Economic evaluation and randomised controlled trial of extracorporeal membrane oxygenation: UK collaborative trial

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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
Extracorporeal membrane oxygenation (involving oxygenation outside the body and providing cardiovascular support if required) for mature newborn infants with severe respiratory failure.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Mature newborn infants with severe respiratory failure.

Setting
Hospital. The economic study was carried out in the UK.

Dates to which data relate
Effectiveness and resource use data were collected between 1993 and 1995. Some of the resource use data (related to days not receiving extracorporeal membrane oxygenation) were obtained from a parallel study conducted by some of the same researchers. The price year was 1994-95.

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

Link between effectiveness and cost data
Costing was performed on the same patient sample as that used in the effectiveness analysis. In addition, data produced by another study were used to estimate the costs of days not receiving extracorporeal membrane oxygenation.

Study sample
Power calculations were not used to determine the sample size. The sample consisted of 185 subjects (with gestational age at birth greater than 35 weeks and birth weight greater than 2kg) randomly assigned to receive extracorporeal membrane oxygenation (n=93) or conventional management (n=92).

Study design
The study was a randomised controlled trial. The intervention was performed in 5 specialist centres, while the conventional method was conducted in 55 hospitals. The duration of the follow-up was until 1 year of age. The loss to follow-up was 1 patient in each study group.

Analysis of effectiveness
The principle used in the analysis of effectiveness was intention to treat. The clinical outcome measures at 1 year were survival, number of survivors without severe disability, number of survivors with no disability, number of survivors with impairment or disability, and readmission rate.

Effectiveness results
The effectiveness results were as follows:

The extracorporeal group had a survival rate, at 1 year of age, of 68% versus 41% in the conventional group.

The respective values for the number of survivors without severe disability were, 61 in the extracorporeal group versus 36 in the conventional group;

the number of survivors with no disability, 49 in the extracorporeal group versus 32 in the conventional group;

the number of survivors with impairment or disability, 17 in the extracorporeal group versus 10 in the conventional group.

The readmission rate for the survivors was 51% in the control group versus 35% in the intervention group.

Clinical conclusions
The (study) results showed that (extracorporeal membrane oxygenation for babies) is more clinically effective (than the conventional management).

Measure of benefits used in the economic analysis
The two benefit measures adopted were the number of survivors without severe disability at 1 year of age and the number of survivors with no disability (with or without impairment) at 1 year of age.

Direct costs
Costs were not discounted as 1-year follow-up was adopted for the cost analysis. Quantities of resource use and the number of journeys were reported in terms of the number of days of health service use and were reported separately from the costs. A breakdown of costs was reported separately. The cost analysis covered the costs of transportation until discharge, services associated with initial inpatient hospitalisation including the cost of death, and follow-up to 1 year. The perspective adopted in the cost analysis was stated to be that of the United Kingdom National Health Service (NHS). The initial inpatient hospitalisation was classified into five categories of days receiving extracorporeal membrane oxygenation; days receiving maximal intensive care (more than 90% oxygen); days on a ventilator (receiving less than 90% oxygen); days on supplementary oxygen; and days in normal care. Cost data related to days not receiving extracorporeal membrane oxygenation were obtained from other published studies (1997 and one in press) in 1991 prices. These were then adjusted to 1994-95 prices employing a combined hospital and community health services index, and were furthermore adjusted by 10% to reflect the size of the neonatal units in the main trial. The cost data related to days receiving extracorporeal membrane oxygenation were gathered from 4 participating centres (using a detailed questionnaire) employing a 'top down' approach when possible. The source of cost for each ambulance journey was personal communication with the London Ambulance Service. The cost of each journey consisted of a fixed fee for the vehicle, a rate for mileage, and an hourly rate for the duration of the ambulance use. The cost data for air transport were obtained from the medical records of the relevant companies and services. Cost data related to the costs of follow-up to 1 year of age were obtained from published unit costs from the University of Kent. The date of the price data was
1994-95. The cost analysis did not consider the costs of lighting, heating, and buildings. The costs of counselling services for the parents of a dead infant and training costs for the staff involved in the intervention programme were not included in the cost analysis.

**Indirect Costs**
Not considered.

**Currency**
UK pounds sterling (). 

**Sensitivity analysis**
A series of one-way sensitivity analyses was conducted on the daily cost of extracorporeal membrane oxygenation, number of patients receiving extracorporeal membrane oxygenation, mode of transport, the difference in survival between the two study groups, and staff levels.

**Estimated benefits used in the economic analysis**
See effectiveness results above.

**Cost results**
The mean cost/case for patients receiving extracorporeal membrane oxygenation was 20,826 versus 7,002 for patients receiving conventional treatment.

**Synthesis of costs and benefits**
An incremental cost-effectiveness ratio was calculated by dividing the additional cost of the intervention over the comparator to the additional survivors without severe disability, and to the additional survivors with no disability, which amounted to 51,222 and 75,327, respectively. The sensitivity analysis produced a range of values from 34,346 to 110,593.

**Authors' conclusions**
Extracorporeal membrane oxygenation for term neonates with severe respiratory failure would increase overall survival without disability. Although the policy will increase costs of neonatal health care, it is likely to be as cost-effective as other life extending technologies.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator is clear, as it was the conventional treatment in the author's setting.

**Validity of estimate of measure of benefit**
The benefit results are likely to be internally valid given the use of a randomised design. Power calculations do not appear to have been used to determine sample size. However, the results suggest that the sample size was appropriate.

**Validity of estimate of costs**
Quantities of resource use were reported separately from the costs and adequate details of the methods of cost estimation were given. Costing was performed on the same sample. However, additional 'secondary' data were obtained from another parallel study. A NHS perspective was adopted in the analysis, however the authors reported that costs to parents and families would be discussed elsewhere. The cost results may not be generalisable to other settings.
Other issues
The author's conclusions seem to be justified given the uncertainties in the data. Appropriate comparisons were not made with other studies.

Implications of the study
Because of the short term perspective of (this) analysis, (the author) concluded that the study supports adoption of extracorporeal membrane oxygenation, but this conclusion should be treated with caution until evidence about longer term effects emerge. The quality of life for all the trial survivors is being assessed in four and seven-year follow up studies in the course of which the cost per quality adjusted life year (QALY) will also be estimated.

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