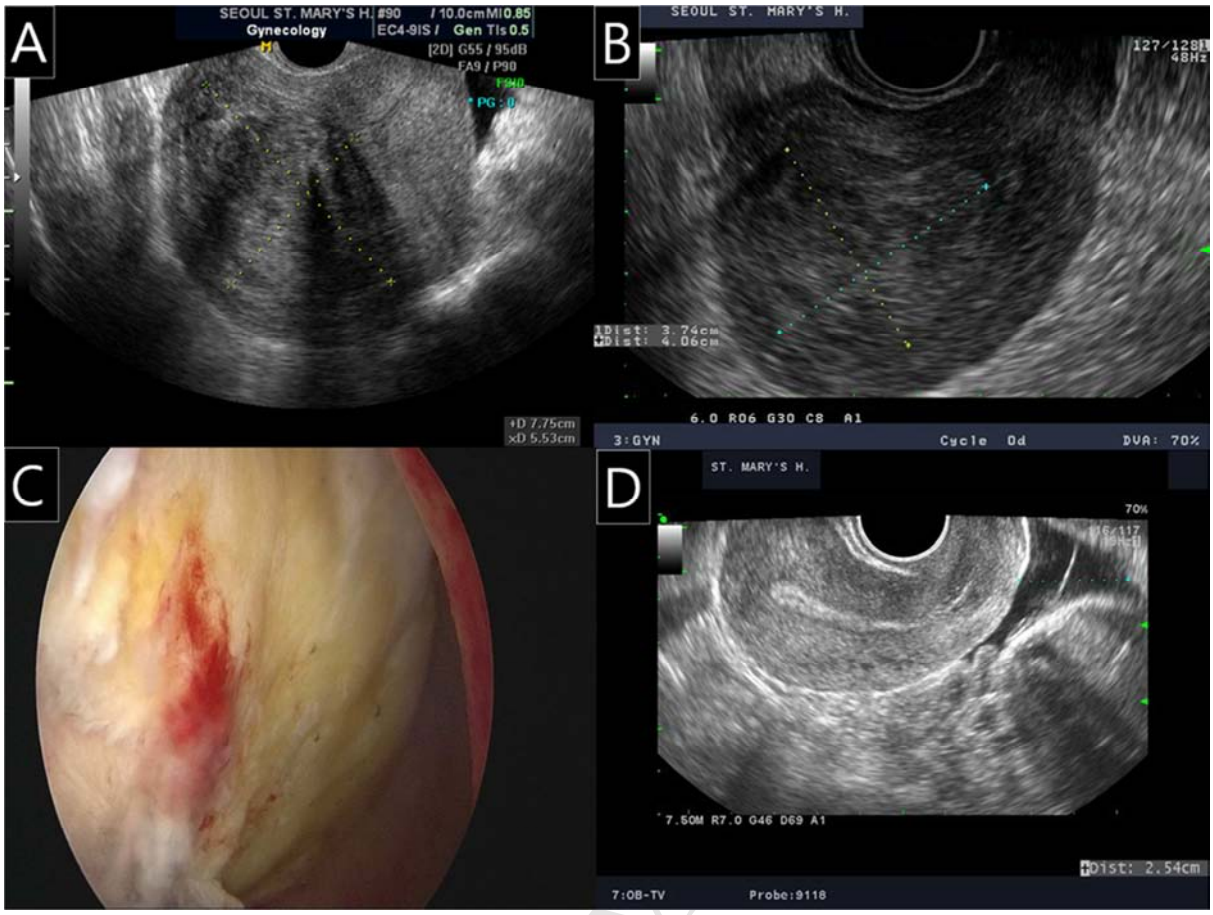
HRQoL: Health-Related Quality of Life

Table IV. Initial volume and volume reduction rate after RFM.

	Initial volume (cm^3)	Post RFM volume (cm^3)					Volume reduction rate (%)
		3 (m)	6 (m)	12 (m)	18 (m)	24 (m)	
Myomas (n=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


Huge, deep intramural positioning myomas
(Lamar grade III)
(n=24)
Radiofrequency
Myolysis
No further
Treatment
(n=18)
Myomectomy
(n=6)
Prompt
(n=0)
Delayed
(n=6)
Table IV.
No remaining
myoma





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Précis

With radiofrequency myolysis, large symptomatic submucosal myomas with deep intramural positioning can be treated in outpatient's department effectively.