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## Guideline

## Position article for the use of extracorporeal life support in adult patients

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## Summary

Extracorporeal life support (ECLS) is one of the recent fields in cardiac surgery which has improved significantly the quality of patient care in acute or chronic end-stage heart disease. The safe use of this new technology requires many different prerequisites which are summarized in this position article. It includes the necessary personnel and their qualifications, the structural assumptions, the required equipment, and the parameters which have to be monitored for the safe usage of these devices. In addition, indications and contraindications for ECLS, the management and control of a wide range of parameters related to the extracorporeal circulation, as well as the necessary equipment are described. Quality assurance and education are also described in this position article.

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## 1. Introduction

The introduction of the heart–lung machine (HLM) in 1953 made routine cardiac surgery possible. Both the HLM and the extracorporeal circulation were improved by many innovations over the following decades.

In recent years, miniaturizations and further technical innovations have led to mobile extracorporeal circulation systems that can be used even outside of cardiac surgical operation theaters [1]. These extracorporeal life support (ECLS) systems are of great advantage to patients in sudden cardiopulmonary failure. These patients not only can receive immediate sufficient cardiopulmonary support but also can be transported, an option which was not available earlier.

The safe use of this new technology requires many different prerequisites which are summarized in this position article. It includes the necessary personnel and their

qualifications, the structural assumptions, the required equipment, and the parameters which have to be monitored for a safe usage of these devices.

## 2. Definition of ECLS

ECLS systems are mechanical devices designed to temporarily support the failing heart and lung. It is a further development of a conventional HLM. Compared to the HLM, it is smaller, and has been reduced to main components only such as the centrifugal pump and a membrane oxygenator. It is highly mobile, and can be used both in and outside of the hospital.

The use of ECLS may be associated with the high risks of bleeding, clotting, infection, limb ischemia, and organ failure [2–4]. Therefore, it is only used for a limited time, and often as a bridge-to-bridge or bridge-to-decision device.

The device is referred to as an ECLS only when the connection to the patient is via veno-arterial (VA) cannulation. Via this VA connection, the blood is drained (a) in closed chest patients from the right atrium via a femoral venous or right internal jugular venous cannula or (b) in patients with an open chest directly from the right atrium. The blood is

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returned to the arterial system either via a cannula placed in a peripheral artery, mostly femoral or subclavian artery (closed chest), or directly in the aorta (open chest). The VA-ECLS provides cardiac and pulmonary support.

### 3. Indications and contraindications for ECLS

#### 3.1. Indications

ECLS is an advanced medical treatment option that requires medical expertise and puts substantial pressure on hospital resources [5]. The decision to institute ECLS should be based on a team approach where a physician/surgeon with experience in the field of extracorporeal circulatory assist is a team member.

The clinical scenario where ECLS should be considered is acute severe cardiac (and respiratory) failure (cardiogenic shock) resulting in inadequate circulation despite conservative treatment including volume load, inotropes, intra-aortic balloon counterpulsation (IABP), etc. ECLS may also be indicated in patients with cardiac arrest undergoing cardiopulmonary resuscitation.

Indications for starting ECLS are dependent on several factors such as:

- patient's age and size;
- availability of sufficient medical expertise in the field of ECLS;
- nature of the underlying illness;
- prognosis of the underlying disease;
- possibilities for definitive therapy, that is, ECLS as a bridge-to-transplant or bridge-to-destination therapy;
- comorbidities;
- severity of circulatory dysfunction; and
- status of central organs such as kidney, liver, and brain.

The ideal indication for ECLS is isolated severe heart failure (one organ failure) and refractory to conventional therapy, where ECLS is instituted before multi-organ failure develops. Typical clinical scenarios are [6–9]:

- postcardiotomy cardiac failure,
- acute exacerbation of chronic severe heart failure,
- acute heart failure due to drug intoxication,
- acute heart failure due to myocardial infarction,
- hypothermia,
- acute circulatory failure due to intractable arrhythmias, and
- cardiac arrest requiring cardiopulmonary resuscitation (CPR) in clinical situations described above.

#### 3.2. Contraindications

In general, ECLS is contraindicated in cases where risks and use of hospital resources outweigh the chances of success. The most common contraindication to ECLS is based on irreversible circulatory failure with multi-organ failure or apparent incompatibility with life. Whenever ECLS is judged to merely prolong the course of the illness without a realistic chance of survival or acceptable quality of life in case of recovery, ECLS should not be instituted. Specific contra-

indications related to pre-existing illness, such as malignancy or coagulation disorders, may exist.

The decision to withhold ECLS may obviously be very difficult. In particular, two aspects of the treatment are difficult to judge:

- (a) severity of brain damage due to insufficient organ perfusion especially in situations with prolonged resuscitation and
- (b) evaluation of chances for recovery and projected quality of life in patients who are not candidates for heart transplantation in acute exacerbation of chronic severe heart failure.

### 4. Management of ECLS

Successful management of ECLS requires in-depth knowledge and control of a wide range of parameters related to the extracorporeal circulation.

#### 4.1. Flow

Perfusion flow (pump minute volume) is the flow generated by the arterial pump of the ECLS device. Shunts that are inserted into the circuit after the arterial pump (i.e., oxygenator shunt, medication port, arterio-venous bridge, etc.) must be closed or removed in order to achieve the desired pump minute volume in the patient circulation. The integration of a flow probe into the arterial line close to the arterial cannula is recommended.

Perfusion flow [10] is calculated according to the formula: flow = body surface area  $\times$  cardiac index. Cardiac index should be in the range of 2.2–2.8 l min<sup>-1</sup> m<sup>-2</sup> [11]. For critically ill patients, a cardiac index of 3.0 l min<sup>-1</sup> m<sup>-2</sup> may be necessary [12].

An echocardiographic evaluation of heart function, and especially the aortic valve competence, is necessary to ensure adequate aortic valve function and to avoid left ventricular distension.

#### 4.2. Oxygenation

The parameters which have to be determined in order to ensure adequate body oxygenation are shown in Table 1.

Particular care must be taken when the heart still ejects and the lungs are not ventilated, as hypoxemic blood from the left ventricle will enter the coronary and cerebral circulation, leading to myocardial or brain hypoxemia. In this case, either ejection of left ventricle must be suppressed or the lungs have to be ventilated.

#### 4.3. Anticoagulation

Infusion of unfractionated heparin may be used for controlled and assessable anticoagulation. Additional anti-adhesive or anti-aggregation therapy may be used [13].

Heparin administration may be accomplished by infusion into a central venous line or into the venous line of the ECLS circuit.

The parameters which have to be determined to guide the anticoagulation therapy are shown in Table 2.

Table 1. Assessment of parameters to control ECLS.

Partial pressure of oxygen	paO <sub>2</sub> of 100–150 mmHg (13–20 kPa) (measured in the patient's right radial artery)
Oxygen extraction (avDO <sub>2</sub> )	5 ml/dl or less
Oxygen delivery (DO <sub>2</sub> )	500 ml min <sup>-1</sup> or higher (critical DO <sub>2</sub> 330 ml min <sup>-1</sup> ) (3)
Oxygen consumption (VO <sub>2</sub> )	250 ml min <sup>-1</sup> or less
Systemic venous oxygen saturation (SvO <sub>2</sub> )	0.70 or higher in normothermia
Venous blood concentration of lactate	2 mmol/l or less

avDO<sub>2</sub> = arterio-venous oxygen difference = oxygen extraction.

DO<sub>2</sub> = oxygen delivery.

VO<sub>2</sub> = oxygen consumption.

SvO<sub>2</sub> = systemic venous oxygen saturation.

Table 2. Assessment of parameters to guide anticoagulation therapy during ECLS.

Activated partial thromboplastin time (APT), should be at 1.5 time baseline [13]
Activated clotting time (ACT), should be in the range of 160–180 s
International normalized ratio (INR), should be less than or equal to 1.3 [13]
Thromboelastography
Heparin concentration
Anti X-a activity

**Cave:** Decrease of pump minute volume (flow 2 l min<sup>-1</sup> or less) or pump stop necessitates an increase in heparin dosage in order to prevent clotting.

#### 4.4. Blood component therapy

It is not advisable to administer blood components into the ECLS circuit. Blood components should be transfused into a central venous line.

The parameters which have to be determined to guide the blood component therapy are shown in Table 3.

#### 4.5. Hemodynamics and cardiac decompression

The arterial pump generates flow into the arterial circulation of the patient. The parameters which have to be measured in order to determine adequacy of perfusion flow and cardiac decompression are shown in Table 4.

Daily chest X-ray and echocardiography are recommended. Both may be necessary more frequently when change of perfusion flow and/or volume status occurs.

Decompression of the heart (right and left ventricle) [14] should be achieved when the patient is on ECLS. Partial loading of right and left ventricle may be used to determine myocardial function (Cave: coronary blood oxygenation).

Decompression of the right ventricle is accomplished by ensuring adequate venous drainage. When venous drainage is not adequate, the following maneuvers may be initiated:

- increase in pump minute volume,
- repositioning of venous cannula, and
- exclusion of hematopericardium.

Table 3. Assessment of parameters to guide the blood component therapy during ECLS.

Hemoglobin	8 mg/dl or higher
Fibrinogen	100 mg/dl or higher
Thrombocyte	45.000 to 65.000/l or higher

Decompression of the left ventricle is accomplished by ensuring adequate venous drainage, adequate arterial pump flow, and a competent aortic valve. The following maneuvers may be initiated when left ventricular decompression is not adequate:

- left ventricular vent, insertion via left upper pulmonary vein (open sternotomy) or with left mini-thoracotomy via the LV apex [14],
- balloon atrioseptostomy, and
- axial flow pump inserted in left ventricle (Impella® LV pump).

#### 4.6. Temperature

ECLS is conducted in normothermia. Mild hypothermia may be beneficial when brain damage (insult and hypoxia) is suspected.

#### 4.7. Functional tests

The function of the ECLS circuit should be assessed at least twice daily. The following tests should be performed:

- maximum oxygenation test: 100% fraction of inspired oxygen (FiO<sub>2</sub>) and measurement of partial pressure of oxygen (paO<sub>2</sub>) in the arterial line,
- oxygenator pressure gradient (pressure difference between inlet and outlet of oxygenator should be stable within expected values),
- visual inspection of circuit, arterial pump, and oxygenator for thrombus and leakage,
- flushing the oxygenator on regular bases for a few seconds to avoid condensation,
- determination of plasma-free hemoglobin and thrombocyte count, and
- peripheral cannulation: check limb perfusion.

Table 4. Assessment of parameters to determine the adequacy of perfusion flow and cardiac decompression during ECLS.

Arterial blood pressure	60 mmHg or higher
Central venous pressure	8 mmHg or lower
Cardiac Index	2.2–2.8 l min <sup>-1</sup> m <sup>-2</sup>
Diuresis	0.5 ml/kg h or higher
SvO <sub>2</sub>	0.70 or higher (normothermia)
Venous lactate concentration	2 mmol/l or less

SvO<sub>2</sub>: systemic venous oxygen saturation.

## 5. Equipment

### 5.1. Cannulation

The design of the cannula should contemplate the largest possible inner diameter to facilitate as unrestricted a blood flow as possible. A number of possibilities are contemplated.

#### 5.1.1. Peripheral/thoracic

Peripheral cannulation requires cannulas of adequate size to match the recipient artery or vein. In adult patients, the femoral artery is the most commonly used; however, any other peripheral arteries can be used, like the iliac or axillary arteries. In peripheral cannulation, the risk of peripheral limb ischemia should be taken into account. Distal limb perfusion with a branch of the ECLS circuit should be considered whenever appropriate.

With the chest open, right and left heart cannulation is performed using large-bore cannulas.

#### 5.1.2. Venous/arterial

Polyurethane cannulas combining flexibility and resistance to bending are preferred. Radiopaque markers should be incorporated for easy control. Length is variable and may range from 50 cm for venous and 18 cm for arterial cannulas depending upon the manufacturer and the anatomy of the patient and the vasculature. A variety of sizes is available and should be carefully chosen in relation to the actual size of the vessel. An 18–26-Fr range for venous and 14–20 Fr for arterial cannulation should address the vast majority of native vessels.

#### 5.1.3. Percutaneous/surgical

Percutaneous cannulation is usually preferred in the case of peripheral vessels like the femoral artery and vein. The Seldinger technique may save procedure time and reduce surgical trauma.

Surgical access for cannulation allows for an accurate placement of peripheral cannulas usually in the common femoral or the distal external iliac arteries. A thorough visual inspection of the recipient artery is also possible. Employing these techniques even hemodialysis through the use of these cannulas is possible [15].

### 5.2. Anticoagulation control

Even though biocompatible tubing is used, control of anticoagulation is mandatory as blood is exposed to foreign surfaces. This is of particular importance in patients with mechanical valves requiring any type of support (Table 2).

### 5.3. Centrifugal pumps

Centrifugal pumps are rotary pumps that generate continuous flow. Continuous flow is directly related to perfusion pressure. Polycarbonate housing allows different types of rotary pump heads to mobilize blood. There should be an apical inlet and basal outlet port. The flow is laminar and nonpulsatile and the pump is nonocclusive. Centrifugal pumps are appropriate for short-term support.

External driving units are of a size small enough to facilitate transportation and to avoid space conflict in a busy environment like the intensive care unit (ICU). Anticoagulation is mandatory through the intravenous (i.v.) route.

### 5.4. Transportation of patients on ECLS

Patients with critical cardiopulmonary conditions refractory to medical therapy require specialized assistance in a multispecialty environment. In such cases, transportation of these patients may be difficult. The use of complex methods of mechanical support such as paracorporeal systems is usually restricted to tertiary care institutions with an intrathoracic organ transplantation program. The clinical situation of patients under mechanical assistance is often a contraindication for transportation to other facilities. In current times, first-line methods of cardiopulmonary support such as IABP and centrifugal pumps are available in community hospitals that may initiate life support promptly after an acute devastating event.

A mobile ICU fully equipped for intensive care can be used for transportation. For airborne transportation, a 220-V energy source is required. An appropriate console is used as the driving and monitoring system. The transport team should include at least a cardiovascular surgeon and a perfusionist. This mobile mechanical circulatory support team may represent an important approach to selected critical patients. Transportation of patients on cardiopulmonary support has been described for short and long distances by ambulance, helicopter, and airplane [1].

## 6. Quality assurance

In the context of application of the ECLS, the aspect of patient safety must be considered. Patient safety intends to indicate ways to not only avoid mistakes but also uncover them early enough so they do not harm the patient. Therefore, the causal correlation between medical condition of the patient, his or her treatment, and the therapeutic success must be contemplated by analyzing undesirable events, failures, near adversities, and nonconformity.

Understanding that the ECLS therapy is a complex medical option, it is recommended to establish a selective quality assurance by developing specific patient safety indicators (PSI). The development of specific PSI should be performed by a comprehensive literature review, review by a panel of clinicians and scientists, implementation of risk adjustment, and empirical analyses.

Despite the PSI, for each patient undergoing ECLS therapy, a standardized, reliable, and valid documentation must be obligatory to fulfill the requirements for risk management and to enable internal quality control.

Beyond that, an external quality assurance must be conducted for quality improvement. The external measurement should be a peer-review process so that the evaluation is performed by qualified specialists. It should not only use a set of quality indicators to compare institutional results but also evaluate processes, institutional assumptions, multidisciplinary teamwork, and staff qualification. Hence, the implementation of obligatory directives for institutions and

certified qualification of staff members are essential to provide best care for patients undergoing ECLS.

## 7. Education

In the field of ECLS, there should be minimum requirements in education and experience to run an extracorporeal circulation system. The ECLS systems should be applied as a teamwork between physicians who have the medical responsibility (including the ability to cannulate the patient, set up all necessary monitoring systems, and the ability to cope with all potential complications immediately) and perfusionists who have the responsibility for the extracorporeal circulation. The use of ECLS systems should be limited to these occupational groups.

ECLS systems need specific medical and technical knowledge in extracorporeal circulation (ECC). There are different previous experiences in 'cardiovascular engineering' for physicians and even for perfusionists. However, it is agreed upon that physicians operating an ECLS system have to have proven experience in (a) indications and contraindications, (b) cannulation of various arterial and venous vessels for immediate start of the ECLS, (c) handling vascular complications secondary to cannulation procedures, (d) techniques avoiding peripheral ischemia after cannulation, (e) various methods to decompress the right and left ventricle, and (f) all monitoring parameters to avoid severe complications such as cerebral hypoxia, myocardial damage, etc.

Perfusionists have to have experience in more than 100 ECC perfusions and more than 2 years of practical experience in perfusion during cardiac surgery procedures.

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