Transcatheter or Surgical Aortic Valve Replacement in Patients With Prior Coronary Artery Bypass Grafting

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Background. **Transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) are treatment options for aortic stenosis in patients with prior coronary artery bypass graft surgery. We assessed the major clinical outcomes of such patients enrolled in the CoreValve High Risk (CHR) study.**

Methods. **Of the 795 CHR study patients, 226 had prior coronary artery bypass graft surgery; 115 underwent TAVR and 111 underwent SAVR. The primary endpoint was a comparison of all-cause mortality at 1 year. Important secondary clinical endpoints were assessed.**

Results. **At 1 year, all-cause mortality was 9.6% for TAVR versus 18.1% for SAVR ($p = 0.06$); cardiovascular mortality was 7.0% for TAVR versus 13.8% for SAVR ($p = 0.09$). A combination of The Society of Thoracic Surgeons risk score greater than 7 and age greater than 80 years was a significant predictor of mortality, with TAVR demonstrating a survival advantage ($p = 0.03$). No differences were seen for stroke. The SAVR group had longer intensive care unit and hospital stays, increased incidence of acute kidney injury, life-threatening or disabling bleeding, and major adverse cardiac and cerebrovascular events ($p < 0.05$). Pacemaker implantation and paravalvular regurgitation were greater with TAVR at all timepoints.**

Conclusions. **For patients with prior coronary artery bypass graft surgery and aortic stenosis, TAVR offers a significant morbidity advantage and a strong trend toward improved survival over SAVR at 1 year.**

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Surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) are treatment options for patients with severe aortic stenosis. Recent success with TAVR has changed the standard treatment paradigm for patients at elevated risk for open SAVR [1–3]. Patients with coronary artery disease (CAD) who have undergone coronary artery bypass graft surgery (CABG) and subsequently have symptomatic aortic stenosis are often elderly and have many comorbidities [1–3]. Although SAVR after CABG can result in excellent outcomes, the operations can be technically challenging. Furthermore, SAVR after previous cardiac surgery, including CABG, has an increased risk of morbidity and mortality compared with that observed after primary SAVR [3–13].

The impact of prior CABG after TAVR is less clear. Coronary artery disease treated by percutaneous coronary intervention or CABG increases the risk of morbidity and mortality after TAVR using the transfemoral or transapical approach [14]. However, some studies have demonstrated no impact of prior CABG [15–18]. Published studies have not demonstrated a survival advantage for TAVR or SAVR in patients with aortic stenosis and prior CABG who require AVR [18–20]. Greason and colleagues [19] reviewed the high-risk patients who underwent SAVR or TAVR in Cohort A of the Placement of Aortic

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Abbreviations and Acronyms

AVR = aortic valve replacement
CAD = coronary artery disease
CABG = coronary artery bypass graft surgery
CHR = CoreValve High Risk
IABP = intraaortic balloon pump
KCCQ = Kansas City Cardiomyopathy Questionnaire
NYHA = New York Heart Association
PROM = predicted risk of mortality
PVL = paravalvular leak
SAVR = surgical aortic valve replacement
STS = The Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement

Transcatheter Valves (PARTNER) trial. They found no differences with respect to the outcomes of death, stroke, and myocardial infarction; however, TAVR patients had more paravalvular regurgitation. At 2 years, there was a trend toward greater all-cause mortality among TAVR patients, and they had a higher incidence of repeated hospitalization, composite outcomes of death from any cause or repeated hospitalization, and death from any cause or stroke [19].

The CoreValve High Risk (CHR) study compared TAVR using the self-expanding CoreValve (Medtronic, Minneapolis, MN) transcatheter aortic valve bioprosthesis with SAVR for patients at an increased risk of death and demonstrated TAVR patients had improved survival at 1 year [1]. Approximately 30% of the patients had undergone prior CABG but this variable was not analyzed. In light of conflicting literature, we sought to further evaluate the outcomes of patients with previous CABG in the CHR study.

Patients and Methods

The CHR study was a randomized clinical trial of 795 high-risk patients with severe aortic stenosis randomly assigned to either SAVR or TAVR at 45 clinical sites. Institutional Review Board approval and informed consent were obtained at each site. From the initial cohort, we identified 226 patients who had CABG before TAVR (n = 115) or SAVR (n = 111). An analysis of the clinical outcomes of this subset of patients was performed. The CHR study design, definitions, and outcomes have previously been reported [1]. The primary endpoint was all-cause mortality at 1 year. Important secondary clinical endpoints were also assessed.

Statistical Analysis

Categoric variables were compared using Fisher's exact test or the χ^2 test. Continuous variables were presented as mean (±SD) and compared using Student's t test. Kaplan-Meier estimates were used to construct the survival rates based on available follow-up for time-to-event analyses. The Cox proportional hazards model was used to determine the association between baseline characteristics and mortality rate. Statistical analysis was performed with SAS software, version 9.2 (SAS Institute, Cary, NC). The analysis population was the as-treated population.

Results

Patient Characteristics

Baseline patient demographics and clinical characteristics are shown in Table 1, and cardiac characteristics are shown in Table 2. There were no significant differences between the TAVR group and the SAVR group. Specific cardiac characteristics are presented in Table 2. There were no differences in anatomic factors such as aortic calcification, chest wall deformities, or a hostile mediastinum that might impact surgery.

Mortality

There was no statistically significant difference in all-cause or cardiovascular mortality at 30 days (TAVR 3.5%, SAVR 6.3%; $p = 0.33$ for both). At 1 year there was a trend toward improved survival in the TAVR group (all-cause mortality: TAVR 9.6% versus SAVR 18.1%, $p = 0.06$; cardiovascular mortality: TAVR 7.0% versus SAVR 13.8%, $p = 0.09$; Table 3 and Fig 1). The observed to expected mortality ratio (O/E) based on The Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM) was less than 1 in both groups (SAVR 0.79 [6.3/8.0]; TAVR 0.48 [3.5/7.3]), indicating better than expected outcomes.

Predictors of Mortality at 1 Year

The Cox proportional hazards model was used to determine the association between each baseline characteristic and the mortality rate at 1 year, with baseline characteristics, treatment, and the interaction between them included in the model. Some baseline characteristics were independent predictors of all-cause mortality. Univariable predictors of mortality at 30 days and one year included a European System for Cardiac Operative Risk Evaluation score greater than 20% (14.9% versus 3.7% for TAVR, 22.0% versus 13.6% for SAVR, $p = 0.04$), peripheral vascular disease (15.2% versus 4.6% for TAVR, 22.8% versus 13.5% for SAVR; $p = 0.03$), left ventricular diastolic dysfunction grade II to IV (13.3% versus 4.3% for TAVR, 29.7% versus 11.8% for SAVR; $p < 0.01$). Age 80 years or less and STS risk score were not significant predictors. A combination of STS PROM score of greater than 7% and age more than 80 years was a significant predictor of mortality, with a survival advantage for TAVR ($p = 0.04$).

Adverse Events

Table 4 presents adverse events. The combined endpoint of all-cause mortality or major stroke occurred more frequently with SAVR (21.8%) than TAVR (11.4%) at 1 year ($p = 0.04$; Fig 2). Similarly, major adverse cardiovascular and cerebrovascular events, which included all-cause death, myocardial infarction, all strokes, and all