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CRD summary
This review concluded that complications for elderly and high risk aortic stenosis patients being treated by transcatheter aortic valve replacement appeared comparable to those selected for conventional surgical aortic valve replacement in the real-world. The authors’ conclusions reliably reflected the limited available evidence and appropriately recommended future head-to-head studies.

Authors' objectives
To assess important complications following transcatheter aortic valve replacement (TAVR) and place these in the context of conventional surgical aortic valve replacement (SAVR) in the high risk and elderly aortic stenosis population.

Searching
PubMed was searched for relevant articles up to 30th September 2010. Search terms were reported. Proceedings from relevant conferences were searched for additional relevant TAVR studies.

Study selection
Studies that reported 30 day mortality in at least 30 patients following TAVR or SAVR were eligible for inclusion. TAVR studies had to evaluate the most widely used self-expanding device (3rd generation Medtronic-CoreValve bioprosthesis, Medtronic, Minneapolis, MN) or balloon-expandable device (Edwards-Sapien bioprosthesis, Edwards Lifesciences, Irvine, CA). To obtain a population comparable with that eligible for TAVR, inclusion of SAVR studies was restricted to those where patients had a mean age of 80 years, an ejection fraction by biplane method of 35, a mean logistic EuroSCORE of 15, or a mean Society of Thoracic Surgeons (STS) score of 10. Studies that looked exclusively at low flow, low gradient aortic stenosis were excluded.

Two authors selected studies for inclusion.

Assessment of study quality
The authors did not assess study quality.

Data extraction
Data were extracted on key study characteristics. Means and standard deviations were extracted for continuous variables; where only medians and interquartile ranges were reported, these were converted under the assumption of a Gaussian distribution. It was not clear how many reviewers extracted the data.

Methods of synthesis
Data were summarised by treatment group. SAVR and TAVR were compared using a two group logistic random-effects Bayesian meta-analysis for 0-1 variables and the pooled mean and pooled standard deviations for continuous variables. A four group analysis was used to compare SAVR to TAVR, Medtronic-CoreValve, transfemoral Edwards-Sapien bioprosthesis and transsubclavian/axillary Edwards-Sapien.

Results of the review
A total of 3,512 patients from 19 series underwent SAVR, 806 underwent concurrent coronary artery bypass graft. A total of 5,024 patients from 16 series underwent TAVR, 3,222 (64.1%) used the Edwards-Sapien device (1,840 transsubclavian/axillary and 1,382 transfemoral) and 1,802 used the Medtronic-CoreValve device (1,649 listed access approach: 1,510 transfemoral, 133 trans-axillary and six ascending aortic access by mini-sternotomy).

At baseline, TAVR subjects had statistically significantly greater renal impairment (P<0.001), higher incidence of prior myocardial infarction (P=0.032), respiratory disease (P=0.005) and a higher logistic EuroSCORE (P=0.039).
There were no statistically significant differences between SAVR and TAVR in terms of 30 day mortality (9% versus 8.5%, P=0.31), one year mortality (18.4% versus 22.8%, P=0.65), 30 day stroke (2.4% versus 2.6%, P=0.72), new permanent pacemaker (5.9% versus 12.1%, P=0.055), or dialysis inception (2.4% versus 4.1%, P=0.70).

Apart from some variation in functional status, there were no significant differences at baseline with different Edwards-Sapien and Medtronic-CoreValve designs. The only difference in complications was a greater need for pacemaker insertion with the Medtronic-CoreValve design (24.5% versus 5.9% P<0.0001).

Authors' conclusions
Complications for elderly and high risk aortic stenosis patients being treated by TAVR appeared comparable to those selected for SAVR in the real-world.

CRD commentary
The research question was broadly defined in terms of the interventions, outcomes, and to some extent, participants of interest. No controlled studies that compared the interventions of interest were included, and the authors appeared to specifically focus on an indirect comparison of case series of TAVR versus case series of SAVR. Details were limited for individual studies, but the authors noted significant differences between patients at baseline. In addition, many SAVR patients also underwent concomitant CABG which may have potentially caused confounding. The quality of the individual studies was not assessed. The author's conclusions appear reliable, but the included evidence had several limitations and the recommendation for head-to-head studies is appropriate.

Implications of the review for practice and research
Research: The authors stated that head-to-head studies were required to establish the comparability of different TAVR designs and that future clinical trials may help better establish whom to refer for each of the AVR modalities, and when to refer them.

The authors did not state any implications for practice.

Funding
Not stated.

Bibliographic details

PubMedID
22415849

DOI
10.1002/ccd.23368

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Age Factors; Aged; Aged, 80 and over; Aortic Valve Stenosis /mortality /therapy; Bayes Theorem; Cardiac Catheterization /adverse effects /instrumentation /mortality; Comorbidity; Female; Heart Valve Prosthesis; Heart Valve Prosthesis Implantation /adverse effects /instrumentation /methods /mortality; Humans; Logistic Models; Male; Prosthesis Design; Risk Assessment; Risk Factors; Treatment Outcome

AccessionNumber
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.