Risk Factors and Outcomes for Conversion to Laparotomy of Laparoscopic Hysterectomy in Benign Gynecology

Original Research

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- A retrospective cohort study of a Michigan multicenter prospective database . Data was abstracted and analyzed from January 1, 2013, through July 2, 2014.
- Includes data from an all-payer quality and safety database maintained by the Michigan Surgical Quality Collaborative (a large sample of hysterectomies from a statewide database that includes all payer groups, academic, and community hospitals)
- The primary objective of the study was to evaluate the incidence and risk factors for conversion to laparotomy for both traditional laparoscopic and robotic hysterectomy performed for benign indications using a statewide multicenter prospective database
- The secondary objective was to determine differences in 30-day outcomes of women who had conversion to laparotomy. This information will enhance risk stratification and improve preoperative planning and patient selection for hysterectomy
- Women with a preoperative indication of cancer or obstetric indications were excluded.
- A logistic regression model was used to calculate odds of conversion using patient preoperative and intraoperative attributes.
  - Covariates were included in the multivariable model with accounting for clustering by site using robust standard errors
  - Covariates: surgeon volume, surgical approach (lap vs. robotic-assisted), patient age, BMI, alternative treatment before hysterectomy, indication for hysterectomy, presence of adhesions, presence of endometriosis, cancer on final pathology, and specimen weight
- During the study period, 6,992 cases were eligible to be included in the analysis of women underwent an attempted laparoscopic hysterectomy (2,464 traditional laparoscopic, 4,528 robotic-assisted)

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Multivariable Logistic Regression of Risk Factors for Conversion of Laparoscopic Hysterectomy to Laparotomy

	Adjusted OR (95% CI)	P
Age		
<40	Referent	
40 to <60	1.55 (1.03–2.31)	.034
60+	1.83 (1.00–3.35)	.050
Nonwhite vs. white	1.07 (0.76–1.52)	.694
Surgeon Volume		
Lower two tertiles	Referent	
Top tertile	0.66 (0.47–0.92)	.015
Robotics vs. traditional laparoscopy	0.14 (0.07–0.25)	<.001
BMI		
Less than 30	Referent	
30 or greater	1.62 (1.24–2.13)	<.001
Indications for hysterectomy (no)	Referent	
Pelvic mass		
Yes	1.64 (1.00–2.69)	.050
Pelvic organ prolapse		
Yes	0.40 (0.19–0.83)	.015
Adhesions		
None or mild	Referent	
Moderate	2.49 (1.58–3.92)	<.001
Severe	8.07 (5.60–11.62)	<.001
Specimen Weight (g)		
<250	Referent	
250-499	2.97 (2.12–4.16)	<.001
500-999	4.88 (2.78–8.58)	<.001
1,000+	5.15 (2.15–12.36)	<.001

OR, odds ratio; CI, confidence interval; BMI, body mass index.

The significant risk factors for conversion with multivariate logistic regression modeling were:

- Age older than 40 years and 60 years or younger
- BMI greater than or equal to 30
- Preoperative indications of pelvic mass
- Presence of moderate or severe adhesions
- Specimen weight greater than 250 g.

The factors most strongly associated with decreased odds of conversion in the multivariate model were:

- Having a robotic-assisted procedure
- Having a high-volume surgeon.

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Results

- 6,992 women underwent an attempted laparoscopic hysterectomy with 3.93% (n=275) converted to laparotomy.
- After adjusting for socioeconomic differences, hysterectomy indication, and intraoperative factors, there were decreased odds of conversion to laparotomy with use of robotic-assisted laparoscopy compared with traditional laparoscopy, with a predicted risk of conversion of 0.8% compared with 5.4% (P<.001).
- Compared with those who underwent traditional laparoscopy, the group of patients undergoing robotic-assisted laparoscopic hysterectomy had characteristics associated with higher surgical complexity, with statistically significantly higher BMIs and more frequent removal of the cervix and presence of endometriosis.
- High-volume surgeons were less likely to convert to laparotomy compared with low- and medium-volume surgeons, with a predicted risk of conversion of 1.4% compared with 2.25% (P=.015).
- Study identified a significant correlation between use of robotic surgery and surgical volume with a significantly greater proportion of high-volume surgeons using the robotic platform (72.02%) compared with the low-volume surgeons (49.09%, P<.001).
- Even among high-volume surgeons, the odds of conversion was lower with the robotic procedure (7.54% compared with 1.46%, P<.001; adjusted OR 0.13, 95% CI 0.06–0.27), even when controlling for other factors including uterine weight and adhesive disease.
- Conversion was associated with moderate or severe adhesive disease and increasing specimen weight. Conversion was associated with increased rates of surgical site infection, blood transfusion, severe sepsis, and reoperation.

Conclusion

- This analysis demonstrates that conversion to laparotomy is associated with increased odds of postoperative morbidity, and robotic assistance and surgeon volume are strongly associated with decreased odds of conversion.

Limitations

- It is difficult to differentiate reasons of conversions in this database (result of an adverse, emergent event and those without complication and related to surgeon judgment).
- Inherent limitation of the sampling methodology, which captures a random sample of patients at each institution and not every patient for each surgeon
- Surgeon skill and decision-making cannot be ascertained from a surgical database, and this analysis is limited to the available variables and cases included in the Michigan Surgical Quality Collaborative database
- The population and practice patterns in Michigan may not be applicable to other regions

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- None

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Important Safety Information

Risks associated with hysterectomy (benign) include urinary tract injury, vaginal cuff problem (separation, adhesions, granulation tissue, infection, cellulitis, hematoma), bladder injury, bowel injury, vaginal tear or laceration, vaginal shortening, voiding dysfunction, fistula formation: vesicovaginal, rectovaginal. Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine tissue during surgery may spread cancer, and decrease the long-term survival of patients.

Serious complications may occur in any surgery, including *da Vinci*® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Individual surgical results may vary.

Risks specific to minimally invasive surgery, including *da Vinci*® Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments. You should discuss your surgical experience and review these and all risks with your patients, including the potential for human error and equipment failure. Physicians should review all available information. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

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The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.