

Results from the PARTNER Trial (Cohort A): Transfemoral TAVI Economically Attractive but Transapical TAVI More Costly

The Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared with Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis: Results from The PARTNER Trial (Cohort A) study [NCT00530894; Leon MB et al. *NEJM* 2010], presented by Matthew R. Reynolds, MD, MSC, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA, compared transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (SAVR) in patients with high operative risk from cohort A of the PARTNER trial. The study combined cost data with survival and quality of life (QoL) data to estimate the 12-month cost-effectiveness of TAVI.

This study was a 12-month analysis that was based on observed survival, QoL, health care resource use, and hospital billing data. The primary effectiveness measure was quality-adjusted life-years (QALYs)

Three populations were analyzed. The primary population (n=647) for the full cost-effectiveness analysis consisted of patients in whom TAVI or SAVR was attempted, with complete follow-up until death or 1 year. The secondary population (n=657) comprised patients in whom TAVI or SAVR was attempted, including patients who withdrew or were lost to follow-up. The per-protocol population (n=647) consisted of those who were analyzed for procedural resource utilization and costs only and excluded patients in whom TAVI or SAVR was abandoned. Due to the significant interaction between treatment effect and access site, TAVI patients were stratified into transfemoral or transapical approach.

Transfemoral Results:

At 12 months, the average QALYs was significantly higher among the 239 patients who underwent transfemoral TAVI compared with the 217 patients who had SAVR (0.659 vs 0.591 QALYs, respectively; difference 0.068, 95% CI, 0.017 to 0.123). Resource use in the per-protocol population was significantly lower for transfemoral TAVI versus SAVR with respect to procedure duration (244±78 vs 330±102 minutes; p<0.001) and total hospital days (10.2 vs 16.4; p<0.001). Major vascular complications were significantly more frequent in transfemoral TAVI

patients versus SAVR patients (13.2% vs 3.2%, respectively; p<0.001). Major bleeding was lower in transfemoral TAVI patients versus SAVR patients (9.4% vs 22.6%, respectively; p<0.001). As noted in Table 1, compared with SAVR, patients who were undergoing transfemoral TAVI had higher procedural costs but slightly lower overall index admission total costs. Total 12-month follow-up costs were not significantly different for transfemoral TAVI versus SAVR (\$22,251 vs \$21,965, respectively; p=0.97).

Table 1. Index Admission Fees.

Fees	Transfemoral TAVI	SAVR	Δ (p value)
Procedure	\$34,863	\$14,451	
Non-procedure	\$31,192	\$54,228	
Total MD fees	\$4742	\$5773	
Total fees	\$71,955	\$74,452	\$2496 (p=0.53)

Transapical Results:

At 12 months, QALYs were lower in the patients who underwent transapical TAVI compared with SAVR (0.570 vs 0.64 QALYs, respectively; difference -0.070, 95% CI, -0.151 to 0.012). Procedural, index admission, and total 12-month costs were increased with transapical TAVI versus SAVR by roughly \$11,000.

Dr. Reynolds concluded that for patients with severe aortic stenosis and high surgical risk, TAVI is an economically attractive and possibly dominant strategy compared with SAVR, provided that patients are suitable for the transfemoral approach. Current results for transapical TAVI compared with SAVR are not attractive from a health economic perspective.

PARTNER Cohort B: TAVI Superior to Standard Therapy at Two Years

Transcatheter aortic valve implantation (TAVI) is the recommended treatment for “inoperable” patients with severe aortic stenosis (AS), based on the 1-year results of the PARTNER trial [NCT00530894; Leon MB et al. *NEJM* 2010]. The objective of this PARTNER trial analysis, presented by Raj R. Makkar, MD, Cedars-Sinai Medical Center, Los Angeles, California, USA, was to evaluate the clinical outcomes of TAVI compared with standard therapy at 2 years in patients with inoperable AS (PARTNER Cohort B).