Retrospective Study of Collection Methods in Laparoscopic Myomectomy

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Introduction: After a FDA recommendation in April 2014, power morcellation (PM) in laparoscopic myomectomy (LM) has become less common. We now collect a myoma using manual morcellation (MM) from a wound in the umbilical region. In this study, we compared the PM and MM methods.
Methods: The subjects were 69 patients who underwent LM from April 2013 to March 2016 using PM (n = 37) or MM (n = 32). With PM, the myoma was collected using a 4-hole 12-mm parallel trocar in the left lower abdomen. Using MM, an EZ ACCESS™ (2-cm skin incision) was placed on the umbilical region, and the myoma was put in a collection purse and guided into the access hole for MM using scissors under direct vision.
Results: None required allogeneic transfusion or a transition to open surgery, and had surgical or post surgical complications. At multiple linear regression analysis, which was adjusted by age, body mass index, and intraoperative blood loss, significant difference was not observed in operation time between the PM and MM groups.
Conclusion: Manual morcellation was found to be a safe method for collection of myoma that prevents scattering of tissues and does not prolong the operation time.

Key words: laparoscopic myomectomy, power morcellation, manual morcellation, myoma, collection

INTRODUCTION

Laparoscopic myomectomy (LM) is a standard uterus-conserving surgical method for patients with uterine myoma [1]. Power morcellation (PM) has commonly been used to remove a myoma from the body cavity, and this method enables easy transabdominal removal even for a huge myoma [2]. However, in April 2014, the US Food and Drug Administration (FDA) recommended [3] that PM should no longer be used due to a concern about dissemination of a malignant tumor in the abdominal cavity, and this has led to a trend away from use of PM. Thus, other collection methods for myoma have attracted attention [4, 5].

Collection methods vary among medical facilities, and include use of the conventional method with PM, morcellation with Cold Knife, transvaginal collection, and in-bag morcellation [4, 5]. After the FDA recommendation [3], we eliminated use of PM, and started to collect myomas in a collection purse using manual morcellation (MM) with Cold Knife from a wound in the umbilical region. In this retrospective study, we compared the surgical results of our new MM method with those obtained using PM.

PATIENTS AND METHODS

The study protocol was approved by the Institutional Review Board of Tokai University, School of Medicine (ref: 18R-225), on December 26, 2018.

The subjects were 106 consecutive patients who underwent LM only between April 2013 and March 2016. A retrospective chart review was performed for all subjects. For removal of myoma, we routinely used PM until April 2014, when the FDA recommendation against use of PM was issued [3]. We started to use MM for myoma tissue removal in May 2014, with occasional use of PM at the discretion of the surgeon. Thus, the period between May and December 2014 was considered as a transitional period, and cases during this period were excluded from the study to avoid selection bias. Therefore, PM cases before the FDA recommendation were compared with MM cases after complete transition to the new method. Among the 106 patients, a case in the PM group was omitted from the analysis due to a mechanical failure of the device during operation. Thus, 37 and 32 patients were included in the PM and MM groups for analysis, respectively. Baseline characteristics and clinical outcomes including age, body mass index (BMI), parity, total number of enucleated myomas, the maximum diameter of enucleated myomas, operation time, intraoperative blood loss, surgical/postsurgical complications, and length of hospital stay were compared between the two groups.

In the surgery, a trocar was positioned after insertion of a Uterine Manipulator™ (Clinical Innovations) and pneumoperitoneum. All surgery was performed by three surgeons including two experienced laparoscopists. For many LM cases, the parallel method is selected because of easy closure for transverse incision of the uterine musculature due to its transversely running blood vessels, although the diamond method is generally used for laparoscopic surgery (Fig. 1A). For

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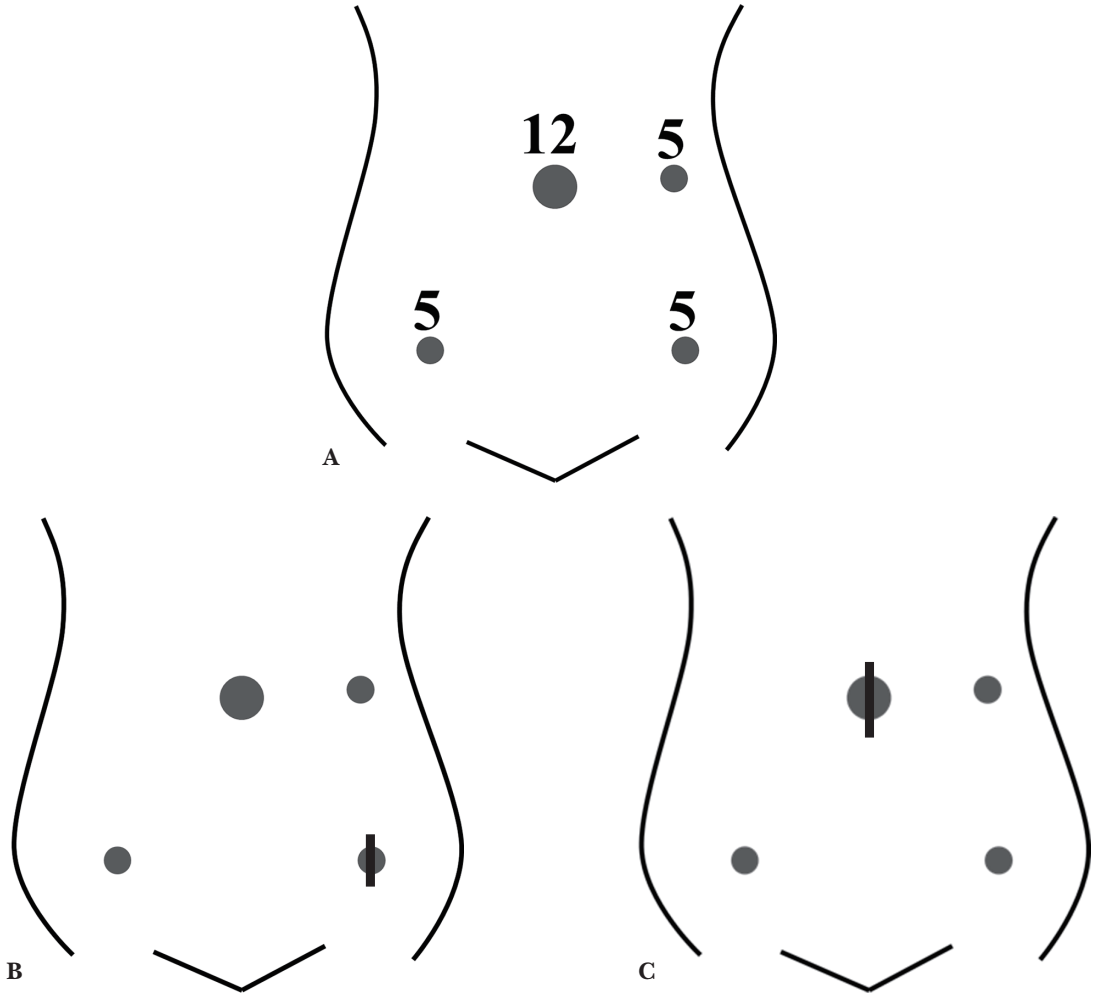

Fig. 1 A: Trocar position. Parallel method: A 12-mm trocar and a 5-mm trocar are used for the umbilical region and other regions, respectively. B: Power morcellation (PM). In PM, the wound in the left lower abdomen is extended to 15 mm for collection. C: Manual morcellation (MM). In MM, collection is performed from a 20-mm wound in the umbilical region.

PM, a 12-mm trocar was used for the umbilical region and a 5-mm trocar was used for the right and left lower abdomen and left upper abdomen. With MM, the umbilical region was sectioned for approx. 20 mm to install EZ ACCESS™ (Hakko Co. Nagano, Japan), and a 5-mm trocar was used for the right and left lower abdomen and left upper abdomen. After local injection of diluted vasopressin (0.2 units/ml) in the uterine musculature to inhibit blood flow to the myoma, the muscular layers were sectioned using Harmonic ACE™ (Ethicon Endosurgery, Japan) and enucleation was performed while holding the myoma with hooked forceps. Continuous suture was performed for 1 to 3 muscle layers depending on the depth, using 1−0 synthetic absorbent suture and 1−0 monofilament suture.

Using PM, the myoma was collected with a 15-mm Morcellator™ (Karl Storz) from the port site in the left lower abdomen. At that time, the skin incision was extended for approx. 15 mm (Fig. 1B). Using MM, collection was performed from the wound in the umbilical region (Fig. 1C). After enucleation of the myoma, it was put in an EZ-purse™ (Hakko) to be guided to the umbilical region. The myoma was held with hooked forceps and cut into small pieces using scissors in the purse for removal from the body (Fig. 2). For cases with a large myoma, preoperative use of a GnRH agonist was considered and autologous blood donation was performed for intraoperative hemorrhage as needed.

Baseline characteristics and clinical outcomes between the PM and MM groups were compared using Mann-Whitney U test. Next, a multiple linear regression analysis was conducted to examine if the two groups were comparable in terms of operation time. Before the analysis, data on operation time were natural-log-transformed to satisfy normal distribution assumptions. The selection of potential confounders was based on clinical experience, previous literature, and the result of univariate analyses. The independent variables included in the multiple regression model were age, BMI, and intraoperative blood loss. Two-tailed P values less than or equal to 0.05 were considered significant. These statistical calculations were performed by JMP (version 13, SAS Institute Japan) and SPSS (version 25, IBM Japan).

RESULTS

The 69 subjects were mostly nulliparous women. Univariate analysis showed statistical significance between the PM and MM groups (Table 1) in age (35 vs. 38 years, $P = 0.014$) and intraoperative blood loss (50 vs. 163 ml, $P = 0.0005$), but not in the operation

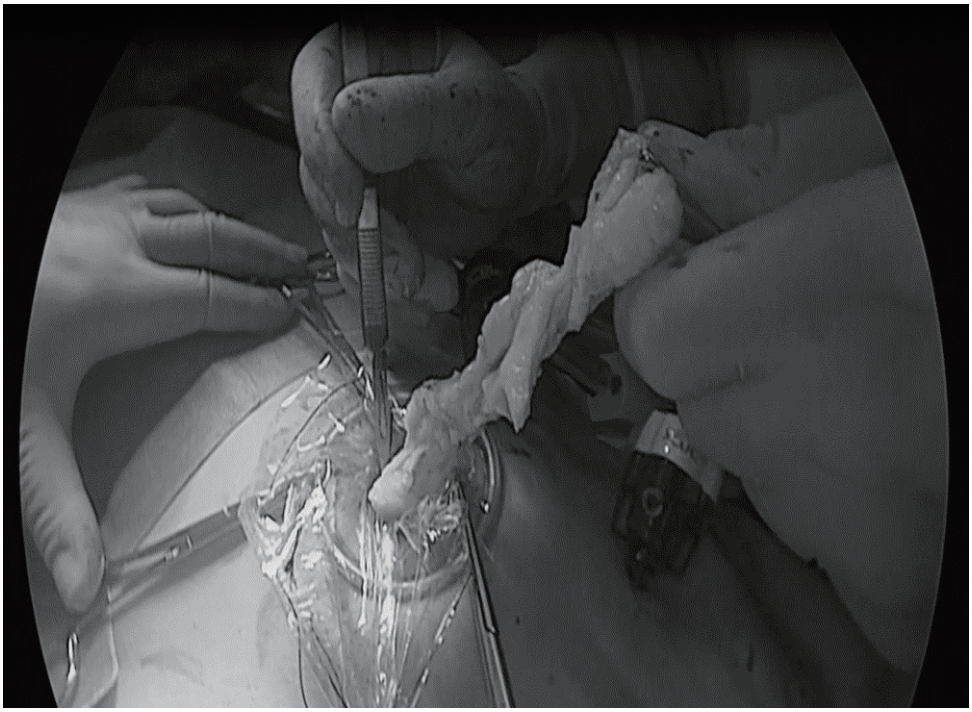

Fig. 2 Manual morcellation (MM) method. The myoma is put in an EZ-purse to be guided to the umbilical region. The myoma is cut into small pieces with scissors while being grasped with a Kocher clamp.

Table 1 Clinical backgrounds of subjects in the power morcellation (April 2013 to April 2014) and manual morcellation (since May 2015) groups.

Item	Power morcellation (n = 37)	Manual morcellation (n = 32)	P-value
Age (years)	35 [32–40]	38 [36–39]	0.014
BMI (kg/m^2)	21.3 [20–23]	22.1 [20–24]	0.63
Parity	0[0–0]	0[0–0]	0.47
0	n = 32	n = 25	
1	n = 4	n = 4	
2 or more	n = 1	n = 3	
Number of myomas	2 [1–4]	2 [1–4]	0.47
Maximum diameter of myomas (cm)	6 [6–7]	7 [5–9]	0.30
Operation time (min)	163 [122–194]	159 [130–212]	0.66
Intraoperative blood loss (ml)	50 [21–153]	163 [90–431]	0.0005
Surgical/postsurgical complications	none	none	
Length of hospital stay (days)	5 [5–5]	5 [5–5]	0.84

Data are shown as median [interquartile range].

time (163 vs. 159 min, $P = 0.66$). Multiple linear regression analysis, which was adjusted by age, BMI, and intraoperative blood loss, also revealed no significant difference in operation time between the PM and MM groups (Table 2).

No subjects required allogeneic transfusion or a transition to open surgery, and none had surgical or post surgical complications, as defined by the Clavien-Dindo classification. All 69 subjects were pathologically diagnosed with leiomyoma, with no cases of malignant tumor.

DISCUSSION

LM consists of 3 steps of removal, repair, and collection. After the FDA recommendation regarding PM, we changed the collection method in the third step from conventional PM to MM, in which the myoma is cut into small pieces in a collection purse. In this study, we found no significant difference in operation time between the methods, which suggests that MM may be an acceptable alternative method that also avoids dissemination of myoma pieces.

Use of LM became common because it is less invasive than open surgery to remove a myoma [1] and is easy to use with PM to cut the myoma into small pieces in the abdominal cavity, which markedly shortens the operation time [2]. PM significantly shortens the steps to remove a myoma from the body [2, 4], but use of an electric morcellator in the abdominal cavity may cause dissemination of myoma pieces. The incidence of

Table 2 Multiple linear regression analysis on factors influencing operation time.

Item	Regression coefficient	95% CI	P-value
Age (years)	0.001	-0.013, 0.016	0.856
BMI (kg/m^2)	0.016	-0.002, 0.035	0.086
Blood loss (ml)	0.001	-0.000, 0.001	< 0.001
Group (PM vs. MM)	0.076	-0.078, 0.230	0.330

parasitic myoma after laparoscopic surgery with PM is 0.12–0.95% [6], with parasitic myomas detected from 2 to 18 years after surgery. Although such parasitic myomas are generally asymptomatic, some cases have pain, hypermenorrhea, and coital pain [7, 8]. Thus, in 2014, the US FDA issued a statement that PM could have a risk of spreading malignant tissues and worsening long-term survival, with a recommendation against use of laparoscopic PM for myomas [3].

Since the FDA recommendation, collection methods that avoid spillage of myoma pieces have attracted attention [4, 5, 9]. However, there are no objective data for the incidence of parasitic myomas for methods such as MM with Cold Knife in a collection purse; in-bag morcellation, in which an electric morcellator is used in a collection purse; and transvaginal collection with culdotomy without using a purse [4, 5, 9]. The in-bag and culdotomy methods are complex techniques [5, 9], and Rimbach *et al.* found that the total operation time was significantly prolonged by 12 min using in-bag morcellation compared to conventional PM [9]. Transvaginal collection with culdotomy is performed in many medical facilities because of reduced wound pain, but is a relatively complicated technique [5]. One problem with MM is that it may be difficult in patients with obesity [4]. In one such case, we found that incision of muscle layers in the umbilical region was required for collection of a myoma. In addition, in our early MM procedures in the transitional period, which were excluded from this study, some cases required more time, but learning of the technique was relatively fast.

Methods with and without use of a morcellator have both advantages and disadvantages. In 78 nulliparous women who underwent LM with an electric morcellator or transvaginal collection with culdotomy, Wang *et al.* [10] found that the time required for collection of a myoma was significantly shorter with an electric morcellator (15 vs. 20 min), and that this method had reduced influence on subsequent sexual activity. Carter *et al.* [11] suggested that use of an electric morcellator required shorter time, but was more costly compared to MM. In a randomized clinical trial in 2016, Venturella *et al.* [4] found no significant difference in collection time, operation time, and intraoperative blood loss between MM in a collection purse and conventional PM without use of a collection purse, similarly to the results in our study.

In laparoscopic surgery, the wound should be minimal for cosmetic reasons. Our change from PM to MM also considered such cosmetic reasons, including the size of the abdominal wound and arrangement of the port. The wound in the umbilical region was extended for cutting and removal of the myoma, which has cosmetic advantages of a hidden wound, compared to a median incision in the lower abdomen [4]. This is because the umbilical region originally has a dent. In most of our cases using MM, the postoperative wound was actually invisible or more difficult to see, compared to the extended small incision in the lower abdomen in the PM method, and the satisfaction level of our patients was high.

We did find a significantly increased intraoperative blood loss using MM compared to PM in this study. However, none of the subjects who underwent MM required allogeneic transfusion, and autologous blood transfusion was sufficient for their treatment. The MM cases also tended to have a heavier myoma, and this might have contributed to the increased blood loss (data not shown). However, this study was performed to compare collection methods after removal of a myoma and suture of the uterine wall. The difference between methods is reflected in the time required, but not by the blood loss. There was no significant difference in operation time between the PM and MM methods in univariate analysis or in multivariate analysis adjusted by age, BMI, and intraoperative blood loss.

In conclusion, the absence of a significant difference in operation time between our new MM method and the conventional PM method, and the avoidance of scatter of tissues using MM, suggest that our new approach is safe and effective. The risk of parasitic myoma and unexpected dissemination of a malignant tumor is very low using the new method, and this is a major advantage of this method.

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