Transcatheter Aortic Valve Replacement: Does It Work and Can We Afford It?

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Since the first procedure was performed just over a decade ago, transcatheter aortic valve replacement (TAVR) has emerged as one of the most significant innovations in cardiovascular medicine since the introduction of percutaneous coronary intervention. Quantitatively, this has been demonstrated by penetration rates of >35% in countries such as Germany and Switzerland. The number of novel devices being developed and the volume of patients being treated continue to expand at exponential rates in both Europe and North America. Intense enthusiasm from the cardiovascular community and the medical industry has driven several multi-institutional registries and randomized controlled trials to assess the clinical- and cost-related outcomes of TAVR in various patient populations.

Clinical Outcomes of TAVR

Clinical outcomes of TAVR should be considered in relation to the patient risk profile and the comparator. The Placement of AoRTic TraNsclathER Valve (PARTNER) B trial reported significantly superior survival outcomes and reduced hospitalizations for ineligible surgical candidates who underwent TAVR, at the cost of higher stroke rates, when compared with medical therapy. For high-risk surgical candidates a recent meta-analysis demonstrated similar overall survival and stroke outcomes for patients who underwent TAVR or surgical aortic valve replacement. TAVR was more likely to result in the need for a permanent pacemaker insertion, major vascular injury, and moderate or severe aortic regurgitation. However, patients who underwent surgical aortic valve replacement were more likely to experience major bleeding. These end points, as well as others such as myocardial infarction and renal failure, have been quantitatively defined by the Valve Academic Research Consortium to facilitate direct comparisons between treatment arms and institutions.

Randomized Controlled Trials

To date, 3 randomized controlled trials have been reported on the comparative outcomes of TAVR versus surgical aortic valve replacement. Results of the PARTNER A trial demonstrated similar survival and stroke outcomes at 1 and 2 years using the Sapien (Edwards Lifesciences) balloon-expandable device. More recently, the US CoreValve High Risk Study reported superior overall survival for TAVR at 12 months using the self-expandable CoreValve (Medtronic) device, with similar stroke outcomes. The STACCATO trial, which remains to be the only trial not sponsored by medical industry, was prematurely terminated by the Data Safety Monitoring Board due to unexpectedly poor outcomes in the TAVR arm. Despite this, the overall encouraging outcomes from these randomized trials and other observational data have driven the recruitment of lower risk patients for current trials that aim to expand the clinical indication for TAVR. Results from the PARTNER-2 and SURTAVI trials will no doubt provide further valuable clinical evidence for patients who are considered to have intermediate risk for surgery (4%-8% mortality) based on their Society of Thoracic Surgeons scores.

Cost-Effectiveness of TAVR

With increasing budget constraints, economic evaluation has become increasingly important in clinical practice guidelines and performance standards, as emphasized by the American Heart Association and the American College of Cardiologists. Cost-related reports on TAVR have to date been largely based on economic models that relied heavily on data from the PARTNER trials. A recent systematic review concluded that TAVR may be economically justifiable when compared with medical therapy for ineligible surgical candidates according to reported incremental cost-effectiveness ratios. However, for high-risk patients who were eligible for surgery, the evidence was not as strong, and significant variations were identified depending on the specific healthcare system setting, procedural approach, and patient selection process. Perhaps one of the most important determinants of the overall cost, other than the transcatheter valve device itself, was the incidence of periprocedural complications. Several studies reported sensitivity analyses that predicted significant improvements in the cost-effectiveness of TAVR if it could be performed with lower periprocedural morbidity and mortality.

Costs Related to Complications

In this issue of Circulation: Cardiovascular Interventions, Arnold et al presented multivariable models using detailed data from 406 of 519 (78%) participants from the PARTNER trial to estimate the independent impact of periprocedural complications on in-hospital costs and duration of hospitalization for patients who underwent TAVR. The authors should...
be congratulated for identifying this important area of interest and conducting a novel and thorough evaluation of specific periprocedural complications. Using the available data, the authors found that 49% of patients had ≥1 complication during their index hospitalization. Patients who encountered a complication were more likely to be women and belonging to cohort B, but less likely to have had previous coronary artery bypass graft surgery. For these patients, the unadjusted incremental cost was $33,196, with an incremental duration of hospitalization of 6.6 days, significantly higher than those patients who did not have a complication. Specifically, 7 complications were found to be associated with significant increases to hospitalization costs according to a multivariable model that adjusted for demographic and clinical characteristics. These included a repeat TAVR procedure, death, renal failure, major bleeding, surgical conversion, major stroke, and major arrhythmias. Death, renal failure, major bleeding, vascular complications, major arrhythmia, and pacemaker implantation were the complications most predictive of a prolonged length of stay, and an estimated 2.4 days of the overall duration of hospitalization were directly attributable to periprocedural complications.

**Key Findings and Future Directions**

Findings from this study have answered some questions, but raised others. Periprocedural complications happened frequently in the PARTNER trial, as acknowledged by the authors, and accounted for a quarter of the non-implant–related in-hospital costs. These findings suggest that there is room for improvement in the cost-effectiveness of TAVR, especially when considering the learning curve encountered by some participating institutions within the PARTNER trial. As the authors suggested, growing procedural experience and evolving technology may significantly reduce periprocedural morbidity and mortality, and therefore improve cost-effectiveness. In addition, by identifying the most costly complications, results of this study may shift focus toward formulating clinical pathways to minimize these morbidities, either by altering clinical management or by revising patient selection. Additional studies will no doubt focus on these high-yield areas to make TAVR a more affordable treatment modality within healthcare systems. With accumulating data, it may soon be possible to predict patients who are more likely to encounter a particular periprocedural complication based on a range of baseline prognostic factors. From a health administration perspective, this may help facilitate the selection process to offer the TAVR procedure to candidates who are more likely to have cost-effective outcomes. To ensure patient safety and economic sustainability, further robust clinical and cost-related data need to be presented before TAVR is performed outside of its current indications.

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**Disclosures**

None.

**References**


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