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Six-year survival of patients with unsuspected uterine malignancy after laparoscopic versus laparotomic myomectomy: An 11-year national retrospective cohort study

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HIGHLIGHTS

- The incidence of unexpected uterine malignancy after myomectomy was 0.08%.
- Laparotomic and laparoscopic myomectomy had no difference in the incidence.
- Laparoscopy did not deteriorate the prognosis of the unexpected uterine malignancy.

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ABSTRACT

Objective. The primary objective was to compare the overall survival of women with unsuspected uterine malignancy (UUM), including sarcomas and adenosarcomas, diagnosed after laparotomic versus laparoscopic myomectomy. The secondary objective was to determine the incidence of UUM diagnosed after myomectomy.

Methods. We analyzed the national health insurance database, which covers almost the entire Korean population, between 2006 and 2010 to calculate the incidence and mortality of UUM diagnosed after myomectomy. Diagnosis and procedure codes were used to identify women with or without UUM.

Results. During the study period, 78,826 patients who underwent myomectomy among women in the database (23 million per year) were enrolled. The women were divided into a laparotomic myomectomy group ($n = 56{,}213$) and a laparoscopic myomectomy group ($n = 22{,}613$). The incidence of UUM diagnosed after myomectomy was 0.08% in both groups (47/56,213 and 18/22,613 women, respectively). There was no difference in mean age, socioeconomic status, diagnostic code, UUM incidence at 5-year intervals, survival rate, or mean survival time. The 5-year survival rates of women with UUM were 95.7% and 88.9% in the laparotomic and laparoscopic groups, respectively. A Kaplan-Meier survival analysis showed no difference in the overall survival rates according to the surgical method ($P = 0.447$).

Conclusions. The incidence of UUM after myomectomy was 0.08% after laparotomic or laparoscopic myomectomy. Although morcellator use does not reduce the overall survival rate, clinicians should explain the risks of intraperitoneal tumor dissemination to patients and do their best to prevent tumor spillage when using this tool.

1. Introduction

In 2014, the US Food and Drug Administration (FDA) issued an advisory regarding the use of a power morcellator because it may contribute to the dissemination of unsuspected uterine malignancy (UUM) into the peritoneal cavity and may worsen prognosis [1]. However, as our previous study indicated, the FDA recommendation was not based on a survival study; furthermore, there is sparse data available on the effect of morcellator use on the survival rate in women with UUM [2,3].

We have previously reported the effect of power morcellation on the overall survival rate of women with UUM diagnosed after myomectomy by comparing women who underwent laparotomic myomectomy (laparotomic group) with those who underwent laparoscopic myomectomy (laparoscopic group) using the Health Insurance Review and Assessment Service (HIRA) claims data that cover almost the entire Korean population [3,4]. Although an indicator of suspicion of death

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(ISD) was used instead of real death to estimate the survival rate, and only the overall survival rate with a follow-up interval of at least one year could be calculated, the study showed no difference between groups in the overall survival of women with UUM with or without endometrial cancer [5].

Therefore, we performed this retrospective cohort study to evaluate the effect of morcellation on a survival rate of at least 6 years in women with UUM diagnosed after myomectomy by comparing women with UUM diagnosed after laparotomic myomectomy and women with UUM diagnosed after laparoscopic myomectomy using the 11-year HIRA database.

2. Materials and methods

By law, South Koreans must subscribe to national health insurance. Medical institutions cannot refuse medical treatment for national health insurance members. The National Health Insurance Corporation (NHIC) is a unique national health insurance provider that provides health insurance services to most citizens in South Korea. Therefore, the NHIC contains most health insurance-related information (sex, age, socioeconomic status (SES), death, diagnosis, surgery, prescription, cost, etc.) for most patients in South Korea, except those undergoing cosmetic surgery. This study utilized data from the NHIC (Serial Number: REQ0000010127); however, the results of the study were not related to the NHIC.

Records for women with UUM were simultaneously extracted the NHIC claims database between January 2006 and December 2010 using diagnosis and procedure codes. The diagnostic code used was C54.x (C54, Malignant neoplasm of the corpus uteri; C54.0, Isthmus uteri; C54.1, Endometrium; C54.2, Myometrium; C54.3, Fundus uteri; C54.8, Overlapping lesion of the corpus uteri; and C54.9, Corpus uteri, unspecified) from the International Classification of Diseases (ICD), 10th revision. The following Health Insurance Medical Care Expenses procedure codes were used: R4121, Abdominal myomectomy for subserosal myoma; and R4122, Abdominal myomectomy for complex myoma.

The identified women were divided into two groups according to whether they underwent laparotomy or laparoscopy (Fig. 1). Women with newly diagnosed UUM after myomectomy were defined as those who had a C54.x diagnostic code twice or more within 60 days after a myomectomy procedure code. Women who had any history of gynecologic cancer prior to myomectomy were excluded from our study. The date of death was based on when the diagnostic code for death was registered in the insurance data until December 31, 2016.

2.1. Data analysis

SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA) was used for data mining and to compare the ages of women who underwent either laparotomic or laparoscopic myomectomy. R version 3.4.2 (The R Foundation for Statistical Computing, Vienna, Austria), was used for all other statistical analyses. P-values < 0.05 were considered statistically significant. The chi-square test was used for the statistical analysis of categorical variables, and Student's t-test was used for the statistical analysis of continuous variables. Categorical variables are reported as numbers or percentages, and continuous variables are reported as the mean $\pm$ standard deviation. The Kaplan-Meier method and log-rank test were used for the survival analysis. Cox proportional hazard regression was used for the survival analysis after adjustment of the variables.

2.2. Ethics statement

This study was approved the Institutional Review Board of Gyeongsang National University Changwon Hospital, Changwon-si, South Korea (GNUCH 2017-02-005). Since the data used in this study were preprocessed so that the included individuals could not be identified, informed consent was not required.

3. Results

Fig. 1 shows the method used to select patients with UUM after myomectomy. We identified 78,826 patients who underwent myomectomy between 2006 and 2010 from among the women in the database (23 million per year). These patients were divided into two groups according to which procedure was performed: a laparotomic myomectomy group ($n = 56{,}213$) and a laparoscopic myomectomy group ($n = 22{,}613$). Over the years, the proportion of laparoscopic myomectomies increased (Table 1).

Table 2 shows the characteristics of women with UUM diagnosed after myomectomy. The incidence of UUM after myomectomy was 0.08% in both groups ($P = 0.046$). There was no difference in the mean age, SES, diagnostic code, UUM incidence at 5-year intervals, survival rate, or mean survival time between the two groups. The peak age at which UUM was diagnosed after myomectomy was 46–50 years in the both groups. From 2006 to 2016, there were three deaths in the laparotomic group (5-year survival rate of 95.7%) and two deaths in the laparoscopic group (5-year survival rate of 88.9%).

A Kaplan-Meier survival analysis of patients diagnosed with UUM after myomectomy showed no difference in overall survival rates according to the surgical method used ($P = 0.447$) (Fig. 2). In the Cox proportional hazard regression analysis after adjusting for age and SES,

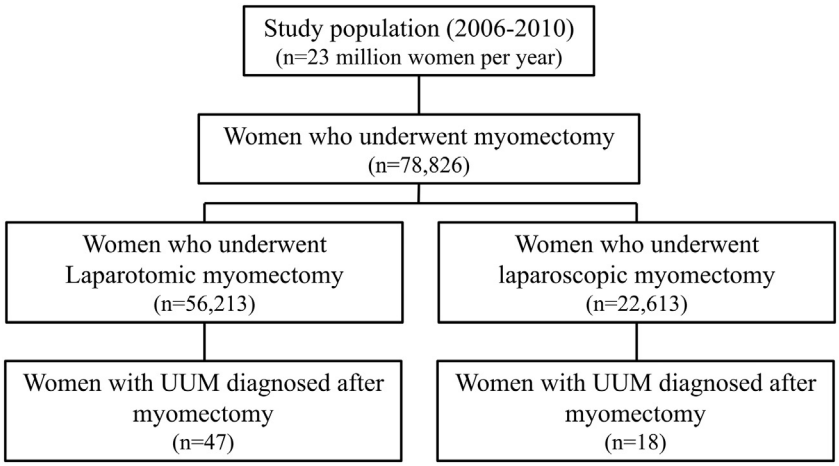

Fig. 1. Flowchart for the selection of patients with unsuspected uterine malignancy after myomectomy from 2006 to 2010 by surgical method. UUM = Unsuspected uterine malignancy.

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Table 1
Characteristics of the women who underwent myomectomy from 2006 to 2010.

	Laparotomic myomectomy	Laparoscopic myomectomy	Total	*P*-value
	Number (%)/mean ± SD			
Number of women who underwent myomectomy	56,213 (71.3)	22,613 (28.7)	78,826	<0.001[a]
2006	10,765 (87.7)	1507 (12.3)	12,272	
2007	10,233 (75.3)	3350 (24.7)	13,582	
2008	11,025 (70.4)	4630 (29.6)	15,655	
2009	11,841 (66.8)	5896 (33.2)	17,737	
2010	12,349 (63.1)	7230 (36.9)	19,579	
Mean age of women who underwent myomectomy (years)	38.23 ± 0.03	39.59 ± 0.05		<0.001[b]

All data are expressed as the number (percentage) or mean ± standard deviation.
[a] Pearson's chi-squared test was used to analyze categorical data.
[b] *t*-Test was used to compare continuous data.

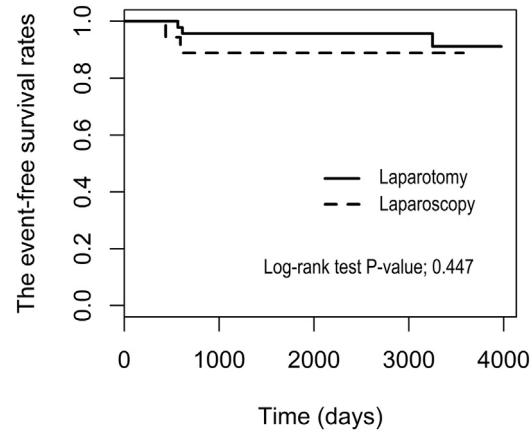

Fig. 2. Survival curves for patients with unsuspected uterine malignancy after myomectomy from 2006 to 2016 by surgical method.

there was no difference in the overall survival rate between the two groups (Table 3). Likewise, these results did not correlate with endometrial cancer.

4. Discussion

Previous studies have reported that the incidence of UUM diagnosed after hysterectomy or myomectomy ranges from 0.04% to 0.29% [3,6–9]. As mentioned in our previous study, the variation in this range is thought to have several causes [3]. First, the incidence of UUM (0.27–0.29%) in women who underwent hysterectomy was higher than the incidence in women who underwent myomectomy (0.04–0.11%) [3,6–9]. This difference may be because hysterectomy might be preferable to myomectomy in women with clinical or radiological suspicion of uterine malignancy or because the mean age of the women who underwent hysterectomy was older than that of the women who underwent myomectomy. Second, each study included different types of gynecologic malignancies in the definition of UUM: 1) leiomyosarcoma alone in some studies [7]; 2) uterine sarcoma, including leiomyosarcoma and

Table 2
Clinical characteristics of the women with unexpected uterine malignancy diagnosed after myomectomy from 2006 to 2010.

	Laparotomic myomectomy	Laparoscopic myomectomy	Total	*P*-value
	Number (%)/mean ± SD			
Number of women per year with UUM diagnosed after myomectomy	47 (0.08%)	18 (0.08%)	65 (0.08)	0.212[a]
2006	11 (23.40%)	0 (0.00%)	11 (16.92)	
2007	9 (19.15%)	6 (33.33%)	15 (23.08)	
2008	7 (14.89%)	3 (16.67%)	10 (15.38)	
2009	9 (19.15%)	5 (27.78%)	14 (21.54)	
2010	11 (23.40%)	4 (22.22%)	15 (23.08)	
Mean age of women with UUM diagnosed after myomectomy (years)	41.2 ± 7.9	39.3 ± 9.5		0.292[b]
SES				0.129[a]
Mid-high	47 (100.0%)	16 (88.9%)	63 (96.9)	
Low	0 (0.0%)	2 (11.1%)	3.1 (3.1)	
Diagnostic code of the women with UUM diagnosed after myomectomy				0.256[c]
C540 (Isthmus uteri)	0 (0.0)	0 (0.0)	0 (0.0)	
C541 (Endometrium)	29 (61.7)	8 (44.4)	37 (56.9)	
C542 (Myometrium)	11 (23.4)	4 (22.2)	15 (23.1)	
C543 (Fundus uteri)	0 (0.0)	0 (0.0)	0 (0.0)	
C548 (Overlapping lesion of corpus uteri)	1 (2.1)	0 (0.0)	1 (1.5)	
C549 (Corpus uteri, unspecified)	6 (12.8)	6 (33.3)	12 (18.5)	
UUM incidence at 5-year intervals for women with UUM diagnosed after myomectomy				0.503[a]
<15 years	0/13 (0.00)	0/5 (0.00)	0/18 (0.00)	
16–20 years	0/18 (0.00)	1/7 (14.29)	1/25 (4.00)	
21–25 years	0/484 (0.00)	1/195 (0.51)	1/679 (0.15)	
26–30 years	4/4832 (0.08)	1/1944 (0.05)	5/6776 (0.07)	
31–35 years	9/12935 (0.07)	3/5212 (0.06)	12/18147 (0.07)	
36–40 years	9/13001 (0.07)	3/5222 (0.06)	12/18223 (0.07)	
41–45 years	9/13498 (0.07)	3/5430 (0.06)	12/18928 (0.06)	
46–50 years	12/8013 (0.15)	4/3223 (0.12)	16/11236 (0.14)	
51–55 years	2/2474 (0.08)	2/995 (0.20)	4/3469 (0.12)	
56–60 years	2/492 (0.41)	0/198 (0.00)	2/690 (0.29)	
>60 years	0/453 (0.00)	0/182 (0.00)	0/635 (0.00)	
Survival of women with UUM diagnosed after myomectomy				0.904[a]
Survival	44 (93.6%)	16 (88.9%)	60 (92.3)	
Death	3 (6.4%)	2 (11.1%)	5 (7.7)	
Mean survival time of women with UUM diagnosed after myomectomy (days)	3034.8 ± 740.5	2635.8 ± 871.7		0.069[b]

All data are expressed as the number (percentage) or mean ± standard deviation.
SES = Socioeconomic status; UUM = Unsuspected uterine malignancy.
[a] Pearson's chi-squared test was used to analyze categorical data.
[b] *t*-Test was used to compare continuous data.
[c] Fisher's exact test was used to analyze categorical data.

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Table 3
Cox proportional hazard model for unexpected uterine malignancy diagnosed after myomectomy from 2006 to 2016.

	UUM	
	HR	*P*-value
Unadjusted HR		
Age per 5 years	1.277 (0.752–2.167)	0.365
SES	0 (0-infinite)	0.999
Laparoscopy	1.981 (0.329–11.93)	0.455
Endometrial cancer (C54.1)	0 (0-infinite)	0.999
Adjusted HR formula 1		
Age per 5 years	1.292 (0.760–2.20)	0.344
SES	0 (0-infinite)	0.999
Laparoscopy	2.536	0.317
Adjusted HR formula 2		
Age per 5 years	1.441 (0.786–2.64)	0.237
SES	0 (0-infinite)	1.000
Laparoscopy	2.399 (0.362–15.91)	0.365
Endometrial cancer (C54.1)	0 (0-infinite)	0.999

HR = Hazard ratio; SES = Socioeconomic status; UUM = Unsuspected uterine malignancy.

endometrial cancer, in some studies [3,6,9]; or 3) leiomyosarcoma, uterine neoplasms of uncertain malignant potential, endometrial cancer, endometrial hyperplasia, cervical cancer and adnexal malignancy in other studies [8]. Therefore, the difference in the incidence of UUM may be due to the different definitions of UUM that were used. Third, *n* the mean age of the enrolled women differed among studies. This difference may also have caused the difference in the UUM incidence because advanced age has been reported to be correlated with uterine cancer [6,8,9]. Considering these points, we believe that the incidence (0.08%) of UUM in this study is acceptable since our study had a relatively young participant mean age (younger than 40 years old) and investigated only uterine sarcoma and endometrial cancer diagnosed after myomectomy. Additionally, the definition of UUM used in this study, which included endometrial cancer and uterine sarcoma, is considered clinically more useful because approximately 60% of UUMs diagnosed after myomectomy are endometrial cancer, as Table 2 shows.

In our study, there was no difference in the overall survival of women with UUM diagnosed after laparotomic versus laparoscopic myomectomy. In terms of the impact of morcellation on the prognosis of women with UUM diagnosed after surgery, some studies have reported that morcellator use increased the rate of abdominopelvic recurrence and negatively affected the disease-free and overall survival rates [10–12]. Conversely, some other studies argued that tumor morcellation had no adverse effect on disease-free survival, overall survival, or both [13–15]. In terms of these conflicting claims, especially in terms of overall survival, the authors postulated that differences in the primary surgery that was performed for women with UUM may have affected survival rates. In the studies that noted no negative effect of morcellation on overall survival, women who had undergone hysterectomy as a primary surgery were divided into a morcellation group or a nonmorcellation group, and women who had undergone hysterectomy, myomectomy, or operative hysteroscopy as a primary surgery were divided into a morcellation group or a nonmorcellation group. Other studies that noted a negative effect of morcellation on overall survival enrolled women who had undergone hysterectomy as a primary surgery in a nonmorcellation group and enrolled women who had undergone myomectomy or hysterectomy as a primary surgery in a morcellation group. For patients with leiomyosarcoma or endometrial carcinoma, an en bloc hysterectomy was recommended to optimize outcomes [4]. In these cases, regardless of whether tumor morcellation occurred, hysterectomy versus myomectomy as the primary surgery may have influenced the prognostic outcomes of women with UUM because myomectomy is not en bloc resection. The authors believe that the previous studies that found no difference in primary surgery between the morcellation groups and nonmorcellation groups are more reasonable. Similar to these studies, the present study of women who underwent either laparotomic or laparoscopic myomectomy as a primary surgery found no difference in overall survival.

In addition, the lack of a difference in overall survival among women with UUM who underwent laparotomic versus laparoscopic myomectomy may be explained by the fact that endometrial cancer, which constituted 60% of the UUM diagnoses in this study, has a good prognosis compared to uterine sarcoma. However, in the Cox proportional hazard regression analysis after adjusting for endometrial cancer, there was no difference in the overall survival rates between groups (Table 3).

A recent decision analysis demonstrated that a minimally invasive approach is a safe option for presumed benign fibroids [16,17]. In addition, our results suggest that the use of a morcellator during laparoscopic myomectomy does not reduce the overall survival rate of women diagnosed with UUM after laparoscopic myomectomy. However, these studies did not consider the abdominopelvic recurrence rate, disease-free survival rate, or patient quality of life. Therefore, the authors believe that clinicians should adequately explain the risks associated with intraperitoneal tumor dissemination and morcellator use to patients and do their best to prevent tumor spillage during the use of a morcellator.

This study has several advantages. First, a large population of 78,826 women who underwent laparotomic or laparoscopic myomectomy was analyzed. Second, selection bias was minimized because data from a national health insurance database that includes all Korean citizens was used. Third, we evaluated the overall survival rate with a follow-up of at least six years. Fourth, compared with our previous study, which used an ISD to verify deaths and may theoretically have overestimated the number of real deaths, we accurately calculated the overall survival rate in the present study [3,5]. However, because data from a health insurance database were used, this study has several main limitations: first, the possibility of coding errors; second, the failure to collect clinical information (main symptoms; menopausal state; preoperative evaluations, such as tumor markers, imaging studies, and endometrial biopsies, etc.) and oncological information (histopathological classification, stage, restaging surgery, adjuvant treatment, recurrence rate, disease-free survival rate, etc.); third, the failure to provide information about whether morcellation was performed and what methods were used for morcellation in the laparotomic or laparoscopic myomectomy group; and fourth, the small number of deaths that occurred in women with UUM diagnosed after laparotomic or laparoscopic myomectomy. However, we believe that the accuracy of the diagnostic codes used in our study was high, as stated in a previous study by the authors [18], because both the HIRA and the insured person pay attention to the diagnostic codes for malignancy as the National Health Insurance Service covers 95% of the medical costs for malignant diseases.

5. Conclusions

The incidence of UUM after myomectomy was 0.08% in the patients in both the laparotomic and laparoscopic myomectomy groups. There was no difference between groups in the overall survival rate with a follow-up of at least six years. However, the authors believe that clinicians should adequately explain the risks associated with intraperitoneal tumor dissemination and morcellator use to patients and do their best to prevent tumor spillage when this tool is used.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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Author contributions

Jin-Sung Yuk collected the data, analyzed the data, and prepared the tables and figures. Jung Hun Lee conceived the study, supervised data analysis, performed the literature search, and wrote the manuscript. All the authors read and approved the final manuscript.

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