Comparison of cost and clinical outcome between transcatheter coil occlusion and surgical closure of isolated patent ductus arteriosus

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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 coil occlusion or surgical closure of the patent ductus arteriosus (PDA).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with isolated PDA who were eligible for either closure technique, not associated with pulmonary hypertension and with no evidence of congestive heart failure.

Setting
Hospital. The study was carried out at the Cleveland Clinic Foundation, Cleveland, Ohio, USA.

Dates to which data relate
Effectiveness, resource use and cost data were collected between August 1993 and June 1996. The price year was not reported.

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

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

Study sample
Patients were identified by retrospectively reviewing the departmental database. No power calculations were reported. Only patients who were eligible for either of the two treatment modalities were included. Thus, the PDA had to be restrictive with no more than mild left ventricular enlargement and no overt clinical evidence of congestive heart failure. Patients were healthy, asymptomatic children, in whom PDA closure was an elective procedure. A total of 39 patients were identified, of whom 3 were excluded because of co-existing medical problems. 24 patients underwent coil occlusion and 12 underwent surgical closure.
Study design
Retrospective cohort study carried out at a single centre. Patients undergoing coil occlusion were followed up for between 0 and 28 months (mean: 6 months). Mean follow-up for surgical patients was 3 weeks.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes used included duration of the procedure, complication rates, and length of stay. At analysis, groups were shown to be comparable in terms of age, weight, and accrual time.

Effectiveness results
The mean duration of the procedure was nearly identical for the two groups: 162 (+/- 59) minutes for coil occlusion and 161 (+/- 38) minutes for surgical closure. Two of the coil occlusion procedures were complicated by coil embolisation. Four patients required more than one coil to achieve closure. Mean length of stay for surgical patients was 3.4. 20 of the 24 coil occlusions were performed as outpatient procedures. Tiny residual leaks were detected in 17% of the coil occlusion patients and in none of the surgical group.

Clinical conclusions
Transcatheter coil occlusion is as effective as surgical closure if silent residual leaks are not considered clinically significant.

Modelling
No modelling was undertaken.

Measure of benefits used in the economic analysis
Successful PDA closure and complications were used as the measures of benefit. Successful PDA closure was defined as absence of a continuous or pathologic sounding systolic murmur at last follow-up. Follow-up data were obtained by review of outpatient hospital records and from communications with referring cardiologists.

Direct costs
It was not clear if direct costs were discounted. Quantities and costs were not reported separately. Direct costs included professional costs, technical costs, costs of inpatient hospital stay, technical and professional costs of tests performed after the procedure, costs of supplies, medication, and blood tests. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. The source of quantity/cost data was the Cleveland Clinic Foundation. Data were derived from a cost accounting system in use at that institution, called Transition Systems, Inc. The price year was not reported.

Statistical analysis of costs
The Wilcoxon rank sum test was used for the statistical comparison of costs between the two groups.

Indirect Costs
Not included.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
None of the coil occlusion or surgical closure patients had a residual PDA murmur after the initial procedure. Follow-up echocardiography was performed in all coil occlusion patients, and tiny residual leaks were detected in 17%. Only 42% of the surgical patients had post-operative echocardiography; none had residual leaks. There were no deaths or major complications in either group. One of the 24 coil occlusion patients had moderate left pulmonary artery stenosis with 30% flow to the left compared with the right lung.

Cost results
The cost of coil occlusion was $5,273 (+/- 1,940), compared to $8,509 (+/- 1,615) for surgical closure, (p<0.001). The cost of inpatient hospital stay was $398 (+/- 217) for coil occlusion and $2,566 (+/- 626) for surgical closure, (p<0.001). Professional costs amounted to $1,506 (+/- 703) for coil occlusion and $2,782 (+/- 516) for surgery. If only those patients who were hospitalised for 3 days were compared with the coil patients, the total costs continue to be significantly lower for coil occlusion ($5,273 versus $7,744, p=0.002). If coil occlusion were to be performed under general anaesthesia, the mean theoretical increase in cost would be $758 for coil patients. If the use of general anaesthesia for coil closure were coupled with a 3-day stay for surgical closure, the difference would be narrowed, but still significant ($6,031 for coil closure versus $7,744 for surgical closure, p=0.003).

Synthesis of costs and benefits
Given that the authors concluded that transcatheter coil occlusion was as effective and less costly than surgical closure, no cost-effectiveness ratios were calculated.

Authors' conclusions
Transcatheter coil occlusion is as effective and less costly than surgical closure if silent residual leaks are not considered clinically significant.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. You, as a user of the database, should verify whether these health technologies are relevant to your own setting.

Validity of estimate of measure of benefit
Relevant measures of benefit were used. The results of the analysis depend on the choice of outcome measure. Controversy remains about the clinical significance of silent residual leaks. The study may suffer from selection bias because the choice of surgical or transcatheter closure was most often based on the preference of the patient or family and occasionally on the preference of the referring physician. The study procedure, being non-randomised and retrospective, would not have dealt with potential confounders or assured comparability of groups and therefore has a number of methodological limitations.

Validity of estimate of costs
Only direct costs were included. Indirect costs, such as costs related to days missed from work, care of siblings during the patient's convalescence, and the psychological cost of a thoracotomy scar were not considered. The relative newness of transcatheter PDA means that its costs are likely to change in the future. The authors combined fixed and variable costs to arrive at the total cost of each procedure. The effect on cost of changes in volume of either procedure was not reflected in the results. The study was limited to one institution. Other institutions may realise different cost relationships between the two methods.
Other issues
The study suffers from a small sample size. However, appropriate comparisons with other relevant studies were made and the generalisability of the results to other settings or countries was discussed. The authors did not present their results selectively. The study enrolled patients with isolated PDA and this was reflected in the authors’ conclusions.

Implications of the study
The results of this study support the continued use of transcatheter coil occlusion as a treatment option for closure of the isolated patent ductus. However, given that transcatheter PDA is a new procedure, costs and clinical protocols are likely to vary across settings. Moreover, additional information is needed on the long-term results of coil occlusion.

Source of funding
None stated.

Bibliographic details

PubMedID
9606229

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM
MeSH
Adolescent; Adult; Cardiac Catheterization /economics; Cardiac Surgical Procedures /economics; Child; Child,
Preschool; Cost-Benefit Analysis; Ductus Arteriosus, Patent /economics /surgery /therapy; Embolization, Therapeutic
/economics; Hospital Costs /statistics & numerical data; Humans; Infant; Retrospective Studies

AccessionNumber
21998000860

Date bibliographic record published
31/05/2000

Date abstract record published
31/05/2000