Surgical risk algorithm as a measure of successful adoption of transapical transcatheter aortic valve implantation

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Objective: This study was performed to assess the Society of Thoracic Surgeons (STS) score as a measure of successful adoption of transapical transcatheter aortic valve implantation (TAVI).

Methods: The STS score for estimated surgical mortality was calculated and used to select the first 140 consecutive patients undergoing transapical TAVI. The STS score also was used to estimate postoperative morbidity. The comparisons were made between the observed and estimated mortality and morbidity in the entire group, as well as in the first 35, second 35, and last 70 consecutive patients.

Results: The differences in outcomes between the first 35, second 35, and last 70 patients were statistically significant for surgical mortality (20.0% vs 14.3% vs 2.9%; $P = .045$), composite morbidity/mortality (34.3% vs 40.1% vs 15.7%; $P = .020$), and long length of stay (34.3% vs 45.7% vs 18.6%; $P = .027$). There were trends of marked decreases in prolonged ventilation (11.4% vs 20.0% vs 4.3%; $P = .061$), and acute renal failure (14.3% vs 20.0% vs 4.3%; $P = .059$). In the first 70 patients there were no significant differences between observed and STS estimated incidences in mortality and composite mortality/major morbidity. In the latter 70 patients the observed incidences were lower than STS predicted values in mortality (2.9% vs 9.6%; $P = .056$), composite major morbidity/mortality (15.7% vs 33.8%; $P = .001$), and prolonged ventilation (4.3% vs 25.1%; $P < .0001$).

Conclusions: Only after a protracted learning curve did the anticipated benefits of transapical TAVI materialize for patients at high risk for surgery as predicted by the STS risk algorithms. (*J Thorac Cardiovasc Surg* 2014;147:1524-8)

Transapical transcatheter aortic valve implantation (TAVI) is a new modality for the treatment of symptomatic aortic valve stenosis.¹ Clinical experience therefore remains limited and predicting the risk of morbidity and/or mortality after transapical TAVI, particularly in any one patient, is difficult. Early studies² showed the efficacy of the procedure, but a more recent randomized trial³ showed only its equivalence to surgical aortic valve replacement (AVR) in high-risk surgical patients. To date, however, the number of patients studied has been comparatively small and therefore formulation of a unique transapical TAVI risk algorithm for predicting outcomes for this procedure will have to await enrolment of a considerably larger number of patients.

In addition to experienced clinical judgment, the most commonly used cardiac surgery risk algorithm, namely

the Society of Thoracic Surgeons (STS) score, has been used to help identify nonsurgical patients and those at high risk for surgical AVR before counseling for a transcatheter approach.²⁻⁴ This study aimed to evaluate the earlier-described widely used and validated STS score risk-stratification model formulated for cardiac surgery as a measure of the anticipated benefits of transapical TAVI versus that predicted for surgical AVR.

PATIENTS AND METHODS

Between October 2005 and March 2011, a total of 140 consecutive patients underwent transapical TAVI. The patient characteristics (Table 1) were used to determine the STS score for expected surgical mortality, composite morbidity and 30-day mortality, neurologic injury, acute renal failure, prolonged ventilation, reoperation, length of stay, and sternal wound infection for surgical AVR.⁵ To evaluate the predictive value of the surgical risk algorithm for transapical TAVI, comparisons were made between the observed and estimated mortality and morbidity in transapical TAVI patients. In addition, to evaluate the impact of the learning curve on the expected better outcomes with TAVI in this high-risk surgical cohort, the study cohort was divided into 3 subgroups: first 35, second 35, and last 70 consecutive patients. The observed mortality and morbidity were compared between the 3 groups and within each group with the predicted mortality and morbidity from the STS scores.

All data were collected prospectively and were summarized using frequency and percentage for categorical variables and mean $\pm$ standard deviation for continuous variables. The χ^2 test was used to compare the observed number of events from TAVI with the expected number of events calculated from the STS scores for surgical AVR. Logistic regression analysis was performed for comparisons of the observed outcomes between the

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Abbreviations and Acronyms

AVR = aortic valve replacement

STS = Society of Thoracic Surgeons

TAVI = transcatheter aortic valve implantation

3 study groups controlling for patient risk mix as determined by the predicted outcomes from STS scores. A *P* value less than .05 indicated a statistically significant difference. All analyses were performed using SAS version 9.3 (Cary, NC).

RESULTS

The mean patient age was 79.7 ± 8.2 years and 82 of the 140 patients were women (Table 1). In the overall 140 patients, there was no significant difference between the observed mortality after transapical TAVI (10.7%) and the estimated mortality for surgical AVR by the STS score (10.0; *P* = .866) (Table 2). In addition, the STS risk algorithm was used to calculate composite surgical morbidity and mortality, and major complications including neurologic injury, renal failure, prolonged ventilation, need for reoperation, and length of stay.⁵ There were no statistical differences in permanent stroke, renal failure, length of stay, and wound infection between the estimated incidence for surgical AVR and observed values in transapical TAVI. In contrast, the STS estimated composite surgical mortality and morbidity, prolonged ventilation, and reoperation were significantly higher for surgical AVR than the observed values for transapical TAVI (Table 2).

The differences in outcomes between the first 35, second 35, and last 70 patients, controlling for corresponding predicted risk scores, were statistically significant for surgical mortality (20.0% vs 14.3% vs 2.9%; *P* = .045), composite morbidity/mortality (34.3% vs 40.1% vs 15.7%; *P* = .020), and long length of stay (34.3% vs 45.7% vs 18.6%; *P* = .027). There were trends for marked decreases in prolonged ventilation (11.4% vs 20.0% vs 4.3%; *P* = .061), and acute renal failure (14.3% vs 20.0% vs 4.3%; *P* = .059). There were no statistically significant differences between the first and second halves of the study cohort for permanent stroke or re-operation (Table 3).

For outcomes with a significant difference between the 3 study cohorts, the comparison between the observed and predicted event rate also was performed separately for each cohort. The observed surgical mortality after transapical TAVI and the STS estimated surgical mortality for surgical AVR were 20.0% versus 11.4% (*P* = .107) for the first 35 patients, 14.3% versus 9.6% for the second 35 patients (*P* = .346), and 2.9% versus 9.6% (*P* = .056) for the last 70 patients. The difference between the observed incidence of composite mortality and major morbidity and the STS estimated incidences for surgical AVR was statistically significant only in the last 70 patients. The observed and STS

predicted incidence of prolonged ventilation was significantly different in both the first 35 patients and the last 70 patients. There was a trend toward a marked decrease in the observed acute renal failure compared with the STS predicted incidence only in the last 70 patients (Table 4).

DISCUSSION

In cardiac surgery, the most commonly used risk algorithm is the STS score.⁵ This algorithm has proven to be important when it comes to predicting surgical mortality and postoperative complications in cardiac surgery. The algorithm is generated using large patient databases⁵ that incorporate characteristics related to the patient as well as the procedure, and the characteristics found to be predictive of outcomes are added to the total risk calculation when assessing any given patient's risk for a cardiac surgery procedure. Large patient databases are required because without a large sample, the prediction of uncommon outcomes including mortality is difficult.

Mortality

We used the STS risk algorithm to initially identify high-risk surgical patients for transapical TAVI and then evaluated the predictive accuracy of the same surgical risk algorithm for outcomes in an essentially nonsurgical procedure (transapical TAVI). We fully expected an immediate and obvious benefit reflected in a decreased mortality rate with transapical TAVI. Considering our entire cohort of 140 patients who underwent transapical TAVI, the STS score estimated mortality for surgical AVR was very similar to the observed mortality with apparent little benefit attributable to the transapical TAVI methodology. Indeed, the observed surgical mortality was higher than the STS predicted mortality in the first 35 and second 35 cases, with only a trend to a decrease in observed surgical mortality from the first 35 patients to the second 35 patients. There was, however, a significant decrease in observed surgical mortality from the first 70 patients to the last 70 patients despite similar patient characteristics and a similar estimated mortality by the STS score for surgical AVR. Therefore, the benefits of the transapical TAVI approach in this high-risk surgical group became evident only after the first 70 patients. This suggests a significant continuing learning curve from initially adopting to finally mastering transapical TAVI. The STS score estimated mortality for surgical AVR was 3 times higher than the observed mortality for the transapical TAVI approach in the last 70 patients (Table 4).

This study suggests that in a high-risk elderly and fragile cohort of patients with numerous comorbidities, patient risk factors initially may far outweigh any anticipated early procedural benefits, particularly if there is unfamiliarity with the procedure. This may well explain the lack of difference in mortality we observed in the first 70 patients between the

TABLE 1. Patient and procedural risk factors

Calculation of STS	Mean $\pm$ SD or number (%)
Risk factors included	
Age (y)	79.7 $\pm$ 8.2
Female	86 (61.4)
Weight/body surface area	68.3 $\pm$ 19.1/1.7 $\pm$ 0.3
Intra-aortic balloon pump/inotropes or emergency surgery	0 (0)
Left ventricular ejection fraction	53.9 $\pm$ 13.2
Renal function averaged creatinine level	120.2 $\pm$ 71.6
Creatinine level >100	72 (51.4)
Lung disease	55 (39.3)
Peripheral vascular disease	86 (61.4)
Diabetes	46 (32.9)
Neurologic dysfunction	37 (26.4)
Active endocarditis	0 (0)
Unstable angina or recent myocardial infarction	39 (27.9)
Previous cardiac surgery	74 (52.9)
Valve surgery	141 (100)
Atrial fibrillation	56 (40)
Risk factors not included	
Porcelain aorta	34 (24.3)
Hypertension	124 (88.6)
Pulmonary hypertension (not in STS): average	45.3 $\pm$ 15.8
≥ 60 mm Hg	25 (17.9)
Recent history of gastrointestinal bleeding	19 (13.6)

STS, Society of Thoracic Surgeons; SD, standard deviation.

transapical and predicted surgical approach without any initial benefit attributable to the former. The term *minimally invasive* applies to a given procedure's method of accessing the tissue of interest and may not accurately represent the insult to the patient while the procedure is being learned and perfected. The high-risk patients in this study, many deemed nonsurgical by 2 senior surgeons, went on to have a minithoracotomy, the apex of the left ventricle was

TABLE 2. Predicted versus observed postoperative mortality and morbidities in all 140 patients

30-Day mortality and morbidity	Predicted (%)	Observed (%)	P value
STS score	10.0	10.7	.866
Permanent stroke	3.6	2.9	.853
Renal failure*	10.7	10.7	1.0
Prolonged ventilation	25.9	10.0	<.001
Reoperation	13.3	5.0	.002
Major morbidity or mortality	34.8	26.4	.042
Long length of stay (>14 d)	18.3	21.4	.394
Short length of stay (<5 d)	16.2	18.6	.516
DSW infection	0.3	0	1.0

STS, Society of Thoracic Surgeons; DSW, deep sternal wound. *Renal failure was defined as meeting 1 or more of the following criteria: (1) increase in serum creatinine level to 2.0 or more times the preoperative creatinine level; or (2) new requirement for dialysis.

TABLE 3. The first 35, second 35, and last 70 patients

30-Day mortality and morbidity	Patients			P value*
	1-35	36-70	71-140	
Mortality	20.0	14.3	2.9	.045
Permanent stroke	2.9	2.9	2.9	.998
Renal failure	14.3	20.0	4.3	.059
Prolonged ventilation	11.4	20.0	4.3	.061
Reoperation	2.9	5.7	5.7	.867
Major morbidity or mortality	34.3	40.1	15.7	.020
Long length of stay (>14 d)	34.3	45.7	18.6	.027
Short length of stay (<5 d)	31.4	11.4	15.7	.063
DSW infection	0	0	0	

DSW, Deep sternal wound. *P value was obtained by logistic regression analysis, adjusting for corresponding Society of Thoracic Surgeons predicted risk.

manipulated, a large catheter was placed in the left ventricle, the stenotic aortic valve was crossed and further obstructed, and rapid ventricular pacing to reduce cardiac output induced significant hypotension during deployment of the transcatheter valve. Although perceived as minimally invasive, the early experience with a less-controlled transapical TAVI approach may in fact be physiologically more invasive in this patient group than a well-controlled circulatory supported open surgical procedure.

Risk models implicitly assume expertise of the surgeons and experience and familiarity of the team with the procedure. This study suggests that the anticipated less-complex and less-invasive procedure was perhaps initially affected negatively by the necessary learning curve that accompanies any new approach. This was indicated by the higher mortality rate found in the first 15 patients (33%) treated compared with the almost one third of the mortality rate in those patients who followed afterward,⁶ and, similarly, the mortality in the first 35 patients (20%) compared with the one seventh of the mortality rate in the last 70 patients, even though the patients had nearly identical risk profiles. The significantly improved outcomes of transapical TAVI in the later cases likely is owing to the cumulative experience of the TAVI team. Because we were among the very early adopters of transapical TAVI in human beings, our initial learning curve may have been longer than subsequent newer TAVI centers coming on board that have benefited from our experience and also availed themselves of the now available enhanced training and proctoring. Important factors that may reduce the learning curve dramatically include the following: (1) collaborative team work, (2) training and proctoring, (3) carefully screening patients for risks and contraindications, (4) meticulous attention to details during TAVI procedures, (5) a clearly discussed back-up plan for each patient, and (6) carefully monitored postoperative care.

Morbidity

We used the STS predictive risk model developed for coronary bypass surgery to assess the predicted incidence of

TABLE 4. Predicted versus observed mortality and morbidities in the first 35, second 35, and last 70 patients

30-Day mortality and morbidity	Patients								
	1-35			36-70			71-140		
	Predicted (%)	Observed (%)	P value	Predicted (%)	Observed (%)	P value	Predicted (%)	Observed (%)	P value
Mortality	11.4	20.0	.107	9.6	14.3	.346	9.6	2.9	.056
Renal failure	11.9	14.3	.661	9.4	20.0	.033	10.8	4.3	.081
Prolonged ventilation	28.2	11.4	.027	24.9	20.0	.502	25.1	4.3	<.0001
Major morbidity or mortality	38.2	34.3	.635	33.5	40.0	.418	33.8	15.7	.001
Permanent stroke	4.3	2.9	.680	3.8	2.9	.771	3.2	2.9	.872

postprocedure morbidity.⁵ This model allows for the calculation of composite morbidity and 30-day postoperative mortality, as well as postoperative neurologic injury, renal failure, prolonged ventilation, reoperation, the length of hospital stay, and sternal wound infection. Interestingly, the STS risk algorithm seems to predict the incidence of postoperative stroke in transapical TAVI regardless of the purported learning curve. The incidence of stroke at 30 days postprocedure in this study was similar to that predicted by the algorithm for surgical AVR for all patient cohorts and similar to the results recently reported in a randomized controlled trial with transcatheter valves.³ The length of hospital stay is subjective and also dependent on many additional factors such as the availability of a social support program, presence of an intermediate-care facility, and the medical insurance systems. Despite these factors, the rate of long length of stay still decreased significantly after the first 70 cases compared with the predicted value by the STS surgical risk algorithm. Similar to the trend of surgical mortality in this study, the significant decrease in composite mortality and major morbidity was observed only after the first 70 cases. Other surgical morbidities, such as prolonged ventilation and acute renal failure, also were markedly lower than the predicted values by the STS risk algorithm because the procedure was learned and better exercised. This study has shown that not only surgical mortality but also major morbidities have to be considered when assessing the successful adoption and mastering of any new surgical procedure, such as transapical TAVI. Compared with previous studies,⁷ the uniqueness of this study was in the comparison of the predicted values by the surgical STS score with the observed values for both mortality and morbidity as an indicator of successful adoption and mastery of the procedure.

In this study, our threshold to master the transapical procedure was a learning curve of approximately 70 cases. Generally speaking, 70 cases is not a large number to master a new complex surgical procedure, such as transapical TAVI. Other approaches, such as direct aortic and subclavian artery approaches, may have relatively shorter learning curves. However, after mastering the transapical approach, we believe that the direct aortic or

subclavian artery approach is not necessarily an easier alternate access option compared with the transapical approach.

Limitations

Patient frailty, a frequently used descriptor, was assessed subjectively by experienced cardiac surgeons, but not standardized with a frailty index in these patients. Frailty, readily recognized but hard to define or quantitate, also is not included in the STS risk algorithm. Therefore, this patient characteristic may not have been the same in all 3 study groups despite similar STS scores. Furthermore, other risks such as severe chronic obstructive pulmonary disease, severe peripheral vascular disease, calcified ascending aorta, dementia, and prolonged preoperative hospitalization were not included or weighted appropriately in the STS surgical risk algorithm, which might have resulted in differences in patient characteristics among the 3 study groups. Our subjective patient selection criteria might indeed have evolved over time, however, the predicted mortality by the objective STS score remained similar among subgroups. Finally, because of our early introduction to clinical transapical TAVI, the prolonged learning curve suggested by this study may no longer be applicable to many new centers that can benefit from the now available detailed proctoring and intense training. Proctoring and training likely shortens the initial learning curve, but may not significantly shorten the course of mastering the procedure.

SUMMARY

The risk stratification model used to predict outcomes in cardiac surgery is based on patients undergoing sternotomy, cardiopulmonary bypass, cross-clamping of the aorta, cardioplegia of the heart, opening of the aorta, excising of the sclerosed valve, implanting a new aortic prosthesis, closure of the aorta, and discontinuance from cardiopulmonary bypass. It is reasonable to assume then that the risk algorithms would overestimate the observed morbidity and mortality in the presumed less-invasive transapical TAVI procedure. However, the expected overestimation did not materialize when we compared the predictions made on

the basis of a much more invasive risk model with our observed experience with transapical TAVI in the first 70 patients. Once the nuances of the procedure were mastered and experience was gained with trouble spots, as in our last 70 patients, we seemed more able to better capitalize on the benefits to be reaped from the less-invasive transapical TAVI.

The number of patients treated with TAVI, both transapical and transfemoral,⁸ remains comparatively small and there are limited data from which to generate unique risk algorithms for this procedure. Our study indicates that the most commonly used STS surgical risk algorithm fails to predict outcomes for transapical TAVI, particularly after the transapical procedure has been mastered. Therefore, the STS cardiac surgery risk algorithm may be used as a gauge to indicate institutional program position along the learning curve of transapical TAVI. Agreement between observed and predicted surgical risk of mortality, renal failure, prolonged ventilation, and composite major morbidity and mortality suggests a need for further learning. Consistent significant overestimation of the earlier-described morbidities and mortality by the STS surgical risk algorithm suggests successful adoption

and mastering of transapical TAVI or similarly any new less-invasive technology.

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