

Extracorporeal membrane oxygenation support in acute circulatory failure: A plea for regulation and better organization

ECMO pour défaillance circulatoire aiguë : plaidoyer pour une meilleure régulation et organisation

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Abbreviations: ECMO, extracorporeal membrane oxygenation; ELSO, Extracorporeal Life Support Organization; ESC, European Society of Cardiology; ICU, intensive care unit; MCS, mechanical circulatory support; UMAC, mobile circulatory support unit; VAECMO, venoarterial extracorporeal membrane oxygenation.

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KEYWORDS

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Summary Emergent implantation of temporary mechanical circulatory support using venoarterial ECMO (ECLS for extracorporeal Life Support) is increasingly adopted in various indications of acute circulatory failure refractory to optimal medical treatment. To implant such devices, but also to provide appropriate daily management, expertise and adapted technical platform are required. Organization, coordination and regulation of such program are not clearly established in our country. We propose a dedicated territorial organization to improve and facilitate management of these specific and most severe patients.

MOTS CLÉS

ECMO ;
ECLS ;
Régulation ;
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Coordination

Résumé La mise en place en urgence d'une assistance circulatoire mécanique temporaire de type ECMO veino artérielle (ou ECLS pour Extra Corporeal Life Support) se développe dans de nombreuses indications d'insuffisance circulatoire aigüe réfractaire au traitement médical optimal. La mise en place de ces dispositifs d'assistance circulatoire, ainsi que leur surveillance et gestion au quotidien, justifient d'une expertise et d'un plateau technique adaptés. L'organisation, la coordination et la régulation de ce programme dans notre pays ne sont pas clairement établies. Nous proposons une organisation territoriale pour faciliter et améliorer la prise en charge de ces patients spécifiques et particulièrement graves.

Background

Acute cardiogenic shock is a life-threatening situation associated with a high mortality rate, despite recent significant improvements in heart failure management. Life-saving temporary mechanical circulatory support using venoarterial extracorporeal membrane oxygenation (VAECMO), also called extracorporeal life support (ECLS), is now well established for providing life support, and may be the last option for these critically ill patients [1,2]. Recently, the perception that VAECMO is safe and easy to use has been growing; as a result, an increasing number of centres are providing temporary mechanical circulatory support (MCS) for patients [3,4].

As life support has been rapidly gaining popularity, cardiology societies in Europe and the USA have started to publish guidelines to define the ideal requirements for the use of MCS devices, including VAECMO, in hospital institutions [2,3,5]. However, the European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure highlight the current lack of randomized trials for VAECMO, and caution against its use [6].

Despite the substantial requirements reported for optimal implantation, monitoring and recovery, none of these publications suggests how best to organize, develop or improve national or regional VAECMO structures and support networks.

France is one of the most eager adopters of VAECMO, with at least 60 active centres, yet its use is currently unregulated, and neither machine operation nor patient care is certified [7]. Heterogeneous distribution makes access to this life-saving therapy limited and problematic. VAECMO is used most frequently in only a few well-equipped centres in major urban areas, whereas smaller regional centres lack the resources to support patients. One group of French experts has warned that without appropriate management, dramatic patient outcomes may result from serious complications after the machine is implanted, such as massive bleeding, limb ischaemia and pulmonary oedema. Specialist care is required to manage these life-threatening issues, until recovery, transplantation or long-term mechanical assistance is obtained [8]. Indeed, as in many areas of medicine, a positive relationship between experience, volume of activity and success rate can be envisaged. Moreover,

the clinical benefit of VAECMO support is not well established for many indications, and remains questionable for others. Lastly, France does not yet have any regional or national registries to collect patient outcome data or provide further evidence for the many specialized medical and paramedical practices required to care for patients with cardiogenic shock treated with VAECMO.

It is clear that widespread diffusion of this technique without any rules or regulations may be deleterious from both a clinical and an economic point of view. There is therefore an urgent need to define requirements for an effective extracorporeal membrane oxygenation service (ECMO) network in France, to ensure better treatment and positive outcomes for patients who experience acute circulatory failure and are treated with temporary MCS.

Purpose of this position paper

The purpose of this paper is to provide an overview of current international guidelines and recommendations for organizing and implementing regional VAECMO; it expresses the expert opinion of the French Society of Cardiology Heart Failure and Cardiomyopathy Special Interest Group (SFC-GICC) – a national group of physicians, ECMO specialists, anaesthesiologists, intensive care specialists and cardiac transplantation surgeons from the French Society for Thoracic and Cardiovascular Surgery (SFCTCV), who have specific expertise relevant to using MCS to treat patients with severe cardiac failure. The authors offer their expert opinion on setting up and running an effective VAECMO network, and propose a programme to develop and regulate VAECMO use in France within an ECMO-equipped centre. Although this paper does not fully describe the indications, contraindications and complications associated with VAECMO support, as these have been reported by both international and French teams, [Table 1](#) summarizes the main indications for the technique [\[9,10\]](#).

Worldwide status of MCS and ECMO organization

In the USA, the number of ECMO implantations has nearly doubled in the past 10 years, and the cost of care has skyrocketed from US \$109 million in 1998 to US \$764 million in 2009 [\[11\]](#).

In Europe, healthcare systems differ significantly between countries. For example, the UK and France have similar populations (66 and 67 million, respectively), yet there are fewer than 10 ECMO centres in the UK, which mainly treat respiratory failure, as the National Health Service states that “there is insufficient evidence to support a proposal for the routine commissioning of VAECMO for adults with acute cardiac failure” [\[12\]](#). In France, there are more than 60 active centres, where both respiratory and cardiac failure are managed, with a global ECMO activity of around 2000 cases [\[7\]](#). Similarly, German VAECMO activity has increased, with a peak of 3000 cases in 2014 [\[13\]](#) for a population of 83 million.

Despite this increased activity worldwide, there is no unique regional or global organization for MCS and VAECMO.

Across Europe, regulations describing how to organize and implement regional VAECMO programmes vary widely in line with the various cultural approaches to treatment, different patient populations, reimbursement systems, health policies and priorities. For example, reimbursement for VAECMO is non-existent in Switzerland and Sweden, partial in the UK and complete in France.

Some countries, such as the UK and Italy, have regulations that limit the number of ECMO centres, while others, such as Germany and France, do not. A recent editorial outlined these differences, and described the number of unrecognized ECMO centres and ECMO providers in France and Germany as being out of control [\[4,13\]](#). Conversely, Sweden has only one ECMO centre!

As the use of these devices has gained momentum, a few publications have suggested requirements for an effective VAECMO team. A number of years ago, an international group of European cardiac surgeons highlighted the need for VAECMO programmes to be confined to dedicated well-trained teams, capable of managing potential complications at a moment’s notice. Additionally, they described the specific role of specialist perfusionists [\[5\]](#). Then, in 2014, the international Extracorporeal Life Support Organization (ELSO) first published guidelines describing the ideal requirements for a hospital institution to run VAECMO [\[3\]](#). This well-respected organization advocated that centres should be located in tertiary centres only, in geographical areas that could support a minimum of six patients per year, and that they should be actively involved in the ELSO registry. Furthermore, ELSO recommended that an ECMO centre should be a part of a multidisciplinary network, with well-trained specialized teams capable of providing a full range of treatments for ECMO patients and round-the-clock care; they also recommended continuing education in this speciality for the whole team, and regular evaluation of programme effectiveness to ensure the best quality of care possible.

More recently, in 2015, an expert consensus document endorsed by the American Heart Association, the Cardiology Society of India, the Canadian Association of Interventional Cardiology and the Societe Latino Americana de Cardiologica Intervencionista provided an exhaustive review of the relevant devices and indications for percutaneous mechanical support. Although the authors briefly described the cost-effectiveness of the various strategies, they did not provide any information about how to organize, develop or improve ECMO structures and support networks in their countries [\[2\]](#). This was equally true for the American College of Cardiology guideline for the management of heart failure [\[14\]](#). Importantly, the recently updated European guidelines for the diagnosis and treatment of acute and chronic heart failure advised using VAECMO cautiously, given the lack of randomized trials in this field. Again, however, the authors did not propose any recommendations for an effective VAECMO structure and support network [\[6\]](#). Nevertheless, the Austrian Cardiology Society proposed a network organization in their country to improve VAECMO use in adults with cardiogenic shock [\[15\]](#). As well as describing the indications for and complications associated with VAECMO, the authors also outlined a system to optimize VAECMO use, in which current ECMO and non-ECMO centres would develop and share experience in a specialized network.

Table 1 Indications and contraindications for venoarterial extracorporeal membrane oxygenation.

Indications	Contraindications
Cardiogenic shock in acute coronary syndrome	Definitive and irreversible myocardial failure and no possibility for long-term mechanical support or transplantation Severe aortic regurgitation
Acute myocarditis with cardiogenic shock (including septic shock with low ejection fraction)	
Postcardiotomy cardiogenic shock (including postcardiac transplantation)	Acute unrepaired aortic dissection
Cardiac refractory arrhythmic storm	Severe peripheral arterial disease with limited vascular access for implantation (central ECMO may be discussed)
Temporary circulatory support as bridge to transplantation or heart transplantation	Any organ failure or disease with limited life expectancy (massive stroke, evolutive and disseminated neoplasia, etc.)
Refractory cardiac arrest (in highly selected cases)	Unwitnessed cardiac arrest
Massive pulmonary embolism (bridge to embolectomy)	Compliance: cognitive, psychiatric, severe social limitations without support
Drug intoxication with acute circulatory failure	

ECMO: extracorporeal membrane oxygenation.

More importantly, at an international level, the ECMO Network (ECMONet) and ELSO proposed a more complete organizational structure for an ECMO programme to manage cardiac failure in adults [16]. Briefly, this robust paper provided four key recommendations:

- ECMO support should ideally be performed in experienced high-volume centres capable of providing other specific cardiac treatments, such as percutaneous coronary intervention, ventricular assist devices and heart transplantation;
- centres performing ECMO support should achieve a minimal volume of 30 cases per year;
- ECMO centres should be linked to a centre with large patient registries;
- there should be an ECMO referral model with different levels of care (from a local centre to a referral centre to a regional referral centre and, ultimately, to a comprehensive care centre).

As far as we know, these are the first solid recommendations for ideal requirements for a well-organized referral, material and resource structure to run an ECMO programme.

More specifically, the European Society of Cardiology task force recently proposed a clear comprehensive position paper on the structure, organization and function of a cardiovascular intensive care unit. Despite the fact that healthcare systems are heterogeneous throughout Europe, this task force succeeded in providing three levels of expertise and technical requirements for an intensive care unit, which could be applied to ECMO centres [17]. Thus, cardiology specialists in both Europe and the USA have started to propose appropriate organizational structures for VAECMO.

ECMO centres in France today

To our knowledge, there is only one publication concerning VAECMO organization in France, written by an expert panel from the Société Française de Chirurgie Thoracique et Cardio-Vasculaire in 2014 [8]. This publication highlights many issues regarding VAECMO in France, including appropriate indications, implantation procedure, follow-up under VAECMO support and mobile ECMO (mobile circulatory support unit [UMAC]) policy, and specifically underlines the need to better organize ECMO support and its diffusion. Yet, similar organizational recommendations exist in France for other specialties, such as obstetrics and neonatology [18]. It is worth noting that there is very little literature about the cost-effectiveness of VAECMO in France. However, one large observational study evaluating the cost of a VAECMO procedure is in completion phase in Rennes (ClinicalTrials.gov Identifier: NCT03686540).

Although there is no national registry as yet, there is epidemiological evidence of the major increase in VAECMO activity in France over the last decade [7]. The estimated number of uses of VAECMO in France was close to 2000 in 2017, and about 20 centres use VAECMO more than 30 times per year (personal data).

The functional quality of VAECMO services around France today varies greatly between well-resourced university hospitals to small local hospitals with limited resources. Although ECMO programmes are mostly implemented in university hospitals and tertiary centres, other less-well-equipped centres also perform ECMO. Indeed, if all university hospitals were capable of providing effective regional ECMO support and management, few general hospitals or private clinics would require an ECMO programme. In France, there is currently no specific regulation that outlines the ideal requirements to ensure the quality of care required by these specific patients. Currently, hospitals care

for ECMO patients in various different intensive care units (ICUs) according to their level of resources: general ICUs, cardiac surgery ICUs, surgical ICUs, medical ICUs or cardiology ICUs.

There are a few UMAC services attached to tertiary hospitals that provide rapid and effective ECMO support in their local area with local hospitals (e.g. Paris, Lyon, Bordeaux and Marseille). It is important to note that these centres are able to allocate non-dedicated resources, and are capable of providing an instant response in terms of medical care and transport (ambulance, helicopters, etc.). In some hospitals, the UMAC service is clearly recognized by the regional administration. However, there are many other centres in which the UMAC service is suboptimal and chaotic as a result of a lack of dedicated resources. These centres are limited to providing as much service as possible, depending on the availability of the local team at the time of the incident. If the local team is occupied elsewhere, there is no specific system for providing backup support to these UMAC services.

The current literature suggests that training ECMO teams is crucial to provide appropriate care and obtain the best patient outcomes for this critically ill patient population with often rare or heterogeneous aetiologies [13]. However, in France, medical, paramedical and nurse certification is not yet required to implant or manage a patient receiving VAECMO. As far as we are aware, there are only three university diplomas that provide extracorporeal life support training for physicians and paramedics in France. These courses are held in La Pitié Salpêtrière in Paris, and in Bordeaux and Lyon. Although these academic courses promote best practice for VAECMO use in acute heart failure, including cannulation approaches and expected outcomes, they do not validate either the technical skills for implantation or the practical complexities of managing a patient receiving VAECMO.

Establishing regional ECMO networks

Developing ECMO centres as part of a regional hospital network, as suggested in the ESC guidelines for ICUs, could provide good coverage for the population over an entire region. Similarly, the recommendation is that ECMO units follow an integrated network model, where each level refers to a higher-level ECMO centre when needed. In addition, specialized UMAC services in Level 3 centres should support the regions they influence [17,19]. Clearly-defined patient pathways, such as those developed for acute coronary syndromes, can facilitate patient transfer to the most appropriate hospital, with an established transfer protocol and standardized procedures between centres. The optimal integrated network should be configured in collaboration with local regions and national health resources to ensure that Level 2 and Level 3 hospitals are sufficiently supported, with enough beds, transport and personnel to support their local region effectively. We believe that this is the best solution for optimal patient management and health economic advantages, although further health economic data are required.

The ECMO team

The ECMO support team should be composed of advanced heart failure specialists [16]. This means a multidisciplinary team of trained specialists that includes, at least, a cardiothoracic surgeon, an anaesthetist or an intensive care specialist, a cardiologist and a perfusionist. This team should be led by an ECMO director and be available 24 hours a day, 7 days a week, to discuss any potential indication for a VAECMO case or the management of VAECMO-related complications. Particular attention should be paid to ensure there is direct contact with a senior ECMO staff member, who will help to decide whether or not to implant or transfer, or to advise on patient management on VAECMO.

An ECMO centre is responsible for providing sufficient equipment and staff to ensure optimal patient care within their hospital and the associated region. So, the functional level of an ECMO unit must be such that it can provide optimal care for the most severe patient for which its hospital has the technical facilities to manage.

Grading the functional criteria for ECMO centres in France

Although we propose to classify VAECMO centres into three levels, as is the case for ICUs, these levels are not equivalent. Thus, a Level 1 ECMO centre may not be a Level 1 ICU (Fig. 1).

Level 1 ECMO (first level cardiology facilities; incapable of providing VAECMO support)

A Level 1 ECMO centre may have cardiology facilities able to provide percutaneous cardiac assistance (such as an intra-aortic balloon pump) 24 hours a day, 7 days a week, if they have the capacity for emergency angiography or percutaneous circulatory support, but not VAECMO support. These centres do not have on-site cardiac surgery facilities; they do not have a dedicated VAECMO team, and the nearest tertiary reference centre should deploy a UMAC team to transfer the patient. These hospitals should not keep patients on VAECMO support.

Team qualifications

It is recommended that all ICU staff are able to identify potential VAECMO candidates based on pathology and severity of cardiogenic shock; they should have a basic understanding of patient pathways and transfer processes in their region.

Equipment or support structures

This level should have clearly-identified procedures for contacting their reference hospital, and for patient pathways and transfer processes. An operating theatre should be provided for the ECMO team; if not, or if the patient is haemodynamically unstable, bedside implantation is acceptable.

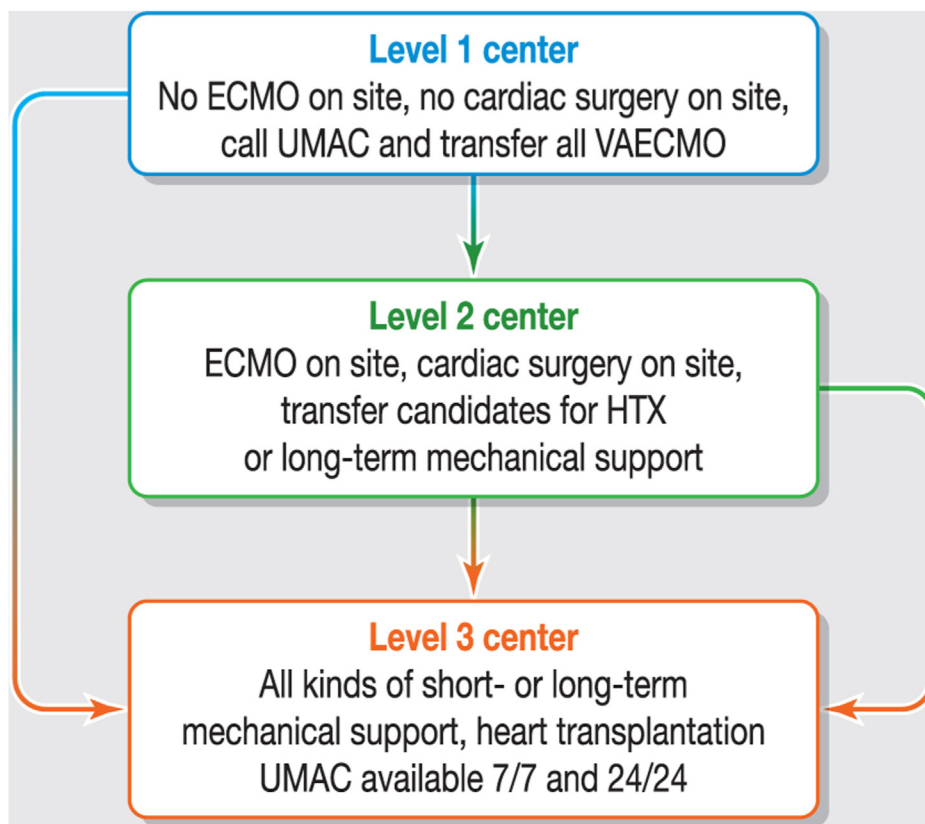


Figure 1. Grading and functional criteria for extracorporeal membrane oxygenation (ECMO) centres in France. HTX: heart transplantation; UMAC: mobile circulatory support unit; VAECMO: venoarterial extracorporeal membrane oxygenation.

Network

Close collaboration with the regional network must be established to ensure a direct contact line to the reference hospital.

Level 2 ECMO centre (second level cardiology facilities; capable of providing VAECMO)

Level 2 ECMO units should have sufficient cardiology facilities to provide VAECMO support, but lack access to long-term mechanical support, including ventricular assist devices and total artificial hearts or heart transplantation. It is recommended that all VAECMO candidates are discussed with the Level 3 centre to identify early candidates for potential transfer. Particularly when the case is difficult and, more importantly, when a possibility of heart transplantation or long-term mechanical support exists, patient transfer should be achieved as early as possible in the patient pathway, while being supported on ECMO. Ideally before transportation, the neurological status must be estimated to avoid futile transfers, especially in case of VAECMO for out-of-hospital refractory cardiac arrest. These centres may keep a patient on VAECMO if transplantation or a long-term project is considered unlikely; they should have decision-making algorithms in place and a continuing programme of training and education. Any complications that may occur while a patient is receiving VAECMO can be appropriately managed on site on a permanent basis, using interventional

cardiology, surgery, imaging and endoscopy. Level 2 centres should be able to regularly report appropriate short- and long-term follow-up for patients treated with VAECMO support.

Team qualifications

It is recommended that all ICU staff are able to identify potential VAECMO candidates based on pathology and severity of cardiogenic shock; they should have a solid understanding of patient pathways and transfer processes in their region. The ICU staff must also receive specific theoretical and practical training to ensure correct cannulation, patient care, pathways and transfer requirements.

Equipment or support structures

This level should have clearly-identified procedures for contacting their reference hospital, and for patient pathways and transfer processes. There should be on-site cardiac surgery, and a specialist perfusionist should be provided for all ECMO implantations.

Network

A close collaboration with the university hospital (Level 3) has to be established to ensure that decisions are made on a case-by-case basis within a structured protocol. The timing of the transfer ought to be discussed.

Level 3 ECMO centre (third level cardiology facilities; highly-specialized tertiary centre)

Level 3 ECMO centres have on-site cardiac surgery, and are able to provide VAECMO support as well as any other cardiac support needed, including devices for short- or long-term circulatory support and heart transplantation. These centres have a ECMO team and an UMAC service. Any complications that may occur while a patient is receiving VAECMO can be appropriately managed on site on a permanent basis (using interventional cardiology, surgery, imaging, endoscopy, etc.). Level 3 centres should be able to regularly report appropriate short- and long-term follow-up for patients treated with VAECMO support; they should also be able to provide ongoing support and training for Level 1 and Level 2 hospitals (educational partnerships).

Team qualifications

It is recommended that all ICU staff are able to identify potential VAECMO candidates based on pathology and severity of cardiogenic shock; they should have a solid understanding of patient pathways and UMAC transfer processes in their region. The ICU staff must also receive continued training to ensure correct cannulation, patient care, pathways and transfer requirements, and will need to recognize and manage complications of VAECMO. The staff must also be qualified in heart transplantation and short- or long-term mechanical support, including artificial heart implants. There should be a continuing education programme to ensure that theoretical and practical knowledge is maintained in this specialist field.

Equipment or support structures

These centres should have decision-making algorithms in place, a continuing evaluation programme, on-site cardiac surgery and availability of long-term mechanical devices (e.g. left ventricular assist devices and total artificial hearts). These centres should have a developed heart transplantation programme, in line with the French Biomedicine Agency laws, and should provide specialist perfusionists for all ECMO implantations.

Network

Level 3 centres should not only provide VAECMO implantation, but should also be the reference centre for technical, clinical and latest knowledge, and continuing education.

UMAC service

Level 3 centres should all provide a UMAC service. All tertiary and university hospitals should ideally establish and coordinate mobile VAECMO teams with their region. It is essential to devise a national network capable of providing emergency circulatory support throughout the country. These UMAC service teams should be available 24 hours a day, 7 days a week, with trained and experienced staff. These teams would be responsible for transporting the patient back to the tertiary centre with cardiopulmonary support. Dedicated and appropriate resources, such as staff, devices, circuits and transport (e.g. helicopters or a dedicated ambulance with a police escort) should be provided

by the institutions. To date, this proposal has had to be moderated given the associated major implementation difficulties.

Education and training recommendations for ECMO support personnel

Initial training

Despite European recommendations for ECMO training and education, this aspect of acute cardiovascular care has yet to be incorporated into resident training for cardiologists, cardiothoracic surgeons and intensive care specialists. These specialties should have specific training on MCS during their studies. Similar to the ESC guidelines, it is recommended that a certification process for acute cardiovascular care is provided, with a common core element to demonstrate knowledge, and flexible modules according to the level of ECMO centre in which the ECMO personnel are working [17].

Continued professional education

All individuals in an VAECMO team should have regular training adapted to their role and the level of centre in which they work. A yearly refresher course would be optimal, including an e-learning option. Effective communication and collaboration between nurses and physicians, as well as between regional hospital networks, is critical for managing these acutely ill patients. Thus, continued professional education organized in collaboration with tertiary centres within their region of influence ensures that teams practice working together, master the necessary medical techniques, know the patient pathway and regional processes and revise various case mixes. Where possible, ECMO-specific training should be encouraged, using specialized simulation technology and teaching programmes, which is in line with the current Haute Autorité de Santé guidelines for continued professional education in healthcare [20]. ECMO Level 2 and Level 3 hospitals should hold additional multidisciplinary meetings about temporary circulatory support for their entire teams.

Governance and data collection

Considering the lack of controlled evidence for VAECMO support, there remain numerous questions about appropriate indications, timing of implantation and case management. In this critically ill, heterogeneous population, randomized controlled studies and observational studies are difficult to perform because of complications with recruitment and ethical dilemmas. Therefore, the most effective way to obtain data to provide evidence and further improve the quality of patient care is via real-life data analyses obtained from patient registries. ECMO centres should therefore have to register prospectively all VAECMO cases in a national registry. This registry does not yet exist in France, and would have to be created. The French health administration should promptly recommend and encourage the creation of such a national ECMO registry.

Registered ECMO centres must operate within a recognized national framework, in collaboration with national cardiovascular societies and health and regulatory authorities. All clinical criteria for transfer will need to be defined, as well as transfer modalities and communication between centres to ensure bed availability. These patients occupy ICU beds for several days, so ECMO activity may disturb any planned surgery. Thus, the successful implementation of these proposed recommendations will depend on the resources made available to hospitals in terms of materials, transport and human resources; otherwise, most hospitals will be unable to provide this level of care. Level 3 hospitals specifically will need to ensure that extra beds are available. In such an ICU unit, given the very high level of care, the nurse-to-patient ratio should be between 1:2 and 1:1, and not 1:2.5, which is often the case. All legal or financial considerations, such as reimbursements, would need to be outlined.

Limits to this structural organization

This position paper proposes an organizational structure for the safe and effective practice of VAECMO to manage refractory cardiogenic shock in France. Although, we recognise that other organizational structures are possible, this proposal fits with ESC guidelines, and is in line with other health systems in Europe, despite the current lack of health economic data available in France to support the value of well-managed ECMO teams.

Other temporary mechanical support programmes – particularly axial flow pump implantation, such as the Impella[®] device (Abiomed Inc., Danvers, MA, USA) – are beyond the scope of this paper, as their future positioning remains a matter of debate.

Finally, the authors have chosen to limit their recommendations to VAECMO, without addressing venovenous extracorporeal membrane oxygenation support (VVECMO) or the growing use of temporary mechanical support in organ donation. These procedures were deemed to be outwith the scope of this paper, as the patient populations and underlying pathologies differed too greatly.

Conclusions

VAECMO is one of the most powerful treatments for patients in acute cardiogenic shock today. The rapid spread of this new technology and equipment in France now needs to be organized into a structured network to ensure that the best patient care is provided, while controlling costs. Systematic data collection is needed for continuing research. The success of VAECMO in France will depend upon resolving the challenges faced by the increased load expected in receiving centres, and regulating VAECMO providers to avoid the deleterious effects of uncontrolled widespread diffusion of this highly risky and complex technique.

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Disclosure of interest

The authors declare that they have no competing interest.

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