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Research article

Laparoscopic myomectomy without uterine manipulator for maintaining endometrial cavity integrity

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ABSTRACT

Background: Preserving the integrity of the endometrial cavity is crucial, particularly for preserving fertility during laparoscopic myomectomy (LM). This study aimed to compare the uterine breaching rate and clinical outcomes of LM performed with and without a uterine manipulator.
Methods: Data from women who underwent LM at our hospital between January 2020 and June 2023 were retrospectively analyzed. The primary outcomes included endometrial cavity breaching rate, conversion rate, abdominal port count, operative time, hospitalization duration, and blood loss. The secondary outcomes included adverse events such as postoperative anemia and emphysema.
Results: We analyzed the data from 50 participants, comparing those with (n=30) and without (n=20) manipulators. No significant differences were observed in age, body mass index, surgical time, hospitalization, blood loss, or hemoglobin drop. However, the incidence of endometrial cavity breach was higher in the manipulator group (p=0.007). The manipulator group required fewer abdominal ports ($p < 0.001$) than the manipulator group. Increased myoma size was associated with increased blood loss and surgical time.
Conclusions: The clinical outcomes of LM without a uterine manipulator were comparable to those of LM with a manipulator. The absence of a manipulator may aid in preserving the integrity of the endometrial cavity. An increase in myoma size was associated with longer surgical time and greater blood loss, while uterine manipulator use was linked to fewer trocars.

1. Introduction

Uterine myomas, also known as fibroids, are common noncancerous growths of the uterus that often appear during childbearing years [1]. They can vary in size, number, and location within the uterus. While many women may have uterine myomas without experiencing any symptoms, they are prevalent, with estimates suggesting that up to 70–80 % of women may develop fibroids by the age of 50 [2]. Heavy menstrual bleeding (menorrhagia), prolonged menstrual periods, and pelvic pain are common symptoms of uterine myomas [3]. Pelvic discomfort, urinary and bowel symptoms, reproductive problems, and pelvic masses are also experienced by patients with uterine myomas [4].

Myomas can be managed using medical and surgical approaches. Treatment choice depends on several factors, including the

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severity of symptoms, age of patients, desire for future fertility, and size and location of fibroids [5]. Hormonal management of myomas includes gonadotropin-releasing hormone agonists, oral contraceptives, progestins, and selective progesterone receptor modulators [6]. Non-hormonal management of myoma includes non-steroidal anti-inflammatory drugs and tranexamic acid [7].

Women may consider surgical intervention after unsuccessful medical treatments; however, fertility-sparing techniques are an important issue during reproductive years. The surgical management of myomas includes myomectomy, hysterectomy, uterine artery embolization, magnetic resonance-guided focused ultrasound surgery, and endometrial ablation [8]. The trend for surgical management is toward minimally invasive techniques, including laparoscopic surgery.

Laparoscopic myomectomy (LM) is a minimally invasive surgical procedure performed to remove uterine myomas while preserving the uterus [9]. A uterine manipulator is a specialized instrument used to manipulate and stabilize the uterus during laparoscopic procedures [10]. During LM, the uterine manipulator assists in accessing and maneuvering the uterus, allowing for better visualization and access to the fibroids [11]. Maintaining endometrial cavity integrity is critical in LM, especially for preserving fertility [12,13].

Breaching the uterine cavity can occur during gynecological procedures, such as myomectomy. This can lead to several potential consequences, including hemorrhage, infection, adhesion, perforation of adjacent organs, impact on fertility, pain, and the need for additional surgery [12,14,15]. Uterine perforation and bowel perforation are risks in laparoscopic surgeries for benign lesions [15]. Once the uterine cavity is breached, 4-0 monocryl is used to close the breach [12].

This study aimed to compare the uterine breaching rate and clinical outcomes of LM performed with and without a uterine manipulator. The novelty of this manuscript lies in addressing the rarely discussed issue of uterine manipulators causing breaches in the uterine cavity.

2. Materials and methods

2.1. Ethics

All research procedures were approved by the Research Ethics Committee of Hualien Tzu Chi Hospital (permit number: IRB112-238-B). The need for informed consent was waived owing to minimal patient safety risks, with full approval from the Research Ethics Committee of Hualien Tzu Chi Hospital. We adhered to the pertinent guidelines and regulations when executing all methods.

2.2. Inclusion and exclusion criteria

We retrospectively analyzed the data of all Hualien Tzu Chi Hospital patients who underwent LM for "myoma" from January 2020 to June 2023 (ICD10 D25.9). The inclusion criteria were as follows: (i) LM was performed for "myoma"; (ii) vital signs were stable, and surgery could be tolerated; and (iii) pathology report showed "myoma". The exclusion criteria were as follows: (i) preoperative ultrasound showing suggestive uterine malignancy and (ii) pathology report showing uterine malignancy.

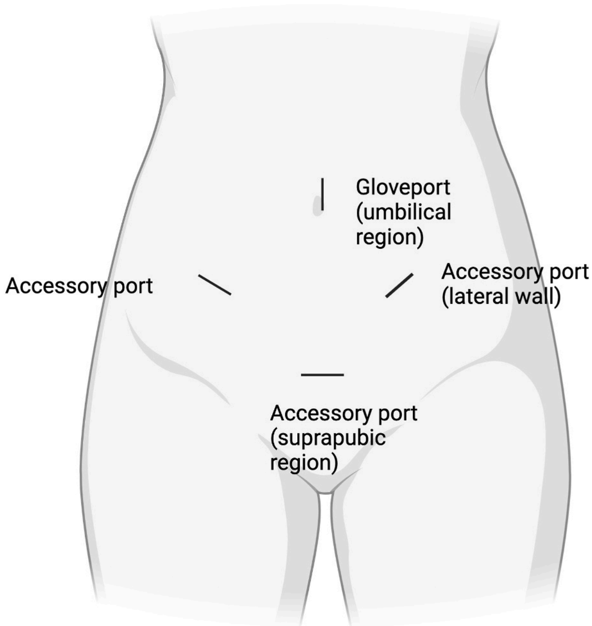

Fig. 1. A picture of different trocar placements. A Gloveport was inserted into the umbilicus, and 2-3 additional 5 mm trocars were inserted into the lateral abdominal wall and suprapubic region.

2.3. Data collection

Patient information was collected: age, body mass index (BMI), comorbidities, prior abdominal surgery, pelvic adhesions requiring adhesiolysis, myoma size, and the number of myomas, myoma classifications (International Federation of Gynecology and Obstetrics (FIGO): 3, 4, 5 intramural types, 6: less than 50 % of their volume intramural) [16].

2.4. Surgical procedures

All patients who underwent LM were administered general anesthesia and placed in the lithotomy and Trendelenburg positions. The pneumoperitoneum was established at up to 12 mmHg using carbon dioxide insufflation throughout the surgery. The reusable manipulator (Normedi Nordic, Tønsberg, Norway) was inserted into the uterine manipulator group's uterine cavity through the cervix.

In LM, a vertical 20-mm incision was made at the umbilicus using a glove port (NELIS, Gyeonggi-do, South Korea). Additional 2−3 trocars measuring 5 mm were inserted into the suprapubic region and both lateral lower abdomens (Fig. 1) under direct vision with a 30° scope.

The excised myomas were placed in a tissue bag and removed via the umbilical port with manual morcellation in LM [17]. Subsequently, the uterine wound was sutured with 1–0 Vloc (Medtronic, Minneapolis, MN, USA) or 2-0 Vicryl (J&J, New Brunswick, NJ, USA). The port sites were closed with 1–0 Vicryl for the fascia and 3-0 Vicryl for the skin.

All patients in both groups received 1500 mL of normal saline and 1000 mL after surgery, and the Foley catheter was removed on postoperative day 1. Discharge was arranged as the patients met two criteria: (i) stayed afebrile for at least 24 h and (ii) showed no evidence of surgical complications.

In this study, one surgeon performed all surgeries on the included patients. He has over 20 years of experience in laparoscopic surgery.

2.5. Outcome measures

The primary outcomes were conversion rate, endometrial cavity breaching rate, surgical time (min), duration of hospitalization (days), estimated blood loss (mL), hemoglobin (Hb) drop (anemia was defined as Hb < 12 g/dL), and number of abdominal ports. Adverse events analyzed included anemia and emphysema. Clavien-Dindo classification of adverse events was performed [18]. Obstetric outcomes of these patients were also recorded.

2.6. Statistical analysis

Continuous variables are presented as mean and standard deviation (SD), and categorical data are expressed as numbers and percentages (%). Independent t-tests were used to compare continuous variables. The chi-square test was performed to evaluate categorical variables. We used univariate and multivariate logistic regression models for categorical outcome variables, incorporating all covariates, including age, BMI, comorbidity, prior abdominal surgery, adhesiolysis, tumor size, and tumor number. We applied univariate and multivariate linear regression models to the continuous outcome variables, considering the same set of covariates. A two-sided probability value < 0.05 was considered significant. All statistical analyses were performed using the IBM SPSS Statistics software (version 29.0; SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Demographics

Table 1 presents the baseline characteristics of the 50 participants, divided into those who underwent manipulation (n=30) and

Table 1
Baseline characteristics of laparoscopic myomectomy with or without manipulators (N=50).

	Manipulator (n=30)	No-manipulator (n=20)	P-value
Age (years), mean ± SD	41.9 ± 6.27	41.1 ± 7.04	0.644
BMI (kg/m^2), mean ± SD	24.0 ± 3.33	26.0 ± 5.62	0.166
Comorbidity, n (%)	5 (16.7)	8 (40.0)	0.065
Prior abdominal surgery, n (%)	13 (43.3)	7 (35.0)	0.556
Adhesiolysis, n (%)	5 (16.7)	4 (20.0)	1
Myoma size (cm), mean ± SD	6.3 ± 5.5	7.3 ± 1.79	0.087
Myoma number, n (%)	2.0 ± 1.43	2.4 ± 2.46	0.482
FIGO classification of myoma, n, (%)			
3,4,5	55(96.4 %)	48(100 %)	0.499
6	2(3.5 %)	0	

SD, standard deviation; BMI, body mass index.
FIGO: International Federation of Gynecology and Obstetrics.

those who did not (n=20). No significant differences were observed in age (p=0.644) or BMI (p=0.166). Comorbidities were higher in the no-manipulator group, but the difference was insignificant (p=0.065). No significant differences between the groups were observed in prior abdominal surgery (p=0.556) or adhesiolysis (p=1). Tumor size showed a trend toward significance (p=0.087), but there was a significant difference in myoma number (p=0.482). Most of the myomas in both groups were classified as FIGO types 3, 4, or 5, with a very small proportion classified as FIGO type 6—no statistically significant difference in the distribution of FIGO classifications between the two groups.

3.2. Primary outcomes

Table 2 summarizes the outcomes of participants with manipulators (n=30) versus those without (n=20). No conversion was observed in the no-manipulator group. The incidence of endometrial cavity rupture was significantly higher in the manipulator group than in the no-manipulator group (p=0.007). Surgical time (p=0.153) and duration of hospitalization (p=0.483) did not significantly differ between the groups. Estimated blood loss (p=0.475) and Hb drop (p=0.265) also showed no significant differences. However, the number of abdominal ports was significantly lower in the no-manipulator group ($p < 0.001$). No pregnancy was noted after LM in either group.

3.3. Adverse events

Table 2 outlines the adverse events of the manipulator (n=30) and no-manipulator groups (n=20). However, there were no significant differences in the occurrence of anemia or emphysema between the groups. In Table 3, postoperative complications were observed with 3 cases of grade II anemia in the manipulator group, where 1 patient required a pRBC transfusion and 2 needed Fe supplement. In contrast, 1 person in the no-manipulator group experienced grade I emphysema without requiring intervention.

3.4. Factors influencing uterine cavity breaching other than manipulators

Table 4 lists the factors influencing uterine cavity breaching adjusted by baseline variables in Table 1. No baseline variable in Table 1 was associated with uterine cavity breaching.

3.5. Factors influencing surgical time, blood loss, and abdominal port numbers

Myoma size was a significant factor influencing surgical time and estimated blood loss; for each 1 cm increase in tumor size, surgical time increased by 10.84 min (p=0.011) (Supplement Table 1), and blood loss increased by 54.8 mL (p=0.003) (Supplement Table 2). Additionally, using a manipulator significantly reduced the number of abdominal ports required by 0.59 (p=0.003) (Supplement Table 3).

4. Discussion

In our study, we compared the baseline characteristics of 50 participants and found no significant differences in age or BMI between the groups. However, the no-manipulator group had a higher prevalence of comorbidities, and myoma size showed a trend toward significance. Endometrial cavity breaching was significantly more common in the manipulator group. An increase in myoma size was associated with longer surgical time and greater blood loss, while uterine manipulator use was linked to fewer trocars.

This is the first study to describe the relationship between uterine manipulators and uterine cavity breaches during LM. We aim to raise awareness among clinicians about potential complications associated with uterine manipulators and suggest alternative instruments, such as myoma screws, to perform surgeries. Uterine manipulators are widely used in gynecological surgery to improve surgical field exposure by mobilizing the uterus. However, complications, including uterine perforation, have been reported, with rates

Table 2
Outcomes of laparoscopic myomectomy with or without manipulators.

	Manipulator (n=30)	No-manipulator (n=20)	P-value
Conversions, n (%)	1 (3.3)	0 (0.0)	1
Endometrial cavity rupture, n (%)	9 (30.0)	0 (0.0)	0.007*
Surgical time (min), mean ± SD	135.4 ± 48.11	163.4 ± 73.65	0.153
Duration of hospitalization (days), mean ± SD	5.0 ± 4.83	5.2 ± 4.64	0.483
Estimated blood loss (mL), mean ± SD	231.3 ± 301.2	185.3 ± 144.9	0.475
Hb drop, n (%)	3 (10.0)	0 (0.0)	0.265
Number of abdominal ports, n (%)	2.7 ± 2.52	3.3 ± 2.99	<0.001*
Post-operative pregnancy, n (%)	0 (0.0)	0 (0.0)	–
Adverse events			
Anemia (Hb < 12.0 g/dL), n (%)	3 (10.0)	0 (0.0)	0.265
Emphysema, n (%)	0 (0.0)	1 (5.0)	0.385

SD, standard deviation; Hb, hemoglobin.

Table 3
Clavien-Dindo classification of surgical complications.

	Manipulator (n=30)	No-manipulator (n=20)
Adverse events		
Grade I, n (%)	0	1
Grade II, n (%)	3	0
Grade IIIa, n (%)	0	0
Grade IIIb, n (%)	0	0
Grade IV, n (%)	0	0
Grade V, n (%)	0	0

3 people in the Manipulator group developed postoperative anemia; 1 required pRBC 2u, 2 required Fe supplement.
1 person in the No-manipulator group developed emphysema without intervention.

Table 4
Factors influencing uterine cavity breaching.

Baseline variables	Crude				Model 1			
	OR	95 %	CI	P-value	OR	95 %	CI	P-value
Age (years)	0.96	0.86	1.08	0.489	0.92	0.81	1.04	0.195
BMI (kg/m^2)	0.93	0.78	1.11	0.432	0.92	0.76	1.12	0.415
Comorbidity	0.78	0.14	4.34	0.776	0.68	0.10	4.54	0.692
Adhesiolysis	1.39	0.24	8.14	0.717	1.33	0.17	10.15	0.786
Prior abdominal surgery	1.25	0.29	5.37	0.764	1.47	0.25	8.55	0.669
Myoma size (cm)	0.83	0.56	1.24	0.368	0.73	0.46	1.15	0.175
Myoma number	0.71	0.37	1.38	0.315	0.65	0.31	1.35	0.247

BMI, body mass index; OR, odds ratio; CI, confidence interval.
Model 1: Adjusted for variables in Table 1.

as high as 11 % in minimally invasive endometrial cancer surgery [19]. While these manipulators are considered safe, they can cause serious complications, such as bowel penetration at the beginning of a hysterectomy procedure [20].

The ability of uterine manipulators to facilitate surgical procedures through anteversion, retroversion, lateral movement, and elevation of the uterus is well-documented [21]. LM can cause obstetric complications, including placenta accreta spectrum, especially in women who experienced uterine cavity breaches during surgery [14]. Maintaining endometrial cavity integrity is, therefore, crucial. In our study, we observed no severe complications such as uterine or bowel perforation, but the endometrial cavity rupture rate was 18 %, all of which occurred in the manipulator group. To preserve endometrial cavity integrity, we opted to use myoma screws instead of uterine manipulators in LM. Our findings showed that LM without a manipulator yielded comparable outcomes to LM with a manipulator, with no significant differences observed at baseline.

Laparoscopic surgery typically involves the use of multiple trocars to facilitate the insertion of surgical instruments and cameras into the abdominal cavity [22]. The number of trocars used can impact the surgery's complexity, time, and recovery time. Using a uterine manipulator has shown promise in optimizing laparoscopic procedures [23], and in our study, the number of abdominal ports was significantly lower in the manipulator group. Using a manipulator decreased the number of trocars, as shown by regression analysis. In contrast, the no-manipulator group often required additional ports due to the use of myoma screws to elevate the uterus during LM. However, no significant differences were observed in conversion rates, surgical time, hospitalization duration, or estimated blood loss.

Myoma size was associated with increased surgical time and blood loss, consistent with previous studies [24]. Larger myomas generally increase the complexity of the surgical procedure, necessitating more extensive dissection and presenting greater challenges in achieving hemostasis [25]. This understanding is critical for preoperative planning and patient counseling, as it helps anticipate potential complications and allocate appropriate resources for managing intraoperative challenges [26], ultimately improving surgical outcomes and patient safety [27].

Lastly, both groups in our study had an identical hospital stay duration of 5 days, likely influenced by the health insurance system, which covers a 5-day hospital stay. As a result, most patients remained hospitalized for this duration.

4.1. Strength and limitations

The strengths of this study are as follows. First, it directly compared LM performed with and without a uterine manipulator, addressing a specific clinical question regarding the impact of uterine manipulators on surgical outcomes and endometrial cavity integrity. Second, both primary (conversion rate, abdominal port count, operative time, hospitalization time, and blood loss) and secondary (adverse events) outcomes were assessed to provide a broad perspective on the effectiveness and safety of the procedures. Third, this study addressed a clinically significant issue, particularly the preservation of endometrial cavity integrity, which is crucial for fertility preservation in women of reproductive age undergoing myomectomy. Lastly, leveraging a retrospective analysis of realworld clinical data provided practical insights into the outcomes of LM with and without uterine manipulators.

The limitations of this study are as follows. First, the study had a relatively small sample size (50 patients), which may limit the generalizability of the findings and the statistical power to detect differences between the groups. Second, as a retrospective study, it was subject to inherent biases related to data collection and patient selection, which may have affected the validity of the conclusions. Third, although no significant baseline differences were observed, potential confounding factors that were not accounted for could have influenced the outcomes (e.g., surgeon experience).

5. Conclusions

The clinical outcomes of LM without a uterine manipulator were comparable with those of LM with a manipulator. The absence of a manipulator may aid in preserving the integrity of the endometrial cavity. An increase in myoma size was associated with longer surgical time and greater blood loss, while uterine manipulator use was linked to fewer trocars. Further investigations with larger prospective cohorts are warranted to elucidate the true impact of uterine manipulator use on the integrity of the endometrial cavity.

CRediT authorship contribution statement

Chi-Han Chang: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Dah-Ching Ding:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Investigation, Formal analysis, Data curation, Conceptualization.

Informed consent statement

The requirement for informed consent was waived due to the low risk to the patients in the study.

Institutional review board statement

This study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethics Committee of Hualien Tzu Chi Hospital (approval number: IRB112-238-B).

Data availability

All relevant data are reported in the article.

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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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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e39550.

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