Meta-analysis of pulmonary valve replacement after operative repair of tetralogy of Fallot

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CRD summary
The review concluded that surgical pulmonary valve replacement in patients after tetralogy of Fallot heart repair was associated with low rates of mortality and significant decreases in right ventricular volumes, but no change in other ventricular functions. The lack of quality assessment and the potential variation between included studies mean that caution is warranted when interpreting the authors' conclusions.

Authors' objectives
To determine the outcomes and effect on right ventricular function of surgical pulmonary valve replacement in patients after repair of tetralogy of Fallot.

Searching
PubMed was searched from inception to April 2009 for articles published in English. Search terms were reported. Reference lists of selected papers were also searched.

Study selection
Observational studies of pulmonary valve replacement after repair of tetralogy of Fallot in adult or paediatric patients were eligible for inclusion. Studies of percutaneous pulmonary valve replacement, case reports and review articles were excluded.

The relevant outcomes were early and late all-cause mortality, valve complications and deteriorations requiring redo-pulmonary valve replacement, changes in QRS duration, and changes in right ventricular volume and ejection fractions.

Included studies assessed homograft, bioprosthetic valve conduit, and mechanical valve pulmonary valve replacement. Included patients had a mean age that ranged from 12 to 34 (where reported).

Two reviewers independently performed study selection and disagreements between them were resolved.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Data were extracted on mortality, valve complications and deteriorations requiring redo-pulmonary valve replacement, changes in QRS duration, and changes in right ventricular volume and ejection fractions; these were used to calculate mean differences and odds ratios (ORs), with 95% confidence intervals (CIs).

The authors did not state how many reviewers were involved in data extraction.

Methods of synthesis
A fixed-effects meta-analysis was conducted to calculate pooled overall mean differences and odds ratios with 95% confidence intervals. Data were also pooled separately for adult and paediatric patients. Statistical heterogeneity was assessed using I² statistic and Cochran’s Q test.

Publication bias was assessed with funnel plots.

Results of the review
Fifteen studies were included in the review (n=736 patients). The study sample size ranged from 16 to 158 patients.
Mean length of follow-up ranged 1.3 to 7.8 years (where reported).

**Mortality:** After tetralogy of Fallot repair, the pooled early mortality rate for all patients was 2.1% per patient year (95% CI 1.1 to 4.0) and the pooled late mortality rate was 0.5% per patient year (95% CI 0.2 to 0.8). For adult patients, the pooled early mortality rate was 1.8% per patient year (95% CI 0.8 to 4.1) and the pooled late mortality rate was 0.5% per patient year (95% CI 0.2 to 0.8). For paediatric patients, the pooled early mortality rate was 2.7% per patient year (95% CI 0.9 to 7.5) and the pooled late mortality rate was 0.4% per patient year (95% CI 0.0 to 1.0).

**Redo pulmonary valve replacement rate:** After tetralogy of Fallot repair, the redo-pulmonary valve replacement rate was 1.9% per patient year (95% CI 1.3 to 2.5) for all patients, 2.2% per patient year (95% CI 1.5 to 2.9) for adult patients, and 1.2% per patient year (95% CI 0.2 to 2.2) for paediatric patients.

**Cardiovascular magnetic resonance imaging-derived outcomes:** Pulmonary valve replacement was associated with a statistically significant reduction in indexed right ventricular end-diastolic volume (mean difference -63mL/m2, 95% CI -72 to -55; I²=67%), indexed right ventricular end systolic volume (mean difference -37mL/m2, 95% CI -45 to -30; I²=0%) and pulmonary regurgitant volume (mean difference -38%, 95% CI -41 to -35; I²=52%). There was no statistically significant effect on right ventricular ejection fraction and QRS duration.

**Authors’ conclusions**
Surgical pulmonary valve replacement in patients after tetralogy of Fallot repair was associated with low rates of early and late mortality and significant decreases in right ventricular volumes, but no change in the right ventricular ejection fracture or QRS duration.

**CRD commentary**
Inclusion criteria for the review were broadly defined. One relevant database was searched. There was the potential for language bias, as only English language studies were sought. Publication bias was reportedly assessed (results not shown); the authors stated that it could not be ruled out. Attempts were made to reduce reviewer error and bias during study selection, but it was not clear if such attempts were made during data extraction.

The authors did not report if quality assessment was conducted, so the impact of study quality on the results was unclear. Studies were pooled using meta-analysis. Statistical heterogeneity was assessed. There was evidence of moderate statistical heterogeneity in some analyses, which was explored. The authors did acknowledge clinical heterogeneity between the studies, primarily due to differences in surgical experience and indications for pulmonary valve replacement.

Overall, the lack of quality assessment and the potential clinical and statistical heterogeneity mean that caution is warranted when interpreting the authors’ conclusions.

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

**Research:** The authors stated that the long-term effect of pulmonary valve replacement remains to be determined.

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**Bibliographic details**

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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.