Clinical outcomes and costs of transcatheter as compared with surgical closure of patent ductus arteriosus


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 Rashkind PDA occluder.

Type of intervention
Treatment

Economic study type
Cost-effectiveness analysis

Study population
Patients with isolated patent ductus arteriosus in whom both implantation of the occluder and surgery were appropriate. Eligible patients were less than 19 years old at admission. They had isolated patent ductus arteriosus without concomitant cardiac disease or clinically important non-cardiac disease. Patients weighing less than 6kg and those in whom the morphologic features of the patent ductus arteriosus were inappropriate were ineligible.

Setting
Tertiary care centre. The economic analysis was carried out in the United States.

Dates to which data relate
Effectiveness and resource usage data was collected during the period June 1982 to December 1987. 1989 prices were used.

Source of effectiveness data
Derived from a single study.

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

Study sample
185 patients in the occluder group and the 446 surgical patients were studied. Of the initial sample of 278 patients who underwent placement of a double-umbrella occluder, 93 were deemed ineligible for the study because of concomitant cardiac disease or non-cardiac conditions, age or weight outside the eligibility criteria, foreseeable absence of follow-up, inappropriate morphologic feature of the patent ductus arteriosus, or more than one of these reasons.
**Study design**
Case-control study was conducted in 14 referral centres. Duration of follow-up was seven months. Loss to follow-up was 12.4% in the implantation group and 37.8% in the surgical group. In these cases, results during hospitalisation were used.

**Analysis of effectiveness**
The analysis of effectiveness was based on treatment completers only and treatment success outcomes were major complication, determined on the basis of the results of cardiac auscultation. Groups were comparable in terms of age, weight and clinical features.

**Effectiveness results**
Overall success rates for the entire study population were 86.5% for occluder patients (95% CI 80.7-91.1%) and 100% for surgery patients (95% CI 99.3-100%). Success rates for the initial procedure only were 77.3% (95% CI 70.6%-83.1%) for occluder patients and 99.8% (95% CI 98.8-100%) for surgery patients. For patients treated in 1987 only overall success rates were 90.5% for occluder patients (95% CI 80.4-96.4%) and 100% for surgery patients (95% CI 96.9-100%). Success rates for the initial procedure only were 87.3% (95% CI 76.5%-94.4%) for occluder patients and 100% (95% CI 96.9-100%) for surgery patients. Major complications occurred in 2.7% (95% CI 0.9-6.2%) of the implantation group patients; and 0.2% (95% CI 0.0-1.2%) of the surgical group patients.

**Clinical conclusions**
The surgical approach produced more successful closures of a patent ductus arteriosus with fewer clinically important complications than did the use of the occluder.

**Measure of benefits used in the economic analysis**
Successful closure and complication rates were used as the outcome measure in the economic analysis.

**Direct costs**
Only the costs of medical care were included. The costs of five categories of care were included: (1) all closure procedures performed (2) management of complications and incidentally identified abnormalities (3) all cardiology follow-up visits, surgical follow-up after the first visit, and all tests ordered during cardiology or cardiology-surgery visits (4) visits to the emergency room or hospitalisations for any reason within 30 days after any closure procedures, and (5) diagnostic catheterisation before or within 7 months after the closure procedure. Average unit costs (including overheads) were used for components of hospital care in undiscounted 1989 US dollars. Data on unit costs were obtained for paediatric patients with patent ductus arteriosus who were treated surgically in 1988 and 1989 at one centre. Occluder costs were calculated by using the unit costs for the cardiac catheterisation, angiography and balloon dilation performed during analogous established procedures. The estimated costs of specialised valvuloplasty equipment were replaced with the 1989 US purchase price for the occluder and its delivery system. Unit costs were available to estimated the costs of inpatient ward care by physicians. For the costs of physicians performing specific procedures estimates were based on maximal charges allowed in fiscal year 1988-89 by Blue Cross and Blue Shield.

**Currency**
US dollars ($).

**Sensitivity analysis**
One way threshold analyses and multiway analysis were performed on the frequency of specific clinical outcomes and patterns of care.
Estimated benefits used in the economic analysis
Overall success rates for the entire study population were 86.5% for occluder patients (95% CI 80.7-91.1%) and 100% for surgery patients (95% CI 99.3-100%). Success rates for the initial procedure only were 77.3% (95% CI 70.6%-83.1%) for occluder patients and 99.8% (95% CI 98.8-100%) for surgery patients. For patients treated in 1987 only overall success rates were 90.5% for occluder patients (95% CI 80.4-96.4%) and 100% for surgery patients (95% CI 96.9-100%). Success rates for the initial procedure only were 87.3% (95% CI 76.5%-94.4%) for occluder patients and 100% (95% CI 96.9-100%) for surgery patients. Major complications occurred in 2.7% (95% CI 0.9-6.2%) of the implantation group patients; and 0.2% (95% CI 0.0-1.2%) of the surgical group patients.

Cost results
Mean costs of $8,838 per surgical case and $11,466 per occluder placement. In 1987 alone, the cost per occluder case was reduced to $10,679 and the cost per surgical case to $8,586.

Synthesis of costs and benefits
The surgical procedure was the dominant strategy.

Authors' conclusions
The more effective and less costly surgical procedure was superior to transcatheter placement of the occluder for closure of isolated patent ductus arteriosus.

CRD Commentary
This is a good retrospective study. Although the surgical technique maintained its relative advantage over the duration of the study it should be noted that this advantage narrowed over time. As the authors note, outcomes of occluder use may improve with time and costs associated with the new procedure may decline. A substantial number of patients who underwent occluder placement were not entered into the study (93/278); it is unclear whether for these patients occluder placement is the only or better treatment option. It would have been useful if the confidence intervals and p-values for the difference of clinical results were reported by the authors.

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