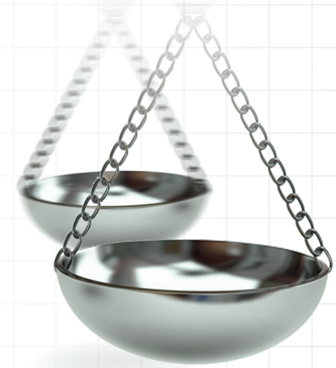
Research Article



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The impact of recent power morcellator risk information on inpatient surgery and patient outcomes

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Aim: We examine the impact of the new risk information about a surgical device on surgery and patient outcomes for hysterectomy in the inpatient setting. **Methods:** We utilize a difference-in-differences approach to assess the impact of new risk information on patient outcomes in the inpatient setting between 2009 and 2014. The inpatient data come from a nationally representative sample of hospitalizations in the USA. We use the likelihood of laparoscopic surgery, measures of resource use and surgical complications as outcome variables. **Results:** We estimate a three-percentage point decrease in the likelihood of receiving laparoscopic hysterectomy, a one-percentage point increase in the likelihood of experiencing a surgical complication and no impact on resource use, relative to pre-existing means. **Conclusion:** Our findings show that there was movement away from laparoscopic surgery in the months following the dissemination of new risk information. These changes had limited effect on patient outcomes.

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It is estimated that up to 80% of women develop uterine fibroids in their lifetime [1]. Uterine fibroids (leiomyomas) are noncancerous growths in the lining of a woman's uterus. The annual costs associated with treating and dealing with uterine fibroids are estimated to be as high as US$34.4 billion [2–4]. Women incur these costs because of symptoms such as excessive uterine bleeding, bladder dysfunction, pelvic pressure, infertility and complications in pregnancy, among others [5]. Because symptoms associated with this condition can be severe, some women elect to surgically remove their uterine fibroids. The most common surgical interventions are hysterectomies and myomectomies, the latter procedure typically performed on women who wish to preserve their fertility [6]. Less invasive types of these procedures, including laparoscopic techniques, were introduced in recent decades and have become increasingly popular [7]. Some of the cited benefits of minimally invasive techniques over traditional surgery, such as myomectomy or hysterectomy done through an abdominal incision, include lower complication rates and quicker recovery times [6].

Many minimally invasive, or laparoscopic, surgeries use power morcellator devices. These devices fragment tissue within the body cavity, allowing for the removal of large pieces of tissue through small incisions. However, there are health risks associated with the use of a laparoscopic power morcellator (LPM) during minimally invasive gynecological surgery. In women with unsuspected uterine sarcoma, a type of rare cancer of the uterus, the cutting action of LPM devices is associated with a risk of spreading and upstaging cancerous tissue within the abdomen and pelvis [8,9]. Uterine sarcoma is classified based on its initial location within the body. Leiomyosarcoma (LMS), the most common type of tumor found, grows on the wall of the uterus and can spread quickly [10]. Medical providers have difficulty preoperatively identifying cancerous tissue due to inadequate diagnostic methods and similarities in the clinical presentation of benign and cancerous tissues within the uterine fibroid [11]. Historically, this risk was thought to be low. For instance, Seidman *et al.* report that patients undergoing surgery were typically informed of a one in 10,000 risk of malignancy occurring with a diagnosis for benign uterine fibroids [12]. Recent US FDA research, however, suggests the prevalence of uterine sarcoma to be from 0.17% (1 in 580) to 0.44% (1 in 225) and for LMS to be between 0.09% (1 in 1100) and 0.20% (1 in 495) [13]. However, the American College of Obstetricians and Gynecologists states, 'there is no consensus' [14]. By comparison, other studies estimate the prevalence of LMS to be from 0.01% (1 in 10,000) to 0.20% (1 in 498) and for uterine sarcoma to be between 0.09% (1 in 1124) and 0.22% (1 in 464) [15–19]. Combined, these estimates correspond to a range of prevalence estimates between 0.01 and 0.44%, with a mean of 0.13%.

The new information on health risks generated controversy and a flurry of private and public responses meant to minimize exposure to accidental cancer dissemination. Beginning in December 2013, the Wall Street Journal published a series of articles about the risks of cancer dissemination from power morcellation [20,21]. In April 2014, the FDA began issuing a series of safety communications and guidance documents warning against the use of LPM devices during surgery to remove uterine fibroids. In these releases, FDA recommended that morcellator manufacturers include two contraindications and a boxed warning on their product labels [22–25]. Medical device manufacturers, medical providers and insurance companies also responded. Ethicon, a subsidiary of Johnson & Johnson and the largest manufacturer of LPM devices in the United States, withdrew its LPM products from the market in July of 2014 [26]. In 2014 major US hospitals began to update protocols and suspend gynecological procedures associated with LPM devices in their facilities [27,28]. Similarly, Aetna and other health insurers announced that they would stop covering procedures that used power morcellators [29–31].

Existing studies suggest that the impact of these responses led to a decrease in the prevalence of minimally invasive procedures, along with a corresponding increase in traditional abdominal surgery [7,32–35]. They also report mixed evidence of an impact on surgical complications [32,33]. Generally, these authors rely on before and after trends while using data drawn primarily from specific hospitals or hospital systems. Thus, their conclusions have limited causal interpretation and are not nationally representative.

To address these shortcomings, we use a difference-in-differences regression approach with a nationally representative sample of hospital discharges. Specifically, we compare inpatient stays for hysterectomy with a similar gynecological surgical procedure: oophorectomy, or the surgical removal of the ovaries. Our treatment period begins in April 2014, or the date of the initial FDA safety communication. While this is the treatment period used in the existing literature, it is roughly coincident with the responses from private entities summarized above. Consequently, our study is an attempt to estimate the net effect of private and public responses to the new risk information, which we also refer to in this paper as the 'dissemination of new risk information' or the 'morcellator risk controversy.'

The ultimate impact of the public and private actions on patient outcomes is uncertain because they may reduce the prevalence of minimally invasive surgery and associated benefits. We seek to answer two research questions. The first is whether the morcellator risk controversy influenced the prevalence of laparoscopic surgery for hysterectomy. The second is whether changes in surgical choice, if any, affected patient outcomes. Answers to these questions have important implications for patient welfare. For example, risk-averse patients and their providers may choose to forgo minimally invasive surgery in response to the new risk information. While decisions over surgical choice may succeed in limiting exposure to accidental dissemination of undetected uterine sarcoma, they may also result in a shift toward relatively invasive traditional surgeries. The consequences of this trade-off, and the ultimate impact on patient welfare, are empirical questions.

Methods

Data

To address potential shortcomings in this literature, we investigate the impact of the new risk information on a nationally representative sample of hysterectomies. Because we aim to evaluate whether the new risk information affects surgical choice, and whether changes in these choices affect patients, the data should include detailed information on procedures and patient outcomes. Consequently, we use data from the 2009 to 2014 waves of the Nationwide/National Inpatient Sample (NIS), which is part of the Healthcare Cost and Utilization Project (HCUP) produced by Agency for Healthcare Research and Quality (AHRQ). The NIS is the largest publicly available all-payer inpatient health care database in the US. The data are at the discharge level, and when weighted represent more than 35 million annual hospitalizations nationally. These data are de-identified and includes other safeguard to protect the privacy of individual patients, physicians and hospitals. This study conforms to the principles of the Declaration of Helsinki.

We do not assess the accuracy of the NIS data. However, we note that the data are used in peer-reviewed scientific literature analyzing national trends in healthcare utilization, resource use and outcomes, including the surgical procedures examined in this study [36]. See for example, Wright *et al.*, Lee *et al.*, Desai *et al.* and Piedimonte *et al.* [37–40].

Our sample includes hospital discharges of females aged 18 years and older with a procedure code for either hysterectomy or oophorectomy. Procedure codes in the NIS are based on the International Classification of Diseases 9th Revision (ICD-9) diagnosis and procedure classification system. Oophorectomies are identified using the ICD-9 procedure codes 65.31, 65.39, 65.41, 65.49, 65.51 to 65.54 and 65.61 to 65.64. Hysterectomies are identified with ICD-9 procedure codes 68.31, 68.39, 68.41, 68.49, 68.51, 68.59, 68.61, 68.69, 68.71, 68.79 and 68.9. A list of these procedure codes and their descriptions are summarized in Supplementary Table 1. HCUP NIS data includes patients who undergo myomectomy. However, we focus on hysterectomy and oophorectomy as treatment and control groups, respectively, because these procedures have separate codes for laparoscopic and non-laparoscopic procedures. We do not separately identify discharges with robotic assisted laparoscopic procedures (ICD-9 codes 17.4x). By itself, these codes are not related to either hysterectomy or oophorectomy and may instead be associated with another procedure on the discharge record.

We use other data sources to supplement the main NIS files. These include cost ratio data from the HCUP NIS Cost-to-Charge Ratio files, which we use to convert hospital charges to hospital costs. Converting charges to costs is necessary, as charges capture the amount that hospitals bill for services but do not reflect resource use or the amount received by the hospital in payment. The cost-to-charge ratio is calculated annually for each hospital using hospital-specific accounting reports by the Centers for Medicare & Medicaid Services. The NIS also provides the All Patient Refined Diagnosis Related Groups (APR-DRG) mortality and severity measures, which we use to investigate underlying changes in the population of patients receiving hysterectomy or oophorectomy. Finally, we use consumer price index and population data from the US Census Bureau to adjust costs for inflation and estimate incidence rates.

All analyses were performed using Stata SE 13.1 (StataCorp, TX, USA).

Methodology

To expand upon the empirical methods used in the existing medical literature, we use data from both before and after the dissemination of new risk information. We also identify a control group similar to hysterectomy, or the treatment group. This approach closely aligns with a standard difference-in-differences empirical methodology, allowing us to plausibly identify the causal impact of the new risk information on surgical choice. A difference-in-differences approach also controls for some sources of bias. For instance, an increasing coincident trend of open surgeries being replaced with robotic-assisted laparoscopic procedures may bias our estimates of surgical choice. However, if this trend is similar across the treatment and control groups then the true effect of the controversy on surgical choice is preserved. The specification of interest is Equation (1) below:

$$y_{ht} = \alpha + \beta_1 \; (post * allhyster)_{ht} + \beta_2 allhyster_{ht} + X'\delta + e_{ht}. \qquad \text{(Eq. 1)}$$

In Equation (1), *h* denotes an inpatient visit and *t* represents the month-year in which the patient was admitted to the hospital. *X* is a set of patient and hospital controls that includes patient age, patient ethnicity, patient insurance coverage and hospital group fixed effects. The hospital groups are explained in more detail later in this subsection, but these measures include information on teaching hospital status, rural or urban hospital location, and hospital ownership. We estimate equation (1) using cluster robust standard errors at the hospital group level. In addition, all regression estimates account for survey weights provided in the NIS data.

The set of outcomes, y_{ht}, measures surgical choice, resource use and patient outcomes related to the dissemination of the new risk information. Medical providers who are sufficiently risk averse may respond to this new information by limiting or eliminating the use of laparoscopic hysterectomy and performing more traditional surgeries instead. Patients receiving these procedures, rather than minimally invasive surgery, may experience additional surgical complications and longer recovery times. This, in turn, may generate additional medical resource use as hospitals respond to longer inpatient stays and additional medical services incurred by relatively invasive surgeries. To investigate these impacts, we define y_{ht} as one of six primary outcomes. These outcomes are:

- a binary indicator for laparoscopic surgery;
- length of stay (LOS), measured in days;
- total medical costs, measured in dollars;

- a binary indicator for the presence of a surgical complication diagnosis code;
- the number of surgical complications; and
- the number of procedures performed during the inpatient stay.

We classify the following ICD-9 diagnosis codes as complications: all codes beginning with 997 (nervous system complications) or 998 (other complications of procedures not elsewhere classified such as postoperative shock, hemorrhage, accidental puncture), 285.1 (acute post hemorrhagic anemia), 512.1 (iatrogenic pneumothorax), 780.62 (postprocedural fever), 995.91 and 995.92 (sepsis and severe sepsis, respectively). These codes are adapted from similar classifications by Mannschreck *et al.* and Rosero *et al.* [41,42]. Multinu *et al.* define these types of complications as major complications [34].

Oophorectomy is often performed at the time of hysterectomy for benign disease. Jacoby *et al.* and Lowder *et al.* estimate that half of hysterectomies involve oophorectomy [43,44]. Thus, we define allhyster_{ht} as a binary indicator equal to one if the discharge record indicates a procedure code for hysterectomy, even if that discharge is also associated with an oophorectomy code. The control group ($\text{allhyster}_{ht} = 0$) includes hospitalizations associated with an oophorectomy code but without hysterectomy. The binary variable post_{ht} is equal to one if the patient's admission to the hospital occurred on or after April 2014. This date corresponds with the publication of the initial FDA safety communication, approximating the period when the new risk information became widely disseminated. Finally, we interact allhyster_{ht} with post_{ht} to form the difference-in-differences variable of interest, $(\text{post*allhyster})_{ht}$. The coefficient of this variable is $\widehat{\beta}_1$, which represents the average estimated effect of the new risk information on the outcome variables. This includes all responses on or after April 2014, including the publication of an additional safety communication and box warning by the FDA in November of that year.

Two recent changes have impacted the NIS data, affecting both the methodology and sample chosen for this study. First, The NIS underwent a redesign in 2012 which removed unique hospital identifiers across time. This prevents us from using standard errors clustered at the hospital level or controlling for hospital fixed effects in a regression analysis. To resolve this issue, we use data in the NIS on hospital characteristics to create a hospital group identification variable for the years 2009 to 2014. This variable identifies unique combinations of hospitals based on US Census division, bed size category, ownership type, rural or urban location, and teaching status. This results in 219 unique hospital groups as compared with approximately 4400 unique hospitals in the 2014 HCUP NIS. We compared the results of analyses using pre-2012 data using hospital groups and hospital fixed effects separately. The results show that hospital groups capture almost as much variation as hospital fixed effects and that the standard errors are similar in each analysis. The magnitude of the estimated coefficients varied little under each of the scenarios. Finally, the NIS data set switched to ICD-10 medical classification codes in 2015. This impacts our ability to compare hospital discharges across time. For this reason, our analysis focuses on the waves of the NIS between 2009 and 2014.

There are two significant threats to the validity of this difference-in-differences approach that we must address for the results to be interpreted as causal. First, identification requires parallel trends in the dependent variables for both treatment and control groups. This condition may be violated if there is an unobserved shock correlated with the provision of new risk information. We use two methods to address this first concern. For the first method, we present graphical evidence of parallel trends in the dependent variables between the treatment and control groups. For the second method, we formally test whether treatment and control group trends are similar using an event history approach. To do so, we estimate a modified version of Equation (1). This equation, shown as Equation (2) below, includes leads and lags of the key difference-in-differences variable post*allhyster.

$$y_{ht} = a + \sum\nolimits_{k=-9}^{2} (quarter\_year_k) * allhyster_{ht} + allhystewr_{ht} + \sum\nolimits_{k=-9}^{2} (quarter\_year_k) + X'\delta + e_{ht} \quad \text{(Eq. 2)}$$

Equation (2) estimates leads and lags that are divided into quarter-year time periods. The set of quarter-year dummies was chosen to keep a parsimonious model and facilitate interpretation of the results. However, we obtain qualitatively similar results when we estimate a specification using month-year time periods instead. We estimate Equation (2) with nine quarter-year leads in the period immediately before April 2014, beginning with the first quarter of 2012 and ending with the first quarter of 2014. In addition, we estimate the effect of the quarter-year

Table 1. Weighted summary statistics.

Variable description	(1) Overall sample	(2) All-hysterectomy (treatment)	(3) Only-oophorectomy (control)	(4) p-value
Laparoscopic procedures (%)	28.00	28.00	25.00	0.00
Length of stay (days)	2.89	2.67	4.38	0.00
Cost (2009 US$)	9,575.27	9,134.18	12,035.11	0.00
Surgical complications (%)	7.00	7.00	7.00	0.00
Number of surgical complications	0.17	0.16	0.24	0.00
Number of procedures	3.22	3.20	3.39	0.00
Number of diagnoses	6.58	6.43	7.60	0.00
Age (years)	48.80	48.83	48.59	0.23
Public insurance (%)	29.00	28.00	39.00	0.00
African–American (%)	16.00	17.00	14.00	0.00
Teaching hospital (%)	52.00	51.00	55.00	0.00
Rural hospital (%)	11.00	11.00	10.00	1.00
Not-for-profit private hospital (%)	73.00	73.00	73.00	79.00
Charlson score	0.87	0.81	1.26	0.00
Number of AHRQ comorbidities	1.23	1.20	1.42	0.00
APR-DRG mortality risk	1.18	1.15	1.38	0.00
APR-DRG severity	1.48	1.44	1.75	0.00
Observations	407,697	354,966	52,731	

p-value is for the difference in means between the treatment and control samples.
Sources: Authors' analysis of the NIS, which is part of the HCUP produced by AHRQ.
AHRQ: Agency for Healthcare Research and Quality; APR-DRG: All Patient Refined Diagnosis Related Group; HCUP: Healthcare Cost and Utilization Project; NIS: Nationwide/national inpatient sample.

coincident with April 2014 (quarter two of 2014, or $quarter\_year_0$) as well as the third and fourth quarter-years in 2014. These effects should be interpreted relative to the 2009 to 2011 period, since the quarter-year effects from this period are not included in Equation (2). Statistically significant leads would indicate a differential trend in the any-hysterectomy treatment group relative to only-oophorectomy and would raise doubts about the validity of our empirical approach.

Another threat to validity involves changes in hospital admissions behavior and patient composition that are coincident with the treatment. Medical providers and hospitals may respond to the new risk information by admitting fewer patients who would normally be candidates for morcellation, or by encouraging the use of nonsurgical treatments. Consequently, estimates of the effect of the new risk information may reflect a change in the mix of patients receiving hysterectomy rather than a shift from laparoscopic to traditional surgery. To evaluate this concern, we estimate Equation (1) using a second set of outcome variables. These variables include the total number of diagnoses on the discharge record, aggregate measures of comorbid conditions and other variables meant to capture mortality risk and disease severity such as the Charlson score, AHRQ comorbidity index, APR-DRG mortality index and APR-DRG severity index. Their use is motivated by Kolstad and Kowalski [45].

The Charlson score measures mortality risk based on the presence of comorbid disease [46]. We use the Charlson module for the Stata statistics and data analysis software to derive the Charlson score for each discharge record [47]. The comorbid conditions included in the APR-DRG indices are, among others, congestive heart failure, hypertension, chronic pulmonary disease, diabetes, hypothyroidism, renal failure, liver disease, peptic ulcer disease, lymphoma, metastatic cancer, solid tumor without metastasis, obesity, weight loss, alcohol abuse, blood loss anemia, drug abuse, psychoses and depression. These measures are meant to capture changes in patient mortality risk, disease severity and comorbid conditions. Apart from the Charlson score, these measures are provided in the HCUP NIS data.

Results

Main results

Table 1 presents summary statistics for the analytical sample, and separately for the treatment and control groups.

Table 2. Difference-in-difference estimates of the impact of new risk information on laparoscopic procedures, length of stay, hospitalization costs, surgical complications and number of procedures.

	(1) Probability of laparoscopic procedure	(2) Natural log of length of stay (LOS)	(3) Natural log of hospitalization cost	(4) Probability of surgical complication	(5) Natural log of surgical complications	(6) Natural log of number of procedures
Post*all-hysterectomy	-0.030‡	0.016	0.012	0.011†	0.007	0.065‡
	(0.010)	(0.011)	(0.009)	(0.005)	(0.006)	(0.009)
Mean	0.279	2.858	US$9,499.49	0.064	0.166	3.192

†$p < 0.05$.
‡$p < 0.01$; standard errors in parentheses. Where indicated, SE are clustered at the hospital group level. Sample includes hospitalizations associated with hysterectomies and oophorectomies performed between 2009 and 2014 (n = 407,697). All regressions account for survey weights, and include age, age squared, indicator for if patient is African–American, or has public health insurance, and hospital group fixed effects. Mean denotes the mean (in levels) of the dependent variable in each specification prior to April 2014. Sources: Authors' analysis of the NIS, which is part of the HCUP produced by AHRQ.
AHRQ: Agency for Healthcare Research and Quality; HCUP: Healthcare Cost and Utilization Project; NIS: Nationwide/national inpatient sample; SE: Standard errors

After applying the survey weights, the sample contains 407,697 observations. Just over a quarter of the sample had a laparoscopic procedure. Overall, discharges in the only-oophorectomy group are associated with longer inpatient stays, higher costs and a greater number of surgical complications and procedures relative to the treatment group. The average length of stay for the control group, shown in column (3), is approximately 4.4 days, almost two full days longer than the average stay length for all-hysterectomy. The estimated mean of hospitalization costs in the control group is US$12,035, while the mean costs in the treatment are US$9,134. While the incidence of surgical complication is similar across both groups, approximately 7%, the average number of complications per discharge is significantly higher in the control group. The mean number of procedures and diagnoses is also greater in the control. This suggests that patients admitted for only-oophorectomies received relatively intensive medical services during their inpatient stays, perhaps reflecting a greater disease severity or number of medical conditions. Confirming this observation are the mean comorbidity measures found on the bottom of Table 1 . The mean score for each of these measures is higher in the control group, suggesting that patients admitted for only-oophorectomy have a more severe set of medical conditions than all-hysterectomy patients. We include patient characteristics variables in our regression to control for observable differences between treatment and control groups.

Table 2 presents results for the six outcomes controlling for age, public health insurance, ethnicity and hospital group fixed effects. For all specifications the estimated coefficient of interest is *Post*All-Hysterectomy*. In column (1) the estimated coefficient implies that the likelihood of laparoscopic surgery declined 3 percentage points and is statistically significant at the 1% level. Relative to the pre-controversy mean of 28%, this estimate is equivalent to a 10.7% ([0.03/0.28]*100) decline in the percent of women receiving laparoscopic hysterectomy.

The results from column (2), where the dependent variable is the natural log of LOS, show an estimated coefficient of interest that is positive but statistically insignificant. Similarly, in column (3), the estimated coefficient is statistically insignificant, suggesting the new information did not impact hospitalization costs. The results of column (4) show that the probability of experiencing a surgical complication during hysterectomy increased 1.1 percentage points (exp [0.011]-1), or 17.2% (0.011/0.0639) of the precontroversy mean of 6.39%, due to the new risk information. This estimate is statistically significant at the 5% level. Results for the number of surgical complications, shown in column (5), indicate little evidence that the morcellator risk information changed the number of complications experienced during hysterectomy, even if it increased the likelihood that a complication might occur. Finally, column (6) shows that there is a significant positive relationship between the new risk information and the number of procedures performed during an inpatient stay. These estimates are large in magnitude, with the estimate corresponding to a 6.7 percentage point increase in the number of procedures (exp [0.065]-1) from the precontroversy mean.

Examining pre-existing trends in the dependent variables

An important assumption underlying difference-in-differences estimation is that there are no pre-existing trends that can explain the estimated impacts. One way to assess this is by estimating the impact of the new risk information as the controversy evolved, both before and after April 2014, on the outcomes of interest. These trends are shown in Supplementary Figure 1. The top panel of this figure shows trends in the rate of laparoscopic surgery for each group. These trends provide visual evidence that treatment and control group trends are similar, with both

Table 3. Estimates of the impact of new risk information on number of diagnoses, comorbidities, mortality risk and disease severity.

	(1) Number of diagnoses	(2) Charlson score	(3) AHRQ comorbidity index	(4) APR-DRG mortality	(5) APR-DRG severity
Post*all-hysterectomy	-0.006	-0.031	0.017	0.002	0.020
	(0.011)	(0.032)	(0.023)	(0.010)	(0.013)

†$p < 0.05$.
‡$p < 0.01$; standard errors in parentheses. SEs are clustered at the hospital group level. Sample includes hospitalizations associated with hysterectomies and oophorectomies performed between 2009 and 2014 (n = 407,697). All regressions account for survey weights, and include age, age squared, indicator for if patient is African–American, or has public health insurance, and hospital group fixed effects.
Sources: Authors' analysis of the NIS, which is part of the HCUP produced by AHRQ.
AHRQ: Agency for Healthcare Research and Quality; APR-DRG: All Patient Refined Diagnosis Related Group; HCUP: Healthcare Cost and Utilization Project; NIS: Nationwide/national inpatient sample; SE: Standard errors.

groups experiencing declines in the prevalence of laparoscopic surgery prior to April 2014. The bottom panel of Supplementary Figure 1 shows trends for the number of procedures on the discharge record. These trends are not parallel, with the control group trend increasing relative to the treatment group throughout much of the period before April 2014. Dependent variable trends in the remaining panels of Supplementary Figure 1 are similar across treatment and control groups.

We further assess the validity of the parallel trends assumption using Supplementary Figure 2, which presents the estimated coefficients and corresponding CIs for each of the outcomes using Equation (2) and controlling for patient characteristics and hospital group fixed effects. Unlike the trends in Supplementary Figure 1, which present unconditional means, the results shown in Supplementary Figure 2 incorporate underlying characteristics that may drive differences between the control and treatment groups. Panel A of Supplementary Figure 2 shows that most of the estimated leads for laparoscopic hysterectomy are small and statistically insignificant. Although the entire set of estimated leads are jointly significant (F = 2.94; p-value = 0.0026), the four lead coefficients in the year prior to the second quarter of 2014 are not jointly significant. This suggests that treatment and control group trends in laparoscopic surgery were similar in the year before April 2014.

Examining potential changes in the underlying inpatient population

Table 3 presents the results of specifications where the dependent variable is a measure of disease severity, mortality risk, or comorbid conditions. Each regression in this table is the same as those in Table 2 except for the dependent variables. Column (1) of Table 3 indicates a statistically insignificant relationship between the controversy and the number of diagnosis codes. Similarly, when the dependent variable is the Charlson score, the estimated coefficient is statistically insignificant. The estimated coefficients in columns (3–5) where the dependent variable is AHRQ comorbidity index, APR-DRG mortality orAPR-DRG severity are also statistically insignificant. With these results we rule out the possibility that our main estimates reflect a change in the mix of patients receiving hysterectomy.

Discussion

The dissemination of new risk information can have important public health implications. The risks associated with the morcellation of potentially cancerous tissue may have encouraged providers and patients to undergo relatively invasive surgeries to remove benign uterine fibroids. These surgeries involve a trade-off: they reduce exposure to accidental dissemination and upstaging of cancer, but do not provide the potential benefits of minimally invasive surgery.

Using a difference-in-differences methodology, we find evidence that the probability of receiving a laparoscopic hysterectomy decreased about 3 percentage points (or 10.7%) from the pre-controversy mean percentage of laparoscopic hysterectomies due to the new risk information. This result is lower than estimates of 4 percentage points and 6.8 percentage points by Barron *et al.* and Harris *et al.*, respectively [32,33]. Although we do not find evidence that hospitalization costs or length of stay changed, our results suggest that the likelihood of experiencing a surgical complication increased about 1.1 percentage points (or 17.2%) from the pre-controversy mean of 6.39%. This estimate is similar in magnitude to the 0.8 percentage point increase in major post-operative complications reported by Harris *et al.* and Multinu *et al.* [33,34]. Our final finding, the statistically significant increase in number of procedures, is likely spurious due to the differential trend in the months prior to April 2014.

These findings suggest that some medical providers and their patients moved away from laparoscopic surgery in the months following the power morcellator risk controversy, and they did so with limited effect on patient outcomes. Risk-averse providers may have acted this way to limit their legal liability. Recent studies argue that medical providers and surgeons stopped or limited their use of power morcellators to avoid potential legal consequences or to comply with a hospital-wide ban [48,49]. Similarly, risk-averse patients may have elected for relatively invasive procedures out of concern of the cancer risks associated with laparoscopic surgeries.

We conduct a back of the envelope calculation to assess the risks and benefits associated with the estimated impacts of this trade-off. Wright *et al.* report that there were about 433,000 hysterectomies performed in the inpatient setting in the USA in 2010 [39]. In this study, we estimate a decline of 10.7% in laparoscopic procedures and that 28% of all hysterectomies were laparoscopic procedures before the controversy; these estimates suggest there were 12,990 (433,000*0.27*0.107) fewer laparoscopic procedures performed after the controversy. The risk of spreading unsuspected uterine sarcoma or LMS in patients undergoing uterine morcellation has been estimated to range between 0.01 and 0.44% [10,12,13,14–18,23,50]. These risk estimates imply a range of 1 (12,990*0.01) and 58 (12,990*0.44) cases of cancer upstaging or dissemination that did not occur due to the decline in laparoscopic surgery. In addition, we know the prognosis of uterine LMS is poor with about 40–66% survival at 5 years [51]. More specifically, the Surveillance, Epidemiology and End Results (SEER) data for 2008–2014 show the 5-year relative survival rate for LMS was 41% for all stages combined; 13% for stage IVB, 35% for stages II, III and IVA, and 64% for stage I cancers [52].

Using 2018 value of statistical life (VSL) estimates ranging from US$4.6 to US$15.1 million and a mean value of US$9.9 million, if the morcellator risk controversy prevented half of these cases from a fatal outcome, they would translate into 1 to 29 preventable deaths, valued at between US$4.60 million (one case*US$4.6 million/case) and US$438 million (29 cases*US$15.1 million/case) [53]. These estimates do not account for discounting medical costs, or morbidity and quality of life impacts associated with late stage cancer. For example, Guest *et al.* estimate a utility weight of 0.33 for female patients with advanced soft tissue sarcoma [54,55]. Hanmer *et al.* estimate that the mean utility for a woman age 40–59 is 0.863 [56]. Assuming the duration of the condition is 5 years, there would be approximately 2.665 life years gained per avoided case. Using cost per quality-adjusted-life-year (QALY) of US$240,000 and US$770,000, the avoided morbidity costs could range between US$0.13 million (1*0.533*5*240,000) and US$23.80 million (58*0.533*5*US$770,000). In addition, Felix *et al.* indicate that treatment of invasive cervical cancer can be up to US$110,000 [55]. This would translate into medical costs between US$0.11 million (1*110,000) and US$6.38 million (58*110,000). Consequently, the estimates of between US$4.60 million and US$438 million represent a lower bound of the benefits associated with the impacts of the morcellator risk controversy.

Our analysis indicates that neither hospitalization costs nor length of stay increased because of the controversy. However, there could be a potential loss in quality of life for patients who experienced a complication due to the decline in laparoscopic surgery. Our estimates suggest there was a 17.2% increase in surgical complications, which implies as many as 4763 additional procedures may have been associated with a surgical complication (433,000*0.0639*0.172, where 6.39% denotes the surgical complication rate before the controversy). Using the difference in utility weights between hysterectomy with and without complications of 0.07, we estimate a value of the change in quality of life to be between US$80 million (US$240,000*0.07*4763) and US$257 million (US$770,000*0.07*4763). To do so we utilize the difference in utility weights of 0.07 between a hysterectomy with and without complications (0.56 vs 0.49) as presented in Miller *et al.* and using a value of a QALY between US$240,000 and US$770,000 using a 3% discount rate [57]. There may also be additional costs associated with having a different type of procedure other than a laparoscopic hysterectomy. However, we do not have enough information to monetize this cost. Fitch *et al.* report an estimated difference of US$1270 between inpatient open hysterectomy and outpatient laparoscopic hysterectomy [58].

Overall, these calculations suggest that the monetized benefit associated with preventing the risk of spreading uterine LMS are likely to exceed the costs of reducing laparoscopic surgery.

Limitations

There are several limitations to our empirical approach. Because our empirical method compares hysterectomies with oophorectomies, we cannot determine the specific surgical treatments that changed in prevalence. Our analysis also includes information on hysterectomies for all gynecologic indications, benign or otherwise. Consequently, we may underestimate the true impacts on patients with benign uterine fibroids because our estimates include treatments unaffected by the morcellator risk controversy. Given the nature of how the risk information was disseminated, our estimates represent the net effect of the private and public responses that led to the observed changes in surgical choice and cannot be attributed to any single response. In addition, this study does not investigate potential behavioral spillovers into other surgical procedures. That is, our results cannot be used to speak about any, if any, impacts to other surgical procedures that are performed laparoscopically.

Because our data ends in 2014, we do not analyze longer-term responses to the controversy. Recent research suggest that the short-term and long-term impacts may be different [59]. The use of hospital discharge data also limits the degree to which our results generalize to specific populations and practices. By design, the NIS does not contain information from the outpatient setting, where more than 40% of hysterectomies are performed [60–62]. This study is nationally representative of all inpatient visits, and recent research has shown that changes in surgical choice were more pronounced in the inpatient setting than the outpatient setting [63]. Finally, we also do not have information on medical devices used during each inpatient stay. This limits our ability to make any inferences about how the use of these devices changed. Because risk-averse patients and providers may choose to forgo minimally invasive surgery entirely in response to the new risk information, it is our view that surgical choice is the preferred outcome of interest in this study. This outcome allows us to investigate the possible public health impacts and trade-offs of a shift toward relatively invasive traditional hysterectomy procedures.

Conclusion

Our back of the envelope calculations suggests that the initial responses to the morcellator risk information were beneficial to patient welfare. The monetized benefit associated with reducing the likelihood of cancer dissemination and mortality likely exceeded the costs of increases in surgical complications. Whether the impacts estimated in this paper are merely transitory or long-lasting may have important implications for the prevalence of minimally invasive gynecological surgery, as well as the surgical outcomes for the women who undergo these procedures.

Future perspective

In the future, the behavioral responses estimated in this study may change as information regarding the cancer risks of uterine fibroids and power morcellation continues to evolve and promulgate. Providers, for instance, may adopt new practices or use different devices that facilitate laparoscopic surgery without the risk of cancer dissemination. Manufacturers may innovate and produce new alternative medical products. For example, the use of medical devices with tissue containment systems that facilitate the morcellation of tissue within a sealed bag may become more prevalent.

The morcellator controversy is just one recent example of new or updated risk information for a medical device. Recent actions by the FDA, for instance, indicate continued efforts by policy makers to reassess available evidence on the safety and effectiveness of medical devices. Some recent examples include an April 2019 order by the FDA requiring manufacturers of urogynecologic surgical mesh implants to stop selling and distributing their products [64]. There has also been a growing discussion about the relationship between breast implants and anaplastic large cell lymphoma [65]. Because such actions necessarily involve costs, including direct costs of enforcement and potential

Summary points

- In 2014, new information about the risk associated with the use of laparoscopic power morcellators during surgery to remove uterine fibroids became available.
- The FDA issued a series of safety communications warning against the use of morcellation to remove uterine fibroids for certain patient populations.
- The FDA warnings raised questions about patient outcomes and trade-offs from moving from minimally invasive surgery to more invasive options.
- The likelihood of laparoscopic hysterectomy declined 3 percentage points following the new information and recommendations on the risk of use of laparoscopic power morcellators.
- There was no difference in the length of hospital stay or medical costs due to the morcellator controversy.
- Surgical complications increased by over 1 percentage point following the morcellator controversy.
- There is no evidence that the results are driven by a change in the patient mix as captured by various measures of disease severity, mortality risk or comorbid conditions.
- In 2014, the monetized benefits of averting disease outcomes likely exceeded the costs of reducing laparoscopic surgery.

loss of beneficial medical therapies, it is critical to evaluate private and public responses to new medical risk information. Doing so allows researchers and the public to determine the extent to which such actions improve the welfare of patients and society. These are areas for future research.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/cer-2019-0093

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Both authors are employees of the agency that regulates the use of medical devices (US FDA). The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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