CRD summary
The authors concluded that transcatheter aortic valve replacement provided clinically important benefits in physical function and disease-specific measures of quality of life, but modest benefits in psychological and general health measures. They recommended further research. The authors’ cautious conclusion reflects the observational evidence presented and seems reliable.

Authors’ objectives
To evaluate the effects of transcatheter aortic valve replacement (TAVR) on functional status and quality-of-life.

Searching
MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched, without language restrictions, for articles from January 2002 to September 2013. Selected search terms were reported. Reference lists of published reviews were screened for additional studies.

Study selection
Eligible for inclusion were prospective studies of TAVR reporting a specified outcome at six months or later. The specific primary outcomes (and minimum clinically important difference) were New York Heart Association (NYHA) Functional Class (≥1 class); SF-12 or SF-36 Health Survey physical and mental component summary scores (≥2.5 points); Six-Minute Walk Test distance (≥250m); Activities of Daily Living (ADL) limitation (≥1 limitation); EQ-5D score (≥0.074 points); Kansas City Cardiomyopathy Questionnaire score (≥20 points); and Minnesota Living With Heart Failure Questionnaire (MLHFQ) score (≥25 points). Greater values indicated better function, except for NYHA Functional Class and MLHFQ score. Secondary outcomes were all-cause mortality, cardiovascular mortality, myocardial infarction, stroke, and re-hospitalisation. Case reports and abstracts were excluded.

Most of the included studies were not direct comparisons, instead they compared data before and after the intervention. The patients' clinical characteristics varied. Where reported, for most studies, the mean age was 73 to 93 years; 14% to 94% of patients were women; the 30-day mortalities, predicted by the Society of Thoracic Surgeons (STS) criteria, were 5% to 25%; and 54% to 100% of patients had NYHA class III or IV symptoms at the start. There were some initial variations between patient groups in the few comparative observational studies (reported in the paper).

Two reviewers independently selected the studies for inclusion. Disagreements were resolved by a third reviewer.

Assessment of study quality
Study quality was assessed using a modified version of the Newcastle-Ottawa Scale, covering how representative the sample was of the source population, the selection of comparison patients, adjustments for differences in initial functional outcome and left ventricular systolic function, the assessment of functional outcome, and the adequacy of follow-up.

Two reviewers independently carried out the quality assessment.

Data extraction
For primary outcomes, the data were extracted to illustrate the range of mean changes in forest plots. For secondary outcomes, the data were extracted to calculate risk estimates and 95% confidence intervals.

Two independent reviewers extracted the data.

Methods of synthesis
For primary outcomes, a narrative synthesis included summaries of the change in the primary outcomes over six to 11
months, 12 to 23 months, 24 to 35 months, and 36 months or more. For secondary outcomes, risk estimates were pooled using the DerSimonian and Laird random-effects model and 95% confidence intervals were calculated, along with I² to quantify statistical heterogeneity.

Results of the review
Sixty observational studies and two randomised controlled trials were included (total 11,205 patients). The overall quality of the studies was considered to be poor. Most provided only before-and-after comparative data, and the six head-to-head studies comparing TAVR with surgical or conservative treatment were considered insufficiently robust to provide definitive conclusions.

Change in NYHA class: There were 51 studies with quantitative data. Most studies showed an improvement of one NYHA functional class following TAVR over six to 11 months (range -0.8 to -2.1 classes); 12 to 23 months (range -0.8 to -2.1 classes); 24 to 35 months (range -1.2 to -2.6 classes); and 36 months or more (range -1.2 to -1.6 classes). Eight studies showed a mean change of less than one NYHA class, suggesting that many patients did not improve after TAVR. Improvements in NYHA class were observed following surgical aortic valve replacement.

SF-12 or SF-36 Physical and Mental scores: Eight studies provided quantitative data. The average Physical score improved at six to 11 months (range 6.3 to 18.4 points) and 12 months (range 4.9 to 26.9 points). Improvements in Mental scores were smaller at six to 11 months (range 2.0 to 13.3 points) and 12 months (range 1.0 to 8.9 points). There were no clinically meaningful changes in Mental score in four studies. Improvements for both scores were observed following surgical aortic valve replacement (one trial).

Other measures of function and quality of life: Clinically important improvements were noted across three studies using the Kansas City Cardiomyopathy Questionnaire; three studies using the MLHFQ; five studies using the Six-Minute Walk Test; and one study using the ADL. The results were less robust in the three studies using the EQ-5D.

Further results, including those for secondary outcomes, were reported.

Authors' conclusions
Transcatheter aortic valve replacement provided clinically important benefits in physical function and disease-specific measures of quality of life, but modest benefits in psychological and general health measures. The authors recommended further research, given the lack of head-to-head evidence and the highly variable clinical characteristics of the included studies.

CRD commentary
The review question was clear and the inclusion criteria were sufficiently specified for all aspects, apart from the population. Consequently, there was wide variation in the patient characteristics across the included studies. The search strategy included relevant sources, and steps were taken to minimise language bias. It was unclear whether unpublished studies were sought.

The review process included measures to minimise error and bias, and an appropriate assessment tool was used to examine the quality of each study's methods. Study details were presented; wide variation was noted, and the chosen method of synthesis was appropriate. The reliance on observational studies, without direct comparisons and with inherent risks of bias, was acknowledged by the authors as a limitation of their review.

The authors' cautious conclusion reflects the observational evidence presented and seems reliable.

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

Research: The authors stated that well-designed prospective comparative studies of TAVR and other treatments, examining functional status and quality of life, were needed for informed treatment decisions. Research should explore the variations in treatment effects to enable better patient selection. NYHA class measures should be supplemented with other validated instruments to measure functional status and quality of life. Research was needed to develop a better classification algorithm to predict procedural success, long-term survival and functional benefit.
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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.