

Pump-assisted coronary artery bypass grafting with low ejection fraction: challenges and disparities in predicting and comparing outcomes to the Society of Thoracic Surgeons risk calculator and database.

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Abstract

Background: Coronary artery bypass grafting (CABG) may be performed with or without cardiopulmonary bypass (CPB). The Society of Thoracic Surgeons (STS) provides a preoperative risk assessment tool for CABG and reports postoperative outcomes from a database that is updated quarterly. This manuscript aimed to analyze the preoperative risk and postoperative outcomes in a subset of CABG patients with ejection fraction < 40% utilizing a pump-assisted beating-heart technique. These study results were compared to the STS risk calculator and database.

Methods: A single-center observational study of 108 patients undergoing pump-assisted direct coronary artery bypass (PAD-CAB) surgery with an ejection fraction < 40% were examined. All patients were evaluated preoperatively with the STS risk assessment calculator. Postoperative outcomes were compared with the expected outcomes using the Wilcoxon signed-rank test and the area under the receiver operating characteristic curve (AUC).

Results: The STS-predicted rates for mortality (3.3% vs 2.7%, $P = 0.11$) and composite morbidity or mortality (21.4% vs 7.4%, $P < .001$) were higher than the observed. STS showed poor discriminatory power for mortality (AUC = 0.48), reoperation (AUC = 0.48), morbidity (AUC = 0.51) and prolonged length of stay (AUC = 0.62).

Discussion: PAD-CAB results compare favorably to the STS database predicted outcomes for CABG. However, comparison of the study group to STS is problematic because specific STS risk calculator definitions are subjective and database outcomes do not consider the technique of PAD-CAB. Further refinements in these areas are necessary.

Keywords: Coronary artery bypass grafting, Beating-heart, outcomes, Risk prediction.

Background

For decades, coronary artery bypass grafting (CABG) has been the standard treatment for surgical coronary revascularization. The evolution of surgical techniques ranges from the traditional approach utilizing cardiopulmonary bypass (CPB), aortic cross-clamping, and cardioplegic arrest (TRAD-CAB) to a totally off-pump method (OP-CAB). A hybrid approach—pump-assisted direct coronary artery bypass (PAD-CAB)—in which circulatory support is maintained with CPB while aortic cross-clamping with cardioplegic arrest is avoided (i.e., Beating-Heart)—has been adopted by some surgeons with evidence of efficacy in certain high-risk patient populations.^{1,2} In an effort to better understand the role of this procedure in patients with low ejection fraction (EF), this observational study was undertaken with the intent to compare the results with the Society

of Thoracic Surgeons (STS) risk calculator and database.

Methods

Patients

A single-center study of 108 patients from April 2017 to August 2021 undergoing pump-assisted direct coronary artery bypass (PAD-CAB) was performed. The study patient group was collected from a single surgeon (LS) database in which all CABG cases were conducted with the PAD-CAB technique. The entry criteria included isolated CABG with an EF < 40%. Demographic data and perioperative outcomes were collected and tabulated with the aim of comparing study points to the STS risk calculator and database. STS definitions were utilized except for the EF. In order to assign a consistent EF, the investigators of this study

chose to use the intraoperative transesophageal echocardiogram (TEE) instead of the STS definition which ranges from days to weeks prior to the procedure. All patients were evaluated on follow-up exams at one month, three months, and six months after discharge.

Surgical Technique

All procedures were performed with a trans-sternal approach and normothermic CPB maintaining a mean arterial pressure between 60 and 80 mmHg. Low tidal volume ventilation was maintained throughout the case to minimize atelectasis. Standard aortic and right atrial cannulation was performed with a soft-flow arterial cannula and two-stage venous cannula. The in situ left internal mammary artery was utilized to revascularize the left anterior descending coronary artery and the greater saphenous vein grafts for all other vessels. All distal anastomoses were performed with a flow-thru intracoronary shunt. Stabilization of the target coronary arteries was accomplished with a tissue stabilizer (Medtronic, Minneapolis, MN, USA or Maquet Cardiovascular, LLC, Wayne, NJ, USA). All completed anastomoses were assessed with an ultrasonic flow probe (Transonic Systems, Inc, Ithaca, NY, USA). Intraoperative trans-esophageal echocardiography (TEE) was used in all cases.

Risk Calculator

All patients were assessed with the STS risk calculator (Version 4.2).³ STS definitions were utilized for study data entry with the exception of the EF for the study patients. The STS risk calculator definition for the EF is an echocardiogram performed no greater than six months prior to surgery—intraoperative echocardiography is not considered an acceptable STS data entry point. The study patient risk calculated outcomes were compared to the actual outcomes for the following established STS parameters: operative mortality, stroke (CVA), renal failure, reoperation,

composite morbidity or mortality, and prolonged postoperative length of stay. STS outcome definitions have been previously published.⁴

Statistical Analysis

Data were expressed as percentages for discrete variables and mean ± standard deviation for continuous variables. The observed and predicted outcomes were compared using the Wilcoxon signed-rank test. The risk-adjusted event ratio was also calculated to evaluate the calibration power of the STS risk model. The risk-adjusted event ratio is defined as observed events divided by the expected events (O/E ratio). An O/E > 1.0 signifies that the model underpredicts the event, while an O/E ratio < 1.0 signifies that the model overpredicts the events. The Mid-P exact test calculated the confidence interval (CI) and P-value. The sensitivity and specificity of the STS scores were tested in our population using the receiver operating characteristic (ROC) curve and its 95% CI from logistic regression. The area under the curve (AUC) was used to summarize the ROC curve. The higher the AUC, the better the performance of the model. Models are considered excellent when the AUC is greater than 0.80. Statistical analyses were performed using IBM SPSS Statistics, version 28.0.1.0 (IBM Corp, Armonk, NY, USA).

Results

The data from 108 patients undergoing isolated PAD-CAB showed the following: 75 males (69.4%) and 33 females (30.5%) with a mean age of 63.5 ± 10.2 years. The mean Body Mass Index (BMI) was 30.6 ± 5.6. There were 99 (91.7%) patients with hypertension, 87 (80.6%) with diabetes, and 10 (9.2%) with end-stage renal disease. In accordance with the STS definitions, there were 24 (22.2%) elective, 78 (72.2%) urgent, and 6 (5.5%) emergent cases. Additional patient demographics are charted in Table 1.

Table 1: Preoperative demographics and comorbidities for the entire cohort (n = 108)

Variable	n (%) or mean (SD)
Age	63.5 (10.2)
Sex (female)	33 (30.5%)
Ethnicity	
- African American	54 (50%)
- Caucasian	30 (27.8%)
- Hispanic	17 (15.7%)
- Asian	5 (4.6%)
Presentation	
- Unstable angina	24 (22.2%)
- Congestive heart failure	28 (25.9%)
- + Exercise stress test	6 (5.5%)
- Shortness of breath	3 (2.7%)
- ST elevated myocardial infarction	10 (9.2%)
- Non-ST elevated myocardial infarction	39 (36.1%)
- Cardiogenic shock	1 (0.9%)
Status	
- Elective	24 (22.2%)

- Urgent	78 (72.2%)
- Emergent	6 (5.5%)
Ejection fraction (%)	32.0 (7.8)
Number of grafts	2.8 (.8)
- 1 vessel	3 (2.8%)
- 2 vessels	31 (28.7%)
- 3 vessels	56 (51.9%)
- 4 vessels	18 (16.7%)
Hypertension	99 (91.7%)
Diabetes Mellitus	87 (80.6%)
HGA1C	7.4 (2.2)
Hyperlipidemia	89 (82.4%)
End-stage renal disease	10 (9.2%)
Obesity	55 (50.9%)
Body mass index	30.6 (5.6)
Cardiopulmonary bypass time	92.4 (23.8)
Post-operation length of stay	8.4 (5.9)
Morbidity/Mortality	
- Reoperation	5 (4.6%)
- Mortality	3 (2.7%)
- Cerebrovascular accident	3 (2.7%)
- Acute kidney injury	0 (0%)
- Long length of stay (> 14 days)	10 (9.2%)
Discharge	
- Home	74 (68.5%)
- Skilled nursing facility	12 (11.1%)
- Rehab	17 (15.7%)

The STS-predicted operative mortality rate for the study patients was calculated at 3.3% whereas the actual mortality rate was 2.7% (P = 0.11). The risk of renal failure (3.8% vs 0%, P < .001), composite mortality or morbidity (21.4% vs 7.4%, P < .001), and long length of stay (10% vs 9.2%, P = 0.42) were calculated

to be higher by the STS predictor tool than what was observed. Conversely, the STS predictor tool calculated CVA (2.3% vs 2.7%, P < .001) and reoperation (3.7% vs 4.6%, P < .001) to be lower than what was observed (Figure 1).

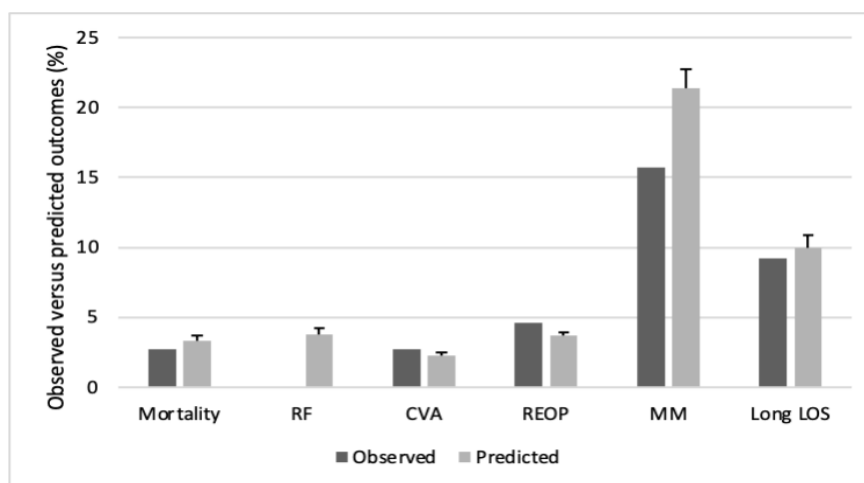


Figure 1: Predicted outcomes of CABG compared to observed outcomes. (error bars showing standard error of mean) CVA = cerebrovascular accident; Long LOS = long length of stay; MM = morbidity or mortality; REOP = reoperation; RF = Renal Failure

The O/E ratio of operative mortality in the STS risk model was 0.83, with the STS risk model overpredicting the operative mortality (CI 0.21–2.27; P = 0.82), as shown in Table 2. The O/E ratio of morbidity or mortality (0.35, CI 0.16-0.66, P < .001) and prolonged length of stay (0.93, CI 0.47-1.65, P = 0.85) also demonstrate that the STS risk model overpredicted the actual occurrence rates (Table 2). The O/E ratio of CVA (1.2, CI 0.31-

3.27, P = 0.70) and reoperation (1.2, CI 0.46-2.77, P = 0.59) were underpredicted by the STS risk model (Table 2). Although predicted occurrence rates of renal failure could not be calculated since the observed outcome was zero, it is implied that the STS predicted occurrence rate overpredicted the actual occurrence rate.

Table 2: Comparison of STS risks and PAD-CABG outcomes (N = 108)

Outcome	Einstein PAD-CABG outcomes n (%)	CABG STS risks Mean (SD)	P-value ^a	Expected events	O/E ratio (95% CI)	P-value ^b
Mortality	3 (2.7%)	3.3% (4.1)	0.11	3.6	0.83 (0.21-2.27)	0.82
Renal failure	0 (0.0%)	3.8% (4.2)	< .001	4.1	-	-
Cerebrovascular accident	3 (2.7%)	2.3% (1.6)	< .001	2.5	1.2 (0.31-3.27)	0.70
Reoperation	5 (4.6%)	3.7% (2.6)	< .001	4.0	1.2 (0.46-2.77)	0.59
Morbidity	8 (7.4%)	21.4% (14.0)	< .001	23.1	0.35 (0.16-0.66)	< .001
Long length of stay (> 14 days)	10 (9.2%)	10.0% (8.9)	0.42	10.8	0.93 (0.47-1.65)	0.85

a. Wilcoxon signed-rank tests were used to compare PAD-CABG outcomes with STS predicted risks for standard CABGs. P values < .05 were considered significant.

b. P-value was calculated by the Mid-P exact test.

CI = confidence interval, O/E ratio = observed events divided by expected events, (PAD-)CABG = (pump-assisted direct) coronary artery bypass graft, STS = Society of Thoracic Surgeons

The distribution of predicted mortality risk was largely below 4%, with a median value of 1.9% and a range from 0.30% to 33.4% (Figure 2). Figure 2 demonstrates the distribution of STS risk scores across other outcomes, which were similarly right-

skewed with distributions less than 4% for renal failure (range 0.50-22.50), 3% for stroke (range 0.30-7.30), 4% for reoperation (range 1.20-17.00), 20% for morbidity or mortality (range 4.10-88.20), and 10% for long length of stay (range 1.00-56.00).

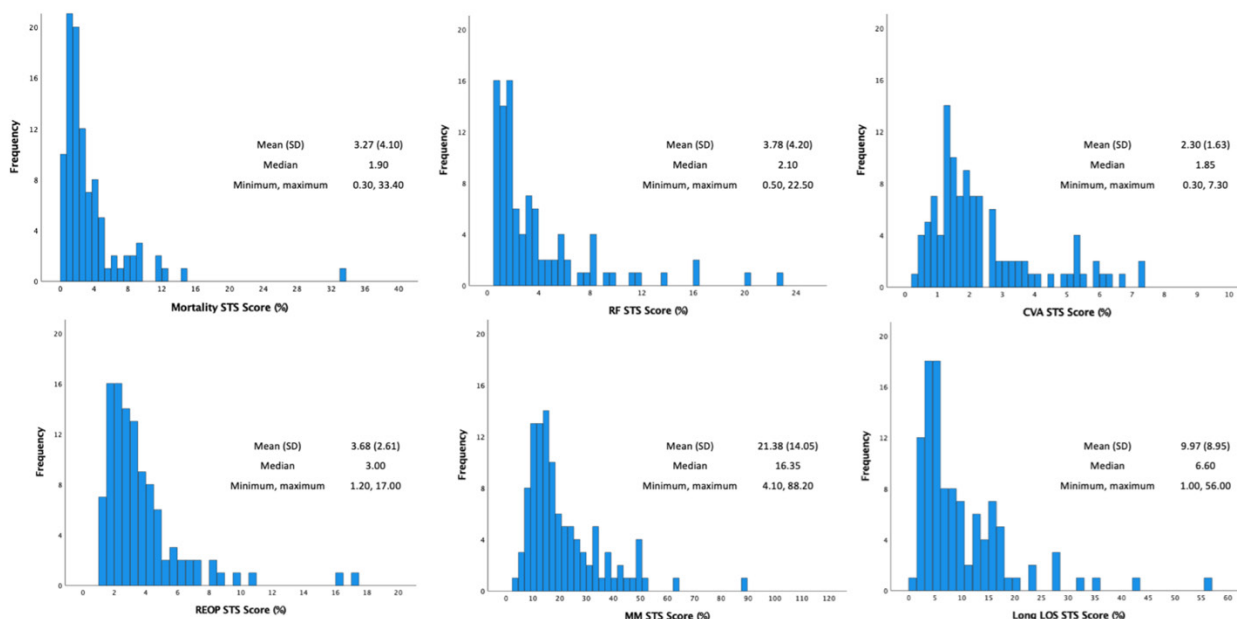


Figure 2: Distribution of STS risk scores across outcomes

CVA = cerebrovascular accident; Long LOS = long length of stay; MM = morbidity or mortality; REOP = reoperation; RF = Renal Failure; STS = Society of Thoracic Surgeons

Regarding discrimination power for operative mortality, the STS risk model has been shown to be a poor predictor for identifying outcomes in our patient population, with an AUC of 0.48 (95% CI 0.04 - 0.91; Figure 3). The AUC for permanent stroke was 0.76 (95% CI 0.57 - 0.94), 0.48 (95% CI 0.16 - 0.81) for reop-

eration, 0.51 (95% CI 0.29 - 0.73) for morbidity, and 0.62 (95% CI 0.44 - 0.81) for prolonged length of stay (Figure 3). The AUC could not be calculated for renal failure since no patients suffered from renal failure post-op.

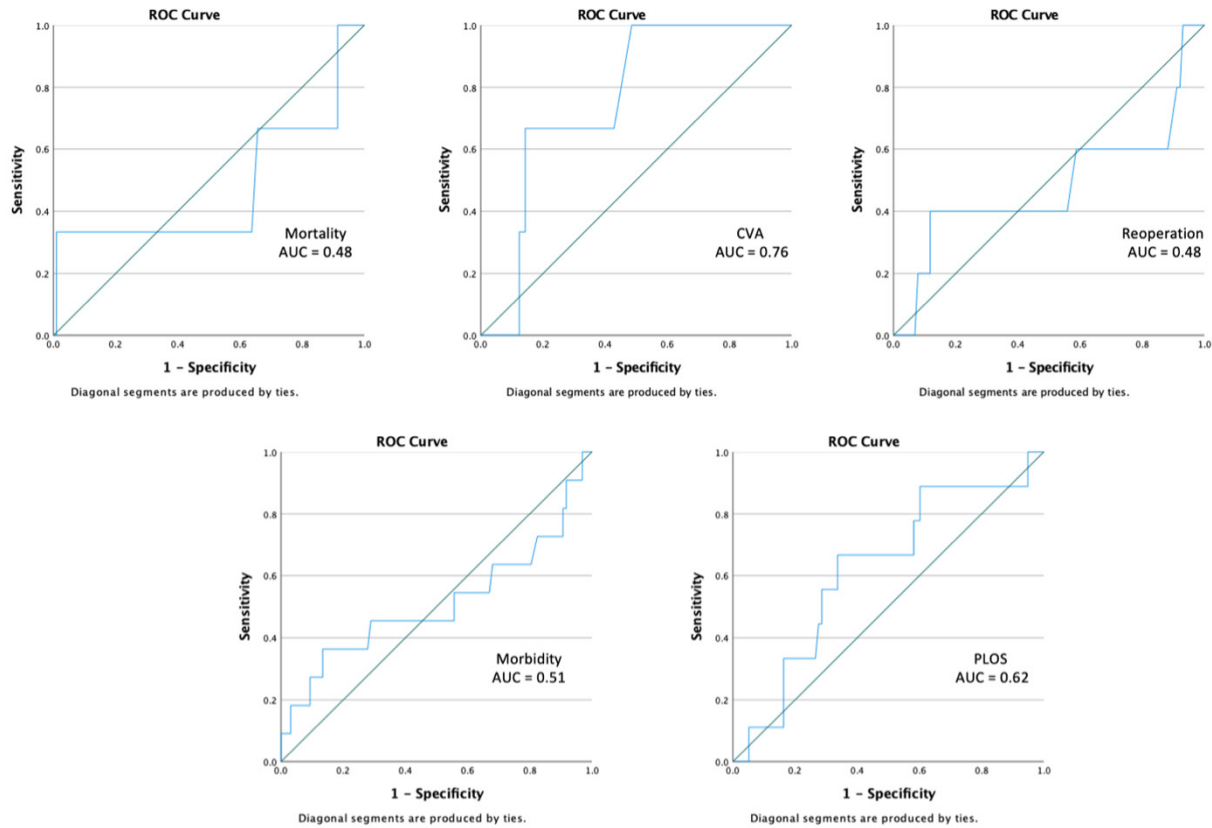


Figure 3: ROC curves for STS model outcomes in PAD-CABG patients with low EF.

CVA = cerebrovascular accident; Long LOS = long length of stay; MM = morbidity or mortality; REOP = reoperation; RF = Renal Failure; STS = Society of Thoracic Surgeons

Discussion

Launched in 1989, the STS database contains more than 6.5 million cardiac surgery procedure records and currently has nearly 3,800 participating physicians, including surgeons and anesthesiologists.⁵ The STS risk assessment tool was first utilized in 2008 and has undergone several upgrades and iterations over the decades that followed. At present, the Adult Cardiac Surgery Database (ACSD) version 4.20 is utilized. Refinements continue to be made to better predict outcomes and establish benchmarks for specific procedures and the techniques used to conduct them.⁶ An example of the evolution of the database now considers the segregation between the off-pump (OP-CAB) vs. non-off-pump CABG (TRAD-CAB). However, there is no specific category for the PAD-CAB technique or other approaches such as minimally invasive direct coronary artery bypass or robotic coronary artery bypass. This study exposed some of the challenges in comparing the PAD-CAB procedure in low EF patients with the STS risk assessment tool and the database where it may be argued that the technique itself may influence outcomes independent of other factors.

Traditional risk models lose accuracy in predicting mortality in high-risk patients undergoing cardiac surgery.^{7,8} La Par et al. suggested that this observation is most likely due to the general population of cardiac surgery patients being low or intermediate risk with a statistically smaller group from which to collect data.⁹ In our study, we used ROC and AUC to compare STS predicted scores with our findings. Similar to other studies, it has been found that STS risk predictions are inaccurate when applied to specific high-risk populations, such as those with a reduced ejection fraction.⁸ This risk adjustment also loses accuracy at the extremes of the population studied, for example, high risk or elderly, where there are too few patients upon which to build a statistically valid model. This accounts for some of the over- and underestimations of risk seen with many models. This study demonstrates that the STS predicted risk of mortality after CABG in patients with an EF $\leq 40\%$ varies substantially from one patient to the next, being less than 2% in nearly 20% of patients but greater than 8% in close to 20% of patients with ranges from 0.3% to 33%. These findings are consistent with those reported by Bouabdallaoui et al.⁸ It is also noteworthy that risk algorithms cannot account for variables not collected or an-

alyzed. One might hypothesize that these models were not built to accurately capture the surgical risk of morbidity and mortality in high-risk subgroups where certain risk factors carry a substantial proportion of the risk.

Although identifying and distinguishing more predictor variables in a patient's pre-operative assessment is inordinate and comes at the expense of user burden, taking into consideration the specific surgical approach is equally important. Goncharov and Kappetein showed that procedure-specific models could be a solution for more accurate risk estimation for high-risk groups.^{7,10} Yan et al. found that ejection fraction less than 35%, age, critical state, recent MI/CVA, and increased creatinine are some of the most significant variables in mortality predictions in patients undergoing CABG with a reduced EF.¹¹ When the predictive variables for outcomes after cardiac surgery remain the same, the most important factor becomes the weight of the coefficient for each variable and how it relates to the specific outcome and group of patients.⁷ Therefore, the variable coefficient determined during validation tests is critical for calibration and how close they relate to actual outcomes.^{7,10} Thus, depending on how the weight of the coefficient is calibrated, significant differences in predictions may be anticipated. Since STS recalibrates risk scores biannually based on updates from the ACSQIP, the regression coefficients within the risk prediction algorithms are not readily available.¹²

The definition of 'high risk' is subject to interpretation. In our group, patients with an EF < 40% were given this label with the understanding that this label may be misleading. Given that the regression coefficients for the STS risk algorithm are not readily available, the weight of EF determining the predicted risk remains uncertain. Equally problematic is the definition of the EF. Separate from the variability of the EF by the interpreter, the STS definition for reporting the preoperative EF to the database is an echocardiogram performed at least six months before the operation.⁴ As such, the STS database echocardiogram may (or may not) reflect the actual cardiac function at the time of surgery. In the author's opinion, the cardiac function (i.e., echocardiogram) at the time of the surgery is more relevant than any other—it provides a real-time assessment of the state of the heart at the time of the procedure. Upon reviewing the study surgeon's database, several patients were either included or excluded from the entry criteria based upon disparities between the preoperative and intraoperative echocardiographic EF. Approximately ten percent of patients were either included or excluded from the study because the intraoperative echocardiogram was significantly different from the preoperative echocardiogram. Some patients were disqualified because their preoperative EF improved at the time of surgery, while others showed deterioration in the EF, awarding them candidacy for study purposes. While the factors responsible for the EF disparities are multifactorial, the fact remains that real-time conditions may vary enough from the predictor tool and/or the database outcomes to result in the discrepancies observed.

The initial aim of this study was to analyze the PAD-CAB operation with regard to outcomes to better understand the influence of the technique in the setting of patients with a low EF.

Previous experience suggested that there may be a benefit of the PAD-CAB technique in various high-risk patients.¹³ Other investigators have observed similar advantages in a subset of patients.^{1,2,14-20} In the present study, the results were generally favorable, with three deaths reported, two of whom expired following discharge from the hospital within thirty days of the procedure. These three deaths had isolated pre-operative complications, including illicit substance abuse and ESRD which influenced their outcome. The higher observed-to-predicted reoperation rate (4.6% vs. 3.7%, $P < .001$) was due to the nature of these cases being urgent or emergent with loading dose platelet-inhibition agents present at the time of incision. The higher observed-to-predicted CVA rate (2.7% vs. 2.3%, $P < .001$) was due to the inaccurate algorithm and definition of what STS constitutes as a "permanent stroke." For example, one of the patients who suffered from a CVA post-op had a history of prior CVAs and other comorbidities, including uncontrolled diabetes, hypertension, hyperlipidemia, and stage three chronic kidney disease. While these variables were added to the STS Risk Calculator, the predicted risk of CVA postop for this patient was less than 5%. The STS language assigns a "permanent stroke" as one that does not resolve within 24 hours.⁴ The patient described resolved his neurologic condition beyond 24 hours and therefore was included in the outcome statistic. If the CVA definition were revised to exclude such patients, the outcomes would be significantly different given the small number of patients in this category.

Composite mortality or morbidity was also favorable, as well as the observed-to-expected outcomes (i.e., < 1.0). However, comparing the study patients with the STS proved to be problematic. For example, based on the study data, the STS predicted risk model for the occurrence rates of mortality, morbidity or mortality, and prolonged length of stay overpredicted the actual occurrence rate. In contrast, the STS predicted occurrence rate for CVA and reoperation underpredicted the actual occurrence rate. Although predicted occurrence rates for renal failure could not be calculated (since the observed outcome was zero) it is implied that the STS predicted occurrence rate would have overpredicted the actual occurrence rate. Furthermore, when using the ROC for comparing STS predicted scores with our findings, the STS was shown to be a poor predictor for identifying outcomes in high-risk patients with low EF undergoing PAD-CAB.

Conclusions

In summary, this is the first study to examine the STS Risk Calculator as a predictor of outcomes in patients undergoing PAD-CABG with an EF < 40% and compare the observed outcomes with the predicted risks from the STS database. There are several limitations of the study, including the absence of a PAD-CAB subcategory within the STS CABG database to afford an accurate comparison, as well as the author's decision to use a different definition for the study patient's EF based on the timing of the echocardiogram. However, the results of this analysis demonstrated favorable outcomes of the PAD-CAB technique for isolated CABG in low EF patients compared to the general population of CABG patients with EF < 40%. Further consideration for propensity-matching the study group with the STS database may help discriminate the results based on surgical technique versus demographic and other factors.

Lastly, this study exposed challenges and disparities in comparing the PAD-CAB operation to the general pool of CABG procedures in the STS database, which serves as a benchmark. Included among the reasons to acknowledge these findings is the desire to provide patients with an informed consent that takes into consideration the technique of surgery being offered. Re-calibrating risk stratification tools to include these different procedure approaches as a variable would provide a more accurate risk assessment and personalize preoperative management. This expertise can be used to counsel collective decision-making and patient concord with an ability to benchmark individual and institutional results against the national experience.

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