GENERAL GYNECOLOGY

Improving quality of care: development of a risk-adjusted perioperative morbidity model for vaginal hysterectomy

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OBJECTIVE: We sought to develop and evaluate a risk-adjusted perioperative morbidity model for vaginal hysterectomy.

STUDY DESIGN: Medical records of women who underwent vaginal hysterectomy during 2004 and 2005 were retrospectively reviewed. Morbidity included hospital readmission, reoperation, and unplanned medical intervention or intensive care unit admission; urinary tract infections were excluded. Multivariate logistic regression identified factors associated with perioperative morbidity (adjusted for urinary tract infection). The resulting model was validated using a random 2006 sample.

RESULTS: Of 712 patients, 139 (19.5%) had morbidity associated with congestive heart failure or prior myocardial infarction, perioperative hemoglobin decrease >3.1 g/dL, preoperative hemoglobin <12.0 g/dL, and prior thrombosis (c-index = 0.68). Predicted morbidity was similar to observed rates in the validation sample.

CONCLUSION: History of congestive heart failure or myocardial infarction, prior thrombosis, perioperative hemoglobin decrease >3.1 g/dL, or preoperative hemoglobin <12.0 g/dL were associated with increased perioperative complications. Quality improvement efforts should modify these variables to optimize outcomes.

Key words: perioperative morbidity, risk adjustment, vaginal hysterectomy

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As in other surgical specialties, quality improvement efforts in gynecologic surgery are gaining momentum. Recently, a large national prospective assessment of morbidity after benign hysterectomy was performed in Finland.[1]

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The overall complication rate was 19%, and this was further stratified among different approaches. Intraoperative complication rates for abdominal, vaginal, and laparoscopic procedures were 2.3%, 3.0%, and 3.2%, respectively. The corresponding postoperative inhospital complication rates were 12.3%, 16.1%, and 8.4%, respectively.[1] Although that study described morbidity from vaginal hysterectomy (VH), there was no description of the impact of concomitant urogynecologic procedures. Complications from urogynecologic surgery range from 20% for minor complications to 0.2% for major complications,[2,3] but they are often compared with those from abdominal hysterectomy. As such, the baseline morbidity associated with VH and the effect of additional reconstructive surgery have been underinvestigated in the literature.

The relatively elective nature of benign gynecologic surgery has led to a delay in the application of morbidity models. In particular, most women undergoing VH are generally healthy, and surgery frequently is performed because of quality-of-life considerations. Consequently, the surgical risk should be low. In this context, quality improvement processes are imperative for identifying characteristics or comorbid conditions that predispose patients undergoing VH to increased perioperative complications. Morbidity can be decreased if specific modifiable variables are identified that can categorize patients at risk. We hypothesized that specific variables could be identified and that, by creating a risk-adjusted model of morbidity, we could predict patients at risk for adverse outcomes in VH.

MATERIALS AND METHODS

This study was a planned secondary analysis on the data of women who underwent VH for benign indications, which was a retrospective cohort study approved by our institutional review board. We retrieved medical records of all women who underwent VH for benign indications from January 2004 through December 2005. Patients were included if they underwent VH with or without salpingectomy, oophorectomy, pubovaginal sling placement, or reconstructive pelvic surgery (anterior, posterior, or combined anteroposterior colporrhaphy). Any patient undergoing

TABLE 1
Patient demographics, medical and surgical characteristics, and perioperative outcomes

Characteristic	Model development cohort (n = 712)[a]	Model validation cohort (n = 100)[a]
Mean (SD) age at surgery, y	52.0 (13.3)	54.6 (13.5)
White	608 (85.4)	95 (95.0)
Primary insurance type		
Private	589 (82.7)	74 (74.0)
Public	110 (15.4)	24 (24.0)
None	8 (1.1)	2 (2.0)
Not documented	5 (0.7)	0
Mean (SD) BMI, kg/m^2	28.2 (6.0)	28.2 (4.7)
Prior incontinence surgery	9 (1.3)	2 (2.0)
Prior prolapse surgery	7 (1.0)	1 (1.0)
Stage 3 or 4 prolapse on initial examination[b]	287/462 (62.1)	40/55 (72.7)
Indication for surgery		
Prolapse	344 (48.3)	50 (50.0)
Bleeding	351 (49.3)	52 (52.0)
Incontinence	157 (22.1)	22 (22.0)
Other (eg, pain)	190 (26.7)	26 (26.0)
Medical comorbidities		
Hypertension	199 (27.9)	30 (30.0)
Congestive heart failure	4 (0.6)	0
Prior myocardial infarction	7 (1.0)	1 (1.0)
Asthma	60 (8.4)	11 (11.0)
Chronic obstructive pulmonary disease	6 (0.8)	1 (1.0)
Emphysema	3 (0.4)	0
Gastrointestinal reflux disease	71 (10.0)	13 (13.0)
Gastric bypass surgery	7 (1.0)	2 (2.0)
Diabetes mellitus	36 (5.1)	2 (2.0)
Thyroid disorder	106 (14.9)	12 (12.0)
Cerebrovascular accident	9 (1.3)	2 (2.0)
Dementia	2 (0.3)	0
Preoperative creatinine value ≥1.2 mg/dL	47/692 (6.8)	5/99 (5.1)
Hemoglobin <12.0 g/dL	95/694 (13.7)	12 (12.0)
Prior thrombosis	23 (3.2)	3 (3.0)
Tobacco use	87 (12.2)	7 (7.0)
Corticosteroid use within past year	18 (2.5)	2 (2.0)
ASA classification 1 or 2	638/706 (90.4)	92/98 (93.9)
Surgical procedures performed		
Oophorectomy (bilateral or unilateral)	504 (70.8)	72 (72.0)
Salpingectomy (bilateral or unilateral)	522 (73.3)	77 (77.0)

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additional nongynecologic procedures, including laparoscopy, was excluded. Medical records were reviewed for demographics, baseline medical status, perioperative findings, surgical procedures, and complications within 9 weeks after the index surgery. Morbidity outcomes included hospital readmission, reoperation, unplanned intensive care unit admission, or any medical problem requiring intervention (eg, antibiotics for infection, blood transfusion for symptomatic anemia, and diuretics for fluid overload). Because urinary tract infection (UTI) was considered a common and relatively minor complication, UTI and antibiotics given for UTI were not considered among the morbidity outcomes.

Composite medical and surgical diagnoses, including a history of congestive heart failure, myocardial infarction, or a thrombotic event, were identified through the initial preoperative surgical consultation and anesthesia medical examination. Standard preoperative laboratory tests included a complete blood cell count, creatinine, and serum glucose. A complete blood cell count was obtained the day after surgery, allowing for comparison of preoperative and postoperative hemoglobin values to determine the absolute decrease in hemoglobin.

Multivariate logistic regression models were fit, using stepwise and backward selection, to identify factors significantly associated with non-UTI perioperative morbidity after forcing type of surgery into the model (VH with or without salpingectomy/oophorectomy vs more complex surgery). A *P* value criterion of < .05 was set for variables to be included in the model. Associations were summarized by calculating odds ratio (OR) and corresponding 95% confidence interval (CI) using the parameter estimates from the model. The predictive ability of the final model was summarized using the c-index ("c" for concordance) proposed by Harrell et al.[4] A c-index ranges from 0-1; 1.0 indicates that the variables in the model perfectly separate women with and without perioperative non-UTI morbidity, and 0.5 indicates that the variables contain discriminant information equal to that obtained by chance alone.

The resulting model was validated with data from a computer-generated random sample of 100 women who underwent VH for benign indications at our institution in 2006 and had complete records through the postoperative evaluation. In this way, we calculated expected and observed complication rates for validation. All calculated *P* values were 2-sided, and $P < .05$ was considered statistically significant. Analyses were performed using a software package (SAS; SAS Institute Inc., Cary, NC).

RESULTS

Of the 736 women who met the inclusion criteria, 712 had complete records through the postoperative evaluation and were included in the final analysis. Table 1 summarizes patient characteristics. The model was developed using 712 patients, of whom 139 (19.5%) had non-UTI morbidity within 9 weeks after VH. Table 2 summarizes the most important variables predicting morbidity. The following variables were found to be significantly associated with increased morbidity: congestive heart failure, prior myocardial infarction, or both (OR, 13.0; 95% CI, 2.7–63.5); difference in postoperative hemoglobin value of >3.1 g/dL from preoperative levels (OR, 2.4; 95% CI, 1.6–3.8); a preoperative hemoglobin value <12.0 g/dL (OR, 3.3; 95% CI, 1.9–5.5); and prior thrombosis (OR, 2.7; 95% CI, 1.0–6.8).

The c-index, summarizing the overall predictive ability of this model, was 0.68 and 0.69, based on the model development cohort and the model validation cohort, respectively. The predicted probabilities of having non-UTI morbidity, as estimated by the model, were similar to the observed rates in the validation sample (Table 3). For example, among patients with decreased hemoglobin <12.0 g/dL as their sole risk factor, the predicted probability of non-UTI morbidity was 29% (95% CI, 21–39%), compared with an observed rate of 20% in the validation sample.

TABLE 1
Patient demographics, medical and surgical characteristics, and perioperative outcomes *(continued)*

Characteristic	Model development cohort (n = 712)[a]	Model validation cohort (n = 100)[a]
Reconstructive pelvic surgery	336 (47.2)	49 (49.0)
Anterior colporrhaphy	24 (3.4)	11 (11.0)
Posterior colpoperineorrhaphy	16 (2.3)	3 (3.0)
Combined anteroposterior colporrhaphy	296 (41.6)	35 (35.0)
Midurethral sling placement	118 (16.6)	20 (20.0)
Suprapubic catheter	271 (38.1)	43 (43.0)
Noncomplex surgery (VH with or without salpingectomy or oophorectomy)	348 (48.9)	48 (48.0)
Anesthesia type		
General	528 (74.2)	80 (80.0)
Spinal	181 (25.4)	20 (20.0)
Epidural	3 (0.4)	0
Mean (SD) estimated blood loss, mL	274.7 (154.2)	289.8 (126.2)
Transfusion	29 (4.1)	2 (2.0)
Mean (SD) change in hemoglobin (preoperative–postoperative), g/dL	2.7 (1.2)	2.6 (0.9)
Change in hemoglobin (preoperative–postoperative) >3.1 g/dL	203/693 (29.3)	22/96 (22.3)
Mean (SD) uterine weight, g	141.4 (109.7)	126.0 (104.5)
Uterine weight >250 g	81 (11.4)	8 (8.0)
Mean (SD) length of hospitalization, d	2.4 (1.1)	2.2 (1.2)
Any complication	224 (31.5)	26 (26.0)
Any non-UTI complication	139 (19.5)	15 (15.0)
Complications		
Unplanned ICU admission	7 (1.0)	1 (1.0)
Hospital readmission	24 (3.4)	3 (3.0)
Reoperation	17 (2.4)	2 (2.0)
Medical problem requiring intervention[c]	97 (13.6)	14 (14.0)
Type of complication		
Cardiopulmonary	19 (2.7)	1 (1.0)
Thromboembolic	15 (2.1)	0
Infectious (not including UTI)	18 (2.5)	4 (4.0)
Genitourinary	37 (5.2)	7 (7.0)
Bleeding	34 (4.8)	3 (3.0)
Neurologic	14 (2.0)	2 (2.0)
Anesthesia related	0	0

ASA, American Society of Anesthesiologists; *BMI*, body mass index; *ICU*, intensive care unit; *UTI*, urinary tract infection; *VH*, vaginal hysterectomy.

[a] No. of patients (%), unless otherwise stated; [b] Percentage of those with documented stage at initial consultation–prolapse may or may not have been the indication for surgery; [c] Including antibiotics for infection (excluding for UTI), blood transfusion for symptomatic anemia, and diuretics for fluid overload.

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TABLE 2

Summary of patient characteristics evaluated for association with perioperative morbidity in the model development cohort

Patient characteristic	OR (95% CI) Univariate	Multivariate[a]
Age at surgery, y[b]	1.05 (0.91–1.20)	
BMI[c]	1.00 (0.97–1.03)	
Stage 3 or 4 prolapse (vs 1 or 2)	1.53 (0.95–2.47)	
Medical comorbidities		
CHF, prior MI, or both	17.41 (3.66–82.90)	13.00 (2.66–63.52)
COPD or emphysema	3.37 (0.89–12.70)	
Gastric bypass surgery	1.66 (0.32–8.64)	
Diabetes mellitus	1.63 (0.77–3.47)	
Hemoglobin $<$12.0 g/dL	2.28 (1.42–3.68)	3.26 (1.94–5.48)
Prior thrombosis	1.85 (0.74–4.58)	2.65 (1.03–6.84)
Corticosteroid use in previous year	2.71 (1.03–7.12)	
Creatinine $\geq$1.2 mg/dL	1.62 (0.83–3.17)	
ASA class 3 or 4 (vs 1 or 2)	2.22 (1.29–3.84)	
Complex surgery (vs VH with/without SO)	1.66 (1.14–2.42)	1.47 (0.97–2.22)
Change in hemoglobin (preoperative–postoperative), g/dL[d]	1.46 (1.24–1.71)	
Change in hemoglobin (preoperative–postoperative) $>$3.1 g/dL	2.20 (1.49–3.25)	2.44 (1.59–3.75)
Uterine weight $>$250 g	0.85 (0.46–1.55)	

ASA, American Society of Anesthesiologists; *BMI*, body mass index; *CHF*, congestive heart failure; *CI*, confidence interval; *COPD*, chronic obstructive pulmonary disease; *MI*, myocardial infarction; *OR*, odds ratio; *SO*, salpingo-oophorectomy; *VH*, vaginal hysterectomy.

[a] Multivariate logistic regression model was fit, using stepwise and backward selection, to identify factors associated with non-urinary tract infection morbidity, after forcing type of surgery (VH with or without salpingectomy or oophorectomy vs more complex surgery) in the model; [b] OR per 10-year increase in age; [c] OR per 1-kg/m^2 increase in BMI; [d] OR per 1-g/dL decrease in hemoglobin.

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COMMENT

We identified variables that predispose women undergoing benign VH to increased perioperative morbidity: congestive heart failure or prior myocardial infarction, change in hemoglobin of $>$3.1 g/dL, preoperative hemoglobin value $<$12.0 g/dL, and prior thrombosis. Although 47% (336/712) of the women had VH with concomitant pelvic reconstructive surgery, complexity of surgery was not significantly associated with increased perioperative morbidity in this model. Determining risk-adjusted rates of complications allows providers to have greater impact on patient care. Ultimately, risk adjustment allows for relevant outcome comparisons to optimize patient and procedure selection. This is the key to quality improvement.[5]

Within the context of general surgery, the most important project in quality improvement is the National Surgical Quality Improvement Program.[6] This program was started in the Veterans Health Administration and subsequently involved other centers. Briefly, data from different participant hospitals are centrally analyzed, and observed/expected ratios for 30-day mortality and morbidity are generated for each of 8 major surgical specialties. Periodic comparative reports are produced to aid hospital managers and health care providers in identifying structures and processes of care that should be improved. Of interest, since the program started in 1991, the 30-day morbidity after major surgery has decreased by 45%, and the 30-day mortality has decreased by 31%.[6]

On the basis of this approach, our gynecologic oncology division piloted a multiinstitutional study that defined risk factors predicting major morbidity, perioperative mortality, length of hospitalization, and ability to receive the planned chemotherapy in patients with advanced ovarian carcinoma.[7] Specifically, endogenous patient factors (age, American Society of Anesthesiologists classification, preoperative albumin level) and complexity of surgery were primary factors for increased morbidity in ovarian cancer surgery.[7]

Various studies have reported perioperative complication rates among patients undergoing benign gynecologic surgery. Lambrou et al[3] estimated the prevalence of perioperative morbidity in reconstructive pelvic surgery to be 46%, with 86% of the study sample having 1 or more preexisting chronic medical illness. Bai et al[2] compared complication rates between women undergoing abdominal hysterectomy or adnexectomy and those undergoing reconstructive pelvic surgery (26.7% vs 34.4%, respectively). The biggest predictors of morbidity were intraoperative blood loss $>$1000 mL, decrease in hemoglobin $>$3.1 g/dL, and longer duration of surgery. These studies support the relationship between specific variables and complications; however, until now no models existed to predict adverse outcomes in VH.

This retrospective review is limited in that not all outcome measures can be assessed and some important variables may have been excluded. Additionally, postoperative complications were determined through 9 weeks after surgery. It is possible that complications occurred after that time and were missed. The 97% data abstraction for the entire cohort (712/736 patients) may minimize this concern, however. Also, any adverse event occurring $>$2 months after surgery may not be immediately related to surgery. Another limitation is that perioperative outcome was not subjectively evaluated, although this was not the fo-

TABLE 3
Predicted probability of having a complication estimated from the main cohort vs observed rates in validation sample[a]

Risk factor: CHF or MI	Decrease in Hb >3.1 g/dL	Preoperative Hb <12 g/dL	DVT or PE	Patients in original cohort (n = 694)[b]	Predicted probability of complication[c] (95% CI)	Observed complications in validation sample (n = 100)[d]
−	−	−	−	389	12% (9–15)	7/63 (11%)
−	−	−	+	17	26% (12–47)	
−	−	+	−	78	29% (21–39)	2/10 (20%)
−	+	−	−	185	26% (20–32)	4/19 (21%)
+	−	−	−	2	65% (27–90)	
−	−	+	+	3	52% (29–75)	
−	+	−	+	2	48% (26–72)	1/2 (50%)
−	+	+	−	10	52% (38–66)	0/1
+	−	+	−	2	85% (53–97)	
+	+	−	−	6	83% (50–96)	
+	−	+	+	0	0	0/1

CHF, congestive heart failure; *CI*, confidence interval; *DVT*, deep vein thrombosis; *Hb*, hemoglobin; *MI*, myocardial infarction; *PE*, pulmonary embolism.

[a] Predicted probability of having perioperative morbidity as estimated from the main cohort using a model that did not include surgical complexity, compared with the observed complication rates in the validation sample, according to the presence or absence of independent risk factors in the final model; [b] Number of patients in original cohort–18 patients were missing data on preop Hb level and were not included; [c] Complications were defined as unplanned intensive care unit admission, hospital readmission, reoperation, or medical intervention (eg, antibiotics for infection excluding urinary tract infection, blood transfusion for symptomatic anemia, and diuretics for fluid overload); [d] Number of patients in validation sample with complications out of the number with a particular combination of risk factors– 4 patients were missing data on preoperative Hb level and were not included (1 of these patients had a complication).

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cus of the study. Last, these operations were performed by high-volume surgeons, which may lead to an underestimation of surgeon-specific variables.

The overall goal of a quality improvement project is to identify existing areas in practice that can be altered to decrease morbidity. Identification of modifiable characteristics would allow surgeons to have a direct effect on decreasing or avoiding complications. Nonmodifiable variables are still important, however, in that they assist the clinician in identifying patients at higher risk before surgery. By considering all these variables, the care of patients can be managed more aggressively (eg, planned postoperative intensive care unit admission), or patients may be counseled more extensively before consenting to surgery to better understand the risks they face.

Prospective studies highlighting methods to decrease adverse events in patients at higher risk will ultimately have the greatest effect on patient outcomes. Such studies are already being conducted in other surgical specialties through the efforts of the National Surgical Quality Improvement Program.[6] By creating a risk-adjusted model, perioperative complications can be accurately identified and the effects of quality improvement programs adequately measured to improve patient outcomes. ■

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