

TAVI Improves QoL in Patients Suitable for Transfemoral TAVI

Transcatheter aortic valve implantation (TAVI) is a less invasive alternative to surgical aortic valve replacement (SAVR) for high-risk patients with aortic stenosis. In PARTNER [NCT00530894; Leon MB et al. *NEJM* 2010] Cohort A, TAVI was shown to be noninferior to SAVR for 1-year mortality in patients who were at high surgical risk. There were differences in procedure-related complications and valve performance at 1 year, with some endpoints favoring TAVI and others favoring SAVR. David J. Cohen, MD, MSc, Saint Luke's Mid-America Heart Institute, Kansas City, Missouri, USA, presented the overall impact of these alternative treatments on health-related quality of life (QoL) from the perspective of the patient.

A total of 1057 patients were stratified into high-risk and inoperable cohorts. Cohort A focused on the high-risk patients, who were assessed for suitability for transfemoral TAVI. Those who were suitable were randomized to transfemoral TAVI (n=244) or SAVR (n=248). The remaining patients were randomized to transapical TAVI (n=104) or SAVR (n=103).

The primary QoL outcome measure was the overall summary score of the Kansas City Cardiomyopathy Questionnaire (KCCQ), a heart failure-specific measure. The secondary QoL endpoints were assessed with the SF-12, a general physical and mental health scale, and EQ-5d (EuroQoL), a generic instrument for assessing utilities and quality-adjusted life-years (QALYs).

Both TAVI and SAVR patients improved substantially over the 12-month follow-up period, with an overall change in the KCCQ summary score of 26 to 30 points (a 10-point difference is considered moderately large, and a 20-point difference is considered substantial). For the overall population, patients who underwent TAVI demonstrated temporally earlier improvement versus those patients who underwent SAVR, with a difference between groups of about 5.5 points (p=0.01). However, after the first few months, QoL then improved more rapidly in the SAVR arm, such that by 6 months there was no difference between groups over the rest of the year.

There was a significant interaction (p=0.001) between treatment effect and access site for the primary endpoint. In the transfemoral subgroup, the TAVI arm had a significant 9.9-point improvement in KCCQ at 1 month (p<0.001) versus the SAVR arm, with no difference at 6 or 12 months. In contrast, among the transapical subgroup, the TAVI arm had no advantage over the SAVR arm in KCCQ QoL at any time point, with a trend toward worse QoL at both 1 and 6 months with TAVI.

Results were similar for the other QoL measures. In the transfemoral subgroup, there were significant improvements with TAVI versus SAVR in the SF-12 physical (p=0.04), SF-12 mental (p<0.001), and EQ-5D (p=0.008) at 1 month but not at 6 or 12 months. In the transapical subgroup, there were no significant improvements in these measures with TAVI versus SAVR.

These results demonstrate that for patients who are suitable for a transfemoral approach, TAVI provides meaningful improvement in the QoL of patients with severe aortic stenosis compared with SAVR. The lack of benefit among patients who are ineligible for the transfemoral approach suggests that the transapical approach may *not* be preferable to conventional surgery in this population. As Dr. Cohen noted, it is possible that continued experience with the transapical approach has overcome some of the limitations that are seen in this very early experience. Future studies should explore whether additional experience and refinements in the transapical technique have overcome these limitations.

Highlights from the

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