Trends in Mode of Surgery for Benign Hysterectomy Relative to FDA Power Morcellation Recommendations

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Introduction: In April and again in November, 2014, the U.S. Food and Drug Administration issued a safety recommendation warning against the use of power morcellators in women with uterine fibroids due to concerns of spreading occult malignant tissue in the peritoneal cavity during morcellation.

Methods: This study is a retrospective review of all patient charts who underwent a hysterectomy for benign indications at Brigham and Women's Hospital in Boston MA, USA from 2013-2015. Patients were identified from hospital coding records and clinical data extracted from electronic medical records. The rates of abdominal, vaginal, laparoscopic and robotic-assisted laparoscopic hysterectomy, as well as the rates of post-operative complications, 60-day readmissions, reoperations and length of stay, were compared over the study period. Postoperative complications were classified using the Clavien-Dindo complication rating. Analysis was performed using multivariable linear, multinomial and logistic regression. Regression models were adjusted for potential confounders.

Results: From 2013 to 2015, 1530 patients underwent benign hysterectomies. There was a slight but non-statistically significant change in the mode of hysterectomy over time. Comparing 2013 to 2015, abdominal hysterectomy increased by 4.4% (12.9% vs. 17.3%), vaginal hysterectomy increased by 1.2% (17.9% vs. 19.1%), laparoscopic hysterectomy decreased by 6.2% (66.1% vs. 59.9%), and there was little change in the frequency of robotic-assisted laparoscopic hysterectomy. From 2013 to 2015 there was a significant decrease in supracervical hysterectomy, by 16.2%. Both 2014 and 2015, when compared to 2013, showed significantly shorter operating room (OR) times and shorter length of stay but an increase in estimated blood loss (47 vs. 56 mL, p=0.05). Additionally, the cases in 2014 were associated with fewer post-operative complications compared with 2013 but there was no significant difference between the year of surgery and incidence of intraoperative complications, readmission or reoperation.

Conclusion: We did not observe a significant shift in the mode of hysterectomy or perioperative outcomes at our institution following the FDA's 2014 safety recommendations regarding morcellation, although the rate of supracervical hysterectomy did decrease markedly. With changing practice patterns and vigilance surrounding power morcellation, gynecologic surgeons may still offer patients minimally invasive procedures with all of the accompanying advantages.

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Abbreviations

AH	Abdominal hysterectomy
BMI	Body mass index
EBL	Estimated blood loss
FDA	Food and Drug Administration
FIGO	Fédération Internationale de Gynécologie et d'Obstétrique
LAVH	Laparoscopic-assisted vaginal hysterectomy
LH	Laparoscopic hysterectomy
LMS	Leiomyosarcoma
MIGS	Minimally invasive gynecologic surgery
NIS	Nationwide inpatient sample
OR	Operating room
VH	Vaginal hysterectomy

1 Introduction

Hysterectomy is the surgical operation to remove the uterus. It is the most common procedure among non-pregnant women in the United States with about 400,000 women undergoing inpatient hysterectomy annually.[1] Mode of hysterectomy can be broadly categorized into four approaches: abdominal hysterectomy, vaginal hysterectomy, laparoscopic hysterectomy and robotic-assisted laparoscopic hysterectomy.[2]

1.1 Prevalence

A cross-sectional analysis of the 2009 Nationwide Inpatient Sample (NIS) found that about 480,000 women underwent hysterectomy in the United States in 2009, 86.6% of these hysterectomies were performed for benign indications. Of the hysterectomies performed for benign indications, 56% were performed abdominally, 20.4% laparoscopically, 18.8% vaginally and 4.5% robotically. When compared to previous years, there is a marked decrease of procedures from year to year and a marked shift in mode of surgical approach.[3] In an analysis of the 2003, NIS 602,000 women underwent a hysterectomy. Of those hysterectomies performed for benign indications, 66.1% were performed abdominally, 21.8% vaginally and 11.8% laparoscopically.[4] A study done at Brigham and Women's found that in 2009, 35.8% of hysterectomies were performed abdominally and 46% laparoscopically. In 2006, 64.7% of hysterectomies at Brigham and Women's Hospital were performed abdominally and 17.7% laparoscopically. There is a significant decrease in the abdominal approach from 2006 to 2009 by 28.9% and a significant increase in the laparoscopic approach. The total number of hysterectomies performed remained stable with 1,054 surgeries in 2006 and 1,079 in 2009. Brigham and Women's Hospital has a specific Minimally Invasive Gynecologic Surgery Division which may explain why more hysterectomies are performed laparoscopically there than on a nation-wide basis.[5]

1.2 Indications

Leiomyomas, commonly known as fibroids, are the leading indication for hysterectomy and they are associated with abnormal bleeding, bulk related symptoms and dysmenorrhea. A leiomyoma is a benign tumor that arises from overgrowth of smooth muscle and connective tissue in the uterus. Endometriosis, adenomyosis, uterine prolapse, precancerous conditions, cancer, prior breast cancer, a family history of cancer, or pain can also be indications for hysterectomy.[6,7]

The surgical indication significantly impacts the approach taken for the hysterectomy. Women with prolapse or menstrual disorders are more likely to undergo minimally invasive operations but the indication of fibroids is more associated with abdominal surgery.[3] Hysterectomy patients' mean age is cited between 45 and 52 years old, but age varies significantly depending on the indication for hysterectomy. Uterine prolapse, pelvic mass and cancer are a more common indication in older women while women with endometriosis, abnormal bleeding and fibroids are usually younger.[6,8]

Obesity is a significant risk factor for having hysterectomy. The majority of patients are overweight (BMI > 25.0) and one study found that obesity was more common among those having endometrial hyperplasia as the main indication for hysterectomy.[6]

This same cross-sectional analysis of the 2009 Nationwide Inpatient Sample (NIS) found that all races, except Native Americans, were less likely to undergo a minimally invasive approach, compared with white women. Factors associated with minimally invasive hysterectomy included diagnosis of prolapse or menstrual disorder, higher income, and patient age over 50 years. Factors favoring an abdominal approach included minority race, diagnosis of fibroids, and increasing severity of illness.[3]

1.3 Alternative options to hysterectomy

While for many patients hysterectomy is the best or only method by which to achieve definitive relief of symptoms or treat disease, there are alternatives. Many patients try to manage their symptoms by these alternative means before ultimately opting for hysterectomy. Improved understanding of the pathogenesis of uterine diseases and symptoms has provided patients with numerous alternative approaches in the care of uterine disorders. In the 1930s, surgical alternatives to hysterectomy started with abdominal myomectomy and endometrial ablation. Among current alternatives to hysterectomy include among others, uterine fibroid embolization, a procedure done by an interventional radiologist; removal of fibroids via hysteroscopy; endometrial ablation, a procedure that surgically destroys the lining of the uterus; and myomectomy, a common alternative to hysterectomy for women desiring fertility preservation by which fibroids are surgically removed from the uterus without removing the uterus.[9] Medical alternatives to hysterectomy such as oral contraceptives are also available but research shows that levonorgestrel-releasing intrauterine device (LNG IUS) is more effective in treating heavy menstrual bleeding.[10]

1.4 Different surgical methods

Benign hysterectomy can be done by a subtotal and total abdominal approach, total vaginal approach, subtotal and total laparoscopic approach and subtotal and total robotic-assisted approach. A total hysterectomy involves the removal of both the uterine body and the cervix; however a supracervical hysterectomy, also called subtotal hysterectomy, refers to the removal of only the uterine body, leaving the cervix intact.[11]

In radical hysterectomy, which is mostly done for cancer, the surgeon takes out the uterus, the ligaments that hold it in place in the pelvis, the cervix and an inch or two of the deep vagina around the cervix.[11]

Open surgery or abdominal hysterectomy involves removing the uterus through an incision in the lower abdomen. The basis for this operation is an open abdomen (laparotomy). This provides the surgeon with sufficient view of the surgical area for isolation of the uterus from surrounding structures to allow cutting and securing of support structures that attach the uterus to the pelvic floor and sidewalls. The procedure is performed by making either a midline abdominal incision from just below the belly button down to just above the pubic hairline, or a transverse incision just above the pubic hairline (Pfannenstiel). The surgeon detaches the uterus from surrounding structures, the ovaries, fallopian tube and upper vagina, as well as the infundibulopelvic ligaments (ovarian arteries and veins), uterine vessels, cardinal and uterosacral ligaments. The specimen is extracted through the abdominal incision.[11]

Vaginal hysterectomy is a procedure where the uterus is removed via the vagina with no abdominal incision. It is therefore a minimally invasive gynecologic surgery and is sometimes called the least invasive of all the hysterectomy approaches. The cervix is grasped, pulled downwards and a circumferential cervical incision is made. The vagina is mobilized both anteriorly and posteriorly. The uterosacral and cardinal ligaments are cut and sutured down. The uterus is detached from surrounding structures and delivered vaginally. In the case of uterine enlargement, uterine fixation or limited vaginal exposure morcellation, the fragmentation of tissue can be used to facilitate the removal of the specimen vaginally.[11]

Laparoscopic hysterectomy involves the use of a laparoscope in the performance of hysterectomy. This mode can be further subcategorized based on whether the suturing of the vaginal vault was undertaken vaginally or whether the ligation of the uterine vessels was done laparoscopically. Laparoscopic-assisted vaginal hysterectomy is a procedure where the laparoscopic part of the operation does not involve division of the uterine vessels. Laparoscopic hysterectomy is where the uterine vessels are ligated laparoscopically and the specimen is removed via the vagina or via the small incisions in the abdomen.[2] Laparoscopic hysterectomy, where the entire operation is performed laparoscopically, is only done by a small portion of gynecologists because it requires greater laparoscopic skills.[12]

Laparoscopic surgery is traditionally performed using a sharp pointed surgical instrument called a trocar that is placed at or above the umbilicus to provide a panoramic view of the pelvis. High flow CO_2 is directed into the peritoneum to establish a pneumoperitoneum and the laparoscope is introduced. Other trocars are inserted in the lower quadrants to facilitate adequate instrument use, visualization, and mobilization of intra-abdominal structures.[11]

Robotic-assisted surgery is a relatively new concept in gynecologic surgery. In 2005, the FDA approved the da Vinci® robot for gynecologic surgery. The surgical instruments are similar to the ones in laparoscopic surgery but they are connected to a robot while the surgeon is seated close to the patient controlling with wristed laparoscopic instruments through masters and foot pedals. The advantages of robotic-assisted surgery are that the surgeon has the ability to move the instruments in a wristed fashion inside the body, and this is a more comfortable working area than having to stand as in traditional surgery.[13]

1.5 Comparing different techniques

Aarts et al. assessed the effectiveness and safety of different surgical approaches to hysterectomy for women with benign gynecological conditions with a Cochrane meta-analysis from 2015 of 47 studies with 5102 women. They found vaginal hysterectomy to be the superior hysterectomy procedure and recommend it to be the first line approach to hysterectomy. Both vaginal and laparoscopic hysterectomy were found to have advantages over the abdominal approach.[2]

The abdominal approach is performed with a large incision in the abdomen and therefore is the most invasive approach. Abdominal hysterectomy has mostly been used for gynecological malignancy in the case of big uteri or if pelvic disease such as adhesions or endometriosis is present. It is considered as a “fallback option” for other approaches.[12]

Abdominal cases are also most commonly associated with a length of stay over 1 day and most post-operative complications such as vaginal cuff infection, wound/abdominal wall infection, blood clots, pulmonary emboli and febrile episodes.[3]

Vaginal hysterectomy is performed without any incision to the abdomen and is therefore sometimes called the least invasive surgery of all the approaches to hysterectomy. Vaginal or pelvic prolapse used to be the main indication for a vaginal hysterectomy but now there are more indications for a vaginal approach.[12] Vaginal hysterectomy has the shortest operating time and is the most cost effective approach to hysterectomy. However, laparoscopic hysterectomy and vaginal hysterectomy are comparable in terms of complications and recovery. Small randomized trials have consistently shown more postoperative pain after vaginal hysterectomy than laparoscopic hysterectomy which has called into question the notion that vaginal hysterectomy is the least invasive approach. This may be due to the use of ligatures instead of vessel sealing and the use of vaginal retractors.[14,15] When comparing laparoscopic approach to vaginal hysterectomy, women undergoing LH were found to be able to return to work one day earlier than women undergoing VH, but there was no difference in the time to return to normal activities. Most results recommended the vaginal approach when technically feasible.[2]

Many reasons have been mentioned in the past as exclusion criteria for women to have a vaginal hysterectomy. The vaginal opening expands after childbirth and therefore was assumed not an ideal approach in nulliparous women. Adhesions after a cesarean section and other abdominal surgeries are also said to be an contraindication towards vaginal hysterectomy. Women in developed countries are having fewer children and are more likely to have had a C-section, and those are factors that seem challenging for a vaginal approach. A study in a district general hospital in the United Kingdom over 5 years found that removing nulliparous uteri vaginally was often easier than expected because of the small size of the cervix and uterus and that all contraindications lose their importance with increasing experience. They recommended the vaginal approach as a preferred method in all hysterectomies.[16] Despite these advantages, the rate of vaginal hysterectomy has been decreasing in the United States. This may be due to low surgeon volumes and their preference for a visual approach to hysterectomy. Laparoscopic hysterectomy may also be easier to teach as it allows multiple learners to see exactly how the procedure is performed while the learner view in vaginal hysterectomy is more limited.[3,4]

Vaginal hysterectomy is also associated with the lowest cost followed by the laparoscopic approach. Robotic surgery has distinctly higher cost than the other methods and longer operating times.[3] However, when the inpatient stay is taken into account, the difference in cost between abdominal and robotic-assisted surgery becomes insignificant.[17]

Laparoscopic hysterectomy compared to abdominal has some significant advantages including quicker return to normal activities, less postoperative pain, fewer febrile episodes and wound or abdominal wall infections, and improved quality of life seen in the first months and, in one study, up to four years after the surgery. The downsides are greater risks of damaging the bladder or ureter and a longer operating time.[2] With the laparoscopic approach, if the specimen is too large to be removed intact vaginally, the uterus must be morcellated to facilitate the removal of the specimen through the small laparoscopic incisions. If laparoscopic power morcellation (in which an electronic tool is used to cut

tissue into smaller pieces) is performed in women with occult leiomyosarcoma, there is a risk that cancerous tissue will spread within the abdomen and pelvis which can worsen the disease. This is also true if a knife is used to cut fibroids through the vagina or through a minilaparotomy.[18]

Regarding robotic surgery, the Cochrane database review found that robotic-assisted hysterectomy did not offer any significant advantages over laparoscopic hysterectomy and actually resulted in longer operating time.[2]

When comparing total hysterectomy and supracervical hysterectomy, studies show that there is no difference either in short term or long term outcomes concerning urinary, bowel, or sexual function. Operating time and blood loss is significantly lower with supracervical surgery as well as postoperative fever, and urinary retention is less likely. Still, there is no difference in the rates of recovery from surgery or readmission rates.[19,20] After a supracervical hysterectomy, there is a possibility of continuous abnormal bleeding. The most concerning difference is the risk of carcinoma of the cervical stump after subtotal hysterectomy.[20]

The approach to hysterectomy has shifted over time with an increasing percentage of laparoscopic hysterectomy due to well documented advantages of minimally invasive hysterectomy including less blood loss, reduced risk of infection, shorter hospital stay and decreased risk of intra- and post-operative complications.[2]

1.6 FDA safety recommendations

On April 17, 2014, the US Food and Drug Administration (FDA) published its first safety communication regarding laparoscopic power morcellators, “discouraging the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids”.[21] On November 24 of the same year, the FDA updated its safety communication “warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.” These safety communications were issued due to a concern of dissemination of unknown malignant tissue within the peritoneal cavity.[22]

The safety recommendations contraindicated laparoscopic power morcellators in patients who are peri- or post-menopausal and those that are candidates for en bloc tissue removal, with a minilaparotomy or vaginally. It is important to note that this applies to the majority of women with leiomyoma who undergo hysterectomy or myomectomy.[22] These safety recommendations have had a significant impact on the field of minimally invasive gynecology.[23] The small group of patients who are not affected by the safety recommendations might include younger women who wish to maintain their fertility or not yet peri-menopausal women who wish to keep their uterus.[22]

Even though the safety recommendations regarding power morcellation did not apply to all women with fibroids, some institutions have responded with broad sweeping protocol changes.

Also on April 17, 2014, Brigham and Women’s Hospital and Massachusetts General Hospital banned all use of laparoscopic power morcellators. Other institutions in the Boston area gradually followed as did a number of other hospitals in the country. Very shortly after publishing the safety communications, Ethicon, a Johnson & Johnson subsidiary that manufactured nearly 80% of the laparoscopic power

morcellators on the market, suspended sale of its morcellators and later requested a withdrawal of the device.[24] The impact of FDA's decision has therefore had both immediate and widespread implications.

1.7 Morcellation

Morcellation refers to the fragmentation of tissue to facilitate removal of a specimen. Morcellation allows for the removal of tissue through small incisions in minimally invasive surgery. It can be performed with a knife or an electromechanical (aka power) morcellator. Leiomyomas that are larger than 10 week pregnancy size normally require either scalpel or power morcellation to remove tissue.[25]

Morcellation-related injuries, whether from knife or power morcellation, have increased with the increase in minimally invasive gynecologic, urologic and general surgeries with the most common injuries being to the bowel and blood vessels. A systematic review evaluated rates of all reported injuries associated with morcellation in published literature and the FDA device database during gynecologic and nongynecologic surgery from 1992-2012. A total of 55 complications were identified; bowel (n=31), vascular system (n=27), kidney (n=3), ureter (n=3), diaphragm (n=1) and 11 of these involving more than 1 organ. Over half (66%) were identified intraoperatively but the others were not identified until up to 10 days after the surgery. They also reported six patients dying of morcellation-related complications, such as injuries to the aorta, vena cava and bowel. This study found that the surgeon's general inexperience, training or control was a common contributing factor to the injuries.[26]

1.7.1 Power morcellation

Morcellation is not a new concept. In the 1970s, the first device for laparoscopic tissue removal was introduced and in 1993, the Steiner electromechanical morcellator was brought to market.[27] Electromechanical morcellators became widely adopted in the setting of benign gynecologic surgery due to marked advantages of laparoscopic procedures over laparotomy.[28]

There is a risk of tissue dissemination and disruption in using power morcellators. Complications caused by dissemination of benign or occult malign uterine tissue during the use of the morcellator have been reported in the literature. Dispersal and spillage of fragments in the peritoneal cavity require thorough retrieval to ensure complete extraction of tissue, but even with thorough retrieval, tissue may be left behind and lead to iatrogenic complications.[28] Dissemination of benign gynecological disease may result in the growth of benign but nonetheless undesirable processes such as endometriosis, adenomyosis and leiomyomas.[29] The most concerning dissemination is that of occult malignant tissue that is only discovered postoperatively.

1.8 Leiomyosarcoma

In the discussion surrounding power morcellation and the dissemination of occult malignant tissue, leiomyosarcoma is of particular concern. Leiomyosarcoma is the most common subtype of uterine sarcoma, but it only accounts for 1-2% of all uterine malignancies. Other uterine malignancies include endometrial stromal sarcoma, adenosarcoma, carcinosarcoma, and smooth muscle tumors of uncertain malignant potential, among others.[30]

The symptoms and signs of leiomyosarcoma resemble those of leiomyoma, which is far more common and therefore preoperative diagnosis, whether clinical or radiographical, is difficult.[30] Endometrial sampling is used almost uniformly for the preoperative diagnosis of endometrial neoplasms. A recent retrospective analysis of prospectively collected databases reported low sensitivity of an endometrial biopsy to detect uterine leiomyosarcoma. They reported that endometrial sampling correctly identified uterine leiomysarcoma specifically in only 35.3% of patients but uterine leiomyosarcoma or a histological lesion concerning for uterine leiomyosarcoma in 51.5% of cases. Chances of detecting abnormality are higher in the cases of women with post-menopausal bleedings rather then in pre-menopausal patients. The most common presenting symptoms for the full cohort was abnormal premenopausal bleeding (30.4%), postmenopausal bleeding (27.7%), pain (19.6%) and bulk syndromes (16.9%).[31]

Patients with leiomyosarcoma have poor prognoses. The 5-year survival for LMS is 51% at stage I and 25% at stage II according to the FIGO stage system. In cases where the cancer had spread outside the pelvis, the patients all died within 5 years.[32]

In the safety communications, the FDA estimated that the prevalence of leiomyosarcoma among women having surgery for presumed fibroids was 1 in 498 and the prevalence of unexpected uterine sarcoma was 1 in 352.[33]

Many have challenged these numbers, but it is hard to estimate the risk with certainty. A recent rigorous meta-analysis of 133 studies determined that in every 1,960 women having surgery for presumed fibroids, one woman would be found to have leiomyosarcoma, or 0.051%. Of those 134 studies, there were 64 prospective analyses that provided the estimated prevalence to be 1 leiomyosarcoma per 8,300 surgeries or 0.012%. There were 70 retrospective analyses that gave the estimated prevalence of 0.057% or 1 LMS for every 1,700 surgeries.[34] Another study found that only 1 of 1,332 patients operated on for presumed leiomyoma was found to have leiomyosarcoma, an incidence of 0.08%.[35] Determining the prevalance of leiomyosarcoma is of particular importance in the controversy surrounding morcellation, but its rarity renders it difficult to estimate with any certainty.

Current literature demonstrates that intraperitoneal tumor morcellation, both manual and power, of undiagnosed uterine leiomyosarcoma worsens the natural course of the disease.[36] One retrospective cohort study compared patients with uterine leiomyosarcoma who underwent morcellation to patients that underwent total abdominal hysterectomy. Intraperitoneal morcellation patients had a significantly increased risk of abdominal/pelvic recurrences and a shorter median recurrence-free survival. The study reported that the risk of recurrence more than tripled among the patients who underwent morcellation. Morcellation is therefore significantly associated with increased risk of tumor recurrence and decreased recurrence free survival compared with the total abdominal approach.[18]

There may be other unexpected malignancies present at the time of the morcellation. A recent retrospective study found that of 1,091 clinically presumed leiomyoma, 13 cases were diagnosed postoperatively as having abnormal pathology. That represents an 1.2% estimated incidence of unexpected variants, atypia, and malignancy. It is important to note that not all pathologies have serious prognoses.[37]

A decision analysis study for a hypothetical cohort of 100,000 premenopausal women who underwent hysterectomy for presumed fibroids by Siedhoff et al compared the abdominal approach to the laparoscopic approach. The decision analysis predicted fewer overall deaths with laparoscopic hysterectomy versus abdominal hysterectomy. There were more deaths from leiomyosarcoma after laparoscopic approach but more deaths related to hysterectomy with the abdominal approach. Concerning the surgical complications, laparoscopic hysterectomy had lower rates of transfusion, wound infections, venous thromboembolism, and incisional hernia, but a higher rate of vaginal cuff dehiscence compared to the abdominal group. Laparoscopic hysterectomy also resulted in more quality-adjusted life years. The authors concluded that the risk of leiomyosarcoma morcellation is therefore balanced by surgical-related complications that are associated with laparotomy, including death.[38]

1.9 Alternatives to open morcellation

The ideal method to avoid risks associated with morcellation is abdominal hysterectomy with intact specimen removal but that prevents the patients of having all of the previously mentioned advantages associated with minimally invasive surgery.[2] As a result of these safety recommendations, new methods are being developed in an effort to both preserve the minimally invasive approach and minimize the spread of tissue.

Laparoscopic surgery with tissue removal via minilaparotomy is considered to be a good alternative to morcellation and is associated with less blood loss and shorter OR time. Minilaparotomy is associated with a significantly higher rate of major wound complications but no significant difference in repeat operation, overnight hospital admission, emergency department visit or conversion. Results show that removal via minilaparotomy has similar postoperative outcomes as laparoscopy, with or without morcellation.[39]

New research on contained tissue extraction also demonstrates feasibility but further refinement of this technique is warranted. Contained power morcellation within an insufflated bag is still in early development but a recent study researching this method showed longer OR time and spillage of fluid or tissue into the abdomen in 9.2% of cases. However, the containment bags were intact in each of these instances. Primary concerns regarding this technique are the containment's bag ability to withstand damage from the morcellator as well as the surgeon's ability to visualize the blade and specimen.[40] Further refinements of this technique will be beneficial towards additional advantages in minimally invasive gynecologic surgery.

For patients with a moderately enlarged uterus requiring morcellation (12-16 weeks), a transvaginal morcellation is typically preferred - a containment bag is introduced vaginally and the specimen is placed in the bag laparoscopically which is exteriorized at the perineum.[28] Manual morcellation then takes place within the confines of the containment system.

1.10 Implications of the safety recommendations

Recent studies have explored the implications of the FDA's safety recommendations regarding power morcellation. The results of a physician survey answered by 615 members of Advancing Minimally Invasive Gynecologic Surgery Worldwide and 24 members of the American College of

Obstetricians and Gynecologists Collaborative Ambulatory Research Network show that the respondents reported decreased use of power morcellation during MIGS after the FDA recommendations. The most commonly cited reason was hospital mandate; the second most common reason was fear of legal consequences. About half of the respondents reported an increase in rates of laparotomy. The majority of responders (80.3%) believed that the FDA safety recommendations had not led to overall improvements in their patients' outcomes and had rather led to harming patients (55.1%). In optional, free-response questions, responders said that the safety recommendations had increased patient anxiety and increased the time spent on preoperative counseling.[41] It is important to note that the survey was answered by minimally invasive gynecology surgeons so it is possible that the participants are subject to bias.

Another survey sent to the American Association of Gynecologic Laparoscopists Minimally Invasive Gynecology Surgery Fellowship program faculty showed that of the 46 faculty members who completed the survey, 84% changed their surgical approach for hysterectomy and myomectomy after the FDA Safety Recommendations. Over half, or 58%, reported using minilaparotomy, 50% using specimen retrieval pouches, 42% using vaginal extraction in a bag. Of surgeons, 48% reported having reduced the use of laparoscopic supracervical hysterectomy and 25% changed the route of hysterectomy to total abdominal hysterectomy.[42]

A recent retrospective cohort study by Harris et al. about the practice patterns and postoperative complications in Michigan before and after the FDA safety communications shows that utilization of laparoscopic hysterectomies decreased by 4.1%, while both vaginal and abdominal hysterectomies increased. They also showed an increase in major surgical complications and that 30-day hospital readmissions increased. Interestingly, rates of laparoscopic supracervical hysterectomy, an approach that most often uses the power morcellation technique, decreased by 59% after the safety communication.[23]

This is the only study to date that evaluates the effect this widespread change in surgical practice has had on surgical complications but it only reviewed the first 8 months of data after the issuance of the FDA safety communications. Therefore, it is necessary to further evaluate the effect this has had on the trends in mode of surgery for benign hysterectomy over a longer period of time.

2 Aim of this study

The primary aim of this retrospective chart review is to assess the trends in the mode of surgery for benign hysterectomy with respect to the issuance of power morcellation guidelines by the FDA. The population in the study includes all patients who underwent a hysterectomy at Brigham and Women's Hospital in 2013-2015. This period of time covers cases before the FDA issued the first report, between the first and second report and after the second report. The null hypothesis is that there is no change in trends in the mode of surgery (laparoscopic, robotic, abdominal or vaginal) used in hysterectomies.

3 Materials and methods

This study was approved by the Partners Institutional Review Board (Protocol number 2015P001459).

3.1 Data extraction

This is a retrospective chart review and data was extracted from patients‘ electronic medical records. The data from the medical record was entered into a database which was used to compare the perioperative outcomes of each approach. The subjects in this study are all patients who underwent a hysterectomy at Brigham and Women’s Hospital from the 1st of January 2013 and until the 31st of December 2015. Exclusion critera include patients younger than 18 years old, those with a pre-operative diagnosis or suspicion of malignant gynecologic disease and those that underwent hysterectomy due to obstetrical problems. The operations were performed by a diverse group of gynecologists at Brigham and Women‘s Hospital, an academic tertiary care center in the northeastern United States. The abdominal hysterectomy group consists of all abdominal hysterectomies, supracervical, total and radical. The vaginal group represents all vaginal hysterectomies. The laparoscopic hysterectomy group contains all laparoscopic hysterectomies, supracervical, total and radical. The robotic hysterectomy group includes all laparoscopic procedures performed with robotic assitance.

Our primary outcome was change in the mode of hysterectomy from 2013 to 2015 and our secondary outcome was the change in the incidence of complications, readmissions and reoperations within 8 weeks of surgery. Postoperative complications were classified using the Clavien-Dindo complication rating.

The following variables were extracted from the medical record: patient race, age, BMI, parity (total deliveries), prior laparoscopic surgery, prior abdominal surgery, specimen weight, date of hysterectomy, type of hysterectomy (total, supracervical, or radical), mode of surgery (laparoscopic, robotic, abdominal, or vaginal), indication for surgery (pain/endometriosis, abnormal bleeding, fibroids, urogynology or other), primary surgeon, type of surgeon (general gynecologist, gynecologic oncologist, minimally invasive gynecologist, urogynecologist and reproductive gynecologist), operative time, estimated blood loss, intraoperative complications (including EBL>1000 ml, bowel injury, bladder/ureter injury), Clavien-Dindo complication rating[43], conversion to laparotomy, readmission, reoperations, days from discharge to readmission, length of hospital stay, and pathology result. If a patients’ medical history included a surgery that was not specified laparotomy or laparoscopic in the medical records, we assumed laparotomy.

3.2 Statistical analysis

Crude associations between patient characteristics and surgical outcomes and year of surgery were assessed using Chi-square and Fisher’s exact tests for categorical variables and analysis of variance (ANOVA) and Kruskal-Wallis tests for continuous variables.

EBL and OR time were both log transformed to create normal distributions and linear regression was used to calculate multivariable adjusted geometric means with 95% CI for both outcomes. Poisson

regression was used to examine the relationship between year of surgery and length of stay, with results expressed as adjusted incidence rate ratios with 95% CI. Logistic regression models were used to estimate the associations between year of surgery and the dichotomous (yes/no) outcome variables: EBL >100cc, intraoperative complications, postoperative complications, readmission, reoperation, and malignant pathology. Additionally, we created a composite outcome for anyone who had either an intra- or postoperative complication, readmission, reoperation or a conversion. Conversions were too rare in this sample to examine individually. Logistic regression results are presented as odds ratios (OR) with 95% confidence intervals (CI).

To control for potential confounding, models were adjusted for BMI (<25, 25-29.9, ≥30), prior laparotomy, type of surgeon (general vs. any other), subtype (total, supracervical, radical), and indications (pain, bleeding, fibroids, urogynecology, other). Year of surgery was modeled categorically, with 2014 and 2015 compared to 2013. To evaluate the trend in associations, we modeled year of surgery continuously and Wald tests were used to test the significance of the trend. Data was analyzed using SAS software (SAS Institute Inc., Cary, NC, USA; Version 9.4).

4 Results

The study included 1,807 women who underwent a hysterectomy in 2013, 2014 and 2015 by any method but 277 cases were excluded for a diagnosis or a suspicion of cancer or obstetrical indications. In total, 1,530 patients were included in the analysis. Of the included hysterectomies, 600 were performed in 2013, prior to the FDA power morcellation safety communications, 484 in 2014, the year of the recommendations, and 446 in 2015, after the safety communications. The procedures were performed by 46 different gynecological surgeons. Therefore, there was a decrease in hysterectomy rates during the time of the study.

4. 1 Patient characteristics by year of surgery

Patient demographics are presented in Table 1. Baseline demographics were comparable between the three cohorts but there was significant difference in BMI where the patients in the 2014 cohort have significantly higher BMI (29.5±7.6 compared with 28.6±6.6 both in 2013 and 2015, p=0.05) but it is presumed clinically insignificant. There were significantly fewer patients who had a prior laparotomy in the 2015 cohort (46.6% versus 38.9% and 40.4%, p=0.04) and there was significant difference in the type of surgeon between the cohorts, with more surgeries in 2013 done by general gynecologists and fewer by a gynecologic oncologists and minimally invasive gynecologic surgeons (p=0.05).

Over the study period, utilization of abdominal hysterectomy increased by 4.4%, vaginal hysterectomy almost stayed the same with an increase by 1.2%, laparoscopic hysterectomy decreased by 6.2% and robotic-assisted laparoscopic hysterectomy increased by 0.6%, these changes however did not reach statistical significance. There was a significant change in distribution of total, supracervical or radical hysterectomy with a 16.2% decrease in supracervical hysterectomies from 2013-2015 (25.9% in 2013, 15.3% in 2014 and 9.7% in 2015, p<0.0001) and a 15.1% increase in total hysterectomy (74.1% in 2013, 84.5% in 2014 and 89.2% in 2015, p<0.0001).

From 2013 to 2015, there was also a marked difference in indications for surgery. The prevalence of pain was similar in 2013 and 2014 but decreased in 2015 (p=0.03) whereas there was an increase in urogynecologic indications (16.7% 2013 to 21.3% 2015, p=0.0001). There were decreasing rates of hysterectomy performed for the indication of fibroids (45.0% 2013 to 36.5% 2015, p=0.0001) as well as decrease in patients undergoing hysterectomy for abnormal bleeding (39.0% 2013 to 28.0% 2015, p=0.0001).

Table 1. Patient characteristics by year of surgery.

	2013 N=600	*2014 N=484*	*2015 N=446*	*p-value*
Age				
Mean (SD)	49.3 (10.5)	50.4 (10.2)	50.2 (11.8)	0.19
Race				
White	408 (68.0%)	356 (73.6%)	333 (74.7%)	0.11
Black	95 (15.8%)	56 (11.6%)	52 (11.7%)	
Asian	18 (3.0%)	14 (2.9%)	15 (3.4%)	
Hispanic/Latina	41 (6.8%)	37 (7.6%)	32 (7.2%)	
Other/missing	38 (6.3%)	21 (4.3%)	14 (3.1%)	
BMI				
Mean (SD)	28.6 (6.6)	29.5 (7.6)	28.6 (6.6)	0.05
Missing	*5*	*5*	*2*	
Parity				
Median (min-max)	2.0 (0 - 9)	2.0 (0 - 8)	2.0 (0 - 6)	0.52
0	122 (21.7%)	101 (22.5%)	82 (20.8%)	0.88
1	80 (14.3%)	69 (15.4%)	57 (14.5%)	
2	191 (34.0%)	161 (35.9%)	136 (34.5%)	
>2	168 (29.9%)	117 (26.1%)	119 (30.2%)	
Missing	*39*	*36*	*52*	
Prior laparoscopy				
No	411 (69.5%)	351 (73.1%)	301 (69.0%)	0.32
Yes	180 (30.5%)	129 (26.9%)	135 (31.0%)	
Missing	*9*	*4*	*10*	
Prior laparotomy				
No	361 (61.1%)	286 (59.6%)	233 (53.4%)	0.04
Yes	230 (38.9%)	194 (40.4%)	203 (46.6%)	
Missing	*9*	*4*	*10*	
Type of surgeon				
General	164 (27.3%)	96 (19.8%)	91 (20.4%)	0.05
Onc	98 (16.3%)	102 (21.1%)	90 (20.2%)	
MIGS	186 (31.0%)	174 (36.0%)	153 (34.4%)	
Uro	56 (9.3%)	46 (9.5%)	47 (10.6%)	
Repro endo	96 (16.0%)	66 (13.6%)	64 (14.4%)	
Missing	*0*	*0*	*1*	
Mode of surgery				
Abdominal	77 (12.9%)	70 (14.5%)	77 (17.3%)	0.22
Vaginal	107 (17.9%)	93 (19.2%)	85 (19.1%)	
Laparoscopic	396 (66.1%)	296 (61.2%)	267 (59.9%)	
Robotic	19 (3.2%)	25 (5.2%)	17 (3.8%)	
Missing	*1*	*0*	*0*	
Subtype				
Total	444 (74.1%)	409 (84.5%)	397 (89.2%)	<0.0001
Supracervical	155 (25.9%)	74 (15.3%)	43 (9.7%)	
Radical	0 (0%)	1 (0.2%)	5 (1.1%)	
Missing	*1*	*0*	*1*	
Pain/endometriosis				
No	420 (70.0%)	346 (71.5%)	344 (77.1%)	0.03
Yes	180 (30.0%)	138 (28.5%)	102 (22.9%)	
Abnormal bleeding				
No	366 (61.0%)	305 (63.0%)	321 (72.0%)	0.0007
Yes	234 (39.0%)	179 (37.0%)	125 (28.0%)	
Fibroids				
No	330 (55.0%)	289 (59.7%)	283 (63.5%)	0.02
Yes	270 (45.0%)	195 (40.3%)	163 (36.5%)	
Urogynecology				
No	500 (83.3%)	397 (82.0%)	351 (78.7%)	0.15
Yes	100 (16.7%)	87 (18.0%)	95 (21.3%)	
Other				
No	469 (78.2%)	329 (68.0%)	306 (68.6%)	0.0001
Yes	131 (21.8%)	155 (32.0%)	140 (31.4%)	

*p-values from chi-square tests, Fisher's exact tests, Kruskal-Wallis tests and ANOVA

4. 2 Outcomes by year of surgery

Table 2 reviews the perioperative outcomes. There was a significant decrease in OR time from 2013-2015 (135.6 min 2013 versus 120.8 min 2015, p=0.0004), fewer postoperative complications in 2014 (10.2% 2014 compared to 15.1% 2013, p=0.05) and an overall significant decrease in length of stay between the years (p<0.0001) with a mean stay decreasing from 0.94 days to 0.82 days. There was no significant difference in EBL, intraoperative complications, postoperative complication rating, conversion to open, readmission, days from discharge to readmission, and pathology.

Table 2. Outcomes by year of surgery.

	2013 N=600	*2014 N=484*	*2015 N=446*	*p-value*
OR time				
Mean (SD)	135.6 (63.5)	133.2 (62.4)	120.8 (59.1)	0.0004
Missing	*5*	*4*	*2*	
EBL				
Mean (SD)	128.0 (197.6)	131.7 (279.6)	120.1 (169.3)	0.15
Median (min-max)	50.0 (0 - 2000)	50.0 (0 - 3800)	50.0 (0 - 1200)	0.81
Missing	*18*	*1*	*4*	
Intraop complications				
No	589 (98.2%)	478 (98.8%)	440 (98.7%)	0.69
Yes	11 (1.8%)	6 (1.2%)	6 (1.3%)	
Postop complication rating				
0	376 (84.9%)	362 (89.8%)	321 (84.5%)	0.36
1	20 (4.5%)	12 (3.0%)	19 (5.0%)	
2	36 (8.1%)	19 (4.7%)	32 (8.4%)	
3a	5 (1.1%)	4 (1.0%)	2 (0.5%)	
3b	6 (1.4%)	6 (1.5%)	6 (1.6%)	
Missing	*157*	*81*	*66*	
Any postop complication				
None	376 (84.9%)	362 (89.8%)	321 (84.5%)	0.05
Any	67 (15.1%)	41 (10.2%)	59 (15.5%)	
Missing	*157*	*81*	*66*	
Conversion				
No	597 (99.5%)	483 (99.8%)	446 (100.0%)	0.39
Yes	3 (0.5%)	1 (0.2%)	0 (0%)	
Readmission				
No	588 (98.0%)	468 (96.7%)	431 (96.6%)	0.26
Yes	12 (2.0%)	16 (3.3%)	15 (3.4%)	
Days from discharge to Readmission				
Mean (SD)	9.31 (10.27)	12.42 (9.96)	13.94 (20.83)	
Median (min-max)	4.0 (0 - 33)	12.0 (0 - 42)	7.0 (0 - 84)	0.60
Reoperation				
No	590 (98.3%)	478 (98.8%)	440 (98.7%)	0.83
Yes	10 (1.7%)	6 (1.2%)	6 (1.3%)	
Length of stay				
Mean (SD)	0.94 (1.44)	0.62 (1.28)	0.82 (1.74)	
Median (min-max)	1.0 (0 - 21)	0.0 (0 - 14)	0.0 (0 - 18)	<0.0001
Length of stay				
0	255 (42.5%)	332 (68.6%)	288 (64.6%)	<0.0001
1	239 (39.8%)	76 (15.7%)	77 (17.3%)	
2	51 (8.5%)	42 (8.7%)	35 (7.8%)	
>2	55 (9.2%)	34 (7.0%)	46 (10.3%)	
Pathology				
Benign	583 (97.2%)	466 (96.3%)	429 (96.2%)	0.62
Malignant	17 (2.8%)	18 (3.7%)	17 (3.8%)	
Uterine weight				
Mean (SD)	305.7 (420.1)	321.8 (465.8)	296.5 (405.7)	0.35
Missing	*5*	*7*	*3*	

4.3 Associations between year of surgery and EBL, OR time and length of stay

Table 3 shows adjusted associations between year of surgery and EBL, OR time, and length of stay. There was a borderline significant evidence of a linear trend of increasing EBL over time (47, 54, 56 mL for 2013, 2014 and 2015, respectively, p=0.05). The overall difference of 9 ml is presumed to be clinically insignificant. There was also strong evidence of a linear trend of decreasing OR times over time (adjusted means are 123, 118, and 107 min for 2013, 2014 and 2015, respectively, p<0.0001). Both 2014 and 2015 have less likelihood of inpatient stay after the surgery (IRR 0.65, 95% CI 0.57-0.75 2013 and IRR 0.79, 95% CI 0.69-0.91 2015), and there was also significant evidence of a linear trend of decreasing likelihood of inpatient stay over time (p=0.0002).

Table 3. Associations between year of surgery and EBL, OR time, and length of stay.

	2013	2014	*2015*	*p-trend*
EBL				
N	582	483	442	
Crude geometric mean (95% CI)	49 (43, 56)	53 (46, 61)	54 (47, 63)	
p-value	Ref.	0.42	0.43	0.31
Adjusted geometric mean (95% CI)	47 (41, 53)	54 (47, 62)	56 (49, 65)	
p-value	Ref.	0.13	0.06	0.05
OR time (minutes)				
N	595	480	444	
Crude mean (95% CI)	122 (117, 126)	119 (114,124)	107 (102, 112)	
p-value	Ref.	0.42	<0.0001	<0.0001
Adjusted mean (95% CI)	123 (118, 128)	118 (113,123)	107 (103, 112)	
p-value	Ref.	0.12	<0.0001	<0.0001
Length of stay				
N	600	484	446	
Crude IRR (95% CI)	1.00	0.66 (0.58,0.76)	0.87 (0.77,1.00)	
p-value	Ref.	<0.0001	0.04	0.01
Adjusted IRR (95% CI)	1.00	0.65 (0.57,0.75)	0.79 (0.69,0.91)	
p-value	Ref.	<0.0001	0.0009	0.0002

Adjusted for BMI (<25, 25-29.9, ≥30), prior laparotomy, type of surgeon (general vs. any other), subtype (total, supracervical, radical), indications (pain, bleeding, fibroids, urogynecology, other).

4.4 Associations between year of surgery and dichotomous outcomes

Table 4 reviews associations between year of surgery and dichotomous outcomes (significant blood loss, conversion to laparotomy, complications). The association between year and postoperative complications shows that a patient in 2014 was less likely of having a postoperative complication compared with 2013 (OR 0.61, 95% CI 0.40-0.94). There was no significant association between year of surgery and the individual variables of intraoperative complication, readmission and reoperation. There was also no significant association between year of operation and a composite variable that incorporates having any complication, conversion, readmission or reoperation.

Table 4. Associations between year of surgery and dichotomous outcomes.

	No	*Yes*	*Crude*		*Adjusted**	
			OR (95% CI)	*p-value*	*OR (95% CI)*	*p-value*
EBL >100						
2013	429 (38.3%)	153 (39.6%)	1.00		1.00	
2014	363 (32.4%)	120 (31.1%)	0.93 (0.70, 1.22)	0.59	0.96 (0.72, 1.29)	0.81
2015	329 (29.3%)	113 (29.3%)	0.96 (0.73, 1.28)	0.79	1.04 (0.77, 1.40)	0.82
p-trend				0.77		0.84
Intraoperative complication						
2013	589 (39.1%)	11 (47.8%)	1.00		1.00	
2014	478 (31.7%)	6 (26.1%)	0.67 (0.25, 1.83)	0.44	0.77 (0.27, 2.18)	0.62
2015	440 (29.2%)	6 (26.1%)	0.73 (0.27, 1.99)	0.54	0.88 (0.31, 2.53)	0.81
				0.49		0.77
Postoperative complication						
2013	376 (35.5%)	67 (40.1%)	1.00		1.00	
2014	362 (34.2%)	41 (24.6%)	0.64 (0.42, 0.96)	0.03	0.61 (0.40, 0.94)	0.02
2015	321 (30.3%)	59 (35.3%)	1.03 (0.71, 1.51)	0.87	0.90 (0.61, 1.35)	0.61
				0.95		0.60
Readmission						
2013	588 (39.6%)	12 (27.3%)	1.00		1.00	
2014	467 (31.4%)	17 (38.6%)	1.78 (0.84, 3.77)	0.13	1.68 (0.78, 3.61)	0.19
2015	431 (29.0%)	15 (34.1%)	1.71 (0.79, 3.68)	0.17	1.64 (0.74, 3.63)	0.22
				0.17		0.23
Reoperation						
2013	590 (39.1%)	10 (45.5%)	1.00		1.00	
2014	478 (31.7%)	6 (27.3%)	0.74 (0.27, 2.05)	0.56	0.68 (0.24, 1.90)	0.46
2015	440 (29.2%)	6 (27.3%)	0.80 (0.29, 2.23)	0.68	0.74 (0.26, 2.10)	0.57
				0.64		0.52
Malignant pathology						
2013	583 (39.4%)	17 (32.7%)	1.00		1.00	
2014	466 (31.5%)	18 (34.6%)	1.33 (0.68, 2.60)	0.41	1.09 (0.53, 2.24)	0.81
2015	429 (29.0%)	17 (32.7%)	1.36 (0.69, 2.69)	0.38	1.15 (0.55, 2.38)	0.72
				0.37		0.81
Any intraop or postop complication, conversion, readmission or reoperation						
2013	525 (39.1%)	75 (40.3%)	1.00		1.00	
2014	436 (32.4%)	48 (25.8%)	0.77 (0.53, 1.13)	0.18	0.71 (0.48, 1.06)	0.09
2015	383 (28.5%)	63 (33.9%)	1.15 (0.80, 1.65)	0.44	1.02 (0.70, 1.48)	0.92
				0.52		0.98

Adjusted for BMI (<25, 25-29.9, ≥30), prior laparotomy, type of surgeon (general vs. any other), subtype (total, supracervical, radical), indications (pain, bleeding, fibroids, urogynecology, other).

4.5 Association between patient characteristics and having a minimally invasive surgery

Table 5 shows the results of logistic regression analysis of predictors for minimally invasive approach (vaginal, laparoscopic and robotic-assisted laparoscopic hysterectomy) with adjustment for variables the following variables: year of surgery, age, race, BMI, parity, prior surgery and indications. The year 2015 was significantly less likely to be associated with minimally invasive surgery in the crude analysis (OR 0.71, 95% CI 0.5-1.00) but when adjusted for variables, the difference became insignificant. Race was a factor in predicting mode of hysterectomy, with African American women (OR 0.53, 95% CI 0.35-0.82) undergoing more abdominal hysterectomy when compared white women. Prior laparoscopic surgery was a significant predictor for minimally invasive hysterectomy (OR 1.64, 95% CI 1.10-2.44) whereas prior laparotomy was a significant predictor for abdominal hysterectomy (OR 0.60, 95% CI 0.43-0.84). An indication of pain and/or endometriosis was predictive of minimally invasive technique (OR 2.29, 95% CI 1.47-3.59) whereas an indication of fibroids was negatively associated with minimally invasive technique (OR 0.31, 95% CI 0.20-0.48). Surgery where abnormal bleeding was the indication was more likely to be performed through minimally invasive technique (OR 1.78, 95% CI 1.23-2.57). Urogynecologic indication was also a significant predictor for the minimally invasive approach (OR 17.6, 95% CI 4.06-76.6).

Table 5. Association between patient characteristics and having a minimally invasive surgery.

	Abdominal	*Minimally Invasive*	*Crude*		*Adjusted**	
	N=224	*N=1305*	*OR (95% CI)*	*p-value*	*OR (95% CI)*	*p-value*
Year of surgery						
2013	77 (34.4%)	522 (40.0%)	1.00		1.00	
2014	70 (31.3%)	414 (31.7%)	0.87 (0.62, 1.24)	0.44	0.79 (0.53, 0.17)	0.24
2015	77 (34.4%)	369 (28.3%)	0.71 (0.50, 1.00)	0.05	0.75 (0.50, 1.12)	0.16
p-trend				0.05		0.15
Age						
≤40	32 (14.3%)	195 (14.9%)	1.00		1.00	
41-50	119 (53.1%)	613 (47.0%)	0.85 (0.55, 1.29)	0.44	1.25 (0.77, 2.03)	0.37
51-60	49 (21.9%)	268 (20.5%)	0.90 (0.55, 1.45)	0.66	1.22 (0.69, 2.15)	0.49
>60	24 (10.7%)	229 (17.5%)	1.57 (0.89, 2.75)	0.12	1.00 (0.49, 2.04)	0.99
p-trend				0.05		0.99
Race						
White	144 (64.3%)	952 (73.0%)	1.00		1.00	
Black	52 (23.2%)	151 (11.6%)	0.44 (0.31, 0.63)	<0.0001	0.53 (0.35, 0.82)	0.004
Asian	10 (4.5%)	37 (2.8%)	0.56 (0.27, 1.15)	0.11	0.64 (0.28, 1.47)	0.29
Hispanic/Latina	13 (5.8%)	97 (7.4%)	1.13 (0.62, 2.07)	0.70	0.99 (0.50, 1.98)	0.98
Other/missing	5 (2.2%)	68 (5.2%)	2.06 (0.82, 5.19)	0.13	2.50 (0.87, 7.24)	0.09
BMI						
<25	65 (29.3%)	441 (34.1%)	1.00		1.00	
25-29.9	71 (32.0%)	397 (30.7%)	0.82 (0.57, 1.19)	0.30	0.90 (0.59, 1.38)	0.64
≥30	86 (38.7%)	457 (35.3%)	0.78 (0.55, 1.11)	0.17	0.99 (0.66, 1.50)	0.97
p-trend				0.19		0.96
Parity						
0	56 (28.6%)	248 (20.6%)	1.00		1.00	
1	33 (16.8%)	173 (14.3%)	1.18 (0.74, 1.90)	0.48	1.20 (0.72, 2.01)	0.47
2	54 (27.6%)	434 (36.0%)	1.82 (1.21, 2.72)	0.004	1.60 (1.03, 2.49)	0.04
>2	53 (27.0%)	351 (29.1%)	1.50 (0.99, 2.25)	0.05	0.99 (0.62, 1.56)	0.95
p-trend				0.02		0.63
Prior laparoscopy						
No	172 (78.5%)	890 (69.2%)	1.00		1.00	
Yes	47 (21.5%)	397 (30.8%)	1.63 (1.16, 2.30)	0.005	1.64 (1.10, 2.44)	0.02
Prior laparotomy						
No	108 (49.3%)	771 (59.9%)	1.00		1.00	
Yes	111 (50.7%)	516 (40.1%)	0.65 (0.49, 0.87)	0.003	0.60 (0.43, 0.84)	0.003
Pain/endometriosis						
No	189 (84.4%)	920 (70.5%)	1.00		1.00	
Yes	35 (15.6%)	385 (29.5%)	2.26 (1.55, 3.30)	<0.0001	2.29 (1.47, 3.59)	0.0002
Abnormal bleeding						
No	155 (69.2%)	836 (64.1%)	1.00		1.00	
Yes	69 (30.8%)	469 (35.9%)	1.26 (0.93, 1.71)	0.14	1.78 (1.23, 2.57)	0.002
Fibroids						
No	82 (36.6%)	819 (62.8%)	1.00		1.00	
Yes	142 (63.4%)	486 (37.2%)	0.34 (0.26, 0.46)	<0.0001	0.31 (0.20, 0.48)	<0.0001
Urogynecology						
No	220 (98.2%)	1027 (78.7%)	1.00		1.00	
Yes	4 (1.8%)	278 (21.3%)	14.9 (5.49, 40.4)	<0.0001	17.6 (4.06, 76.6)	0.0001
Other						
No	133 (59.4%)	971 (74.4%)	1.00		1.00	
Yes	91 (40.6%)	334 (25.6%)	0.50 (0.38, 0.68)	<0.0001	0.56 (0.36, 0.88)	0.01

5 Discussion

5.1 Main results

A slight shift in mode of hysterectomy occured at Brigham and Women‘s Hospital between 2013 and 2015. There was an increase in abdominal approach from 12.9% in 2013 to 17.3% to 2015 with laparoscopic approach decreasing from 66.1% to 59.9%; however, these results were insignificant. Supracervical approach significantly decreased by 16.2% from 25.9% in 2013 to 9.7%. The years 2014 and 2015 saw a reduction in the rate of minimally invasive approach but when adjusted for variables, the difference was insignificant. There was a significant decrease in OR time and length of stay but a slight significant increase in EBL. Regarding postoperative complications, 2014 was significantly associated with less post-operative complications compared with 2013. Minimally invasive surgery was significantly associated with white race, higher parity, prior laparoscopy, pain/endometriosis, abnormal bleeding and urogynecology. Factors associated with the abdominal approach to hysterectomy include prior laparotomy and fibroids.

5.2 Results from similar studies

When examining the data for mode of access of hysterectomy, some interesting trends can be seen. Rates of supracervical hysterectomy significantly decreased 16.2% which is consistent with a retrospective cohort study by Harris et al.[23] Supracervical laparoscopic hysterectomy commonly utilizes power morcellation. The Harris et al study showed that utilization of laparoscopic hysterectomies decreased significantly by 4.1%, but both vaginal and abdominal hysterectomies increased along with rates of major surgical complications and 30-day hospital readmissions. Brigham and Women’s Hospital experienced insignificant shifts in mode of hysterectomy, better OR times and decreasing inpatient stay. We also found slight significant increased blood loss but it is presumed clinically insignificant. The difference between our results and those of Harris et al could potentially be explained by the presence of a dedicated minimally invasive gynecologic surgery division actively seeking alternatives to power morcellators in laparoscopic hysterectomy.

5.3 Race associated with mode of hysterectomy

Our results show that race is associated with mode of hysterectomy. Those findings are consistent with existing literature that African American women are more associated with abdominal surgery and a higher rate of abdominal hysterectomy among minority women.[3] Our findings show abdominal surgery being significantly associated with African Americans when controlling for other baseline factors and surgical indications. We did not control for uterine weight which can be a factor in these results since African American women often have larger uteri due to large fibroids. Possible other explanations for this racial disparity are unequal access to laparoscopic facilities and surgeons, provider bias and perhaps patient preferences.[44]

5.4 Minimally Invasive Gynecologic Surgery Division

The Minimally Invasive Gynecologic Surgery Division at Brigham and Women's Hospital opened in 2006 and brought increased consciousness of alternative methods in performing hysterectomies. Since the FDA safety recommendations in April 2014, the MIGS team has been actively pursuing alternative measures to power morcellation for laparoscopic hysterectomy. There is also a research team focusing on alternative methods such as contained extractions.[40] This may explain why there is only a slight decrease in laparoscopic hysterectomy after the publication of the FDA safety recommendations. Our findings also show significantly better OR times and less length of inpatient stay.

5.5 Strengths and weaknesses

The strengths of this study include the large volume of cases and associated characteristics available for analysis. There is also variety of surgeons, long term follow-up and diversity in cases, such as uterine weight, which ranged from 6.5 to 3,000 grams. As this study was conducted at one institution, data was easily accessible and therefore a more complete dateset was collected, although the drawback is that these results may not be generalizable to all patient population. It is also possible that our study did not include enough cases so the changes in trends in mode of surgery we saw were significant. This study represents a large patient database but is limited in its retrospective nature with inherent selection bias. The data collection itself is subject to measurement bias with errors in data gathering or inaccurate coding; however, any misclassification due to coding error would presumably have been nondifferential.

5.6 Conclusion

With changing practice patterns and vigilance surrounding power morcellation, we are still able to offer patients minimally invasive gynecologic procedures. With a special minimally invasive gynecologic surgery division and a research team that focuses on alternative methods, it is possible to continue performing minimally invasive surgeries with all of the associated advantages.

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Appendix

The Clavien-Dindo Classification of Surgical Complications	
Grades	**Definition**
Grade I:	*Any deviation from the normal postoperative course without the need for pharmalocical treatment or surgical, endoscopic and radiological interventions.* *Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at bedside.*
Grade II:	*Requiring pharmacological treatment with drugs other than such allowed for grade I complications.* *Blood transfusions and total parenteral nutrition are also included.*
Grade III:	*Requiring surgical, endoscopic or radiological intervention*
Grade IIIa:	*Intervention not under general anesthesia*
Grade IIIb:	*Intervention under general anesthesia*
Grade IV:	*Life-threatening complication (including CNS complications)‡ requiring IC/ICU-management*
Grade Iva:	*Single organ dysfunction (including dialysis)*
Grade Ivb:	*Multi organ dysfunction*
Grade V:	*Death of a patient.*
Suffix ‘d‘:	*If the patients suffers from a complication at the time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.*