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A risk model and cost analysis of post-operative incisional hernia following 2,145 open hysterectomies—Defining indications and opportunities for risk reduction

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ABSTRACT

Background: Incisional hernia (IH) is a complication following open abdominal hysterectomy. This study addresses the incidence and health care cost of IH repair after open hysterectomy, and identify perioperative risk factors to create predictive risk models.
Methods: We conduct a retrospective review of patients who underwent open hysterectomy between 2005 and 2013 at the University of Pennsylvania. The primary outcome was post-hysterectomy IH. Univariate/multivariate cox proportional hazard analyses identified perioperative risk factors. We performed cox hazard regression modeling with bootstrapped validation, risk stratification, and assessment of model performance.
Results: 2145 patients underwent open hysterectomy during the study period. 76 patients developed IH, and all underwent repair. 31.3% underwent reoperation, generating higher costs ($71,559 vs. $23,313, $p < 0.001$). 8 risk factors were included in the model, the strongest being presence of a vertical incision (HR = 3.73 [2.01–6.92]). Extreme-risk patients experienced the highest incidence of IH (22%) vs. low-risk patients (0.8%) [C-statistic = 0.82].
Conclusions: We identify perioperative risk factors for IH and provide a risk prediction instrument to accurately stratify patients in effort to offer risk reductive techniques.
Summary: Open hysterectomies account for a magnitude of surgical procedures worldwide. This study presents an internally validated risk model of IH in patients undergoing open hysterectomy after a review of 2145 cases. With an increasing emphasis on prevention in healthcare, we create a risk model to improve outcomes after open hysterectomies in effort to identify high-risk patients, facilitate preoperative risk counseling, and implement evidence-based strategies to improve outcomes.

1. Introduction

Approximately 600,000 women undergo hysterectomy annually in the United States.[1,2] Several surgical approaches are used for hysterectomy, however, the open abdominal approach is most prevalent.[1–4] While each surgical approach has its own risk profile, incisional hernia (IH) is perhaps the most debilitating and costly complication associated with the open abdominal approach. IH is estimated to complicate 8–16.9% of all abdominal hysterectomies.[5–7]

Abbreviations and Acronyms: IH, incisional hernia; PMA, prophylactic mesh augmentation; BMI, body mass index; WHO, World Health Classification; COPD, chronic obstructive pulmonary disease; SBO, small bowel obstruction; HR, hazard ratio; EMR, Electronic Medical Record; HITECH, Health Information Technology for Economic and Clinical Health; CDSS, clinical decision support systems.

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IH is a pervasive complication across surgical specialties and presents a significant burden to both the patient and healthcare system.[8–15] Several risk factors for the development of IH after midline laparotomy have been identified including obesity, immunosuppression, and malnutrition, however there is a substantial knowledge gap regarding which procedure-specific factors govern risk, and there is a continued need for reliable and valid prediction instruments to identify at-risk patients who could benefit from prevention strategies.[16]

Risk prediction models can identify patients who are most likely to develop IH, serve as part of a pre-operative decisional framework to support risk counseling, and help to generate algorithms for governing the use of prophylactic mesh augmentation (PMA) at the time of the index procedure.[17] Despite the ubiquity of gynecologic procedures, no such model has been developed for open hysterectomy.

To address the aforementioned needs, we propose to: 1) assess the incidence and healthcare cost of surgically repaired IH after open abdominal hysterectomy; 2) identify modifiable, perioperative risk factors; and 3) create an actionable predictive risk model and instrument.

2. Methods

2.1. Study design

A retrospective review was performed including all patients undergoing open hysterectomy through an open abdominal approach at a single institution from January 2005 through June of 2013. Relevant exclusion criteria included patient age less than 18 years, vaginal hysterectomy procedures, laparoscopic approaches without an open component, documented IH diagnosis prior to index procedure, concurrent ventral hernia repair with index procedure, hysterectomy in the setting of pregnancy complication, death within 1 year of procedure, clinical follow-up of less than 1 year, surgery performed in the outpatient setting, and emergent surgery. This study was approved by the institutional review board (protocol #820208).

2.2. Data collection

Demographic information, past medical history, and operative indications were obtained by querying the electronic medical record (EMR). The Agency for Healthcare Research and Quality classifications system was utilized to define comorbidities, and body mass index (BMI, kg/m^2) was coded according to the World Health Classification (WHO) classification.[18] Appendix 1 presents the coding schema in detail. Cardiovascular disease was defined by the presence of coronary artery disease, peripheral vascular disease, or congestive heart failure; pulmonary disease included history of chronic obstructive pulmonary disease (COPD), acute or chronic respiratory failure, or ventilator-dependence; renal disease was defined by acute or chronic renal failure requiring dialysis; finally, liver disease included a documented history of cirrhosis, ascites, or varices.[19–21]

Open hysterectomy was defined by the ICD-9 CM and CPT procedural codes summarized in Appendix 2. The primary procedures considered in this study included subtotal, total or radical abdominal hysterectomy, and pelvic exenteration. Additionally, a subset of patients underwent intraperitoneal operations concurrently with hysterectomy. These additional procedures were categorized as hepatobiliary, bowel resection, or ostomy creation/takedown and bowel surgery was further subdivided into small bowel and large bowel procedures. These gastrointestinal operative subclassifications were not considered mutually exclusive; thus, patients undergoing multiple procedures across groupings were treated similarly as those undergoing procedures in one group only. Prior intra-abdominal surgery was noted, as was a documented history of surgical wound complications (wound infection, wound dehiscence, abscess, seroma, hematoma, post-operative bleeding, small bowel obstruction (SBO) requiring an operation, and enterocutaneous fistula. Operation in the setting of an acute intra-abdominal inflammatory process or disseminated systemic infection was recorded as well. Acute intra-abdominal inflammatory processes included diverticulitis (majority), appendicitis, gastritis, intestinal abscess, cholecystitis, peritonitis, and sepsis with or without an abdominal source.

The primary outcome of interest was post-hysterectomy IH repair, defined as an abdominal wall fascial defect occurring at a prior fascial incision site (Appendix 3). This endpoint was chosen because it has been demonstrated that the presence of a diagnostic code is not as reliable an indicator of disease as the presence of a procedural code in large quality improvement or claims datasets.[22] Patients were excluded from analysis if they had an IH diagnosis prior to the index procedure or if they underwent an IH repair prior to or concurrently with the index procedure. Secondary outcomes included time to IH repair, incidence of post-operative hospitalizations for surgical complications, incidence of unplanned reoperations, and post-operative wound complications, defined as superficial wound cellulitis, deep-space infection, wound dehiscence, seroma, hematoma, acute wound bleeding, enterocutaneous fistula, sepsis, and operative SBO. Clinical follow-up time was defined from the date of surgery to the patient's final post-operative clinic visit.

2.3. Financial cost data

The financial department at our institution provided cost data for each index admission and subsequent readmissions related to either the index procedure or complications within the study period. Cost data consisted of direct variable costs (operating room, labs, radiology, pharmacy, blood product, surgical implants, and perioperative services) and total costs incurred by the hospital for the duration of each admission. Costs for readmissions related to the index procedure and subsequent surgical complications, such as hernia, were also tabulated for the duration of patient follow-up. These charges were adjusted for inflation to 2014 U.S. dollars using the medical component of the consumer price index.[23] Professional fees were not included in financial reports.

2.4. Data analysis and model generation

Descriptive summary statistics were performed for patient demographics, surgical characteristics, and post-operative outcomes. Categorical variables were reported as proportions and continuous variables as means with standard deviations. Univariate analyses of independent variables and post-operative hernia repair incidence were performed. Pearson $\chi 2$, Fisher's exact test, and Cox proportional hazards were used to analyze categorical variables; unpaired Student t-tests were employed for continuous variables. Variables with a $p < 0.1$ in univariate analysis were included as independent variables in an initial Cox proportional hazards regression analysis. Variables yielding $p < 0.1$ in the initial regression model were included in a bootstrap analysis in order to determine the set of variables that should remain in our final risk model.[23,24]

In the bootstrap procedure, 1000 random samples of the cohort were generated with replacement. Each sample was then subject to stepwise multivariate Cox regression, covariates entered the model if $p < 0.1$ and remained in the model if $p < 0.05$. Frequencies of occurrence of each independent variable in the final model were noted; if predictors occurred in 50% (500 samples) or more of the