Stentless versus stented bioprosthetic aortic valves: a systematic review and meta-analysis of controlled trials


CRD summary
This review compared the effectiveness of stentless and stented bioprosthetic valves in patients who underwent aortic valve replacement. The authors concluded that stentless aortic valves improved short-term haemodynamic outcomes. There was no evidence of impacts on patient morbidity, mortality and resource-related outcomes. Due to the unclear quality of included trials, some caution is warranted when interpreting the authors' conclusion.

Authors' objectives
To compare the clinical and resource outcomes of stentless and stented bioprosthetic valves in patients who underwent aortic valve replacement.

Searching
Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE were searched from 1990 to 2008 with no language and publication status restrictions. Search terms were reported. Reference lists of included studies and reviews were handsearched for additional studies. Experts were contacted for unpublished material. Conference meeting abstracts of American Association of Thoracic Surgery, Society of Thoracic Surgery and European Association of Cardiothoracic Surgery were reviewed.

Study selection
Randomised and non-randomised controlled trials (RCTs) were eligible for inclusion if they compared stentless with stented valves in patients who underwent aortic valve replacement and reported on at least one relevant clinical or resource-related outcome. Trials that compared stentless valves with mechanical heart valves, homograft aortic root replacement and pulmonary autograft (Ross procedure) were excluded.

All included studies were English-language publications. Just under half of the trials were conducted in UK. Approximately half of the patients were men. Mean age range was 68 to 73 years. Studies compared various stented valves with various stentless valves. All RCTs inserted stentless valves in the subcoronary configuration. Details of the valve manufacturers and a wide range of clinical and resource outcomes were reported in the paper.

Two independent reviewers carried out the study selection. Disagreements were resolved by consensus with a third reviewer.

Assessment of study quality
The authors did not report any formal assessment of trial quality. Enrolment procedure, baseline comparability of groups and loss to follow-up were assessed by two independent reviewers. Disagreements were resolved by consensus with a third reviewer.

Data extraction
Data were extracted to enable calculation of odds ratios (OR) for dichotomous outcomes and mean differences for continuous outcomes, together with 95% confidence intervals (CI). Intention-to-treat data were extracted where possible.

Methods of synthesis
Odds ratios, weighted mean differences (WMD) and 95% CIs were pooled in a random-effects meta-analysis. Statistical heterogeneity was assessed using $I^2$ (<50% indicated low heterogeneity, 50% to 75% indicated moderate heterogeneity and >75% indicated high heterogeneity). Potential reasons for heterogeneity were determined a priori. The primary analysis included only RCTs and these results were compared with a secondary analysis of non-RCTs. Subgroup analysis by valve type was planned, but not carried out due to limited data.
Results of the review

Seventeen RCTs (n=1,317 participants, sample size range 17 to 223) were included in the primary analysis. Fourteen non-RCTs (n=2,485) were included in the secondary analysis. Study groups were comparable on a number of baseline variables (age, annulus size and valve size were exceptions). The authors reported that completeness of follow-up was poorly reported. The authors stated that few studies reported follow-up data beyond one year.

**Primary analysis (RCTs only):** There was no significant difference between stentless and stented valves in all-cause mortality (30 days, one-year and two to 10 years); valve complications (generally poorly reported), stroke and thromboembolic events, overall complications and prosthesis patient mismatch.

For haemodynamic outcomes, a significantly greater effective orifice area index (EOAI) was reported in patients who received stentless aortic valves compared with stented valves at 30 days (WMD 0.12cm$^2$/m$^2$, 95% CI 0.03 to 0.21), two to six months (WMD 0.15cm$^2$/m$^2$, 95% CI 0.02 to 0.28) and one year (WMD 0.26cm$^2$/m$^2$, 95% CI 0.10 to 0.41). Statistically significant differences were reported for mean and peak gradient in favour of stentless valves. Mean gradient was significantly lower at one month (WMD -6mmHg, 95% CI -10 to -2), two to six months (WMD -4mmHg, 95% CI -7 to -1), one year (WMD -3mmHg, 95% CI -6 to -1) and up to three years follow-up (WMD -3mmHg, 95% CI -3 to -2). Peak gradient was significantly lower at one month (WMD -8mmHg, 95% CI -13 to -3), two to six months (WMD -8mmHg, 95% CI -13 to -3), one year (WMD -8mmHg, 95% CI -14 to -3) and three to eight years follow-up (WMD -10mmHg, 95% CI -16 to -5). Statistically high heterogeneity was found for EOAI and mean and peak gradient.

For resource-based outcomes, there were statistically significant increases in cross-clamp time (WMD 23 minutes, 95% CI 18 to 27) and bypass time (WMD 24 minutes, 95% CI 19 to 30) that arose from stentless valve replacement procedures.

There were no other statistically significant differences between groups.

The results of non-randomised data did not materially alter the findings of the primary analysis.

Authors’ conclusions

Subcoronary stentless aortic valves improved short-term haemodynamic outcomes, There was no evidence to suggest these improvements impacted on patient morbidity, mortality and resource-related outcomes. No definitive conclusions were possible without further long-term evidence.

**CRD commentary**

The review question was clear and supported by potentially reproducible inclusion criteria. The search strategy included a number of relevant data sources. Attempts were made to minimise language and publication biases. The review process was carried out with sufficient measures to minimise error and bias. Despite some reported aspects of trial quality, the absence of any formal assessment made it difficult to judge the overall reliability of the included trials. Study details were reported. An appropriate method of synthesis was chosen in the presence of statistical and clinical heterogeneity. The authors drew attention to several methodological limitations in the included studies (such as small sample sizes and absence of long-term follow-up). The recommendations for future research seemed justified.

This was a largely well-conducted review, although the unclear quality and variability of the included trials means that some degree of caution is warranted when interpreting the conclusion.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that adequately powered RCTs were needed to determine differences between stentless and stented valves on patient survival and function.

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