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Postoperative Morbidity of Minimally Invasive Hysterectomy Approach and Uterine Size

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Abstract

Background: The optimal approach to minimally invasive hysterectomy when uterine size is larger than 250 g is unclear. The aim of this study was to evaluate 30-day postoperative complications after minimally invasive hysterectomy by surgical approach and uterine size.

Methods: The American College of Surgeons National Surgical Quality Improvement Program database was searched for patients who underwent laparoscopic or vaginal hysterectomy between 2005 and 2012. Patient demographics and 30-day postsurgical complication rates were compared by hysterectomy approach and uterine size classified as either less than or equal to 250 g (small uterine size) and greater than 250 g (large uterine size) by billing codes. Multivariable regression analyses were used to study the independent effect of uterine size on outcomes.

Results: Of patients undergoing hysterectomy, 31,754 (86.2%) patients had small uterine size and 5,067 (13.8%) patients had large uterine size. No surgical approach was associated with better or worse outcomes in the large uterus size group (adjusted odds ratio (aOR): 1.00, 95% CI: 0.76 - 1.30, P = 0.990). Overall morbidity was significantly more common with large uterine size than small uterine size (5.78% and 3.44%, respectively, P < 0.001). Blood transfusions were significantly more common with large than small uterine size (3.04% and 1.11%, respectively, P < 0.001). Median operative time is increased in the large uterus size group 148 minutes compared to 111 minutes in the small uterine size group (P < 0.001). Multivariable logistic regression analyses showed that uterine size was a significant predictor of overall postoperative morbidity (aOR: 1.73, 95% CI: 1.31 - 2.29).

Conclusions: No approach to hysterectomy of large uteri is clearly superior in this study. Patient and surgeon preference may guide surgical approach to minimally invasive hysterectomy with large uterine size.

Keywords: Minimally invasive hysterectomy; Enlarged uterus; Laparoscopic hysterectomy; Vaginal hysterectomy; Postoperative complications

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Introduction

Gynecologic surgeons often choose the surgical approach to hysterectomy based on uterine size [1]. Increased uterine size may limit surgical exposure, alter expected anatomical landmarks, make obtaining hemostasis more difficult, and has historically required the use of morcellation techniques. Therefore uterine size is an important variable accounted for during preoperative planning and surgical approach to hysterectomy. Patients and surgeons would benefit from having evidence-based knowledge of the differences in complications, operative time and length of stay in order to provide more accurate informed consent to patients and make the most educated decision on surgical approach.

The effect of enlarged uterine size has been studied when examining the most beneficial and least harmful surgical approach to hysterectomy. Numerous studies comparing minimally invasive approaches to abdominal hysterectomy included patients with enlarged uteri [2-9]. Laparoscopic hysterectomy has been shown to have lower intraoperative loss, more urinary tract injuries, longer operation time, smaller postoperative hemoglobin loss, shorter hospital stay, fewer wound or abdominal wall infections, and speedier return to normal activities when compared to abdominal hysterectomy [10]. Several studies have examined the differences in morbidity with minimally invasive approaches to hysterectomy, but many of these studies have excluded patients suspected of having a large uterus [11-17].

The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) was established as a tool for quantifying and improving patient outcomes during and after surgery [18, 19]. Within the Physicians' Current Procedural Terminology Coding System, 4th edition (CPT-4),

Table 1. Current Procedural Terminology Coding System, 4th Edition for Minimally Invasive Hysterectomy

CPT-4 code	Description
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
55844	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g, with removal of tube(s) and/or ovary(s)
58550	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(ies)
58553	Laparoscopy surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy surgical, with vaginal hysterectomy, for uterus greater than 250 g, with removal of tube(s) and/or ovary(ies)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(ies)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g, with removal of tube(s) and/or ovary(ies)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(s), with repair of enterocele
58267	Vaginal hysterectomy, for uterus 250 g or less, with colpo-urethrocystopexy (Marshall-Marchetti-Kranz type, Pereyra type, with or without endoscopic control)
58270	Vaginal hysterectomy, for uterus 250 g or less, with repair of enterocele
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g, with removal of tube(s) and/or ovary(ies)
58292	Vaginal hysterectomy, for uterus greater than 250 g, with removal of tube(s) and/or ovary(ies), with repair of enterocele
58293	Vaginal hysterectomy, for uterus greater than 250 g, with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58294	Vaginal hysterectomy, for uterus greater than 250 g, with repair of enterocele

there are different codes for hysterectomies involving uteri weighing less than or more than 250 g [19]. This uterine mass is estimated by the surgeon at time of surgery and confirmation of uterine mass by surgical pathology is not required. Using billing codes for hysterectomy approach and uterine size and the NSQIP registry, the objective of the present study was to evaluate the outcomes of minimally invasive hysterectomy by surgeon-coded estimated uterine size.

Methods

Data from the NSQIP participant use file from 2005 to 2012 were retrospectively analyzed. The methods of data collection for the registry have been described previously [20]. Data containing patient demographics, comorbidities, and perioperative events were prospectively collected for patients within the NSQIP by a trained nurse data abstractor. Postoperative outcomes within 30 days of the procedure were tracked by medical records, a follow-up letter and/or phone call to the patient. These data are subjected to random audits with a previously reported disagreement rate of less than 1.8%.

The study population was patients undergoing total laparoscopic hysterectomy (TLH), laparoscopic supracervical hysterectomy (LSCH), laparoscopic-assisted vaginal hysterectomy (LAVH), and total vaginal hysterectomy (TVH) with or without concurrent adnexal surgery performed by gynecologists. We included patients with the following CPT-4 codes listed in Table 1.

Procedures performed for the indication of malignant disease by International Classification of Disease, Ninth Revision, Clinical Modification codes were excluded. Information on the presence of robotic assistance was not available in this dataset.

For each type of laparoscopic hysterectomy, patients were grouped into those coded as having hysterectomies of uteri greater the 250 g and those of uteri 250 g or less by CPT-4 code.

The primary outcomes were the rates of 30-day postoperative vascular, wound, respiratory, renal, blood transfusion, venous thromboembolism, and infectious morbidity as well as a composite morbidity score. All complications were defined as dichotomous variables (present or absent). Vascular morbidity was classified as cardiac arrest, myocardial infarction with new-Q waves on electrocardiogram or stroke. Wound morbidity was classified as a surgical site infection of super-

Table 2. Characteristics of the Study Population

	Uterine size < 250 g by CPT-4 (n = 31,754)	Uterine size > 250 g by CPT-4 (n = 5,067)	P*
Age (years)	47.9 ± 11.7	47.4 ± 7.2	0.002
BMI (kg/m^2)	29.6 ± 7.3	30.7 ± 8.0	< 0.001
Race			
White	78.6%	64.5%	< 0.001
Hispanic	10.3%	11.4%	0.854
Black of African American	8.0%	22.7%	< 0.001
Asian	2.2%	3.6%	< 0.001
Other	11.2%	9.2%	< 0.001
Clinical characteristics			
Active smoker	19.5%	14.2%	< 0.001
Steroid use	1.1%	0.7%	0.012
Comorbidities			
Hypertension	25.1%	25.2%	0.818
Diabetes	6.5%	5.7%	0.023
Dyspnea	3.4%	3.0%	0.185
History of cardiac procedures	0.6%	0.4%	0.059
History of TIA or stroke	0.8%	0.5%	0.005
Bleeding disorder	0.9%	1.1%	0.200
Primary indication			
Fibroids	53.1%	73.3%	< 0.001
Abnormal bleeding	24.2%	16.1%	< 0.001
Pelvic pain	9.2%	2.3%	< 0.001
Endometriosis	7.3%	4.0%	< 0.001
Prolapse	20.4%	4.2%	< 0.001
Postmenopausal	2.9%	2.1%	< 0.001
Ovarian mass	2.8%	1.8%	< 0.001
Endometrial hyperplasia	4.7%	3.0%	< 0.001
Cervical dysplasia	3.6%	1.0%	< 0.001
Surgical characteristics			
Concurrent adnexal surgery	47.7%	41.7%	< 0.001
Concurrent pelvic support procedure	19.0%	7.1%	< 0.001
Total concurrent RVU	7.2 ± 12.0	4.7 ± 9.6	< 0.001
Pre-operative hematocrit < 30%	38%	25%	< 0.001

CPT-4: current procedural terminology, 4th edition; TIA: transient ischemic attack; RVU: relative work value unit. Data are mean ± standard deviation or % unless otherwise specified. *χ^2 or Student's *t*-test.

ficial, facial, muscle, or internal organ layers, or wound dehiscence. Respiratory morbidity was classified as prolonged mechanical ventilation more than 2 days after surgery or unplanned reintubation. Renal morbidity was classified as acute renal failure requiring dialysis or renal insufficiency classified as an increase in creatinine of more than 2 mg/dL from the preoperative value. Blood transfusion morbidity was classified as receiving a blood transfusion within 3 days of the surgery. Venous thromboembolism was classified as pulmonary embolism or deep vein thrombosis. Infectious morbidity was classified as a urinary tract infection, pneumonia, sepsis, or septic shock. Composite morbidity score was classified as combining the above mentioned complications into a single score where any complication or complications was classified as a dichotomous variable (present or absent). Secondary outcomes were the length of surgery (excluding anesthesia time) and length of hospital stay.

Patient variables for risk adjustment included demograph-

Table 3. Comparison of Unadjusted Minimally Invasive Hysterectomy Outcomes by Uterine Size

	Uterine size < 250 g by CPT-4 code (n = 31,754)	Uterine size > 250 g by CPT-4 code (n = 5,067)	P*
Overall morbidity	1,093 (3.4)	293 (5.8)	< 0.001
Vascular morbidity	18 (0.1)	2 (0.7)	0.625
Wound morbidity	592 (1.9)	122 (2.4)	0.009
Respiratory morbidity	25 (0.1)	3 (0.1)	0.640
Renal morbidity	15 (0.1)	2 (0.1)	0.811
Blood transfusions	353 (1.1)	154 (3.0)	< 0.001
DVT/PE morbidity	68 (0.2)	11 (0.2)	0.966
Infectious morbidity	166 (.5)	35 (0.7)	0.132
Return to OR	412 (1.3)	85 (1.7)	0.030
Operative time (min)	124.1 ± 65.4	162 ± 78.1	< 0.001
Length of stay (days)	1.31 ± 5.3	1.36 ± 7.5	0.535

CPT-4: current procedural terminology, 4th edition; DVT: deep vein thrombosis; PE: pulmonary embolus; OR: operating room. Data are n (%) or mean ± standard deviation unless otherwise specified. *χ^2 or Wilcoxon rank-sum tests.

ics, diagnosis, and comorbidities information. Patient demographic data included age, race, ethnicity, body mass index (BMI), active smoking, oral steroid use, hypertension medication use, and uterine size. Patient primary diagnosis data were from primary procedure International Classification of Diseases, Ninth Revision, Clinical Modification codes. Patient comorbidity data included diabetes, dyspnea, history of cardiac procedure, history of stroke or transient ischemic attack, and history of bleeding disorder. Surgical factors included concurrent adnexectomy, concurrent pelvic support procedure, concurrent relative work value units (RVU) (a measure of complexity of the total procedures) and preoperative hematocrit lower than 30%.

Descriptive statistics and complications rates were calculated for the study population using χ^2 test for categorical variables, and Student's *t*-test and Wilcoxon rank-sum test for continuous variables. A multivariable logistic regression model constructed with variables selected for inclusion in the model based on bivariate statistics ($P < 0.2$). Variables selected for final model were uterine size, age, race, diabetes, smoking, dyspnea, history of cardiac procedure, hypertension medication, history of stroke or transient ischemic attack, steroid use, bleeding disorder (i.e. a deficiency of blood clotting elements excluding anemia), BMI, concurrent adnexectomy, concurrent pelvic support procedure, concurrent RVU, and preoperative hematocrit lower than 30%. Alpha level was specified as 0.05. SAS 9.3 (SAS, Cary, NC) was used for analysis.

This secondary analysis of a de-identified dataset was deemed exempt from review by the University of Kentucky Office of Research Integrity.

Results

There were 36,821 patients who underwent vaginal or laparoscopic hysterectomy within the study inclusion period, of whom 31,754 (86.2%) had CPT-4-coded small uterine size and 5,067 (13.8%) had CPT-4-coded large uterine size. A com-

Table 4. Independent Risk Factor Association With Overall Morbidity

Preoperative variable	aOR	95% CI	P
Uterine size > 250 g by CPT-4 code	1.73	1.31 - 2.29	< 0.001
Black race	1.77	1.13 - 2.79	0.013
Hispanic ethnicity	1.82	1.30 - 2.54	0.004
Bleeding disorders	4.35	2.43 - 8.46	< 0.001
BMI > 30	1.37	1.07 - 1.74	0.011
Concurrent pelvic support procedure	0.48	0.33 - 0.70	< 0.001
Total concurrent RVU	1.47	1.04 - 2.07	0.027
Hosmer-Lemeshow	0.941		
C-statistic	0.672		

aOR: adjusted odds ratio; CI: confidence interval; BMI: body mass index; RVU: relative work value units.

Table 5. Independent Association of Operative Approach With Overall Morbidity by Uterine Size

Hysterectomy approach	aOR	95% CI	P	Hosmer-Lemeshow	C-statistic
Among uterine size < 250 g by CPT-4 code					
LAVH (n = 8,687)	1.36	0.99 - 1.85	0.052	0.939	0.650
LSCH (n = 4,877)	0.76	0.53 - 1.10	0.152	0.188	0.651
TLH (n = 8,192)	0.61	0.42 - 0.90	0.012	0.379	0.651
TVH (n = 9,998)	1.32	0.97 - 1.806	0.079	0.005	0.652
Among uterine size > 250 g by CPT-4 code					
LAVH (n = 1,430)	1.23	0.73 - 2.07	0.448	0.020	0.645
LSCH (n = 863)	1.081	0.55 - 2.120	0.821	0.039	0.648
TLH (n = 2,112)	0.66	0.40 - 1.10	0.108	0.025	0.654
TVH (n = 626)	1.41	0.74 - 2.69	0.290	0.226	0.651
All MIS hysterectomy > 250 g by CPT-4 code (n = 5,067)	1.73	1.30 - 2.29	< 0.001	0.941	0.672

aOR: adjusted odds ratio; CI: confidence interval; CPT-4: current procedural terminology, 4th edition; LAVH: laparoscopic-assisted vaginal hysterectomy; LSCH: laparoscopic supracervical hysterectomy; TLH: total laparoscopic hysterectomy; TVH: total vaginal hysterectomy, with or without concurrent adnexal surgery; MIS: minimally invasive.

parison of the patient characteristics is summarized in Table 2. There were small but significant differences between the two groups' patient and clinical characteristics. The small uterine size group was older (47.9 years old compared with 47.4, P = 0.002) and had a lower BMI (29.6 compared to 30.7, P = 0.001). There was an unequal distribution of race with black patients in the large uterine size group and more white patients in the small uterine size group (P = 0.001). There were small but significant differences in the distribution of comorbidities; the small uterine size cohort was more likely to be diabetic, smoke tobacco, have a history of transient ischemic attack of cerebral vascular accident, actively using steroid medications (P = 0.023, < 0.001, 0.059, 0.005, and 0.012, respectively). The indication for hysterectomy in the large uterine size cohort was more likely to be fibroids (P < 0.001). The small uterine size cohort was more likely to have concurrent adnexal surgery, concurrent pelvic support procedures, higher concurrent RVU, and hematocrit less than 30%.

Overall morbidity was low but differed significantly among the cohorts, with small and large uterine size patients experiencing morbidity rates of 3.4% and 5.8% respectively (P < 0.001) (Table 3). Among the individual morbidity classifications, wound complications, blood transfusions, and reoperations were all increased in the large uterine size cohort. Wound complications were in 1.9% of the small uterine size cohort and 2.4% of the large uterine size cohort (P = 0.009). Blood transfusion occurred in 1.1% of the small uterine size cohort and 3.0% of the large uterine size cohort (P < 0.001). Reoperations within 30 days were increased in the large uterine size cohort compared to the small uterine size cohort, 1.3% compared to 1.7%, respectively (P = 0.030).

The median operative time was significantly increased in the large uterine size cohort, 148 min compared to 111 min in the small uterine size cohort (P < 0.001). The length of stay differed a clinically insignificant time, but was statistically significant between the cohorts, with small uterine size and large uterine size hospitalized 1.31 days and 1.36 days, respectively (P = 0.001).

When adjusting for potential confounders, a significant association between uterine size and 30-day morbidity was observed (adjusted odds ratio (aOR): 1.73, 95% confidence interval (CI): 1.31 - 2.29, P < 0.001) (Table 4). Black race, Hispanic ethnicity, bleeding disorders, BMI > 30, and higher than average total concurrent RVU were all independent risk factors in the development of postoperative complications. Concurrent pelvic support procedures were independently associated with a decreased OR of development of postoperative complications (aOR: 0.48, 95% CI: 0.33 - 0.70, P < 0.001). Patients with bleeding disorders were four times more likely to have postoperative complications compared to patients without bleeding disorders (P < 0.001). Patients of black race were more likely to have postoperative complications (aOR: 1.77, 95% CI: 1.13 - 2.79, P = 0.013).

When 30-day morbidity between hysterectomy approaches was compared within uterine size less than 250 g, TLH was independently associated with decreased OR of complications compared to all hysterectomies involving small uterine size (aOR: 0.61, 95% CI: 0.43 - 0.90, P = 0.012, respectively) (Table 5). LAVH was an independent predictor of increased postoperative complications compared to all small uterine size hysterectomies (aOR: 1.17, 95% CI: 1.03 - 1.34, P = 0.017).

Among uterine size greater than 250 g, no significant association between the hysterectomy technique and 30-day morbidity was observed (aOR: 1.00, 95% CI: 0.76 - 1.30, P = 0.990 (Table 5). Adjusting for potential confounders, among procedures with small uterine size, TLH was associated with decreased risk of postoperative transfusion (aOR: 0.54, 95% CI: 0.32 - 0.90, P = 0.017). Among procedures with large uterine size, there was no procedure that was significantly associated with increased or decreased risk of transfusion compared to other approaches to minimally invasive hysterectomy. Adjusting for potential confounders, there was no procedure associated with increased or decreased risk of wound complications within either the small or large uterine size cohort. When

stratified by hysterectomy technique, TVH had the smallest differential in median operative time between small and large group, 14 min (90 min compared to 104 min, $P < 0.001$) while TLH had the largest time differential, 37 min (140 min compared to 177 min, $P < 0.001$). Reoperation in the large uterine size cohort was not statistically significant, after adjustment for potential confounders (aOR: 1.18, 95% CI: 0.63 - 2.23, $P = 0.592$).

Among the regression models between uterine size cohorts, Hosmer-Lemmeshow tests demonstrate an adequate model discrimination (Table 4). Among the regression models between various surgical approaches, the presence of significance in some models found with the Hosmer-Lemmeshow tests demonstrates a poor discrimination (Table 5). However, the C-statistic approaches the frequently desired threshold of 0.7 for all regression models, which indicates appropriate discriminatory power or low variation among patient-level factors.

Discussion

Minimally invasive techniques to hysterectomy of the enlarged uterus are becoming more common. With vaginal, laparoscopic and procedures combining both approaches, both patient and surgeon face several options when hysterectomy is indicated. The current analysis of more than 36,000 minimally invasive hysterectomies provides a large, multicenter series comparing postoperative complications and effects of risk factors by uterine size.

There was no statistically superior or inferior approach to hysterectomy of large uteri. Previous Cochrane meta-analysis suggests superiority of vaginal hysterectomy in comparison to laparoscopic hysterectomy due to laparoscopic hysterectomy being associated with longer operations and a higher rate of significant bleeding [10]. Cost-effectiveness analysis also suggests a vaginal hysterectomy may be superior to laparoscopic hysterectomy [21]. Laparoscopic hysterectomy is rapidly gaining in prevalence while vaginal hysterectomy is stable to decreasing in prevalence; this may reflect patients and surgeons changing preferences about approach. The balance between costs and quality of life is constantly changing as surgical skill, health care costs, and patient perceptions of quality of life evolve; therefore, the cost-effectiveness of vaginal and laparoscopic hysterectomy deserves periodic reevaluation. Strengths of this study include a large, diverse, national, multicenter patient cohort, a validated data collection system, and a recent study period. This large retrospective cohort confirms previous studies and provides new, useful data on the respective safety of different hysterectomy approaches by uterine size. This study confirms that for each approach, the risk of postoperative complications increases with uterine size greater than 250 g. The morbidity associated with the larger uterus for all surgical approaches is primarily due to increased postoperative blood transfusions and wound complications. Importantly, there was no difference in morbidity between any of the approaches to hysterectomy when the uterine size was greater than 250 g, suggesting that other patient characteristics and surgeon preferences should guide choosing surgical approach other than uterine size.

Weaknesses of the study include the retrospective nature of the study, the lack of data on the pathology measured weight of the hysterectomy specimen, and the absence of important patient information such as socioeconomic status, presence of robotic assistance, hospital type, insurance information, and surgeon experience. Outcomes such as ureteral injury, vaginal cuff dehiscence, patient satisfaction, quality of life, and economic impact are also absent.

The NSQIP database was designed to improve patient care by comparing outcomes across participating hospitals. It was not designed to answer specific questions regarding procedures or diseases. Without location information on which hospitals and physician were performing which procedures, it is impossible to evaluate clustering of procedures between hospitals. The hospitals included in the database may be particularly committed to quality improvement biasing the selection of patients and procedures.

With increased knowledge of the differences in blood transfusions and operative time, patients may be counseled more clearly about the difference or lack thereof of risks of their procedure. The absence of large differences between procedures suggests that surgeons may choose the minimally invasive approach that they believe best fits his or her patient's individual needs and the surgeon's operative preferences. The relatively small difference in overall morbidity and length of stay reinforce the safety and efficiency of minimally invasive hysterectomy for the enlarged uterus.

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Sources of the Study

American College of Surgeons National Quality Improvement Program public use dataset.

Disclaimer

ACS-NSQIP Disclaimer: The ACS-NSQIP and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors. This study does not represent the views or plans of the ACS or the ACS-NSQIP.

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Conflicts of Interest or Financial Disclosures

The authors have no relevant conflicts of interest or financial interests to disclose.

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