Utility of daily head ultrasonography for infants on extracorporeal membrane oxygenation

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
Daily head ultrasonography (HUS) in the diagnosis of intracranial haemorrhage (ICH) for infants on extracorporeal membrane oxygenation (ECMO) for severe respiratory failure.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Infants on extracorporeal membrane oxygenation (ECMO) for severe respiratory failure.

Setting
Hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to infants under treatment between February 1986 and March 1995. The price year was not explicitly specified.

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

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 298 patients on ECMO with a mean gestational age of 38 (range: 33-43) weeks. It was reported that "no patients were excluded from the study". The total number of HUS examinations performed on 298 patients was 2,518, 31% of which (768) were performed after day 5 on 248 patients.

Study design
Retrospective cohort study, carried out in 5 centres. A faculty radiologist at each study site reviewed the clinical records. HUS was performed on all patients before the application of ECMO and daily while on ECMO.
Analysis of effectiveness
The principle used in the analysis of effectiveness was intention to treat. The clinical outcomes were the total number (percentage) of patients diagnosed as having ICH, the classification of the diagnosed ICHs (using the Papile Classification for ICH), the distribution of new ICH detected by HUS with respect to the day of the ECMO course, and the number of patients taken off ECMO support and their distribution in terms of day of the ECMO course and extension to higher grades.

Effectiveness results
The total number (percentage) of patients diagnosed to have ICH, was 52 (17.5%).

The distribution of new ICH detected by HUS with respect to the day of the ECMO course and their corresponding grade levels were as follows:

9 (17.3%) cases of ICH (all grade 1) were detected before the application of ECMO therapy;

43 (82.7%) cases were identified while on ECMO, including 15 cases of grade I, 10 cases of grade II, 10 cases of grade III, and 8 cases of grade IV.

The number (percentage) of cases of ICH diagnosed during the first 5 days of the ECMO course was 40 (93%) of 43 patients whose ICH was detected while on ECMO;

3 new cases of ICH detected after day 5 included 2 cases of grade I (either resolved or persisted but never extended beyond grade I) and one with grade VI (who, in any case, had the clinical indications for performing HUS).

The number of patients taken off ECMO support and their distribution in terms of day of the ECMO course and extension to higher grades were as follows:

9 patients were taken off (8 during the first 5 days). Of these, 5 had no extension, 4 had extension to grade III and one to grade IV. The management of one patient with ICH detected after 5 days was changed because of significant ICH.

No extension was observed for 15 patients with grade I ICH detected after the ECMO course.

Clinical conclusions
Based on (the results of this study), it would seem that, barring clinical indication, the chances of missing a clinically significant ICH would be minimal if the HUS were performed for only the first 5 days of the ECMO. (This) study shows that a grade I ICH never progressed beyond 5 days. Therefore, if not clinically indicated, patients with a grade I ICH should not require surveillance with a daily HUS beyond 5 days.

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

Direct costs
Costs were not discounted due to the short time frame of the study. Quantities were only reported separately from the costs in terms of the number of HUS performed. Cost items, however, were reported separately. Cost analysis covered the estimated charges for portable HUS. The perspective adopted in the cost analysis was not explicitly specified. The source of charge data was the study institutions. The date of the price data was not explicitly specified.

Indirect Costs
Not considered.
Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The estimated charge for each portable HUS was between $400 and $600. The associated cost with the 786 HUS performed after 5 days of ECMO course was between $314,400 and $471,600.

Synthesis of costs and benefits
Not combined.

Authors' conclusions
Almost all ICH occur during the first 5 days of an ECMO course. Unless there is a clinical suspicion, it is not cost-effective to perform HUS after the fifth day on ECMO, because subsequent HUS examinations are unlikely to yield information significant enough to alter management.

CRD COMMENTARY - Selection of comparators
Routine use of HUS in the context in question was compared with performing HUS for the first 5 days after the initiation of ECMO therapy only. You, as a database user, should consider which health technology is the more widely used in your own setting.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results cannot be guaranteed due to the retrospective nature of the study design. As acknowledged by the authors, the study sample may have been insufficient for the purposes of the study. The study was a cost-consequences analysis.

Validity of estimate of costs
Quantities were only reported separately from the costs in terms of the number of HUS performed. Insufficient details of methods of cost estimation were given. Charge data were used as opposed to data on true costs. The cost results may not be generalisable to other settings.

Other issues
The authors' conclusions may not to be fully justified given the retrospective nature of the study design, lack of sensitivity analysis, and lack of statistical analysis of the costs. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies.

Implications of the study
Larger numbers of patients would be needed in order to assess whether HUS can be performed less frequently during the first 5 days and to assess the necessity of performing a HUS at all during second ECMO courses or for specific
diagnoses.

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