



Contents lists available at ScienceDirect

# European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: [www.elsevier.com/locate/ejogrb](http://www.elsevier.com/locate/ejogrb)

Full length article

## Clinical recurrence of submucosal myoma after a mechanical hysteroscopic myomectomy: Review after 5 years follow up



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### ARTICLE INFO

#### Article history:

Received 20 August 2019

Received in revised form 1 October 2019

Accepted 17 October 2019

#### Keywords:

Hysteroscopic myomectomy  
Submucosal fibroid  
Mechanical morcellation  
Office hysteroscopy  
Clinical recurrence

### ABSTRACT

**Objective:** Evaluation of five years follow up of the clinical recurrence after hysteroscopic myomectomies with MyoSure<sup>®</sup> morcellator in our district.

**Study design:** Premenopausal patients from April 2013 to October 2018, with symptoms of abnormal uterine bleeding, and/or infertility, and sonographic suspicion of submucosal myoma, confirmed by diagnostic hysteroscopy prior to myomectomy were included in the prospective, not randomized cohort study (N = 320). All patients had a follow up visit between three to six months post procedure. Further follow up was established by chart review. The information was extracted from the medical records. Patient characteristics were expressed as mean  $\pm$  SD or median (interquartile range) for continuous data (assumption of normality assessed using the Kolmogorov-Smirnov test). Dependence relationship between presence of corporal myomas and the performance of a major long-term surgery, and between the amount of submucosal myomas and clinical recurrence throughout the 5 years of follow-up were studied were studied by  $\chi^2$ .

**Results:** After one year follow up, no recurrence or symptoms were noted. 53 (16.6%) re-morcellations were performed due to incomplete resection. At the second year, three women who were discharged previously were classified as recurrence (0.9%). There were 99 women remaining to be evaluated (30.90%) in the second year. A percentage estimation of 5–6 recurrences with the 100% of women evaluated. In the third year, only one woman was classified as recurrence (0.3%), with 176 (55%) women not evaluated. At the fourth and fifth year of follow-up, 75% are still awaiting complete of the study five years.

No relationship was observed in the presence of corporal myomas and recurrence throughout the 5 years of follow-up ( $\chi^2 = 0.000$ ,  $p = 0.994$ ). Dependence relationship was observed between the presence of corporal myomas and the performance of a major long-term surgery ( $\chi^2 = 11.757$ ,  $p = .001$ , OR = 3.528). **Conclusion:** In office hysteroscopic mechanical myomectomy with MyoSure<sup>®</sup> morcellator of submucosal fibromas was a highly effective therapy for women, at three years of follow-up. It appears to give satisfactory long-term results with a low recurrence rate and without significant complications.

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### Introduction

Uterine myomas, are benign uterus tumours that could affect up to 80% of reproductive age-women and may cause bleeding, severe pain, and infertility. In U.S. health care system, myomas have been estimated to cost up to \$34.4 billion dollars per year [1]. The most common treatment for uterine myomas is hysterectomy. However, myomectomy is an alternative option with advantages such as less bleeding and preservation of reproductive capacity. A

disadvantage is the potential clinical recurrence associated with this procedure [2,3]. Submucous myomas are more likely to cause abnormal uterine bleeding when compared to subserosal and intramural myomas (FIGO leiomyoma subclassification system). Hysteroscopic myomectomy can be considered as a first-line conservative surgical treatment. This technique allows to remove the myoma and conserve the uterus with minimal complications and fast recovery times [4–6].

On the other hand, this technique could have the disadvantage of myoma recurrence in some cases. Emanuel et al [7] discovered a relationship between uterine size and number of submucosal myomas with clinical recurrence. It was noted that, for patients with a normal-sized uterus and no more than two myomas, the

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probability of avoiding surgery due to recurrence at 5 years was 90.3%. In patients with an enlarged uterus and three or more myomas, the chance of avoiding recurrent surgery at 5 years was only 64.8%, making hysterectomy a reasonable alternative unless fertility was still desired. Furthermore, half of the patients with incomplete resection required surgery for clinical recurrence within 2 years [7,8]. Another factor that has been associated with recurrence and need for re-opening was the degree of intramural penetration of submucosal myomas [9]. It was noted that incomplete excision was more likely if the intramural penetration was greater than 50%. Newer techniques have allowed minimal invasive procedures in office [10–13]. The advantages observed with equipment such as MyoSure [14,15] include myomectomies without the need for cervical dilation, general anesthesia, and the use of monopolar/bipolar energy. Studies have found that these advantages can represent an important step in improving perioperative outcomes, patient satisfaction and reduce public health costs [10,11].

Our objective was to evaluate the clinical recurrence of submucosal myomas in our community, after performing the hysteroscopic myomectomy with MyoSure<sup>®</sup>, and to study the characteristics associated with clinical recurrence after five years of follow-up.

## Methods

### Study approval

The bases of the study were reviewed and approved by our hospital in 2013. Patients signed and informed written consent in this prospective long term follow up

## Patients and methods

We completed a prospective study of all patients who underwent a hysteroscopic myomectomy at the Hospital Juan Ramón Jiménez in Huelva (Spain), a tertiary university hospital, from April 2013 to October 2018. 320 patients with one or more submucosal myomas during diagnostic hysteroscopy were treated with mechanical resection with Myosure<sup>®</sup> morcellator. All myomas were diagnosed by hysteroscopy and confirmed by pathological study. Indications for hysteroscopic myomectomy included abnormal uterine bleeding (AUB) and/or infertility. Patient selection was performed by the presence of submucosal myomas during ultrasound evaluation and confirmed with hysteroscopy (Fig. 1). The number, types and size of myomas were all considered.

The information extracted from the medical records included age, parity, number and type of submucosal myomas, extension of the base, concomitant intramural myomas, and preoperative medical preparation.

### Surgical technique

All submucosal myomas type 0,1,2 were resected, only those larger than 5 cm were excluded. GnRH agonists and ulipristal acetate (UAP) [16] were used. Small myomas were treated with desogestrel for preoperative endometrial preparation. Preoperative endometrial preparation facilitates the resection with a better hysteroscopic vision. Treatment of submucosal myomas with intramural penetration is more difficult and resection is more likely to be incomplete in one step [8,17]. In case of incomplete resection, a re-morcellation (new resection procedure) was offered three months later. All

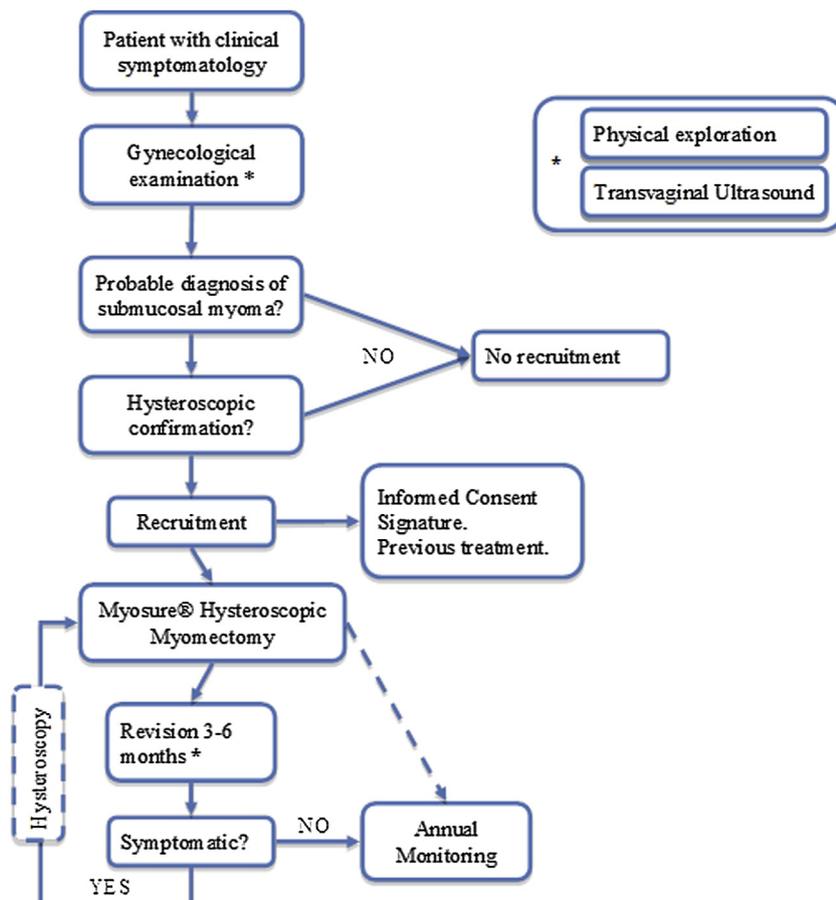


Fig. 1. Flow chart.

resections were performed by several hysteroscopy surgeons. The procedures were performed by two hysteroscopists with high level skills. All myomectomies were performed under oral sedation with Diazepam 5 mg and Misoprostol 200 µg sublingual 10 min before surgery to facilitate cervical maturation and paracervical anesthesia [18,19]. Patients were instructed to take an oral analgesic before the procedure. We used a 6.25 mm hysteroscope specific to the MyoSure® device. No patient received prophylactic antibiotics. The continuous infusion of isotonic saline solution with a pressure between 80 and 90 mmHg was used for uterine distension and intrauterine pressure control was performed by pumps [20,21] The surgical time did not exceed 30 min. All resected samples were sent separately for histological examination. All procedures were performed in office and patients were discharged at the end. All patients completed an ad-hoc satisfaction survey of the procedure before hospital discharge. There were no complications related to surgery or clinical follow up. All patients had a follow up visit three to six months after the procedure. Patients were cited in the hysteroscopy consultation. The clinical evolution of the patients throughout the study time was measured in the gynecological medical record of each patient when they will attend their annual gynecological review in a follow-up consultation. Clinical recurrence was established if patient had recurrent abnormal uterine bleeding and if the myoma was observed by ultrasound or hysteroscopy. Then, patients underwent a new myomectomy or hysterectomy was needed

### Statistical analysis

All analyses were performed using SPSS software (Version 24, IBM) for a two-sided Type I error of =5%. Patient characteristics were expressed as mean ± SD or median (interquartile range) for continuous data (assumption of normality assessed using the Kolmogorov-Smirnov test) Numbers and associated clinical recurrence rates were investigated for individual characteristics including: mean age, previous treatment with different drugs, type of submucosal myomas, size of myomas, existence of more submucosal myomas, and the existence of associated intramural myomas (Table 1).

## Results

### Patient characteristics

The average age of the patients at the time of surgery was 43 years old (± 6), 100% premenopausal, 90.6% (N = 290) had AUB, and

9.4% (N = 30) had infertility factors. The percentage of nulliparous patients was 35% (N = 112). The total of patients who received preoperative treatment was 89.7% (N = 287), of which 4.1% (N = 13) were GnRH agonists, 45.9% (N = 147) with UAP and 39.7% (N = 127) with oral contraceptives, mainly desogestrel (34.4%, N = 110).

In total, 353 myomas were resected in 320 patients (rate of 1.1 per patient), where 87.2% (N = 279) of the patients had a single submucosal myomas, 8.8% (N = 28) 2 submucosal myomas, and 1.9% (N = 6) 3 submucosal fibroid. Patients who did not have associated body myomas were 71.8% (N = 229). A re-morcellation was required in 16.6% (N = 53) of the patients.

The FIGO classification was used to characterized submucosal myomas; in the case of more than one myoma, the myoma of greater hysteroscopic complexity was classified, and the size was calculated as the total sum of all myomas. The results of the FIGO classification and the average sizes according to it, can be observed in the Table 2, with the average size of submucosal myomas being 24.6 mm (±11.3). The recurrence is greater depending on the type of myoma (Type 0 was 10.8%, Type1 was 26.2% and Type 3 was 33.3%)

The follow-up was carried out from the moment the first myomectomies were performed up to five years later. In the first postsurgical evaluation 53 (16.6%) re-morcellations were recorded. in second year of follow-up, 3 women who in the previous evaluation period were classified as Recurrence (0.9%), with 99 women remaining (30.9%). In the third year of follow-up, 1 woman was classified as Recurrence (0.3%), who underwent a re-morcellation, evaluating a total of 176 women (55%). The following years, and a breakdown of the years of follow-up, can be seen in Table 3. No dependence relationship was observed in the amount of submucosal myomas and clinical recurrence during the 5 years of follow-up ( $\chi^2 = 6.621$ ,  $p = .085$ ). A relationship was found in the presence of intramural myomas and the performance of a major long-term surgery 5 years of follow-up ( $\chi^2 = 11.757$ ,  $p = .001$ , OR = 3.528). Taking the results of this OR, the risk of performing a hysterectomy in the presence of intramural myomas is greater than when there are no intramural myomas.

### Comment

The main objective of our study was to present the results of hysteroscopic myomectomy with the MyoSure® morcellator in relation to clinical recurrence after a five-year follow-up period in our population. And so, identify those factors that will increase the risk of clinical recurrence after hysteroscopic myomectomy

The majority of patients consulted for AUB and were not older than menopause, a factor that could also have influenced the risk of reducing recurrences and could have been taken as a bias

We were also interested to know if the type of myoma, the number and the associated body myomas were predictive factors of recurrence as mentioned in the literature [2,3,7–9].

We know that the complexity of a myoma is determined by several factors: the location, the extent of the base and the type of myoma. The Wamsteker classification system and other systems such as the STEPW system can be used to determine the probability of successful extraction of submucosal myomas by hysteroscopic myomectomy [9,22,23].

In our study, the recurrence increases according to the complexity of the myoma, the capacity of the hysteroscopist did not influence because all the procedures were performed by two hysteroscopists with high level skills, without existing biases due to the operator's variability

No dependence relationship was observed in the number of submucosal myomas and clinical recurrence during the 5 years of follow-up, but there was a dependency relationship in the

**Table 1**  
Descriptive statistics overall sample.

Age		43 (±6)
Submucosal fibroids Size		24.6 (±11.3)
Hysteroscopy indication	Infertility	30 (9.4%)
	Discharge	6 (20%)
	Remorcellation	12 (40%)
	HRT	12 (40%)
	AUB	290 (90.6%)
Parity	Nulliparous	112 (35%)
	Primiparous	64 (20%)
	Secondiparous	126 (39.4%)
	Multyparous (+2 birth)	18 (5.6%)
Submucosal fibroids Type	FIGO Type 0	130 (40.8%)
	FIGO Type 1	126 (39.5%)
	FIGO Type 2	63 (19.7%)
Frecuency Body Myomas	0	229 (71.8%)
	1	45 (14.1%)
	2	23 (7.2%)
	3	9 (2.8%)
	> 3	13 (4.1%)

**Table 2**  
Myoma type frequency and average size.

Type	Post-Quirurgical	2y Rev.	3y Rev.	4y Rev.	5y Rev.
FIGO 0	40.8% (130)	23.9 (±10,6)			
No evaluated	0.8% (1)	25.4% (33)	46.9% (61)	71.5% (93)	87.7% (114)
Discharged	83.8% (109)	66.9% (87)	49.2% (64)	24.6% (32)	10.8% (14)
HRT	4.6% (6)	5.4% (7)	3.8% (5)	0% (0)	0% (0)
Recurrence	10.8% (14)	2.3% (3)	0% (0)	3.8% (5)	3.8% (5)
FIGO 1	39.5% (126)	23.2 (±10,5)			
No evaluated	0.8% (1)	30.2% (38)	50.8% (64)	71.4% (90)	83.3% (105)
Discharged	69.8% (88)	58.7% (74)	46% (58)	27.8% (35)	16.7% (21)
HRT	3.2% (4)	5.6% (7)	0% (0)	0.8% (1)	0% (0)
Recurrence	26.2% (27)	5.6% (7)	3.2% (4)	0% (0)	0% (0)
FIGO 2	19.7% (63)	28.4 (±13,3)			
No evaluated	1.6% (1)	44.4% (28)	81% (51)	90.5% (57)	98.4% (62)
Discharged	55.6% (35)	39.7% (25)	11.1% (7)	9.5% (6)	1.6% (1)
HRT	9.5% (6)	6.4% (4)	3.2% (1)	0% (0)	0% (0)
Recurrence	33.3% (21)	9.5% (6)	4.8% (3)	0% (0)	0% (0)
Total		24,6 (±11,3)			

**Table 3**  
Overall sample frequencies and percentages.

Postsurgical Evolution	Pending	3 (0.9%)
	Discharged	233 (72.8%)
	Hysterectomy	15 (4.7%)
	Re-Morcellation	53 (16.6%)
	Fertility Clinic	16 (5%)
2 years revision	Pending	99 (30.9%)
	Discharged	187 (58.4%)
	Hysterectomy	11 (3.4%)
	Recurrence	3 (0.9%)
	Fertility Clinic	20 (6.3%)
3 years revision	Pending	176 (55%)
	Discharged	130 (40.6%)
	Hysterectomy	3 (0.9%)
	Recurrence	1 (0.3%)
	Fertility Clinic	10 (3.1%)
4 years revision	Pending	241 (75.3%)
	Discharged	73 (22.8%)
	Hysterectomy	3 (0.9%)
	Recurrence	3 (0.9%)
	Fertility Clinic	0 (0%)
5 years revision	Pending	282 (88.1%)
	Discharged	36 (11.3%)
	Hysterectomy	2 (0.6%)
	Recurrence	0 (0%)
	Fertility Clinic	0 (0%)

presence of intramural myomas and the performance of a long-term major surgery of the 5 years of follow-up. -above.

In our study we wanted to evaluate whether Mechanical morcellation with Myosure [14,15] was safe for the realization of myomectomy as the traditional technique with monopolar or bipolar resector [8,10,17].

Myosure allowed to perform all myomectomies in office [10–13] without the need for cervical dilation, general anesthesia, and the use of monopolar/bipolar energy. This procedure in office reduces public health costs, improves perioperative results and increases patient satisfaction [10,11].

Our clinical practice shows that hysteroscopic myomectomy with MyoSure® of submucosal myomas is an effective long-term therapy for women with AUB and infertility factors. Our study shows satisfactory long-term results with a low complication rate. However, treatment failure may occur after conservative intervention, but as this study showed, the failure rate was low.

A limitation of our study was the need for greater follow up of subjects. It is presumed that the incidence of recurrence increases over time. As more of the patients reach 5 year follow up, more information will be obtained to control recurrence. The present

study showed good results after conservative intervention of submucosal myomas with a low clinical recurrence.

### Declaration of Competing Interest

None.

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