

## Occult Malignancy Rate of 1498 Hysterectomies or Myomectomies with Morcellation: A Retrospective Single-Arm Study

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### Abstract

**Background and Purpose** Since April 2014, the FDA warns against the use of morcellation during minimally invasive uterine surgery because of the risk of occult malignant spreading in the abdominal cavity. It is clear, however, that more studies are needed to define the incidence of occult uterine cancers, its risk factors, preoperative identification and postoperative follow-up. The present retrospective single-arm study defines the prevalence of occult uterine malignancies in a large group of patients treated with hysterectomy or myomectomy for benign indications.

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**Methods** In the year of 2014, 1498 women admitted for a myomectomy or hysterectomy in benign conditions at the clinic of minimally invasive surgery (Minimal Invasive Chirurgie or MIC) in Berlin (Germany) were included in this study. The morcellated uterine specimens of operated patients were histologically analyzed for the presence of cancerous tissue.

**Results** We detected malignancies in three of the 1498 women (0.2%): two patients had endometrial cancer, while we observed cervical cancer in situ in the third patient. No sarcoma was found.

**Conclusion** We detected a very low prevalence of occult uterine malignancy which is in line with several other recent studies. To define a clear policy on the use of morcellation, more studies are required. In the meantime, patients should be informed about the risks of morcellation in case of undetected cancer prior to surgery.

**Keywords** Morcellation · Laparoscopy · Hysterectomy · Myomectomy · Malignancy

## Introduction

After cesarean section, hysterectomy is the second-most commonly performed procedure in gynecology today. In 70–90% of cases, the indications are benign and most patients are relatively young (between 40 and 49) [1, 2]. These factors make it all more important to continuously optimize hysterectomy techniques in order to decrease (co)morbidity rates, traumatization, formation of intra-abdominal adhesions or scarring and convalescence [2–4]. Since the first laparoscopic hysterectomy in 1989, a shift toward minimally invasive techniques is apparent as they have been proven to be advantageous in the above-mentioned aspects [4–6]. Nowadays, laparoscopic-assisted vaginal hysterectomy (LAVH) and laparoscopic

supracervical hysterectomy (LASH) are the widely applied minimally invasive techniques to remove the uterus or the corpus uteri (in case the cervix can be retained), respectively. Both can make use of a morcellator during laparoscopic preparation after which the tissue can be removed vaginally. As such, even larger uteri can be removed, and an abdominal hysterectomy is rarely required at the MIC clinic, Berlin. At our clinic, morcellation is also applied during laparoscopic myomectomy (LM), while we make use of a resectoscope when performing hysteroscopic myomectomy (HM).

In all cases, there is a potential risk for dissemination of occult uterine malignant cells which can worsen the prognosis. For that reason, the Food and Drug Administration (FDA) issued a statement recently, discouraging the use of power morcellation during hysterectomy or myomectomy in the majority of patients [7]. However, the validity of this claim is being questioned by among others the American Association of Gynecologic Laparoscopists (AAGL) based on the notion that the frequency of occult uterine malignancies remains unclear [8]. According to the US National Cancer Institute, there are 4.4 deaths and 25.1 new cases of endometrial cancer per 100,000 women yearly [9]. Uterine sarcomas are rare and only represent 7–8% of all uterine cancers. Nevertheless, the FDA specifically mentions the risk of occult uterine sarcoma, which they estimate as 0.3% in all women undergoing hysterectomy or myomectomy for the treatment of fibroids, as the main reason for avoiding morcellation. To verify the need for morcellation limitation, its disadvantages in rare instances of postoperative discovery of malignancy versus extra risks and complications of open surgery should be carefully weighed against each other. The aim of this study is to evaluate the prevalence of occult malignancies in women treated with hysterectomies or myomectomies for benign indications at the MIC clinic during the period of 1 year.

## Materials and Methods

### Patient Selection and Exclusion Criteria

From January to December 2014, 1498 patients admitted for a myomectomy or hysterectomy in benign conditions were considered for this study. Retrospectively, we selected our patient group based on matching inclusion and exclusion criteria, and we contacted each of those patients to obtain informed consent before the inclusion of their data in this study.

Patients were referred to our clinic by their general physician or had personally chosen our institute for their procedure. Patients with premalignant or malignant

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findings in the area of the cervix and the corpus uteri were excluded. The main indication (diagnosed in 882 patients) for surgery was the presence of fibroids (uterine leiomyoma) which caused discomforts, bleeding or both. Other indications involved adenomyosis or other benign endometrial abnormalities with or without atypia of which the non-malignant nature was checked preoperatively. As such, all patients were submitted to preoperative vaginal sonographic examination as well as cytological evaluation of the cervical smear test according to Papanicolaou. In two patients, sonographic endometrial abnormalities were detected and a diagnostic hysteroscopy and endometrial curettage were performed before the procedure which revealed no presence of malignancies.

Two hundred and twenty-four patients underwent a laparoscopic and 37 patients a hysteroscopic myomectomy (LM and HM), while 1177 patients were treated with a laparoscopic-assisted supracervical hysterectomy (LASH), and in 60 patients, a laparoscopic-assisted vaginal hysterectomy (LAVH) was performed.

### Surgical Techniques

All surgical techniques are standardized and well established and were performed in the customary manner [10–14]. Morcellation (all cases without containment of in-bag system) was used during LAVH, LASH and LM, while tissue removal during HM was done by a resectoscope. All surgeries were performed by two surgeons.

### Histological Analysis

After the procedure, we performed a histological analysis of the removed tissue in order to reveal or exclude occult uterine malignancies. The material was immediately fixed in 7.5% buffered formaldehyde. After fixation for minimally 24 h, all cores were macroscopically examined by two experienced gynecological pathologists according to color, consistence, necrosis and margins. All suspicious cores were separated. Photograph documentation was done. Cut sections (4–5  $\mu\text{m}$ ) were stained in hematoxylin–eosin in a fully automatic stainer (Symphonie Fa Roche). Microscopy was done using an Olympus BX51. Immunohistochemistry was

obtained by using the Benchmark XT (Fa Roche/Ventana). All sarcoma and diagnoses were re-examined and confirmed in a German pathologic reference center. The key diagnostic microscopic criteria for leiomyosarcoma were proliferative or mitotic activity, nuclear and cytological atypia and findings of geographic necroses. In case of endometrial stromal sarcoma, enrichment of small uniform cells was detected microscopically. Endometrial stromal morphology was still discernible and resembles proliferation phase stroma. Significant atypia or conspicuous pleomorphism was not detectable. In case of endometrial stromal sarcoma, CD10 was found positive during immunohistochemistry. Potential malignant myoma was defined as epithelial leiomyoma larger than 6 cm. Less than 4 mitoses/10 HPF (high power fields) and mild atypia may happen.

### Statistics

Data were analyzed using Windows–Excel (Microsoft Office 2010). Mean values were calculated and shown with standard deviations.

### Results

We evaluated the removed tissue of 1498 patients treated with either hysterectomy or myomectomy during which tissue was fragmented with either a power morcellator (LASH, LAVH, LM) or a resectoscope (HM) for the occurrence of occult malignancies. Patient demographics are listed in Table 1.

All procedures were successful without complications. Table 2 shows the results of postoperative histological analysis.

In total, malignancies were found in three patients only (1/500 or 0.2%). Demographic data of the three women are shown in Table 3. In two patients, endometrial cancer cells were detected. Both received LASH treatment. Histological analysis also detected hyperplasia with atypia in one of the latter two patients. With the third patient, who was treated with LAVH, cervical cancer in situ was documented next to hyperplasia without atypia. No sarcomas or other uterine cancers were detected.

**Table 1** Patient demographics (mean  $\pm$  SD)

	Number of patients	Age	Weight (kg)	Height (m)	BMI
LM	224	38 $\pm$ 8.73	68 $\pm$ 13.29	1.68 $\pm$ 0.07	23.9 $\pm$ 4.481
HM	37	40 $\pm$ 8.50	66 $\pm$ 8.86	1.69 $\pm$ 0.06	23.3 $\pm$ 3.55
LASH	1177	47 $\pm$ 7.21	71 $\pm$ 14.49	1.67 $\pm$ 0.06	25.6 $\pm$ 4.93
LAVH	60	51 $\pm$ 10.02	73 $\pm$ 20.45	1.66 $\pm$ 0.06	26.9 $\pm$ 8.21
All patients	1498	46 $\pm$ 8.33	71 $\pm$ 14.56	1.67 $\pm$ 0.07	25.4 $\pm$ 5.06

**Table 2** Histological uterine findings after HM, LM, LASH or LAVH

	<i>n</i>	%
Uterine malignancies	3	0.20
Endometrial cancer	2	0.13
Cervical cancer in situ	1	0.07
Sarcoma	0	0.00
Benign abnormalities	1480	98.80
Only leiomyoma	888	59.28
Only adenomyosis uteri	306	20.43
Both leiomyoma and adenomyosis uteri	282	18.83
Hyperplasia without atypia	69	4.61
Atypical hyperplasia	4	0.27
Without pathological findings	15	1.00

## Discussion

In the present retrospective single-arm study, we detected a very low number of cases with an occult uterine malignancy in patients treated with morcellation-assisted hysterectomy or myomectomy (three women of the entire group of 1498). What is more, no sarcoma was detected.

The FDA rightfully raised awareness of the risk of morcellation. Indeed, a significant amount of cases of disseminated malignant tissue, months after a performed hysterectomy or myomectomy for benign indications, have been reported [15–21]. Next to remaining undetected for a relative long time, malignant spreading due to morcellation is presumed to complicate postoperative management and worsen the prognosis [22]. The FDA's warning to limit morcellation proceeds from the estimation that approximately one in 350 patients (0.3%) treated with hysterectomy or myomectomy for benign fibroids is found to have unsuspected uterine sarcoma. Yet, these numbers are based on nine studies only, all with a rather low number of patients (mean = 1018; median = 1115) [23]. It is important to consider many scientifically demonstrated advantages of minimally invasive surgery, and to evaluate whether the risks of morcellation outweigh the higher morbidity and mortality rates associated with abdominal or vaginal surgery. A recent study by Harris et al. [24] compared hysterectomy approaches and postoperative complications before and after the FDA warning (April 17, 2014).

In their retrospective study which included 15,372 patients treated with hysterectomy for benign indications, they found that laparoscopic hysterectomies decreased with 4.1%, while vaginal and abdominal hysterectomies increased with 2.4% and 1.7%, respectively. Interestingly, they observed an increase in both major complications not including blood transfusions (from 2.2 to 2.8%) and hospital readmission within 30 days after surgery (from 3.4 to 4.2%) [24]. Before a steady policy is formulated, we and others believe that more studies are required to define a solid estimate of the occult malignancy prevalence as well as its risk factors and preventive measures. After the FDA warning, several studies have appeared already, reporting different numbers and varying concluding opinions. For example, Lieng et al. [25] found uterine leiomyosarcoma (LMS) in 26 of the 4791 women (one in 183 or 0.54%) treated for benign fibroids, while Graebe et al. [26] detected occult cancer in ten of 1370 hysterectomy patients (one in 137 or 0.73%) of which three were LMS (0.2%) and Brown et al. [27] found an occult malignancy rate of 0.4% (three of 778 patients or one in 259). Tan et al. [28] found malignancy in three morcellated specimens of 734 study subjects (one in 245 or 0.41%) of which two were LMS (0.27%). Evaluating a large study population of 10,731 patients treated with LASH and morcellation, Bojahr et al. [29] detected occult malignancy in 14 patients only (one in 767 or 0.13%), two of those had LMS (0.02%). In December 2017, the FDA reaffirmed their advice against the use of power morcellators for the removal of uterine fibroids in most women. Yet, they recognized that several health organizations have reported a lower estimate of risk of spreading occult uterine malignancy, and they are committed to continue to review new relevant data to assure patient safety.

It is clear that morcellation is contraindicated when a tumor is established or suspected. Yet, when assuming no malignancy, preoperative endometrial assessment is still highly recommended, especially when patients display risk factors. Hill et al. [16] found that postmenopausal women are affected significantly more. Other groups noticed a higher risk with increasing age as well [27, 30, 31]. Graebe et al. [26], on the other hand, did not observe a correlation with age, yet a high uterus weight was found to be a predisposing factor. Furthermore, hereditary cancer

**Table 3** Demographic data of patients with occult malignant findings

	Age	Weight (kg)	Height (m)	BMI
Patient 1 detected with endometrial cancer	83	46	1.62	17.5
Patient 2 detected with endometrial cancer	52	90	1.67	32.3
Patient detected with cervical cancer in situ	48	64	1.73	21.4
Mean	61	67	1.67	23.7

syndromes, especially those inducing a higher uterine cancer risk, should be considered [31]. Several morcellation techniques exist; hence, specialists should be trained appropriately in order to minimize specimen disruption and intra-abdominal spread. In this view, it is worth to mention the ongoing development of an in-bag system which may prevent spreading of potential tumorous tissue; however, this technique is still in a preliminary phase [32]. After each procedure, the uterine specimen should be histologically analyzed. Even then, malignancy can be overlooked; hence, radiologists should be informed about a possible malignant spread and its imaging appearance [15, 33].

Based on their results of less recurrence and improved survival, when the uterus is removed en bloc, several study groups discourage the use of uterine morcellation altogether [34–36]. However, their study population is small and results are highly biased [37]. When an informed decision is made to apply morcellation, taking risk factors and preventive measures to exclude occult malignancy into account, it seems that the advantages of facilitating minimally invasive hysterectomy by means of morcellation generally outweigh the risks of spreading occult malignancy [27, 30]. What is more, Pritts et al. [37] could not find proof that morcellation substantially induces tumor upstaging. Moreover, a timely surgical follow-up according to the oncologic guidelines in the unfortunate case of malignant spread does not necessarily worsen the prognosis [29].

## Conclusion

In our study, we observe a very low incidence of occult uterine malignancy (1 in 500 or 0.2%, no sarcoma was found) in the 1498 women treated with hysterectomy or myomectomy for benign indications. Even though, since the FDA made its warning, many groups focused to shed light on a correct estimation of the prevalence of occult uterine cancers as well as on its risk factors and preventive and postoperative measures, it is clear that more large-scale studies and meta-analyses are needed to define a steady policy which clearly states when morcellation is contraindicated and when its benefits outweigh the risks of abdominal or vaginal hysterectomy or myomectomy. At this point, it is imperative to inform patients preoperatively about the rare possibility of an occult malignancy and the associated potential risks of morcellation.

## Compliance with Ethical Standards

**Conflict of interest** Garri Tchartchian, Bernd Bojahr, Sven Becker, Attilio Di Spiezio Sardo, Vasilis Tanos, Hugo Christian Verhoeven, Markus Wallwiener, Rudy L De Wilde declare that they have no conflict of interest.

**Ethical Approval** For the present retrospective study, no ethical approval is required in Germany. Prof. Dr. Rudy L De Wilde, head of the University Clinic of Gynecology in Oldenburg, Germany, approved and supervised the present study from conception through manuscript submission.

**Informed Consent** Retrospectively, we selected our patient group based on matching inclusion and exclusion criteria, and we contacted each of those patients to obtain informed consent before the inclusion of their data in this study.

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