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Full length article

Impact of power morcellator removal on hysterectomy practice patterns☆,☆☆

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ABSTRACT

Objective: This study was a quality improvement project investigating patterns of hysterectomy practice including changes in surgical techniques and patient outcomes after manufacturer withdrawal of a laparoscopic power morcellator from our hospitals in July 2014.
Study design: This time-series pre and post retrospective review examined data from electronic health records, comparing one year when a laparoscopic power morcellator was available (Year 1, mid-2013 to mid-2014) to one year after withdrawal (Year 2, mid-2014 to mid-2015). Data were from patients of 8 gynecologists in a multispecialty group associated with a large, integrated care and coverage delivery system in Washington State. Analyzed were 100 patients for Year 1 and 133 patients for Year 2. Analysis was by two-sided chi-square tests comparing practice patterns and outcomes in the two years.
Results: For hysterectomy route, no significant difference was seen between Years 1 and 2 in percent surgeries that were abdominal or laparoscopic (including robotic). For minimally invasive hysterectomies, significantly more transvaginal hysterectomies were performed in Year 2 (22%) than Year 1 (14%) ($p < 0.05$). In Year 2, no laparoscopic supracervical hysterectomies occurred, with total laparoscopic or vaginal hysterectomies performed instead. Transvaginal uterus morcellation increased from 13% in Year 1 to 24% in Year 2 ($p < 0.05$). Bilateral salpingectomies increased in Year 2 as well ($p < 0.05$). Among patient factors, estimated blood loss, surgical site infection, total operative time, and hospital length of stay were not significantly different between Years 1 and 2. Body mass index, race/ethnicity, and age did not differ between years. No patients had occult uterine sarcoma.
Conclusion: Surgical practice patterns changed for our group of 8 gynecologists in the year after a laparoscopic power morcellator was withdrawn. Though open hysterectomies did not increase, no laparoscopic supracervical hysterectomies were performed. Total laparoscopic and vaginal hysterectomies and bilateral salpingectomies increased, with reliance on transvaginal uterine tissue-removal techniques. Patient outcomes including surgical infections, length of surgery, estimated blood loss and total hospital stay did not change. Our results suggest that experienced vaginal surgeons can adapt to removal of important surgical equipment and continue to provide minimally invasive hysterectomies without compromising patient outcomes and safety.

Introduction

The benefits of minimally invasive hysterectomy are well established and include less post-surgical pain, less blood loss, decreased surgical infection rates, smaller scars and faster postoperative recovery, shorter duration of hospital stay, lower intraoperative blood loss and fewer wound infections [1,2]. Open abdominal hysterectomy is associated with 1.7 times more complications, 1.9 times more febrile morbidity and 2.1 times more blood transfusions compared to minimally invasive hysterectomy [3].

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The mechanical laparoscopic power morcellator, which divides tissue into fragments, has been a key instrument for gynecologic laparoscopists performing minimally invasive hysterectomies for large fibroid uterus. In 1995, the U.S. Food and Drug Administration (FDA) approved the first laparoscopic power morcellator, which was used routinely until April 2014 when the FDA released a warning about the risk of spreading leiomyosarcoma if a cancerous fibroid tumor is morcellated during surgery [4]. Following this FDA warning, while many hospitals banned laparoscopic power morcellation outright, others created requirements for power morcellation such as mandatory pre-surgical endometrial biopsies and new consent processes [5]. In response to hospital bans on morcellator technology, several prominent surgical societies including the American Urogynecology Society and the American Congress of Obstetricians and Gynecologists (ACOG) released statements calling for the continued availability of power morcellation at the discretion of individual surgeons after informed patient consent [6–10].

In July 2014, Gynecare (Johnson and Johnson, New Brunswick, NJ) withdrew their morcellator from all three of the hospitals at which we practice. This study reviews practice patterns and patient outcomes for hysterectomies comparing one year prior to removal of the laparoscopic power morcellator from our facilities (July 2013–2014) to one year after (July 2014–2015). The purpose was to evaluate the impact of removing the morcellator from this community gynecological practice. The primary outcome was surgical route for hysterectomy and procedure practice patterns following physical removal of the power morcellator technology. Our secondary outcomes included evaluation of intraoperative blood loss, length of surgery and postsurgical complications such as hospital length of stay, infection and death.

Materials and methods

The study setting was 3 hospitals and 1 community clinic in the Seattle area where providers in the Kaiser Permanente (formerly Group Health) delivery system perform minimally invasive hysterectomies. The 8 providers whose data were used in this study are part of a group of 7 obstetrician/gynecologists and 1 board-certified urogynecologist who is the only robotic surgeon.

We performed a pre/post retrospective chart review of the electronic health records for all patients who had a hysterectomy during either of two time periods: Year 1, when the laparoscopic power morcellator (Gynecare, Johnson and Johnson, New Brunswick, NJ) was available (July 2013 to July 2014) and Year 2, after its removal (July 2014 to July 2015). We used the master surgery schedule to identify patients for review.

We collected demographic information; type of hysterectomy; numbers of secondary procedures (such as sacrocolpopexy, uterosacral ligament suspension, bilateral salpingectomy or bilateral salpingo-oophorectomy); type of morcellation used; operative times; length of stay; blood loss; and parameters for surgical recovery including infection rates and death. Preoperative antibiotics were used for all hysterectomies.

We used chi-square analysis to compare the two groups. All statistical tests were two-sided and $p < 0.05$ was considered statistically significant. All analysis was performed with R software [11]. The Kaiser Permanente Washington Region Institutional Review Board (IRB) determined that this project was quality improvement and therefore did not require IRB review or oversight.

Results

To determine practice pattern changes after removal of the laparoscopic power morcellator, we reviewed 233 patient charts. Year 1 was 100 patients who had a hysterectomy from mid-July 2013 to mid-July 2014, when the morcellator was available. Year 2 was 133 patients who had the operation from mid-July 2014 to mid-July 2015, after it was withdrawn by Gynecare. We compared the number of surgeries that used minimally invasive surgery techniques, including traditional and robotic laparoscopic and vaginal hysterectomy, to the number that used open total and supracervical hysterectomy. No significant difference was identified between Years 1 and 2 in the percent of hysterectomies that used a laparoscopic (including robotic laparoscopic) or an abdominal route (Table 1). The proportion of laparoscopic straight stick compared to laparoscopic robotic hysterectomies was not significantly different for the groups, with 19 patients (19% of hysterectomies) receiving robotic technology in 2013–2014 compared to 35 patients (26% of hysterectomies) in 2014–2015 ($p = 0.2$).

Table 1
Hysterectomy types.

Hysterectomy	Year 1, 2013–2014 Number (%)	Year 2, 2014–2015 Number (%)
Abdominal	1	1
SHYST	1 (1)	4 (3)
HYST	14 (14)	11 (8)
L/S including robotic	7	8
LSH	25 (25)	0[a] (0)
LTH	37 (37)	81[a] (61)
LAVH	9 (9)	8 (6)
Vaginal	14 (14)	29[a] (22)

Abbreviations: SHYST, open supracervical hysterectomy; HYST, open total hysterectomy; L/S, laparoscopic; LSH, laparoscopic supracervical hysterectomy; LTH, laparoscopic total hysterectomy; LAVH, laparoscopic assisted hysterectomy.
[a] $p < 0.5$ comparing Years 1 and 2.

We compared the minimally invasive hysterectomy techniques that were used when the morcellator was available versus after its removal. Twice as many transvaginal hysterectomies were performed in Year 2, after the morcellator, compared to Year 1, before morcellator removal ($p < 0.05$). There were 2.2 times as many total laparoscopic hysterectomies in Year 2 compared to Year 1 ($p < 0.001$).

Our group performed no laparoscopic supracervical hysterectomies after removal of the morcellator (chi-square test = 20, $p < 0.001$). Open total hysterectomies and laparoscopic-assisted vaginal hysterectomies did not increase. Compared to Year 1, before removal of the morcellator, four additional open hysterectomies were done in Year 2, after removal (data not shown). The overall percent of supracervical hysterectomies (open and laparoscopic) was 35% in Year 1 compared to 3.8% in Year 2, therefore, any type of supracervical hysterectomy was 9 times less likely after the morcellator was removed.

After removal of the morcellator, most uterus specimens from total laparoscopic hysterectomies were removed via the vagina using bivalve and coring techniques. Compared to Year 1, almost 2.5 times as many manual transvaginal uterus morcellation procedures were performed in Year 2 for both vaginal and laparoscopic hysterectomies. The number increased from 13 to 32 for all hysterectomies, which was 11% more than in Year 1 ($p < 0.05$). Mean uterine weights (252 g in Year 1 versus 258 g in Year 2) were not significantly different between the two study periods (Table 2).

During Year 2, after morcellator removal, we performed more secondary procedures including salpingo-oophorectomy, salpingectomy, sacrocolpopexy, uterosacral ligament suspension and colporrhaphy compared to Year 1 (88 versus 172). More bilateral salpingectomies were performed in Year 2 than in Year 1 (44% versus 18%, $p < 0.05$) (Table 3).