Transcatheter aortic valve implantation: evidence on safety and efficacy compared with medical therapy: a systematic review of current literature

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CRD summary
The authors concluded that transcatheter aortic valve implantation offered significantly improved one-year survival in patients with severe symptomatic aortic stenosis compared to sole medical treatment. Potential for bias in the review process, a lack of available high-quality studies and unsuitable statistical methods mean the authors' conclusions should be treated with caution.

Authors' objectives
To assess the efficacy and safety of transcatheter aortic valve implantation (TAVI) at one year follow-up and to compare the survival benefit of TAVI with medical therapy.

Searching
MEDLINE, EMBASE, Centre for Reviews and Dissemination (CRD) databases and The Cochrane Library were searched up to April 2010 for articles published in English or German. CRD, International Network of Agencies for Health Technology Assessments, Institut fur Qualitat und Wirtschaftlichkeit im Gesundheitswesen and National Institute for Health and Clinical Excellence were searched for reviews and health technology assessments. Search terms were reported. Bibliographies of key papers were handsearched.

Study selection
Peer-reviewed full-text clinical studies that assessed TAVI in patients at risk for surgical aortic valve replacement with severe aortic stenosis and assessed safety or efficacy of TAVI were eligible for inclusion. Studies needed to have a mean population age of 75 years or greater. At least 10 participants needed to be included. Follow-up had to be greater than 12 postoperative months. Studies of asymptomatic patients were excluded. Inclusion criteria for medical therapy were studies of no intervention or palliative balloon aortic valvuloplasty in symptomatic patients with severe aortic stenosis who refused or were denied aortic valve replacement and that assessed safety or efficacy of medical therapy.

Included studies evaluated TAVI with CoreValve, Cribier-Edwards or Edwards Sapien Valve prostheses using transvascular or transapical approaches. Patients had a mean age of 82 years in the TAVI studies and 79.9 years in the medical therapy studies. Patients who underwent TAVI had a higher pre-operative risk as assessed by the log Euro score compared to patients who underwent medical therapy (range 15.0 to 44.2 for TAVI compared to 9.0 to 25.4 for medical therapy). Primary outcomes reported in the review were procedural success rate, complications, mortality and survival. Secondary outcomes were post-procedural haemodynamic data, New York Heart Association Classification and length of stay. Mean follow-up ranged from 7.4 months to 13.0 months in the TAVI group and 6.0 to 30 months in the medical therapy group. Studies were conducted in UK, France, Germany, The Netherlands, Canada and USA.

The papers were selected by screening at the title and abstract and then at the full-text stage. The authors did not state how many reviewers performed the study selection.

Assessment of study quality
The authors stated that study quality was assessed using checklist 2a of the German Scientific Working Group.

Data extraction
For continuous data, means and standard deviations were extracted for each study. For dichotomous data, the number of patients for each outcome was extracted and expressed as a percentage for each study. For survival rates, 95% confidence intervals were also approximated. Data were extracted using a structure data extraction form.

The authors did not state how many reviewers performed data extraction.

Methods of synthesis
For dichotomous data, overall percentages were calculated for each outcome and the range was reported. For continuous data, overall means and the range of means were reported. Outcomes were reported separately for transvascular and transapical procedures. X² was used to compare TAVI and medically treated groups.

Results of the review
Twenty studies were included for review (1,995 participants). Twelve studies assessed TAVI (1,049 participants): one prospective study (339 participants), six prospective case series (494 participants), two prospective cohort (57 participants) and three retrospective matched cohort studies (159 participants). Eleven studies evaluated medical therapy (946 participants): three prospective cohort studies (124 participants) and eight retrospective cohort studies (822 participants). Three studies evaluated both TAVI and medical therapy.

The mean procedural success rate for TAVI was 93.3% (range 86% to 100%; 948 participants). Procedural, post-procedural and cumulative in-hospital/30 day mortality was 11.4% (range 5.3% to 23%; 116 participants). The mean one-year survival rate for patients who underwent TAVI was 75.9% (range 64.1% to 87%) compared to 62.4% (range 40% to 84.8%) in medically treated patients. The difference between these patient groups was significant (p<0.01). Separate outcomes for transvascular and transapical procedures were reported.

The authors reported that patients with successful TAVI had improved valvular function, left ventricular ejection fraction (LVEF) and functional status. Mean aortic valve area changed from 0.61cm² at baseline to 1.65cm² at 30-day follow-up and 1.49cm² at one year (282 participants). Mean transaortic valve gradient changed from 47.6mmHg at baseline to 10.3mmHg at 30 days and 10.1mmHg at one year follow-up (282 participants). Mean left ventricular ejection fraction changed from 52.7% at baseline to 56.2% at 30 days and 60.2% at one year follow-up (240 participants). Mean NYHA functional class changed from 3.3 at baseline to 2 at 30 days and 1.8 at one year (301 participants). Mean hospital stay for TAVI patients was 9.5 days (range five to 19 days). Mean intensive care unit stay was 2.7 days.

Incidence of aortic regurgitation across seven studies was reported. Incidence of major vascular complications, cerebrovascular accidents/strokes, myocardial infarction, cardiac tamponade, valve in valve and the number of patients needing a permanent pacemaker or heart block was reported for each TAVI study.

Authors' conclusions
TAVI offers significantly improved one-year survival in patients with severe symptomatic aortic stenosis compared to sole medical treatment.

CRD commentary
The review addressed a clear question with well-defined inclusion criteria. It was unclear whether all inclusion criteria were adhered to as studies with a shorter than stipulated duration were included. Several relevant databases were searched. It appeared that no attempts were made to include unpublished data and the search was restricted to articles published in English or German. Therefore publication and language bias could not be ruled out. It is unclear whether appropriate steps were taken in the study selection process to minimise reviewer error and bias. The authors reported that they carried out a validity assessment, but did not report the results so it was not possible to determine the quality of included studies. However, all studies were of a weaker methodological design and only three directly compared TAVI and medical therapy. Statistical heterogeneity was not assessed.

The statistical methods used to combine studies were not appropriate and it appeared that no tests of significance were not carried out for many outcomes and so the results were unreliable.

Potential for bias in the review process, the lack of available high-quality studies and the unsuitability of the statistical methods mean the authors’ conclusions should be treated with caution.

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

Research: The authors stated that further research was needed into quality of life following TAVI.

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