Failure of Colorectal Surgical Site Infection Predictive Models Applied to an Independent Dataset: Do They Add Value or Just Confusion?

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BACKGROUND: Colorectal surgical site infections (C-SSIs) are a major source of postoperative morbidity. Institutional C-SSI rates are modeled and scrutinized, and there is increasing movement in the direction of public reporting. External validation of C-SSI risk prediction models is lacking. Factors governing C-SSI occurrence are complicated and multifactorial. We hypothesized that existing C-SSI prediction models have limited ability to accurately predict C-SSI in independent data.

STUDY DESIGN: Colorectal resections identified from our institutional ACS-NSQIP dataset (2006 to 2014) were reviewed. The primary outcome was any C-SSI according to the ACS-NSQIP definition. Emergency cases were excluded. Published C-SSI risk scores: the National Nosocomial Infection Surveillance (NNIS), Contamination, Obesity, Laparotomy, and American Society of Anesthesiologists (ASA) class (COLA), Preventie Ziekenhuisinfecties door Surveillance (PREZIES), and NSQIP-based models were compared with receiver operating characteristic (ROC) analysis to evaluate discriminatory quality.

RESULTS: There were 2,376 cases included, with an overall C-SSI rate of 9% (213 cases). None of the models produced reliable and high quality C-SSI predictions. For any C-SSI, the NNIS c-index was 0.57 vs 0.61 for COLA, 0.58 for PREZIES, and 0.62 for NSQIP: all well below the minimum "reasonably" predictive c-index of 0.7. Predictions for superficial, deep, and organ space SSI were similarly poor.

CONCLUSIONS: Published C-SSI risk prediction models do not accurately predict C-SSI in our independent institutional dataset. Application of externally developed prediction models to any individual practice must be validated or modified to account for institution and case-mix specific factors. This questions the validity of using externally or nationally developed models for "expected" outcomes and interhospital comparisons. (J Am Coll Surg 2016;222:431−438. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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Surgical site infections are one of the most common postoperative complications.[1] In particular, colorectal surgical site infections (C-SSIs) are a major source of postoperative morbidity.[2,3] Hospitals' C-SSI rates are modeled[4-9] and analyzed.[10,11] The Centers for Medicare and Medicaid Services tracks composite hosptial-based outcomes and reports them for public comparison.[12] Along with C-SSI, other hospitals' clinical outcomes are increasingly being compared with standardized metrics of expected and/or modeled performance, which is used for hospital comparisons and performance-related payments.[13] Given the morbidity, costs, and payment implications assocated with C-SSIs they commonly are a focus of hospital quality improvement projects.[14]

To facilitate quality improvement and understanding of the factors that drive C-SSI, many models have been

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Abbreviations and Acronyms

ACS	= American College of Surgeons
ASA	= American Society of Anesthesiologists
COLA	= Contamination, Obesity, Laparotomy, and ASA class
C-SSI	= colorectal surgical site infection
NNIS	= National Nosocomial Infection Surveillance
PREZIES	= Preventie Ziekenhuisinfecties door Surveillance
ROC	= receiver operating characteristic

developed to predict C-SSI occurrence. These models have been used to understand expected risk and have been proposed as a way to facilitate risk adjustment and compare outcomes across institutions.[15] Commonly used models include the National Nosocomial Infection Surveillance score (NNIS)[16]; Contamination, Obesity, Laparotomy, and ASA class (COLA)[6]; Preventie Ziekenhuisinfecties door Surveillance (PREZIES)[7]; and American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP)-based models.[8] Many of these models have not been externally validated and the predictive capability often is poor.[17,18]

With the importance of C-SSI as a patient outcome and health policy metric, we sought to validate previously published C-SSI predictive models against our institutional ACS-NSQIP dataset to determine how well these models perform against externally sampled data. We hypothesized that such a validation study would illustrate that current models for predicting C-SSI have poor discriminatory quality and therefore should be considered insufficient for the purposes of risk adjustment and comparison of expected outcomes across institutions.

METHODS

We analyzed all colorectal resections performed at a quaternary care academic medical center in the upper Midwest by the Division of Colon and Rectal Surgery, between April 2006 and June 2014, that were included in our institutional ACS-NSQIP database. Board certified colorectal surgeons performed all operations, assisted by general surgery residents or colorectal surgery fellows. Postoperative care was provided on dedicated colorectal surgery nursing floors using standard clinical pathways. Patients who declined research particpation (n = 51), had incomplete data (n = 15), or underwent emergency procedures were excluded.

Data source and outcomes

The ACS-NSQIP is a well-described and externally validated clinical database whose objective is to assess and improve quality of care in surgery.[19] Clinical abstractors trained to use standard sampling methods collect patient-specific, disease-related, and intraoperative variables. Patients are included based on a random sampling of procedures performed at participating institutions, and approximately 20% of all procedures performed at a given institution are included. Additional sampling methodology and description of the ACS-NSQIP data structure have been detailed previously by other authors.[20]

The cases included in this study were identified from our institution's ACS-NSQIP sample from a prospectively maintained database of the Division of Colon and Rectal Surgery. Billing data were reviewed to determine the number of diagnoses present at discharge. The primary outcomes of interest were development of a C-SSI according to the classification scheme used by ACS-NSQIP: any, superficial, deep, or organ space.

Surgical site infection models

Four C-SSI prediction models were included in the study. The National Nosocomial Infection Surveillance (NNIS) model was developed in the 1990s and is commonly used to predict SSI risk in operative procedures.[21] The NNIS risk score ranges from 0 to 3 and assigns points to predict the total risk based on American Society of Anesthesiologists (ASA) preoperative risk assessment of at least grade III, an operation classified as contaminated, and operative time of at least 3 hours,[16] with 1 point is assigned for each factor. The second model tested was the Contamination, Obesity, Laparotomy, and ASA (COLA) score, which ranges from 1 to 4 and assigns 1 point each for contaminated case, BMI > 30 kg/m^2, open surgical procedure, and ASA class of III or greater.[6] The third and fourth models considered both used multivariable logistic regression to determine the risk score. The references for each model provided intercept (β0) and βi terms, which were used in the following general formulation to calculate the risk score:

$$Risk\ Score = \sum_{n=0}^{i} \frac{e^{\beta_0+\beta_i x}}{1+e^{\beta_0+\beta_i x}}$$

Each βi coefficient was multipied by its corresponding x variable's value for continuous variable and 0 or 1 to indicate false or true, respectively, for dichotomous variables. The third model considered was the Preventie Ziekenhuisinfecties door Surveillance (PREZIES) a Dutch model reported in 2006. This model included parameters for ASA class (II/II vs III/IV), surgical indication (neoplasm, colitis, obstruction/diverticulum, or other), number of discharge diagnoses (1 to 4 vs 5 or more), and wound contamination class (I/II vs III/IV). The PREZIES score was calculated as outlined above and using coefficients as displayed in Table 1.[7] Finally, the ACS-NSQIP risk score

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