GYNECOLOGY

Practice patterns and postoperative complications before and after US Food and Drug Administration safety communication on power morcellation

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BACKGROUND: In April 2014, the US Food and Drug Administration (FDA) published its first safety communication discouraging "the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids." Due to the concern of worsening outcomes for patients with occult uterine malignancy, specifically uterine leiomyosarcoma, the FDA recommended a significant change to existing surgical planning, patient consent, and surgical technique in the United States.

OBJECTIVE: We sought to report temporal trends in surgical approach to hysterectomy and postoperative complications before and after the April 17, 2014, FDA safety communication concerning the use of power morcellation during myomectomy or hysterectomy.

STUDY DESIGN: A retrospective cohort study was performed with patients undergoing hysterectomy for benign indications in the Michigan Surgical Quality Collaborative from Jan. 1, 2013, through Dec. 31, 2014. The rates of abdominal, laparoscopic, and vaginal hysterectomy, as well as the rates of major postoperative complications and 30-day hospital readmissions and reoperations, were compared before and after April 17, 2014, the date of the original FDA safety communication. Major postoperative complications included blood transfusions, vaginal cuff infection, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, deep and organ space surgical site infection, acute renal failure, respiratory failure, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, cerebral vascular accident, cardiac arrest, and death. We calculated the median episode cost related to hysterectomy readmissions using Michigan Value Collaborative data. Analyses were performed using robust multivariable multinomial and logistic regression models.

RESULTS: There were 18,299 hysterectomies available for analysis during the study period. In all, 2753 cases were excluded due to an indication for cancer, cervical dysplasia, or endometrial hyperplasia, and 174 cases were excluded due to missing covariate data. Compared to the 15 months preceding the FDA safety communication, in the 8 months afterward, utilization of laparoscopic hysterectomies decreased by 4.1% ($P = .005$) and both abdominal and vaginal hysterectomies increased (1.7%, $P = .112$ and 2.4%, $P = .012$, respectively). Major surgical complications not including blood transfusions significantly increased after the date of the FDA safety communication, from 2.2-2.8% ($P = .015$), and the rate of hospital readmission within 30 days also increased from 3.4-4.2% ($P = .025$). The rate of all major surgical complications or hospital reoperations did not change significantly after the date of the FDA communication ($P = .177$ and $P = .593$, respectively). The median risk-adjusted total episode cost for readmissions was $5847 (interquartile range $5478-10,389).

CONCLUSION: Following the April 2014 FDA safety communication regarding power morcellation, utilization of minimally invasive hysterectomy decreased, and major surgical, nontransfusion complications and 30-day hospital readmissions increased.

Key words: hysterectomy, morcellation, postoperative complications

Introduction

On April 17, 2014, the US Food and Drug Administration (FDA) published a safety communication discouraging "the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids."[1] Due to the concern of worsening outcomes for patients with occult uterine malignancy, specifically uterine leiomyosarcoma, the FDA recommended a significant change to existing surgical planning, patient consent, and surgical technique.

Uterine power morcellation allows for an efficient retrieval of large surgical specimens through small laparoscopic skin incisions. Laparoscopic and vaginal approaches to hysterectomy are generally associated with improved outcomes and decreased complications compared to abdominal approaches.[2] However, due to an inability to ensure benign pathology and a concern for worsening the outcomes for patients with occult, aggressive malignancies, patients and surgeons are shifting away from power morcellation as a surgical tool used during hysterectomy. A recent survey of minimally invasive surgeons found that 84% have changed their surgical approach planning after the FDA communication. Of surgeons, 25% reported changing to total abdominal hysterectomy for selected patients.[3] Although utilization of abdominal hysterectomy may decrease the specific risk of dissemination of occult malignancy, patients are at risk for increased surgical morbidity with open procedures.[4] Consequently, patients and their surgeons may be trading the risk of one complication for another. To date, the effect that this widespread change in surgical practice has had on surgical complications has not been evaluated.

Cite this article as: Harris JA, Swenson CW, Uppal S, et al. Practice patterns and postoperative complications before and after US Food and Drug Administration safety communication on power morcellation. Am J Obstet Gynecol 2016;214:98.e1-13.

0002-9378/$36.00

http://dx.doi.org/10.1016/j.ajog.2015.08.047

Therefore, we sought to analyze changes in surgical approach to hysterectomy and postoperative surgical complications before and after the April 2014 FDA power morcellation safety communication for patients undergoing hysterectomy for benign indications from a statewide database.

Materials and Methods

This study evaluated patients undergoing hysterectomy from the Michigan Surgical Quality Collaborative, a voluntary statewide surgical collaborative including community and academic hospitals. Data were abstracted from charts by specially trained, dedicated nurse abstractors. Patient characteristics, intraoperative processes of care, and 30-day postoperative outcomes from hysterectomy cases at member hospitals are prospectively collected by trained nurse abstractors using standard data collection instruments. To reduce sampling bias, a standardized data collection methodology is employed that uses only the first 25 cases of an 8-day cycle. Routine validation of the data is maintained by scheduled site visits, conference calls, and internal audits. Detailed methods of the registry's data collection have been described previously.[5,6]

Hysterectomies performed from Jan. 1, 2013, through Dec. 31, 2014, were included. To focus on patients with benign indications for hysterectomy, we excluded hysterectomies with an indication of malignancy, endometrial hyperplasia, or cervical dysplasia.

Our primary outcome was the change in utilization of hysterectomy surgical approach: abdominal, vaginal (including laparoscopic-assisted vaginal), and laparoscopic (including robotic-assisted) before and after April 17, 2014. Our secondary outcome was the change in incidence of major postoperative complications, readmissions, and reoperations within 30 days of surgery. Postoperative complications were classified using a database-wide classification system. Major postoperative complications included blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff infection, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

The primary independent variable was whether or not the surgery was performed after April 17, 2014, the day of publication of the FDA power morcellation safety communication.

To adjust for the baseline differences between the cases of the 2 time periods, several case-mix characteristics were included as covariates in the statistical models. Covariates included in the analysis were patient and surgical characteristics: age, race, body mass index, surgical indication, history of pelvic surgery, pathologist-measured uterine specimen weight; and a modified Charlson comorbidity score including: history of myocardial infarction, congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, stroke, diabetes, chronic kidney disease, cancer diagnosis, liver disease, and age in the score calculation.[7] To help control for confounding by overall surgical procedure complexity, we included in the model the total concurrent operative procedure total relative value units based on codes from the *Physicians' Current Procedural Terminology Coding System, Fourth Edition*.

The cost of hospital readmissions was calculated using the Michigan Value Collaborative, a voluntary statewide collaborative including community and academic hospitals that collects and risk-adjusts claims payments from a large private insurance provider and Medicare. All payments are risk-adjusted by age and medical comorbidities and standardized to published Medicare payment amounts. The episode cost of hospital readmission represents the 90-day costs for hospital readmissions for any patient who was readmitted.

Multinomial outcomes (ie, surgical approach to hysterectomy) were analyzed using tests on the equality of proportions and multinomial regression models controlling for the covariates noted previously, as well as robust SE accounting for hospital-level clustering.

Dichotomous outcomes (ie, the presence of a postoperative complication) were analyzed with χ^2 tests and multivariable logistic regression models controlling for the covariates noted previously, as well as robust SE accounting for hospital-level clustering. By accounting for violations in model assumptions due to nonindependence of observations within clusters of the data, Huber-Eicker-White robust SE better reflect the collected data characteristics.[8-10] Readmission episode costs are reported by their median value and interquartile range.

We reported the outcome in terms of the marginal effect: the predicted outcome probabilities when the independent variable is present or not, holding all other covariates at their known values, because effect sizes cannot be directly inferred from coefficients of logistic regression models.

To detect a 1% increase from a baseline hospital readmission rate of 3.5%, type 1 error of 5%, type 2 error of 20%, and a 2:1 ratio of number of cases before the safety communication to cases after the safety communication, a sample size of 10,540 hysterectomies was required. The study was deemed exempt by the University of Michigan Institutional Review Board-Medical. Software (STATA 13.1; StataCorp LP, College Station, TX) was used for all analyses.

Results

There were 18,299 hysterectomies that met the inclusion criteria, with 2753 cases excluded due to malignant or premalignant surgical indications and an additional 174 cases excluded for missing covariate data (Supplemental Figure 1). Of the included hysterectomies, 9597 were performed prior to the FDA power morcellation safety communication and 5775 were performed afterward. Groups were similar in terms of demographics and perioperative characteristics (Table 1).

Table 2 and Figure 1 show the comparison of hysterectomies by route before and after the FDA power morcellation safety communication. Overall, utilization of all minimally invasive routes of hysterectomy decreased from 77.1% before to 75.4% after the safety communication. After adjustment for small differences in case-mix characteristics, laparoscopic hysterectomies decreased by 4.1% ($P = .005$), while abdominal and vaginal hysterectomies increased by 1.7% and 2.4% ($P = .119$ and $P = .012$), respectively. Laparoscopic supracervical hysterectomies, a technique that frequently employs power morcellation, decreased by 59% after the safety communication ($P < .001$). Figure 2 and Supplemental Figure 2 show the monthly rates of hysterectomy by approach and monthly rates of supracervical hysterectomy by approach during the study period.

Compared to the time period before it, after the FDA safety communication, major postoperative complications did not increase significantly, from 4.4-5.0% ($P = .177$) (Table 3). The prevalence of major postoperative complications excluding blood transfusions did increase significantly, from 2.2-2.8% ($P = .015$). Furthermore, hospital readmissions increased significantly, from 3.4-4.2% ($P = .025$). There was no significant increase in surgical reoperations after the FDA communication.

Sensitivity analyses were performed by surgical approach, surgical indication, and uterine size. The comparison of postoperative complications before and after the FDA safety communication by laparoscopic surgical approach found an increase in major postoperative complications excluding blood transfusions from 1.9% before to 2.6% after ($P = .048$) (Supplemental Table 1). There was no significant difference in any complications for abdominal or vaginal surgical approaches. Within laparoscopic cases, robotic-assisted approaches were associated with an increase in major postoperative complications excluding blood transfusions, from 2.1% before to 2.9% after ($P = .045$) (Supplemental Table 2). When comparing postoperative complications before and after the FDA safety communication by surgical indication, there were no significant differences in any postoperative complications (Supplemental Table 3). When comparing postoperative complications before and after the FDA safety communication by measured uterine size <300 g or >300 g, there were no significant differences in any postoperative complications for the large uterine mass group, but in the small uterine mass group, there was a statistically significant increase in major postoperative complications, excluding blood transfusions, from 2.0% before to 2.8% after ($P = .005$) and hospital readmissions, from 3.3% before to 4.3% after ($P = .017$) (Supplemental Table 4).

Of the 476 patients who were readmitted and for whom we had cost data, median risk-adjusted total episode cost per readmission was $5847 (interquartile range $5478-10,389).

TABLE 1
Demographics of women undergoing hysterectomy before and after US Food and Drug Administration safety communication

Characteristic	Before FDA safety communication (n = 9597)		After FDA safety communication (n = 5775)	
Age, y				
<65	8758	91.3%	5310	92.0%
Race				
White	7177	74.8%	4397	76.1%
Black	1760	18.3%	1054	18.3%
Other	660	6.9%	324	5.6%
Body mass index, kg/m^2				
<25	2320	24.2%	13814	23.9%
25-29.9	2889	30.1%	1690	29.3%
>30	4388	45.7%	2704	46.8%
Charlson comorbidity index score				
≥4	7409	77.2%	4392	76.1%
Diabetes	815	8.5%	523	9.1%
Hypertension	2678	27.9%	1533	26.6%
Prior pelvic surgery	5796	60.4%	3414	59.1%
Indication				
Family history	650	6.8%	535	9.3%
Fibroids and/or abnormal uterine				
Bleeding	6254	65.2%	3758	65.1%
Pelvic mass	909	9.5%	490	8.5%
Prolapse	1017	10.6%	559	9.7%
Pelvic pain	731	7.6%	401	6.9%
Other	36	0.4%	32	0.6%
Measured specimen mass				
<250 g	7512	78.3%	4530	78.4%

FDA, Food and Drug Administration.

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Comment

In this analysis of changes in hysterectomy practice patterns and postoperative

TABLE 2
Hysterectomy practice patterns before and after US Food and Drug Administration safety communication

Surgical approach	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597)		After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775)		*P* value	
	Crude	Case-mix adjusted[a]	Crude	Case-mix adjusted[a]	Crude	Case-mix adjusted[a]
Abdominal (n = 3560)	22.6%	22.9%	24.1%	24.6%	.025	.119
Vaginal (n = 3654)	22.2%	21.9%	26.5%	24.3%	<.001	.012
Laparoscopic (n = 8158)	55.3%	55.2%	49.4%	51.1%	<.001	.005
Supracervical cases						
Abdominal (n = 565)	3.4%	3.4%	4.2%	4.5%	.007	.058
Laparoscopic (n = 1308)	11.0%	11.0%	4.4%	4.5%	<.001	<.001

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering.

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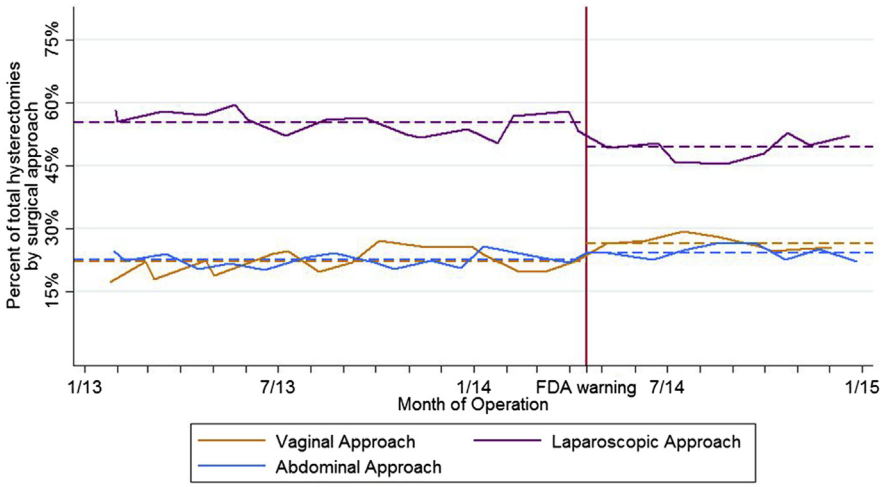
surgical complications within a large statewide surgical cohort, we found that compared to the preceding 16 months, after the April 17, 2014, FDA safety communication, the utilization of laparoscopy decreased. More concerning was the finding that overall serious surgical complications, as well as hospital readmissions, increased significantly after the FDA communication. We observed a 24% increase in readmissions, which suggests that there are now 9 more readmissions per day based on the assumption that there are approximately 400,000 hysterectomies performed in the US each year.[11]

FIGURE 1
Percent of total hysterectomies by approach during study period



Dashed lines are percent of total hysterectomies performed by hysterectomy approach before and after April 2014 Food and Drug Administration (FDA) safety communication. Vertical red line represents April 17, 2014, date of release of FDA safety communication.

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Additionally, with a median episode cost of $5847, the increased readmissions translate to an additional $23 million in annual health care costs.

There is a paucity of data regarding how the FDA safety communication and related media coverage has impacted practice patterns of gynecologic surgeons and patient-oriented outcomes. A study by Desai et al[3] found that, for an indication of fibroids, 50% of minimally invasive gynecologists considered changing the procedure to avoid morcellation due to the November 2014 FDA safety communication. For example, surgeons increasingly considered total hysterectomy rather than myomectomy or supracervical hysterectomy. Compared to the study by Desai et al[3] that noted 25% considering transitioning certain patients cases to laparotomy, we found that the utilization of laparoscopic hysterectomies actually decreased by only 3.9%. One explanation may be that our study was not limited to fibroids as an indication for surgery, but included all hysterectomies performed for benign indications. We found that the use of supracervical laparoscopic hysterectomy, a procedure for which power morcellation is often used, decreased by 59% after the FDA safety communication. Of surgeons, 39% were considering decreasing their use of supracervical hysterectomy in the survey by Desai et al.[3] All of these temporal findings appear to be credible and expected in the setting of a safety communication that altered the planning for laparoscopic hysterectomy and myomectomy. As novel methods of laparoscopic tissue removal develop, these changes in surgical practice may shift back toward laparoscopic surgery, and the current trends may not prove to be long-lasting.[12-20]

The study found an association between the FDA morcellation safety communication and surgical morbidity for patients. We found a 27% increase in major, nonblood transfusion, postoperative complications following the FDA safety communication, as well as a 25% increase in hospital readmissions. These findings are concerning for several reasons. First, the aim of the FDA safety

communication was to protect patients from harm related to cancer outcomes that may be adversely affected by power morcellation. Specifically, the FDA safety communication highlights the concern of potentially disseminating an occult uterine sarcoma that preoperatively was presumed to be a benign uterine fibroid. However, a recent study of women undergoing hysterectomy for benign indications found the prevalence of occult uterine sarcoma to be between 0.07-0.49%.[5,21-25] Unfortunately, there are no reliable predictors of uterine sarcoma to help focus interventions or surgical modifications to high-risk groups.[26] Despite the fact that the FDA safety communication specifically addresses power morcellation in hysterectomies performed for uterine fibroids, we found that the utilization of laparoscopic hysterectomy decreased for all benign indications. Of note, vaginal hysterectomies, which have been encouraged by professional organizations and payer groups, increased after the safety communication. Therefore, as surgeons, we need to ensure that increased utilization of certain procedures such as abdominal hysterectomy, which is known to carry increased surgical risk compared to a vaginal or laparoscopic route, is justified based on sound evidence regarding the risk of morcellation.

Secondly, media portrayal and misperception of the FDA safety communication may have contributed to a heightened concern about any type of morcellation for any indication by patients and surgeons alike. However, these data suggest that the corresponding change in surgical practices, with increased use of an abdominal approach and decreased use of a laparoscopic approach, is also associated with increased postsurgical morbidity. The additional risks associated with changes in surgical practice over time, possibly due to a decline in the use of morcellation, must be discussed with patients to provide comprehensive informed consent. Furthermore, novel practices, such as contained morcellation within a sterile surgical bag, are now being utilized by surgeons as a means of increasing the safety of morcellation procedures and may cause continued evolution in practice patterns over time. The rare event of worsened outcomes from an occult malignancy after morcellation must be balanced with advantages of decreased

TABLE 3
Postoperative complications before and after US Food and Drug Administration safety communication

Postoperative complication	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597) Case-mix adjusted[a]	After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775) Case-mix adjusted[a]	*P* value
Major postoperative complications[b]	4.4%	5.0%	.177
Major postoperative complications[b] not including blood transfusions	2.2%	2.8%	.015
Hospital readmission	3.4%	4.2%	.025
Hospital reoperation	2.2%	2.3%	.593

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering; [b] Blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

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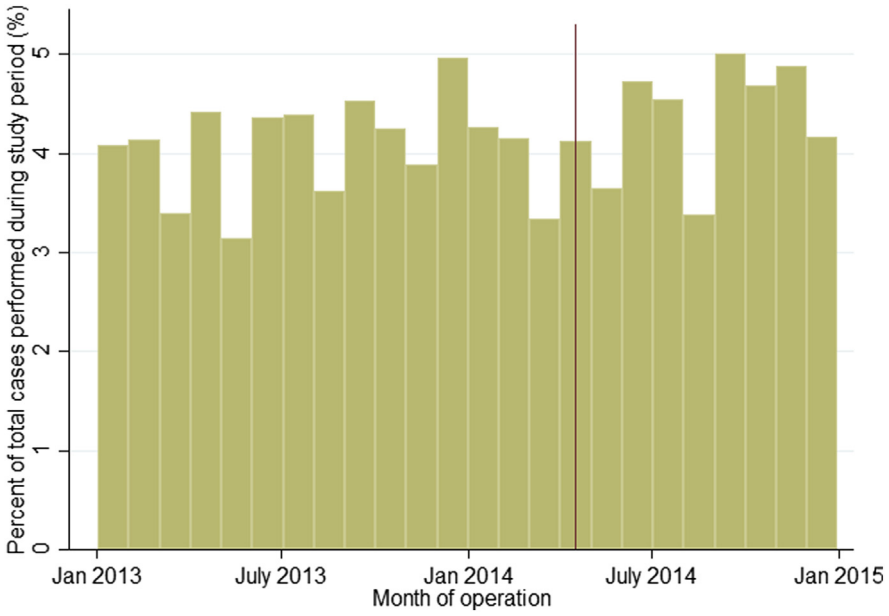
FIGURE 2
Percent of total hysterectomies performed during study period by month of operation



Vertical red line represents April 17, 2014, date of release of Food and Drug Administration safety communication.

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complications, length of stay, and improved satisfaction associated with minimally invasive hysterectomy.[2]

Our findings should be interpreted within the limitations of our study design. We examined only Michigan statewide hysterectomy data from 2013 through 2014, which may not be representative of providers in other regions or of patterns related to myomectomy procedures. Next, we only examined the first 8 months of data after the FDA safety communication. Additional communication from the press, medical professional organizations, regulatory bodies, device manufacturers, and health insurance companies may continue to affect the way patients and providers approach the management of fibroids, the uterine corpus, and the cervix at the time of hysterectomy. For instance, multiple health insurance providers have specified that they will not reimburse claims involving morcellation devices. Next, regardless of the strength of this quasiexperimental study design, we cannot prove causation, but can only suggest evidence for causation through temporal changes in practice patterns and complications immediately before and after the FDA communication. A true experimental design including randomized assignment is impossible due to the nature of such a public, regulatory communication, and other factors such as patient preference, surgeon preference, hospital policy, and procedure reimbursement may all be changing over time and were not measured or controlled for in this analysis. Even if the changes are due to the FDA safety communication, it may act as an initial shock that surgeons and patients will adjust to and return to previous patterns, or it may be a persistent change. This analysis does not include enough post-communication data to understand the long-term trends. Many readers would be interested in a comparison of the rate of diagnosis of occult malignancy before and after the date of the FDA safety communication release. Due to the low rate of occult malignancy in this cohort, the present study population was inadequately powered to be able to evaluate this research question. The sampling design of the Michigan Surgical Quality Collaborative database also precludes the possibility of estimating population rates of hysterectomy, and consequently estimating the effect on overall procedure volume after the FDA communication. Finally, this database does not collect reported use of power morcellation devices or laparoscopy with mini-laparotomy specimen extraction during procedures, so we are unable to report the rate of power morcellation or mini-laparotomy use during laparoscopic procedures before and after the FDA communication.

The present discussion in the public and in the medical community concerning power morcellation is remarkable in the history of gynecologic surgery.[27-35] In this setting, there are likely to be multiple, complex changes in how patients and surgeons approach managing uterine pathology over time. This study notes a temporal change in practice patterns, namely a decrease in laparoscopic hysterectomies and an increase in postoperative complications and readmissions, in a short time period after the date of the FDA safety communication release. We must strive to base our surgical decision-making on sound, evidence-based guidelines and continue to investigate ways to properly avoid cases of occult malignancy, decrease surgical morbidity to all patients, and measure patient-centered outcomes such as quality of life and satisfaction for women undergoing hysterectomy in the current practice context.

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Received June 30, 2015; revised Aug. 11, 2015; accepted Aug. 19, 2015.

Michigan Surgical Quality Collaborative database is funded by Blue Cross and Blue Shield of Michigan/Blue Care Network. Dr Harris is a Robert Wood Johnson Foundation Clinical Scholar at the University of Michigan. The Robert Wood Johnson Foundation and Blue Cross and Blue Shield of Michigan/Blue Care Network were not directly involved in study design, data acquisition and interpretation, manuscript preparation, or review. Any opinions expressed herein do not necessarily reflect the opinions of the Robert Wood Johnson Foundation.

The authors report no conflict of interest.

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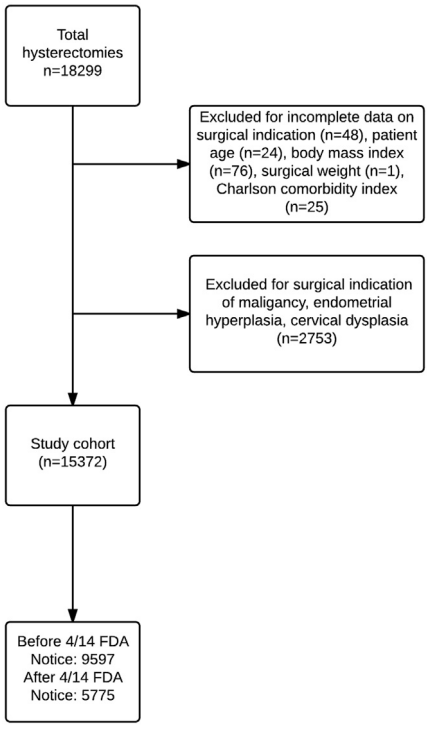
SUPPLEMENTAL FIGURE 1
Selection criteria flow diagram

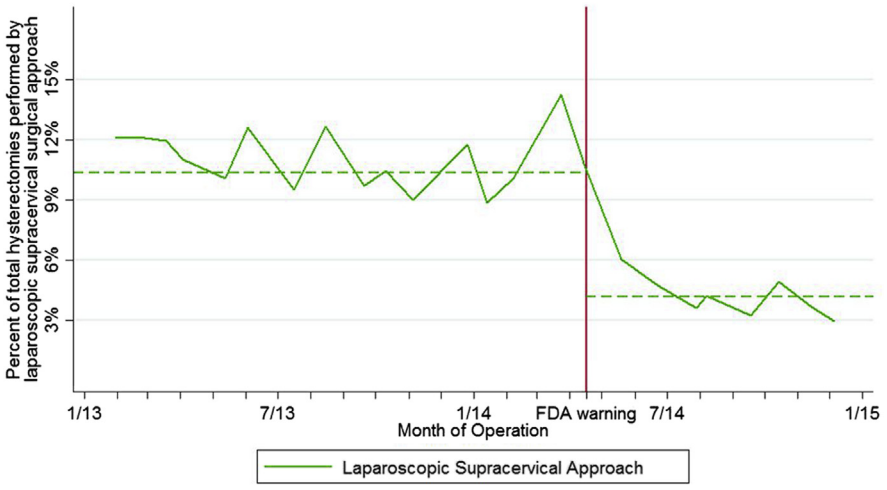


FDA, Food and Drug Administration.

Harris et al. FDA morcellation communication and surgical complications. Am J Obstet Gynecol 2016.

SUPPLEMENTAL FIGURE 2

Percent of total hysterectomies performed by laparoscopic supracervical approach during study period



Dashed lines are percent of total hysterectomies performed by laparoscopic supracervical approach before and after April 2014 Food and Drug Administration (FDA) safety communication. Vertical red line represents April 17, 2014, date of release of FDA safety communication.

Harris et al. FDA morcellation communication and surgical complications. Am J Obstet Gynecol 2016.

SUPPLEMENTAL TABLE 1

Postoperative complications before and after US Food and Drug Administration safety communication by operative approach

Postoperative complication	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597) Case-mix adjusted[a]	After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775) Case-mix adjusted[a]	*P* value
Abdominal (n = 3385)			
Major postoperative complications[b]	9.7%	10.2%	.596
Major postoperative complications[b] not including blood transfusions	3.3%	3.9%	.291
Hospital readmission	4.6%	6.1%	.112
Hospital reoperation	3.4%	3.4%	.957
Laparoscopic (n = 7759)			
Major postoperative complications[b]	2.7%	3.4%	.071
Major postoperative complications[b] not including blood transfusions	1.9%	2.6%	.048
Hospital readmission	3.1%	3.7%	.229
Hospital reoperation	1.6%	2.0%	.328
Vaginal (n = 3272)			
Major postoperative complications[b]	3.1%	3.1%	.944
Major postoperative complications[b] not including blood transfusions	1.8%	2.2%	.523
Hospital readmission	3.0%	3.6%	.422
Hospital reoperation	2.2%	2.3%	.849

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering; [b] Blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

Harris et al. FDA morcellation communication and surgical complications. Am J Obstet Gynecol 2016.

SUPPLEMENTAL TABLE 2

Postoperative complications before and after US Food and Drug Administration safety communication by primary surgical indication

Postoperative complication	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597) Case-mix adjusted[a]	After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775) Case-mix adjusted[a]	*P* value
Pelvic mass (n = 1400)			
Major postoperative complications[b]	9.9%	8.5%	.490
Major postoperative complications[b] not including blood transfusions	4.1%	3.9%	.856
Hospital readmission	4.7%	6.3%	.213
Hospital reoperation	3.8%	3.3%	.584
Family history (n = 1185)			
Major postoperative complications[b]	3.3%	4.5%	.249
Major postoperative complications[b] not including blood transfusions	2.0%	3.3%	.200
Hospital readmission	3.4%	5.9%	.090
Hospital reoperation	2.6%	2.6%	.959
Pelvic organ prolapse (n = 1576)			
Major postoperative complications[b]	2.0%	2.7%	.494
Major postoperative complications[b] not including blood transfusions	1.1%	2.0%	.183
Hospital readmission	2.8%	2.6%	.808
Hospital reoperation	1.9%	1.0%	.095
Pelvic pain/endometriosis (n = 1132)			
Major postoperative complications[b]	2.6%	3.4%	.430
Major postoperative complications[b] not including blood transfusions	1.6%	2.7%	.180
Hospital readmission	3.7%	4.3%	.692
Hospital reoperation	2.2%	3.0%	.483
Abnormal uterine bleeding/fibroids (n = 10,014)			
Major postoperative complications[b]	4.2%	4.9%	.153
Major postoperative complications[b] not including blood transfusions	2.2%	2.7%	.093
Hospital readmission	3.3%	3.9%	.180
Hospital reoperation	1.9%	2.3%	.291

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering; [b] Blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

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SUPPLEMENTAL TABLE 3

Postoperative complications before and after US Food and Drug Administration safety communication by operative approach

Postoperative complication	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597) Case-mix adjusted[a]	After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775) Case-mix adjusted[a]	*P* value
Laparoscopic, nonrobotic (n = 2009)			
Major postoperative complications[b]	3.4%	3.6%	.853
Major postoperative complications[b] not including blood transfusions	1.9%	2.4%	.469
Hospital readmission	3.0%	4.4%	.170
Hospital reoperation	1.8%	2.5%	.380
Laparoscopic, robotic (n = 7420)			
Major postoperative complications[b]	2.7%	3.4%	.066
Major postoperative complications[b] not including blood transfusions	2.1%	2.9%	.045
Hospital readmission	3.5%	3.9%	.461
Hospital reoperation	1.8%	1.9%	.719

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering; [b] Blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

Harris et al. FDA morcellation communication and surgical complications. Am J Obstet Gynecol 2016.

SUPPLEMENTAL TABLE 4

Postoperative complications before and after US Food and Drug Administration safety communication by uterine size

Postoperative complication	Before FDA safety communication (Jan. 1, 2013, through April 17, 2015) (n = 9597) Case-mix adjusted[a]	After FDA safety communication (April 18, 2015, through Dec. 31, 2015) (n = 5775) Case-mix adjusted[a]	*P* value
≥300 g Measured uterine mass (n = 2714)			
Major postoperative complications[b]	8.3%	8.4%	.936
Major postoperative complications[b] not including blood transfusions	2.9%	3.0%	.918
Hospital readmission	3.6%	4.1%	.595
Hospital reoperation	2.6%	1.9%	.315
<300 g measured uterine mass (n = 12,661)			
Major postoperative complications[b]	3.5%	4.2%	.084
Major postoperative complications[b] not including blood transfusions	2.0%	2.8%	.005
Hospital readmission	3.3%	4.3%	.017
Hospital reoperation	2.1%	2.4%	.346

FDA, Food and Drug Administration.

[a] Adjusted for age (continuous), Charlson comorbidity score (continuous), race (3 categories), body mass index (continuous), history of pelvic surgery, surgical indication (6 values), total relative value units of concurrent procedures, measure uterine specimen weight, hospital-level clustering; [b] Blood transfusion, vaginal cuff infection, pelvic abscess diagnosis, vaginal cuff dehiscence, ureteral obstruction, vesicovaginal fistula, ureterovaginal fistula, rectovaginal fistula, intestinal obstruction, central line infection, deep space surgical site infection, organ space surgical site infection, sepsis, pulmonary embolism, deep vein thrombosis requiring therapy, unplanned intubation, acute renal failure, cerebral vascular accident, myocardial infarction, cardiac arrest requiring cardiopulmonary, and death.

Harris et al. FDA morcellation communication and surgical complications. Am J Obstet Gynecol 2016.