

NVIC-ENDORSED GUIDELINE

Extracorporeal life support for cardiac and respiratory failure in adults in the intensive care unit in the Netherlands. Indications for ECLS and requirements for an ECLS centre

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Introduction

ECLS stands for extracorporeal life support, also known as extracorporeal membrane oxygenation (ECMO). ECLS is a form of extracorporeal support, in which an external pump drains the venous blood from the patient to a membrane oxygenator (artificial lung), where the blood is oxygenated and carbon dioxide is removed. The blood is then returned to the circulation of the patient.

There are two forms of ECLS: veno-arterial and veno-venous ECLS. In veno-arterial ECLS (va-ECLS) blood is drained from a large vein, passes through the oxygenator and is delivered back to an artery. In this setting both the respiratory function and the cardiac function can be supported. In veno-venous ECLS (vv-ECLS) blood is drained from a large vein, through the oxygenator and returned to the right heart. In this setting only the respiratory function is supported. The blood flow in both settings is between the 3-8 l/min, and therefore these are referred to as high-flow devices or systems. A variant of vv-ECLS is extracorporeal CO₂ removal (ECCO₂-R). This is, in fact, a vv-ECLS system but with a much lower blood flow (0.5-1.0 l/min). Because of the low blood flow, the blood cannot be oxygenated but smaller cannulas (such as continuous veno-venous haemofiltration (CVVH) catheters) can be used, with a lower complication rate. Extracorporeal CO₂ removal systems are low-flow devices.

So:

1. High-flow va-ECLS is applied in cardiac and respiratory failure
2. High-flow vv-ECLS is applied in respiratory failure
3. Low-flow vv-ECLS (<1 l/min) only supports CO₂ removal, and is applied in ultra protective ventilation or prevention of intubation in patients with chronic obstructive pulmonary disease (COPD)

This document describes the most common indications for ECLS in the intensive care unit (ICU) in the Netherlands and conditions for the safe application of this technique in your unit.

Indications and contraindications for ECLS

ECLS is a technical challenge and is expensive. Foremost is that ECLS is exclusively indicated for potentially reversible life-threatening forms of respiratory and/or cardiac failure, whereby conventional measures have failed.[1] The indications and contraindications are arbitrary because strong evidence is lacking and therefore the indications are mainly based on the criteria used by the ExtraCorporeal Life Support Organisation (ELSO).[1]

Va-ECLS

Veno-arterial ECLS is directly derived from the concept of the cardiopulmonary bypass, first used by Gibbon in 1953, after Kolff had discovered that blood can be oxygenated through a membrane. There are no randomised trials available for the use of va-ECLS. The available evidence is based on observational cohorts and case reports. Studies in patients in cardiogenic shock, during resuscitation or postcardiotomy patients show varying survival percentages: 20-70%. Patients on va-ECLS for cardiogenic shock who survive have been shown to have a better general health, and they function better socially than patients on dialysis, and patients with severe heart failure or acute respiratory distress syndrome (ARDS).[2] It is possible to bridge haemodynamically instable patients on va-ECLS to different situations: 'bridge to decision', 'bridge to recovery', and 'bridge to transplant'.

Indications for va-ECLS

1. Refractory but potentially reversible cardiogenic shock, after conventional therapies have failed
2. Cardiac arrest

Syndromes

1. Myocardial infarction
2. Postcardiotomy
3. Intoxication
4. Myocarditis
5. Per partum cardiomyopathy
6. Septic cardiomyopathy
7. Failing cardiac transplant
8. Pulmonary embolus
9. Bridge to transplantation
10. Bridge to decision
11. Accidental hypothermia with arrest

Contraindications (relative, depending on the experience of the ECLS team)

1. Multi-organ failure (>2 organ systems)
2. Age >70 years
3. Acute cerebral haemorrhage or other life-threatening bleeding
4. Chronic severe pulmonary hypertension (mPAP >50 mmHg)
5. Life expectancy <1 year
6. Graft-versus-host illness
7. Bone marrow transplant in the last six months
8. BMI >40 kg/m²
9. Aortic dissection
10. Severe aortic valve regurgitation

Vv-ECLS

In 1972, ECLS was applied successfully in an adult patient in respiratory failure after trauma. The first randomised trial in 1979 showed no improvement in survival after ECLS for patients with ARDS.^[3] The following study, 15 years later, did not show any benefit for this patient category either.^[4] In both studies, ECLS systems were home built and the mechanical ventilation of ARDS patients was different to that used nowadays: high PEEP levels (20-25 cm H₂O), large tidal volumes (10-12 ml/kg) and high peak pressures (40-50 cm H₂O). Thereafter, several observations showed a more positive effect of ECLS with a survival of 45-65% in patients with severe ARDS. The recent experience with ECLS in ARDS patients in the 2009 H1N1 pandemic was positive, but there are no randomised trials available for ECLS in combination with protective ventilation strategy in this patient category. The CESAR trial, a controlled trial in 180 patients, was done in adult patients with severe ARDS.^[5] The patients were treated with mechanical ventilation in their own hospital or were referred to a specialised centre for ECLS treatment. The ECLS patients were ventilated with volume or pressure limits, with the focus on lung rest. The control group was on protective ventilation as much as possible, but there was no specific protocol. In the ECLS group (n=90), 68 patients received ECLS while 22 patients did not because

they improved after conventional treatment in the ECLS centre. Mortality or severe disability after six months was 37% in the ECLS group and 53% in controls. Thus, this study is not an actual randomised study between ventilation and ECLS but mainly demonstrates the benefit of a strategy to transfer severe ARDS patients to a specialised centre.

Indications for vv-ECLS

1. Refractory but potentially reversible respiratory failure, after conventional therapies have failed. Severe hypoxia and or hypercapnia after conventional mechanical ventilation has failed, including prone positioning. Suggestion: PaO₂/FiO₂ ratio <100 mmHg (13.3 kPa) or SaO₂ <88%, or pH <7.15 during ventilation with a PEEP ≥15 cmH₂O and plateau pressure >30 cmH₂O. In the literature the oxygenation index >30 is mentioned. The oxygenation index is calculated as follows: FiO₂ (in %) / PaO₂ (mmHg) x mean airway pressure (cmH₂O)^[6]
2. Untreatable air leak

Syndromes

1. Severe pneumonia
2. ARDS
3. Trauma with severe lung contusion
4. Smoke inhalation
5. Drowning
6. Fistula or severe air leak after trauma of thoracic surgery
7. Status asthmaticus
8. Bridge to transplant

Contraindications (relative, depending on the experience of the ECLS team)

1. Multi-organ failure (>2 organ systems)
2. Age >70 years
3. Acute cerebral haemorrhage or other life-threatening bleeding
4. Chronic severe pulmonary hypertension (mPAP >50 mmHg)
5. Severe right- or left-sided heart failure (ejection fraction <25%)
6. Cardiac arrest
7. Non-reversible respiratory illness (unless bridge to transplant)
8. Non-reversible neurological damage
9. Life expectancy <1 year
10. Graft-versus-host illness
11. Bone marrow transplant in the last six months
12. BMI >40 kg/m²

Conditions for the application of ECLS in a centre

The intensivist is, as primary physician, well suited to be in charge for this complex patient group. In treating these patients several disciplines are involved. We believe that high-flow ECLS

systems should only be applied in centres where perfusionists,^[7] cardiothoracic surgeons, vascular surgeons and an intervention-radiologist are available. Extracorporeal CO₂ removal (ECCO₂-R) can be applied in centres without these specialties. In the ECLS centre, there should be clear protocols on: indications, responsibilities, equipment and education of staff.

The work group distinguishes three different types of ECLS centres:

1. *Cardiothoracic centre*: a centre where only va-ECLS is performed.
2. *ECLS centre*: a centre where vv-ECLS and/or va-ECLS is performed with at least six ECLS runs/year
3. *ECLS reference centre*: a centre where vv-ECLS and/or va-ECLS is performed with at least 30 ECLS runs/year

When va-ECLS is applied in a cardiothoracic centre, the ICU is able to take care of these patients postoperatively, regardless of the number of ECLS runs/year. As with other rare and complex medical treatments, quality and safety of the procedure increases with regular use. The ELSO registry states a minimum of six ECLS runs/year. A retrospective analysis from the ELSO data showed that there is lower mortality in centres with >30 ECLS runs/year in adult patients in comparison with centres with <6 runs/year.^[8] Vv-ECLS is one of the treatment options for patients with severe respiratory failure (such as ARDS, lung transplant and interstitial lung disease) and thus the ICU is used to treat these types of patients. An ECLS reference centre should perform at least 30 ECLS runs/year (vv-ECLS + va-ECLS) to be eligible for referral of ECLS-specific problems from other hospitals.^[8] We believe that clear agreements should be made in each region about which type of ECLS system is used in which hospital, so adequate experience can be obtained. In addition, agreements should also be reached for referral of ECLS patients to a reference centre.

Staff needed for ECLS

An ICU that offers ECLS should have an ECLS team available 24/7 for the treatment of this specific patient category. This team consist of intensivists, ICU nurses, ICU physicians and/or perfusionists skilled and competent with the used ECLS equipment. A team of intensivists, with extra skills in the care of these patients on ECLS have a continuous consultant function for the ICU. The ECLS training consists of regular 'hands-on' training with the equipment, keeping updated with the literature, and regular attending of ECLS complication meetings. Participation in training is recorded for all members of the expert team in a local registration system. It is our recommendation that each ECLS centre joins the international registry (ELSO), or a surrogate international registry or national registry.

Availability of staff

1. 24/7 presence of ICU physician or perfusionist, skilled and competent in using the ECLS equipment and bedside availability within several minutes in case of an ECLS-related calamity
2. 24/7 presence of ICU nurses, skilled and competent in using the ECLS equipment and bedside availability within several minutes in case of an ECLS-related calamity
3. 24/7 availability of an intensivist, skilled and competent in using ECLS with a consultant function for the staff on the ICU

CO₂ removers

The principle of extracorporeal CO₂ is relatively simple and resembles renal replacement therapy such as CVVH. However, this treatment takes place in highly complex patients and the care has to be performed in an appropriate ICU. With the limited blood flow of 0.5-1.0 l/min, CO₂ can be partially eliminated but there is no significant contribution to oxygenation.^[9] With the use of cannulas with a smaller diameter (such as CVVH catheters), the risk of complications has been greatly reduced. As with ECLS, there is little strong evidence for the use of extracorporeal CO₂ removal. Extracorporeal CO₂ removal can be applied to decrease severe hypercapnia in combination with protective mechanical ventilation (tidal volume 6 ml/kg and plateau pressure <30 cmH₂O) or ultra-protective mechanical ventilation (tidal volume 3-4 ml/kg and plateau pressure <25 cm H₂O).[10] With CO₂ elimination the tidal volumes and plateau pressures can be lowered. Extracorporeal CO₂ removal can also be used to prevent invasive mechanical ventilation in patients with a COPD exacerbation.^[11]

Possible indications:

1. Persistent severe respiratory acidosis (pH <7.15) during lung protective ventilation: tidal volume ≤6 ml/kg and plateau pressure ≤30 cm H₂O
2. Prevention of invasive mechanical ventilation in COPD patients with an exacerbation, often in combination with a no-intubation policy
3. Undesirable hypercapnia, for example in pregnant women or patients with raised intracranial pressure

Training

As with other equipment used in the ICU, such as echography and CVVH, the staff have to be trained and competent in using the equipment. This training must be documented. A local protocol is required with indications and standard operation procedures for the procedure of inserting the cannula, assembling and priming of the system, and trouble-shooting procedures on the unit.

