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Assessment of the Addition of Hypoalbuminemia to ACS-NSQIP Surgical Risk Calculator in Colorectal Cancer

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Abstract: The aim of this study was to evaluate the benefit of adding hypoalbuminemia to the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) Surgical Risk Calculator when predicting postoperative outcomes in colorectal cancer patients.

The ACS-NSQIP Surgical Risk Calculator offers qualified risk evaluation in surgical decision-making and informed patient consent. To date, malnutrition defined as hypoalbuminemia, an important independent surgical risk factor in colorectal cancer, is not included.

This is a retrospective, multi-institutional study of ACS-NSQIP patients (n = 18,532) who received colorectal surgery from 2009 to 2012. Models were constructed for predicting postoperative mortality and morbidity using the risk factors of the ACS-NSQIP Surgical Risk Calculator before and after adding hypoalbuminemia as a risk factor. The 2 models' performance was then compared using c-statistics and Brier scores. The ACS-NSQIP database in 2008 was used for validation of the created models.

The prevalence of hypoalbuminemia (27.8%) is higher in colorectal cancer, when compared with other most common cancers. In univariate analyses, hypoalbuminemia was significantly associated with postoperative mortality and morbidity in colorectal cancer patients. In multivariate logistic regression analyses, 15 postoperative complications, including mortality and serious morbidities, were significantly predicted by hypoalbuminemia. Most of the models with hypoalbuminemia showed better performance and validation in predicting postoperative complications than those without hypoalbuminemia.

In colorectal cancer, hypoalbuminemia, with levels below 3.5 g/dL, serves as an excellent assessment tool and preoperative predictor of postoperative outcomes. When combined with hypoalbuminemia as a risk factor, the ACS-NSQIP Surgical Risk Calculator offers more

accurate information and estimation of surgical risks to patients and surgeons when choosing treatment options.

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Abbreviations: ACS-NSQIP = American College of Surgeons-National Surgical Quality Improvement Program, BMI = body mass index, CPT = current procedural terminology, ICD-9 = International Classification of Disease, Ninth Revision, ROC = receiver operating characteristic, WHO = World Health Organization.

INTRODUCTION

Accurate evaluation of surgical risk is essential for both patients and surgeons in the process of making medical and surgical decisions.^{1,2} Previously, postoperative mortality and morbidity were estimated based on an individual surgeon's experience, or on data published by institutions. With the improvement of qualified databases and the accumulation of information, many scoring systems³⁻⁵ and risk calculators^{1,6} have been developed to predict patient-specific surgical risks and to provide more precise informed consent.

The prevalence and effects of malnutrition have been reported in surgical and hospitalized patients.⁷⁻⁹ The association between postoperative outcomes and malnutrition has been explored in different fields including geriatric patients,^{10,11} orthopedic surgery patients,^{12,13} pediatric surgery patients,¹⁴ vascular surgery patients,¹⁵ pancreatic surgery patients,¹⁶ gastrointestinal surgery patients,¹⁷⁻¹⁹ and cancer surgery patients.²⁰⁻²² In the United States, colorectal cancer is the 3rd most common cancer in both men and women.²³ Malnutrition is a more common and important issue in colorectal cancer²⁴⁻²⁶ than in many other common cancers, and serves as a significant preoperative risk factor.²⁷⁻²⁹

The Surgical Risk Calculator of the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) was created using an aggregate high-quality database which includes preoperative risk factors and postoperative outcomes from more than 500 medical institutions in the United States and Canada.^{1,30,31} Surgeons can easily input 21 patient-specific variables to predict the risk for a series of postoperative complications. Hypoalbuminemia, which, according to our previous study,³² predicts the surgical risk of malnutrition more accurately than the underweight subgroup of body mass index (BMI), is not currently included in the calculator as a risk factor.

We used the ACS-NSQIP database to compare 2 groups of surgical risk factors to predict postoperative complications in colorectal cancer patients: the current ACS-NSQIP Surgical Risk Calculator with 21 risk factors; and the ACS-NSQIP Surgical Risk Calculator with hypoalbuminemia added as the 22nd risk factor. We hypothesized that the model which

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included hypoalbuminemia would improve the accuracy of the current ACS-NSQIP Surgical Risk Calculator.

MATERIALS AND METHODS

Patient Selection

Information from the ACS-NSQIP database during the years 2009 to 2012 was used, selecting patients with the most common cancers which included: prostate; breast; lung and bronchus; colorectal; urinary bladder; uterus corpus and cervix; and thyroid according to the ICD-9 (International Classification of Disease, Ninth Revision) diagnostic codes (Table S1, <http://links.lww.com/MD/A751>). Colorectal cancer patients undergoing major operations were identified by the current procedural terminology (CPT) codes (Table S2, <http://links.lww.com/MD/A751>) in the category of Principle Operative Procedure. The number of included patients was 18,532.

Preoperative Risk Factors

The 21 preoperative risk factors of the ACS-NSQIP Surgical Risk Calculator were used and made categorical. BMI was subdivided according to World Health Organization criteria into: underweight (BMI < 18.5 kg/m²); normal weight (18.5–24.9 kg/m²); overweight (25–29.9 kg/m²); obese class I (30–34.9 kg/m²); obese class II (35–39.9 kg/m²); and obese class III (≥40 kg/m²).³³ Hypoalbuminemia was defined as serum albumin levels <3.5 g/dL.

Postoperative Outcomes

Postoperative 30-day mortality, morbidities, and overall complication were selected as the postoperative outcomes. The selected morbidities included: surgical site infection (superficial, deep, and organ); urinary tract infection; wound disruption; pneumonia; re-intubation; on ventilator for longer than 48 h; progressive renal insufficiency; acute renal failure; pulmonary embolism; deep vein thrombosis; stroke; cardiopulmonary resuscitation; myocardial infarction; blood transfusion; sepsis; septic shock; and return to operating room. Accordion Severity Grading System was used for grading and weighting postoperative mortality and morbidities.^{34,35} We defined postoperative overall complication as the sum of the weighted score for each colorectal cancer patient.

Statistical Analysis

Univariate analyses were performed to assess the association between risk factors and postoperative outcomes using Chi-squared test. Multivariate logistic regression models were constructed for postoperative 30-day mortality, morbidities, and overall morbidity by including the risk factors having a *P* value <0.15 in univariate analyses.³⁶ Purposive selection of variants was performed. Risk factors were removed from the model, in order from the least significant 1 if they had no statistical significance. Model performance was assessed using c-statistics and Brier scores. The c-statistic, referred to as the area under the receiver operating characteristic (ROC) curve, is a measure of discrimination. The discrimination is perfect if the c-statistic is 1, or no better than chance if the c-statistic is 0.5. The Brier score is defined as the mean of the squared difference between predicted probability and observed postoperative outcome for all patients (1 or 0 depending on occurrence or nonoccurrence of an event).^{37–39} The Brier score will approach 0 for perfect prediction and reflect discrimination and calibration simultaneously. Multiple linear regression analysis was computed for overall complication with

the 22 risk factors. The 2008 ACS-NSQIP database was used as validation for the logistic regression models. The ratios of observed to predicted outcomes (O:P) and c-statistics were calculated to identify the differences in prediction between models with and without hypoalbuminemia.^{2,40,41} A ratio closer to 1 indicates a better prediction. Tests were 2-tailed and statistical significance was defined as *P* < 0.05. All statistical analyses were performed on SPSS for Windows, Version 22.

RESULTS

When using the hypoalbuminemia criterion of serum albumin levels <3.5 g/dL, the prevalence of malnutrition ranged from 9% to 36% in surgical specialties and from 4% to 30% in most common cancers (Table S3, <http://links.lww.com/MD/A751>). The number of patients with malnutrition was highest in general surgery, and malnutrition was more prevalent in colorectal cancer than in other common cancers.

The association between the hypoalbuminemia status of patients and postoperative outcome was assessed after excluding patients with missing data and without related operations. The resultant patient group included 18,532 colorectal cancer patients undergoing major operations, and among these, 5146 (27.8%) patients were identified as malnourished by the hypoalbuminemia criterion. In univariate analysis, we found that hypoalbuminemia status was significantly associated with 30-day mortality and all previously listed postoperative morbidities except organ surgical site infection and pulmonary embolism (Table 1).

Multivariate logistic regression models were then used to evaluate the relationships between each postoperative outcome and the preoperative risk factors with and without hypoalbuminemia as a risk factor. The adjusted odds ratios when hypoalbuminemia was included in the models with statistically significant differences are presented in Figure 1. The odds ratios ranged from 1.14 to 2.475 in the 15 regression models including 30-day mortality and other serious complication.

When using only the risk factors of the ACS-NSQIP Surgical Risk Calculator for the 15 regression models, the c-statistics ranged from 0.615 for superficial SSI to 0.849 for mortality. With hypoalbuminemia added to the calculator as another risk factor, the increments of c-statistics were noted in all models, except sepsis, with the same result (Figure 2). The models performed better with hypoalbuminemia added as a risk factor when comparing Brier scores (Table 2).

Compared to other risk factors, the number of postoperative outcomes significantly predicted by hypoalbuminemia was greater than by all other risk factors except gender in multivariate logistic regression models (Figure S1, <http://links.lww.com/MD/A751>). The postoperative complications predicted by BMI of <18.5 kg/m² were only 30-day mortality and acute renal failure.

In multiple linear regression analysis, hypoalbuminemia was significantly associated with overall complication (*P* < 0.001; Table 3). No significant association was noted between overall complication and some risk factors including previous cardiac event, ventilator dependence, acute renal failure, diabetes mellitus, and BMI.

The observed and predicted numbers of postoperative outcomes in the validation data set including 5391 colorectal cancer patients are listed in Table 4. The ratios of observed to predicted outcomes in the models with hypoalbuminemia are better or almost equal to those of models without hypoalbuminemia. Improvements in the c-statistics were noted in the

TABLE 1. Association Between Postoperative Outcome and Hypoalbuminemia

Postop Outcome	Albumin \geq 3.5, g/dL, 13,386 (72.2)	Albumin <3.5, g/dL, 5146 (27.8)	P Value
30-d mortality	156 (1.2)	316 (6.1)	<0.001
Superficial SSI	982 (7.3)	422 (8.2)	0.046
Deep SSI	203 (1.5)	106 (2.1)	0.01
Organ SSI	534 (4.0)	219 (4.3)	0.411
UTI	464 (3.5)	250 (4.9)	<0.001
Wound disruption	171 (1.3)	89 (1.7)	0.019
Pneumonia	287 (2.1)	265 (5.1)	<0.001
Reintubation	255 (1.9)	262 (5.1)	<0.001
On ventilator >48 h	222 (1.7)	257 (5.0)	<0.001
PRI	101 (0.8)	83 (1.6)	<0.001
ARF	71 (0.5)	71 (1.4)	<0.001
PE	106 (0.8)	56 (1.1)	0.052
DVT	145 (1.1)	154 (3.0)	<0.001
Stroke	39 (0.3)	46 (0.9)	<0.001
CPR	58 (0.4)	66 (1.3)	<0.001
MI	121 (0.9)	69 (1.3)	0.008
Transfusion	938 (7.0)	810 (15.7)	<0.001
Sepsis	496 (3.7)	299 (5.8)	<0.001
Septic shock	167 (1.2)	184 (3.6)	<0.001
Return to OR	688 (5.1)	363 (7.1)	<0.001

Values in parentheses are percentages. P value, chi-squared test.

ARF = acute renal failure, CPR = cardiopulmonary resuscitation, DVT = deep vein thrombosis, MI = myocardial infarction, OR = operating room, PE = pulmonary embolism, PRI = progressive renal insufficiency, SSI = surgical site infection, UTI = urinary tract infection.

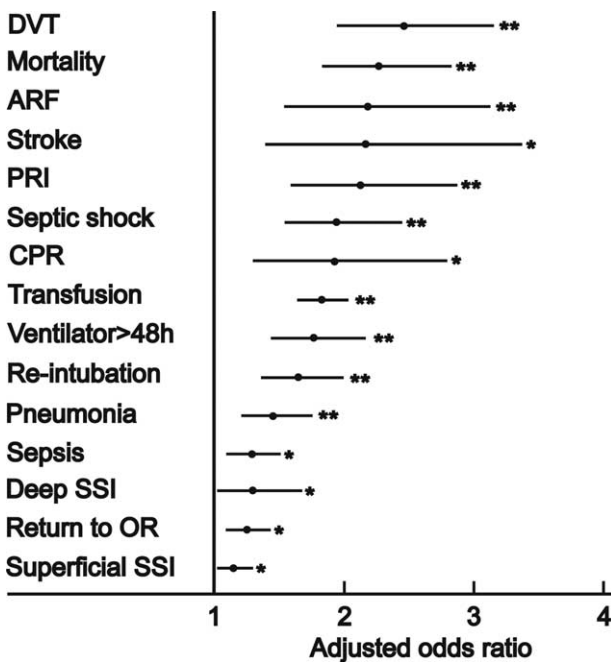


FIGURE 1. Adjusted odds ratio plot of the association between significant postoperative outcomes with malnutrition evaluated by hypoalbuminemia. * $P < 0.05$, ** $P < 0.001$, multivariate logistic regression. ARF = acute renal failure, CPR = cardiopulmonary resuscitation, DVT = deep vein thrombosis, OR = operation room, PRI = progressive renal insufficiency, SSI = surgical site infection.

hypoalbuminemia models predicting the most postoperative complications which include mortality, blood transfusion, progressive renal insufficiency, cardiopulmonary resuscitation, deep vein thrombosis, stroke, septic shock, ventilator more than 48 h, and acute renal failure. Compared with the model without hypoalbuminemia, the model which included hypoalbuminemia showed a better O:P ratio and equivalent c-statistics in the prediction of pneumonia. In the other complications, the

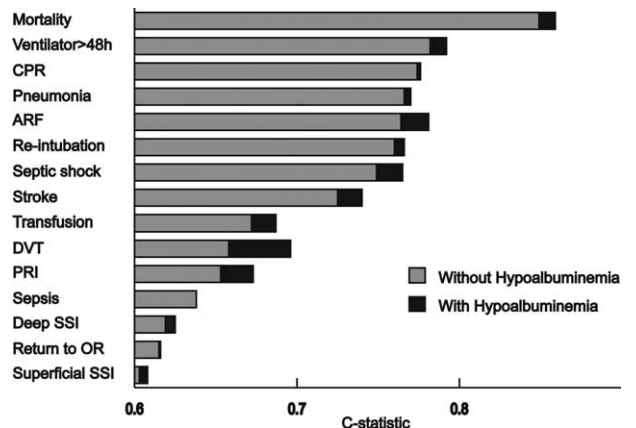


FIGURE 2. Comparison of c-statistics in the postoperative complication models with and without hypoalbuminemia as a risk factor. Increments of the c-statistic were noted after adding hypoalbuminemia. ARF = acute renal failure, CPR = cardiopulmonary resuscitation, DVT = deep vein thrombosis, OR = operation room, PRI = progressive renal insufficiency, SSI = surgical site infection.

TABLE 2. Comparison of Brier Score Between Without Hypoalbuminemia and With Hypoalbuminemia Models for Postoperative Outcomes

Postop Outcome	Brier Score	
	Without Hypoalbuminemia Model	With Hypoalbuminemia Model
30-d mortality	0.02216	0.02199
Transfusion	0.08270	0.08217
DVT	0.01581	0.01576
Septic shock	0.01823	0.01819
Reintubation	0.02634	0.02631
Superficial SSI	0.06913	0.06911
ARF	0.00754	0.00753
Sepsis	0.04057	0.04056
Pneumonia	0.02792	0.02791
Return to OR	0.05301	0.05300
Stroke	0.00454	0.00453
Deep SSI	0.01634	0.01634
On ventilator >48 h	0.02346	0.02346
PRI	0.00978	0.00978
CPR	0.00659	0.00659

ARF = acute renal failure, CPR = cardiopulmonary resuscitation, DVT = deep vein thrombosis, OR = operating room, PRI = progressive renal insufficiency, SSI = surgical site infection.

c-statistics of the models with hypoalbuminemia had a minor decrease but their O:P ratios were almost equal to the models without hypoalbuminemia.

DISCUSSION

This research used data from the bulk and high quality of database of the ACS-NSQIP, and showed the prevalence of malnutrition by surgical specialty and common cancers and high incidence of malnutrition in general surgery and colorectal cancer. The ACS-NSQIP Surgical Risk Calculator is an important and easy tool that allows surgeons to estimate patient-specific postoperative complications and to discuss those potential complications with patients to aid decision making. However, improving the accuracy of predicting complications by adding critical factors is essential for particular patient groups and surgical specialties. After adding a malnutrition factor defined by hypoalbuminemia, the Surgical Risk Calculator had improved discrimination and calibration in predicting postoperative complications in colorectal patients.

Using the NSQIP database, Cohen et al⁶ and Longo et al⁴² reported that hypoalbuminemia was an independent risk factor for mortality and morbidity in colorectal surgery. Gibbs et al⁴³ further demonstrated that serum albumin level was a predictor of mortality and morbidity in operations including general, orthopedic, and thoracic surgery. Bromage et al⁴⁴ concluded that the accuracy of the Colorectal Physiologic and Operative Severity Score for the Enumeration of Mortality and Morbidity (CR-POSSUM) scoring system would be improved after adding albumin levels as an important risk factor. Hypoalbuminemia also served as a factor indicating poor prognosis in long-term survival.^{24,29} Underweight (BMI < 18.5 kg/m²) and body weight loss >10% are also screening tools for malnutrition.

TABLE 3. Multiple Regression Analysis for Overall Complication

Variables	β (Coefficient)	95% CI	P Value
Chronic heart failure	0.180	0.113–0.246	<0.001
Ascites	0.144	0.076–0.211	<0.001
Disseminated cancer	0.086	0.060–0.113	<0.001
Emergency	0.086	0.047–0.124	<0.001
COPD	0.083	0.050–0.116	<0.001
Hypoalbuminemia	0.080	0.062–0.098	<0.001
Gender (male)	0.067	0.051–0.082	<0.001
Smoking	0.039	0.017–0.060	<0.001
Dialysis	0.164	0.060–0.262	0.001
Chronic steroid use	0.077	0.029–0.126	0.002
Hypertension	0.018	0.001–0.035	0.035
Previous cardiac events	0.023	–0.001 to 0.048	0.065
Ventilator dependence	0.117	–0.020 to 0.374	0.078
Acute renal failure	0.055	–0.100 to 0.210	0.483
FS			
Independent	0.000		
Partially dependent	0.113	0.079–0.148	<0.001
Totally dependent	0.200	0.117–0.283	<0.001
SS			
No	0.000		
SIRS	0.187	0.142–0.233	<0.001
Sepsis	0.232	0.156–0.307	<0.001
Septic shock	0.617	0.436–0.799	<0.001
Wound			
II	0.000		
III	0.089	0.058–0.120	<0.001
IV	0.073	0.026–0.119	0.002
Dyspnea			
No	0.000		
Exercise	0.034	0.009–0.058	0.008
Rest	0.096	0.025–0.167	0.008
Age			
<65	0.000		
65–74	–0.007	–0.027 to 0.012	0.473
75–84	0.024	0.002–0.045	0.032
>84	0.057	0.028–0.086	<0.001
ASA			
I	0.000		
II	0.016	–0.041 to 0.072	0.587
III	0.081	0.023–0.138	0.006
IV	0.220	0.155–0.285	<0.001
V	0.090	–0.170 to 0.350	0.496
DM			
No	0.000		
Oral	–0.002	–0.026 to 0.021	0.833
Insulin	–0.012	–0.046 to 0.021	0.476
BMI			
18.5–24.9	0.000		
<18.5	0.003	–0.041 to 0.047	0.833
25.0–29.9	–0.004	–0.023 to 0.015	0.658
30.0–34.9	0.007	–0.015 to 0.030	0.536
35.0–39.9	0.018	–0.013 to 0.049	0.260
≥40.0	0.029	–0.007 to 0.066	0.112

ASA = American Society of Anesthesiologists, BMI = body mass index, COPD = chronic obstructive pulmonary disease, DM = diabetes mellitus, FS = functional status, SIRS = systemic inflammatory response syndrome, SS = systemic sepsis, Wound II = clean/contamination, Wound III = contamination, Wound IV = dirty.

TABLE 4. Observed and Predicted Postoperative Outcomes and C-Statistics Between Models Without and With Hypoalbuminemia in Validation Data

Outcome	Observed, n	Without Hypoalbuminemia			With Hypoalbuminemia		
		Predicted, n	O:P	C-Statistic	Predicted, n	O:P	C-Statistic
Mortality	154	146	1.05	0.827	147	1.04	0.845
Transfusion	30	511	0.05	0.664	509	0.05	0.702
Progressive renal insufficiency	68	53	1.28	0.652	53	1.28	0.684
Cardiopulmonary resuscitation	40	38	1.05	0.678	39	1.02	0.704
Deep vein thrombosis	74	89	0.83	0.607	89	0.83	0.617
Stroke	30	26	1.15	0.727	26	1.15	0.736
Septic shock	143	107	1.33	0.700	107	1.33	0.707
Ventilator >48 h	172	113	1.52	0.742	147	1.17	0.746
Acute renal failure	37	42	0.88	0.628	42	0.88	0.632
Pneumonia	177	155	1.14	0.719	171	1.03	0.719
Superficial surgical site infection	465	404	1.15	0.595	404	1.15	0.594
Deep surgical site infection	82	91	0.90	0.602	91	0.90	0.599
Sepsis	235	235	1.00	0.627	234	1.00	0.621
Reintubation	157	157	1.00	0.727	157	1.00	0.724
Return to operating room	314	309	1.01	0.601	310	1.01	0.592

O:P = the ratio of observed to predicted numbers.

Body weight loss >10% is used as an independent item in the Association of Française de Chirurgie score to predict postoperative mortality after colorectal resection.^{5,45} However, hypoalbuminemia appeared in more models predicting postoperative outcomes than BMI < 18.5 kg/m² in this study (15 vs 3) or body weight loss >10% in Gibbs's study (8 vs 2).⁴³ The adverse effects of malnutrition in surgical patients were accurately represented by hypoalbuminemia in the evaluation of multivariate regression models.

The diagnosis and reason for conducting a surgical procedure is a certainly an important contributor to postoperative outcome^{6,46,47} and for the clinical face validity of the Surgical Risk Calculator.¹ However, the ACS-NSQIP Surgical Risk Calculator does not include underlying diagnosis as an independent variable for evaluating the risks of postoperative complications. Our study focused on patients with colorectal cancer, which is the major indicator for colorectal surgery, to exclude the effects of indication and to highlight the influence of hypoalbuminemia. Further studies are needed to identify the surgical risk of hypoalbuminemia in patients with other underlying disease, but it is expected that it will serve as an independent risk factor to varying degrees.

Compared with other variables in the Surgical Risk Calculator, previous cardiac events including myocardial infarction, percutaneous coronary intervention, angina, and any major cardiac surgical procedure had more missing data and were not collected after 2013 in the ACS-NSQIP database. The Physiologic and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM) scoring system and its related scoring systems^{3,4,44} created a cardiac parameter with the cardiac failure classification, which is similar to the American Society of Anesthesiologists (ASA) classification and to the chronic heart failure variables in the ACS-NSQIP Surgical Risk Calculator. Cohen et al⁹ did not include coronary artery disease in their risk calculator because it did not contribute more significance to the model's ability to predict postoperative mortality and morbidity. In this study, previous cardiac events

only significantly predicted 4 postoperative outcomes, which were 30-day mortality, cardiopulmonary resuscitation, myocardial infarction, and blood transfusion. Modifying the risk calculator will help avoid the loss of the valuable data of the other important risk factors in multivariate evaluation due to no record of previous cardiac event after 2013.

According to its definition, Brier score is related to the predicted probability, which calculated by multivariate logistic regression model and used to assess the performance of the model. Based on the good prediction of ACS-NSQIP Surgical Risk Calculator, Brier score was closer to 0 after adding hypoalbuminemia as the 22nd risk factor. Hypoalbuminemia for malnutrition assessment increased predictive capacity, although it is not substantial. Further study is required to evaluate the predictive accurate of subgroups stratified by serum albumin level.

We identified the following limitations in our study. The ACS-NSQIP database only includes those patients who receive surgical intervention. Overall rates of malnutrition in some cancers where surgical treatment is not indicated cannot be addressed exactly. The database only records events that happen within the 30-day postoperative window, and this may underestimate the true rate of many postoperative outcomes, which may occur after 30 days. The c-statistics for some postoperative outcomes is below 7, which some have agreed is needed for acceptable discrimination. Similar limitations were noted in previous studies that compared models.^{1,6,39} Hypoalbuminemia still improves the discrimination of the models by increasing the c-statistics in the training data and validation data. Finally, in multivariate analyses, the records of other confounding variables would be excluded because of data miscoding and omission in some risk factors.

Personalized treatment and patient-centered informed consent are both based on qualified and accurate tools for estimating surgical risks. The ACS-NSQIP Surgical Risk Calculator offers surgeons the ability to evaluate patient-specific postoperative risks quickly, easily, and accurately. The

discrimination and calibration of the tool improve after adding hypoalbuminemia into the calculator as an independent risk factor in colorectal surgery for colorectal cancer patients. The modified Surgical Risk Calculator can give surgeons and patients a more precise evaluation of the risks and benefits of associated with surgical procedures.

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