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MINIMALLY INVASIVE HYSTERECTOMY SURGERY RATES FOR ENDOMETRIAL CANCER PERFORMED AT NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) CENTERS

Jennifer Bergstrom, MD^{1,*}, Alessia Aloisi, MD², Shannon Armbruster, MD³, Ting-Tai Yen, MD¹, Jvan Casarin, MD⁴, Mario M Leitao Jr, MD^{2,5}, Edward J. Tanner, MD¹, Rayna Matsuno, PhD⁶, Karime Kalil Machado, MD¹, Sean C. Dowdy, MD⁴, Pamela T. Soliman, MD³, Stephanie Wethington, MD¹, Rebecca Stone, MD¹, Kimberly Levinson, MD¹, and Amanda N. Fader, MD¹

¹Kelly Gynecologic Oncology Service, Department of Gynecology and Obstetrics, Johns Hopkins Medicine, Baltimore, MD, USA

²Department of Gynecologic Surgery, Memorial Sloan Kettering Cancer Center, New York, NY, USA

³Department of Gynecologic Oncology and Reproductive Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, USA

⁴Division of Gynecologic Oncology, Mayo Clinic, Rochester, MN USA

⁵Department of Obstetrics and Gynecology, Weill Cornell Medical College, New York, NY, USA

⁶Moore's Cancer Center, University of California, San Diego, La Jolla, CA USA

Abstract

Objectives: Minimally invasive surgery (MIS) is a quality measure for endometrial cancer (EC) established by the Society of Gynecologic Oncology and the American College of Surgeons. Our study objective was to assess the proportion of EC cases performed by MIS at National Comprehensive Cancer Network (NCCN) centers and evaluate perioperative outcomes.

Methods: A retrospective cohort study of women who underwent surgical treatment for EC from 2013–2014 was conducted at four NCCN centers. Multivariable mixed logistic regression models analyzed factors associated with failure to perform MIS and perioperative complications.

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Corresponding Author: Amanda Nickles Fader, MD, Johns Hopkins University School of Medicine, 600 N. Wolfe St, Phipps 287, Baltimore, MD 21287, 410-955-8240, afader1@jhmi.edu.

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Results: In total 1,621 patients were evaluated; 86.5% underwent MIS (robotic-assisted 72.5%, laparoscopic 20.9%, vaginal 6.6%). On multivariable analysis, factors associated with failure to undergo MIS were uterine size >12cm (Odds Ratio [OR]: 0.17, 95% CI 0.03–0.9), stage III (OR: 0.16, 95% CI 0.05–0.49) and IV disease (OR: 0.07, 95% CI 0.02–0.22). For stage I/II disease, complications occurred in 5.1% of MIS and 21.7% of laparotomy cases ($p<0.01$). Laparotomy was associated with increases in any complication (OR: 6.0, 95% CI 3.3–10.8), gastrointestinal (OR: 7.2, 95% CI 2.6–19.5), wound (OR: 3.7, 95% CI 1.5–9.2), respiratory (OR 37.5, 95% CI 3.9–358.0), VTE (OR 10.5, 95% CI 1.3–82.8) and 30-day readmission (OR: 2.6, 95% CI 1.4–4.9) compared to MIS.

Conclusions: At NCCN-designated centers, the MIS hysterectomy rate in EC is higher than the published national average, with low perioperative complications. Previously identified disparities of age, race, and BMI were not observed. A proposed MIS hysterectomy benchmark of >80% in EC care is feasible when performed at high volume centers.

Introduction

An estimated 61,380 new cases of endometrial cancer will be diagnosed in 2017, the majority of which will be confined to the uterine corpus at the time of diagnosis. [1] It is well established that minimally invasive surgery (MIS) is superior to laparotomy in the management of women with apparent early-stage endometrial cancer. Eight randomized controlled trials and a Cochrane database review have demonstrated laparoscopic surgery is associated with less blood loss, fewer severe postoperative adverse events, and shorter hospital stay compared to laparotomy in this setting.[2–10] Additionally, laparoscopy is as effective as laparotomy in detection of advanced uterine cancer during surgical staging and does not compromise oncologic outcomes, with no significant survival difference noted between surgical approaches in several phase III studies.[11,12]

In 2014, the Society of Gynecologic Oncologists (SGO) and the American College of Surgeons' Commission on Cancer jointly approved the use of MIS as a quality measure for the treatment of stage I-III endometrial cancer.[13] Shortly thereafter, the SGO Clinical Practice Committee and the American College of Obstetricians and Gynecologists (ACOG) stated, "Minimally invasive surgery should be embraced as the standard surgical approach for comprehensive surgical staging in women with endometrial cancer." [14] Further, the National Comprehensive Cancer Network (NCCN) guidelines were updated in 2017, with the recommendation that hysterectomy be performed by an MIS approach in those with apparent uterine-confined disease. [15]

Despite these endorsements, and the overwhelming evidence to support the use of MIS in endometrial cancer care, recent studies suggest only 50% of hysterectomies are performed via MIS nationwide and significant disparity in surgical care exists for this disease. Previously published studies have demonstrated that MIS is less likely to be performed in the elderly or obese, racial minorities, those who are uninsured or with Medicaid insurance, those with aggressive tumor histologies, and those who are treated at rural, low-volume hospitals.[16, 17]

A recent National Inpatient Sample Database study of 9,799 patients with non-metastatic endometrial cancer who underwent hysterectomy from 2012–2013 demonstrated that laparotomy was associated with an increase in perioperative complications and an increased cost of \$1,243 per case, as compared to an MIS approach. The authors proposed that if 80% of all endometrial cancer cases were performed by an MIS approach, approximately 2,733 complications could be averted and over \$19 million in direct health care costs could be saved per year. [17]

With this in mind, our primary study objective was to assess whether this proposed MIS benchmark is feasible at large-volume, NCCN centers. Secondary objectives were to determine factors associated with failure to undergo MIS and to compare perioperative complications between MIS and laparotomy at these same centers during a contemporary time period.

Methods

A retrospective, multisite cohort study was performed using prospectively-maintained data at four, high endometrial cancer volume (>75 cases/year), NCCN-designated centers. Institutional Review Board approval was obtained from the Johns Hopkins School of Medicine (JHH; Baltimore, MD), The Mayo Clinic (Rochester, MN), Memorial Sloan Kettering Cancer Center (MSKCC; New York, NY), and The University of Texas M.D. Anderson Cancer Center (MDACC; Houston, TX). Patients treated surgically for a primary diagnosis of endometrial carcinoma on hysterectomy specimen from January 2013 through December 2014 were included. This contemporary time period was chosen to analyze the years directly following the time period that was analyzed in the National Inpatient Sample Database study described above. All procedures were performed by gynecologic oncology surgeons (JHH n=4, Mayo n=8, MSKCC n=9, MD Anderson n=19). Patients were eligible if they had pathologically confirmed endometrial carcinoma and received primary surgical treatment at one of these large-volume centers during the specified years.

Demographic data were collected on patient factors including age at diagnosis, body mass index (BMI), race, and medical comorbidities. Pre-operative variables of past surgical history, pre-operative histology, uterine size, pre-operative imaging, presumed pre-operative stage, and concern for distant metastases were recorded. Operative variables included primary endometrial cancer procedure performed, route of surgery, conversion to laparotomy, length of surgery, and estimated blood loss. MIS was defined as robotic-assisted, laparoscopic, or vaginal hysterectomy. Post-operative information regarding length of hospital stay, in-hospital complications, and readmissions were reviewed. In-hospital complications that were analyzed in this study were unplanned admission to the ICU, need for reoperation, severe pulmonary, urinary tract, or cardiac complications, deep incisional or organ space surgical site infection, bowel obstruction, ileus > 7 days, hemorrhage requiring > 4 units of packed red blood cell transfusion, venous thromboembolism, and death before discharge.

The majority of data was extracted from pre-existing endometrial cancer databases at each individual site. Given each database contained differing variables, missing values for certain

pre-operative factors were noted. Given the extent of missing data from two institutions, only the two sites (site 1 and 2) with complete data sets were included in the multivariable mixed logistic regression models to determine factors associated with failure to undergo MIS. All sites were included in mixed logistic regression models that involved hospital complications within the entire population and only those patients with stage I or II disease.

Demographic and clinical characteristics for MIS and laparotomy patients were compared using Chi-square and Fisher's exact tests for categorical variables and t-test for continuous variables. Multivariable mixed logistic regression models were used to analyze combined data, where clinical site was treated as random effect, and logistic regression models were used for site-specific analyses. All statistical calculations were performed using SAS 9.4 and a p-value of <0.05 was considered significant.

Results

A total of 1,621 patients were included in the analysis. The clinical and demographic characteristics of the study population are presented in Table 1. The mean patient age was 62.2 (SD=11.1) and mean BMI was 33.7 (SD= 9.6). The majority of patients were Caucasian (79.6%). With regards to pre-operative histology, 983 (60.6%) patients were diagnosed with endometrioid FIGO grade 1–2 disease, 156 (9.6%) had endometrioid FIGO grade 3, 117 (7.2%) had uterine serous carcinoma, 74 (4.6%) had a noncancerous pre-operative lesion, 32 (2%) were clear cell carcinoma, and 259 (16.0%) had an unknown or other pre-operative lesion. All included patients underwent hysterectomy, the majority who also underwent USO or BSO (99.1%) and pelvic lymphadenectomy (75.5%). Fewer patients underwent omentectomy (20.4%), para-aortic lymphadenectomy (27.3%), or small or large bowel resection (0.4% and 1.0% respectively). Cancer stage distribution was: Stage I (75.7%), stage II (3.2%), Stage III (13.6%), Stage IV (6.4%), unknown (1.2%).

Distribution of surgical route by clinical site is presented in Table 2. When all centers were combined, 86.5% of hysterectomy cases performed for endometrial cancer were completed via a minimally invasive approach. Individual center MIS rates were 79.6%, 84.4%, 90.9%, and 87.0% for sites 1–4, respectively, $p < 0.01$ (Figure 1). The majority of MIS cases were performed via a robotic-assisted approach (72.5%), followed by traditional laparoscopy (20.9%) or vaginal routes (6.6%). Each center differed in terms of MIS approach, with Site 3 having significantly more vaginal surgery (20%) and Site 4 more traditional laparoscopy (54.3%), $p < 0.01$.

Laparotomy was associated with longer operative times (236 minutes vs. 199.3 minutes, $p < 0.01$) and increased estimated blood loss (486mL vs. 125mL, $p < 0.01$) compared to MIS. Mean length of hospital stay was 1.3 days (SD= 1.9) for the MIS cohort compared to 5.6 days (SD= 4.2) for the laparotomy cohort. Patients undergoing laparotomy were more likely to have an in hospital complication (23.5% vs 5.6%, $p < 0.01$) and be re-admitted within 30 days (14.2% vs. 6.1%, $p < 0.01$) compared to the MIS cohort.

Laparotomy was associated with increased risk of ICU admission, serious wound, respiratory, and gastrointestinal complication, and venous thromboembolism within the

entire cohort. Within those patients with stage I/II disease, laparotomy was associated with increased risk of serious wound, respiratory, and gastrointestinal complication and venous thromboembolism. On multivariable logistic regression for those patients with uterine confined disease (stage I/II) from all 4 institutions, patients undergoing laparotomy were more likely to suffer any complication (OR: 6.0, 95% CI 3.3–10.8), gastrointestinal complication (OR: 7.2, 95% CI 2.6–19.5), wound complication (OR: 3.7, 95% CI 1.5–9.2), respiratory complication (OR 37.5, 95% CI 3.9–358.0), venous thromboembolism (OR: 10.5; 95% CI 1.3–82.8) or 30-day readmission (OR: 2.6, 95% CI 1.4–4.9) compared to those who underwent MIS, as seen in table 4.

On univariate analysis, women of “other” race, endometrioid grade 3 histology, serous histology, and “Other” or “Unknown histology” on pre-operative sampling were more likely to undergo laparotomy when all sites were combined ($p < 0.01$). Ultimately, on multivariable mixed logistic regression modeling, race and pre-operative histology did not remain significantly associated with surgical approach after controlling for other factors (Table 3), whereas uterine size greater than 12 cm (OR: 0.17, 95% CI 0.03–0.9) and pre-operative impression of stage III (OR: 0.16, 95% CI 0.05–0.49) or IV (OR: 0.07, 95% CI 0.02–0.22) disease were associated with failure to undergo MIS.

Conclusions

In this cohort study performed at four, high-volume NCCN institutions, a proposed 80% minimally invasive hysterectomy surgery (MIS) benchmark for endometrial cancer care was attainable. While there was a significant difference in MIS among study sites, collectively, an MIS rate of 86.5% was observed, with each participating institution at or above the 80% mark. Notably, the MIS rate at these NCCN centers was considerably higher than the reported national average of approximately 50% from recently published national database studies performed during the same time period. [16,17] Recognizing that women diagnosed with endometrial cancer are often elderly, obese and have multiple medical co-morbidities which predispose them to costly perioperative complications and increased length of hospital stay, this is a population who will particularly benefit from a minimally invasive approach to their cancer care [26].

There is substantial literature demonstrating that when patients receive surgical care at high-volume hospitals with high-volume surgeons, they experience improved outcomes. Recently, a meta-analysis within colorectal surgery and a systemic review of urologic patients undergoing radical prostatectomy both demonstrated improved surgical outcomes when surgeries were performed by high-volume surgeons. [18, 19] Within the gynecologic oncology specialty women treated at high-volume ovarian cancer hospitals are more likely to receive NCCN adherent care and experience better survival outcomes compared to those treated at low volume centers. [20] A centralized care model within the Swedish population demonstrated improved rates of complete cytoreduction, decreased time from primary surgery to initiation of chemotherapy, and improved survival outcomes in those with advanced ovarian cancer. [21] Our data demonstrating improved MIS rates and decreased complications within the endometrial cancer patient population at high-volume NCCN

designated centers contributes to this growing body of literature to support a centralized care model within the United States.

Recently, disparities in receipt of appropriate treatment for many malignancies, including gynecologic cancers, have been reported. It is well documented that women of low socioeconomic status, black race, no insurance or publicly funded insurance are less likely to receive standard of care therapy and have lower survival rates in ovarian, cervical and endometrial cancer. [16, 17, 22–25] For endometrial cancer, in particular, women were more likely to undergo open hysterectomy for uterine confined endometrial cancer if they were black or “other race” or if they underwent primary surgical treatment at a rural or low-volume hospital. [16] It is encouraging to observe in our study that at high-volume NCCN centers, these disparities are eliminated and receipt of MIS was only impacted by disease-related factors (i.e, size of uterus and advanced-stage disease at diagnosis). This study provides further evidence that MIS procedures can be more broadly offered at high-volume centers, regardless of patient factors or surgical complexity.

While not all hysterectomies for endometrial cancer can be performed via minimally invasive techniques, most can when performed by high volume surgeons. For women with uteri larger than 12–14 centimeter in length, surgeons may use techniques in select patients to exteriorize surgical specimens in a minimally invasive fashion. These include utilization of a sturdy laparoscopic tissue retrieval bag through the vagina to allow either 1) easier delivery of a bulky uterus with or without minimal tissue fragmentation within the bag or 2) a similar technique with mini-laparotomy to exteriorize the specimen abdominally. Care should be taken to avoid fragmentation or morcellation a uterine specimen with known cancer inside the peritoneal cavity and to limit any tissue fragmentation within a bag so as not to distort pathological assessment of the uterus. Additionally, unless there is gross, multisite metastatic disease evident at surgery, it is our preference to remove suspicious or known metastatic lymph nodes minimally invasively, as there is no difference in oncologic outcomes when compared to removal of nodes by laparotomy [27] and the interval for receipt of adjuvant therapies will be shorter for those patients who undergo the MIS approach due to the faster recovery.

In our current climate of rising health care costs with increased focus on quality health care being delivered at lower expense, it is critical to focus on the impact surgical approach has on direct health care costs. In a recent National Inpatient Sample database study, an estimated cost savings of \$1200 per case was observed in those who underwent an MIS hysterectomy (either robotic or laparoscopic) for endometrial cancer compared with laparotomy. This was largely due to decreases in hospital length of stay and a significant decrease in complications observed in the MIS cohort. [16] If all institutions caring for patients with endometrial cancer had an MIS rate at or above the proposed 80% benchmark, as opposed to the reported average near 50%, the health care cost savings would be enormous.

Study limitations include analysis of only NCCN-designated institutions, the retrospective study design, and the fact that each institution had a pre-existing endometrial cancer database with differing variable collection systems, rendering some comparisons among

institutions challenging. Due to missing pre-operative variables, two sites were not included in the multivariable analysis to determine factors associated with failure to undergo MIS. A centralized gynecologic cancer registry with uniform data collection methods, such as that used in the Society of Gynecologic Oncology Clinical Outcomes Registry, may provide more comprehensive and generalizable data to study these types of questions.

In conclusion, data from high-volume NCCN centers demonstrates that a proposed MIS rate of 80% is an achievable benchmark for the management of women with newly-diagnosed endometrial cancer, and should be added to the existing minimally invasive surgery quality measures. Furthermore, previously identified disparities in surgical approach based on age, race, BMI, prior surgical history, and pre-operative histology can be eliminated at high-volume centers. Perioperative complications for those undergoing primary surgery via a minimally invasive technique were much lower than those undergoing laparotomy, which is consistent with previously reported data. Referral of women with endometrial cancer to larger, high-volume centers with reported high rates of MIS should be encouraged by the American College of Obstetrics and Gynecology and the Society of Gynecologic Oncology to reduce preventable surgical harm, avert unnecessary health care spending, and minimize treatment disparities.

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Highlights:

- Minimally invasive surgery is a quality measure for endometrial cancer.
- NCCN centers have a high rate of minimally invasive surgery for endometrial cancer.
- Disparities in surgical approach can be eliminated at high-volume centers.
- A proposed MIS hysterectomy benchmark of >80% in endometrial cancer is feasible.

★ Proposed 80% MIS benchmark

Figure 1:
Route of Surgical Procedure

Table 1.

Demographic and clinical characteristics for all endometrial cancer patients

Demographics	All sites (N=1,621)
Age, mean (SD)	62.2 (11.1)
BMI, mean (SD)	33.7 (9.6)
Race	
White	1,290 (79.6)
Other/Unknown	331 (20.4)
Previous abdominal surgery	
No	725 (44.7)
Yes	880 (54.3)
Unknown	16 (1.0)
Pre-op dx	
Non-invasive	74 (4.6)
Endometrioid, FIGO grade 1–2	983 (60.6)
Endometrioid, FIGO grade 3	156 (9.6)
Clear cell	32 (2.0)
Serous	117 (7.2)
Other or unknown *	259 (16.0)
Procedure performed (not mutually exclusive)	
Hysterectomy	1,621 (100)
USO/BSO	1,606 (99.1)
Omentectomy	331 (20.4)
Pelvic lymphadenectomy	1,224 (75.5)
Paraaortic lymphadenectomy	443 (27.3)
Peritoneal washings	419 (25.9)
Small bowel resection	6 (0.4)
Large bowel resection	16 (1.0)
Appendectomy	12 (0.7)
Other **	264 (16.3)

* Includes carcinosarcoma, leiomyosarcoma, mixed histology, dedifferentiated carcinoma

** Other procedures include lysis of adhesions, cholecystectomy, hernia repair, cystoscopy

Table 2.

Distribution of surgical route by clinical site

	All Sites	Site 1	Site 2	Site 3	Site 4
Route of hysterectomy	n (%)	n (%)	n (%)	n (%)	n (%)
Laparotomy	219 (13.5)	33 (20.4)	98 (15.6)	46 (9.1)	42 (13.0)
MIS	1,402 (86.5)	129 (79.6)	530 (84.4)	461 (90.9)	282 (87.0)
Laparoscopy/Laparoscopic assisted	293 (20.9)	13 (10.1)	103 (19.4)	24 (5.2)	153 (54.3)
Robotic assisted	1,016 (72.5)	115 (89.1)	427 (80.6)	345 (74.8)	129 (45.7)
Vaginal	93 (6.6)	1 (0.8)	0 (0.0)	92 (20.0)	0 (0.0)

* Percentage is number of patients who underwent surgical route divided by total number of patients for all sites combined, and then within each site (ie, column percent)

Table 3.

Odds of undergoing MIS versus open surgery

	OR	95% CI	P
Age at diagnosis (years)	1.00	0.98, 1.02	0.87
Race			
White	REF	REF	
Other / unknown	0.74	0.03– 20.31	0.46
Comorbid conditions			
No comorbidities	REF	REF	
1 comorbidity	0.79	0.14– 4.40	0.61
2 or more comorbidities	0.57	0.12– 2.62	0.25
Uterine size (cm)			
<12 cm	REF	REF	
12+ cm	0.17	0.03– 0.90	0.04
Unknown	1.19	0.43– 3.29	0.55
Pre-op histology			
Non-invasive	2.60	0.22– 30.93	0.34
Endometrioid, grade 1 or 2	REF	REF	
Endometrioid, grade 3	0.65	0.27– 1.56	0.25
Clear cell or serous	0.71	0.26– 1.98	0.41
Other or unknown	0.47	0.18– 1.20	0.09
Pre-op stage			
Stage I	REF	REF	
Stage II	0.19	0.03– 1.19	0.06
Stage III	0.16	0.05– 0.49	0.01
Stage IV	0.07	0.02– 0.22	<0.01
Unknown	0.16	0.01– 2.88	0.09

Note: OR, odds ratio; CI, confidence interval; P, p-value corresponding to odds ratios. Mixed logistic regression model to evaluate selected factors that may be associated with undergoing MIS versus open surgery. Clinical site was a random effect; fixed effects (covariates) are shown in the table.

Table 4.

Odds of having an in hospital complication for patients who underwent laparotomy versus MIS surgery (all sites, stage I/II patients only)

	All Sites		
	OR	95% CI	P
<u>Complications</u>			
Any complication	5.95	3.28–10.79	<0.01
Intensive Care Unit stay	3.06	0.81–11.52	0.1
Re-operation	0.94	0.12–7.57	0.9
Respiratory	37.5	3.93–357.98	<0.01
Wound	3.68	1.47–9.22	<0.01
Urinary	1.88	0.53–6.68	0.33
Gastrointestinal	7.18	2.64–19.53	<0.01
VTE	10.53	1.34–82.77	0.03
Readmitted within 30 days	2.58	1.38–4.84	<0.01

Notes: OR, odds ratio; CI, confidence interval; P, p-value

Odds ratio corresponds to odds of complication for open surgery compared to MIS. Model adjusted for: age and race.