

Proportion of Uterine Malignant Tumors in Patients with Laparoscopic Myomectomy: A National Multicenter Study in China

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Abstract

Background: The Food and Drug Administration recently announced that the use of morcellation may cause fibroids or pelvic dissemination and metastasis of uterine sarcoma; therefore, the use of morcellation is limited in the USA. A large sample study is necessary to assess the proportion of uterine malignant tumors found in patients with laparoscopic myomectomy.

Methods: A national multicenter study was performed in China. From 2002 to 2014, 33,723 cases were retrospectively selected. We

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calculated the prevalence and recorded the clinical characteristics of the patients with malignancy after morcellation application. A total of 62 cases were finally pathologically confirmed as malignant postoperatively. Additionally, the medical records of the 62 patients were analyzed in details.

Results: The proportion of postoperative malignancy after morcellation application was 0.18% (62/33,723) for patients who underwent laparoscopic myomectomy. Nearly 62.9% (39/62) of patients had demonstrated blood flow signals in the uterine fibroids before surgery. And, 23 (37.1%) patients showed rapid growth at the final preoperative ultrasound. With respect to the pathological types, 38 (61.3%) patients had detectable endometrial stromal sarcoma, 13 (21.0%) had detectable uterine leiomyosarcoma, only 3 (3.2%) had detectable carcinosarcoma, and 5 (8.1%) patients with leiomyoma had an undetermined malignant potential.

Conclusions: The proportion of malignancy is low after using morcellation in patients who undergo laparoscopic myomectomy. Patients with fast-growing uterine fibroids and abnormal ultrasonic tumor blood flow should be considered for malignant potential, and morcellation should be avoided.

Key words: Laparoscopic Myomectomy; Morcellation; Sarcoma

INTRODUCTION

It has been nearly 30 years since the development and application of laparoscopic morcellation. Minimally invasive resection of uterine fibroids using power morcellation significantly reduced the intraoperative bleeding, operation time, incidence of postoperative complications, and hospital stay, and it obviated the need for an abdominal incision. Therefore, an increasing number of patients prefer minimally invasive surgery. However, after a literature search of previous studies, the Food and Drug Administration (FDA) announced that the prevalence of unsuspected uterine sarcoma in patients undergoing hysterectomy or myomectomy for a presumed benign leiomyoma was 1 in 352 and the prevalence of an unsuspected uterine leiomyosarcoma was 1 in 498.^[1-9] Furthermore, previous studies reported that power morcellation had a risk of dispersing missed fragments all over the pelvic cavity, which can negatively affect patient prognosis and cause a range of complications.^[10,11] Therefore, more clinical data are needed to reach a convincing clinical decision. In this study, we proposed to obtain the incidence of unsuspected uterine sarcoma in patients who are exposed to a power morcellation during laparoscopic myomectomy for presumed benign leiomyoma using retrospective analysis of a large sample of cases.

METHODS

Ethical approval

All participants signed the informed consent and this study was approved by the Commission for Medical Ethics of Peking Union Medical College Hospital before its initiation.

Population enrollment

The retrospective data of all patients were collected from the Medical Records Home Page from thirty provinces/autonomous regions/municipalities in China and the data were submitted in the form of electronic data to the Clinical Research Institute of Peking University by the hospital information system. The missing data on the hospital stay were calculated from the date of admission to the discharge date. The missing data on the surgery date were recorded using the date after the admission data. According to the International Classification of Diseases (ICD)-10

disease code, the primary diagnosis code is D25 (myoma). Based on the ICD-9-CM-3 encoding operation, the operation code is 68.29 (laparoscopic myomectomy). The missing diagnostic code is supplied by the main diagnosis of the disease code according to ICD-10 coding, while the missing surgery code is supplied by the operation name according to the ICD-9-CM-3 encoding operation. Abnormal code and numeric variables were corrected according to the original record.

Finally, from 2002 to 2014, a total of 33,723 cases were retrospectively selected from thirty tertiary hospitals in thirty provinces/autonomous regions/municipalities in China. The participants were those women who were presumed to suffering from fibroids and underwent laparoscopic myomectomy using electro-mechanical morcellation.

A total of 62 cases were finally pathologically confirmed as malignant postoperatively. In addition, the medical records of the 62 patients were analyzed in detail. Preoperative information included the family history, fibroid age, irregular bleeding history, the diameter, location, blood flow of pseudo-capsule of the largest myoma according to ultrasound, and whether there was excessive growth compared with the previous ultrasound examination. Then, the intraoperative information of the patients such as blood loss; blood transfusion; intraoperative complications; the diameter, number, location, and histological type of the myoma; and the postoperative morbidity were all observed.

Statistical analysis

The statistical analyses were performed with SAS software, version 9.2 (SAS Institute, Cary, North Carolina, USA). Continuous variables were presented as the mean and standard deviation (SD), and categorical variables were presented as the frequencies and percentages.

RESULTS

Population enrollment

From January 2002 to April 2014, a total of 33,723 cases were retrospectively selected from thirty provinces/autonomous regions/municipalities nationwide in China, including 4833 (14.33%) from Beijing, 4385 (13.00%) from Zhejiang, 3981 (11.80%) from Sichuan, 3373 (10.00%) from

Guangdong, 1844 (5.47%) from Henan, 1657 (4.91%) from Shanxi, and 1500 (4.45%) from Fujian. The prevalence of the postoperative pathological diagnosis of malignancy after morcellation application was 0.18% (62/33, 723) in this study.

Clinical characteristics of the malignant participants

Furthermore, more detailed medical records of 62 patients with malignant pathology were described. The mean age of the patients was 41.0 ± 8.1 years, while the premenopausal patients accounted for 91.9% (57/62) and postmenopausal for 8.1% (5/62). Only three patients (4.8%) had a history of previous myomectomy in this study. The mean course of suffering from myoma was 28.9 months. In addition, more than forty patients had a disease course of <12 months (time from suffering from uterine fibroids to having myomectomy). Forty-five patients were with single fibroid, while 17 patients had multiple fibroids. Moreover, the survey of the preoperative ultrasound blood flow signals showed that 62.9% (39/62) of patients had demonstrated blood flow signals in the uterine fibroids before surgery. Furthermore, 23 (37.1%) patients showed rapid growth at the final preoperative ultrasound [Table 1]. The mean operation time for 62 patients was 132.0 ± 75.0 min, and blood loss was 164.9 ± 205.8 ml. The percentage of patients with a single uterine fibroid was 67.7% (42/62), while 32.3% (20/62) had multiple uterine fibroids. The average diameter of the largest fibroid was 6.70 ± 1.96 cm found in the operation. With respect to the pathological types, 38 (61.3%) patients had detectable endometrial stromal sarcoma, 13 (21.0%) had detectable uterine leiomyosarcoma, only 3 (3.2%) had detectable carcinosarcoma, and 5 (8.1%) patients with leiomyoma had an undetermined malignant potential [Table 2]. The average hospital stay was 13.1 ± 7.3 days, and the prevalence of the postoperative morbidity rate was 11.3%.

DISCUSSION

Since 1993, morcellation had been used in gynecological laparoscopic surgery, and most studies suggested that it was a milestone to laparoscopic surgery.^[12] However, the FDA announced in April 2014 that the use of morcellation might cause the spread of uterine fibroids and sarcoma, which might cause a tremendous controversy in the world of obstetrics and gynecology. The announcement came after the results of several studies. While a study recently reported that 28.5% of patients with Stage I uterine leiomyosarcoma and 25% of patients with presumed Stage I smooth muscle tumor of uncertain potential had detectable disseminated intraperitoneal disease at immediate surgical re-exploration, with the rate of lymph node and accessory involvement being 3%.^[13] In addition, some studies found that the fragments of the myoma from morcellation using might form parasitic myoma.^[14,15] Therefore, the application of morcellation has become a controversial issue. Meanwhile, the management dilemma also reminds us of another key issue: malignant cases that occur following morcellation application may be

Table 1: Characteristics of malignant patients before surgery (n = 62)

Characteristics	Results
The course of uterine fibroids* (months), mean \pm SD	28.9 \pm 35.6
Number of the fibroids, n (%)	
Single	45 (72.6)
Multiple	17 (27.4)
Blood flow signals in the uterine fibroids, n (%)	
No	23 (37.1)
Yes	39 (62.9)
Rapid growth at the final preoperative ultrasound, n (%)	
No	39 (62.9)
Yes	23 (37.1)

*Time from suffering from uterine fibroids to having myomectomy. SD: Standard deviation.

Table 2: Characteristics of malignant patients during the surgery (n = 62)

Characteristics	Results
Operation time (min)	
Mean \pm SD	132.0 \pm 75.0
Minimum, maximum	40, 410
Blood loss (ml)	
Mean \pm SD	164.9 \pm 205.8
Minimum, maximum	10, 1000
Blood transfusion, n (%)	
No	59 (95.2)
Yes	3 (4.8)
Location of fibroid, n (%)	
Subserosal	9 (14.5)
Intramural	42 (67.7)
Broad ligament fibroids	4 (6.4)
Others	7 (11.3)
Number of fibroids, n (%)	
Single	42 (67.7)
Multiple	20 (32.3)
Pathological type, n (%)	
Leiomyosarcoma	13 (21.0)
Endometrial stromal sarcoma	38 (61.3)
Uterine sarcoma cancer	2 (3.2)
Uterine smooth muscle tumor uncertain malignant potential	5 (8.1)
Others, n (%)	4 (6.4)

SD: Standard deviation.

missed when using ultrasound scanning confocal and uterine artery embolization to treat uterine fibroids.^[16]

Data of this multicenter study were calculated by combining those from thirty provinces/autonomous regions/municipalities in China. Sixty-two cases were confirmed malignant pathology, and the prevalence of pathological malignant after morcellation application in those patients who were presumed to have uterine fibroids before the operation was 1/544. The proportion is half incidence of that in FDA's statement. As a result, imprudently stopping the use of morcellation is unreasonable. Previous studies have shown that the frequency of the malignant

diagnosis in patients undergoing laparoscopic hysterectomy and myomectomy with presumed benign uterine lesions was 0.22–0.49%.^[1,3,4,9,17] Compared with previous studies, this study reports a lower prevalence which is more credible and meaningful, because of the larger sample size and comprehensive covering of various regions. Although some studies indicated that morcellation application might make missed tissue disperse throughout the peritoneal cavity, which might change the original metastasis and spreading pathways, and make the treatment more difficult.^[18-21] To date, few studies have determined the exact impacts of morcellation use on the prognosis of sarcoma patients. Moreover, it is very difficult to distinguish whether the pelvic, abdominal, or retroperitoneal disseminated lesions are formed from the remaining fragments of uterine fibroids or transferred from the primary tumor. Additionally, although there are only a few options for treating malignant patients, immediate surgical re-explorations are very important for these people. Surgery can detect the pelvic, abdominal, and peritoneal spread after morcellation application and then lay a foundation for further diagnosis and treatment.

Moreover, compared with previous studies, this study obtained different results by detailed analysis of the clinical and pathological data from 62 malignant patients. Previous studies suggested that uterine malignancies were common in women who were approximately 50 years old,^[22] while our study found that, for the total 62 patients, only five were postmenopausal, suggesting that premenopausal women with uterine sarcoma are common. Moreover, a shorter disease course and fast growth compared with the previous ultrasound, which are consistent with the biological behavior of malignant tumors, are detected in patients with malignancy. At the same time, preoperatively, we should pay more attention to the ultrasound blood flow signals in uterine fibroids. Ultrasound blood flow signals can be very helpful to reveal the differences between malignant and benign uterine fibroids before surgery,^[23] but few studies support this result. This study suggests that 62.9% (39/62) of patients undergoing ultrasound before surgery had blood flow signals in the uterine fibroids, suggesting the potential role of ultrasound blood flow signals in preoperative evaluation of the malignant transformation of uterine fibroids. Patients with fast-growing uterine fibroids and abnormal ultrasonic tumor blood flow should be considered to have malignant potential; therefore, we suggest that patients with such characteristics should avoid operations using a morcellation, while other patients should undergo morcellation operations as usual. The histological type of endometrial stromal sarcoma is the most detected one in this study. In addition, most pathologists believe that endometrial stromal sarcoma has a relatively low degree of malignancy compared with other sarcomas. Furthermore, this study analyzed the clinical data of 30,000 cases, which is the largest sample size at present to the best of our knowledge.

Purely from the perspective of avoiding malignant tumors, the FDA's announcement is cautious. However, considering

the health economics and complications, the announcement is not necessarily suitable for all countries. This study included thirty hospitals in the different regions all over China, which offers a good representation of various districts. The sample size of this study is currently the largest one in the world to the best of our knowledge. However, this study is a retrospective one and bias is inevitable. Prospective, randomized controlled studies are warranted to clarify the conclusions presented here.

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Conflicts of interest

There are no conflicts of interest.

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