

## Research Report

## Impact on prognosis of unexpected uterine sarcoma with scalpel morcellation or enucleation

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## ABSTRACT

**Objective:** It is well known that power morcellation of unexpected uterine sarcoma affects prognosis. There are few reports on the effects of scalpel morcellation or myomectomy of uterine sarcoma on prognosis, which is not well understood. This study investigated the effect on recurrence and prognosis when tumors of uterine sarcoma undergo scalpel morcellation or myomectomy.

**Methods:** We performed a retrospective, observational study by collecting data from the medical records of patients who were histologically diagnosed with uterine sarcoma at our hospital between 2005 and 2017. All patients with unexpected uterine sarcoma were diagnosed after laparoscopic hysterectomy with scalpel morcellation or myomectomy (abdominal and laparoscopic) for presumed myoma. We evaluated recurrence rate, recurrence site, progression-free survival (PFS), and overall survival (OS).

**Results:** A total of 15 patients were examined in this study. Twelve patients underwent myomectomy (7 patients with open surgery, 5 patients with laparoscopic surgery), and 3 patients underwent total laparoscopic hysterectomy with transvaginal scalpel morcellation. There were 11 cases of recurrence, and the recurrence rate was 78%. The recurrence site was peritoneal dissemination in 10 cases (91%) and lymph node metastasis in 1 case (9%). The median PFS was 32 months [95% confidence interval (CI) = 6.5-NA], and the median OS was 95.5 months [95% CI = 55.8-NA].

**Conclusion:** Power morcellation, scalpel morcellation, and myomectomy may affect recurrence and prognosis. Further studies are needed in the future.

## 1. Introduction

The likelihood of finding sarcoma in patients with a preoperative diagnosis of leiomyomas has been consistently reported in observational studies of 1000 or more patients as approximately 0.2% (Parker, W. H., 1994; Hagemann et al., 2011; Leibsohn et al., 1990; Leung and Terzibachian, 2012; Theben et al., 2013).

A meta-analysis of four observational studies in patients with uterine sarcoma found that morcellation (scalpel or power methods) was associated with a significantly higher recurrence rate and mortality rate than no morcellation (Bogani et al., 2015). It was suggested that the possibility of intra-abdominal recurrence rate was higher in patients who had undergone morcellation compared to other patients, while the extra-abdominal recurrence rate was higher in patients who had not undergone morcellation.

In July 2014, the US Food and Drug Administration (FDA) convened

a public meeting of the Obstetrics and Gynecology Medical Devices Advisory Committee. Based on this meeting and a review of the use of electromechanical morcellation, the FDA issued a warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for the treatment of fibroids [FDA executive summary: Laparoscopic power morcellation during uterine surgery for fibroids, 2014]. However, the FDA's recommendation is for power morcellation. Scalpel morcellation and myomectomy may also affect the prognosis, but there are few reports on them, and their effect on the prognosis is unclear.

This study aimed to investigate the effects on recurrence and prognosis when laparoscopic hysterectomy with scalpel morcellation or myomectomy was performed for unexpected uterine sarcoma.

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## 2. Materials and methods

We performed a retrospective, observational study by collecting data from the medical records of patients who were histologically diagnosed as having uterine sarcoma at the Cancer Institute Hospital of the Japanese Foundation for Cancer Research between 2005 and 2017.

All patients with unexpected uterine sarcoma were diagnosed after myomectomy (abdominal and laparoscopic) or total laparoscopic hysterectomy with transvaginal scalpel morcellation for presumed myoma before being introduced to our hospital. In-bag morcellation was not performed in all patients. All patients who had laparoscopic vaginal hysterectomy underwent scalpel morcellation of the uterus from the vagina. In all cases of laparoscopic-assisted myomectomy, the tumor was removed from the wound by scalpel morcellation. This study and its protocols were approved by the institutional review board at our hospital (2021-GB-037), this board waived the requirement of obtaining informed consent.

We evaluated recurrence rate, recurrence site, progression-free survival (PFS), and overall survival (OS). We collected data from the patients' medical records, including the age, stage, operative surgical procedure, histologic type, presence or absence of postoperative adjuvant therapy, presence or absence of recurrence, prognosis, and follow-up interval.

### 2.1. Statistical analysis

Patient characteristics were presented using descriptive statistics. The data was presented as the median (range). Survival analysis of PFS and OS was performed using the Kaplan-Meier method. PFS and OS were defined from the date of diagnosis until the date of first progression, recurrence, death, or last follow-up. Statistical analyses were performed using the R software package [R Core Team (2019). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>].

## 3. Results

### 3.1. Patients' characteristics

During the 12 years, 15 patients were examined and included in this study. Twelve patients underwent myomectomy (seven patients with open surgery, five with laparoscopic surgery), and three underwent total laparoscopic hysterectomy with transvaginal scalpel morcellation. Eleven patients were histologically diagnosed with leiomyosarcoma (LMS), one patient with undifferentiated endometrial sarcoma (UES), and three patients with low-grade endometrial stromal sarcoma (LG-ESS). Eight patients received postoperative adjuvant chemotherapy, five received a combination therapy of docetaxel and gemcitabine, one was treated with ifosfamide, etoposide, and cisplatin, and two received oral administration of medroxyprogesterone acetate. Table 1 details the characteristics of the study population.

There were 11 cases of recurrence, and the recurrence rate was 78%. The histological types of recurrent cases were LMS in eight cases, ESS in two cases, and UES in one case. The surgical procedure was myomectomy in ten cases and total laparoscopic hysterectomy with transvaginal scalpel morcellation in one case. The recurrence site was peritoneal dissemination in ten cases (91%) and lymph node metastasis in one case (9%) (Table 2).

The median follow-up was 55 months (range: 13–220 months). The median PFS was 32 months (95% confidence interval [CI] = 6.5-NA) (Fig. 1), and the median OS was 95.5 months (95% CI = 55.8-NA) (Fig. 2).

## 4. Discussion

This study investigated the recurrence rate, recurrence site, and

**Table 1**  
Patients' characteristics.

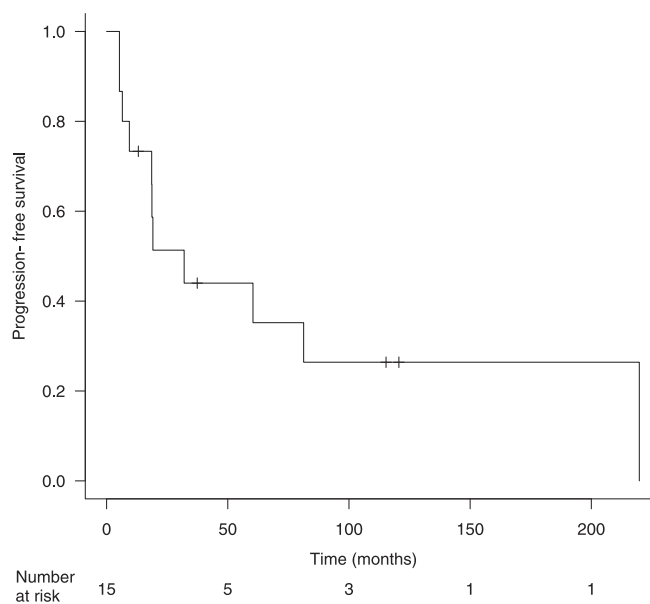
	Patients (n = 15)
Age, median (range)	47 (30–56)
FIGO stage	
I	8
II	5
III	2
Operation procedure	
Myomectomy (open surgery)	7
Myomectomy (laparoscopic surgery)	5
Hysterectomy with transvaginal extraction	3
Pathology	
LMS	11
UES	1
LG-ESS	3
Adjuvant chemotherapy	
DG	5
IEP	1
MPA	2
no chemotherapy	7

LMS: leiomyosarcoma, UES: undifferentiated endometrial sarcoma, LG-ESS: low-grade endometrial stromal sarcoma, DG: docetaxel and gemcitabine, IEP: ifosfamide, etoposide and cisplatin, MPA: medroxyprogesterone acetate.

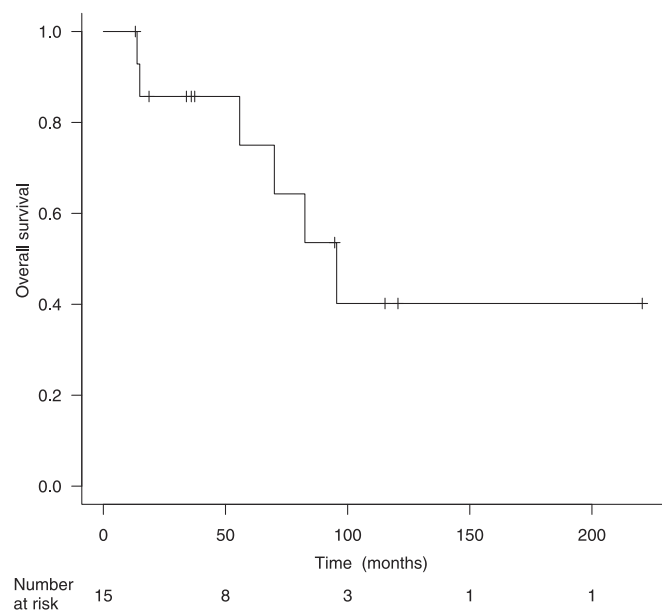
**Table 2**  
Details of recurrence.

	Patients (n = 11)
Pathology	
LMS	8 (73%)
UES	1 (9%)
LG-ESS	2 (18%)
Surgical procedure	
Myomectomy	10 (91%)
Hysterectomy with transvaginal extraction	1 (9%)
Recurrence site	
peritoneal dissemination	10 (91%)
lymph node metastasis	1 (9%)

LMS: leiomyosarcoma, UES: undifferentiated endometrial sarcoma, LG-ESS: low-grade endometrial stromal sarcoma.



**Fig. 1.** Kaplan–Meier analysis of progression-free survival (PFS) in this study. The median PFS was 32 months (95% confidence interval = 6.5-NA).



**Fig. 2.** Kaplan–Meier analysis of overall survival (OS) in this study. The median OS was 95.5 months (95 % confidence interval = 55.8–NA).

prognosis when laparoscopic hysterectomy with scalpel morcellation or myomectomy was performed for unexpected uterine sarcoma. The recurrence rate was as high as 78 %, and peritoneal dissemination was often observed at the recurrence site.

Surgery that requires tumor morcellation includes laparoscopic hysterectomy, laparoscopic myomectomy, and vaginal hysterectomy, and morcellation methods include power morcellation and scalpel morcellation. Even when myomectomy is performed by laparotomy, malignant tumor tissue may be disseminated by surgical operation without morcellation.

In 2014, FDA issued a recommendation restricting the use of power morcellation [FDA executive summary: Laparoscopic power morcellation during uterine surgery for fibroids, 2014]. Even in the 2020 update, the use of a power morcellator is contraindicated in principle, and providing sufficient information to patients when using it is necessary (it may affect the prognosis if it is malignant) [Product Labeling for Laparoscopic Power Morcellators. US Food and Drug Administration, 2020; UPDATED laparoscopic uterine power morcellation in hysterectomy and myomectomy: FDA safety communication, 2020]. Several reports suggest that power morcellation affects prognosis (Bogani et al., 2015; Hartmann et al., 2019). However, only a few reports have examined the prognostic effects of scalpel morcellation of uterine sarcoma.

In a meta-analysis examining the treatment of uterine fibroids, the 5-year survival rates were 30 % (95 % CI, 13–61 %) for power morcellation, 59 % (95 % BCI, 33–84 %) for scalpel morcellation, and 60 % (95 % CI, 24–98 %) for no morcellation (Hartmann et al., 2019).

The meta-analysis based on four observational studies examined the recurrence rate and prognosis by comparing the morcellation group (scalpel or power methods) and the no-morcellation group. The recurrence rate was high in the morcellation group (61 vs 39 %, odds ratio [OR]: 3.16, 95 % CI: 1.38–7.26), and the prognosis was poor (48 vs 29 %, OR: 2.42, 95 % CI: 1.19–4.92). The recurrence site was primarily the intra-abdominal area. Extra-abdominal recurrence tended to occur more frequently in the no-morcellation group (Bogani et al., 2015).

One study included patients who underwent vaginal or laparoscopic-assisted vaginal hysterectomy (n = 1629). Morcellation was performed in 19 percent of patients. Postoperative diagnoses included two sarcomas, three smooth muscle tumors of uncertain malignant potential (STUMP), and eight endometrial carcinomas. Among these, only one STUMP was morcellated. The two patients with sarcomas had no

evidence of disease at 2 and 16 months, respectively, and the STUMP had no evidence of disease (Balgobin et al., 2016).

A study of patients who underwent total hysterectomy for presumed benign leiomyomas who were found to have uterine sarcoma included 18 patients, most of whom had transvaginal scalpel morcellation. Follow-up data at 17 to 54 months were available for 15 patients, all of whom had no evidence of disease (Zhang et al., 2016).

Two reports examined the prognosis of scalpel morcellation and found that scalpel morcellation did not affect prognosis. However, the prognosis of scalpel morcellation is unclear because of problems such as the inclusion of histological types, such as STUMP and endometrial cancer, which are considered to have a relatively good prognosis in previous reports.

Thomassin-Naggara et al. (2013) reported that the use of signal intensity (SI) on diffusion weighted image (DWI), SI on T2-weighted MRI, and the apparent diffusion coefficient (ADC) value in a multivariate model was accurate in classifying benign and malignant tumors in 47 of 51 cases (92.2 %); however, preoperative diagnosis of uterine sarcoma can be difficult.

Recommendations from the FDA and American Congress of Obstetricians and Gynecologists (ACOG) include the following items when planning morcellation: (1) perform an appropriate preoperative evaluation for cervical cancer / uterine body cancer; (2) evaluate risk factors for uterine sarcoma; (3) explain to patients that there is a risk of disseminating tumors by performing morcellation [FDA executive summary: Laparoscopic power morcellation during uterine surgery for fibroids., 2014; ACOG Committee Opinion No. 770: Uterine Morcellation for Presumed Leiomyomas., 2019]. From this study, similar caution may be required for scalpel morcellation and enucleation.

This study has two limitations. It is a retrospective observational study, and all cases were initially treated at another hospital and referred to our hospital after recurrence. The strength of this study is that we examined many cases diagnosed as uterine sarcoma after surgery by myomectomy and scalpel morcellation. In addition, the pathological diagnosis is highly reliable because it was re-diagnosed at our hospital. Clinical information was also examined in detail.

In conclusion, apart from power morcellation, scalpel morcellation and myomectomy may affect recurrence and prognosis. Further studies are needed in the future.

#### Data availability statement

The datasets generated during and analyzed during the current study are available from the corresponding author upon reasonable request.

#### CRediT authorship contribution statement

**Terumi Tanigawa:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing. **Kohei Omatsu:** Methodology, Validation, Writing – review & editing. **Yoichi Aoki:** Data curation. **Atsushi Fusegi:** Writing – review & editing. **Makiko Omi:** Writing – review & editing. **Sachiho Netsu:** Writing – review & editing. **Sanshiro Okamoto:** Validation. **Mayu Yunokawa:** Writing – review & editing. **Hidetaka Nomura:** Writing – review & editing. **Hiroyuki Kanao:** Conceptualization, Writing – review & editing.

#### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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