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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,

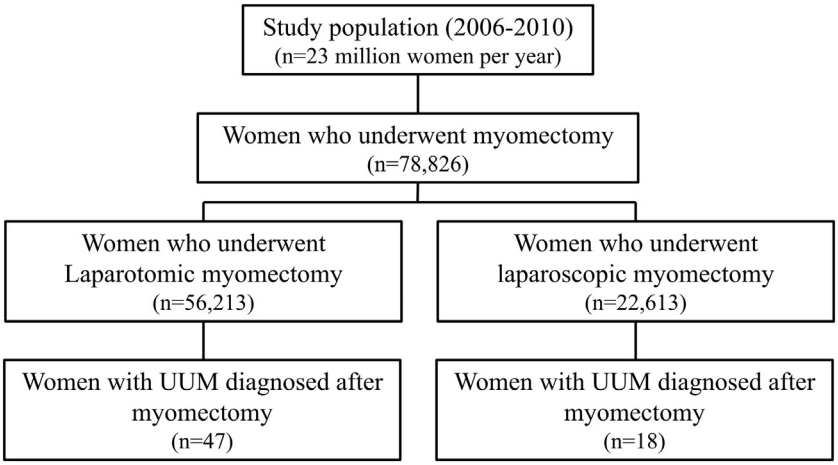

Fig. 1. Flowchart for the selection of patients with unsuspected uterine malignancy after myomectomy from 2006 to 2010 by surgical method. UUM = Unsuspected uterine malignancy.

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