Transcatheter aortic valve implantation for high-risk patients with severe aortic stenosis: a systematic review

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CRD summary
This review assessed the safety and clinical effectiveness of trans-catheter aortic valve implantation for patients at high surgical risk with severe aortic stenosis and concluded that it had potential for serious complications. There was evidence of short-term but not long-term effectiveness. The conclusions may be overstated given the poor quality of the evidence available.

Authors' objectives
To assess the safety and clinical effectiveness of trans-catheter aortic valve implantation for patients at high surgical risk with severe aortic stenosis.

Searching
MEDLINE, EMBASE, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews and DARE were searched for relevant studies published between January 2000 and March 2009. Search terms were reported. Reference lists of all retrieved articles were searched for relevant studies.

Study selection
Eligible studies were experimental or observational studies of patients of high surgical risk with aortic stenosis or those deemed not suitable for surgical aortic valve replacement, where transcatheter aortic valve implantation was considered. Studies needed to report primary endpoints for feasibility and safety (including procedural success rate and 30-day mortality), secondary outcomes related to efficacy and durability (based on echocardiographic findings) and clinical outcomes at one, six and 12 months.

In the included studies, mean age ranged from 80 to 84 years. Mean/median logistic euroSCORE ranged from 11 to 37. Most studies used general not local anaesthetic. Definitions of high-risk patients varied across studies.

The number of reviewers who performed the study selection was not stated.

Assessment of study quality
Both reviewers independently assessed study quality according to criteria of representativeness of study sample, explicitness of selection criteria, baseline similarity and appropriateness of subseries analysis. Quality of outcome data was assessed according to adequacy of description, type of variable used, whether outcome was related to intervention and whether terms were clearly explained.

Data extraction
Both reviewers extracted a range of data required to conduct a narrative synthesis. Disagreements were resolved by discussion and consensus with a third reviewer.

Methods of synthesis
A narrative synthesis was conducted.

Results of the review
Seventeen studies (n=1,143, range three to 646) were included in the review. All were experimental studies without control groups.

Procedural success rates ranged from 74% to 100%. Mean procedure duration varied from 2.5 to 2.9 hours. Mean length of hospital stay ranged from seven to 17 days. Sixteen of the 17 studies reported echocardiographic measurements, all of which demonstrated significant improvement in haemodynamic performance. Death rates at six
months postprocedural ranged from 18% to 48%. A number of other summaries were reported.

A range of serious adverse events (which included 30-day mortality) were reported.

**Authors’ conclusions**
Transcatheter aortic valve implantation had potential for serious complications. Although evidence of short-term efficacy was good, there was little evidence on long-term outcomes.

**CRD commentary**
This review addressed a clear research question using appropriate and clearly defined study selection criteria. The search appeared adequate, but further measures could have been taken to identify unpublished studies and so reduce the risk of publication bias. Reporting of primary study characteristics was adequate. Quality assessment appeared appropriate; all of the included studies were experimental control groups and so subject to substantial risk of bias. The results were reported clearly and indicated both the types and possible range of frequencies of serious adverse events. The conclusions appeared to reflect the results presented, but may be overstated given the poor quality of the evidence available.

**Implications of the review for practice and research**
**Practice:** The authors state that a formal team approach to patient selection and outcome analysis was mandated given the relatively unproved nature and inherent risks of this therapy. Use of aortic valve implantation should be considered only within the boundaries of clinical trials.

**Research:** The authors did not state any implications for research.

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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.