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Title **Randomized Controlled Trial and Parallel Economic Evaluation of Conventional Ventilatory Support versus Extracorporeal Membrane Oxygenation for Severe Adult Respiratory Failure (CESAR)**

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Aim

To determine the comparative effectiveness and cost effectiveness of conventional ventilatory support versus extracorporeal membrane oxygenation (ECMO) for severe adult respiratory failure.

Conclusions and results

Compared with conventional management (CM), transferring adult patients with severe but potentially reversible respiratory failure to a single center specializing in treating severe respiratory failure, for consideration of ECMO, significantly increased survival without severe disability. This use of ECMO is likely to be cost effective compared to other technologies. In total, 180 patients (90 in each arm) were randomized from 68 centers. Of the 90 patients randomized to the ECMO arm, 68 received that treatment. ECMO was not given to: 3 patients who died prior to transfer, 2 who died in transit, 16 who improved with conventional treatment given by the ECMO team, and 1 who required amputation and could not be heparinized. Of the 90 patients who entered the CM (control) arm, 3 patients later withdrew and refused follow-up, leaving 87 patients for whom primary outcome measures were available. CM consisted of any treatment deemed appropriate by the patient's intensivist, with the exception of extracorporeal gas exchange. No CM patients received ECMO, although 1 received a form of experimental extracorporeal arteriovenous carbon dioxide removal support (a protocol violation). Fewer patients in the ECMO arm than in the CM arm had died or were severely disabled 6 months after randomization (33/90 [36.7%] versus 46/87 [52.9%] respectively). This equated to 1 extra survivor for every 6 patients treated. Only 1 patient (in the CM arm) was known to be severely disabled at 6 months. Patients allocated to ECMO incurred average total costs of 73 979 pounds sterling (GBP) compared to GBP 33 435 for those undergoing CM (UK prices, 2005). A lifetime model predicted the cost per quality-adjusted life-year (QALY) of ECMO to be GBP 19 252 (95% confidence interval GBP 7622 to GBP 59 200) at a discount rate of 3.5%. Lifetime QALYs gained were 10.75 for the ECMO group compared to 7.31 for the conventional group. Costs to patients and their relatives, including out-of-pocket and time costs, were higher for patients allocated to ECMO.

Recommendations

A limitation of this study is the lack of standardized care in the conventional arm (the conventional intensive care providers could not reach a consensus as to what constituted optimal care). An alternative strategy of transferring all patients to Glenfield to be cared for by the ECMO team was dismissed by collaborators as they did not consider the ECMO team to be sufficiently expert in providing conventional intensive care. The other option considered was to use a single center to provide all of the conventional care, but this was impossible as the UK has no such center. Hence, the trial team took the pragmatic decision to recommend what was proven to be the best ventilation strategy (the low volume ARDSNet protocol), but allow individual intensivists to determine what they thought was the best treatment for their patients. Had this decision not been taken, it would have been impossible to conduct the study. The pragmatic design meant that CESAR was comparing treatment in an expert center (where ECMO was part of the treatment algorithm) to treatment available to the general public in the UK as a whole.

Methods

See Executive Summary link www.hta.ac.uk/project/1150.asp.

Further research/reviews required

See Executive Summary link www.hta.ac.uk/project/1150.asp.

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