Is Surgical Intervention the Optimal Therapy for the Treatment of Aortic Valve Stenosis for Patients With Intermediate Society of Thoracic Surgeons Risk Score?

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Background. Patients at intermediate risk (IR) according to The Society of Thoracic Surgeons risk score are today frequently oriented toward the transfemoral aortic valve replacement (TAVR) option. Our goal was to evaluate the best treatment strategies for IR patients with severe aortic stenosis.

Methods. Of a consecutive series of 1,144 surgical aortic valve replacements (AVRs) performed in our institution between 2008 and 2014, we reviewed the early and late outcomes of two different groups: a low-risk (LR) group of 470 patients, and an IR group of 620. We eliminated from the analysis 54 high-risk patients who were currently candidates for TAVR. All patients underwent surgical AVR with or without concomitant coronary artery bypass grafting. Social Security database interrogation provided long-term information.

Results. The early mortality rate (30 days) between LR and IR patients was similar (1.70% vs 2.74%, $p = 0.25$) and both lower than predicted mortality rates. However, cumulative 5-year survival was significantly higher in LR patients (86.3%) than in IR patients (75.4%; $p = 0.0007$ by log-rank test), although excellent in IR group. Comparing IR survivors and nonsurvivors, ages at operation were 69.5 ± 12.7 years for survivors vs 75.4 ± 9.6 years for those experiencing late deaths ($p = 0.002$). Risk factors for late deaths after multivariate analysis were age, hemodialysis, and chronic lung disease.

Conclusions. Most IR patients today should undergo surgical AVR, but because of survival rates combined with still unavailable late structural deterioration rates in TAVR valves, patients in the IR group with high Society of Thoracic Surgeons scores and known risk factors may be better served with TAVR as data regarding late percutaneous valve function accrue.

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Surgical aortic valve replacement (SAVR) is still the standard of care to treat calcified aortic stenosis, the most common valve disease in the United States, found in 2% to 5% of the elderly population. When untreated, symptom progression increases, and the median survival is 2 years once heart failure symptoms settle in, with no satisfactory medical therapy options [1].

Since transcatheter aortic valve replacement (TAVR) technologies were approved and commercialized to treat aortic stenosis [2, 3], surgical options have shifted over a few years to the point that patients with high predictive risk of operative death (Society of Thoracic Surgeons [STS] Predicted Risk of Mortality [PROM] score >8) are offered today almost systematically a TAVR. Over time and after publications of progressively better results after TAVR, including in the long-term [4, 5], a number of structural heart teams are now proposing TAVR in some patients with an intermediate STS PROM risk score (between 4 and 8), and this trend is likely to grow in the future.

Although the TAVR literature is abundant, it is also noticeable that the role of coronary artery disease (CAD) in patient's outcomes seems to be underestimated, because significant CAD is present in up to 50% of patients with symptomatic aortic stenosis [6].

Our main objective with this work was to look at our own "real world" in an active single center to analyze what is currently the optimal therapy for patients with aortic stenosis and who are in the large intermediate-risk (IR) PROM group. More specifically, we tested the hypothesis that most of the patients within the IR group

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could still benefit from a traditional SVR, whereas some patients with identifiable risk factors could enjoy better long-term outcomes through alternatives like TAVR.

Material and Methods

Our Mission Health Institutional Review Board (Asheville, NC) approved the study and waved the need for informed consent.

Study Patients

We evaluated all adult patients who underwent SAVR for aortic stenosis, with or without concomitant coronary bypass grafting (CABG), in our institution between January 1, 2008, and June 30, 2014. A consecutive series of 1,144 SAVRs was identified, as patients and procedures data were entered prospectively in our in-house STS database up until the patient's discharge. We then retrospectively analyzed the patients' data and procedures extracted into our clinical research department database from STS database V 2.61 and 2.73.

We reviewed and compared the early and late outcomes of two groups of patients: a low-risk (LR) group (PROM score <4) of 470 patients (41%) and an IR group (PROM score >4 and <8) of 620 patients (54%). We eliminated from analysis 54 high-risk patients (5%), with PROM score exceeding 8, who were currently candidates for TAVR. The review included patients who underwent a prior aortic valve or CABG procedure, but those undergoing SAVR associated with any other valve operation were excluded.

Surgical procedures have remained stable over the years, with a standardized technique among the surgical team. The approach was through a midline sternotomy and cardiopulmonary bypass with moderate hypothermia and retrograde and antegrade cardioplegic arrest. Distal coronary anastomoses were generally created first, with valve replacement performed next. After the valve procedure was completed, proximal anastomoses, when needed, were performed under cross clamp, followed by reperfusion and rewarming. A bioprosthesis was the substitute valve in more than 85% of the cases. Late follow-up was obtained after querying the Social Security Death Index up to April 1, 2015.

Statistical Analysis

For continuous variables we used mean with SD or median with interquartile ranges, as appropriate, along with frequencies and percentage for categoric variables. Between-group comparisons used t tests and Fisher exact test or χ^2 tests, when appropriate, with the statistical significance set at a two-tailed p value of 0.05.

Early morbidity was computed by frequencies with the 95% confidence interval (CI) and early and long-term mortality was analyzed by logistic regression and multivariate analysis to adjust for numerous baseline confounders and to identify independent predictors of death. Univariate odds ratios and their 95% CIs were computed using univariate logistic regression in R software (The R Foundation for Statistical Computing, Vienna, Austria). Variable selection for predicting late death was done using multivariate logistic regression. Finally, actuarial survival (Kaplan-Meier) was computed for long-term survival analysis, and comparisons between the two groups were assessed by log-rank test. All tests were performed using Statistica 13 software (StatSoft, Tulsa, OK).

Results

Perioperative Outcomes

Table 1 reports the baseline data in the LR and IR groups. The IR patients (n = 620), as expected, were significantly different, with generally more and more severe comorbidities. They were older (59% aged >70 years and 27% were >80 years), had a higher preoperative creatinine level, more frequent diabetes, hypertension, chronic lung disease, peripheral vascular disease, prior CABG operations, valve operations, and myocardial infarctions. Objectively, their ejection fraction was lower, as was their mean transaortic pressure gradient. The incidence of redo operations was also higher in this IR group, and CABG concomitant to SAVR was more frequent than for LR patients (55.3% vs 44.7%, $p < 0.001$), so that cardiopulmonary bypass and aortic exclusion times were longer, and hospital and intensive care unit lengths of stay

Table 1. Baseline Characteristics in Intermediate-Risk and Low-Risk Groups

Variable[a]	IR Group (n = 620)	LR Group (n = 470)	p Value
Age, y	70.30 ± 12.47	67.43 ± 10.73	<0.001
BMI, kg/m^2	28.93 ± 6.33	29.42 ± 6.15	0.1991
Creatinine, mg/dL	1.13 ± 0.61	0.95 ± 0.29	<0.001
Diabetes	132 (28.09)	218 ± (35.16)	0.0132
Hypertension	514 (82.90)	367 (78.08)	0.0454
Chronic lung disease	77 (12.00)	37 (7.87)	0.0058
PVD	111 (17.90)	31 (6.59)	<0.001
Prior			
TIA[b]	25 (4.03)	25 (5.31)	0.0146
CABG	71 (11.45)	24 (5.10)	0.2209
Valve operation	61 (9.81)	24 (5.10)	0.6831
PCI	73 (11.77)	36 (7.65)	0.3642
MI	126 (20.32)	34 (7.23)	<0.001
Ejection fraction	0.5048 ± 0.1079	0.5312 ± 0.0851	<0.001
Aortic valve area, cm^2	0.85 ± 0.52	0.83 ± 0.58	0.7706
Mean gradient, mm Hg	41.80 ± 17.80	46.77 ± 15.96	<0.001
Mean STS PROM score	0.041 ± 0.012	0.017 ± 0.06	<0.001

[a] Continuous variables are reported as mean ± SD and categoric variables as frequencies (%). [b] More common in LR group.

BMI = body mass index; CABG = coronary artery bypass graft; IR = intermediate risk; LR = low-risk; MI = myocardial infarction; PCI = percutaneous coronary intervention; PVD: peripheral vascular disease; STS PROM: The Society of Thorac Surgeons Predictive Risk of Mortality; TIA = transient ischemic attack.