



## Fibroid morcellation: a shared clinical decision tool for mode of hysterectomy



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### ABSTRACT

**Objective:** To compare risks and benefits of laparoscopic hysterectomy with morcellation versus abdominal hysterectomy without morcellation for large fibroids.

**Study design:** We developed a shared clinical decision tool to communicate risks and benefits of laparoscopic versus abdominal hysterectomy to patients with large fibroids as mandated by the FDA. The decision tool was designed to serve as a framework for providers to counsel patients about mode of hysterectomy to facilitate shared decision-making between patient and provider. Risks and benefits were estimated from the literature, including surgical complications (venous thromboembolism, small bowel obstruction, adhesions, hernia, surgical site infections, and transfusions), uterine sarcoma risks, and quality-of-life endpoints. The shared clinical decision tool was applied to a hypothetical population of 20,000 patients with large uterine fibroids, of which 10,000 underwent laparoscopic hysterectomies and 10,000 had abdominal hysterectomies.

**Results:** Abdominal hysterectomy would result in 50.1% more adhesions, 10.7% more hernias, 4.8% more surgical site infections, 2.8% more bowel obstructions, and 2% more venous thromboembolisms compared to laparoscopic hysterectomy. Abdominal hysterectomy would also result in longer hospital stays (2 days), slower return to work (13.6 days), greater postoperative day 3 narcotic requirements (48%), and lower SF-36 quality-of-life scores (50.4 points lower). 0.28% of fibroid hysterectomy patients would have unsuspected uterine sarcomas. Among these patients, laparoscopic hysterectomy with morcellation would have a 27% reduction in 5-year overall survival rates and a 28.8 month shorter recurrence-free survival period.

**Conclusion:** Some evidence suggests laparoscopic hysterectomy with morcellation may result in increased risk of cancer dissemination with worse survival outcomes among uterine sarcoma patients compared to abdominal hysterectomy without morcellation, however, the current data is limited and the exact risks associated specifically with electromechanical morcellation are not conclusive. Data also supports abdominal hysterectomy would lead to a net detriment in other outcomes, with greater risks of venous thromboembolism, obstruction, hernia, adhesions, infection, and blood loss compared to laparoscopic hysterectomy. This shared clinical decision tool may aid the patient and physician in determining an optimal mode of hysterectomy for large uterine fibroids while taking account of risks and benefits as mandated by the FDA.

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### Introduction

The benefits of laparoscopic surgery are well known. Laparoscopy offers improved visibility during surgery, enabling greater

detection rates and more thorough treatment of certain conditions. Patient benefits include faster healing, recovery, return to work and resumption of daily activities as compared to laparotomy [1–5]. Patients also have reduced postoperative pain, analgesic requirements, infection, blood loss, hernias and adhesion formation [1,5–18]. Given these benefits, laparoscopic hysterectomies and myomectomies for treatment of uterine fibroids have become increasingly common [1,3].

In recent years, gynecologists have mastered laparoscopic hysterectomy for larger and larger uteri, affording the benefits of

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laparoscopy to patients who previously could not benefit from a minimally invasive approach. In order to remove large fibroid uteri laparoscopically, the uterus must be cut into smaller pieces (morcellated) for extraction. A common morcellation technique involves an electromechanical device with a cylindrical blade, which circulates at high speed within a trocar to cut the enlarged specimen into narrow strips. The specimen is often morcellated within the abdominal–pelvic cavity without an enclosing trap to collect the tissue (“open” power morcellation), exposing the disrupted specimen to the abdominopelvic cavity. Complications from “open” morcellation include injury to surrounding structures such as the bowel or major vessels, difficult histologic examination of a specimen because of piecemeal presentation, and inadvertent dissemination of morcellated specimen within the abdominal–pelvic cavity if uterine sarcoma is present [19]. Uterine sarcomas are generally associated with a poor prognosis, and some studies suggest morcellation of a uterine sarcoma may result in a worse prognosis [20–22]. As preoperative testing to definitively diagnose uterine sarcomas is not possible, there are ongoing concerns surrounding the morcellation of uterine fibroids.

The U.S. Food and Drug Administration (FDA) released a Safety Communication in April 2014 advising physicians and patients to consider all treatment options for fibroids and discouraging open electromechanical morcellation [19]. Following this communication, several manufacturers halted production of this device and recalled morcellators. In a subsequent statement, the FDA advised against laparoscopic power morcellation of fibroid uteri “in the majority of women undergoing myomectomy or hysterectomy for the treatment of uterine fibroids.” The FDA notes that “open” power morcellation is contraindicated among perimenopausal or postmenopausal women, those suspected to have malignancy of the tissue to be morcellated, or candidates for intact removal of fibroid uteri through the vagina or mini-laparotomy delivery.

The FDA instructed providers to “thoroughly discuss the benefits and risks of all treatments with patients.” To facilitate this discussion, we explored the medical literature to compare risks and benefits of laparoscopic hysterectomy with morcellation versus abdominal hysterectomy without morcellation by evaluating the difference in surgical complications when comparing outcomes. Our goal was to develop a shared clinical decision tool (CDT) to assist providers and patients in the shared decision-making and informed consent process for individuals with large fibroids to determine the optimal mode of hysterectomy.

## Materials and methods

We developed a non-weighted shared CDT to evaluate the estimated incidence of surgical outcomes after laparoscopic versus abdominal hysterectomy. We included surgical outcomes that differ for laparoscopy versus laparotomy to reflect risks that gynecologists might consider when establishing mode of incision for patients undergoing hysterectomy. The main outcome measure was the net difference in surgical complications between laparoscopic hysterectomy and abdominal hysterectomy. The outcomes evaluated in the CDT were divided into three categories for each mode of hysterectomy: (1) hysterectomies without surgical complications, (2) hysterectomies with surgical complications, and (3) cancer risk. In the *hysterectomies without complications* category, patient endpoints included length of hospital stay (LOS), time to return to work, postoperative pain and analgesic requirements, and patient satisfaction after hysterectomy. In the *hysterectomy with surgical complications* category, outcomes were divided into *more morbid* surgical complications and *less morbid* complications. The *more morbid* surgical complications included venous thromboembolic events (VTE), small bowel obstruction (SBO), adhesions, and hernia. The *less morbid* surgical complications

included surgical site infection (SSI) and estimated blood loss (EBL). Cancer risk was assessed by incidence of uterine sarcoma among fibroid patients undergoing hysterectomy, risk of peritoneal dissemination, time to recurrence, and 5-year overall survival rates. See Fig. 1.

Two independent investigators performed a comprehensive literature search of PubMed. Incidence parameters for the CDT were determined by the existing data, which was limited for some outcomes. For outcomes with limited data or wide range of incidence, two or more reviewers discussed the data and came to consensus for an estimate. The incidence parameters were assumed for the general population and were not selected for special patient populations.

The shared CDT was designed for use in a modular fashion. Providers may select specific outcomes relevant to their individual patient and incorporate patient preferences into the decision-making process. Furthermore, estimates for each outcome can be substituted with different values to address special patient populations, or to update the tool when better data become available.

A hypothetical patient population with symptomatic enlarged fibroid uteri undergoing surgical treatment with hysterectomy was divided into two strategies: (1) laparoscopic hysterectomy requiring morcellation for specimen removal, or (2) abdominal hysterectomy without morcellation. An estimated net difference in the incidence of surgical outcomes was calculated by subtracting the number of complications in the laparoscopic hysterectomy strategy from the number of complications in the abdominal hysterectomy strategy. Each strategy was assigned 10,000 patients to allow for whole numbers due to the rare incidence of some outcomes.

## Results

The framework of the analysis was a hypothetical randomized trial. 20,000 hypothetical patients with enlarged fibroid uteri underwent hysterectomy, with 10,000 patients assigned to laparoscopic hysterectomy (LH) with morcellation and 10,000 patients assigned to abdominal hysterectomy (AH) without morcellation.

Incidences for outcomes of the two surgical approaches are presented in Table 1. The estimated net difference in incidences for the following complications were increased among AHs when compared to LHs (positive values indicate a greater incidence associated with AH than LH): adhesions +50.1% for midline laparotomies and +18.2% for transverse laparotomies [10,11], hernia +10.7% for midline laparotomies (range 50–58%) and +4% for transverse laparotomies [6,9,14], surgical site infection +4.8% [1], small bowel obstruction +2.8% [7,8,13], venous thromboembolism +2% [23,24], estimated blood loss +45 cc [1,12]. In addition, LH patients reported shorter hospital stays [1,15–17], quicker return to work [1], less narcotic requirements [18,25], and higher quality of life with a 50.4 point mean difference in the short form (SF-36) health survey that demonstrated a quality-of-life score favoring LH over AH up to 4 years after initial hysterectomy (see Table 3) [5].

Uterine sarcoma is reported to occur in one of 357 (0.28%) hysterectomies for fibroids [19]. If an occult malignancy is encountered, LH with morcellation has a recurrence-free survival period of 10.8 months versus 39.6 months for AH (net difference 28.8 months), 5-year recurrence free survival rate of 40% versus 65% (net difference 25%), and 5-year overall survival rate of 46% versus 73% (net difference 27%) [20,21]. See Table 2.

Reference to three hypothetical patients demonstrates the application of the CDT. Please refer to the Appendix.

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