



RESEARCH CORRESPONDENCE



Underclassification of Predicted Risk of Mortality Using the Latest Society of Thoracic Surgeons Risk Models

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The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) is a comprehensive cardiac surgery registry that has been used to monitor quality measures of cardiac surgical programs and to develop risk models to estimate the predicted risk of mortality (PROM) of various cardiac surgical procedures.¹ The STS online risk calculator is used clinically to classify patients into different surgical risk groups, and was one of the main risk-stratifying tools used for inclusion into the major transcatheter aortic valve replacement (TAVR) clinical trials across the various risk groups. The initial STS risk model was developed in 2008 and has since undergone periodic recalibration based on updated cardiac surgical patient characteristics and outcomes.¹ The currently available STS online risk calculator was released in November 2018, with version 4.2 being the most up-to-date as of November 2020. Notably, most TAVR clinical trials used older versions of the STS risk models. In particular, version 2.81 (released in 2014) was used as the main risk-stratifying tool for inclusion into the low-risk TAVR trials.^{2,3} While the PARTNER-3 low-risk trial used a STS PROM score of <4%,² the Evolut Low-Risk Trial used a score of <3% for inclusion into the trial.³ As the growth of TAVR in low-risk patients accelerated after its approval by the US Food and Drug Administration in 2019, growing calls for caution have been raised given the lack of long-term follow-up data in this population. Relevantly, updated STS risk models have previously been shown to produce lower risk scores than earlier versions.⁴ This calls into question the possibility of continued risk creep with the existing risk models in the current era of TAVR in low-risk patients.

Following appropriate institutional review board (IRB) approval, we retrospectively reviewed 85 consecutive patients who underwent TAVR before the release of the 2018 STS online calculator at the Brigham and Women's Hospital (January–May 2017) and the Boston VA Medical Center (July–October 2018), and compared their previously calculated STS PROM using the 2014 STS risk calculator to their corresponding scores using the currently available online calculator

(Version 4.2). Due to the retrospective nature of this study the need for informed consent was waived. Mean age of patients was 80.2 ± 9.0 years. Using the 2014 STS risk model, the mean STS score was $5.2 \pm 2.6\%$. Risk stratification based on STS PROM showed that 9 patients (10.6%) were high risk, 45 (52.9%) were intermediate risk, and 31 (36.5%) were low risk. The mean recalculated STS PROM using the current STS risk calculator was now $3.5 \pm 1.7\%$ ($P < 0.001$) with 32 (37.7%) patients having their STS risk profile reclassified and downgraded (Figure 1). Of the 9 patients previously classified as high risk, 7 (77.8%) had their risk profile downgraded (5 were reclassified to intermediate risk and 2 were reclassified to low risk). Of the 45 patients previously in the intermediate-risk range, 27 (60.0%) were reclassified to low risk. The mean age of patients who are classified as low risk in the current risk model is 78 ± 9 , compared with 75 ± 11 using the previous model. Even when using a STS PROM cutoff of <3%, 26 of the 59 (44.07%) intermediate-risk patients were reclassified to low risk.

In conclusion, we found that the current STS risk model downgrades a significant proportion of patients that were previously deemed intermediate risk into a low-risk category. Such recalibration has important implications when interpreting the results of the current STS risk calculator of an individual patient, where their true surgical risk may in fact be higher. There are two possible explanations for this observed recalibration of STS scores. First, surgical techniques continue to evolve and improve, potentially resulting in improved outcomes. Second, TAVR cases now exceed surgical aortic valve replacement (SAVR) cases in the United States, and many patients who are at higher risk for surgical morbidity and mortality are now being treated with TAVR, resulting in overall lower morbidity and mortality for SAVR. While the STS PROM score continues to be an important risk stratification tool when considering patients for aortic valve replacement, the recalibration of the STS risk model must be recognized by heart teams. An individual patient's risk score in the modern era may not be reflective of their score at an earlier time point when clinical trials of TAVR were performed. This highlights the ever-growing importance of the multidisciplinary

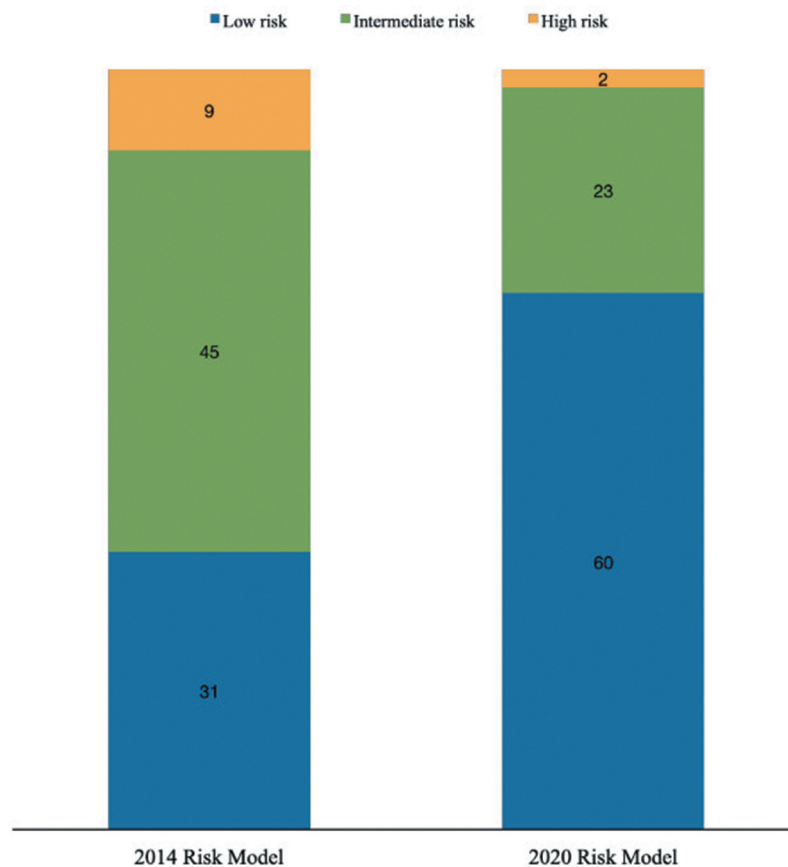


Figure 1. Comparison of number of patients reclassified into a different surgical risk group between the 2014 and current STS risk model: high risk (STS PROM > 8%), intermediate risk (STS PROM > 4 and ≤ 8%), low risk (STS PROM ≤ 4).

heart team in helping determine optimal treatment option for an individual patient, taking into account the patient's age, life expectancy, anatomic risk features on imaging, baseline coronary artery disease and need for future access, feasibility of future valve-in-valve interventions, and treatment preference. These considerations were emphasized in the recently updated 2020 ACC/AHA Heart Valve Disease Guidelines.⁵ Predicted surgical risk was only one of several factors to be considered in selecting the optimal valve replacement approach, as determined by a multidisciplinary heart team experienced in the evaluation and treatment of patients with aortic valve disease.

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