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The Society of Thoracic Surgeons 2021 Adult Cardiac Surgery Risk Models for Multiple Valve Operations

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ABSTRACT

BACKGROUND The Society of Thoracic Surgeons (STS) Quality Measurement Task Force has developed risk models and composite performance measures for isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR), isolated mitral valve replacement or repair (MVRR), AVR+CABG, and MVRR+CABG. To further enhance its portfolio of risk-adjusted performance metrics, STS has developed new risk models for multiple valve operations ± CABG procedures.

METHODS Using July 2011 to June 2019 STS Adult Cardiac Surgery Database data, risk models for AVR+MVRR (n = 31,968) and AVR+MVRR+CABG (n = 12,650) were developed with the following endpoints: Operative Mortality, major morbidity (any 1 or more of the following: cardiac reoperation, deep sternal wound infection/mediastinitis, stroke, prolonged ventilation, and renal failure), and combined mortality and/or major morbidity. Data were divided into development (July 2011 to June 2017; n = 35,109) and validation (July 2017 to June 2019; n = 9509) samples. Predictors were selected by assessing model performance and clinical face validity of full and progressively more parsimonious models. Performance of the resulting models was evaluated by assessing discrimination and calibration.

RESULTS C-statistics for the overall population of multiple valve ± CABG procedures were 0.7086, 0.6734, and 0.6840 for mortality, morbidity, and combined mortality and/or morbidity in the development sample, and 0.6953, 0.6561, and 0.6634 for the same outcomes, respectively, in the validation sample.

CONCLUSIONS New STS Adult Cardiac Surgery Database risk models have been developed for multiple valve ± CABG operations, and these models will be used in subsequent STS performance metrics.

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The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) is estimated to include data from more than 96% of adult

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cardiac surgical operations performed in the United States.[1-3] Although these data serve multiple purposes, their primary use is to assess the quality of adult cardiac surgery. Since the publication of its 2008 risk models,[4-6] the STS Quality Measurement Task Force has developed an expanding portfolio of composite performance measures, all of which have incorporated robust risk adjustment based on the ACSD.

In 2015, STS published a multiprocedural, multidomain, adult cardiac surgical composite measure suitable for evaluating performance of individual surgeons.[7] Though not currently used for public reporting, this composite metric is based on the following endpoints (ie, outcomes domains): risk-adjusted Operative Mortality and risk-adjusted major morbidity, the latter defined as the occurrence of any 1 or more of the following complications: cardiac reoperation, deep sternal infection, permanent stroke, prolonged ventilation, and renal failure. This surgeon-level composite performance measure includes risk-adjusted outcomes for the following operations: isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR), isolated mitral valve replacement or repair (MVRR), AVR+CABG, and MVRR+CABG, and results are estimated based on running 3-year analytic periods.

In 2018, STS published updated risk models for Operative Mortality and major morbidity for the following operations: isolated CABG, isolated AVR, isolated MVRR, AVR+CABG, and MVRR+CABG.[8,9] These new risk models are currently used in the estimation of their corresponding STS composite performance measures.

Most recently, STS has developed a multiprocedural, multidomain composite measure suitable for evaluating adult cardiac surgical performance at the level of an STS participant.[10] An STS Database Participant is most often either a hospital's cardiothoracic surgery division or department or a practice group of cardiothoracic surgeons. Uncommonly, an STS Database Participant is an individual cardiothoracic surgeon. Similar to the previously developed multiprocedural, multidomain composite for individual surgeons,[7] this new participant-level multiprocedural, multidomain composite performance measure includes isolated CABG, isolated AVR, isolated MVRR, AVR+CABG, and MVRR+CABG. However, in order to more broadly encompass the majority of procedures performed by an STS participant, this new participant-level multiprocedural, multidomain composite performance measure also includes the following multiple valve operations: AVR+MVRR and AVR+MVRR+CABG. Although STS previously published a risk model for Operative Mortality after multiple valve operations ± CABG procedures in 2013,[11] it was decided to develop new risk models for AVR+MVRR±CABG so that these procedures could be included in the new participant-level multiprocedural, multidomain composite performance measure.

The purpose of this article is to report the recently developed STS 2021 adult cardiac surgical risk models for Operative Mortality, major morbidity, and combined mortality and/or morbidity for the following multiple valve operations: AVR+MVRR and AVR+MVRR+CABG.

MATERIAL AND METHODS

ENDPOINTS. Using definitions consistent with previous STS risk models and performance measures,[7-9] risk models for multiple valve operations ± CABG procedures were developed for the following 3 endpoints: Operative Mortality, major morbidity, and combined mortality and/or major morbidity. Operative Mortality is defined in all STS databases as (1) all deaths, regardless of cause, occurring during the hospitalization in which the operation was performed, even if after 30 days (including patients transferred to other acute care facilities); and (2) all deaths, regardless of cause, occurring after discharge from the hospital, but before the end of the 30th postoperative day.[12,13] Major morbidity is defined as the occurrence of any 1 or more of the following 5 major complications: cardiac reoperation (ie, bleeding, tamponade, coronary graft occlusion, prosthetic or native valve dysfunction, and other cardiac reasons, but not for other noncardiac reasons), deep sternal wound infection or mediastinitis, permanent stroke, prolonged ventilation, and renal failure.[7-9] Deep sternal wound infection or mediastinitis is captured if it occurs during the index hospitalization or within 30 days of operation. Stroke is defined as an acute episode of focal or global neurologic dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction in which the neurologic dysfunction lasts for more than 24 hours. Prolonged ventilation is defined as greater than 24 hours of postoperative mechanical ventilatory support.[14] Renal failure is defined as a new requirement for dialysis, or meeting the RIFLE (Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease) criteria for renal failure based on creatinine levels or glomerular filtration rate.[15] Combined mortality and/or major morbidity is defined as the occurrence of any 1 or more of these endpoints. The follow-up period for endpoint definitions was from operation until the latter of hospital discharge or 30 days for mortality and mediastinitis or deep sternal wound infection, and during the index hospital admission for all other endpoints.

STUDY COHORT. Study data were divided into a development sample (July 1, 2011, to June 30, 2017) and a validation sample (July 1, 2017, to June 30, 2019). Data collected using STS-ACSD version 2.73 (July 1, 2011, to June 30, 2014) and STS-ACSD version 2.81 (July 1, 2014, to December 31, 2017) were used to develop the models and to perform a preliminary internal assessment of

discrimination and calibration (ie, development sample). Data collected using STS-ACSD version 2.9 (July 1, 2017 to December 31, 2019) were used to assess model performance in a separate validation sample.

Model development was limited to the following 4 major procedure populations: AVR + mitral valve replacement and AVR + mitral valve repair, referred to as the multiple valve cohort, and CABG + AVR + mitral valve replacement and CABG + AVR + mitral valve repair, referred to as the multiple valve + CABG cohort. Each operation type includes patients undergoing these operations only and excludes planned major concomitant operations, with a few exceptions. Specifically, concomitant tricuspid valve repair, surgical ablation for atrial fibrillation, and repair of atrial septal defect are allowed concomitantly with MVRR in both the multiple valve cohort and the multiple valve + CABG cohort. Patients on dialysis preoperatively were excluded from models predicting new onset postoperative renal failure.

Among 2,303,839 STS-ACSD records for patients greater than or equal to aged 18 years of age undergoing a cardiac operation at an STS participating site in the United States or Canada during the study period, 44,618 (1.94%) records met criteria for the AVR+MVRR (n = 31,968) and the AVR+MVRR+CABG (n = 12,650) cohorts (Supplemental Table 1). These 44,618 multiple valve operations were divided into the development (n = 35,109) and the validation (n = 9509) cohorts (Table 1).

TABLE 1 Sample Sizes for Model Development and Evaluation

		Sample for Development	Sample for Validation
	Date Range	July 1, 2011, to June 30, 2017	July 1, 2017, to June 30, 2019
	STS-ACSD Version(s)	2.73, 2.81	2.9
Category Number	Procedure		
1	Overall	35,109	9509
2	Multiple valve: AVR+MVRR	24,912	7056
3	AVR + mitral valve repair	10,150	2417
4	AVR + mitral valve replacement	14,762	4639
5	Multiple valve + CABG: CABG+AVR+MVRR	10,197	2453
6	CABG+AVR + mitral valve repair	5205	1011
7	CABG+AVR + mitral valve replacement	4992	1442

ACSD, Adult Cardiac Surgery Database; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; MVRR, mitral valve replacement or repair; STS, The Society of Thoracic Surgeons.

RISK MODELS. For each of the 3 endpoints, separate risk models were developed for each of the 2 major procedure populations, for a total of 6 risk models (ie, 3 endpoints [Operative Mortality, major morbidity, and combined mortality and/or major morbidity] and 2 populations [multiple valve cohort and multiple valve + CABG cohort]). For both the multiple valve cohort and multiple valve + CABG cohort, we developed a single model for each endpoint and included both mitral valve replacement and mitral valve repair in each of the 6 models. These 6 models then used indicator variables to adjust for the mitral operation type (ie, mitral valve replacement and mitral valve repair) and included interaction terms to account for the importance of selected risk factors that differ across these 2 mitral operation types (ie, mitral valve replacement and mitral valve repair).

SELECTION OF CANDIDATE PREDICTOR VARIABLES. The 2021 adult cardiac surgery risk models for multiple valve operations were developed using data from STS-ACSD versions 2.73 and 2.81, and were validated using data from STS-ACSD version 2.9, but these models will be applied to patients entered into the STS-ACSD using versions 2.9 and later. Accordingly, to be an acceptable candidate variable, it was necessary to assure that in all 3 STS-ACSD versions utilized (2.73, 2.81, and 2.9), either the variable was present or a similar, mappable analog was present. Only preoperative variables were considered for inclusion because the main goal of the risk models is to adjust for case mix.

To begin the process of selecting candidate predictor variables for both the multiple valve and the multiple valve + CABG risk models, a working group of cardiac surgeons and statisticians was assembled. This group decided that the candidate predictors (and their coding and interactions) for the new multiple valve risk models would be identical to the candidate predictors for the STS-ACSD 2018 isolated valve models,[8,9] and that that the candidate predictors (and their coding & interactions) for the new multiple valve + CABG risk models would be identical to the candidate predictors for the STS-ACSD 2018 valve + CABG models.[8,9] Because of their smaller sample sizes, the working group subsequently reduced the number of candidate covariates and interaction terms for the multiple valve + CABG risk models to reduce overfitting and to resolve the frequent lack of model convergence in subsequent bootstrap analyses. Mapping of predictors across data versions followed the previously published conventions adopted for these STS-ACSD 2018 risk models.[8,9] The difficulty of mapping arrhythmias was discussed in detail, and the strategy used was the same that was used for other recent STS models.[8,9]

SELECTION OF FINAL PREDICTOR VARIABLES. After identifying candidate covariates, the final set of covariates for each model was selected. The approach to variable selection mirrored the previously published approach used to develop the STS-ACSD 2018 risk models.[8,9] For each population and endpoint (ie, 6 possible combinations of 2 populations and 3 endpoints), a full model and a set of progressively more parsimonious models were estimated using backward selection with P values of $P = .1, .05, .01, .001$, and .0001, respectively.

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Unlike the common approach of arbitrarily selecting a significance level for variable selection, we used both statistical and expert clinical criteria to determine the optimal significance level and the corresponding final model covariates and coefficients. As described in the recent 2018 STS risk model manuscripts,[8,9] we first used bootstrap resampling and repeated split-sample cross-validation to assess the relative performance of models developed with different significance levels in a backward selection procedure. Performance metrics included the C-statistic, calibration slope, maximum and average absolute deviations between observed and expected event rates across deciles of predicted, and the maximum and average Hosmer-Lemeshow chi-square statistic for model fit across cross-validation samples. Also, for each candidate model, calibration was assessed graphically in a set of multiple cross-validation samples by plotting observed vs expected endpoint event rates across deciles of predicted risk among patients in each testing sample. This assessment of discrimination and calibration was done for the full model and for each significance level when using backward selection. The main objective of this testing was to determine whether compelling statistical differences were present between the significance levels to support the choice of one particular model.

We also used clinical content expertise to inform this process. In the absence of compelling statistical differences between the performance of various models, the final model was chosen by surgeon members of the working group, as previously described.[8] Beginning with the full model, surgeon members of the working group carefully reviewed the predictors in each model (full, and using backward selection criteria $P = .1$, .05, .01, .001, and .0001). Each progressively more parsimonious model was evaluated to be certain that no variables had been eliminated that would jeopardize clinical face validity. Generally, the most statistically parsimonious model that did not compromise clinical face validity was chosen as the final model.

MISSING DATA AND IMPUTATION STRATEGIES. Management of missing data was similar to the method used in the development of the STS-ACSD 2018 risk models.[8,9] Briefly, variable selection was performed using a simple single imputation strategy. After selecting variables, coefficients were estimated in a multiple imputation procedure to account for missing endpoints and covariates with greater than or equal to 1% missing data. Covariate data were missing in fewer than 1% of cases for all but 15 candidate predictor variables. We used multiple imputation for the 15 remaining covariates with missing rates over 1% (range, 1.1%-8.1%). Before imputation, 8.1% of records had missing or unknown mortality data for at least 1 component of the Operative Mortality definition. Rates of missing or unknown data were 0.11% for discharge mortality status and 8.1% for 30-day mortality status. Missing data rates for endpoints other than mortality were less than 0.2%.

An analysis of data from STS-ACSD linked to the Social Security Death Master File was published in 2013.[16] Using linked data from January 1, 2008, and December 31, 2010, this analysis documented that the capture of 30-day mortality occurring before hospital discharge by STS is highly accurate (sensitivity of 98.8%) and that these in hospital deaths represent the majority (79%) of all 30-day deaths. However, capture of the remaining 30-day deaths occurring after discharge from the hospital was less complete. In response to this analysis, STS implemented more stringent requirements for all data fields related to Operative Mortality. For operations performed after January 1, 2015, participants were not included in the benchmark population for STS performance metrics, nor were these participants eligible to receive an STS performance star rating, unless their rate of missing data for 30-day mortality and discharge mortality was less than 10% missing or unknown; this threshold was further decreased to 5% for operations occurring after January 1, 2016, and 2% for operations occurring after January 1, 2017.

FINAL MODEL ASSESSMENT. The validation sample was created by using STS-ACSD data from July 1, 2017, to June 30, 2019 and applying the identical inclusionary and exclusionary criteria used to create the development sample. Discrimination was quantified by the C-statistic. Calibration was assessed by plotting observed vs expected event rates across deciles of predicted risk in the validation sample.

INSTITUTIONAL REVIEW BOARD AND APPROVAL OF MODELS. The Duke Clinical Research Institute serves as the analytic center for STS-ACSD. This study was approved by the Duke University Health System Institutional Review Board. Because the data used in analysis represent a limited dataset (no direct patient identifiers) that was originally collected for nonresearch purposes, and because the investigators do not know the identity of individual patients, the analysis of these data was declared by the Duke University Health System Institutional Review Board to be research not involving human subjects.

RESULTS

Supplemental Table 1 provides case counts from STS-ACSD stratified by year from July 1, 2011, through June 30, 2019, inclusive.

Table 1 documents the sample sizes for model development and evaluation. A total of 35,109 records met study inclusion criteria and were included in the development samples for multiple valve (AVR+MVRR;

TABLE 2 Number and Percentage of Endpoint Events by Model Population in Development Sample

Category Number	Procedure	Mortality		Morbidity		Combined Mortality and/or Morbidity	
		n	%	n	%	N	%
1	Overall	2915	8.30	10,636	30.29	11,364	32.37
2	Multiple valve: AVR+MVRR	1800	7.23	6887	27.65	7336	29.45
3	AVR + mitral valve repair	495	4.88	2209	21.76	2341	23.06
4	AVR + mitral valve replacement	1305	8.84	4678	31.69	4995	33.84
5	Multiple valve + CABG: CABG+AVR+MVRR	1115	10.93	3749	36.77	4028	39.50
6	CABG+AVR + mitral valve repair	441	8.47	1643	31.57	1744	33.51
7	CABG+AVR + mitral valve replacement	674	13.50	2106	42.19	2284	45.75

AVR, aortic valve replacement; CABG, coronary artery bypass grafting; MVRR, mitral valve replacement or repair.

n = 24,912) and multiple valve + CABG (CABG+AVR+MVRR; n = 10,197) (Table 2).

Table 2 documents the number and percentage of endpoint events by model population in the development sample.

Supplemental Table 2 summarizes the final list of candidate covariates. These 166 variables were included in the "full" model for each endpoint and population and were the starting point for variable selection by backward selection with bootstrapping and cross-validation, and subsequent clinical assessment by the surgeon panel. Details of how each candidate variable was parameterized in the model are previously published in the articles describing the STS-ACSD 2018 risk models, in the Supplemental Material of these prior publications.[8,9]

Performance of the final STS 2021 adult cardiac surgical risk models for AVR+MVRR and AVR+MVRR+CABG in the development sample and validation sample are presented in Tables 3 and Figures 1 and 2. Table 3 provides the C-statistics in development and validation samples. In order to contextualize these results, appropriate comparisons are the C-statistics in the validation sample of the STS-ACSD 2018 risk models, which ranged from 0.588 for reoperation in valve + CABG procedures to 0.826 for renal failure in CABG procedures.[9] The C-statistics for the multiple valve ± CABG models in the current study range from 0.602 for the composite morbidity model in the multiple valve + CABG validation cohort to 0.734 for mortality in the AVR + mitral valve repair development cohort. Figure 1 shows the calibration for each endpoint in the following 3 populations: overall study population (multiple valve ± CABG (AVR+MVRR±CABG), the multiple valve cohort (AVR+MVRR), and multiple valve + CABG cohort (CABG+AVR+MVRR). Figure 2 shows the calibration for each endpoint in the following 4 subpopulations: AVR + mitral valve repair, AVR + mitral valve replacement, CABG+AVR + mitral valve repair, and CABG+AVR + mitral valve replacement. Calibration plots based on cross-validation revealed acceptable calibration and no obvious violation of modeling assumptions.

Supplemental Table 3 summarizes risk factors in the final selected model for each population and endpoint. The number of risk factors in these models ranged from 37 in the model for Operative Mortality in the multiple valve + CABG cohort to 60 in the model for composite mortality and/or major morbidity in the multiple valve cohort. Full specifications for these models including formulas, coefficients, and intercept parameters are available in Supplemental Table 4A, 4B, 4C and are publicly available from the STS website. Supplemental

TABLE 3 C-Statistics in Development and Validation Samples

Category Number	Procedure	Development Sample			Validation Sample		
		Mortality	Combined Mortality and/or Morbidity	Morbidity	Mortality	Combined Mortality and/or Morbidity	Morbidity
1	Overall	0.7086	0.6840	0.6734	0.6953	0.6634	0.6561
2	Multiple valve: AVR+MVRR	0.7077	0.6715	0.6598	0.7004	0.6729	0.6652
3	AVR + mitral valve repair	0.7336	0.6881	0.6748	0.7227	0.7136	0.7091
4	AVR + mitral valve replacement	0.7165	0.6969	0.6783	0.7102	0.6899	0.6788
5	Multiple valve + CABG: CABG+AVR+MVRR	0.6942	0.6508	0.6378	0.6474	0.6122	0.6023
6	CABG+AVR + mitral valve repair	0.7186	0.6953	0.6756	0.7047	0.6826	0.6669
7	CABG+AVR + mitral valve replacement	0.6971	0.6844	0.6669	0.6595	0.6361	0.6212

AVR, aortic valve replacement; CABG, coronary artery bypass grafting; MVRR, mitral valve replacement or repair.

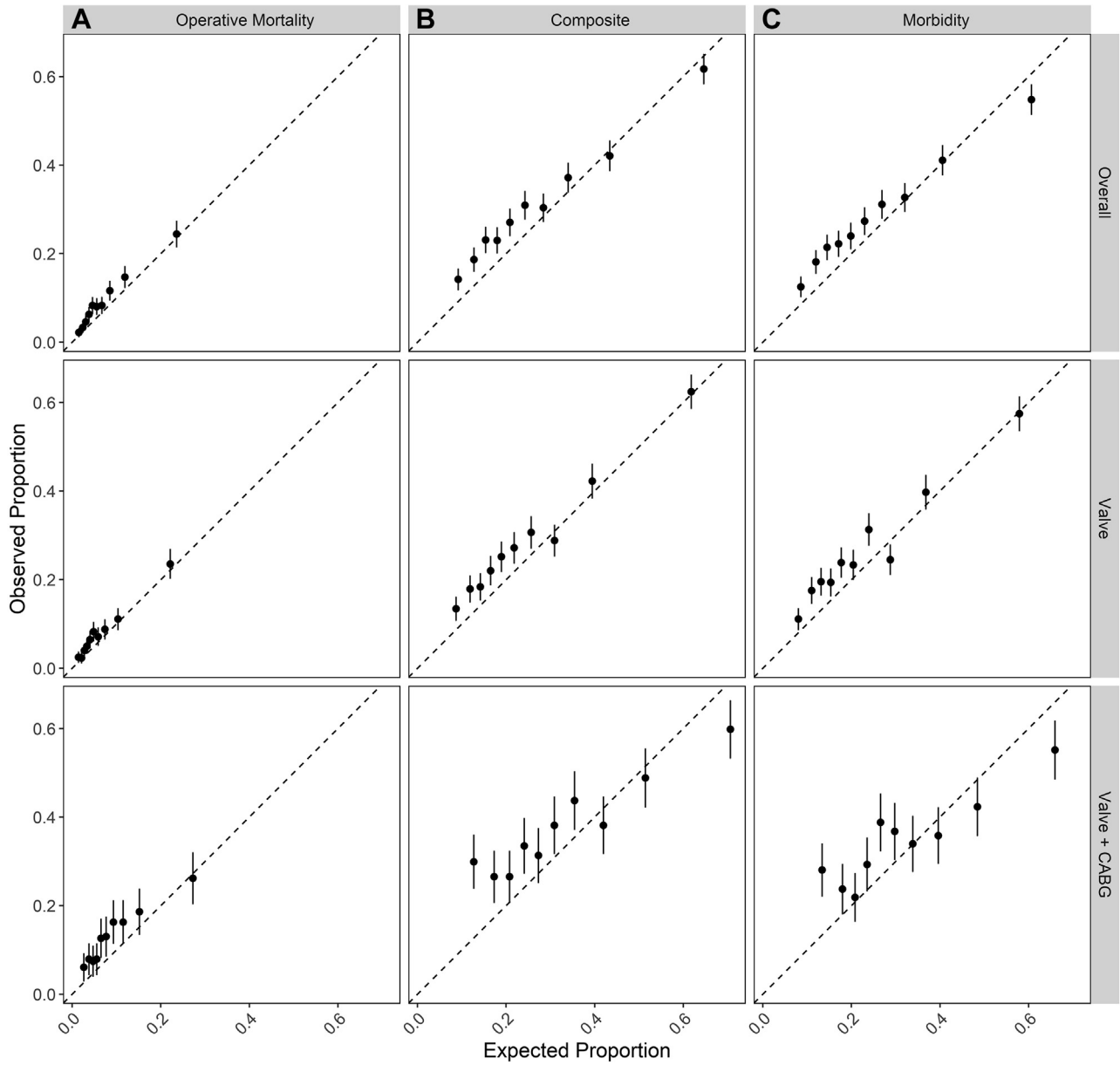

FIGURE 1 Calibration for each endpoint in the following 3 populations: (1) overall study population (multiple valve ± coronary artery bypass grafting [CABG]) = (aortic valve replacement [AVR] + mitral valve replacement or repair [MVRR] ± CABG]), (2) the multiple valve cohort (AVR + MVRR), and (3) the multiple valve + CABG cohort (CABG + AVR + MVRR). (A) Operative Mortality; (B) combined Operative Mortality and/or major morbidity; (C) major morbidity (any 1 or more of the following: cardiac reoperation, deep sternal wound infection/mediastinitis, stroke, prolonged ventilation, and renal failure).

Table 4A documents which variables are in each model. Supplemental Table 4B summarizes odds ratios in the AVR+MVRR models. Supplemental Table 4C summarizes odds ratios in the AVR+MVRR+CABG models.

COMMENT

We have described the development and validation of a comprehensive set of completely new STS adult cardiac surgical risk models for multiple valve operations, including AVR+MVRR and AVR+MVRR+CABG. The statistical performance of these models, including discrimination and calibration, reveals that they are suitable for use in STS composite metrics, although their discrimination is lower than that of most other STS risk models due to the smaller number of procedures.

The population of patients undergoing benchmark operations assessed by current STS risk models (ie, isolated

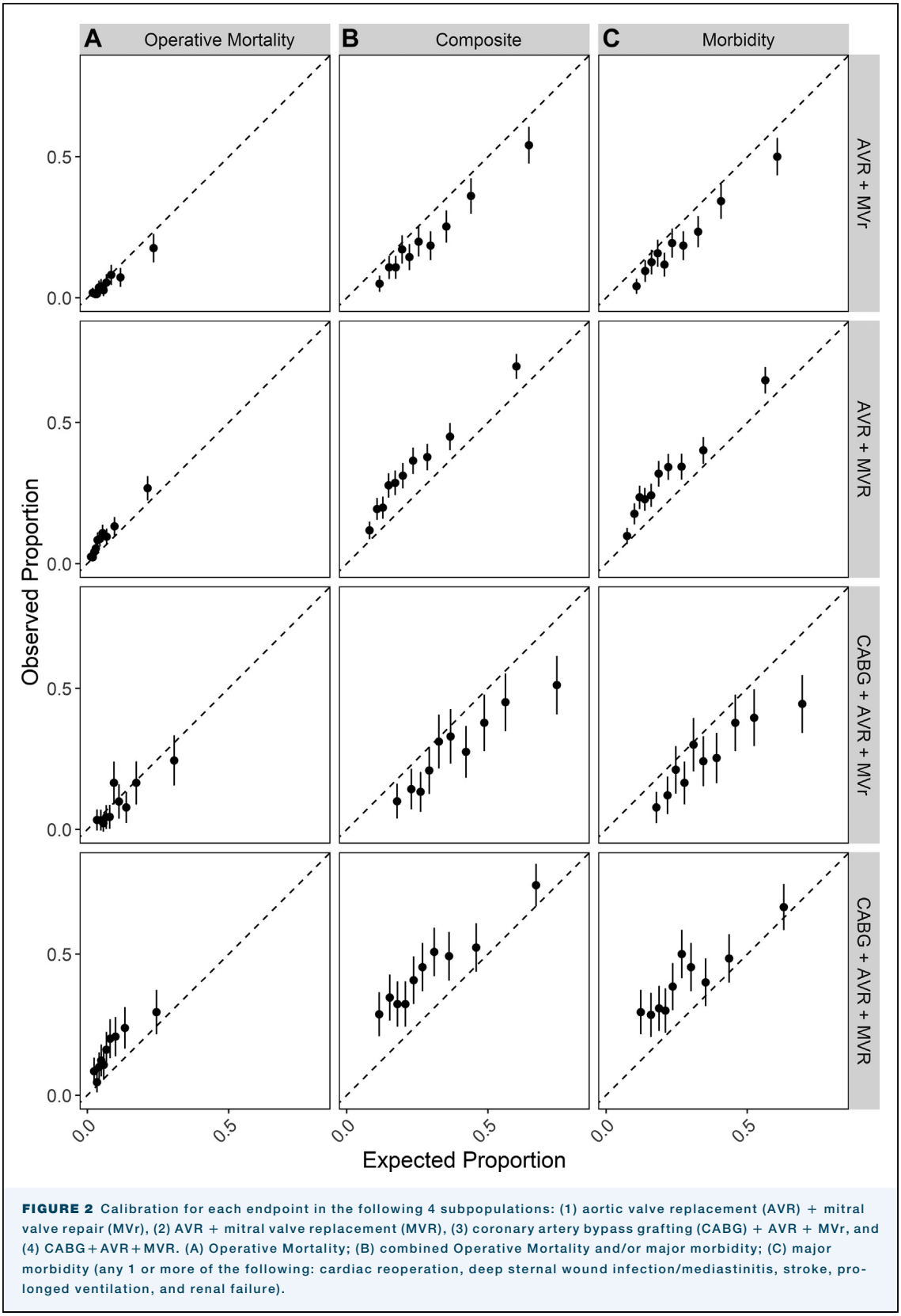

FIGURE 2 Calibration for each endpoint in the following 4 subpopulations: (1) aortic valve replacement (AVR) + mitral valve repair (MVr), (2) AVR + mitral valve replacement (MVR), (3) coronary artery bypass grafting (CABG) + AVR + MVr, and (4) CABG + AVR + MVR. (A) Operative Mortality; (B) combined Operative Mortality and/or major morbidity; (C) major morbidity (any 1 or more of the following: cardiac reoperation, deep sternal wound infection/mediastinitis, stroke, prolonged ventilation, and renal failure).

CABG, isolated AVR, isolated MVRR, AVR+CABG, and MVRR+CABG) represents 79.94% (n = 1,841,670 of 2,303,839) of all adult cardiac surgical operation in STS-ACSD from July 2011 to June 2019 (Supplemental Table 1). The population of patients undergoing operations assessed by these new STS multiple valve risk models (ie, AVR+MVRR and AVR+MVRR+CABG) represent only 1.94% (n = 44,618 of 2,303,839) of all adult cardiac surgical operation in STS-ACSD from July 2011 to June 2019 (Supplemental Table 1). By adding these multiple valve operations to the current benchmark procedure population, the proportion of patients in the new benchmark population (which will include AVR+MVRR and AVR+MVRR+CABG procedures) will increase to 81.88% (n = 1,886,288 of 2,303,839) of all adult cardiac surgical operations in STS-ACSD. Furthermore, the addition of these higher-risk multiple valve operations to the current benchmark group will have important impact on the assessment of performance at centers that perform a disproportionately higher proportion of these complex multiple valve operations.

FUTURE DIRECTIONS. These new STS risk models for AVR+MVRR and AVR+MVRR+CABG have been incorporated into the new STS participant-level multiprocedural, multidomain, adult cardiac surgical composite performance measure.[10] Analysis of outcomes based on these new risk models for AVR+MVRR and AVR+MVRR+CABG will be added to the STS-ACSD Feedback Reports. The coefficients of these risk models are reestimated with each data harvest and Feedback Report, assuring that they reflect current practice. In the future, the risk models for AVR+MVRR and AVR+MVRR+CABG may be used to develop procedure-specific multiple valve ± CABG composite performance measures; furthermore, multiple valve ± CABG operations may also be added to the existing STS individual surgeon multiprocedural, multidomain, adult cardiac surgical composite performance measure.[7]

CONCLUSION. The recently developed STS 2021 adult cardiac surgical risk models for Operative Mortality, major morbidity, and combined Operative Mortality and/or morbidity for AVR+MVRR and AVR+MVRR+CABG have suitable performance for incorporation into STS performance metrics, including the new STS participant-level multiprocedural, multidomain, adult cardiac surgical composite performance measure.

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