Percutaneous heart valve replacement for aortic stenosis: state of the evidence

Coeytaux RR, Williams JW, Gray RN, Wang A

CRD summary
This review concluded that the available evidence was inadequate to determine the most appropriate clinical role of percutaneous heart valve replacement or the specific patient populations for whom it might eventually be indicated. There were a number of limitations with the review, and the methodological quality of the evidence was weak, so this conclusion seems appropriate.

Authors' objectives
To evaluate the use of percutaneous heart valve replacement for aortic stenosis.

Searching
PubMed (1990 to June 2010) and EMBASE (1990 to October 2009) were searched for articles published in English; search strategies were available in on-line appendices (accessed 10 September 2010, see URL for Additional Data).

Study selection
Studies of any design that described the use of percutaneous heart valve replacement for aortic stenosis in adults, and that reported at least one clinical outcome, were eligible for inclusion.

All included patients had symptomatic, severe aortic stenosis considered at high surgical risk. Where reported, the mean age of participants was 80 years (age range 48 to 96 years), and the mean or median European System for Cardiac Operative Risk Evaluation (EuroSCORE) ranged from 11 to 41%. Delivery of the valve was via the femoral artery in most patients; the transapical approach was used in a large minority of patients.

One reviewer screened titles and abstracts, and two independent reviewers screened full papers for inclusion for the original review (see Other Publications of Related Interest); disagreements were resolved by discussion.

Assessment of study quality
Study quality was not assessed.

Data extraction
The proportions of patients with successful procedures, surviving/dying after 30-days, and experiencing an adverse event or complication were extracted.

The authors did not state how many reviewers extracted data.

Methods of synthesis
Studies were combined in a narrative synthesis; differences between studies were discussed in the text and study details were tabulated. The outcomes were synthesised for all studies, by valve manufacturer as a proxy for detailed prosthetic characteristics, and by implantation approach.

Results of the review
Seventy-six studies across 84 publications were included in the review (n=2,375 apparently unique patients; range one to 646); 50 publications were case reports (n=67 patients) and 34 were case series (n=2,311 patients).

Overall, percutaneous heart valve replacement was successful for 1,843 out of 1,967 (94%) patients. The 30-day survival across all studies was 89%; the overall 30-day mortality rate was 11%. For the femoral artery approach, implantation success was 93% and 30-day survival was 90%. For the transapical approach, implantation success was 94% and 30-day survival was 88%.
Serious adverse events associated with percutaneous heart valve replacement included: major access site complication, life-threatening arrhythmias, need for haemodynamic support, need for a second valve, and ventricular perforation. Large case-series reported approximately 8% of patients experiencing a major adverse cardiovascular or cerebrovascular event.

Authors' conclusions
The available evidence was inadequate to determine the most appropriate clinical role of percutaneous heart valve replacement or the specific patient populations for whom it might eventually be indicated.

CRD commentary
The review addressed a clear review question, supported by broad but appropriate inclusion criteria. The search was limited to two databases, and unpublished and foreign language studies were not sought, so relevant studies may have been missed. Only one reviewer screened titles and abstracts, which increased the possibility that errors and/or bias affected the screening process. There was no indication whether methods to reduce error and bias were employed during data extraction.

Study quality was not assessed. Most of the included studies were case reports or small case series, so the overall quality of evidence was low. The use of a narrative synthesis was appropriate given the evidence retrieved.

Given the limitations of the review and the included studies, the authors’ conclusion seems appropriate.

Implications of the review for practice and research
Practice: The authors did not state implications for practice.

Research: The authors stated that further studies are needed to evaluate factors related to improved long-term results, and the effectiveness and cost-effectiveness of various percutaneous heart valves. Also, studies evaluating percutaneous heart valve replacement in younger patients with fewer co-morbidities should include a comparison group undergoing surgical aortic valve replacement, and use of logistic EuroSCORE may be a way of assessing short-term benefits or harms associated with percutaneous heart valve replacement. Three trials are on-going: one comparing percutaneous heart valve replacement with conventional heart surgery and medical management; one comparing percutaneous heart valve replacement with surgical aortic valve replacement; and one comparing percutaneous heart valve replacement with a biological valve inserted via conventional surgery.

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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.