Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

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Period of study

- SAPIEN 3 transcatheter aortic valve replacement (TAVR) intermediate-risk patient observational study: Feb 2014 – Sept 2014 (to assess 1-year outcomes)
- Propensity score analysis: Dec 2011 – Nov 2013 (to compare these outcomes with those for similar patients given surgical heart valve replacement (SAVR) in the PARTNER2A randomised trial)

Objectives

To obtain clinical outcome data in intermediate-risk patients given SAPIEN 3 TAVR beyond previously reported 30 days, and to compare outcomes to those of similar patients given SAVR.

Study design

Observational study followed by propensity score analysis.

Materials and methods

- In the SAPIEN 3 observational study, 1077 intermediate-risk patients at 51 sites in the USA and Canada were assigned to receive TAVR with the SAPIEN 3 valve via transfemoral access. All-cause mortality and incidence of stroke, re-intervention and aortic valve regurgitation were assessed in these patients at 1 year post implantation
- The outcomes in this population were compared with those of similar patients treated with SAVR in the PARTNER 2A trial, using a propensity score analysis. The primary endpoint was the composite of death from any cause, all strokes and incidence of moderate or severe aortic regurgitation

Key results

- A propensity score analysis may not eliminate confounders that might influence the results
- Analysis included only death, stroke and aortic regurgitation endpoints
- Intermediate-risk patients will be unlikely to have the underlying co-morbidities of older, high-risk patients
- Each TAVR system is unique, and it is not possible to generalise across all TAVY systems
- Long-term durability of bioprosthetic transcatheter valves has not been established

Limitations of study

- A propensity score analysis may not eliminate confounders that might influence the results
- Analysis included only death, stroke and aortic regurgitation endpoints
- Intermediate-risk patients will be unlikely to have the underlying co-morbidities of older, high-risk patients
- Each TAVR system is unique, and it is not possible to generalise across all TAVR systems
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Conclusions

- TAVR is superior to surgery at 1-year follow-up, with lower rates of all-cause mortality, stroke and the composite endpoint of mortality, stroke and moderate or severe aortic regurgitation
- This is the first rigorously designed and carried out clinical study to compare TAVR with the SAPIEN 3 device with surgery in intermediate-risk patients, the propensity analysis allowing for meaningful comparisons between the two groups

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