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Original Article

Outcomes After Transcatheter Aortic Valve Replacement: A Propensity Matched Retrospective Cohort Study

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Objectives: To examine patient acuity and perioperative outcomes in a contemporary cohort of patients undergoing either transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR).

Design: A retrospective propensity-matched cohort study with univariable logistic regression to assess postoperative outcomes.

Setting: Hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program.

Participants: The study comprised 2,043 patients who underwent either TAVR or SAVR that was reported in the American College of Surgeons-National Surgical Quality Improvement Program.

Interventions: None.

Measurement and Main Results: Age greater than 65 years, patients with dyspnea with moderate exertion or dependence in activities of daily living, high American Society of Anesthesiologists physical status classification, and history of chronic obstructive pulmonary disease were associated with TAVR, whereas body mass index greater than 25 was associated with SAVR. After propensity matching, no differences in 30-day mortality, length of stay, or most postoperative outcomes were observed between the 2 cohorts. Patients undergoing TAVR were less likely to require a perioperative blood transfusion and on an individual patient basis had a lower number of complications than patients in the SAVR group.

Conclusions: Patients undergoing TAVR have similar mortality, length of stay, and risk for postoperative complications as do patients undergoing SAVR, but patients undergoing TAVR are less likely to have blood transfused.

Key Words: cardiac surgery; transcatheter aortic valve replacement; TAVR, outcomes; anesthesia; mortality

AORTIC STENOSIS that manifests with the classic symptoms of angina, syncope, or dyspnea is associated with significant short- and medium-term mortality, with a mortality rate of up to 50% of patients with angina, syncope, or dyspnea symptoms deceased in 5, 3, and 2 years, respectively.[1] Historically, however, up to one third of patients with indications for aortic valve replacement were unable to undergo surgery due to excessive surgical risk.[2,3] Over the past 15 years, new methods of transcatheter aortic valve replacement (TAVR) have been developed, allowing for patients previously deemed at excessive surgical risk to undergo aortic valve replacement. Beginning with the PARTNER trial, several randomized controlled trials have

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demonstrated noninferiority between TAVR and surgical aortic valve replacement (SAVR), allowing for gradual expansion of this treatment modality to lower-risk cohorts.[4–7] As a result of these studies, the 2014 American College of Cardiology/American Heart Association valvular heart disease guidelines provided a class I recommendation for TAVR in patients who have prohibitively high surgical risk.[8]

However, during the development of this percutaneous approach to aortic valve replacement, conflicting data emerged regarding the risk of neurologic injury, acute kidney injury, and the overall benefit to hospital length of stay.[9–17] Even though numerous randomized controlled trials have been published, significant heterogeneity in their study designs, inclusion and exclusion criteria, specific interventions and postoperative monitoring, and definition of adverse postoperative events have made it more difficult to draw conclusions regarding the superiority of one approach over the other. While longer-term outcomes remain of interest, the perioperative period represents a time of significant risk and morbidity, with postoperative complications significantly increasing total costs of hospitalization.[18–20] Several recent studies have raised questions regarding the cost-effectiveness of TAVR among lower-risk patients.[21–23] As the use of TAVR expands into low- and intermediate-risk patients, additional insight is needed into the benefits and limitations of TAVR in real-world clinical practice.

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) is a large, well-validated, national database that was developed to help improve the quality of surgical care.[24,25] Given the need for additional insights into contemporary TAVR practice and clinical outcomes, especially when data are pooled from a large number of hospitals, we used this database to assess the variability in patient acuity between cohorts undergoing TAVR and SAVR and analyze whether the use of TAVR would result in improved perioperative outcomes. The primary hypothesis was that the TAVR cohort would have improved 30-day mortality compared with the SAVR cohort. The secondary hypotheses were that the TAVR cohort would have improved 30-day outcomes and reduced hospital length of stay compared with those of the SAVR group.

Methods

The ACS NSQIP is a data registry consisting of de-identified cases reported from approximately 600 different participating sites.[26] Institutional review board approval was obtained for analysis of the data and was exempted from the consent requirement due to the de-identified nature of the data. The authors retrospectively examined abstracted information for patients undergoing TAVR and SAVR between January 1, 2013, and December 31, 2015.

Patient Selection

For this study, the 2013 to 2015 ACS NSQIP data were compiled into a single data file containing 328 variables across 2,287,389 surgical cases and queried for cardiac surgery cases. TAVR and SAVR cases were included based on their current procedural terminology codes, as shown in Figure 1. Excluded from the analysis due to exclusion from participation in ACS NSQIP were all patients younger than 18 years at the time of surgery; trauma cases; transplantation surgeries; and all cases in which the patient was listed as an American Society of Anesthesiologists physical status class 6, representing a brain-dead organ donor. In addition, concurrent cases, defined as cases performed by a different surgical team using the same anesthetic were only reported as a single procedure. NSQIP data entry is performed by trained surgical clinical reviewers and undergoes an auditing process including ongoing assessment of inter-rater reliability.[27,28] Previous studies have demonstrated the data to be valid and accurate compared with comparative data sets.[29–31]

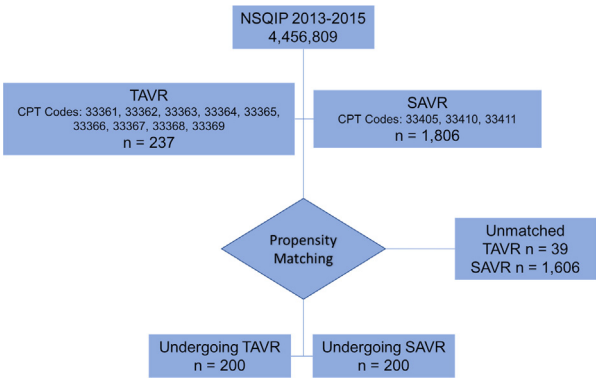

Fig 1. Data inclusion and exclusion criteria.

Statistical Analysis

Baseline, preoperative demographic and clinical characteristics, index procedure characteristics, and the postoperative course were analyzed. TAVR and SAVR cohorts were defined based on current procedural terminology codes as listed in Figure 1, resulting in an initial cohort of 237 TAVR and 1,806 SAVR procedures. Initial comparison of the cohort undergoing TAVR was performed using the Student *t* test for continuous variables and the chi-square test for categorical variables along with conditional univariable logistic regression. To develop the matched cohort, this initial data set was analyzed for statistically significant associations defined as a p value of $<$ 0.05 on Student *t* or chi-square testing as previously described or a 95% confidence interval (CI) not containing 1.0 on logistic regression. These covariables were incorporated into a propensity score model, before matching. For matching, a 1:1 greedy nearest neighbor matching strategy was used, resulting in successful matching of 200 TAVR cases to 200 SAVR cases. Successful matching was assessed using Student *t* test for continuous variables and Pearson's chi-square test for categorical variables along with univariable logistic regression. The association between TAVR and patient outcomes was assessed in this propensity-matched cohort using multivariable logistic regression incorporating the exposure and any

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