The Ross procedure: shorter hospital stay, decreased morbidity, and cost effective

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Adult patients undergoing the Ross procedure or mechanical aortic valve replacement.

Setting
Hospital. The economic study was carried out at the Duke University Medical Centre, North Carolina, USA.

Dates to which data relate
The main effectiveness and resource use data were obtained from a single study conducted between 1991 and 1997. The price year was 1996.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Overall 49 patients were included in the analysis: 22 (17 male) consecutive patients underwent the Ross procedure (mean age: 38 +/- 10.8 years) and 27 (17 male) patients had mechanical aortic valve replacement (mean age: 41 +/- 11.3 years). The latter patients were selected from more than 850 patients undergoing mechanical aortic valve replacement, based upon the following selection criteria:

1. age range, 20 to 60 years;
2. lack of concomitant valve or coronary disease;
3. lack of renal dysfunction, peripheral or cerebrovascular disease, or pulmonary disease; and
(4) comparable ventricular function and heart failure classification.

Power calculations to determine the sample size were not reported.

**Study design**
The study was a non-randomised trial with concurrent controls carried out at a single centre. The duration of the follow-up period was 30 versus 11 months for the Ross procedure group and the mechanical aortic valve replacement group, respectively. There was no loss to follow-up.

**Analysis of effectiveness**
The analysis of effectiveness was based on intention to treat. The primary health outcomes included length of stay, incidence of valve-related complications, perioperative mortality, perioperative bleeding and morbidity.

**Effectiveness results**
The length of stay was 5.9 (±2.1) days for the Ross procedure group versus 8 (±1.85) (p<0.01) days for the mechanical aortic valve replacement group. The incidence of significant valve-related complications was 5% in the Ross procedure group and 22% in the mechanical aortic valve replacement group. There was no perioperative mortality in either group (p=0.03). There was no significant perioperative bleeding that necessitated return to the operating room in either group. There was little morbidity in the Ross procedure group. There were two late deaths in the group with mechanical aortic valve replacement.

**Clinical conclusions**
The Ross procedure can be carried out safely, with short hospital stays and decreased morbidity when compared with mechanical aortic valve replacement.

**Modelling**
No modelling was undertaken.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the analysis and as such the authors conducted a cost and consequences analysis.

**Direct costs**
An annual inflation rate of 5% was applied. Quantities and costs were not reported separately. Direct costs included costs related to the operation and post-operative in-hospital course. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities/costs was based on actual data. Data were collected from the Transition I cost accounting system used by the hospital. The price year was 1996.

**Statistical analysis of costs**
Cost data were compared by Student's t-test for unpaired data with a p value of less than or equal to 0.05 indicating statistical significance.

**Indirect Costs**
Not considered.
Currency
US dollars ($).

Sensitivity analysis
Not reported.

Estimated benefits used in the economic analysis
See "Effectiveness results" above.

Cost results
The mean cost amounted to $23,140 (+/- 7,825) for the mechanical valve group and $23,220 (+/- 6,960) for the Ross procedure group, (p=0.47).

Synthesis of costs and benefits
Cost and benefit measures were not combined into a cost-effectiveness ratio.

Authors' conclusions
The study demonstrates that the Ross procedure can be carried out safely with short hospital stays, decreased morbidity and costs comparable with those of standard mechanical aortic valve replacement in patients with isolated aortic valve disease.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. The Ross procedure was considered an acceptable, and sometimes a preferred, procedure for the treatment of aortic valve disease. However, the Ross procedure carried higher operative mortality, morbidity rate and hospital costs compared with the standard mechanical aortic valve replacement. You, as a user of this database, should consider whether this health technology is relevant to your own setting.

Validity of estimate of measure of benefit
The summary benefit measure was used in the analysis and as such the authors developed a cost and consequences analysis. The authors acknowledged that, given the small sample size and the short follow-up period, the conclusions need to be treated with some caution. The patients in the mechanical aortic valve replacement group were not consecutive.

Validity of estimate of costs
Only post-operative hospital costs were included in the analysis. Costs of subsequent medical treatment for complications were not included. Patients undergoing mechanical aortic valve replacement require anticoagulant therapy for the rest of their life and these costs were not included. As noted by the authors, the availability of cost data has probably motivated cost-related changes in patient management during the study period. Given that the cost data are likely to be hospital specific, the authors could usefully have conducted a sensitivity analysis on their cost estimates.

Other issues
Results do not appear to have been presented selectively. The issue of the generalisability of the results to other settings or countries was not addressed.

Implications of the study
Further analysis is required to consider both in-hospital costs and the costs of subsequent medical therapy for complications over an extended period of time.