Prospective comparison of costs and short-term health outcomes of surgical versus device closure of atrial septal defect in children

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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
The study examined surgical repair or device closure with the Amplatzer septal occluder in children with an isolated secundum atrial septal defect (ASD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all children admitted to the hospital for closure of an isolated ASD.

Setting
The setting was tertiary care. The economic study was carried out in Australia.

Dates to which data relate
The dates of the effectiveness evidence were 1999 - 2001. Resource use data were from the period 1999-2001. There was no adjustment to a common price year.

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

Link between effectiveness and cost data
Costing was carried out on the same patient sample as in the effectiveness study but it was not clear whether the costing was carried out before the effectiveness results were known.

Study sample
No power calculations were used. There was no method of sample selection, patients being allocated to the two treatment groups on the basis of a discussion between the treating cardiologist and the parents. Patients were considered to be suitable for either kind of treatment. No details were given of the considerations that might lead the patients to have a particular kind of treatment. 19 children underwent surgical repair and 43 underwent device closure. Apart from the 62 patients in the study there had been an additional 5 patients who had originally been admitted for device closure but who, during transoesophageal echocardiography, were found to be unsuitable. They were excluded from the analysis.
Study design
This was a single centre trial. The decision regarding closure was made during the outpatient assessment by the treating cardiologist and the parents. Patients were followed up until an echocardiogram 3 months after treatment.

Analysis of effectiveness
The analysis was based on intention to treat. The following primary health outcomes were used: time in hospital, post-procedure pain score, the number of days after which patients resumed preadmission physical activity levels, the amount of concern expressed by the parents, and an echocardiographic evaluation three months after the procedure. The groups were shown to be not comparable. Patients in the device closure group weighed more and were older than those in the surgical closure group, although there was no significant difference between the size of the defects across the two groups.

Effectiveness results
One patient started off having device closure that was unsuccessful and then had successful surgery.

The median time taken in the ICU was 20 hours (IQ range: 18 - 21) for patients undergoing surgery and 0 hours for the device closure patients. The median hospital stay was 88 hours (IQ range: 78 - 112) for the surgery group compared to 29 hours (IQ range: 28 - 39) (p<0.01) for the device closure group. The median post-procedural pain score was higher for the surgery group at 4.9 (IQ range: 3.1 - 7.7), compared to 1.2 (IQ range: 0.4 - 3.0, p<0.0001) for device closure patients. 13 of the 19 patients needed analgesia after 48 hours in the surgery group compared to none in the device closure group.

One day after the procedure 1/19 of the surgical patients and 14/43 of the device closure patients had resumed preadmission physical activity levels, (p<0.01) and after 1 week 4/19 and 36/43 of the patients had achieved this, (p<0.01).

3 months after the procedure, echocardiography showed a small residual shunt in 4 patients in the device group and none in the surgical group, (p=0.3).

There were two complications in the surgical group and three in the device closure group, one of the latter being left with a left embolic cerebrovascular accident.

As far as parental satisfaction was concerned, one third of both parental groups were concerned about the long term consequences of the procedure.

Clinical conclusions
All effectiveness outcomes favoured device closure over surgical closure.

Measure of benefits used in the economic analysis
No summary measure of benefits was used, and this study is thus a cost-consequences analysis.

Direct costs
Discounting was not carried out as it was not relevant because costs were incurred over a period of less than a year. A bar chart was used to present the following costs for both kinds of procedure: the actual procedure, nursing costs, pathology tests, radiology, and pharmacy. Unit costs and resource quantities were not reported separately. Costs were taken from the hospital records of each patient in the study using the hospital’s computerised clinical costing system. No price year was given.
Statistical analysis of costs
No statistical analysis was carried out.

Indirect Costs
Although the study asked how much time parents had taken off work, no attempt was made to calculate a monetary value for this time.

Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
No summary measure of benefits was derived as this was a cost consequences analysis. The reader is referred to the effectiveness results given earlier.

Cost results
The total cost (median) for surgery was Aus$12,969 (range: Aus$11,569 - Aus$14,215) and for device closure was Aus$11,848 (range: Aus$10,669 - Aus$12,555).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Device closure of ASD was associated with a shorter stay in hospital, less pain and less family disruption than surgical closure, as well as being less expensive. However, device closure should be treated with caution until long-term data becomes available.

CRD COMMENTARY - Selection of comparators
The choice of comparators was justified as the two treatments studied were those that currently used for ASD in children.

Validity of estimate of measure of effectiveness
The difference between the two groups before treatment, the surgical group having younger and lighter patients, suggested that these characteristics may have biased the decision towards surgery and that device closure carried out on the surgical patients might have given different results from the ones in the study. Also a major complication in the device closure group occurred in the youngest patient. The study suggested that device closure can be better in the short term for the patient when the patient has been appropriately selected. The authors highlighted the need for a long-term follow-up in order to carry out a reliable comparison of the two procedures.

Also, the measures of effectiveness lose some of their value as no long-term follow-up data on the outcome and safety of the intracardiac prostheses was available. Although the authors carried out surveys of parental opinion before and after treatment, they did not give detailed results and, although they suggest that the data show that the experience of the treatment from the patient's point of view is better in the device closure group than the surgical group, this does not take account of the one patient in the device closure group who experienced a left embolic cerebrovascular accident.
Validity of estimate of measure of benefit
No summary measure of benefit was used. Please refer to the commentary above.

Validity of estimate of costs
Although the authors tried to take account of indirect costs by asking about parental leave, they did not quantify this. As the authors suggested that a true evaluation of these two treatments requires long-term data, this would also imply that long-term cost data is needed. Unit costs and resource quantities were not given separately. This limits the usefulness of the results, as does the lack of a common price year. All the costs were obtained from the hospital's costing system.

Other issues
The authors made comparisons of their results with those from other studies and, although the issue of generalisability was discussed, the absence of cost data broken down by price and quantity makes it difficult for other institutions and countries to assess the applicability of the results to their setting. The authors were aware that the results of their study have limited usefulness as they were only short-term, but they did not see the lack of comparability in the two groups as a major disadvantage. If the groups had been shown to be comparable, or if patients had been assigned randomly, this would have greatly increased the usefulness of the study.

Implications of the study
The authors recommended a long-term study comparing the two treatments. Such a study should also study patient groups with similar pre-treatment characteristics.

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Bibliographic details

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Other publications of related interest


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