

Mediastinum & Esophagus: Research

2024 Update of The Society of Thoracic Surgeons Short-term Esophagectomy Risk Model: More Inclusive and Improved Calibration



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ABSTRACT

BACKGROUND The Society of Thoracic Surgeons General Thoracic Surgery Database (STS-GTSD) previously reported short-term risk models for esophagectomy for esophageal cancer. We sought to update existing models using more inclusive contemporary cohorts, with consideration of additional risk factors based on clinical evidence.

METHODS The study population consisted of adult patients in the STS-GTSD who underwent esophagectomy for esophageal cancer between January 2015 and December 2022. Separate esophagectomy risk models were derived for 3 primary end points: operative mortality, major morbidity, and composite morbidity or mortality. Logistic regression with backward selection was used, with predictors retained in models if $P < .10$. All derived models were validated using 9-fold cross-validation. Model discrimination and calibration were assessed for the overall cohort and specified subgroups.

RESULTS A total of 18,503 patients from 254 centers underwent esophagectomy for esophageal cancer. Operative mortality, morbidity, and composite morbidity or mortality rates were 3.4%, 30.5%, and 30.9%, respectively. Novel predictors of short-term outcomes in the updated models included body surface area and insurance payor type. Overall discrimination was similar or superior to previous STS-GTSD models for operative mortality (C statistic = 0.72) and for composite morbidity or mortality (C statistic = 0.62). Model discrimination was comparable across procedure- and demographic-specific subcohorts. Model calibration was excellent in all patient subgroups.

CONCLUSIONS The newly derived esophagectomy risk models showed similar or superior performance compared with previous models, with broader applicability and clinical face validity. These models provide robust preoperative risk estimation and can be used for shared decision making, assessment of provider performance, and quality improvement.

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Esophageal cancer is currently the eighth most common malignancy and the sixth leading cause of cancer mortality, despite only accounting for 1.1% of all new cancer cases worldwide.^{1,2} Esophagectomy, typically after

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neoadjuvant therapy, is a key component in the multidisciplinary treatment of this malignancy.³

Statistical risk models are important tools to estimate the patient-specific risks of esophagectomy. These estimates are used in shared decision making between surgeons and patients and to assess the results of surgeons and hospitals compared with what would have been expected for their specific mix of patients. The Society of Thoracic Surgeons General Thoracic Surgery Database (STS-GTSD) has developed and reported 2 previous esophagectomy risk models, first in 2009, followed by a revised version in 2016, that reflected surgical practices at the time.^{4,5}

Considering the rapid advancement of minimally invasive techniques and evolving perioperative treatment regimens, the purpose of this study was to update the STS risk models of esophagectomy for cancer by using the most current data from a more inclusive cohort. In doing this, we hope to provide a basis for future clinical decision tools, preoperative risk estimation, enhanced GTSD harvest analytics, and quality improvement. This effort included a focus on the use of preoperative variables, the inclusion of high-risk patients, imputation of missing required data, reexamination of race, ethnicity, and payor variables, revised configuration of GTSD fields, and the consideration of new potential risk factors based on recent scientific evidence.

PATIENTS AND METHODS

DATA SOURCE AND PATIENT POPULATION. We queried the STS-GTSD to identify adult patients aged ≥ 18 years undergoing esophagectomy for esophageal cancer between January 2015 and December 2022. The cohort was limited to patients undergoing 1 of 7 types of esophagectomy, including 4 open (Ivor Lewis, transhiatal, McKeown, and thoracoabdominal) and 3 minimally invasive (Ivor Lewis, transhiatal, McKeown) esophagectomy procedures (Supplemental Table 1). Only patients with unknown 30-day mortality status and high acuity (American Society of Anesthesiologists Physical Status Classification [ASA] VI) status were excluded from the study population (Supplemental Table 2). Notably, this differs from previous STS esophagectomy models, which excluded nonelective patients.

Analyses were conducted at the STS Research and Analytic Center. This research was determined to be exempt research with a waiver of

informed consent from Advarra Institutional Review Board (Mod01760092, Version 1.1; approval date, July 17, 2023).

END POINTS. The study end points were defined the same as previous STS risk model publications and included operative mortality, defined as a death during the index hospitalization for surgery or within 30 days of the procedure, major morbidity, and composite mortality or major morbidity (M&M). Major morbidity was defined as the presence of ≥ 1 of the following complications: unexpected return to the operating room, anastomotic leak, reintubation, initial ventilatory support >48 hours, pneumonia, renal failure, and recurrent nerve paresis.

SELECTION OF CANDIDATE PREDICTOR VARIABLES. Candidate predictor variables for the derived models are summarized in Supplemental Table 3. These were selected based on prior STS-GTSD risk models, clinical expertise, and consistent availability of data over the study period (GTSD data versions 2.3, 2.5, and 5.21.1). To adjust for patient case mix, only preoperative patient variables were considered for inclusion, except for esophageal cancer histology, due to data available. Given its potential importance for risk estimation, we included postoperative pathologic histology as a potential risk factor. Newly considered predictor variables included body surface area (BSA), insurance status, surgical priority status (elective vs nonelective), and preoperative creatinine. Induction therapy and clinical cancer staging were considered in separate interaction terms with the type of esophagectomy procedure. Lastly, surgery date was considered to assess temporal trends in end point occurrence rates.

PARAMETERIZATION AND IMPUTATION. Predictor variable parameterization was based on clinically relevant coding and prior STS approaches (Supplemental Table 4). To the extent possible, and for common factors (eg, age, body mass index [BMI], BSA, creatinine), these were harmonized with the approaches used in risk model derivations in the STS Adult Cardiac Surgery Database (ACSD).⁶ Missingness was rare for candidate predictors ($<2\%$) and imputed, as previously described.⁷ Briefly, missing information for categorical variables was imputed to the least risky category, except for histology and smoking. Patients with missing pathologic histology type were nonnegligible (3.5%) and were modeled as a separate subcategory based on distinctly worse observed outcome rates. Missing smoking status ($<0.5\%$)

was imputed to the overwhelming mode (former smoker). In the rare event of missing clinical cancer stage, values were imputed based on whether the patient received induction therapy as (1) stage III if the patient had induction therapy and (2) stage I if no induction therapy was administered.

STATISTICAL ANALYSIS. Predictor variables were included in models based on clinical face validity, statistical significance, and, if needed, to guarantee models were well calibrated in subgroups. Model variables included for clinical face validity, regardless of statistical significance, were age, sex, procedure type, clinical cancer stage, cancer histology, and type of induction therapy. Induction therapy was defined as preoperative chemotherapy and/or radiotherapy for the same disease within 6 months of surgery.

After preliminary models were derived, subgroup calibration was assessed using observed-to-expected (O/E) ratios in corresponding patient subgroups of both included and excluded model variables. STS regularly reexamines its risk model parametrization including race, ethnicity, and other social determinants of health (eg, payor). Including race and ethnicity risk variables in the current esophageal cancer risk models was tested rigorously and were found to be necessary to ensure the models are well calibrated across all race groups.^{8,9} A small number of patients in the study population self-identified as multiracial (0.74%), and these were allocated into mutually exclusive race subcohorts according to the hierarchy described in Shahian and colleagues.¹⁰ Allowing multirace patients to be allocated to multiple race groups was explored, but this approach did not improve model performance, even with 2 additional degrees of freedom. Multicollinearity was assessed using variance inflation factors. Trends through time were assessed using the Cochran-Armitage test.

Separate multivariable logistic regression models with backward selection were derived for each outcome (operative mortality, morbidity, and M&M) on 100% of the study population, with predictors retained if $P < .10$. The P value of .10 was used based on methods previously described.⁷ Next, model variables found to be statistically significant in any 1 of the 3 outcomes' models were combined in final derived models for all outcomes (Supplemental Table 3).

Model discrimination was quantified by examining the area under the receiver operator characteristic curve (C statistic) in the overall

population and in procedure subgroups. Model calibration was assessed graphically by plotting end point event rates across deciles of predicted risk, both overall and in procedure groups, and by calculating the overall and subgroup O/E ratio. As a result of sample size constraints, procedure subgroups were collapsed into open and minimally invasive for the calibration plots.

Model performance was confirmed using 9-fold cross-validation. Briefly, the overall cohort was split into 9 groups, and models were iteratively developed on eight-ninths of the data. Discrimination and calibration were calculated as mentioned in one-ninth of the data and repeated until all groups had been used as the validation cohort. Cross-validation methodology confirms that the derived models are not grossly overfit and that selection bias is minimal.

The threshold for statistical significance was .10 for risk model inclusion and .05 for all other analyses. All statistical tests were 2-tailed. Stata 17.1 software (StataCorp LLC) was used for data management and statistical analyses.

RESULTS

A total of 18,503 patients undergoing esophagectomy for esophageal cancer met the study criteria from 254 STS-GTSD participating hospitals over the 8-year study period. There were no discernable time trends in total operations; however, the proportion of minimally invasive procedures increased from 38.6% in 2015 to 57.5% in 2022. Observed overall rates of study end points were 3.4% for operative mortality, 30.5% for morbidity, and 30.9% for M&M. Operative mortality was stable across the 8-year period ($P = .64$), whereas morbidity ($P = .05$) and M&M decreased ($P < .001$). The observed outcome rates varied with the type of esophagectomy procedure and whether the procedure was performed in an open or minimally invasive fashion. (Table 1).

COHORT CHARACTERISTICS AND SURGICAL OUTCOMES.

Patient characteristics are summarized in Supplemental Table 5 for the overall patient population and stratified by operative mortality and M&M subcohorts for comparison. Postoperative adverse outcomes more commonly developed in current or former smokers and in patients less likely to have commercial or health maintenance organization insurance. Other notable baseline risk factors included the presence of hypertension, cerebral vascular disease, peripheral vascular disease,

TABLE 1 Observed Outcome Rates by Procedure Type and Outcomes

Procedure Type	Patients	End Point/Outcome Observed Outcome Rates		
		OM	Morbidity	M&M
All esophagectomy	18,503 (100)	624 (3.4)	5645 (30.5)	5722 (30.9)
Open surgery				
Ivor Lewis	5677 (30.7)	359 (3.8)	2988 (31.6)	3039 (32.2)
McKeown/three hole	1140 (6.2)	56 (4.9)	481 (42.2)	486 (42.6)
Transhiatal	2106 (11.4)	68 (3.2)	692 (32.9)	711 (33.8)
Thoracoabdominal	531 (2.9)	19 (3.6)	112 (21.1)	117 (22.0)
Minimally invasive surgery				
Ivor Lewis	6811 (36.8)	265 (2.9)	2657 (29.4)	2683 (29.7)
McKeown/three hole	1451 (7.8)	59 (4.1)	524 (36.1)	527 (36.3)
Transhiatal	787 (4.3)	21 (2.7)	282 (35.8)	283 (36.0)

Data are presented as n (%). M&M, composite mortality or major morbidity; OM, operative mortality.

cardiothoracic reoperation, and low performance status based on ASA and Zubrod scores. Mortality and M&M rates were higher among patients with squamous cell carcinoma compared with patients with adenocarcinoma, whereas only mortality rates were higher among patients with clinical stages II, III, and IV cancer compared with stage I cancer. Sex, BMI, preoperative creatinine levels, and use of steroid medication did not differ by end points in univariate analysis.

DISTRIBUTION OF ESOPHAGECTOMY PROCEDURE TYPES.

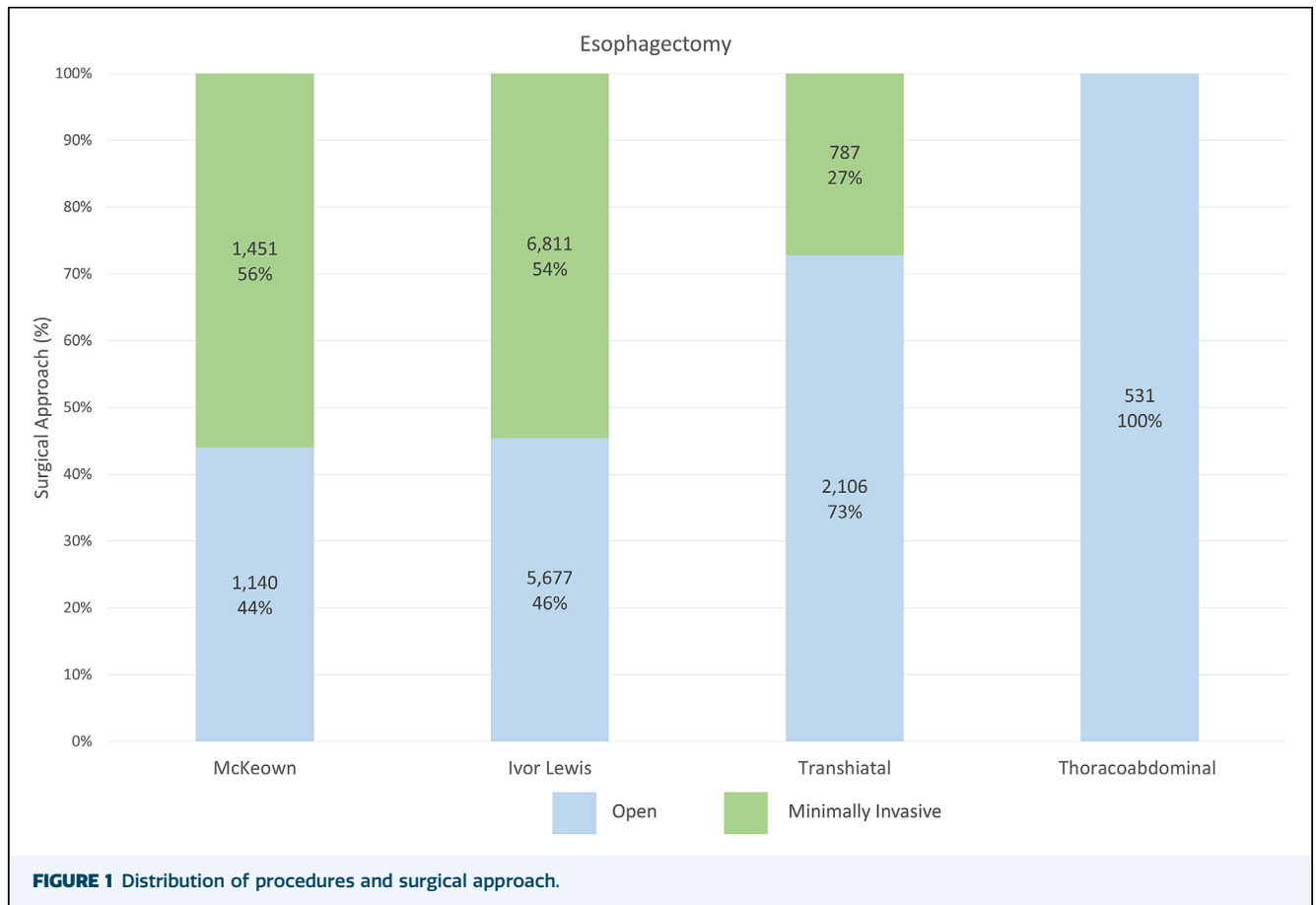
The distribution of procedure counts and corresponding relative fraction of open vs minimally invasive surgical approaches are shown in [Figure 1](#). Patients undergoing Ivor Lewis esophagectomy represented 67.5% of all cases, and of these, 54% were minimally invasive. The distribution of open vs minimally invasive surgical approach was similar for McKeown esophagectomy, whereas most transhiatal (73%) and all thoracoabdominal (100%) esophagectomies were performed in an open fashion. Patients undergoing a minimally invasive Ivor Lewis esophagectomy were less likely to experience adverse outcomes. In contrast, patients undergoing a minimally invasive or open McKeown esophagectomy had worse observed rates of operative mortality and M&M.

MULTIVARIABLE PREDICTORS. Multivariable analyses revealed several risk factors for operative mortality, morbidity, and M&M after esophagectomy for esophageal cancer. The directionality and effect size of the risk factors for operative mortality, major morbidity, and M&M are presented in [Table 2](#). Patients with adverse outcomes were

more likely to have preoperative comorbidities, including high acuity as measured by the ASA/Zubrod, congestive heart failure, cerebral vascular disease, and peripheral vascular disease. BMI and BSA had significantly nonlinear relationships with outcomes. Furthermore, Medicaid insurance increased the risk of operative mortality, and dual Medicare/Medicaid increased the risk of major morbidities. Compared with minimally invasive or open Ivor Lewis esophagectomy, open McKeown esophagectomy significantly increased the risk of all 3 end points. Race/ethnicity and insurance were not significant predictors of worse esophagectomy outcomes but were included in the final unified models to optimize calibration of all outcome models across all race groups.

RISK MODEL PERFORMANCE. C-statistics (model discrimination) and O/E ratio (calibration) are presented in [Table 3](#) for the overall population and stratified by procedure type for each of the 3 modeled outcomes. Model performance was generally acceptable to very good across all end points. The overall C-statistic was 0.72 for operative mortality and 0.62 for both major morbidity and M&M ([Figure 2](#)). Calculating cross-validation performance measures in certain procedure subgroups was not feasible due to small counts with too few outcome events.

Calibration plots comparing observed vs expected rates averaged in decile subgroups are presented for operative mortality in [Figure 3](#) and for major morbidity and M&M in [Supplemental Figures 1 and 2](#). These reveal excellent calibration overall and within procedure subgroups for all end points. Similar outcomes are observed using cross-validation



methodology, confirming that the derived models are not grossly overfit and that selection bias is negligible. Subgroup O/E ratios were generally near 1.0, confirming excellent calibration (Supplemental Table 6).

COMMENT

The STS-GTSD has developed revised risk models for patients undergoing esophagectomy for cancer that demonstrate similar performance compared with previous versions. STS-GTSD participant morbidity and mortality rates continue to be excellent, despite the inclusion of high-risk cohorts that make the new models more widely applicable. Furthermore, we believe including nonelective patients (1.5%) strengthens our findings because we can apply these data for a planned future risk calculator for elective and nonelective esophagectomy. Developed with more than quadruple the number of patients as the 2016 models, the current models rely on exclusively preoperative variables, allowing for future preoperative risk assessment tools, similar to those available from the STS-ACSD.^{6,7,11}

Importantly, harvest analytic models will use hierarchical models applied to elective patients only, with a random intercept for each participant, and will leverage the maximum of clinical and pathologic cancer stage to avoid the potential for understaging.

Currently, the STS-GTSD contains >800,000 procedures from nearly 300 participating hospitals.¹² Of the 18,503 esophagectomies examined in the current study, roughly equal numbers were performed using minimally invasive and open techniques. This proportion reflects an increase in minimally invasive esophagectomies (MIEs) being performed compared with the 2016 models, in which only 33.8% of esophagectomies were performed in a minimally invasive fashion.⁵

The 30-day operative mortality rate in the current cohort was 3.4%, with open esophagectomy slightly higher than MIE (3.8% vs 2.9%, respectively). The continued low operative mortality rate of STS-GTSD participants is particularly noteworthy considering the new risk models included high ASA patients and nonelective operations. These low mortality rates have been previously reported from the STS^{5,12} and are

TABLE 2 Directionality and Effect Size of Predictors of Esophagectomy Operative Outcomes: Mortality, Major Morbidity, and Morbidity and Mortality

Variable	Operative Mortality	Major Morbidity	Morbidity and Mortality
Female sex	— —	— —	— —
Former smoker ^a	++	++	++
Current smoker ^a	+++	+++	+++
Hypertension	+	+	+
Steroid use	++	+	+
Coronary artery disease	++	+	+
Congestive heart failure	+++	+++	+++
Transient ischemic attack	++	++	++
Cerebral vascular disease or accident	+++	++	+++
Peripheral vascular disease	++	++	++
Diabetes	+	+	+
Dialysis	+++	+++	+++
ASA III ^b	+++	++	++
ASA VI, V ^b	+++	+++	+++
Zubrod/ECOG = 1 ^c	++	+	+
Zubrod/ECOG > 1 ^c	+++	+++	+++
Insurance ^d			
Medicaid	+++	+	+
Dual Medicare/Medicaid	—	—	—
Commercial/HMO	— —	—	—
None/self/other	++	+	+
Elective surgical status	— — —	— —	— —
Reoperation (cardiothoracic surgery)	+++	+	+
Open transhiatal ^e	++	++	++
Open McKeown ^e	+++	+++	+++
Open Ivor Lewis ^e	+++	+++	+++
Open thoracoabdominal ^e	+++	— — —	— — —
MIE transhiatal ^e	—	+++	+++
MIE McKeown ^e	+++	+++	+++
Clinical cancer stage ^f			
II	++		
III	++	—	—
VI	+++	+	+
Induction therapy ^g			
Chemotherapy only	—		
Radiotherapy only	+++	— —	— —
Chemotherapy and radiotherapy		— —	— —
Race/ethnicity ^h			
Black		+	
Asian	— —	+	+
Native American		—	— —
Pacific Islander			
Hispanic		—	—
Pathologic histology ⁱ			
Squamous carcinoma	++	++	++
Other			
Missing	+++		
Continuous variables			
Age, y	Nonlinear; higher with increasing age		
Body mass index, kg/m ²	Nonlinear; U-shaped		
Body surface area, m ²	Nonlinear; lower with increasing body surface area		
Creatinine, mg/dL	Linear; higher with increasing creatinine		

^aNever smoker; ^bAmerican Society of Anesthesiologists Physical Status Classification (ASA) I, II; ^cZubrod/ Eastern Cooperative Oncology Group (ECOG) = 0; ^dMedicare is the reference category; ^eMinimally invasive esophagectomy (MIE) Ivor Lewis; ^fClinical cancer stage I; ^gInduction—none: chemotherapy and/or radiotherapy defined as for the same disease ≤6 months of surgery; ^hWhite race; ⁱPathologic histology—adenocarcinoma. Reference categories. Key: — — — = adjusted odds ratio (AOR) <0.70—high protective; — — = AOR 0.70–0.85—moderate protective; — = AOR 0.85–0.95—mild protective; blank = AOR 0.95–1.05—no effect; + = AOR 1.05–1.20—mild risk; ++ = AOR 1.20–1.40—moderate risk; +++ = AOR >1.40—high risk. HMO, health maintenance organization.

Procedure Type	Patients	Model Discrimination (C Statistic)			End Point/Outcome			Model Calibration (Observed/Expected)		
		OM	Morbidity	M&M	OM	Morbidity	M&M	OM	Morbidity	M&M
All esophagectomies	18,503	0.72 (0.69–0.74)	0.62 (0.61–0.63)	0.62 (0.62–0.63)	1.00 (0.96–1.05)	1.00 (0.98–1.02)	1.00 (0.98–1.02)			
Open surgery										
Ivor Lewis	6811 (36.8)	0.71 (0.66–0.73)	0.62 (0.60–0.63)	0.62 (0.60–0.64)	1.00 (0.88–1.12)	1.00 (0.96–1.05)	1.00 (0.96–1.05)			
McKeown	1140 (6.2)	0.76 (0.69–0.81)	0.60 (0.56–0.63)	0.60 (0.56–0.63)	1.00 (0.76–1.24)	1.00 (0.95–1.05)	1.00 (0.95–1.05)			
Transhiatal ^a	2106 (11.4)	0.68	0.61	0.62	1.00	1.00	1.00			
Thoracoabdominal ^b	531 (2.9)	NA	NA	NA	NA	NA	NA			
Minimally invasive surgery										
Ivor Lewis	6811 (36.8)	0.72 (0.68–0.76)	0.60 (0.58–0.61)	0.60 (0.58–0.61)	1.00 (0.85–1.16)	1.00 (0.95–1.05)	1.00 (0.95–1.05)			
McKeown	1451 (7.8)	0.73 (0.65–0.75)	0.60 (0.56–0.63)	0.60 (0.57–0.63)	1.00 (0.75–1.22)	1.00 (0.94–1.06)	1.00 (0.94–1.06)			
Transhiatal ^a	787 (4.3)	0.64	0.61	0.61	1.00	1.00	1.00			

^aLow counts—subgroup cross-validation not performed; ^bLow counts—subgroup performance measures not performed. Patient data are presented as n (%), and model discrimination and calibration data are presented with the 95% CI. M&M, composite mortality or major morbidity; NA, not applicable; OM, operative mortality.

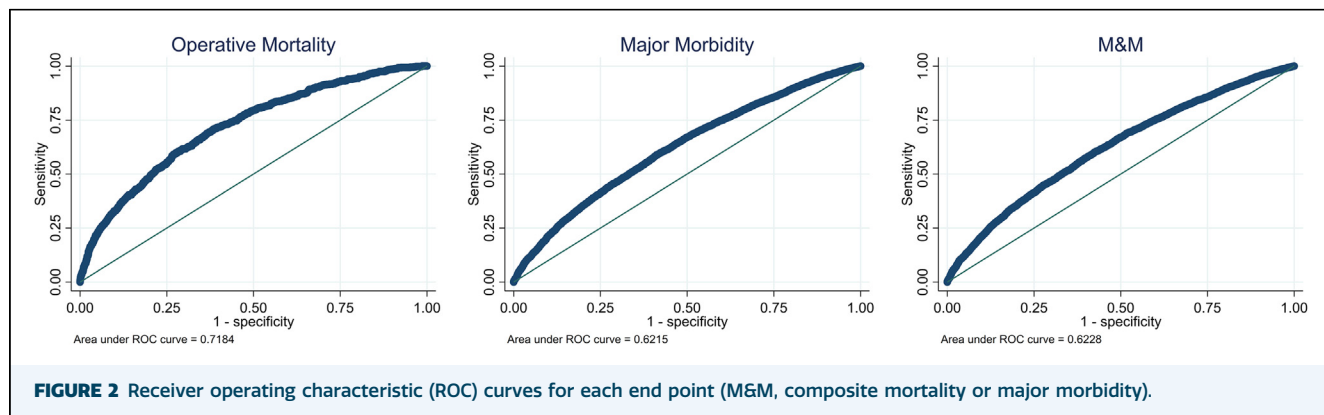
consistent with a recent large National Surgical Quality Improvement Program database study.¹³ The overall major morbidity rate in the current study is 31.6% for open esophagectomy and 29.4% for MIE, similar to previously reported rates.⁵

In the current model, open McKeown and open Ivor Lewis esophagectomy were associated with increased mortality, major morbidity, and composite M&M, whereas open transhiatal esophagectomy was associated with increased major morbidity and composite M&M compared with minimally invasive Ivor Lewis. An open McKeown approach was similarly associated with increased major morbidity and mortality in the 2016 STS-GTSD risk model.⁵

The current data suggest that any technique of open esophagectomy is associated with an increased risk of major morbidity and mortality relative to MIE and should be taken into consideration when deciding which approach to offer esophageal cancer patients. The superior outcomes observed in the minimally invasive cohort have been well established in multiple large prospective and retrospective meta-analyses showing MIE to have decreased pain, pulmonary complications, wound infections, blood loss, and similar or better short-term and long-term survival than open esophagectomy.^{14–18} However, the current analyses do not specifically address the center-specific proportions of MIEs vs open cases, and it is possible that optimal MIE results are achieved mainly by those programs and surgeons performing a significant proportion of their cases with MIE approaches.

Furthermore, in our updated model, transhiatal MIE and McKeown MIE were both associated with increased rates of composite M&M compared with Ivor Lewis MIE. Our findings are similar to the previous STS esophagectomy risk model, which demonstrated a protective effect of the Ivor Lewis MIE with a 50% reduced risk of major morbidity.⁵ Taken together, these findings illustrate the continuing debate about the best type of MIE to perform, a decision generally guided by the location of the tumor and surgeon preference, experience, and technical superiority in a given approach. Therefore, the results from this study should act purely as a guide for surgeons to understand the outcomes from Ivor Lewis, transhiatal, and McKeown esophagectomy.

The authors of a propensity score-matched analysis of Ivor Lewis MIE compared with McKeown MIE from 4 high-volume Dutch centers between 2009 and 2017 concluded that Ivor Lewis MIE had lower anastomotic leak rate



(12.4% vs 23.3%, $P = .003$), pulmonary complications (31.9% vs 46.7%, $P < .05$), and 90-day mortality (2.9% vs 7.1%, $P < .05$) with similar RO resection rates compared with McKeown MIE.¹⁹

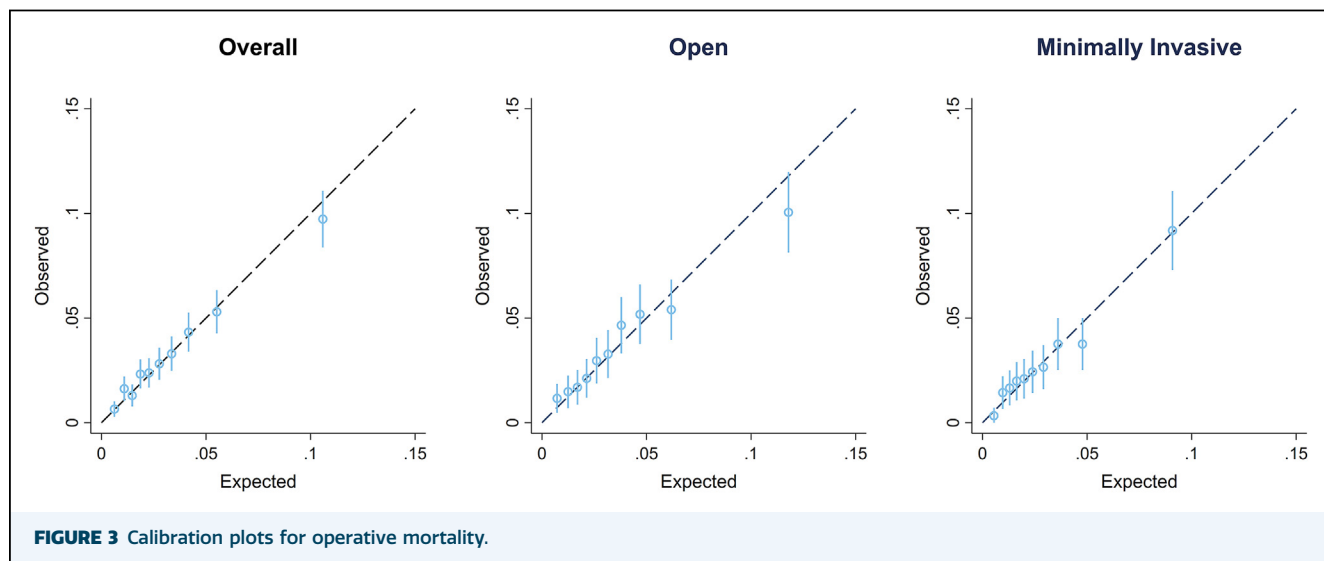
Wang and colleagues²⁰ performed a meta-analysis including 23 cohort studies with 4933 esophagectomy patients comparing Ivor Lewis MIE with McKeown MIE. They found that Ivor Lewis MIE demonstrated a lower rate of 30-day and 90-day mortality, anastomotic leak, and pulmonary complications, with no differences in estimated blood loss, number of lymph nodes harvested, or RO resection rates compared with McKeown MIE.¹⁹

There will be continual debate about which type of MIE to perform because no head-to-head randomized controlled trials have compared MIE operative types. We hope the findings from this study will further aid surgeons in deciding which type of esophagectomy to perform.

This study has some limitations. First, the STS-GTSD is a completely voluntary database, and participating programs may be more focused on the quality of their outcomes. Thus, these models may not generalize to centers not participating in the GTSD.

Second, even though the STS esophagectomy risk models will allow the inclusion of more esophagectomies, there is still a fairly low proportion of programs that have sufficient volumes to achieve esophagectomy composite score ratings compared with pulmonary resections (38.4% vs 74%, respectively).

Third, there continues to be a lack of uniformity in preoperative clinical staging methods for esophageal cancer in the GTSD similar to what is seen internationally. However, our data set did capture 58% of patients with endobronchial ultrasonography and 79% with positron emission tomography scans. Lastly, the STS-GTSD for



esophagectomy in its current form does not include all preoperative variables; however, the additional inclusion of extra variables for this study is a step in the right direction.

In conclusion, the revised STS-GTSD risk models for esophagectomy for cancer were developed using the most current, inclusive, and diverse spectrum of clinical and sociodemographic characteristics to date. These updated models will provide a basis for future decision tools, preoperative risk assessment, enhanced STS-GTSD harvest analytics, and quality improvement. In addition, the inclusion of high-risk patients, imputation of missing required fields, reassessment of race and ethnicity variables, and the consideration of new potential risk factors based on recent scientific evidence will

help refine patient selection and further advance quality improvement initiatives.

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