#### **Original Article**

# Risk Factors Associated with Perineal and Vaginal Lacerations and Vaginal Removal in Total Laparoscopic Hysterectomy

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## Abstract

**Objectives:** This study aimed to identify risk factors associated with perineal and vaginal lacerations related to vaginal removal during total laparoscopic hysterectomy (TLH).

Materials and Methods: We retrospectively assessed 134 patients who underwent TLH, of whom 44 (32.8%) had vaginal lacerations.

**Results:** Univariate analysis revealed that for patients with myomas and adenomyosis, gonadotropin-releasing hormone agonist use and myomas with a transverse diameter of  $\geq 5$  cm were significant risk factors, while multiparity (vaginal delivery) was a protective factor for perineal and vaginal lacerations. Moreover, multivariate analysis indicated that multiparity was the only statistically significant protective factor. For cervical intraepithelial neoplasia, endometrial cancer, and endometrial hyperplasia, only a uterine transverse diameter of  $\geq 5$  cm was a significant risk factor for perineal or vaginal lacerations.

**Conclusion:** For patients with large myomas, multiple vaginal delivery was a protective factor, and in patients with normal-sized uteri, a uterine transverse diameter of  $\geq 5$  cm was a risk factor for perineal or vaginal lacerations.

Keywords: Hysterectomy, laparoscopic surgery, morcellation, perineal laceration

### **INTRODUCTION**

Total laparoscopic hysterectomy (TLH) has been reported to be safe and effective in cases of large uteri; however, removing the uterus from the abdominal cavity remains challenging.<sup>[1,2]</sup> In April 2014, the U. S. Food and Drug Administration (FDA) stopped recommending the use of power morcellation in minimally invasive hysterectomy because of the risk of undiagnosed sarcoma.<sup>[3]</sup> As an alternative method, in-bag power morcellation or vaginal morcellation has been used to reduce the risk of tissue dissemination.<sup>[4,5]</sup> Currently, manual vaginal morcellation is performed to remove the uterus from the abdominal cavity after TLH.<sup>[5,6]</sup> Manual vaginal morcellation remains safe despite occult malignancies and does not appear to negatively impact prognosis or relapse;<sup>(7)</sup> therefore, it is the first choice

Article History: Submitted: 02-Nov-2021 Revised: 10-Feb-2022 Accepted: 03-May-2022 Published: 05-Aug-2022

Access this article online			
Quick Response Code:	Website: www.e-gmit.com		
	DOI: 10.4103/gmit.gmit_118_21		

of intervention for TLH.<sup>[8]</sup> Moreover, vaginal morcellation is faster than other treatment options.<sup>[9]</sup> At our institution, we remove the uterus with manual morcellation through the vagina with the patients' consent.

After uterine removal, perineal and vaginal lacerations often occur because the excised uterus is usually larger than the vaginal canal. In obstetrics, operative vaginal delivery is a significant risk factor for severe perineal lacerations,<sup>[10]</sup> as is the rapid traverse of the birth canal and a quick delivery (short duration of the second stage of labor).<sup>[11]</sup> Nulliparity, infant birth weight, and a newborn large head circumference are also risk factors for perineal lacerations.<sup>[12,13]</sup> There is

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How to cite this article: Chikazawa K, Imai K, Ko H, Ichi N, Misawa M, Kuwata T. Risk factors associated with perineal and vaginal lacerations and vaginal removal in total laparoscopic hysterectomy. Gynecol Minim Invasive Ther 2022;11:150-4.

a paucity of studies on perineal and vaginal lacerations during TLH. Therefore, an observational study investigating this would be beneficial. Furthermore, this information is essential for the safety of the patients. In this study, we evaluated the risk factors that might predispose patients to vaginal injuries caused by removing the uterus through the vagina during TLH.

# MATERIALS AND METHODS

#### **Ethical approval**

This retrospective study was approved by the Institutional Review Board of (redacted) (S19-045) (Institute is Jichi Medical University, Saitama Medical Center). The requirement for informed consent was waived by the institutional ethics body due to the retrospective nature of the study and the comprehensive written consent that had been preobtained for the use of patient data for research purposes. We reviewed the medical records of 134 patients who underwent TLH with the removal of the uterus through the vagina between November 2016 and June 2019 at the Department of Obstetrics and Gynecology of the Jichi Medical University, Saitama Medical Center. The exclusion criteria were as follows: a previous laparoscopic vaginal hysterectomy, laparoscopically assisted abdominal hysterectomy, and the removal of the uterus through an abdominal incision. The requirement of obtaining informed consent was waived for all participants because the data were collected through a retrospective review of medical records. Informed consent was obtained for clinical treatment, and the study was conducted according to the provisions of the Declaration of Helsinki proposed in 1995 and as revised in Tokyo in 2004.

We collected data regarding age, gravidity, parity, vaginal birth experience, histopathology, body mass index, gonadotropin-releasing hormone agonist (GnRHa) use, maximum diameter of the myomas, and maximum transverse diameter of the uterus in patients without myomas. Vaginal and perineal lacerations in this study were defined as complications that require repair or stoppage of hemorrhages. A GnRHa was administered to patients with a large uterus and for those with anemia and a small uterus to stop menstruation. During the TLH procedure, the uterus was extracted through the vagina. If the uterus was too large to be extracted without morcellation extraction, transvaginal morcellation was performed. After the uterus was delivered, the vaginal vault was closed laparoscopically by intracorporeal suturing. The sites of trocar insertion were closed in a similar fashion.

We performed vaginal morcellation techniques to track the uterine cervix and incise the sidewall of the uterus



Figure 1: Small myomas are usually completely enucleated, whereas larger ones are partially enucleated. The maximum diameter of the myoma becomes the largest diameter of the morcellated uterus. (a) Planned line of incision; the myoma encircles the uterus; (b) actual striated uterus http://www.apagemit.com/page/video/show. aspx?num=291&kind=2&page=1

to straighten the round uterus. Usually, the maximum transverse diameter of the uterus is the longest diameter of the morcellated uterus. During vaginal morcellation, because it involved a blinded technique, we tried to reduce the time spent cutting the uterus to mitigate the risk of organ injury. A myoma, if present, was usually partially enucleated, and the maximum transverse diameter of the myoma became the widest diameter when the morcellated uterus passed through the birth canal [Figure 1]. To perform vaginal morcellation, we made a convex U-shaped incision toward the left side of the patient, cutting straight from this incision toward the cranium; subsequently, the uterus was straightened with this procedure after being returned to the upper pubic bone. If the uterus could not be removed with a single incision, we continued creating more incisions in a spiral pattern inward around the uterine body until it could be retrieved [Video 1]. The indications for myoma or adenomyosis and other conditions (cervical intraepithelial neoplasia [CIN], endometrial cancer, and endometrial hyperplasia) were analyzed separately because, in cases of myomas or adenomyosis, the uterus is large; however, in other cases, the uterine size is almost normal.

JMP for Windows (version 10.0.0; SAS Institute Japan, Minato, Japan) was used to perform statistical analyses. Demographic variables are reported as mean and standard deviation. Variables with nonnormal distributions are reported as medians and ranges. For variables with normal distributions, continuous data were compared using the Student's *t*-test. For variables with nonnormal distributions, data were compared using the Wilcoxon signed-rank test. Fisher's exact test was used to determine the associations between the demographic parameters, such as the vaginal birth rate, GnRHa use, diameter of the myoma or uterus, and perineal or vaginal lacerations. A multivariate logistic regression analysis was used to calculate the odds ratios and evaluate the association between the clinical variables and the perineal or vaginal lacerations. For all statistical tests, two-sided P < 0.05 was considered statistically significant. For the hazard ratio, 95% confidence intervals were estimated. Based on our previous research (unpublished findings), we calculated that a sample size of 15 patients per group and an overall study population of 30 patients were needed. This would ensure that 60% of the patients in the myoma and adenomyosis transverse diameter  $\geq 5$  cm group would be expected to have perineal or vaginal lacerations and that 10% of the patients in the <5 cm group would not have perineal or vaginal lacerations if the ratio was similar to that identified previously.

# RESULTS

In total, 134 patients who underwent TLH were eligible for this study. The baseline values of their clinical characteristics are reported in Tables 1 and 2.

Overall, 32.8% (44/134) of the patients had perineal or vaginal lacerations. Of the 91 cases with myomas and adenomyosis (n = 91), 37.4% (34/91) involved perineal or vaginal lacerations; however, 10 (23.3%) of the remaining 43 patients (n = 43; those with CIN, endometrial cancer, and endometrial hyperplasia) had perineal or vaginal lacerations [Table 2].

Table 3a shows the results of the logistic regression analysis of perineal/vaginal lacerations during TLH for myomas and adenomyosis. According to the univariate analysis, GnRHa use and myomas with a transverse diameter of  $\geq$ 5 cm were identified as significant risk factors. Multiparity was identified as a significant protective factor. However, according to the multivariate analysis, only multiparity was a significant factor. Table 3b shows the results of the logistic regression analysis of CIN, endometrial cancer, and endometrial hyperplasia. According to the univariate analysis, only a uterine transverse diameter of  $\geq$ 5 cm was classified as a significant risk factor.

# DISCUSSION

In this study, 32.8% (44/134) of the patients developed perineal or vaginal lacerations during TLH. GnRHa use and myomas with a transverse diameter of  $\geq$ 5 cm were risk factors for TLH performed in patients with myomas and adenomyosis that led to uterus enlargement, which resulted in perineal and vaginal lacerations, whereas multiparity was a protective factor. In contrast, for TLH performed in patients with CIN, endometrial cancer, and endometrial

#### **Table 1: Patient characteristics**

Patient characteristics	Indication ( <i>n</i> =134), <i>n</i> (%)
Age (years)	48.8±8.3
BMI (kg/m <sup>2</sup> )	23.0±4.6
Gravidity (n)	6-0; median 2
Parity (n)	4-0; median 2
Vaginal birth experience	102 (76.1)
GnRHa use	59 (44.0)
Diameter of myoma/uterus diameter (cm)	51.4±20.0
Perineal/vaginal laceration	44 (32.8)
Myoma	80 (59.7)
Adenomyosis	11 (8.2)
CIN	28 (20.9)
Endometrial cancer and endometrial hyperplasia	15 (11.2)

BMI: Body mass index, GnRHa: Gonadotropin-releasing hormone agonist, CIN: Cervical intraepithelial neoplasia

#### Table 2: Characteristics of the patients with myoma or adenomyosis and other conditions

	Patients with myoma and adenomyosis (n=91)	Othersª (n=43)	Р
Age (years)	46±0.57	54±1.6	< 0.0001*
BMI (kg/m <sup>2</sup> )	22.5±3.9	24±5.6	0.088
Gravidity	6-0; median, 2	4-0; median, 2	0.76
Parity	3-0; median, 2	4-0; median 2	0.77
Uterine weight (g)	270±120	140±94	< 0.0001*
Vaginal birth, n (%)	70 (76.92)	32 (74.42)	0.83
Maximum diameter of myoma/ adenomyosis (cm)	57.9±19.7		
Maximum transverse diameter of the uteri (cm)		37.9±12.5	
Perineal/vaginal laceration, <i>n</i> (%)	34 (37.4)	10 (23.3)	0.12

\*CIN: Cervical intraepithelial neoplasia, \*The significance of P was set at<0.05 in the study. BMI: Body mass index

hyperplasia, none of which caused uterine enlargement, a uterine transverse diameter of  $\geq 5$  cm was the only risk factor for perineal and vaginal lacerations. This is the first report of birth canal lacerations during TLH involving the removal of the uterus through the vagina.

In cases of myomas and adenomyosis in nulliparous women with large uteri, there is a risk of perineal and vaginal lacerations during TLH. In our study, while multivariate analysis revealed that GnRHa use and myomas with a transverse diameter of  $\geq$ 5 cm were not significant risk factors for lacerations, cases like these tend to experience lacerations. It has been reported that nulliparity is a risk factor for vaginal lacerations during birth<sup>[12]</sup> and gynecological surgery. If the uterus has a benign condition, to reduce lacerations, we might

Table 3a: Analysis of perineal or vaginal lacerations in patients with myomas and adenomyosis						
	Analysis of perineal or vaginal laceration in myoma and adenomyosis					
	OR	95% CI	Р	OR	95% CI	<b>P</b> †
	Univariate analyses		Multivariate analyses			
Age over 55 years	0.000004	<2.7	0.17			
BMI>25 kg/m <sup>2</sup>	1.1	0.37-3.2	0.86			
GnRHa use	3.7	1.5-10.5	0.0056	2.8	0.96-9.2	0.059
Myoma transverse diameter ≥5 cm	4.2	1.5-14	0.0049	2.8	0.87-11	0.085
Multiparity of vaginal birth	0.15	0.047-0.42	0.0003	0.16	0.047-0.48	$0.0008^{\dagger}$

<sup>†</sup>The significance of P was<0.05 in this study. CI: Confidence interval, OR: Odds ratio, BMI: Body mass index, GnRHa: Gonadotropin-releasing hormone agonist

#### Table 3b: Analysis of perineal lacerations in the absence of myoma and adenomyosis

	Analysis of perineal laceration in the absence of myoma and adenomyosis				
	OR	95% CI	Р		
Age>55 years	1.1	0.21-5.2	0.87		
BMI>25 kg/m <sup>2</sup>	3.1	0.71-13	0.13		
GnRHa use	8	0.69-185	0.095		
Uterine transverse diameter ≥5 cm	6.7	1.2-42	0.031		
Multiparity of vaginal birth	0.75	0.16-4.1	0.72		

CI: Confidence interval, OR: Odds ratio, BMI: Body mass index, GnRHa: Gonadotropin-releasing hormone agonist

consider morcellating the uterus such that the transverse diameter is <5 cm, either vaginally or abdominally.

We observed that the use of GnRHa is associated with the tendency for lacerations during the course of our study. GnRHa is often used to reduce the uterine size before performing TLH, resulting in shorter operative times and reduced blood loss.<sup>[14]</sup> Unfortunately, GnRHa use has the side effect of vaginal atrophy, which causes difficulty in removing the uterus through the vagina.<sup>[6]</sup> During TLH, removing the uterus through the birth canal could lead to perineal or vaginal lacerations, depending on the size of the myoma. In addition, a large newborn head circumference is a risk factor for birth canal lacerations during vaginal birth.<sup>[10]</sup>

In TLH performed for CIN, uterine endometrial cancer, and endometrial hyperplasia, none of which enlarge the uterus, only a uterine transverse diameter of  $\geq 5$  cm is a risk factor for perineal/vaginal lacerations. Multiparity did not affect the incidence of lacerations in such cases. As the patients were close to or older than the age of menopause onset, the vagina was already atrophic in these patients; therefore, the uterine size may have had the greatest effect on perineal and vaginal lacerations. Compared to patients with myomas and adenomyosis, patients with CIN and endometrial neoplasms have a soft and elastic uterus; therefore, during vaginal removal, older patients with CIN and patients with

endometrial neoplasms may have a lower laceration rate than patients with myomas or adenomyosis.

As the Food and Drug Administration no longer recommends power morcellation for minimally invasive hysterectomy, the frequency of transvaginal morcellation during vaginal hysterectomy and TLH has increased; however, the number of laparoscopic supracervical hysterectomy procedures has decreased.<sup>[15-18]</sup> The techniques used for vaginal hysterectomy and vaginal morcellation may become more important when avoiding abdominal hysterectomy in cases with a large uterus. Moreover, increasing the awareness of evidence supporting vaginal hysterectomy can improve the use of this approach to hysterectomy.<sup>[19]</sup> In addition, preventing perineal or vaginal lacerations in malignant conditions, such as benign diseases, is difficult. Further, morcellating the intra-abdominal cavity is a risk factor for cancer cell spillage.<sup>[20,21]</sup> For malignant conditions, especially cervical cancer, there is a risk of recurrence in laparoscopic hysterectomy.<sup>[20]</sup> The route of lymph node removal was indicated as a risk factor for recurrence,[22] and laparoscopic surgery for malignant diseases is associated with several other complications, including urinary dysfunction.<sup>[23,24]</sup> Therefore, further studies on TLH with vaginal morcellation and its complications should be conducted because accumulating evidence regarding vaginal techniques, as presented in our study, is extremely important for benign and malignant diseases.

This study had some limitations. It was a retrospective, single-center study with a modest sample size. Moreover, the population group was not diverse. There were inadequate data regarding TLH performed to treat conditions other than fibroids, adenomyosis, CIN, and endometrial hyperplasia. Some variables tended to increase the risk of lacerations; however, the increase was not significant. This may have been attributable to the inadequate study power. In addition, the average dimension of the removed uterus, which may be a risk factor for lacerations, was not available in the records. The rate of vaginal lacerations in this study could be considered high. However, there are few reports of vaginal lacerations associated with TLH; for example, Ng et al. reported a 0.9% vaginal laceration rate following TLH.<sup>[25]</sup> Other reports have not included the rate of vaginal lacerations, even in cases of large uteri. We speculate that vaginal lacerations may be easy to repair for gynecologists without the help of other specialists such as urologists (bladder, ureter, and bowel). In addition, cases of vaginal lacerations included in this study were defined as complications requiring repair or stoppage of hemorrhages. The repair of vaginal lacerations requires a simple surgical procedure, which can only be addressed by a gynecologist; however, if there is a need for a repair, this should be re-evaluated. Although this is a limitation, noting these complications is important in clinical practice.

# CONCLUSION

In cases of myomas with a large diameter, multiparity was a protective factor for perineal and vaginal lacerations during TLH. For a normal-sized uterus, a uterine transverse diameter of  $\geq$ 5 cm was a risk factor for perineal and vaginal lacerations. To the best of our knowledge, this is the first study to evaluate perineal and vaginal lacerations during TLH. Surgeons should ensure that perineal and vaginal lacerations are not overlooked at the end of the TLH procedure. Although they may be tired and could lose concentration, surgeons should remember to check for lacerations when assessing vaginal bleeding after skin closure, which is the last part of the procedure. The accumulation of more cases may aid in accumulating knowledge regarding vaginal removal of the uterus during TLH. Nevertheless, future studies focused on new morcellating techniques that reduce the uterine diameter are required.

# **Financial support and sponsorship**

Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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