Cost and efficacy of surgical ligation versus transcatheter coil occlusion 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
Using transcatheter coil occlusion techniques or surgical ligation with new critical pathway methods for the treatment of patent ductus arteriosus (PAD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Non-neonatal children with isolated PDA.

Setting
Hospital. The economic study was carried out in Utah, USA.

Dates to which data relate
The effectiveness and resource use data corresponded to patients treated between 1994 and 1996. The price year was not clearly reported.

Source of effectiveness data
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
Power calculations were not used to determine the sample size. A total of 40 patients were included in the study, 20 in the thoracotomy and surgical ligation group and 20 to the coil occlusion option. The criteria used for the assignment of patients to the study groups were their preferences and/or PDA size (PDAs <= 5mm were assigned to the coil occlusion, whilst those considered too large for coil occlusion were assigned to surgical ligation).

Study design
The study was a retrospective non-randomised trial with concurrent controls performed in a single centre. The duration
of follow-up was not clearly reported, although data at 22 months after the procedure were reported in one case.

Analysis of effectiveness
The analysis was based on treatment completers only. The primary health outcome investigated in the analysis was the rate of success as defined by no evidence of any residual flow under late colour-flow Doppler echocardiographic assessment (the time at which such assessments were undertaken was not reported). The alternative health technologies were also compared in terms of procedure length and duration of hospitalisation. Although the mean age and weight of the coil occlusion group were higher than those of the surgical ligation group, the differences did not reach statistical significance (p<0.05).

Effectiveness results
The rate of patency was reported as 11% (2 cases, one found at 1 month and the other at 22 months of follow-up) in the coil occlusion and 0% in the surgical ligation group. The procedure length was 101 minutes (SD = 42) for the coil group versus 46 minutes (SD = 6) for the surgical group (P<0.05). The duration of hospitalisation was 11 hours (SD = 6) for the coil group versus 27 hours (SD = 6) for the surgical group (P<0.05).

Clinical conclusions
The authors believed that double or triple ligation and division of the PDA are associated with a negligible residual patency rate as indicated by the results of this study and those of others and likely remain the standard by which the efficacy of newer therapies should be measured.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic study and only separate clinical outcomes were reported.

Direct costs
The quantities were not fully reported separately from the costs. The costs measured were those incurred within a period of one month after the procedure and included inpatient and outpatient hospital charges and professional fees. The cost analysis was performed from the patient’s perspective. The price year was not clearly reported. The source of cost data was the hospital records. The costs associated with pre-procedure diagnostic tests were not included in the analysis (reported as undertaken by all patients). The costs associated with all post-procedure echocardiograms were free of charge and were not included in the cost analysis. The authors included the costs associated with the operation incurred by the two patients who were initially offered coil occlusion but who ultimately underwent the surgical ligation procedure.

Statistical analysis of costs
It appears that Student’s t test was used to compare the groups in terms of mean cost total charges.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean cost (charges) associated with the coil occlusion option was $7,105 (+/- 886) whilst, for the surgical ligation option the cost value was $7,101 (+/- 407).

Synthesis of costs and benefits
Costs and benefits were not combined due to the observed dominance of the surgical ligation option.

Authors’ conclusions
Surgical treatment of PDA remains the standard by which newer, less invasive techniques must be measured both in terms of cost and efficacy. Transaxillary, muscle sparing thoracotomy without tube thoracotomy, triple ligation, and critical pathway methods allow safe and effective ligation of a PDA with early hospital discharge. This surgical method has a similar overall cost, higher efficacy rate, and applicability in all patients as compared with newer transcatheter coil occlusion techniques for closure of PDA. Nevertheless, coil occlusion is the procedure of choice in the study institution due to its cost-effectiveness and lower morbidity in smaller PDA.

CRD COMMENTARY - Selection of comparators
No specific justification was given for the choice of coil occlusion as the comparator (for example against Rashkind occlusion device closure). You should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit
Due to lack of randomisation, the internal validity of the effectiveness results is not assured. Furthermore, it seems that the alternative health technologies were applied to two different patient populations since the allocation of patients to study groups was based on whether the PDA was larger or smaller than 5 mm. The results may, therefore, not be comparable for the two health technologies involved in the study.

Validity of estimate of costs
The quantities associated with the length of hospital stay and procedure were not fully reported separately from the costs. Adequate details of methods of cost estimation were not given. The price year was not clearly reported. Indirect costs, as important elements of the cost analysis in the study context, were not included.

Other issues
Given the lack of randomisation and sensitivity analysis, the results need to be treated with some caution. The conclusions reached by the authors were not fully justified given the uncertainties in the data. The issue of generalisability was not directly addressed.

Implications of the study
Better designed studies are needed, with adequate entry criteria, prospective designs and appropriate study sizes, as well as the adequate collection of economic data. Only after the research questions have been adequately posed and set up, can a valid statement about the most efficient option for a given population of patients with PDA be made.

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