Original Article

Transvaginal radiofrequency thermal ablation: A day-care approach to symptomatic uterine myomas

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Background: In patients with myoma, the traditional surgical treatment of choice is myomectomy for women who wish to retain their uterus. However, myomectomy must be performed under general anaesthesia, and the patient requires a long time to recover.

Aims: In the present study, we report our experience with a group of patients who underwent transvaginal radiofrequency (RF) thermal ablation of uterine myomas, with emphasis on the safety and efficacy of this procedure.

Methods: Premenopausal women with symptomatic uterine myoma or recently growing myoma were included in this study. The pre- and postoperative myoma volumes were measured by 3D ultrasonography. The impact of the symptoms on health-related quality of life (HRQL) was assessed using the Uterine Fibroids Symptom and Quality of Life questionnaire.

Results: The mean initial size of the dominant myoma was 5.3 cm (standard deviation ± 1.58). The reoperation rate was 4.3%. The final reduction rate of the volume of the dominant fibroid was 73%. The symptom scores and HRQL scores showed great improvement after 18 months of myolysis.

Conclusions: The results of this study suggest that RF ablation may represent a safe, well-tolerated, and effective day-care alternative to conventional surgery for the treatment of uterine myomas.

Key words: coagulation, quality of life, radiofrequency, uterine myoma.

Introduction

Uterine fibroids are the most common pelvic tumours in women of reproductive age.[1,2] In women who wish to retain their uterus in order to remain fertile or for other reasons, the traditional surgical treatment of choice is transabdominal or laparoscopic myomectomy. However, myomectomy must be performed under general anaesthesia, and the patient usually has to remain hospitalised and requires several days to recover.

Myolysis – an alternative to the conservative surgical treatment of uterine fibroids – was introduced in the late 1980s in Europe.[3] A variety of energy sources have been used in myolysis, including the neodymium:yttrium aluminum garnet (Nd:YAG) laser,[4,5] bipolar electrode,[6,7] diathermy,[8] cryoprobe,[9] etc. These conventional myolysis methods are performed under general anaesthesia by laparoscopy.

We have performed transvaginal radiofrequency (RF) myolysis since 2004. In the present prospective observational study, we report our experience with a group of patients undergoing transvaginal RF thermal ablation of uterine myomas with emphasis on the safety and efficacy of this procedure.

Methods

From October 2004 to March 2006, premenopausal women with symptomatic uterine myoma or recently growing myoma were included in this study. All patients had completed child bearing and declined hysterectomy or myomectomy. The exclusion criteria were as follows: previous treatment with gonadotropin-releasing hormone agonists, more than three uterine fibroids, presence of any abnormalities in cancer screening tests, abnormal coagulation tests, current

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pregnancy, recent pelvic/endometrial inflammatory disease, and a positive *Chlamydia*/gonorrhoea polymerase chain reaction (PCR) test. The size of the myoma was not considered as an exclusion criterion.

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

The pre- and postoperative myoma volumes were measured by 3D ultrasonography. Sonographic evaluation was repeated at one, three, six, nine, 12 and 18 postoperative months. When more than one myoma was treated in a single patient, the characteristics of only the dominant and largest myoma were considered for statistical analysis, even though RF myolysis was applied to all the myomas. In order to minimise interpersonal variation, the ultrasonograms were assessed by a single trained gynaecologist. Patients were followed up for postoperative complications such as vaginal bleeding, abdominal pain, fever/febrile sense, increased vaginal discharge, and dyspnoea at every visit for routine follow-up ultrasonograms. At 18 postoperative months, the patients were questioned on their satisfaction regarding RF myolysis. The impact of the symptoms on health-related quality of life (HRQL) was assessed at the first and the last follow-up visits by using the Uterine Fibroids Symptom and Quality of Life (UFS-QOL) questionnaire.[10] This questionnaire contains 37 questions about symptoms and impacts of uterine fibroid.

Scores from UFS-QOL are calculated as two; one is symptom severity score and the other is HRQL score. Symptom score is calculated from the scores of questions number 1–8 (higher scores indicate greater symptom severity or bother and lower scores indicate minimal symptom severity). HRQL score consists of six subscales and HRQL total score. Six subscales are as follows; concern, activities, energy/mood, control, self-conscious and sexual function. Scores of these subscales are created form the special formula with the scores of UFS-QOL questions number 9–37. Higher scores are indicative of better HRQL.

Equipment

The RF delivery system (RF Medical System, M-1004) consisted of an RF generator that operates at 400 KHz with a maximum power of 120 W and at temperatures ranging from 40°C to 99°C.

The generator displays the temperature of the needle tip, tissue impedance characteristics, and procedure time. The system is connected through a needle to a 25-cm long 18-gauge needle with an exposed tip at the distal end. The needle for RF myolysis was straight firm type with a sharp end.

Procedure

RF ablation of uterine myomas was performed under intravenous anesthesia with propofol sodium. Propofol was administered intravenously by a single bolus dose (2 mg/kg) and then injected continuously (5 mg/(kg·h)) via an infusion pump. The patients inhaled 8 L/min oxygen through a mask and were monitored using a pulse oximeter.

The patients were in the lithotomy position. Preoperative intravenous antibiotics, skin preparation and enema were not performed. To confirm the pathology, needle biopsy was performed at the centre of the myoma under ultrasonographic guidance before myolysis.

The RF needle was transvaginally inserted through the cervical canal. Under ultrasonographic guidance, the tip of the needle was centralised in the leiomyoma. Ultrasonography was performed transabdominally or transrectally. If centralisation appeared to be difficult because of poor location of the myoma, puncture of Douglas pouch or vesicouterine fold was performed under sonographic guidance.

After the centralisation of the needle, ablation was performed. The temperature of the needle tip was 85°C, and the generator automatically adjusted the power to maintain the selected temperature. During ablation, the myoma was monitored by ultrasonography, and the duration of ablation was determined based on the increased echogenicity of the myoma. The progression of ablation was considered to be good if a postechogenic shadow was observed. The myoma exhibited high echogenicity during ablation, and ablation was stopped when the area of high echogenicity reached up to 90% of the leiomyoma cut area. Increased echogenicity disappeared in 20 min after ablation. The complete ablation of a 3-cm-large myoma usually takes five minutes, while that of an approximately 5-cm-large myoma takes almost ten minutes. Multiple overlapping ablation cycles were performed for fibroids with a mean diameter of greater than 5 cm.

After the operation, the patients were monitored for two hours. A routine intramuscular injection of 75 mg diclofenac sodium was used to control pain. The postoperative medication regimen was as follows: 100 mg b.i.d. aceclofenac and 250 mg t.i.d. cefaclor monohydrate for seven days. If the patients did not demonstrate any abnormal findings (unstable vital

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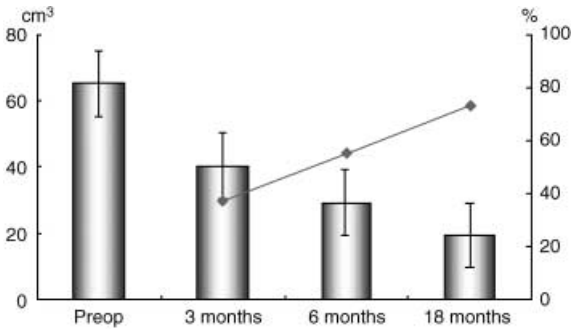

Figure 1 Reduction rate and volume of fibroid. The mean preoperative volume of the fibroids was 65.12 cm^3, and it decreased to 19.3 cm^3 at 18 postoperative months. The final reduction rate after 18 months was 73%. (▬) Volume of fibroid, and (—◆—) reduction rate.

signs, increased temperature, severe abdominal pain and profuse vaginal bleeding) within two hours postoperation, they were discharged and permitted to resume daily activities.

Statistical analysis

The reduction rate was calculated as follows: (initial volume – final volume) × 100/initial volume. Statistical differences were determined using Student's *t*-tests and ANOVA multiple comparison. Statistical significance was set at $P < 0.05$.

Results

During the study period, 153 patients underwent RF ablation of uterine fibroids; of these 153 patients, 14 were excluded from the study during the follow-up period. These 14 patients did not visit hospital on the appointment day because of regional limitations or other unknown reasons. The mean age of the patients was 43 years (standard deviation (SD), ± 3.6), and the mean parity was 1.6 (SD, ± 0.64). Preoperative chief complaints included menorrhagia (43.1%), dysmenorrhoea (5.0%), pelvic pain (6.4%) and mixed symptoms (22.3%).

The mean initial size of the dominant myoma was 5.3 cm (SD, ± 1.58). The operative time ranged from ten to 40 min. No intraoperative complications occurred during the RF procedure. Only one patient requested admission after the operation because of pain, and most of the patients were discharged two hours after the operation and were allowed to resume their daily activities. Almost all of the procedures were via transcervical route (92.9%), and in ten cases (7.1%), puncture of Douglas or vesicouterine fold was performed.

Reoperation after myolysis was performed in six cases (4.3%). The types of operations were as follows: re-myolysis (one case), total hysterectomy (two cases) and myomectomy (three cases). The reoperations were performed within six months in four cases, at nine months (one case) and at 16 months (one case) after the myolysis. The final reduction rate of the volume of the dominant fibroid was 73% (Fig. 1). The reoperated cases were not included in the calculation of the final reduction rate. The symptom scores and HRQL scores showed great improvement at 18 postoperative months (Table 1). Women with myomas of more than 75 cm^3 showed higher reoperation rates and low satisfaction (Fig. 2). Their symptom scores and HRQL scores demonstrated considerably less improvement than those of the other patients (Table 1). The level of satisfaction of patients at 18 postoperative months was as follows:

Table 1 Symptom scores and health-related quality of life (HRQL) scores (mean ± standard deviation) at baseline and at 18 months after operation

	Symptom score		HRQL score	
† (cm^3)	Baseline	18 months	Baseline	18 months
≤ 25	40.8 ± 9.8	2.1 ± 1.7★	68.7 ± 13.7	98.4 ± 5.6★
≤ 50	45.2 ± 7.7	2.8 ± 4.1★	64.2 ± 19.8	99.4 ± 4.2★
≤ 75	46.9 ± 7.8	4.2 ± 3.9★	66.9 ± 20.2	97.7 ± 3.7★
≤ 100	53.3 ± 12.2	30.7 ± 5.9★	54.2 ± 8.7	67.2 ± 9.8
> 100	59.7 ± 14.8	43.7 ± 6.7	41.9 ± 6.4	60.3 ± 9.6
Total	49.1 ± 11.4	16.7 ± 5.5	59.2 ± 16.2	84.7 ± 11.3

★*P*-value < 0.05 versus the previous assessment.
†Preoperative initial volume of the dominant fibroid.

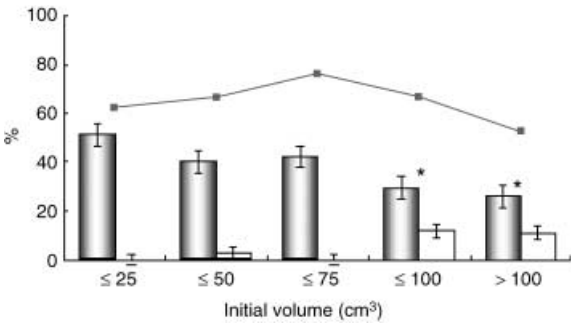

Figure 2 Levels of satisfaction and reduction rate of myoma after myolysis according to the initial volume of the dominant myoma. The levels of satisfaction were significantly low and the reoperation rates were significantly high if the volume of the dominant myoma was greater than 75 cm^3. 'Level of satisfaction' implies the percentage of patients who answered 'very good' regarding satisfaction with radiofrequency ablation at 18 postoperative months. *Implies $P < 0.05$. (▬) Satisfaction rate, (▭) reoperation rate, and (–■–) reduction rate.

'very satisfied', 37%; 'satisfied', 35%; 'not bad', 24%; 'unsatisfied', 4%; and 'very unsatisfied', 0%. These results did not include the reoperated cases.

Complications

Penetration/burn injuries of the bowel or bladder, sepsis and peritonitis were not reported. The distribution of postoperative pain duration was within two hours (62.3%), two to 24 hours (41.8%), and one to seven days (1.7%), and that of postoperative vaginal spotting was two weeks (41.8%), two to four weeks (50.4%) and four to eight weeks (9.6%). Increased vaginal discharge was observed in 14.5% women.

Discussion

Ablation therapy using thermal energy sources such as RF, microwaves, laser and high-intensity focussed sonography has recently received substantial attention as minimally invasive strategies for the treatment of both malignant and benign focal diseases.[11,12]

The possible advantages of ablative therapies over surgical resection include the anticipated reduction in morbidity and mortality, low cost, suitability for real-time imaging guidance and the possibility of performing ablative procedures on outpatients.

Thermal ablation was first introduced in the late 1980s. Thermal myolysis can be proposed as an alternative to myomectomy, which is performed by laparoscopy or laparotomy.[4] The fibroids are not removed but coagulated by using the YAG laser,[5] bipolar coagulation,[7] cryoprobe,[9] monopolar coagulation[8] or diode laser.[3] Myoma coagulation is followed by necrosis, resulting in a dramatic decrease in the size of the myoma. Nisolle reported that the Nd:YAG laser decreased the myoma size by approximately 50%, and no regrowth occurred after 12 months. Since the publication of this report, some studies have reported leiomyoma shrinkage by 30–50%.[7,13,14] Our study showed 73% shrinkage rate at 18 months after coagulation and the level of satisfaction of patients showed that about 72% of the patients were 'very satisfied' or 'satisfied'. But reoperated cases were not included in the final reduction rate and level of satisfaction, so it could be overestimated.

The shrinkage rate after 12 months was 72% (data not shown), and we think that the shrinkage of the coagulated myoma stops at 12 months after myolysis. These results show numerical superiority to thermomyolysis (50% reduction after six months)[7,13] and cryomyolysis (50% reduction after six months[14,15] and 62% reduction after 12 months)[16] with no statistical evidence. RF myolysis was performed without general anaesthesia and laparoscopic additional procedures, which is not possible in the case of thermomyolysis and cryomyolysis. Hence, with regard to cost-effectiveness, RF myolysis has more economic benefits of outpatient surgery, rapid recovery and resuming of a normal life than the other methods of myolysis. Moreover, the subsequent reoperation rates for recurrence or persistence of symptoms are quite low.

In the present study, reoperation after myolysis was required in six cases (4.3%). Of these, two patients who showed abnormal findings in the cervical cancer screening test underwent total hysterectomy, and two patients underwent myomectomy because of increasing pain due to the enlarging myoma, which showed cystic hyaline degeneration at operation. Among these six patients, the last patient had a submucosal myoma with size greater than 8 cm. This patient underwent transvaginal myomectomy at two months after myolysis because of uncontrolled bleeding. The myoma showed secondary degeneration and was easily dissected on hysteroscopy. The stalk of the myoma was coagulated, and the patient recovered rapidly.

In one patient, who underwent re-myolysis after 16 months, a new myoma that developed 12 months after the first myolysis was observed. This patient underwent re-myolysis because the newly developed myoma had grown rapidly.

It remains unclear whether RF myolysis is safe for women who wish to bear children. Some published data have clearly demonstrated that viable pregnancies are possible after laparoscopic myolysis.[7,8] However, coagulation of the normal myometrium or endometrium

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and devascularisation of these tissues could affect fertility, pregnancy, or both. Moreover, there is a possibility of uterine rupture because of the scarred myometrium.[17,18] Therefore, it is important to carefully select patients for myolysis. Patients older than 40 years or who do not want to bear children and have symptomatic myomas under 75 cm^3 but wish to preserve the uterus are suitable candidates for this procedure.

If the dominant symptomatic myoma measured more than 75 cm^3, the patient satisfaction decreased, and the quality of life scores did not improve. If the volume of the myoma was more than 100 cm^3, the patient's symptoms persisted and did not improve after myolysis. Uterine fibroids are very common tumours and may not require treatment if the myomata are asymptomatic. Therefore, symptomatic improvements and increased quality of life after treatment are very important for patients because sometimes, these are the only reasons for opting for treatment. If the satisfaction after RF coagulation is significantly low in patients with a specific-sized myoma, it would be better to recommend myomectomy for preserving the uterus and improving symptoms.

The UFS-QOL questionnaire demonstrated an excellent discriminative validity in distinguishing not only normal subjects from leiomyomata patients but also patients with varying self-rated and physician-rated symptom severities.[10] Women with leiomyomata exhibited significant decrements in HRQL scores, particularly when experiencing severe symptoms. The UFS-QOL questionnaire is a useful tool for detecting the symptom severity and HRQL score among patients with uterine leiomyomata. In our study, patients who had myomas measuring less than 75 cm^3 showed considerable improvements in symptoms and quality of life scores after myolysis. This result implies that RF myolysis could be one of the choices for patients with symptomatic myomas after child bearing who want to improve their quality of life and preserve the uterus.

To adequately destroy a tumour, the entire lesion must be subjected to cytotoxic temperature. Heat deposition is the greatest around the tip of the probe, while less heat is deposited at locations deeper in the tissues. This variation in heat concentration is caused by both a rapid falloff of energy from the applicator and poor heat conduction in the tissue. Heat conduction through the tissue is limited by tissue boiling and vaporisation. When tissue vaporisation occurs, gas is formed. In RF, gas formation increases tissue impedance that prevents the deposition of the heating current. Increased impedance is the main reason why large fibroids yield poor results. Another reason is the vascular flow. If a large number of vessels are present, perfusion-mediated tissue cooling reduces the extent of coagulation necrosis produced by thermal ablation. Large fibroids require extensive blood flow for survival; therefore, it is difficult to evenly coagulate large fibroids, even through multiple overlapping ablations.

The results of this study suggest that RF ablation may represent a safe, well-tolerated and effective day-care alternative to conventional surgery for the treatment of symptomatic uterine myomas, particularly those that are equal to or less than 75 cm^3.

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