Transcatheter coil occlusion of the small patent ductus arteriosus (< 4 mm): improved results with a "multiple coil-no residual shunt" strategy

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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 of the patent ductus arteriosus (PDA) using the multiple coil-no residual shunt strategy was compared with a single coil strategy or surgical closure. All patients receiving transcatheter closure of PDA were admitted for overnight observation and released the next morning if no complications occurred. They received antibiotics pre- and post-procedure. Surgical patients were also admitted overnight to the cardiac ward for at least 23 hours. Unless there was intra-operative bleeding, a chest tube was not inserted.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing treatment for PDA were studied. All patients referred for coil occlusion had echocardiographic confirmation of their PDA using 2D, Doppler and colour Doppler echocardiography. Those undergoing surgical closure of PDA were non-premature patients with uncomplicated PDAs, <4 mm as determined by echocardiography. Surgery patients were either referred without being offered coil closure or chose surgical closure over coil closure.

Setting
The practice setting was secondary care. The economic study was carried out in Dallas, Texas, USA.

Dates to which data relate
Patients undergoing the single coil strategy received the intervention between November 1995 and December 1996. Those undergoing the multiple coil-no residual shunt strategy were treated between January 1997 and September 1998. Patients receiving the surgical intervention were operated on between November 1995 and September 1998. The same years related to resource use and prices.

Source of effectiveness data
The effectiveness data were 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
The methods used to determine sample size (i.e. power calculation) and to select patients were not described. The authors did not explicitly justify the choice of patient sample, but the patients selected appear to have been appropriate given the study objective. Overall, 59 patients were recruited for the study, including 15 in the single coil strategy group, 20 in the multiple coil-no residual shunt strategy group, and 24 in the surgery group. The number of clinicians and hospitals involved was not specified. Information relating to the number of patients refusing to participate and those excluded from the initial sample was not provided.

**Study design**

The study consisted of three case series, one for each intervention, that were not completely concurrent with one another. The number of centres involved in the study was not specified. The method of group allocation was not reported. However, it was stated that some surgical patients were permitted to chose between this and coil closure. All patients were followed up for 6 months. Details of withdrawals and the methods used for blinding outcome assessment were not mentioned.

**Analysis of effectiveness**

It was unclear whether the analysis of effectiveness was based on intention to treat or treatment completers only. The following were analysed in the two transcatheter PDA closure groups: the pulmonary to systemic flow ratio, the length of hospital stay, incidence of complications, mortality rates, acute closure rates determined by angiography and echocardiography, and closure rates at 6 months using complete 2D, Doppler and colour Doppler echocardiography.

Similar outcomes were measured in the surgical patients with the following exceptions: the pulmonary to systemic flow ratio was not assessed, and because echocardiography was not routinely carried out at follow-up, closure rate data were not available (the PDA was assumed to be completely closed). Surgical patients were examined at 2 weeks, 6 weeks, and 6 months post-operatively.

Patients were older in the single coil group compared to the two other groups. However, the authors reported that the differences seen were not statistically significant. The mean (SEM) age of patients was 5.34 (1.31) years for those undergoing the single coil strategy, 3.61 (0.91) years for those undergoing the multiple coil-no residual shunt strategy, and 3.17 (0.15) years for surgical closure. The authors reported that there were no statistically significant differences between the two transcatheter coil groups with respect to pulmonary artery pressure, the pulmonary to systemic flow ratio, minimal PDA diameter (all PDAs were less than 4 mm in diameter), PDA length, ampulla size, aortic diameter, and PDA type. Comparability between the two transcatheter coil groups and the surgical group was not reported.

**Effectiveness results**

For patients undergoing single coil strategy:

Six out of 15 patients had a residual shunt assessed by angiography at the end of the case. Three of the six shunts closed spontaneously by 6 months, one had surgical closure, one was closed by one year and one had a persistent shunt. Thus, the complete closure rate for coil embolisation was 60% immediately, 80% at 6 months, and 87% at one year.

For patients undergoing the multiple coil-no residual shunt strategy:

Fifteen out of 20 patients required one coil to achieve total closure assessed by angiography at the completion of the case. Four patients required 2 coils, and one patient required 3 coils. The acute and 6 month closure rates were both 100%.

The mean (SEM) shunt grade (calculated by adding the grades of shunt in each group and dividing by the number of patients in each group) was significantly different between the two groups: 0.67 (0.23) in the single coil group versus 0.14 (0.08) in the multiple coil group, (p=0.021).

**Complications:**

There were no procedural or acute post-procedure complications in the coil groups. In the surgical group,
complications consisted of readmission for fever within 48 hours (one patient), chest tube for pneumothorax (three patients), and prolonged hospitalisation because of the need for pain control (three patients). No patient died in any group.

The mean (SEM) length of stay for the coil groups was 1 (0) day and for the surgical group 1.54 (0.16) days, (p=0.024).

Clinical conclusions
The multiple coil-no residual shunt strategy is better than the single coil strategy and equals the closure rates of the surgical alternative for small PDAs. Mortality was similar to that of surgical closure, however morbidity seems to be less with coil closure than with surgical closure.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis and only separate clinical outcomes were reported. As such, a cost-consequences analysis was performed.

Direct costs
Hospital costs and charges were obtained from the hospital financial database for patients in both coil groups and in the surgical group. Hospital costs were derived from hospital cost accounting formulae. The variable costs were dependent upon procedure time, equipment, medication, technical staff time, anaesthesia time and nursing acuity used in each procedure for each patient. The mark-up for hospital charges was based on the cost of the product plus a profit margin and was inversely proportional to the cost of the product. The physician charges were obtained from the billing sheets utilised for each procedure and were standardised per procedure. Resource quantities and costs were not reported separately, and discounting was not mentioned. However, discounting was probably not relevant due to the short period of analysis, i.e. less than one year. The price data appear to refer to the period between November 1995 and September 1998.

Statistical analysis of costs
Results were expressed as means (SEM). The unpaired t-test was used to compare a single variable between two groups. Analysis of variance was used to compare multiple means and multiple groups. A p-value equal to or less than 0.05 was considered statistically significant.

Indirect Costs
Indirect costs were not mentioned, and no justification was given for their exclusion.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis
Please see the effectiveness results reported above.

Cost results
Cost results were based on 14 patients from the single coil group, 18 patients from the multiple coil group, and 24 patients from the surgical group. The mean (SEM) cost was $4,420 (279) for the single coil group, $5,259 (305) for the
multiple coil group, and $4,710 (282) for the surgical group (non-significant difference between groups). The mean (SEM) cost for the two coil groups combined was $4,883 (221): a non-significant difference when compared with the surgical group. Mean (SEM) hospital charges were $7,372 (503) for the single coil strategy, $9,584 (584) for the multiple coil strategy, and $9,079 (704) for the surgical group, (non-significant difference between groups). If physician charges were added to the hospital charges, the total charges were $12,089 (584) for the single coil strategy, $14,565 (616) for the multiple coil strategy, and $14,729 (704) for the surgical group, (non-significant difference between multiple coil and surgical groups; p<0.05 for single coil group versus multiple coil strategy group).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The results suggest that transcatheter closure with multiple coils can achieve the same closure rate as surgery at similar hospital charges with fewer complications.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was given for the comparators used (single coil strategy and surgical closure), they would appear to represent alternatives in current practice in the authors’ setting. Consideration should be given to the appropriateness of the comparators used in relation to other settings.

Validity of estimate of effectiveness:
The analysis was based on a retrospective examination of three case series (one for each treatment strategy) that were not entirely concurrent with one another, which hampers somewhat the validity of the results. Whilst an adequately powered randomised controlled trial with concurrent prospective study groups would have been preferable, it is possible that sufficient numbers of eligible patients may be difficult to recruit, and also randomisation may be considered unethical in such patients. The study sample is likely to be representative of a more general population with small (less than 4 mm) PDA. Data were reported on important clinical variables at baseline, and the study groups appeared to be comparable. It was unclear whether all the patients were accounted for in the analysis. However, relevant numbers were reported for the cost data.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study. For the interventions considered this approach is more informative and appropriate.

Validity of estimate of costs
A cost perspective was not defined, and only direct costs were considered. Hospital costs and charges were obtained from the hospital financial database, with hospital costs derived from hospital cost accounting formulae. Physician charges were obtained from the billing sheets utilised for each procedure and were standardised per procedure. Discounting was not mentioned, but is unlikely to be applicable due to the short period of analysis.

Other issues
The authors made appropriate comparisons between their findings and those from other studies. The issue of generalisability to other settings was not addressed. The study recruited young patients with small (<4 mm) PDAs and this was reflected in the authors' discussion.

Implications of the study
Implications for changes in policy or practice:
The authors stated the following: "We feel that for the PDA <4 mm, coil occlusion using multiple coils, if necessary, to achieve complete closure is an excellent alternative to surgical closure in many respects and should become the treatment of choice. For larger PDAs, the results with a multiple coil strategy are very promising, even in small children. For coil occlusion to become the treatment of choice for all or the majority of PDAs, however, complete closure strategies should be implemented and seem to be achievable."

Implications for further research:

None stated.

Source of funding

None stated.

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