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Can We Predict Incisional Hernia?

Development of a Surgery-specific Decision–Support Interface

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Objective: The aim of this study was to identify procedure-specific risk factors independently associated with incisional hernia (IH) and demonstrate the feasibility of preoperative risk stratification through the use of an IH risk calculator app and decision–support interface.

Summary Background Data: IH occurs after 10% to 15% of all abdominal surgeries (AS) and remains among the most challenging, seemingly unavoidable complications. However, there is a paucity of readily available, actionable tools capable of predicting IH occurrence at the point-of-care.

Methods: Patients ($n = 29,739$) undergoing AS from 2005 to 2016 were retrospectively identified within inpatient and ambulatory databases at our institution. Surgically treated IH, complications, and costs were assessed. Predictive models were generated using regression analysis and corroborated using a validation group.

Results: The incidence of operative IH was 3.8% ($N = 1127$) at an average follow-up of 57.9 months. All variables were weighted according to β-coefficients generating 8 surgery-specific predictive models for IH occurrence, all of which demonstrated excellent risk discrimination (C-statistic = 0.76–0.89). IH occurred most frequently after colorectal (7.7%) and vascular (5.2%) surgery. The most common occurring risk factors that increased the likelihood of developing IH were history of AS (87.5%) and smoking history (75%). An integrated, surgeon-facing, point-of-care risk prediction instrument was created in an app for preoperative estimation of hernia after AS.

Conclusions: Operative IH occurred in 3.8% of patients after nearly 5 years of follow-up in a predictable manner. Using a bioinformatics approach, risk models were transformed into 8 unique surgery-specific models. A risk calculator app was developed which stakeholders can access to identify high-risk IH patients at the point-of-care.

Keywords: abdominal surgery, decision–support interface, incisional hernia, risk calculator app, risk prediction

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Incisional hernia (IH) complicates 10% to 15% of all abdominal surgeries (AS) causing morbidity and significant impairment in quality of life.[1–3] A diversity of operations in the abdomen lead to IH, indicating a need for surgery-specific predictive models. IH can be a remarkable cost burden to society with hernia-related healthcare expenditures in the United States increasing 52% from 2007 to 2011 estimated at $7.3 billion (adjusted to 2015 dollars) annually.[4,5] Over 350,000 people experience an abdominal wall hernia necessitating surgical treatment[4,5] and considering the comorbidities that hernia patients often present with, it is not surprising that IH repair fails in up to 60% of procedures and exhibits a 30-day mortality of 1%.[6] Failed repair increases the difficulty of future herniorrhaphy, further prolonging restoration of abdominal wall integrity and often perpetuating a cyclical and chronic disease state.[7] Implementing a preventative approach to this problem may reduce its incidence and mitigate operative morbidity associated with treatment and, in turn, provide a more cost-effective manner.

Opportunities to reduce IH occurrence at the time of index AS cannot be understated. Interventions such as smoking cessation and weight loss programs have been implemented in surgical practices to prevent IH in those who are considered high risk.[8,9] Minimally invasive approaches, reduction of wound complications, and optimization of suture technique provide surgeons with other methods to reduce risk.[10–15] In addition, several high-quality studies establish significantly decreased IH risk with the use of prophylactic mesh augmentation (PMA) at the time of index AS.[16–18] With a growing body of literature supporting PMA as a proven strategy reducing the risks and costs associated with IH, it seems that the emphasis is shifting from treating IH to preventing this chronic disease process. Instruments capable of risk stratifying such patients would enhance preoperative counseling and perioperative strategies to prevent IH formation.

Current predictive models for patients at high risk of IH based upon smaller cohort experiences have proven inaccurate with attempted external validation[19] and often fail to provide individualized surgery-specific models.[20,21] Big data analytics have shown promise for a variety of surgical research questions, but lack longitudinal follow-up or data granularity to study IH.[22] National Surgical Quality Improvement Project (NSQIP) has short-term follow-up and Healthcare Cost & Utilization Program (HCUP) strictly uses administrative claims. The ideal dataset for accurate and specific prediction models would be a hybrid of administrative claims coupled with electronic medical record (EMR) chart review and long-term follow-up. Furthermore, hernia risk prediction has yet to be developed into an actionable tool surgeons can utilize to aid in their decision process and offer preventative strategies. Given the broad range of diverse surgical procedures of the abdomen where IH is an outcome, the aims of this study are 3-fold: (1) to identify patient and operative factors independently associated with IH, (2) to create predictive models for IH across surgical subspecialties, and (3) to generate a portable, user-friendly IH prediction app allowing surgeons to offer individualized discussions of risk.

METHODS

Study Design

An institutional review board-approved retrospective cohort study was conducted of consecutive adult patients undergoing intra-abdominal, urologic, or gynecologic surgery within a single health system from January 2005 to June 2016. Eligible patients were identified by querying the EMR system for *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9 CM). Open and laparoscopic approaches were considered, and surgeries were grouped into bariatric, colorectal, gastric, gynecologic, hepatobiliary, transplant, urologic, and vascular surgery (Supplemental 1, http://links.lww.com/SLA/B700).

Patients with a preexisting diagnosis of abdominal hernia before the index procedure or those undergoing concurrent hernia repair with the index procedure were excluded, as well as those with <12 months of follow-up. An assumption was made that if an IH was repaired after an index operation, then the IH was due to the index operation. If a patient had multiple AS, then the most recent operation preceding the hernia repair was counted as the index operation and all previous AS were analyzed as risk factors. Patients undergoing cesarean section were not included due to the infrequency of hernia and variations in surgical approach that differ from the included cohort.[23] Lastly, medical records with missing or incomplete data were excluded from final analysis.

Database Description and Data Collection

The Penn Data Store (PDS) is an initiative designed to provide easier access to clinical data for researchers through retrieval of standardized data from the EMR.[24] In the present study, 558 variables were analyzed from 164,014 encounters belonging to 78,030 patients across 3 major hospitals (Hospital of the University of Pennsylvania, Presbyterian Hospital, and Pennsylvania Hospital). Patients are followed longitudinally for every inpatient and outpatient healthcare encounter, enabling reliable long-term follow-up for a substantial cohort.

Demographic information, indication for index surgery, and medical history were abstracted from the medical record using ICD-9 diagnostic codes. Elixhauser index was used to define comorbid conditions, whereas body mass index (BMI) (kg/m^2) was encoded according to the World Health Organization classification.[25,26] Composite risk factors were created and defined as such: cardiovascular disease (coronary artery disease, peripheral vascular disease, congestive heart failure, prior myocardial infarction, or percutaneous intervention), pulmonary disease (chronic obstructive pulmonary disease, acute or chronic respiratory failure, or pulmonary hypertension), liver disease (cirrhosis, ascites, or varices), renal disease (acute or chronic renal failure, chronic dialysis).

Index operations were classified into general categories by organ system and surgeries with similar characteristics were also grouped into composite operative categories. Open approaches via midline laparotomy, laparoscopic approaches, and open-assisted laparoscopic approaches were all considered, as was elective or emergent nature of the procedure. For patients undergoing multiple procedures concurrently, procedures were not treated as mutually exclusive and each individual procedure was assessed as a separate potential risk factor. Prior AS was documented, as was presence of ostomy or enterocutaneous fistula at the time of index procedure.

Postoperative IH requiring surgical repair was the primary outcome of interest, defined by the presence of both ICD-9 diagnosis of abdominal hernia and ICD-9 CM procedure code for IH repair. This endpoint reflected the most reliable indicator of true IH. Secondary outcomes included the time interval to reoperation for IH, additional postoperative surgical complications, and financial costs of care. Financial data were provided by the institutional department of finance for each index admission and subsequent readmissions that were related to the index procedure. Costs reflected direct variable costs (operating room, labs, radiology, pharmacy, blood product, surgical implants, perioperative services) and total costs incurred by the hospital for the duration of each admission. Professional fees were not included, and inflation was accounted for by adjusting cost data to 2016 US dollars using the medical components of the consumer price index.[27]

Data Analysis and Model Generation

The eligible sample was randomly split into a derivation group (2/3 of sample) and a validation group (1/3 of sample). The risk model was generated solely upon the derivation data sample. The regression model and composite risk scoring system were then cross-validated in the validation data sample.[28] If any statistically and clinically significant differences were seen between the derivation and validation cohorts, the groups would be rerandomized, and this process would be repeated. Bivariate analyses of independent variables and operative IH incidence were performed. Pearson χ^2 or Fisher exact test was used to analyze categorical variables. Variables with $P \leq 0.05$ in univariate analysis were used as independent variables in an initial logistic regression analysis and remained in the model if $P < 0.1$.[29] Model performance and risk discriminatory capacity were assessed by calculating the bias-corrected C-statistic and the Hosmer–Lemeshow goodness-of-fit statistic.[30] A simplified clinical risk assessment tool was derived by assigning point values to the rounded ratios of the previously derived logistic coefficients (β-coefficients). A composite risk was defined as the summation of these point values for each individual patient. Risk stratification groups were then created based on the composite IH risk scores for each patient. Internal cross-validation of the regression model and composite risk score models were performed by applying the predicted risks to the validation cohort and assessing model discriminatory capacity and calibration against the ideal.

Beta-coefficients for all independent variables within the model, along with the model constant, were then used to generate Predicted Probability Equation (PPE). The PPE calculates the predicted probability of the multivariable regression model's outcome (ie, IH occurrence) in a patient population similar to that of the operative group (ie, bariatric surgery) included in the multivariable regression model. This PPE was then translated into a web-based decision–support interface allowing one to calculate the predicted probability of the outcome of interest for a patient who has a combination of the particular model's independent variables present or absent. This allows for an approximation of where on a continuum of probabilities a given patient may fall. A website was created (http://www.pennherniariskcalc.com) and the online app (iOS and Android "Penn Hernia Risk Calculator") was tested using real patient. Data management and analysis were performed using STATA SE 15.0 (StataCorp, College Station, TX).

RESULTS

Patient and Operative Characteristics

Patients (n = 78,030) were assessed for eligibility of which 29,739 patients met inclusion criteria and were included for quantitative analysis (Fig. 1). Age averaged 52.6 years, 36.6% were male, and BMI averaged 30.1 kg/m^2 (Table 1). The most prevalent comorbidities included hypertension (50%), pulmonary disease (29%), cardiovascular disease (26%), and diabetes (19%). Smoking history was present in 27% of patients, and nearly 63% of patients had 2 or more Elixhauser comorbidities. Overall, 62% of surgeries were open. Emergent laparotomy was performed in 11.8% of cases, contaminated peritonitis was present in 7.4%, bowel perforation or ischemia

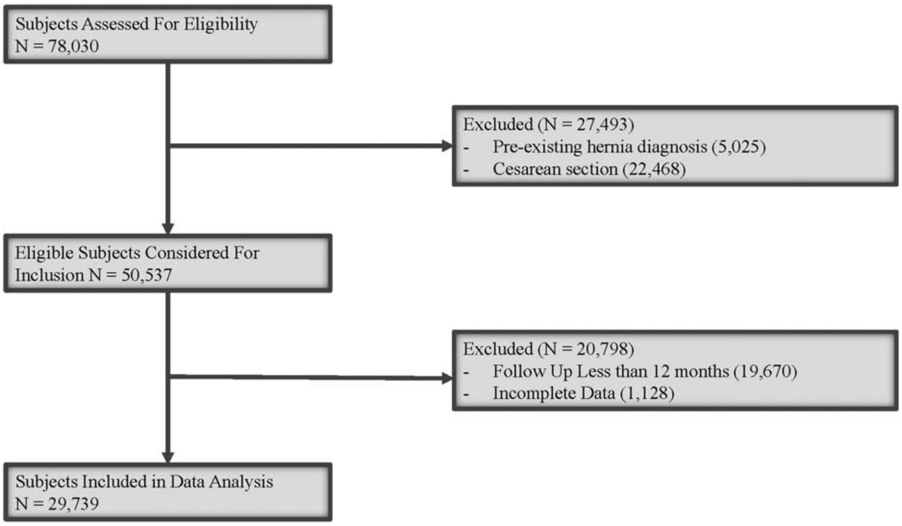

FIGURE 1. Flow diagram of included study subjects.

in 4.2%, and vascular indication in 1.3% of patients. 12.7% of patients had a history of AS.

Risk Factors for Operative IH

For the entire cohort, IH requiring reoperation occurred in 3.8% of patients (N = 1127) after an average follow-up of 57.9 months (range 12–132 mo) (Table 2). Individual risk factors were assigned weighted risk scores according to their β-coefficients ranging from 4 to −4, with the strongest risks including emergent surgery [odds ratio (OR) = 4.17, $P < 0.001$], history of AS (OR = 2.56, $P < 0.001$), and Caucasian race (OR = 1.95, $P < 0.001$), and protective factors including BMI<25 (OR = 0.59, $P < 0.001$) and laparoscopic hysterectomy (OR = 0.44, $P < 0.001$). Of note, obesity was a significant risk associated with IH; however, its weighted risk

TABLE 1. Summary of Patient and Operative Characteristics and Association With Incisional Hernia (N = 29,739)

Patient Factor	Subgroup	Prevalence, N (%)	Factor Absent, % IH	Factor Present, % IH	*P*
Sex	Male	10,894 (36.6)	3.1	5.0	<0.001
Race/ethnicity	Asian	697 (2.34)	3.9	0.6	<0.001
	African American	8,728 (29.3)	4.1	3.0	<0.001
	Caucasian	18,702 (62.8)	2.7	4.5	<0.001
	Hispanic	950 (3.25)	3.8	3.7	0.838
Age	Under 45 y	8,837 (29.7)	4.2	2.8	<0.001
	45–65 y	13,895 (46.7)	3.1	4.6	<0.001
	Over 65 y	7,007 (23.5)	3.9	3.5	0.19
Body mass index, kg/m^2	<18 kg/m^2	1,103 (3.70)	3.9	1.8	<0.001
	18–25 kg/m^2	8,021 (26.9)	4.1	2.9	<0.001
	>30 kg/m^2	10,687 (35.9)	3.0	5.1	<0.001
Smoker		8,102 (27.2)	2.7	6.7	<0.001
Cardiovascular disease		7,678 (25.8)	3.0	6.0	<0.001
Pulmonary disease		8,632 (29.0)	2.8	6.3	<0.001
Hypertension		14,776 (49.6)	2.7	4.9	<0.001
Diabetes		5,720 (19.2)	3.3	5.7	<0.001
Recent weight loss		2,427 (8.16)	3.4	8.2	<0.001
Cancer		6,654 (22.3)	3.2	5.7	<0.001
History of chemotherapy/radiation		1,306 (4.39)	3.5	9.6	<0.001
History of drug/alcohol abuse		1,555 (5.22)	3.5	8.8	<0.001
Chronic anticoagulation		3,016 (10.1)	3.3	8.2	<0.001
2 or more Elixhauser comorbidities		18,711 (62.9)	1.6	5.1	<0.001
Surgical factor					
Open approach		11,628 (39.1)	2.2	6.3	<0.001
Laparoscopic approach		6,815 (22.9)	4.3	2.2	<0.001
Open hysterectomy		4,751 (15.9)	4.1	2.3	<0.001
Laparoscopic hysterectomy		2,446 (8.22)	4.1	0.8	<0.001
Emergent laparotomy		3,523 (11.8)	2.2	15.8	<0.001
Emergent vascular surgery		354 (1.19)	3.7	11.9	<0.001
Preoperative small bowel obstruction		3,561 (11.9)	2.8	10.7	<0.001
History of abdominal surgery		3,781 (12.7)	2.7	11.1	<0.001

IH indicates Incisional hernia.

TABLE 2. Risk Model for Operative Incisional Hernia in Derivation, Validation, and Combined Cohorts (IH = 3.8% N = 1127)

Risk Factor	Derivation OR (95% CI) (N = 19,799)	*P*	Validation OR (95% CI) (N = 9,940)	*P*	Combined OR (95% CI) (N = 29,739)	*P*	Weighted Risk
Emergent laparotomy	4.65 (3.90–5.55)	<0.001	3.36 (2.60–4.33)	<0.001	4.17 (3.61–4.83)	<0.001	4
History of abdominal surgery	2.33 (1.95–2.79)	<0.001	3.04 (2.38–3.89)	<0.001	2.56 (2.22–2.96)	<0.001	2
Emergent vascular procedure	2.21 (1.39–3.50)	0.001	2.15 (1.14–4.08)	0.018	2.21 (1.52–3.21)	<0.001	2
Caucasian	1.95 (1.63–2.32)	<0.001	1.97 (1.53–2.55)	<0.001	1.95 (1.69–2.25)	<0.001	2
Indication: SBO	1.66 (1.38–2.00)	<0.001	1.86 (1.42–2.44)	<0.001	1.71 (1.47–2.00)	<0.001	1
Smoker	1.65 (1.40–1.94)	<0.001	1.60 (1.26–2.02)	<0.001	1.63 (1.42–1.86)	<0.001	1
2+ Elixhauser comorbidities	1.51 (1.18–1.91)	0.001	1.03 (0.75–1.41)	0.830	1.31 (1.08–1.59)	0.005	1
Open approach	1.42 (1.18–1.72)	<0.001	1.55 (1.19–2.02)	0.001	1.47 (1.26–1.71)	<0.001	1
WHO BMI >30 kg/m^2	1.42 (1.17–1.72)	<0.001	1.73 (1.30–2.30)	<0.001	1.51 (1.29–1.77)	<0.001	1
Chronic liver disease	1.36 (1.12–1.65)	0.001	1.52 (1.15–1.99)	0.002	1.41 (1.20–1.65)	<0.001	1
History of cancer	1.34 (1.11–1.60)	0.001	1.07 (0.81–1.40)	0.603	1.25 (1.07–1.45)	0.003	1
History of chemotherapy/XRT	1.33 (1.01–1.76)	0.042	1.21 (0.80–1.82)	0.348	1.29 (1.02–1.62)	0.030	1
Concurrent fistula/ostomy procedure	1.28 (1.02–1.59)	0.028	0.85 (0.60–1.19)	0.349	1.12 (0.93–1.34)	0.216	1
ASA/anticoagulant use	1.28 (1.04–1.56)	0.017	1.39 (1.04–1.85)	0.022	1.31 (1.11–1.55)	0.001	1
Chronic pulmonary disease	1.24 (1.05–1.46)	0.011	1.38 (1.08–1.75)	0.009	1.28 (1.12–1.47)	<0.001	1
Laparoscopic hysterectomy	0.56 (0.33–0.95)	0.033	0.20 (0.06–0.64)	0.007	0.44 (0.27–0.70)	0.001	−2
WHO BMI 18–25 kg/m^2	0.52 (0.42–0.64)	<0.001	0.75 (0.56–1.00)	0.052	0.59 (0.49–0.69)	<0.001	−2
WHO BMI <18 kg/m^2	0.20 (0.11–0.37)	<0.001	0.30 (0.13–0.68)	0.004	0.23 (0.14–0.37)	<0.001	−4

Derivation cohort *C*-statistic = 0.84, Validation Cohort *C*-statistic = 0.82, combined cohort *C*-statistic = 0.83.
ASA indicates aspirin; BMI, body mass index; CI, confidence interval; OR, odds ratio; SBO, small bowel obstruction; WHO, World Health Organization; XRT, radiation therapy.

was less than the aforementioned factors. Risk stratification model was generated based upon the derivation cohort, and application of the risk model to the validation cohort demonstrated no significant difference in model performance (derivation ROC $C = 0.84$, validation ROC $C = 0.82$, $P = 0.11$) (Fig. 2). The discriminatory capacity and reliability of the risk model were excellent, with a *C*-statistic = 0.83 for the overall study cohort. All 29,739 patients were assigned a composite risk score based upon individual risk profiles and grouped into the following categories of predicted risk: low (IH risk = 0.5%), average (IH risk = 2.2%), high (IH risk = 7.4%), and extreme (IH risk = 26.2%).

Surgery-specific Risk Models

IH incidence was determined across specialty. Colorectal (7.7%), vascular (5.2%), bariatric (4.8%), and transplant (4.5%) specialties demonstrated the highest incidence of surgically repaired hernia (Supplemental 2, http://links.lww.com/SLA/B700). In terms of SSI occurrence, colorectal (4.9%), hepatobiliary (3.0%), and

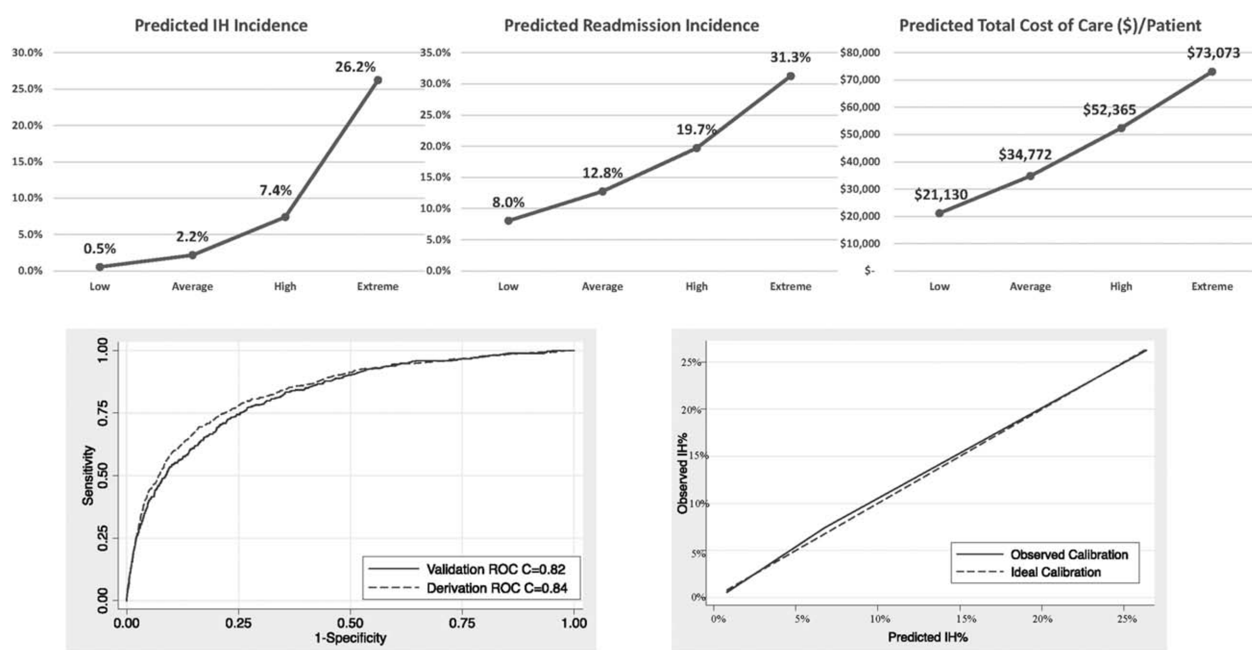

FIGURE 2. Risk-stratified outcomes and model performance. (A) Predicted IH risk. (B) Days to hernia diagnosis. (C) Readmission risk. (D) Total cost of care. (E) Comparison of derivation and validated cohort receiver–operator curves.

FIGURE 3. Penn hernia risk calculator app walkthrough. A) Search then dowanload Penn Hernia Risk Calculator (1) on iOS App store and Google Play and click 'Start'. Read the user agreement and click 'I agree'. B) Scroll through the type of abdominal surgery (2) and the click 'Next step' at bottom of page. Check off patient in formation (3) and then click 'Submit'. C) Details about patient risk for incisional hernia, operative hernia, and SSI are displayed (4) 'Run Simulation' allows user to modify the patient risk and change the factors and re-caluclate the risk. Once final statistics (5) are presented user has ability to 'Send Result ad Email'.

vascular (3.0) were the most likely. The most common occurring risk factors among the 8 index operations that increased the likelihood of developing IH were history of AS (87.5%), smoking history (75%), and history of a recent acute infection (75%). The 8 individual models showed excellent reliability with C-statistic between 0.77 and 0.89: high—bariatric ($C = 0.89$) and gastrectomy ($C = 0.89$); low—urologic ($C = 0.77$) and vascular ($C = 0.77$). The individual risk model parameters were incorporated into specialty-specific modules and implemented into an accessible web-based platform (http://www.pennherniariskcalc.com) and an iOS/Android compatible mobile app, entitled "Penn Hernia Risk Calculator" (Fig. 3).

Secondary Outcomes and Costs

Secondary outcomes were compared among the entire cohort with and without IH (Table 3). Patients with IH were more likely to be readmitted (30% vs 13%, $P < 0.001$) and develop a superficial infection (33% vs 9%, $P < 0.001$). IH likewise led to an average readmission added length of stay of 8 days compared with 4 days for those patients without IH ($P < 0.001$); overall, increased complications and readmissions translated into significantly higher resource utilization and total cost of care for patients experiencing IH ($57,661 per patient with IH vs $33,781 per patient without IH, $P < 0.001$). Combined cost of care for patients experiencing IH was $62 million.

TABLE 3. Summary of Secondary Outcomes and Comparison for Patients With (N = 1,127) and Without IH (N = 28,612)*

Outcome	Subgroup	Overall	Without IH (N = 28,612)	With IH (N = 1,127)	P
Surgical complication	Overall	4,896 (16.4%)	15.18%	49.11%	<0.001
	Superficial infection	2,842 (9.55%)	8.64%	32.95%	<0.001
	Wound dehiscence	820 (2.75%)	2.41%	11.55%	<0.001
	Seroma	459 (1.54%)	1.26%	8.70%	<0.001
	Hematoma	632 (2.12%)	1.98%	5.86%	<0.001
	Bleeding	1,041 (3.50%)	3.36%	7.10%	<0.001
	Fistula	756 (2.54%)	2.22%	10.83%	<0.001
	Sepsis	2,265 (7.61%)	7.26%	16.61%	<0.001
	Small bowel obstruction	4,250 (14.2%)	13.38%	37.39%	<0.001
Index case LOS days		6.4 (14.4)	6.2 (14.1)	10.6 (15.2)	<0.001
Readmission	Incidence overall	3,916 (13.1%)	12.49%	30.28%	<0.001
	2+ Readmissions	608 (2.04%)	1.81%	8.08%	<0.001
	Reoperation	1,833 (6.16%)	5.18%	31.17%	<0.001
	Readmit added LOS days	4.2 (3.3)	4.0 (3.3)	7.8 (3.9)	<0.001
	Number of readmissions	1.6 (0.4)	1.5 (0.4)	4.2 (7.2)	<0.001
Costs	Index admission	$31,824 (57,270)	$31,175 (56,428)	$48,283 (73,323)	<0.001
	Total cost of readmissions	$15,937 (35,675)	$14,719 (33,895)	$26,408 (51,930)	<0.001
	Combined cost of care	$34,687 (61,913)	$33,781 (60,423)	$57,661 (88,256)	<0.001
Months follow-up		57.9 (33.5)	57.4 (33.4)	69.7 (33.0)	<0.001

LOS indicates length of stay in days.
*Summary data reported as proportions for binary outcomes and as means (standard deviation) for continuous outcomes.

DISCUSSION

IH has plagued abdominal surgeons for decades. One of the main barriers to implementing effective strategies to reduce incidence IH and costs and the associated treatment morbidity is the rapid and precise identification of at-risk patients. With the advent of the EMR and utilization of bioinformatics, we have the ability to automate data acquisition and understand risk. In this study of nearly 5 years of follow-up, across 3 major hospitals, analyzing 558 variables from 164,014 encounters belonging to 78,030 patients, we characterize the incidence of operational IH, demonstrate risk variation IH across treating specialties, and integrate several models into a single unifying risk-prediction app. We expect this app to permit the identification of at-risk patients and advance the science of hernia prevention.

Summary of Study Findings

This study demonstrates a 3.8% incidence of operative IH among 29,739 patients undergoing AS after an average follow-up of 57.9 months. It characterizes the morbidity and costs of IH and emphasizes the economic value of hernia prevention among the largest longitudinal cohort of patients described to date. Important risk factors predisposing all patients who undergo AS to IH included emergent surgery, prior AS, open approach, and high comorbidity burden. In contrast, nonobese individuals and those undergoing laparoscopic procedures were at lower risk for developing IH. An internally validated risk stratification model predicted IH risk ranging from 0.5% to 26.2% and identified patients at greater risk for readmission and higher healthcare resource utilization after AS. Furthermore, by using a hybrid of robust augmented claims data through the EMR and a bioinformatics approach, we were able to accurately predict operative IH in multiple surgery-specific models (C-statistic = 0.76–0.89). We have converted these models into a singular surgeon-facing interface that encourages patient engagement and risk counseling.

Current literature discussing the evaluation and management of IH has conventionally focused on addressing modifiable risk factors such as obesity and smoking as methods of risk reduction.[31] Despite significant advances in technique and available technology, however, IH continues to present a formidable challenge with persistent and unacceptably high rates of recurrence, associated morbidity, and healthcare costs.[32] To further accentuate the problem, a major challenge in improving IH outcomes has been the overall low quality of hernia research available to date which may be a byproduct of the necessity for long-term follow-up and sufficiently powered comparisons among diverse hernia subpopulations. Big data analytics has yielded major success for a variety of research questions.[33] However, large data sets, such as the NSQIP or HCUP samples, either fail to provide adequate follow-up or lack granularity to be clinically useful for predicting IH.[22] Administrative claims, powerful institutional EMR data coupled with chart review, permitted investigation of 558 variables from 164,014 encounters belonging to 78,030 patients across 3 major hospitals. It is robust in sample size, provides long-term follow-up, encompasses information from the full spectrum of healthcare settings, including inpatient, ambulatory, diagnostic labs, and imaging resources, and was able to generate 8 specialty specific predictive models (Fig. 4).

The unique predictive models highlight the development of the Penn Hernia Risk Calculator app. We felt that there was an unmet need for a portable, bedside tool to identify at risk patients quickly and efficiently. Medical app usage has increased substantially[34–37] in the last several years with one study reporting that 80% of physicians use their smartphone apps for a multitude of medical purposes: review of evidenced-based practices, modes to educate residents, and prediction of outcomes. The Carolinas Equation for Determining Associated Risks (CeDAR) is one user interface app that calculates wound-related complications and costs associate with repair of ventral hernias.[38] However, there is no consensus risk calculator due to significant limitations in methodology and applicability to a generalized population.[6] In addition, they do not take into account individualize risks for abdominal surgery treating specialties. The most appealing model to date, the HERNIAscore, considers operative approach, chronic obstructive pulmonary disease (COPD), and increased BMI in risk stratifying a prospective sample of 625 patients with adequate follow-up. Strengths of the HERNIAscore include a generalizable patient population, exclusion of postoperative variables from analysis, and a relatively accurate model with C-statistic = 0.77, but it fails to address the heterogeneity of surgical sub-types or the potential power of broader variable captures.[39] Our model factors index AS which, as we have shown, greatly impacts risk of IH. Colorectal surgery (IH rate of 7.7%), for example, has a 5.5-fold increased risk of IH compared with gynecologic surgery (IF rate of 1.4%) highlighting the need for surgery specific prediction. Furthermore, the model presented here includes a broader, significantly larger patient cohort with average follow-up of nearly 5 years, which improves validation and generalizability.

Building on our prior work,[20] we believe that the bioinformatics approach is the best method to model the heterogeneity of variables and multiple abdominally based operations increasing IH risk. The translation of traditional, risk models into a surgeon-facing interface and app with point-of-care risk estimation fulfills an unmet technologic and clinical need and provides the ability for meaningful, real-time patient risk counseling regarding hernia risk. A shift in focus to IH prevention hinges upon our ability to precisely define those at risk and the models presented herein provide a significant step toward this future. With regard to IH prevention and future studies, interventions guided toward high-risk patients, such as prophylactic mesh augmentation, are not without potential harm. One foreseeable problem is mesh infection which leads to recurrent hernias, increased costs, and chronicity of disease which could have been prevented if not for the prophylactic intervention.[7,40] The potential harms of these interventions must be adequately analyzed within future studies.

Study Limitations

This study is not without limitations that deserve further consideration. We recognize that administrative data codes are dependent on how information is interpreted by those entering the data and may not be representative of what a physician actually documented. Furthermore, although internal validation certainly improves the robustness of analysis and overall model accuracy, external validation should still be pursued to ensure generalizability, ideally with a prospective design. The primary endpoint chosen was surgically treated IH which likely underestimates the true incidence of IH. The retrospective nature of the study along with the lack of standardized criteria informing hernia diagnosis would have led to unreliable results if diagnostic codes were used. Furthermore, the authors acknowledge the IH incidence may have also been underestimated if data regarding diagnosis or surgery of IH were missing, incorrect, or if the patient was lost to follow-up from our healthcare system. Some factors associated with hernia, such as incision type and degree of wound contamination, were excluded from analysis. The authors recognize this limitation and attempt to mitigate confounding by indirectly modeling these via procedure type. In an effort to address this inherent design issue, our analysis was limited to only those patients who had $\geq$1 year of follow-up. In addition, the development of the app is not without limitations. The functionality

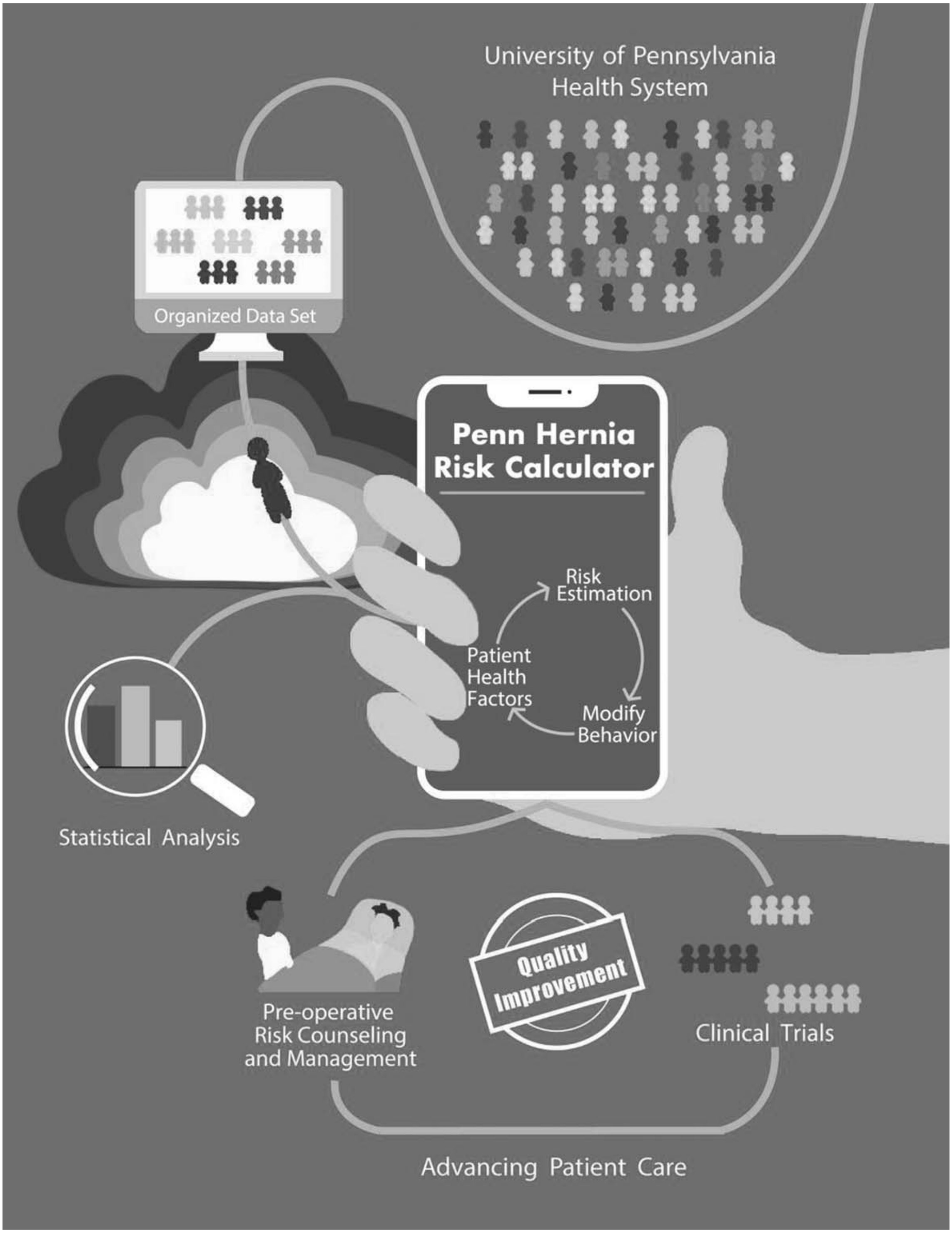

FIGURE 4. Graphic design depicting the framework of how to transform large institutional datasets into a real-time, interactive decision–support interface.

and user-friendliness will improve as we obtain feedback from our subscribers. The risk calculator does not capture emergent cases which impacts the development of IH; however, the acuity and urgent nature of those cases limits the application of the decision interface before surgery.

CONCLUSIONS

Among 29,739 patients undergoing abdominal surgery with an average follow-up of 5 years, operative IH was identified in 3.8% of patients. Several modifiable and unmodifiable risk factors spanning all levels of the health system demonstrate the critical disease burden of IH. Using a bioinformatics approach to IH occurrence risk prediction, we have created a model individualized to index abdominal operations. It provides an evidence-based means to predict IH risk with greater accuracy and reliability than current literature. The model has led to a fully designed unifying, surgeon-facing, and point-of-care risk calculator app generated from a multiyear, longitudinal multihospital dataset. The need to develop further risk-reduction strategies to optimize treatment and improve patient care cannot be understated.

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DISCUSSANTS

Dr Michael Rosen (Cleveland, OH):

First of all, I would like to congratulate Dr Fischer for a great presentation and his group for making another important contribution to our understanding of not only hernia disease, but, in particular, hernia prevention.

In this study, they have looked at a large internal database in their hospital system that has allowed them to perform a very sophisticated analysis to identify an individual patient's risk of developing an IH and requiring surgery for that hernia during several different index operations. They also took it one step further and developed a user-friendly app to allow this information to be readily available, easily calculated, and provide a means for shared decision-making with the patients. I think this type of work is extremely important, and I really do think for hernia surgery, this is where we need to go in trying to come up with ways to prevent this problem.

I do have several questions for Dr Fischer, and they are mainly going to center around 2 issues.

First, although not directly addressed in your study, there are implications of your findings as well as some of your past work that perhaps suggests that there should be the use of prophylactic mesh. I have several concerns about its unmeasured harm in these patients.

My second set of questions will be based on what do we do with this data and what have you done?

Number one, with regard to the potential harm that the suggestion of prophylactic mesh brings up, I have several questions. Your entire population actually had a fairly low rate of IH formation at only 3.8% which I think was probably relatively surprising to you as well. I think there is no doubt, as you mentioned, some of this is underreporting because you only looked at hernias that actually did require an operation, but if you look at your most extreme high-risk group, the rate of hernia formation was only 23%, and whether you are a glass half full or half empty depends on how you look at that because three-quarters of the patients in that group did not actually go on to develop a hernia. And if prophylactic mesh was applied to that group of patients, three-quarters of them would be getting a mesh that they did not need, and certainly some of them are going to suffer complications. Furthermore, in that specifically high-risk group, when you look at all those variables, those are the patients who are also most likely to suffer mesh-related complications.

So I am curious what you will do with your app to allow that information to be portrayed to patients. Will there be a rate of mesh infection, rate of reoperation due to complications, a rate of chronic pain that will adequately inform patients as a tool when doing this as the potential downsides of mesh?

You also reported that there was $62 million spent on the care of hernias as a result of this 3.8% of patients. But I also wonder what the number would look like if everyone at your hospital started to use prophylactic mesh or, say, an absorbable synthetic or a biologic mesh that could cost several thousand dollars per piece, and ultimately who is going to be paying for that mesh?

My final set of questions are really related to what is next? What have you done with this data at your institution? Have you been able to identify a specific risk level based on your calculator that justifies the placement of prophylactic mesh or some other intervention other than just good surgical care? Really, what has been the buy-in even at your institution? Are vascular surgeons, gynecologists, urologists, colorectal surgeons now putting in mesh prophylactically or doing something different? If so, how did you roll this out? Did you set up workshops to not only teach people who do not typically put in mesh how to place that mesh? Did you also teach them how to potentially close fascia with the 4:1 suture-to-wound ratio? Because that has been shown in multiple randomized controlled trials to reduce recurrence.

And in summary, I think one of the dangers of this type of research is that we might be simply promoting the addition of another medical device, in this case potentially mesh, to overcome poor surgical technique.

Again, I look forward to your responses. I appreciate the opportunity to discuss this paper, and I congratulate you on a very impressive study. Thank you very much.

Dr John P. Fischer (Philadelphia, PA):

Dr Rosen, thank you for those fantastic comments and great questions. I will answer them in order.

I think the first fundamental question really relates to the use of mesh to support a fascial closure and potentially prevent incisional hernia. I think that more data are certainly needed. I think that in our study we had a lower incidence of incisional hernia. I think it is important, and I think it really does relate to how we defined this outcome. The rigor of this study, I think, is derived from the fact that our outcome was a surgical intervention, that is, a repair of an incisional hernia, which I think is very important both to the accuracy of the data and how it should be interpreted because all of these patients developed a complication after the index abdominal surgery that required a second surgery, that is, hernia repair.

I think that the comment about the risk of IH is very important, and I wanted to share with the group that one slide of the stratification with the patients in the extreme risk group and having a hernia incidence of 24% is for a cohort or group. Certainly, if you do point risk estimation for many of these surgical specialties within this app, the risk goes well into 30% and 40% ranges. So I think that individualized risk assessment is important, and I think that if we can point estimate risk, we can certainly get a better sense as to what a patient's risk of a complication is. I think linearly it does go up above 23%. But your point about potentially doing a prophylactic or preventive surgical intervention which carries potential morbidity and risk in a group of patients in whom they are all not going to get the outcome is critically important and, therefore, has to be weighed carefully.

I would take it one step further and say that there is a near direct linear correlation between surgical site infection and postoperative hernia. I think this fundamentally relates to the fact that IH is a wound healing issue. The overlap between those postoperative conditions, surgical site infections and hernia make it very important that if a piece of mesh is put inside a patient, you may have a postoperative wound event and potentially a mesh infection. Certainly, the choice of anatomic plane and type of mesh would have to be considered carefully and this additional prophylactic procedure carefully and thoroughly discussed with each patient. I think that is got to be carefully evaluated. And my hope with that initial slide in which I tried to characterize how we can avoid hernia, I think it has to be a multipronged approach. It is not just about putting a piece of mesh in someone. I think it is, as you alluded to, education, improved technique, surgical site infection reduction, maybe a different surgical approach. And the STICH trial, although a fantastic study, I think has limitations. I mean, the patient population was not obese. They used 2 0 Maxon and a short stitch technique and compared it to kind of 1 cm number one Maxon close, and I do not think it has been replicated in the United States. I think certainly that is an area of opportunity.

In the PRIMA study, which showed very favorable results, randomized controlled trial, onlay and retromuscular prophylactic mesh compared with primary suture closure, and a big statistically significant difference in hernia occurrence with no difference in other outcomes and no mesh infections reported in the study, the only complications really of interest were seromas, frankly.

So I think it is very, very important, and I think that as you look at this data and the associated costs and the context of the potential costs of putting in resorbable mesh or biologic mesh, the picture may be very different. But I would just suggest that we do not have enough long-term data to even truly understand the impact of mesh on hernia repair, frankly.

So I think that this is an area of significant opportunity for us to advance the understanding of this disease and improve outcomes for patients. But the intention of this app is not a decision tool to tell someone to put in prophylactic mesh. I think it is to create awareness and potentially to be even used in clinical trials. I think the cost of mesh certainly would be important, but this app is not intended to suggest the use of mesh, although it may do it unintentionally, as you indicate.

Hopefully, I got all the questions you asked me. What to do with this app, again, this is just kind of happening, and the app has just been released. We are hoping that people use it, that people give us feedback about it. We are collaborating with the department of surgery to implement this, and I think that successful implementation hinges upon several key things. First, the data should be prospectively validated both within our health system and externally to really rigorously evaluate how accurate it is. I think second is to engage stakeholders. I think that those stakeholders are broad and diverse, as I alluded to at the beginning of this talk, various different surgical specialties.

So I think that that process has to begin. We have to educate. We have to engage, and we have to understand, and I think that through that, and kind of through this, and as I have worked in this area, I have definitely engaged many different specialists, including urologists, gynecologists, and many different general surgery specialties with interest from them to both improve the way we evaluate and talk to patients but potentially to be involved in clinical trials.

I think that at this point, we are not doing something different. We are not just putting in prophylactic mesh or modifying our suturing technique, but we are trying to bring this to the point of care to see how it is going to impact our conversations and our interactions with our patients.

I think more to come on that. I think the next step for this is going to be prospective validation to really make sure that this is rigorous enough to accurately predict what we are trying to, and hopefully have an impact someday in the way we take care of patients. Thank you for your questions.

Dr Selwyn Vickers (Birmingham, AL):

Two quick questions. One in relationship to the app and some of the fixed risk factors and modifiable risk factors. Will the app have the potential of actually, in elective cases, to allow the physician to know where prehabilitation and modifiable risk factors may impact the cost and the risk of hernia recurrence? So when someone is having elective surgery, not for cancer, but for an elective procedure, and you have a significant number of risk factors, what is the role and opportunity of prehabilitation in changing the outcome?

And then the final question, the CMS and the Affordable Care Act now is requiring institutions to deal with cost transparency. You have listed a lot of numbers around the cost of hernia repair. What role does cost play, and is it a part of your app to allow a surgeon to understand the cost differential as well as the patient of a procedure?

Dr John P. Fischer (Philadelphia, PA):

Thank you for those questions, Dr Vickers. To respond to the first question, which really focuses on can we identify risk factors in elective surgery? The answer is yes. And I think that the intention of this app—and I did not actually show all features—you can rerun the simulation and actually uncheck risk factors. The 2 most common you could do would be smoking and reducing obesity which would, in turn, change the predicted risk. I think that giving the surgeon the ability to show this or demonstrate this to a patient is a very, very powerful thing that the visual messaging behind changing someone's risk of a potential outcome at the bedside I think could really impact care. More specifically, your question about prehabilitation and eventual hernia, I think there is a lot of good data. A randomized controlled trial in *Annals of Surgery* by Michael Lee Yang showed it reduced complications in patients undergoing hernia repair. I think that there is a role here. I think we try to think very carefully about the ultimate use of this app and how it would work in clinical practice to really optimize its design. We take it one step further to say that the predicted risk can be e-mailed to the physician or the patient through this interface, and we are working on trying to find a way to communicate, have the app communicate with the electronic health record.

I think lastly, as it relates to cost transparency, we fit our models around the IH outcome, and it did correlate nicely with cost. We're currently not displaying cost because I think that cost is a very complicated thing. Is it institution dependent? Is it charges? Is it direct cost? How long is the time horizon? So we do not necessarily plan on having costs be part of this because it is so institution dependent. But I think in the end, trying to find a way to more indirectly capture healthcare expenditures related to this issue, I think, would be very, very important to display inside the app. Thank you for your questions.

Dr Kamal Itani (Boston, MA):

Congratulations. A very nice study, very well presented. I have 2 concerns. The first one is regarding that you are probably underestimating the number of ventral hernias that occurred in your database because as Dr Rosen mentioned, you are only capturing those patients who had surgery after the hernia was detected. You are probably missing those who were not operated on.

The second concern is the short time line of your database. You do not have long-term follow-up on those patients, and we know that incisional hernias are long-lived problems that can occur after a long time. So you are also underestimating the number of hernias that occur over time.

For these 2 concerns you are probably, in your calculator, underestimating the number of incisonal hernias.

Dr John P. Fischer (Philadelphia, PA):

Thank you for the comments and questions. I think those are all spot on. Full disclosure, I think that the decision between picking an outcome that we know happened versus picking an outcome that we are unsure of, I think for the purposes of precision risk prediction, in our mind, made more sense to go with the surgically treated incisional hernias. I would tell you that the app actually does display the incidence of predicted IH operative repair and occurrence. It's about twice as high with just a diagnosis or occurrence. I think you are absolutely right. Not only did we underestimate it by calculating it for operative hernia, we underestimated all the patients that went to different hospitals to have their hernias fixed. I think that the ideal situation would be following all patients for as long as possible across all health systems. We did do that with the HCUP project, and it allowed us to track patients longitudinally over 4 years. I think what is most interesting is you look at the low incidence in that group of 560,000 patients, the incidence of hernia, primary hernia, primary IH was 3%. But as time elapses, those patients that were treated develop a high incidence of recurrence, almost exponential over time.

I would say—and I may have not been clear here—the follow-up average in this cohort of 29,000 patients was 58 months, so that is 5 years.

Dr Kamal Itani (Boston, MA):

One other quick question. In your model, or in the example that you showed, the incidence was 22%. Was this over a lifetime or was it over 5 years?

Dr John P. Fischer (Philadelphia, PA):

It is over the average follow-up for the cohort. And in the colorectal cohort, I do not recall offhand. I think it was 50-plus months. It individualizes the estimation of risk for the average amount of follow-up in that group. So it is surgery subspecialty specific across 8 different modules.