Cost-Effectiveness of Transcatheter Aortic Valve Implantation Versus Surgery for High-Risk Patients With Aortic Stenosis

PARTNER (Placement of Aortic Transcatheter Valve Trial) remains the only randomized-controlled trial to compare transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (AVR) for patients with severe aortic stenosis (1–3). The survival, symptomatic, and cost benefits of TAVI compared to medical therapy in inoperable patients has been previously demonstrated (2,4). However, optimal treatment for “high-risk” patients remains controversial, and there is conflicting evidence on the cost-effectiveness of TAVI compared to AVR in different healthcare settings.

Reynolds et al. (5) should be commended on their economic evaluation of TAVI versus AVR based on a modified intention-to-treat cohort of 647 patients from the PARTNER A trial, which represents the first cost analysis to separately assess the transfemoral (TF) and transapical (TA) approaches. Results of this study reported that the entire TAVI cohort did not demonstrate significant differences in cost-effectiveness compared with AVR. However, when stratified according to access site, patients who underwent the TF approach were more likely to be economically attractive compared with AVR than the TA approach. This finding partially reflects the “transfemoral-first” patient selection process utilized in a number of institutions. Compared with the TF group, the TA group had increased comorbidities, which translated into higher perioperative mortality and morbidity and therefore reduced cost-effectiveness.

Some limitations of this study should be discussed. Firstly, major bleeding is known to be more likely after AVR than TAVI, and has been emphasized in the study. However, complications that are more likely to be associated with TAVI, such as stroke, atrioventricular block necessitating pacemaker, significant aortic regurgitation, and conversion to AVR, were not closely examined (6). Secondly, the assumption that TAVI is performed in the catheterization laboratory setting for the TF approach may not be applicable to centers where TAVI is performed in hybrid theaters, which is often the case in institutions learning this procedure. Most importantly, the cost-effectiveness of TAVI compared with AVR is largely dependent on the cost and duration of postoperative hospitalization. It has been shown that patients who undergo surgery have a longer length of hospitalization compared with TAVI, and this increase in cost largely offsets the more expensive cost of the TAVI valve device. For patients who underwent AVR in the PARTNER trial, the mean hospitalization was 16 days, which was comparatively longer than other studies involving high-risk candidates (7). In addition, the cost of hospitalization is much higher in the United States compared with other countries, favoring the cost benefit of TAVI. This was demonstrated by Neyt et al. (8) and Osnabrugge et al. (9), who reported incremental cost-effectiveness ratio (ICER) values of US$975,697 and US$232,128 in Belgium and the Netherlands, respectively, compared with US$76,877 reported by Reynolds et al. (5).

In conclusion, Reynolds et al. (5) provided insightful data that compared TF and TA approaches of TAVI with AVR. However, follow-up was relatively short at 12 months and a number of complications associated with TAVI might have been neglected. Their findings were based on the American healthcare system and may be less applicable to other countries. Nation-specific economic assessments should be performed in the future and a systematic review of the cost-effectiveness of TAVI may be warranted.

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http://dx.doi.org/10.1016/j.jacc.2012.11.066

REFERENCES

**Reply**

As Dr. Cao and colleagues point out, our recently published cost-effectiveness analysis, based on patient-level data from the PARTNER (Placement of Aortic Transcatheter Valves Trial) (1) has some important limitations. Our analysis used a 12-month timeframe. From a health economic perspective, this analytic timeframe is similar to an analysis that assumes that long-term outcomes between study groups will be comparable. Although there is presently no empirical evidence suggesting otherwise, this remains an unproven assumption, which we explicitly noted in the manuscript.

Also correctly noted was the fact that hospital length of stay (LOS) was shorter after transcatheter aortic valve replacement (TAVR) than after surgical aortic valve replacement (AVR), and the savings associated with reduced LOS play a key role in offsetting the higher acquisition cost of a transcatheter valve. The LOS following surgical AVR in the PARTNER trial was indeed long—about 6 days longer than average LOS for AVR for all U.S. patients (2). We believe the long LOS after surgical AVR in the PARTNER trial was primarily related to the unique risk profile of the patient population, who represent the highest 5% to 8% risk of patients operated on for aortic stenosis in the United States. Based on recent publications, it is clear that “high-risk” patients who currently undergo TAVR in other countries tend to be lower risk than those who were studied in the PARTNER A trial. For example, the SOURCE-XT registry of 2,700 consecutive patients undergoing TAVR in 17 countries enrolled patients with a mean Society of Thoracic Surgeons (STS) mortality risk of 8.5% (4) whereas the PARTNER trial population had a mean STS mortality risk of 11.8% (3). Moreover, as we noted in our discussion, even for similar patients, clinical results and resource utilization patterns may differ across healthcare systems. We agree that country-specific analyses are needed, but we are concerned about conclusions reached by comparing non-randomized groups (5). In the absence of randomization, careful risk adjustment is required to reach balanced conclusions.

Finally, it is not correct to state that our analysis ignored or neglected complications associated with TAVR. For the TAVR and AVR groups in the trial, we measured costs for index and follow-up hospitalizations primarily by collecting and analyzing hospital bills from the enrolling centers. Thus, while we have not yet reported the excess costs associated with specific complications, those costs were incorporated into analysis through the 12-month timeframe of the study.

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http://dx.doi.org/10.1016/j.jacc.2013.01.010

**REFERENCES**


**Diagnosis of Heart Failure With Preserved Ejection Fraction Still a Challenge**

Campbell et al. (1) addressed a key issue of heart failure with preserved ejection fraction (HFPEF). Does it really exist? They concluded that it does, because of the differences in outcomes, comorbidities, and biomarkers between hypertensive and HF-PEF patients in clinical trials. When these studies were carried out, the performance of diagnostic criteria for HFPEF was poor. These criteria were omitted from the latest guidelines of the European Society of Cardiology (ESC). Diagnosis of HFPEF relies more on left ventricular mass and left atrial size (2) than on the signs of diastolic dysfunction. The study fails to discuss whether the majority of patients included in clinical trials actually had HFPEF. Our view is that inclusion of patients with a clinical picture similar to HF—termed the EXIT (EXercise InTolerance) syndrome (3)—may account for the observed differences. Ingle et al. (4) showed that a proportion of patients diagnosed with HFPEF actually had another entity, clinically similar to HF, with lower B-type natriuretic peptide concentrations and a better prognosis. Among exercise-intolerant patients, age, comorbidities, atrial fibrillation, obesity, deconditioning, and unexpected degrees of renal dysfunction might play an important role. This might explain why sensitive markers of glomerular filtration rate, such as cystatin C, perform so well in patients with HFPEF (5). Almeida et al. (6) showed that patients with acutely decompensated HFPEF, who fulfilled the ESC diagnostic criteria had a worse prognosis, comparable to HF and a reduced ejection fraction (HFREF). These data suggested an exercise-intolerance syndrome, similar to HFPEF, with a better prognosis—a factor that could have distorted the results of HFPEF clinical trials and might account for the differences in prognosis between HFPEF and HFREF. We consider HFPEF to be a reality, although doubts as to its clinical profile and diagnostic criteria still persist beyond the conclusions of the study by Campbell et al. (1). The challenge is to identify them without the need for complex assessments.