Surgical and transcatheter (Amplatzer) closure of atrial septal defects: a prospective comparison of results and cost

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
Two procedures for atrial septal defect (ASD) closure were examined, a surgical strategy versus a non surgical option (Amplatzer, AMP).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing ASD closure. Specific inclusion and exclusion criteria were not reported.

Setting
The setting of the study was tertiary care. The economic study was conducted at the Department of Paediatric Cardiology and Cardiac Surgery of the Yorkshire Heart Centre, Leeds, UK.

Dates to which data relate
The effectiveness and resource use data were gathered from May 1998 to February 2000. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations do not appear to have been performed. A sample of 43 consecutive patients undergoing ASD closure participated in the study. There were 24 patients in the AMP group and 19 in the surgery group. The median age in the AMP group was 9.7 years (age range: 2.1 - 44.6) and 22% were males. The median age in the surgery group was 5.5 years (age range: 2.7 - 15.5) and 11% were males.
**Study design**
This was a non-randomised controlled trial, which was carried out in a single centre, the Department of Paediatric Cardiology and Cardiac Surgery of the Yorkshire Heart Centre. The patients were allocated to the study groups on the basis of their suitability for the intervention. Patients with suitable margins on transthoracic echocardiography were offered AMP closure. Patients in the surgical group were those with deficient margins on two dimensional transthoracic echocardiography, those in whom attempted non-surgical closure had failed, and patients with defects suitable for non-surgical closure but who opted for surgery. The patients were followed for one year and no loss to follow-up reported.

**Analysis of effectiveness**
All patients included in the initial study sample were taken into account when estimating the effectiveness. The health outcomes used in the analysis were:

- the procedural success rate,
- the complication rate,
- the percentage of complications affecting treatment,
- the rate of decrease of right ventricular end diastolic diameter (RVEDD) at 6 months,
- the rate of decrease of cardiothoracic ratio at 6 months,
- the median hospital stay, and
- the median time to normal activities.

The study groups were different at baseline in terms of their median age (higher in the AMP group) and size of atrial septal defect size (larger in the surgical group).

**Effectiveness results**
The procedural success rate was 89% in the AMP group versus 100% in the surgical group, (p not significant); the complication rate was 11% (AMP group) versus 47% (surgical group), (p=0.02); complications affecting treatment were 11% (AMP group) versus 21% (surgical group), (p = not significant); the rate of decrease of RVEDD at 6 months was 17.5% (AMP group) versus 15.1% (surgical group), (p not significant); the rate of decrease of cardiothoracic ratio at 6 months was 7.9% (AMP group) versus 7.5% (surgical group), (p not significant); the median hospital stay was 1 day (AMP group) versus 6 days (surgical group), (p<0.01); and the median time to normal activities was 2 weeks (AMP group) versus 5.5 weeks (surgical group), (p<0.01).

**Clinical conclusions**
The effectiveness study showed that the two study interventions were equally effective in terms of the success rate and post-intervention outcomes. However, there were fewer complications in the AMP group. Hospital stay and time to normal activities after the intervention were also significantly lower in the AMP group.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis
was therefore conducted.

**Direct costs**
Discounting was not relevant because the costs per patient were incurred in a short time. The unit costs were not reported separately from the quantities of resources used. The health services included in the economic evaluation were staff and disposables used, catheter laboratory or theatre time, anaesthetics, laboratory or clinical tests, and hospital stay. The cost/resource boundary adopted in the study was not explicitly stated, but it appears to have been that of the NHS. The resource use data were collected prospectively alongside the effectiveness study. The unit costs were estimated from an institution accountant of the study hospital. The resource use data were collected from May 1998 to February 2000. The price year was not reported.

**Statistical analysis of costs**
Standard statistical tests were conducted to test the statistical significance of differences in the total costs between the two study groups.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not conducted.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The median hospital costs were 5,375 (range: 5,252 - 8,439) in the AMP group and 5,412 (range: 5,112 - 7,512) in the surgical group, (p non significant).

**Synthesis of costs and benefits**
Not relevant because a cost-consequences analysis was conducted.

**Authors' conclusions**
The two procedures were similar in terms of the success rate and treatment costs. Complications were more frequent in surgical patients, but this did not affect the patients' treatment. However, hospital stay and time taken off work or school were shorter in the Amplatzer (AMP) group.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear. The surgical approach represented the standard strategy for patients requiring ASD closure. AMP represented a more recently introduced technique. You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness

The effectiveness analysis used a non-randomised controlled trial, which was appropriate for the study question. However, several issues may have affected the internal validity of the analysis. First, the study groups were not well balanced at baseline. Second, power calculations were not conducted and there was no evidence that the sample size was appropriate. Third, selection bias cannot be excluded due to the procedure adopted to allocate the patients to the study groups, which guaranteed that the patient groups would be different according to the Reddy technique used. Finally, it was unclear whether the study sample was representative of the study population.

Validity of estimate of measure of benefit

No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences analysis.

Validity of estimate of costs

The analysis appears to have been conducted from the perspective of the NHS and all the relevant categories of costs appear to have been included in the economic evaluation. The unit costs were not reported separately from the quantities of resources used and the price year was not mentioned. This makes the replication of the study in other settings difficult. Standard statistical tests were conducted to compare the costs per patient estimated in each group. However, the cost estimates were specific to the study setting and sensitivity analyses were not conducted. Only the total costs per patient were reported.

Other issues

The authors made some comparisons of their findings with those from other studies. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. Thus, the external validity of the analysis was low. The study referred to patients undergoing ASD closure and this was reflected in the conclusions of the analysis.

Implications of the study

The study results suggested that both techniques are similarly costly and effective. AMP has the advantage of fewer days spent in hospital, thus permitting earlier return to normal activities.

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