Clinical outcomes and costs of Amplatzer transcatheter closure as compared with surgical closure of ostium secundum atrial septal defects

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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
Transcatheter implantation of the Amplatzer septal occluder (ASO) was compared to the conventional surgical closure of isolated secundum atrial septal defects (ASDs).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients of any age and gender, completely free of concomitant cardiac disease or clinically important non-cardiac disease, who presented with simple isolated secundum ASDs (with a maximum diameter of 38 mm in the device group and no upper limit in the surgical group). A further criterion of the ASO group was that they had margins greater than 5 mm from the coronary sinus, the atrioventricular valves, the right upper pulmonary vein, and superior vena cava.

Setting
The setting was an academic referral tertiary care centre. The economic study was carried out in Chicago, USA.

Dates to which data relate
Effectiveness evidence and resource use came from patients recruited from January 1997 to December 2000. The price year was 2000.

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

Link between effectiveness and cost data
Retrospective costing was carried out on the same sample of patients as that used in the effectiveness analysis.

Study sample
The study enrolled consecutive patients who fulfilled the study criteria. No power calculations were reported; neither were specific details of subjects who refused to participate or who were excluded from the initial sample. Eighty patients were finally enrolled: 48 in the ASO group (mean age 37.9 +/- 23; 64.6% females) and 32 in the surgical group (mean age 19.7 +/- 19; 68.8% females).
Study design
This was a retrospective cohort study carried out in a single centre. The follow-up period for the ASO group was one year after the procedure, and between one to six months after closure for the surgical group. There was no possibility of blinded outcome assessment, as echocardiographers knew the patients' treatment.

Analysis of effectiveness
The analysis seemed to be based on treatment completers only. The primary health outcomes assessed in the study were the treatment success, determined by cardiac auscultation and Doppler transthoracic echocardiography (TTE) by experienced echocardiographers, and the rates of death and complication. Patients were considered to have successful ASD closure if they had no, trivial (less than 1 mm colour jet width), or small (1 - 2 mm colour jet width) residual shunt as assessed by colour Doppler TTE. The two groups were similar in baseline gender and symptoms, but the surgical group was performed on younger patients with larger septal defects.

Effectiveness results
Both groups had similar successful closure of the ASDs.

The initial procedure was successful in 95.8% of the 48 ASO patients, and in 96.8% of the 32 surgical patients, (p=0.8).

There were no deaths in either group.

Complications occurred in 10.4% of patients in the ASO group (all minor) and in 31.2% of patients who underwent surgery, 2 of which were major.

Clinical conclusions
The ASO was equally effective as surgical closure in achieving successful closure in isolated secundum ASDs, and it was also associated with significantly lower morbidity.

Measure of benefits used in the economic analysis
No single measure of benefit was used in the study, therefore it was, in effect, a cost-consequences analysis.

Direct costs
Discounting was appropriately not carried out, as the time horizon was less than two years. No quantities or unit costs were reported. The authors reported that they included all aspects of hospitalisation costs, and the quantity/cost boundary adopted seems to be that of the hospital. They used a cost-accounting system of Transition Systems, Inc. (TSI) of the University of Chicago to estimate average unit costs for various components of hospital care in undiscounted 2000 US dollars. To extrapolate total costs per patient, the authors multiplied the unit costs of components of care by their documented use of the study patients.

Statistical analysis of costs
Costs were treated in a stochastic way, and although statistical tests were performed, they were not reported by the authors.

Indirect Costs
Indirect costs were not reported.
Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were performed with standard decision-analytic software to assess the cost implications of some scenarios. Scenarios evaluated the effect of eliminating the 5 or 10 patients in the surgical group who had the most costly complications, eliminating 48% of failed ASO implantation, or changing the frequency of various clinical outcomes (multi-way threshold analysis).

Estimated benefits used in the economic analysis
The reader is referred to the "Effectiveness results" section reported previously.

Cost results
Total costs were $25,126 +/- $2,996 in the ASO group and $39,351 +/- $7,975 in the surgical group, (p<0.001).

The most important contributors to the cost difference between the two groups were clearly length of hospital stay and length of intensive care unit (ICU) stay (mean length of hospital stay for ASO patients was 1.04 +/- 0.2 days and the mean length of ICU stay was 0 days, while surgical patients had a mean length of hospital stay of 4.3 +/- 1.0 days, and a mean length of ICU stay of 1.3 +/- 0.5 days).

Scenarios that evaluated the effect of eliminating the 5 patients in the surgical group who had the most costly complications reduced the mean cost per case by only $1,817, and eliminating the 10 patients in the surgical group who had the most costly complications reduced the mean cost per case by $3,435.

In all scenarios, the mean cost of surgery still significantly exceeded the mean cost of ASO placement.

In a threshold analysis, the cost of ASO would not exceed the cost of surgery unless approximately 48% of the initial transcatheter procedures failed, and the patients were then required to undergo an additional surgical closure (the actual failure rate of the ASO was only 4%).

In multi-way threshold analyses, surgery was not preferable to the ASO under any plausible combination of outcomes.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
The equally effective and less costly Amplatzer septal occluder appears superior to surgical closure of isolated secundum atrial septal defects in qualifying patients. The transcatheter method was also associated with significantly lower morbidity.

CRD COMMENTARY - Selection of comparators
As the authors pointed out, few data exist that compare transcatheter techniques, such as the ASO, to conventional surgical closure of isolated secundum ASDs. No other transcatheter techniques were compared, but the authors stated that the ASO is one of the most commonly used techniques. The application of the results to your setting may depend on the similarity of this setting to yours.

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study, which was appropriate for the study question, as it allowed the
authors to identify patients who had undergone the two procedures quickly and at little cost. However, it would have been more appropriate if a randomised controlled trial or prospective cohort study with concurrent controls had been undertaken, as these studies, if well conducted, are considered to be the gold-standard design when comparing health interventions, as they are less prone to bias. The study sample appears to have been representative of the study population. Patient groups were shown not to be comparable at analysis, with important group differences that were not taken into consideration in the analysis. Group differences are probably attributable, as the authors reported, to a degree of self-selection bias and due to the technical limitations of device closure. Moreover, no power calculations were reported. Since the study sample was small, there may have been insufficient power to detect statistically significant differences in outcomes.

Validity of estimate of measure of benefit
The authors did not derive a single measure of benefit, so the study was categorised as a cost-consequences analysis.

Validity of estimate of costs
The cost perspective was not specifically reported, though it appears to be that of the hospital. Quantities and costs were not reported separately, and there was not sufficient detail to describe the costing methodology, making it difficult to extrapolate results to other settings or evaluate important omissions. The authors inappropriately separated professional fees from direct costs. Ambulatory costs seem to have been omitted, although their impact on results would have been minor. Resource use was based on the study patients, and prices used were taken from the hospital accounting system. A statistical analysis was performed on costs, without reporting some of its details. The costs date was adequately reported, which will ease any possible inflationary exercises. Different sensitivity analyses were performed, allowing the uncertainty in the authors results to be examined.

Other issues
The authors compared their clinical results with those from other studies, and reported that this is the first study to evaluate in depth cost-effectiveness of ASO versus open surgery. As they stated, though their surgical complication rate is higher than the national average, this clearly did not explain the differential cost observed. The authors acknowledged that their results are not necessarily applicable elsewhere since hospital charges were used to proxy costs. The authors did not present their results selectively, and the conclusions seem to reflect the scope of the analysis. The authors did not report any limitations other than those reported above.

Implications of the study
The authors state that the study supports the use of the ASO as an alternative to surgery for the management of isolated secundum atrial septal defects.

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