Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

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Objectives

Comparison of major outcomes for patients with aortic stenosis who are at low risk of death from surgery, following either transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR).

Study design

Multicentre, randomised trial.

Materials and methods

- Patients were considered eligible for the trial (1) if they had severe calcific aortic stenosis , (2) if they were considered at low surgical risk, (3) if they were eligible for transfemoral placement of the balloon-expandable SAPIEN 3 system, and (4) if they did not have anatomical features that increased the risk of complications associated with either TAVR or surgery
- Eligible patients (n=950) were randomly assigned in a 1:1 ratio to undergo either of the 2 procedures
- The primary endpoint was a composite of death from any cause, stroke or rehospitalisation at 1 year after the procedure. All patients underwent neurological examinations at baseline and at 30 days
- Key secondary endpoints included stroke, a composite of stroke or death, new-onset atrial fibrillation at 30 days, length of the index hospitalisation and a poor treatment outcome
- Adjudication of all endpoints was not blinded

Key results

- TAVR (transfemoral placement of the balloon-expandable SAPIEN 3 system) was superior to surgery with regard to the primary composite endpoint of death, stroke or rehospitalisation at 1 year. Results for the three components of the primary end point favoured TAVR at both 30 days and 1 year
- Analyses of key secondary endpoints showed that TAVR, compared to surgery, was associated with a significantly lower rate of new-onset atrial fibrillation at 30 days, a shorter index hospitalisation and a lower risk of poor treatment outcome at 30 days
- Patients who underwent TAVR had more rapid improvements than those who underwent surgery

Limitations of study

- Results reflect only 1-year outcomes, and do not address the problem of long-term structural valve deterioration
- Bias in outcome assessment may have been introduced as a result of the adjudication of endpoints not being blinded
- The defined trial population excluded patients with clinical or anatomical features that could have increased the risk of complications associated with either TAVR or surgery
- Results cannot be extrapolated to TAVR performed with either other systems or less experienced operators
- More patients in the surgery group than in the TAVR group withdrew from the trial
- The analysis did not examine the rate and relevance of asymptomatic valve thrombosis

Conclusions

Among patients with severe aortic stenosis who are at low risk for death with surgery, the rate of the composite of death, stroke or rehospitalisation at 1 year was significantly lower with TAVR than with surgical aortic valve replacement.