Position Paper for the Organization of Extracorporeal Membrane Oxygenation Programs for Acute Respiratory Failure in Adult Patients

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Abstract

The use of extracorporeal membrane oxygenation (ECMO) for severe acute respiratory failure (ARF) in adults is growing rapidly given recent advances in technology, even though there is controversy regarding the evidence justifying its use. Because ECMO is a complex, high-risk, and costly modality, at present it should be conducted in centers with sufficient experience, volume, and expertise to ensure it is used safely. This position paper represents the consensus opinion of an international group of physicians and associated health-care workers who have expertise in therapeutic modalities used in the treatment of patients with severe ARF, with a focus on ECMO. The aim of this paper is to provide physicians, ECMO center directors and coordinators, hospital directors, health-care organizations, and regional, national, and international policy makers a description of the optimal approach to organizing ECMO programs for ARF in adult patients. Importantly, this will help ensure that ECMO is delivered safely and proficiently, such that future observational and randomized clinical trials assessing this technique may be performed by experienced centers under homogeneous and optimal conditions. Given the need for further evidence, we encourage restraint in the widespread use of ECMO until we have a better appreciation for both the potential clinical applications and the optimal techniques for performing ECMO.

Keywords: extracorporeal membrane oxygenation; acute respiratory distress syndrome; hospital organization; critical care networks; position article

The use of extracorporeal membrane oxygenation (ECMO) for severe acute respiratory failure (ARF) in adults is growing rapidly given recent advances in technology, although there is controversy regarding the evidence justifying its use (1–9). The recent experience in 2009 using ECMO for pandemic influenza A (H1N1)–associated acute respiratory distress syndrome (ARDS) revealed that many centers initiated ECMO programs without significant experience and with

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variable results (7, 9–16). Because ECMO is a complex, high-risk, and costly modality, at present it should be conducted in centers with sufficient experience, volume, and expertise to ensure it is used safely. Additionally, further clinical trials are essential for identifying and clarifying the indications, contraindications, and techniques for use of this technology.

Purpose of this Position Paper

This position paper represents the consensus opinion of an international group of physicians and associated health-care workers who have expertise in therapeutic modalities used in the treatment of patients with severe ARF, with a focus on ECMO. The aim of this paper is to provide physicians, ECMO center directors and coordinators, hospital directors, health-care organizations, and regional, national, and international policy makers a description of the optimal approach to organizing ECMO programs for ARF in adult patients. This will help ensure that ECMO is delivered safely and proficiently at centers capable of both providing high-quality ECMO and participating in high-impact clinical research. It is of the utmost importance to ensure that future observational and randomized clinical trials assessing this technique be performed by experienced centers under homogeneous and optimal conditions Given the need for further evidence, we encourage restraint in the widespread use of ECMO until we have a better appreciation for both the potential clinical applications and the optimal techniques for performing ECMO.

Definitions

Extracorporeal life support (ECLS) systems are mechanical devices designed to temporarily support the failing heart or lungs (17). They differ from cardiopulmonary bypass systems used in the operating room for very short-term support during surgery in both their configuration and intent. The term ECMO is often used interchangeably with ECLS, as we will use it here, although it denotes a form of ECLS in which the primary purpose is to provide blood oxygenation. There are two anatomic approaches that are used to implement ECMO: venoarterial (VA) and venovenous (VV). Virtually all applications are variations on these.

- VA ECMO drains the blood from the right atrium via a femoral venous or internal jugular venous cannula or, in patients with an open chest, directly from the right atrium (17). The blood is pumped through a membrane oxygenator allowing oxygen to be added and carbon dioxide to be removed. After passing through the oxygenator, blood is then actively pumped into the arterial system either via a cannula placed in a peripheral artery, usually femoral or subclavian (closed chest), or directly into the aorta (open chest). VA ECLS is typically a high blood flow extracorporeal circuit that can pump up to 7 L/min and provide full or partial cardiopulmonary support (18–25). VA ECMO is a closed system, which differs from standard cardiopulmonary bypass used in the operating room, which is an open system with a blood–air interface.
- VV ECMO drains blood from the venae cavae via a femoral venous or right internal jugular venous cannula (17). The blood is, once again, pumped through a membrane oxygenator; however, in this case it is returned to the venous system either via a femoral venous or right internal jugular venous cannula. A single bicaval double-lumen cannula inserted in the internal jugular vein can be used for venous drainage (26). VV ECMO is a high blood flow (up to 7 L/min in some cases) extracorporeal circuit that may provide full or partial extracorporeal pulmonary support (1, 7, 8, 11, 14, 16, 27–33).
- Extracorporeal carbon dioxide removal ($ECCO_2R$) uses a venovenous (or arteriovenous) extracorporeal device at low blood flow rates (200–1,500 ml/min). This low flow rate is adequate for substantial CO_2 removal but will allow only minimal blood oxygenation (34–36). Cannulae types and insertion location vary and are currently evolving. If proven to be effective, $ECCO_2R$ could potentially be used in an approach that is similar to continuous renal replacement techniques and available in most intensive care units (ICUs). This paper does not specifically address the appropriate use of $ECCO_2R$.
- Extracorporeal gas exchange refers to VV ECMO and $ECCO_2R$ techniques.

Nationwide/Regional Organization of ECMO for ARF

- ECMO is a high-risk and complex therapy that may be considered for the sickest patients with ARF. Potential indications for the use of ECMO include severe ARF from: severe ARDS, status asthmaticus, bridge to lung transplantation, post lung transplantation primary graft failure, diffuse alveolar hemorrhage, pulmonary hypertensive crisis, pulmonary embolism, severe bronchopleural fistula, and other forms of severe ARF.
- Although some evidence suggests that ECMO may be life-saving in severe ARF, the risk-to-benefit ratio of ECMO in this setting has yet to be fully elucidated, and the evidence for a benefit for less severe forms of ARF is lacking. The occurrence of ARDS severe enough to warrant consideration of ECMO (except in the context of large pandemics) may not exceed 5 to 10 cases per million population per year (our personal data, greater Paris Area, 2012). Because of this relatively infrequent level of activity, we propose that ECMO should be organized at regional and national levels to provide the best care possible in high-volume, dedicated centers, because inappropriate use of ECMO may markedly increase hospital costs and expose individual patients to important risks.
- Referral to an expert ECMO center, where ECMO is offered as part of a larger management protocol for ARF, may be associated with improved outcomes (7, 8). This is also consistent with the literature on the number of mechanically ventilated ICU patients, where again, the more cases a center performs, the better the outcome (37).
- Because of the many advantages of shared knowledge, training, personnel, and facilities, the organization and experience of an ECMO referral center is important in considering the case volume needed to maintain competence. Such a center should be able to maintain the skills and institutional support to justify the expense of a comprehensive program. Because ECMO for adult respiratory failure may be one component of the full spectrum of extracorporeal support provided at a given medical center, the

presence of other groups of patients in the hospital with indications for other forms of extracorporeal circulation (cardiac failure, cardiac surgery, neonates, and so on) will facilitate such a program. Centers providing ECMO for adult respiratory failure should also maintain robust expertise in the care and ventilatory management of patients with severe ARF.

- Based on the neonatal and pediatric literature, recent data demonstrated that ECMO centers caring for more than 20 to 25 cases per year have significantly better outcomes than centers that have either 10 to 20 cases per year or fewer than 10 cases per year (38, 39). Moreover, the learning curve to establish competence requires at least 20 cases for optimal results (38–40).
- The question of the minimum acceptable volume for an ECMO center is an area of considerable controversy. The concept of a minimum annual volume as a surrogate for experience is a common measure in other specialties, and the pediatric ECMO literature supports the use of such thresholds. However, it is not clear that the relationship between volume and outcomes in ECMO for adult ARF demonstrates a positive inflection point in the annual volume of cases. It is also true that volume alone does not guarantee best practices or good outcomes. Other factors should be taken into account, including the cumulative experience of the center over time and the entire center's ECMO volume (adult and pediatric, respiratory and cardiac). Consideration should also be given for centers that routinely perform continuing medical education and training in ECMO, as this will serve to maintain a degree of competency over time. The annual number of patient days on ECMO may be an alternative measure of center experience. These alternative approaches to evaluating the quality of a given center are particularly important considerations for programs covering sparsely populated areas where ECMO referral to a major center is not always feasible. We therefore recommend that centers adhere to best practices, perform continuing medical education and training in ECMO, and work closely with their pediatric and cardiac ECMO colleagues.
- We recommend that for most centers, an annual volume for the entire center should be at least 20 cases per year and that at minimum of 12 ECMO cases for ARF should be performed per year. Therefore, taking into account that potential indications may not exceed 5 to 10 cases per million population per year, one such center should cover a catchment area of at least 2 to 3 million population. These recommendations, as noted, are not currently based on data in adult patients who received ECMO, and a lower case volume may be acceptable, as described above. Although further data are needed to continue to provide guidance in this area, establishing new centers in regions well served by existing high-volume ECMO centers should be discouraged.
- Centers referring patients with ARF but without rapid access to a mobile ECMO team may be trained to perform ECMO cannulation and initiation under supervision of the referral center until prompt transfer to the closest regional ECMO center can be arranged. Close coordination with the receiving ECMO center is essential to maintain quality control over indications, techniques for cannulation, and maintenance on ECMO. Indeed, the difficulty in developing and maintaining the necessary clinical expertise in a center performing a low volume of annual ECMO cases, combined with the likely diminished cost-effectiveness of a low-volume program, must be taken into account when developing a new program. It is important that new programs establish close partnerships with more experienced, high-volume centers.
- Networks of hospitals at the local, regional or interregional level should be created around each ECMO center located in tertiary referral hospitals. Such networks have been successfully organized in the UK (41), Italy (42), and Australia (43) and have been associated with encouraging results for the treatment of the most severe forms of influenza A(H1N1)–associated ARDS (7, 11, 16). The feasibility of a network-wide system to evaluate the daily capacity for receiving patients receiving ECMO at individual centers was also demonstrated in Germany (44) and in France (9, 45).
- Hospitals in these networks should adhere to written standardized protocols detailing criteria for both the initiation of ECMO (indications and exclusions) (17) as well as optimization of conventional treatments to be undertaken before the consideration of ECMO (such as low-volume, low-pressure, lung-protective ventilation or the use of prone positioning [46] in patients with severe ARDS).
- Comprehensive plans regarding access to mobile ECMO should be created within networks.
- Referral centers and other network members should hold regular meetings to discuss network activity, including review of ECMO cases as well as those patients who were deemed inappropriate for ECMO.

Mobile ECMO Team

Each ECMO network should ideally create mobile ECMO teams to retrieve patients and to deal with patients who have critical cardiopulmonary failure refractory to conventional therapy. Their coordination would run through the tertiary ECMO referral center. This mobile team should be available 24 hours a day, 7 days a week and employ experienced personnel trained in the transport of critically ill patients, insertion of ECMO cannulae, as well as circuit and patient management. The team variably includes a mix of physicians, transport specialists, nurses, perfusionists, or other ECMO specialists. Imaging requirements at the referring hospital should be considered, and a clinician trained in echocardiography should be considered for some transfers. Portable ultrasound equipment should also be considered. Highly successful transportation of patients on cardiopulmonary support has been described for short and long distances by ambulance, helicopter, and airplane (47–53).

Intrahospital Transport of the Patient Receiving ECMO

ECMO centers should develop specific guidelines and train staff to provide 24-hour-a-day intrahospital transport of the patient receiving ECMO. Checklists should be considered for equipment (Table 1) and vital actions performed before and during transport as well as for equipment. Briefings before transport and after-action reviews are recommended.

Table 1. Physical Facilities and Equipment Needed in the Extracorporeal Membrane Oxygenation Unit

Backup components of the ECMO system and supplies for all circuit components
Uninterrupted Power System (UPS) supporting all equipment monitors and pumps for at least 45 min
Adequate lighting to support surgical interventions
Clamps
Surgical instrument set for revision of cannulae or exploration for bleeding complications
ECMO water heater
Doppler echocardiography machines
Fiberoptic bronchoscopes
Equipment for intrahospital transport
Mobile ECMO cart
Uninterrupted power system for all mobile equipment
Mobile monitoring device
Emergency transport backpack, with ECMO clamps and emergency drugs
Wet-primed circuit available for immediate use

Definition of abbreviation: ECMO = extracorporeal membrane oxygenation.

General Structure of an ECMO Tertiary Referral Center

- The ECMO center should be located in a tertiary-level ICU with experience in the care of patients with severe ARF (17). The ICU should conform with the relevant national guidelines and be able to offer supportive therapy for multiorgan failure. This is particularly important for the pre-ECMO management as well as the on-ECMO handling of the lungs, which includes the interaction between the ECMO circuit and the contribution of the lungs.
- To maximize efficiency and to benefit from the expertise and experience of all professionals, ECLS programs for cardiac and respiratory failure should be located in the same institution, although not necessarily in the same ICU department.
- An ECMO referral center devoted strictly to the care of ARF might be set up independent of a cardiac ECMO program if its anticipated annual case volume exceeds 20 cases. However, as noted above, establishing new centers in regions well served by existing high-volume ECMO centers should be discouraged. Additionally, because some patients with ARF may have refractory cardiac failure necessitating the use of VA ECLS for some days during the patient's course, it is best to combine the expertise for respiratory and cardiac failure at a single center.
- The ECMO program director should be a physician with responsibility for the overall operation of the center, including assuring appropriate continued specialist training and performance, maintenance of equipment, as well as directing quality-improvement meetings and projects (17).
- Policies and procedures outlining the indications and contraindications for ECMO, clinical management of the patient receiving ECMO, maintenance of equipment, termination of ECMO therapy, and follow-up of the patient receiving ECMO should be available (17).
- The ICU must be able to provide 24-hour access to renal replacement therapy.

Staffing

- Staff involved in ECMO should meet the requirements of their subspecialty training as set forth by their specific governing national or regional board (17).
- The medical director should be a board-certified critical care specialist; cardiovascular specialist; thoracic, vascular, or trauma surgeon; or other board-certified specialist with specific training and experience in ECMO support (17).
- Every member of the staff treating patients receiving ECMO should have received specific ECMO training and demonstrate competencies on an ongoing basis (17).
- A physician comfortable with managing patients receiving ECMO should provide 24-hour on-call coverage for the patient receiving ECMO.
- Selected physicians on the ECMO team should be trained in vascular Doppler echocardiography and cardiac Doppler echocardiography for insertion, maintenance, and surveillance of the ECMO device when needed.
- In clinical settings where the patient receiving ECMO is primarily managed by the ICU nurse (the single caregiver model), the ICU nurse should be specifically trained in management of the patient receiving ECMO and the ECMO circuit (17). Fully trained ECMO personnel should be immediately available for circuit-related concerns, which may include ECMO circuit exchange.
- The ratio of nurses to patients receiving ECMO should be at least 1:1 to 1:2 (one nurse for up to two patients receiving ECMO where necessary based on unit staffing standards) depending on local or national regulations and organization.
- The ECMO team should be as self-sufficient as possible, and specifically should be trained to prime and set up the ECMO circuit. The ECMO specialist team might also be responsible for managing equipment and supplies, circuit preparation, troubleshooting, daily rounds, education, and service administration (17).
- An ECMO coordinator (typically a nurse, respiratory therapist, or perfusionist) may assist the medical director with organizing and implementing the training of the ECMO team, staffing, quality improvement, maintaining equipment and supplies, and ensuring that patient data are entered into the Extracorporeal Life Support Organization (ELSO) registry or other database.

Physical Facilities and Equipment

The equipment that should be readily available is listed in Table 1. Importantly, a wet-primed circuit should be available for immediate use around the clock, because there is some evidence that an assembled circuit can be stored for up to a few days to weeks (54) without presenting an additional risk of infection. It should be possible to change the ECMO circuit in considerably less than, but not exceeding, 15 minutes in cases of sudden malfunction. In high-volume centers, primed circuits are routinely used in much less time, a further advantage to concentrating volume.

Non-ICU Support Services

Table 2 lists medical-surgical and laboratory personnel from the permanent hospital staff who should be available 24 hours a day. The ECMO center should be able to provide emergency access (<30 min) to cardiovascular or thoracic surgery, abdominal surgery,

Table 2. Non–Intensive Care Unit Support Services

Medical-surgical staff with emergency access (<30 min)
Cardiovascular or thoracic surgery
Abdominal surgery
Esophagogastroduodenal endoscopic interventions
Interventional radiology including specific competencies in vascular embolization
Medical-surgical staff needed 24 h/d
Cardiology, with transthoracic and transesophageal echocardiography
Anesthesiology
Pulmonology
Neurology
Neurosurgery
Nephrology
Gastroenterology
Ear nose throat surgery
Obstetrics
General radiology for emergency ultrasound and CT scanning
Pharmacy
Laboratory staff needed 24 h/d
Blood gas laboratory
Blood chemistry and hematologic testing laboratory
Blood coagulation testing laboratory
Blood bank with rapid blood product delivery capacity
Microbiology laboratory

esophagogastroduodenal endoscopic interventions, and interventional radiology.

A biomedical engineer should maintain ECMO equipment on a regular basis. Staff responsible for data collection should maintain the appropriate databases. Nonemergent services, such as pastoral and palliative care or other patient and family support services, should be available.

Staff Training and Continuing Education

- Members of the ECMO staff should receive regular training and education on theoretical and practical aspects of ECMO support. Participation of staff members to this continuing education program should be recorded and their proficiency evaluated (17).
- It is recommended that team members not involved in ECMO management for prolonged periods of time go through a retraining process as defined by the ECMO program (17).
- All staff members caring for patients receiving ECMO should be trained in emergency procedures in case of sudden circuit failure or other events that require emergent discontinuation of ECMO support.
- There should be clearly articulated delineations of responsibilities for who manages specific aspects of the patient care, including anticoagulation, blood component transfusions, ECMO pump speed adjustments, sweep gas flow rate and mechanical ventilator changes, ECMO cannula securing, and wound management. Personnel responsible for these components of care should be specifically trained and internally credentialed to be part of the ECMO team.

Program Evaluation and Quality Assurance

- The multidisciplinary ECMO Team should have quality assurance review procedures in place for annual internal ECMO program evaluation (17).
- Each ECMO center should hold formal meetings on a routine basis to analyze its activity and review its equipment needs. Minutes to these meetings should be accessible for review (17).
- Meetings, which include the referral center and non-ECMO performing centers within the ECMO network, should be held regularly to discuss and report the activities of the network (17).
- A prompt review of any major complication or death should be held both with ECMO team members and with the responsible Morbidity and Mortality committee in the hospital, if available. These reviews should be conducted under the relevant quality assurance laws for the location (e.g., state or province) where the center is located (17).
- Morbidity and mortality meetings should be held rapidly to review any major complication or death related to ECMO support. These meetings should adhere to relevant quality-assurance regulations of the state in which the center is located (17).
- Formal clinical-pathological case reviews with a multidisciplinary approach should be conducted regularly.
- Records documenting maintenance of equipment and supplies should be kept (17).
- An Annual Data Report summarizing the center's collected data regarding ECMO indications and results should be available for quality assurance review.
- ECMO centers are strongly encouraged to submit their data to large national or international databases, such as the ELSO registry (55), to cross-analyze their results with other national and international institutions.
- Regional and national accreditation organizations should be created to evaluate ECMO programs regularly. Centers with poorer than expected results should be encouraged to engage in extensive practice evaluation and improvement strategies.
- There should be an ongoing mechanism to assure sustainability of the program, with financial performance evaluated based on the anticipated business plan. This review should be constructed to identify strengths and weaknesses within the program to help ensure its sustainability.
- We recommend that new programs create an advisory committee consisting of experts from outside the institution to assist with program development and quality review. Such a committee could provide oversight for approximately the first 1 to 2 years after launching a program, depending on the volume and success of the program.

Patient Follow-up

Each ECMO center should consider a follow-up program for patients receiving ECMO with establishment of customized, patient-centered, rehabilitation programs that might help improve long-term outcomes.

Research

There is a clear need for further randomized, controlled trials and other high-level evidence with respect to the use of ECMO in ARF. These data will help guide clinicians with respect to specific indications and contraindications of the various techniques. As the number of ECMO cases is relatively small at each center, national and international organizations of ECMO centers (such as ELSO and the International ECMO Network) are vital to promote research activity and further advance our knowledge. The International ECMO

Network is a growing consortium of ECMO-proficient centers and individuals dedicated to undertaking high-quality, high-impact research in the field. By ensuring that expert centers adhere to current best practices for the organization and conduct of their ECMO programs, this group hopes to foster an environment conducive to the highest-quality evidence.

The currently ongoing ECMO to Rescue Lung Injury in Severe ARDS (EOLIA) trial (NCT01470703) (56), an international multicenter, randomized controlled trial comparing mechanical ventilation with or without ECMO in cases of severe ARDS, is a very good example of the ECMO community coming together to build on the current body of literature. The International ECMO Network hopes to expeditiously and responsibly support further research in various applications of ECMO in all forms of ARF.

Conclusions

The role of ECMO for patients with severe ARF has not been definitively established, and further studies are needed to evaluate its impact (56). The standardization of current best practices and the accumulation of experience at high-quality centers will facilitate the conduct of future research. In the meantime, optimization of conventional treatments (such as low-volume, low-pressure, lung-protective ventilation or prone positioning) should always be undertaken before considering ECMO in patients with severe ARDS. Because the successful delivery of ECMO requires highly experienced staff and a minimum number of cases per year, organization of ECMO programs on a regional or national level is needed to provide the best, safest, and most efficient care possible to the population. Local, regional, or interregional networks of hospitals with a mobile ECMO team should ideally be created around each ECMO center; such a system has recently successfully been organized in a few countries (41–43). Staff training and continuing education as well as regular audits evaluating program performance should be routinely organized to assure quality. We believe that this initiative will result in better quality of care, although it will require energy and motivation to encompass many logistical and political challenges. We recognize, however, that differences in hospital policies and national regulations may result in variations in the models for ECMO programs caring for patients with severe ARF. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

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