Hemodynamic performance of stentless versus stented valves: a systematic review and meta-analysis

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CRD summary
The review concluded that stentless valves did not demonstrate haemodynamic benefits in terms of left ventricular mass or postoperative mean gradients, but appeared to display superior peak gradients; further research was needed. There were some methodological problems with the included trials and these limited the reliability of the pooled results; the authors’ call for further research appeared appropriate.

Authors’ objectives
To determine whether stented valves improved cardiac haemodynamics, as assessed by postoperative transvalvar gradients and left ventricular mass regression.

Searching
PubMed, EMBASE, CINAHL, The Cochrane Library and EMB reviews were searched without restrictions. Search terms were reported. Canadian Cardiovascular Society (2005), American Thoracic Society (2001 to 2005), American Association for Thoracic Surgery (2005) and Society of Thoracic Surgery (2003 to 2005) were electronically searched. Reference lists of recent review articles were searched.

Study selection
Randomised controlled trials (RCTs) and quasi-RCTs of stentless versus stented bioprosthetic aortic valves in adult patients (aged 18 years and over) who underwent aortic valve replacement surgery were eligible for inclusion. Trials had to report preoperative and postoperative measures of left ventricular mass and/or preoperative and postoperative measures of mean transvalvar gradient.

The included trials evaluated patients with predominantly aortic stenosis. Reported outcomes included left ventricular mass, mean gradients, peak aortic valve gradients and effective orifice areas.

Two blinded reviewers independently performed study selection of English-language studies and one reviewer performed study selection of the non English-language articles. Discrepancies for English-language trials were resolved by consensus or referral to a third reviewer.

Assessment of study quality
Two reviewers independently assessed trial quality using five quality factors: randomisation, maintenance of allocation concealment, blinding, patient follow-up and intention-to-treat analysis.

Data extraction
Two reviewers independently extracted data on left ventricular mass and mean transvalvar gradient, and used these data to calculate standardised mean differences (SMD) for left ventricular mass and weighted mean differences (WMD) for mean transvalvar gradient, each with 95% confidence intervals (CIs). Data on peak gradients was extracted and used to calculate weighted mean differences and 95% CIs. Discrepancies were resolved by consensus or referral to a third reviewer.

Methods of synthesis
The pooled standardised mean differences and weighted mean differences, with 95% CIs, were calculated using random-effects meta-analysis. Left ventricular mass outcomes were grouped as early (one to six months postoperatively) and late (more than six months). Mean transvalvar gradients were grouped as postoperative (less than one month), early (one to six months) and late (more than six months). Statistical heterogeneity was assessed using $X^2$ and $I^2$ statistics. Various sensitivity analyses were conducted, these included: quality, age, sex, concomitant treatments with coronary artery bypass surgery (CABG), follow-up, preoperative heart scores, preoperative ejection fraction,
preoperative diagnosis of aortic insufficiency and addition of trials with no preoperative data.

**Results of the review**
Eight RCTs (n=546 patients) were included in the review. Study sample size ranged from 20 to 190 patients. Loss to follow-up, where reported, varied from less than 2% to 20%. Quality scores were not estimated; most trials did not provide sufficient information on their methodology to enable quality assessment.

**Primary outcomes:** Compared with unstented valves, there was no statistically significant difference in the left ventricular mass with stented valves prior to six months (SMD -0.1, 95% CI –0.49 to 0.29; four RCTs, I²=50%) and after six months (SMD -0.11, 95% CI -0.46 to 0.24; four RCTs, I²=51%). Compared with unstented valves, there was no statistically significant difference in mean gradients with stented valves prior to six months (WMD -1.86, 95% CI -5.22 to 1.5; three RCTs, I²=76%) and at 12 months (WMD -0.24, 95% CI -1.6 to 1.12; two RCTs, I²=4%).

Sensitivity analyses did not reveal any significant differences for left ventricular mass. Sensitivity analysis of transvalvar gradients showed a difference postoperatively when four RCTs with no preoperative data were added, but not for early and late outcomes.

**Secondary outcomes:** Compared with unstented valves, there was a statistically significant difference in peak gradients with stented valves for early outcomes (WMD -6.63, 95% CI -9.6 to -3.66; four RCTs, I²=49%) in favour of unstented valves. There was no significant difference for preoperative outcomes or late outcomes, unless previously excluded studies were introduced into the analysis.

Results for postoperative mean gradients and orifice areas were reported in the review.

**Authors’ conclusions**
Stentless valves did not demonstrate haemodynamic benefits in terms of left ventricular mass or postoperative mean transvalvar gradients, but appeared to display superior peak gradients; further research was needed to fully address this question.

**CRD commentary**
Inclusion criteria for the review were clearly defined. Several relevant databases were searched. Publication bias was not assessed and could not be ruled out. Two reviewers undertook study selection, data extraction and quality assessment to minimise risks of error and bias in the analysis. The included trials were generally not well reported and did not provide sufficient methodological detail to enable quality assessment. Half of the trials had small sample sizes (<50 patients), which the authors acknowledged. The trials were combined using random-effects meta-analysis and sensitivity analysis was undertaken, which appeared appropriate. However, inclusion of previously excluded trials in certain analyses may not have been appropriate and made interpretation of the results difficult.

The review was generally well conducted, but small sample sizes combined with the uncertain methodological quality of the included trials limited the reliability of the pooled results; the authors’ call for further research appeared appropriate.

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

**Research:** The authors stated that further well-designed randomised controlled trials were required to fully determine whether stented valves improved cardiac haemodynamics.

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