Operative Mortality Prediction for Primary Rectal Cancer: Age Matters

Zhan Li, MD, JoAnn Coleman, DNP, ACNP-BC, Christopher R D'Adamo, PhD, Joshua Wolf, MD, FACS, Mark Katlic, MD, FACS, Nita Ahuja, MD, MBA, FACS, David Blumberg, MD, FACS, Vanita Ahuja, MD, MPH, MBA, FACS

BACKGROUND: The risk of colorectal cancer increases with age, and the number of older adults requiring operations has increased. The purpose of this study was to determine whether a current risk calculator can accurately predict operative mortality for rectal cancer and whether the predictive accuracy varied with age.

METHODS: The American College of Surgeons NSQIP database using ICD-9/10 codes for rectal cancer and CPT codes for proctectomy was accessed (2012 to 2015). The prognostic value of the risk calculator was evaluated using the predicted mortality variable code. Age categories were 18 to 64 years, 65 to 79 years, and 80 to 89 years. Analysis of variance was performed to assess differences between age categories in predicted and actual mortality and Pearson correlation coefficients were computed. Logistic regression models were constructed to evaluate associations adjusted for key covariates.

RESULTS: There were 9,289 patients included, with age distribution as follows: 18 to 64 years (n = 5,674), 65 to 79 years (n = 2,899), and 80 to 89 years (n = 716). Both predicted and actual mortality increased with age, adjusting for functional status, comorbidity, and other covariates ($p < 0.0001$). The overall correlation between predicted and actual mortality was low ($r = 0.20$). The correlation was weakest from 18 to 64 years ($r = 0.07$), strongest from 65 to 79 years ($r = 0.25$), and in between from 80 to 89 years ($r = 0.13$). Predicted mortality was overestimated in the 18 to 64 years and underestimated in both the 65 to 79 years and 80 to 89 years age groups. Predicted mortality by age category interaction terms was also significantly associated with actual mortality in covariate-adjusted logistic regression models, providing additional evidence that the accuracy of predicted mortality varies by age.

CONCLUSIONS: The American College of Surgeons NSQIP mortality risk estimates appear to be poorly associated with actual mortality and the accuracy might differ between younger and older patients with primary rectal cancer. Goals of care discussion with the older patient about outcomes are indicated, as there is an almost twice predicted mortality. (J Am Coll Surg 2019;228:627–634. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

In the US, colorectal cancer (CRC) is one of the most common cancers and cause of death and CRC incidence increases with age.[1] Operation is one of the main treatments for CRC.[2] In the recent healthcare structure, multiple reimbursement models for surgical specialties have emerged. Although different in implementation, most of these reimbursement models share the need for evaluating quality of care through measured outcomes.[3]

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From the Department of Surgery, Sinai Hospital of Baltimore (Li, Coleman, Wolf, Katlic, Blumberg, V Ahuja), Departments of Family and Community Medicine and Epidemiology and Public Health, University of Maryland School of Medicine (D'Adamo), Baltimore, MD, and Department of Surgery, Yale School of Medicine, New Haven, CT (N Ahuja).

Correspondence address: Vanita Ahuja, MD, MPH, MBA, FACS, Department of Surgery, Sinai Hospital, 2401 W Belvedere Ave, Baltimore, MD 21215. email: Vahuja@lifebridgehealth.org

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The Centers for Medicare and Medicaid Services stated its goal of having 50% of Medicare payments tied to quality or value through the Medicare Incentive-Based Payment or alternative payment models.[4] This goal supports a patient-centered quality system where patients are informed about their options and can make treatment decisions based on available information.

Preoperative risk assessment calculators can be valuable tools for determining patients at high risk for morbidity and mortality. Presenting the probability of perioperative adverse events to the patient can help facilitate shared decision-making and selection of lower-risk options, or decision to proceed with an operation but with a better appreciation of the potential risks.[5]

The American College of Surgeons (ACS) NSQIP was developed to provide risk assessment to facilitate physician-patient discussion and includes a database that provides analyzed data collected from preoperative patient risk factors and postoperative morbidity and mortality. This information is then used to evaluate surgical quality.[6] The ACS NSQIP provides probability of morbidity and mortality based on patient characteristics and CPT code retrospectively in its data set. This end point can be obtained concurrently by physicians using the ACS NSQIP Risk Calculator (RC).[7] The RC provides patient-level risk evaluations for specific adverse outcomes based on patient predictors and the planned procedure.[8] In addition, the surgical RC has been recommended by the ACS as an important tool for surgeons and patients during preoperative interactions and discussion of treatment.[9] Additional evaluation of the RC for its accuracy in predicting morbidity and mortality as a component of a value-based payment model is needed.

A previous study of the RC demonstrated good calibration and discrimination characteristics. In addition, the RC performed comparably with colorectal procedural-specific risk calculators, although this was not expanded to other subspecialties.[10] Subsequent studies, however, re-examining procedural-specific validity, have not shown similar concordance. Arce and colleagues[11] studied the predictive accuracy of the RC compared with observed outcomes in head and neck cancer patients undergoing microvascular reconstruction with free flaps and suggested the RC is not a useful metric for risk stratification in the studied population as it does not predict hospital length of stay accurately. The RC also has limitations when predicting outcomes for procedures that have inherently higher risks for specific complications. Although studies have shown the RC to have good internal validity, external validation studies performed at the institutional level on surgical subspecialties have concluded the opposite, that the RC lacked accuracy when applied to selective populations.[8-10]

There is controversy that the NSQIP database might not accurately reflect the higher postoperative morbidity in certain subspecialties. As a selective population, patients undergoing rectal cancer procedures present challenges due to the inherent nature of the disease and related procedures where wound infection rates can range from 9.4% to 18%.[12] Value-based payment models rely partly on administrative data gathered from national databases. Accuracy of predicted patient risks becomes increasingly important when transitioning to new payment models. If higher-risk patient characteristics are not risk-adjusted and reported accurately, there can be substantial financial consequences to payers in the future.

There is a paucity of studies on the ability of the RC to accurately predict mortality in patients undergoing primary rectal cancer operations. The goal of this study was to compare the accuracy of the RC mortality variable in predicting overall 30-day mortality within various age groups who had operations for primary rectal cancer.

METHODS

Data source

Data were obtained from the 2012 to 2015 ACS NSQIP Participant Use Data File from patients undergoing operations across a wide range of specialties from approximately 700 hospitals in the US and Canada. These data are compiled directly from patients' medical records by trained staff at each institution and include a wide variety of preoperative patient characteristics, operative variables, and 30-day outcomes. Previous studies have used ACS NSQIP data for analysis of proctectomy outcomes.[12]

Inclusion criteria

Patients were included in the study based on ICD-9/10 codes for rectal cancer (154.0, 154.1, C20) and CPT codes for proctectomy (44145, 44146, 44147, 44207, 44208, 45110, 45111, 45112, 45114, 45119, 45395, 45397, 44207, 44208, 44395, 44397). Because ACS NSQIP does not differentiate age older than 90 years, these patients were excluded from the study. There were no other restrictions for inclusion.

Age classification

In accordance with studies published previously, patient age was categorized as 18 to 64 years, 65 to 79 years, and 80 to 89 years.

Study outcomes

The primary outcomes of interest in this study were actual 30-day mortality and ACS NSQIP-predicted 30-day mortality; secondary outcomes were actual morbidity and ACS NSQIP-predicted morbidity. As categorized in previous studies, actual morbidity was defined as occurrence of at least 1 of the following complications: organ space infection, pneumonia, unplanned intubation, pulmonary embolism, ventilator requirement longer than 48 hours, progressive renal insufficiency, acute renal failure, CVA, cardiac arrest, MI, deep venous thrombosis, sepsis, septic shock, and return to operating room.[7]

Statistical methods

Descriptive statistics (mean and SD and frequency and range) were calculated to characterize the study population based on demographics, preoperative comorbidities, preoperative laboratory results, and factors related to operation (emergency vs elective, wound class, operating time). Normality of continuous data was assessed via Kolmogorov-Smirnov test. Unadjusted differences in patient characteristics between age categories were evaluated using chi-square test for categorical variables and analysis of variance for continuous variables. Pearson correlation coefficients were computed to determine the accuracy of predicted and actual mortality overall and in each age category. Analysis of variance was used to evaluate the statistical significance of the unadjusted relationship between actual and predicted mortality overall and between the 3 age categories. Logistic regression models were also constructed to estimate this relationship while adjusting for key covariates. Regression models were adjusted for sex, BMI, race, smoking, and functional status. Age × predicted mortality interaction terms were included in regression models to determine the extent of effect modification of the relationship between predicted and actual mortality by age category. Statistical significance was defined as $p < 0.05$. All analyses were performed in SAS, version 9.4 (SAS Institute).

RESULTS

There were 9,289 patients included in the analysis. The age distribution of the sample was as follows: 18 to 64 years, n =5,674; 65 to 79 years, n = 2,899; and 80 to 89 years, n = 716. As described in Table 1, older age was associated with female sex, lower BMI, more diabetes, less smoking, less disseminated cancer, more transfusions, and longer length of stay ($p < 0.05$). There was no difference in emergency procedure frequency between age categories ($p = 0.10$). Although the frequency of some CPT codes varied meaningfully by age (44207, 45110, 45395, 45397; $p < 0.05$), most CPT codes included in the analysis did not differ widely across age categories.

Table 2 provides the predicted and actual mortalities across age categories. As expected, both predicted and actual mortality increased with age ($p < 0.0001$) (Fig. 1A). The overall correlation between predicted and actual mortality across the entire study sample was weak ($r = 0.20$). The correlation was weakest from age 18 to 64 years ($r = 0.07$), strongest from age 65 to 79 years ($r = 0.25$), and in between from age 80 to 89 years ($r = 0.13$). Predicted mortality was overestimated in the 18 to 64 years age group and underestimated in both the 65 to 79 years and 80 to 89 years age groups.

These relationships between predicted and actual mortality were robust to adjustment for covariates (BMI, race, smoking, functional status, and CPT codes that varied substantially by age in bivariate analyses [44207, 45110, 45395, and 45397]) in logistic regression modeling of actual mortality. With the 18 to 64 years age category as the referent group in the logistic regression model, the maximum likelihood estimates in the 65 to 79 years age group (-0.0053; $p = 0.016$) reflected decreased odds of mortality and increased mortality in the 80 to 89 years age group (0.0128; $p = 0.0037$). The age × predicted mortality interaction terms were statistically significant in the regression models, signifying the varying accuracy of the predicted mortality with actual mortality by age ($p < 0.0005$).

Table 3 provides the predicted and actual morbidities across age categories. Both predicted and actual morbidities increased with age ($p < 0.0001$) (Fig. 1B). The correlation between predicted and actual morbidity across the entire study sample was weak ($r = 0.14$). The correlation did not vary substantially by age, with age 18 to 64 years ($r = 0.14$) and both 65 to 79 years and 80 to 89 years ($r = 0.13$). Predicted morbidity was considerably overestimated across all age groups.

The relationships between predicted and actual morbidity were also robust to adjustment for the same set of covariates in logistic regression modeling of actual morbidity. With the 18 to 64 years age category as the referent group in the logistic regression model, the maximum likelihood estimates in both the 65 to 79 years age group (-0.0062; $p = 0.49$) and the 80 to 89 years age group (0.0138; $p = 0.44$) reflected no statistically significant differences by age in the consistent overestimation of morbidity. The age × predicted morbidity interaction terms were not statistically significant in the models ($p > 0.1$), thereby reflecting the consistency in overestimation of the predicted morbidity across age groups.

DISCUSSION

Currently, CRC is one of the most common cancers and cause of death in the US.[1] Increasing age has been shown to be a risk factor for postoperative complications after

Table 1. Characteristics of Study Population by Age Category

Variable	Age category 18–64 y (n = 5,674)	65–79 y (n = 2,899)	80–89 y (n = 716)	p Value*
Female sex, %	38.8	37.5	43.6	<0.0001
BMI, kg/m^2, mean (SD)	28.4 (6.6)	27.9 (6.0)	25.7 (4.6)	<0.0001
Current smoker, %	21.0	14.0	5.9	<0.0001
Functionally dependent, %	0.8	1.9	6.3	<0.0001
Disseminated cancer, %	10.7	8.9	6.3	<0.0001
Transfusion, %	0.4	0.8	1.4	<0.0001
Diabetes mellitus, %	11.8	20.0	19.2	<0.0001
Elective operation, %	95.9	93.5	89.7	<0.0001
Emergency operation, %	0.32	0.45	0.84	0.10
Wound disruption, %	1.4	2.2	2.4	<0.0001
Length of stay, d, mean	7.3	8.8	10.3	<0.0001

*Difference between age categories estimated by chi-square test for categorical variables and analysis of variance for continuous variables.

colorectal operations for cancer.[13-15] The RC has been recommended as a useful tool for preoperative discussion with the patient, including goals of care.[16] In addition, the tool is well known and an easily accessible outcomes prediction tool. There is the possibility it will eventually be implemented as part of the Medicare Incentive-Based Payment program. As such, it is important that this tool be relatively accurate in predicting risks, especially mortality.

The goal of this study was to evaluate the predictive accuracy of the RC for mortality rate and serious postoperative complications in patients who had operations for primary rectal cancer by comparing predicted and actual patient outcomes. The study found that although both predicted and actual mortality increased with age, the overall correlation between predicted and actual mortality was low. Correlation remained low after stratification into different age groups. These results remained true after adjusting for covariates via logistic regression analysis. Meanwhile, overall serious complications were overestimated in each age group.

In this study, the RC was found to underestimate overall and age-stratified mortality and overestimate serious comorbidities in all age groups after operation for primary rectal cancer. In addition, there is variation in the accuracy of the RC between different age groups, as demonstrated by the underestimation of mortality in older age groups and overestimation of mortality in the younger age group. Earlier studies reported that although the RC was a capable tool for overall morbidity and mortality risk assessment, it is less accurate when used for individual quality outcomes or when applied to a more focused subset of a patient population, as seen in various subspecialties.[17-27] A single institution study by Keller and colleagues[8] found that in elective colorectal operations the RC correlated well for predicting complications in general but predictive accuracy for identifying actual occurrences was poor, except mortality, which had good accuracy. Another study from an independent academic medical center noted the RC underestimated specific and overall complication rates in colorectal operations.[28] A similar finding reported by Bergquist and colleagues[29] was that the RC failed to predict surgical site infection in an independent prospective database of colorectal operations performed at the Mayo Clinic. Of note, there are few studies on the predictive accuracy of RC in older populations undergoing primary rectal cancer operations.

Overestimation of serious comorbidities in all age groups might be due to improving care since the start of the ACS NSQIP. This was discussed in a recent article by Cohen and colleagues,[30] who found reductions in adverse events after operations in hospitals participating in ACS NSQIP, with the magnitude of quality improvement increasing with time of participation. Although the ACS NSQIP database is updated continuously, the RC itself might still be incorporating older data with much higher complication rates, skewing overestimation of comorbidities. A similar

Table 2. Correlation Between Predicted and Actual Mortality after Rectal Cancer Resection

Age, y	n	Predicted mortality, %	Actual mortality, %	*r**	p Value†
18–64	5,674	0.35	0.25	0.07	<0.0001
65–79	2,899	0.95	1.03	0.25	<0.0001
80–89	716	1.90	3.49	0.14	<0.0001

*Pearson correlation coefficient.
†Difference between age categories estimated by analysis of variance.

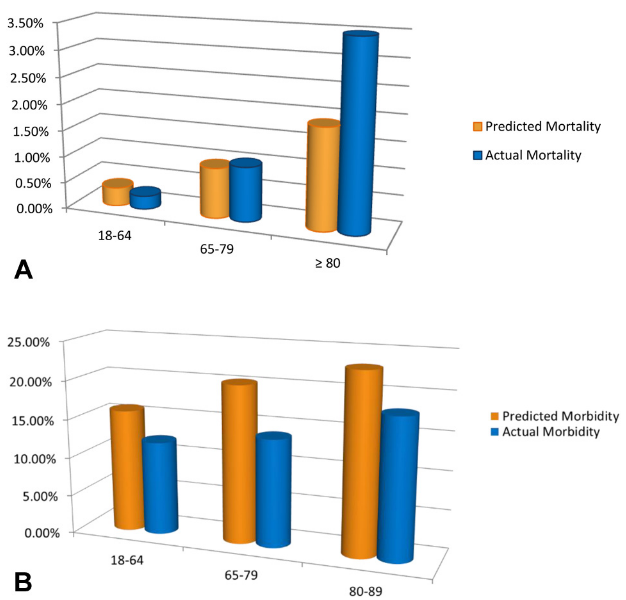

Figure 1. (A) Predicted mortality versus actual mortality by age group and (B) predicted morbidities versus actual morbidities by age group.

study could be done if there is an RC update to examine whether current data would change predictive accuracy.

The oldest patient population subgroup faces unique challenges, such as cumulative loss of physiologic reserve in nearly all organ systems, which might require additional adjustment of the RC risk modifiers.[31] McMillan and colleagues[32] previously compared the RC and a procedural-specific model for pancreaticoduodenectomy that incorporated intraoperative factors and demonstrated better morbidity and mortality predictive accuracy with the latter. A similar model might be applicable to the older patient population as well. Colorectal operations are also associated with higher inherent risks of complications, often independent of surgical technique and quality of patient care.[12,33] The RC algorithm needs refinement for calculating predicted risk in older patients undergoing primary rectal cancer operations.

This study has special implications for octogenarians, as overall mortality is especially underestimated in this age group. The 80 years and older age group is the fastest growing cohort in the US and is projected to rise from 5.8 million to more than 19 million by 2050.[34] Incorporating a frailty measurement in the RC can better predict morbidity and mortality in this age group.[35,36]

There is the ongoing ACS NSQIP Geriatric Surgery Pilot program that expands the surgical database to include information that reflects the unique needs of older adults. This expanded database was created to look at geriatric-specific risk factors to improve the ability of surgeons to predict outcomes and to provide the best possible care focusing on quality outcomes. This new pilot program might be better suited for risk prediction in the older surgical population because it incorporates variables that identify patients with characteristics of frailty.[37]

Limitations of this study include retrospective study design with its inherent shortcomings. Other limitations include accuracy of the ACS NSQIP and the RC with potential for errors in data collection and coding, which has been described previously.[10,13] In addition, there was no adjustment for surgeon experience as this was not reported. The number of actual mortalities is low relative to sample size, which might limit reliable estimates of predictive accuracy. Surgical RC parameters were not re-estimated for validation data sets, which might increase effects of case-mix homogeneity from model inadequacy.

CONCLUSIONS

The ACS NSQIP RC predictive variables in older patients appear to underestimate overall mortality and overestimate overall serious morbidity risk. Despite this, ACS NSQIP RC remains a useful tool for the surgeon in preoperative patient education; however, accuracy is still lacking as a predictive tool. Surgeons should be mindful of limitations of risk calculators when discussing procedures with patients. Additional refinement of the ACS NSQIP RC is needed before being used as part of a quality-based healthcare metric.

Table 3. Correlation Between Predicted and Actual Morbidity after Rectal Cancer Resection

Age, y	n	Predicted morbidity, %	Actual morbidity,* %	r†	p Value‡
18−64	5,674	15.9	12.1	0.14	<0.0001
65−79	2,899	20.3	13.9	0.13	<0.0001
80−89	716	23.1	18.0	0.13	<0.0001

*Includes occurrence of at least 1 of the following complications: organ space infection, pneumonia, unplanned intubation, pulmonary embolism, ventilator requirement longer than 48 hours, progressive renal insufficiency, acute renal failure, CVA, cardiac arrest, MI, deep venous thrombosis, sepsis, septic shock, and return to operating room.
†Pearson correlation coefficient.
‡Difference between age categories estimated by analysis of variance.

Author Contributions

Study conception and design: Coleman, V Ahuja
Acquisition of data: Wolf
Analysis and interpretation of data: Li, D'Adamo, Katlic, N Ahuja, V Ahuja
Drafting of manuscript: Li, Katlic, N Ahuja
Critical revision: Li, Coleman, D'Adamo, Wolf, Katlic, N Ahuja, Blumberg, V Ahuja

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Discussion

DR JULIE A FREISCHLAG (Winston-Salem, NC): The findings regarding the younger and older patient outcomes being significantly different than predicted make one pause. Were the procedures, as listed by CPT code, the same in each age group? Were more extensive procedures done on the older patients, which could predict worse outcomes? What difference does the significant increase in urgent/emergent procedures done in the older patients make in the worse outcomes observed? Finally, how are you now approaching the older patient once you calculate their risk outcomes? What discussions are you having? Do you alter your procedure or course?

DR MICHAEL E ZENILMAN (Brooklyn, NY): This manuscript reminds me of a paper by Dr Boyd from West Virginia (Ann Surg 1980; 192:743−746), who showed that in patients older than 50−that was old then−mortality after colectomy rose with age in an arithmetical manner, but the rise was exponential when comorbidities of cardiac, respiratory, and renal systems were included. The exponential rise in mortality was a result of comorbidities.

The authors today showed that the NSQIP calculator loses its efficacy with increasing age. The increase in mortality with age in their graph reminds me of the study from Dr Boyd. What really is missing in the latter cohort and specifically, in the patients over the age of 80 years? What I think is missing is the variable that is not measured by NSQIP. It is not measured very well yet. It is the syndrome of frailty, which we heard about earlier from the Texas A&M group. Frailty is an influential weapon as an indicator of risk. It's actually more powerful than the American Society of Anesthesiologists (ASA) score.

In 2015, Dr Clifford Ko, one of the coauthors, Dr Mark Katlic, myself, and members of the American College of Surgeons Task Force on Geriatric Surgery reported results of a pilot program in which 16 geriatric-specific variables were included in 27 NSQIP hospitals. New variables, like arrival to the hospital from a nursing home, dementia, implementation of palliative care, and novel post-operative complications like delirium were analyzed. I doubt these metrics were included in the NSQIP calculator because the NSQIP calculator is only about 4 or 5 years old, a timeline that overlaps with this study. But embedded in NSQIP are other proxy measures for frailty−malnutrition, low albumin, and activity of daily living−which I think you could take advantage of.

Can you use proxies for frailty already in the NSQIP cohort that you are measuring to predict the outcomes? How about polypharmacy, comorbidities, ASA score, serum albumin, and history of weight loss? Once done, you might be able to develop a specific multivariate model for colectomy in the over-the-age-of-80 population, or you might just want to wait for the geriatric indicators that I mentioned previously to get more steam and put into the calculator.

Lastly, for a panel session I am hosting at the upcoming 2019 American College of Surgeons meeting, named, "Optimizing Care for the Frail Patient," we will be discussing assessment, prehabilitation, and the results of the Coalition of Quality for Geriatric Surgery, which has identified best practices in surgical services across the nation for care of the vulnerable, frail patients.

DR ERIC G WEISS (Weston, FL): One thing that is not taken into account with the NSQIP calculator is neoadjuvant therapy. Was neoadjuvant therapy either added or omitted in the older patients? Could that have an effect on outcomes? Second, what operations were done in the elderly patients? I think that somebody brought that up. Were these sphincter-preserving operations? And were the deaths related to leaks as opposed to other comorbidities?

DR EDWARD COPELAND (Gainesville, FL): I want to tell you a story about my favorite patient, a gentleman aged 101 years. I met him in the emergency room of the Hospital of the University of Pennsylvania when I was chief resident. He suffered from an obstructing carcinoma of the right colon. Someone had recommended a cecostomy. He looked healthy enough to me. We did a right colostomy and primary anastomosis. He did fine. I decided to send him to physical therapy. He rode the exercise bike there and was walked in the hall by the nurses. At discharge as he was walking out, he said, "Doc, this operation is the best thing that has happened to me in a long time. I have not been able to walk in 10 years, and now I am walking out of the hospital."

Age obviously matters in survival for any major operation. But do not rely totally on risk adjusted nomograms and protocols. Rely a little on your past experience and common sense. Hopefully,