FRESENIUS
MEDICAL CARE

Critical Care – ECMO

Understanding ECMO and possible indications

Heart & Lung Therapies

Extracorporeal membrane oxygenation
Critical care for patients with severe heart and lung failure

Extracorporeal membrane oxygenation (ECMO) is a form of extracorporeal life support (ECLS). It provides temporary respiratory and/or systemic circulatory support by enriching deoxygenated blood with oxygen and removing carbon dioxide. The ECLS system includes cannulas for vascular access, a blood pump and an oxygenator for gas exchange.

"The primary indication for ECLS is acute severe heart or lung failure with high mortality risk despite optimal conventional therapy. ECLS is considered at 50% mortality risk, ECLS is indicated in most circumstances at 80% mortality risk."[1]

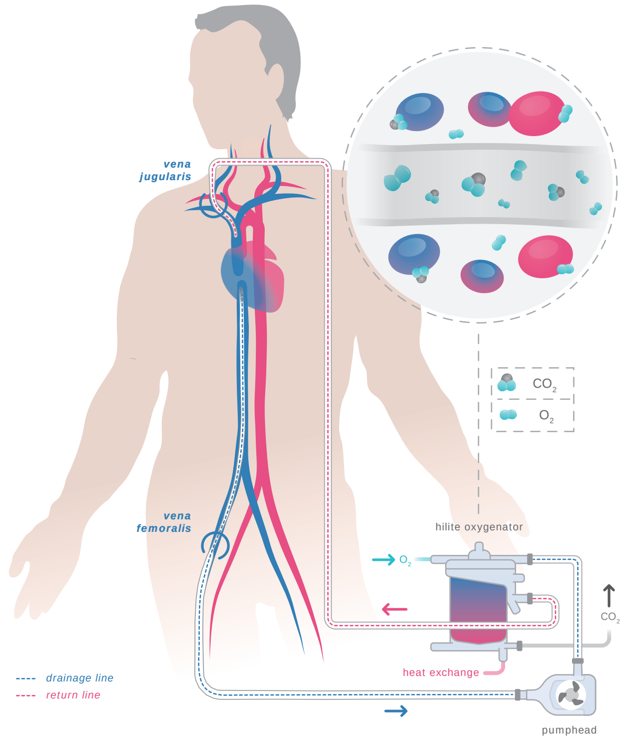
Different cannulation strategies - different treatment options[2]

The cannulation makes the difference

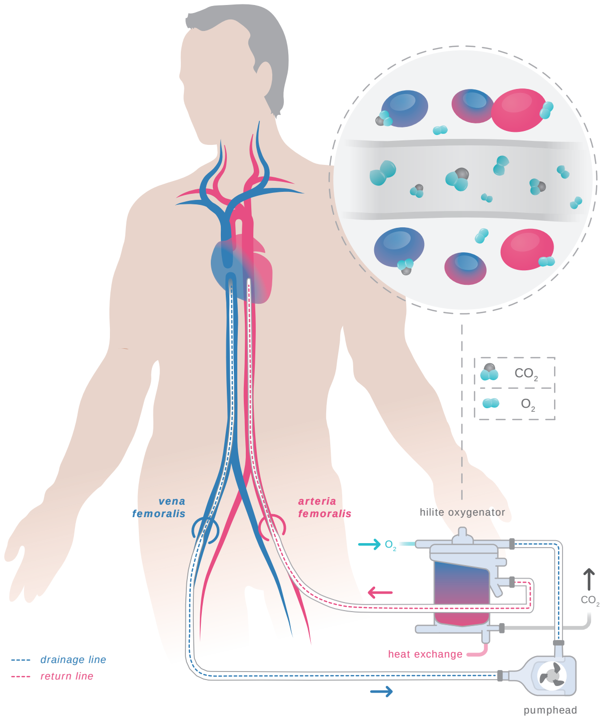
Cannulation configuration depends on the organ which needs to be supported. The patient is cannulated using appropriate cannulas for drainage and return of blood. Thereby, the required blood flow determines the size of the drainage and return cannulas.

Veno-venous ECMO (VV ECMO)

- Supports mainly the lungs (respiratory functions)
- Drains blood from a major vein and returns it to a major vein
- Adequate circulation is provided by the native cardiac output



VV ECMO adult femoro-jugular



VA ECMO adult femoro-femoral

Veno-arterial ECMO (VA ECMO)

- Supports heart and lung (circulatory and respiratory functions)
- Drains blood from a major vein and returns it to a major artery

The figures shown represent only each one of the possible types of cannulation. If you want to find out more, visit our Heart & Lung Campus at www.heart-and-lung-campus.com

Acute respiratory distress syndrome
A challenge in intensive care medicine

Classification of ARDS according to the Berlin Definition[3,4]

Acute respiratory distress syndrome (ARDS) is a diffuse lung injury characterized by the acute onset of impaired gas exchange within one week. Depending on the symptoms and degree of hypoxemia, ARDS is classified into three different stages to allow a better separation of prognosis and treatment selection: mild, moderate and severe ARDS.[3,4]

	 Mild ARDS	 Moderate ARDS	 Severe ARDS
Pattern of onset	Acute (within one week)		
Image findings	Bilateral pulmonary infiltrates on chest x-ray		
Horowitz-index PaO_2/FiO_2	201–300 at PEEP ≥ 5 cmH_2O	101–200 at PEEP ≥ 5 cmH_2O	≤ 100 at PEEP ≥ 5 cmH_2O
Cardiac function	Normal (ECHO)		

Diagram modified from [3]

Etiology[5]

Risk factors for developing ARDS can be stratified by direct and indirect lung injuries (table 1). Although the determination of the exact cause for ARDS development in patients is challenging, approximately one-half of all ARDS patients experience direct lung injuries. However, independent of the cause, most patients show systemic inflammation and organ dysfunction, not limited to the lung. The most common cause of indirect lung injury is sepsis, with an overall risk to ARDS development ranging between 30% and 40%. The most common cause for direct lung injury is pneumonia due to bacterial, viral, or fungal infections.

Table 1: Risk factors for the development of ARDS[5]

Direct	Indirect
Pneumonia (bacterial, viral etc.)	Sepsis
Aspiration of gastric content	Multiple trauma
Pulmonary contusion	Cardiopulmonary bypass
Fat, amniotic fluid, or air emboli	Drug overdose
Near-drowning	Acute pancreatitis
Inhalational injury	Transfusion of blood products
Reperfusion pulmonary edema	

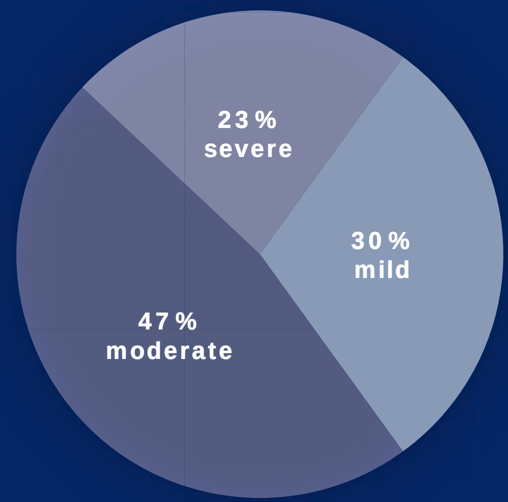
Epidemiology[5,6]

The exact incidence of ARDS is difficult to estimate and ranges from 7 to 85 cases per 100,000 people.[5]

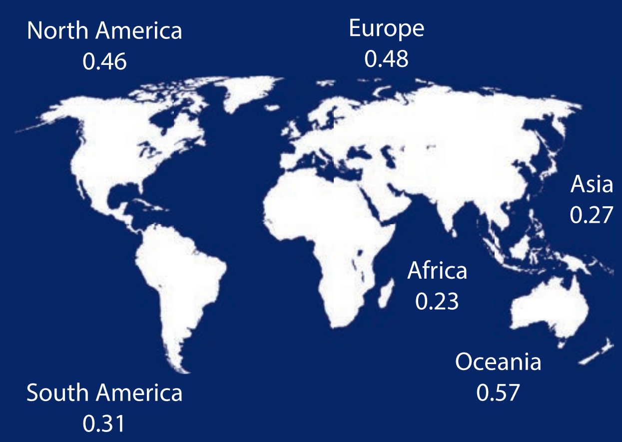
About 10% of patients admitted to the ICU have ARDS. The occurrence of ARDS within ICU patients that are mechanically ventilated is even higher with ~23%.

According to the LUNG SAFE study, ARDS is under-recognized in around 50% of mild cases and 21% of severe cases.[6]

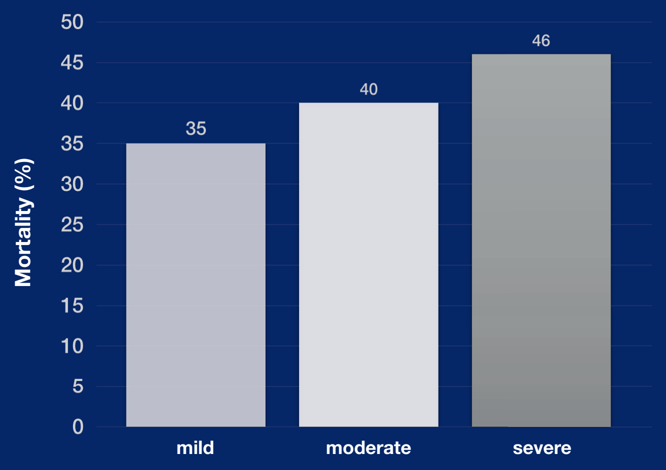
ARDS severities in intubated ICU patients[6]



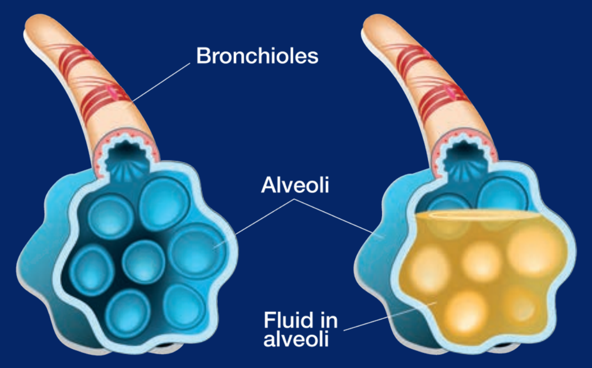
ARDS cases per available ICU bed over four weeks[6]



Hospital mortality in ARDS patients[6]



Healthy alveoli vs. injured alveoli



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Pathogenesis[7]

ARDS affects diffusion, perfusion and ventilation. Patients experience diffuse alveolar damage. Epithelial injury causes a loss of lung surfactant with subsequent reduction of lung compliance. An increased endothelial permeability leads to pulmonary infiltrates, resulting in a reduced aerated lung volume. As a consequence, patients are experiencing an increased work of breathing and impaired gas exchange. On the long term, patients may develop lung fibrosis.

Management of ARDS[8]

Besides treatment of the underlying disease, conventional treatment options include among others: administration of corticosteroids, inhaled vasodilators, neuromuscular blocking agents, invasive mechanical ventilation using lung-protective ventilation strategies and prone positioning. ECMO is considered an ultimate measure to rescue ARDS patients where conventional treatment failed.

Guidelines for ARDS management

- Guidelines on the management of acute respiratory distress syndrome (ICS)[9]
- Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome: An Official ATS/ESICM/SCCM Clinical Practice Guideline Implementation Tools[10]
- S3-Leitlinie: Invasive Beatmung und Einsatz extrakorporaler Verfahren bei akuter respiratorischer Insuffizienz (DGAI)[11]
- Guidelines for Adult Respiratory Failure (ELSO)[12]

Evidence for ECMO in ARDS

Extracorporeal membrane oxygenation for severe acute respiratory distress syndrome[13]

VV ECMO in severe ARDS - results of the EOLIA trial show benefits in favor of ECMO[13]

The ECMO to Rescue Lung Injury in Severe ARDS (EOLIA) trial, published in 2018, compared immediate application of ECMO versus continued conventional management in patients with severe ARDS. In this study, 249 patients were randomized and stratified according to center and length of time receiving ventilation prior to randomization (≥72 hours versus <72 hours). A reduction of 11% in mortality rate in ARDS patients treated with ECMO compared to patients treated with conventional treatment alone could be demonstrated.

However, the observed reduction in mortality rate was not statistically significant (35% versus 46%, p=0.09). The trial was designed to detect an absolute mortality risk reduction of 20%. As there was no significant difference at the 4th interim analysis, the trial was stopped after 75% of the maximum calculated sample was achieved. The secondary composite endpoint of treatment failure (defined as death in the ECMO group and death/crossover to ECMO in the conventional management group) significantly favored the ECMO group (35% treatment failure versus 58% treatment failure, p<0.001). Conversion to ECMO (in the control group) showed, despite prolonged ventilation prior to ECMO initiation, some survival benefit for ECMO treatment: 43% of these patients survived. The 28% crossover rate was regarded as a potentially confounding element by the authors.

The EOLIA trial has suggested improvements of clinical outcome with ECMO therapy in ARDS patients – even if the primary endpoint could not be reached. More clinical data from further RCTs are needed to strengthen clinical evidence for ECMO therapy in ARDS. However, there is common consensus that it is unlikely that there will be further large trials comparing outcome between ECMO therapy and conventionally treated ARDS patients again, as it is very difficult to design and conduct such trials to completion.[14,15]

In future studies, it will be more important to evaluate the optimal ECMO management and treatment algorithm to achieve the best possible benefit for the patients, including definition of criteria for patient selection.[14]

Evidence for ECMO in ARDS

ECMO for severe ARDS: Systematic review and individual patient data meta-analysis[14]

Analysis of data from 429 patients from two RCTs (EOLIA and Conventional ventilatory support vs Extracorporeal membrane oxygenation for Severe Adult Respiratory failure (CESAR) trial) showed that 90-day mortality rate in severe ARDS patients who received VV ECMO was significantly lower than in conventionally treated patients (36% vs. 48%; p=0.013). Moreover, ECMO patients had more days alive out of the ICU and without respiratory, cardiovascular, renal as well as neurological failure. Even though mortality rate was similar between treatment groups in patients with three or more organs failing, the mortality rate was nearly halved in the VV ECMO group (22% vs. 41%) in patients that showed less than two organs failing at randomization.

"In conclusion, this meta-analysis of individual patient data of the CESAR and EOLIA trials showed strong evidence of a clinically meaningful benefit of early ECMO in severe ARDS patients. Another large study of ECMO appears unlikely in this setting and future research should focus on the identification of patients most likely to benefit from ECMO and optimization of treatment strategies after ECMO initiation."[14]

Extracorporeal membrane oxygenation versus mechanical ventilation alone in adults with severe acute respiratory distress syndrome: A systematic review and meta-analysis[16]

In this recently published meta-analysis, data from the EOLIA and CESAR trial as well as five observational studies were pooled. Analysis showed that 90-day mortality was significantly reduced in the ECMO group compared to mechanical ventilation alone, which was found consistently in the interventional and observational studies.

Is extracorporeal membrane oxygenation the standard care for acute respiratory distress syndrome: A systematic review and meta-analysis[18]

In this systematic review and meta-analysis, data from 2399 ARDS patients from 18 studies (four RCTs, including CESAR and EOLIA; 14 retrospective studies) were pooled and analyzed.

Analysis of the data indicated that in ARDS patients receiving ECMO, 60-day and 1-year mortality may be reduced compared to conventionally treated patients. However, ICU-mortality was increased in ECMO patients.

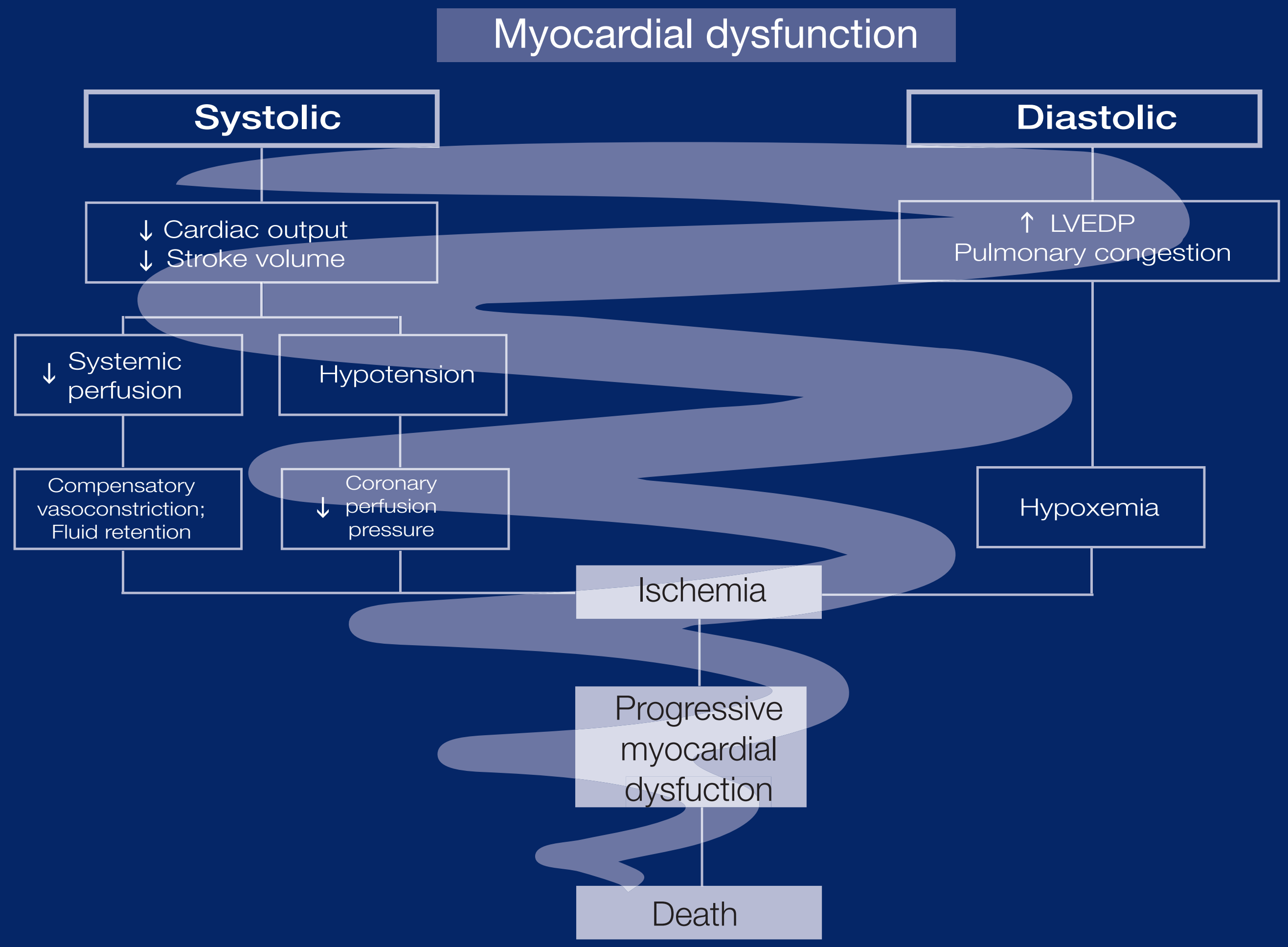
„Extracorporeal membrane oxygenation can be used as a standard step in the management of ARDS. It should be used immediately when high-risk criteria are satisfied, rather than as a late-stage rescue therapy in end-stage ARDS or multi-organ failure. […]"[18]

Assessment of therapeutic interventions and lung protective ventilation in patients with moderate to severe acute respiratory distress syndrome: a systematic review and network meta-analysis[17]

This meta-analysis analyzed data of 25 RCTs to evaluate interventions for patients with moderate to severe ARDS that were treated with lung protective ventilation. VV ECMO and prone positioning were associated with significantly lower 28-day mortality compared to lung protective ventilation alone. It can be concluded that the use of prone positioning or ECMO in addition to lung protective ventilation can increase chance of survival.

"[…] our results are consistent with recent data suggesting that VV ECMO may be considered as an early strategy for adults with severe ARDS."[17]

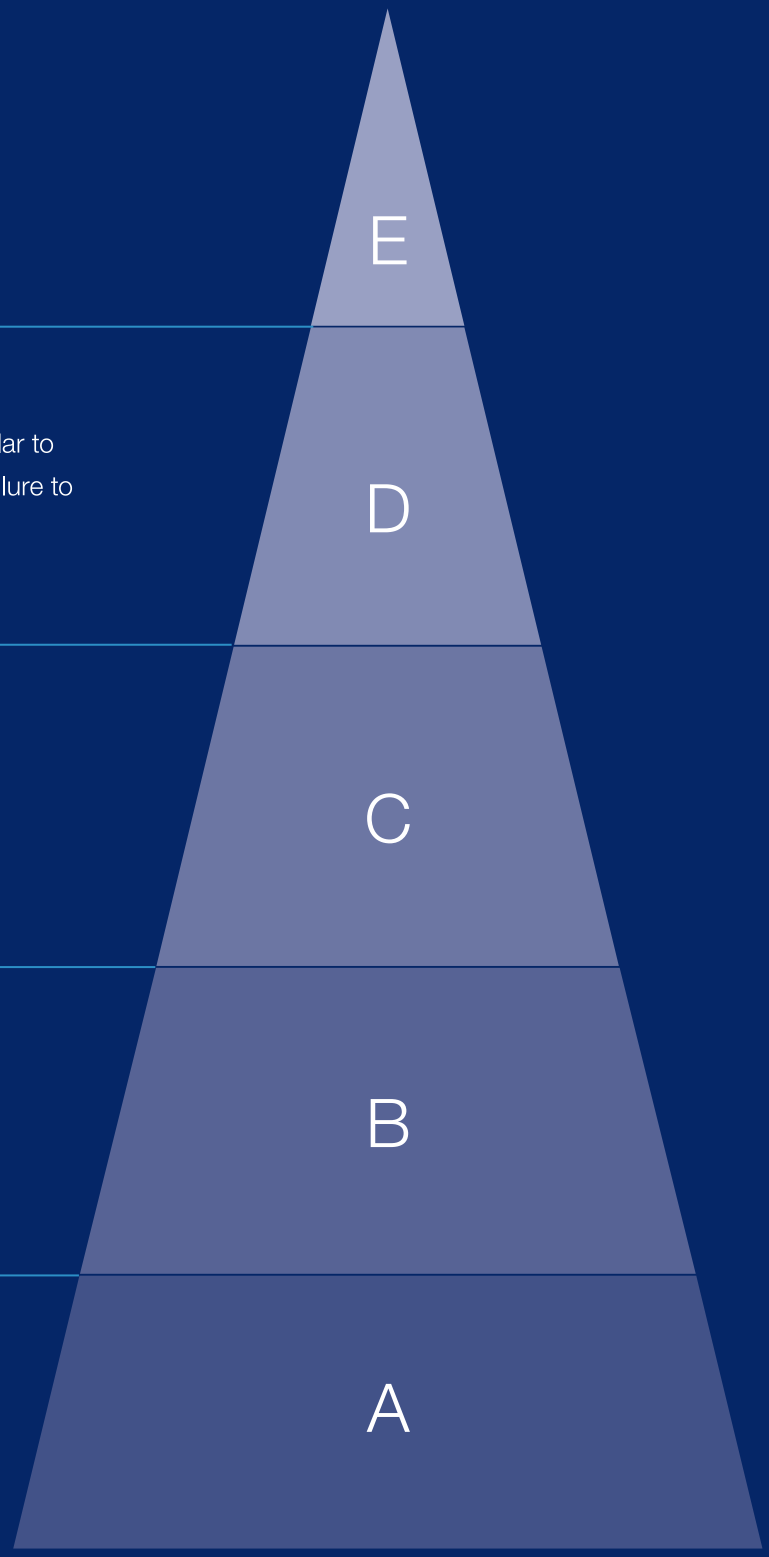
Cardiogenic shock - A race against time



Cardiogenic shock (CS) is a state of low/reduced cardiac output caused by systolic or diastolic dysfunction, leading to impaired hemodynamics and critical end-organ hypoperfusion with insufficient oxygen supply. Underlying causes can be acute myocardial infarction (AMI) with dysfunction of the left ventricle or arrhythmias. CS is refractory to volume resuscitation and distinct from hypovolemic shock, distributive or obstructive shock.[19]

The most common cause for CS is AMI with subsequent ventricular dysfunction (~80%). CS complicates AMI in 5 to 15% of patients. It is the leading cause of death in AMI patients (~50% mortality) which account for ~40,000 – 50,000 patients in Europe and 60,000 - 70,000 patients in the USA annually.[20]

Classification of CS according to the Society for Cardiovascular Angiography and Interventions[21]*



Extremis state CS patients experience cardiac arrest with ongoing CPR and/or ECMO while being supported by multiple interventions.

Deteriorating or dooming patients that are similar to category C but getting worse. Patients have failure to respond to initial interventions.

Classic CS manifests with hypoperfusion that requires intervention (inotrope, pressor or mechanical support, including ECMO) beyond volume resuscitation to restore perfusion. These patients typically present with relative hypotension.

Beginning of CS with clinical evidence of relative hypotension or tachycardia without hypoperfusion.

At risk patient who is not currently experiencing signs or symptoms of CS, but is at risk for its development. May include patients with large AMI or prior infarction, acute and/or acute on chronic heart failure symptoms.

***Definitions and classifications vary between major randomized controlled trials and guidelines.[22]**

Management of cardiogenic shock

As evidence on CS treatment is scarce and has not evolved much since the SHOCK trial[23] and the CULPRIT-SHOCK trial[24], not many guidelines address CS treatment. So far, only immediate revascularization has been shown to effectively reduce mortality in CS complicating AMI.[25]

Guidelines on the treatment of CS usually cover inotropic agents, vasopressors and mechanical circulatory support[22], but recommendations may vary between regions.

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) recommends to consider ECMO for patients with Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles 1-3[.26] The American Heart Association suggests ECMO in CS if the patient is poorly oxygenated and no other form of mechanical circulatory support (MCS) is expected to improve oxygenation promptly.[27]

"Short-term MCS should be considered in patients with cardiogenic shock as a BTR, BTD, BTB. Further indications include treatment of the cause of cardiogenic shock or long-term MCS or transplantation."[26]

"We suggest that veno-arterial ECMO may be the preferred temporary MCS option when there is poor oxygenation that is not expected to rapidly improve with an alternative temporary MCS device or during cardiopulmonary resuscitation."[27]

Guidelines for cardiogenic shock management

- 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure[26]
- Contemporary Management of Cardiogenic Shock: A Scientific Statement From the American Heart Association[27]
- General Guidelines for all ECLS Cases (ELSO)[28]
- The German-Austrian S3 Guideline "Cardiogenic Shock Due to Myocardial Infarction: Diagnosis, Monitoring, and Treatment" (DGK)[29]

Cardiogenic shock
German national registry 2007-2017

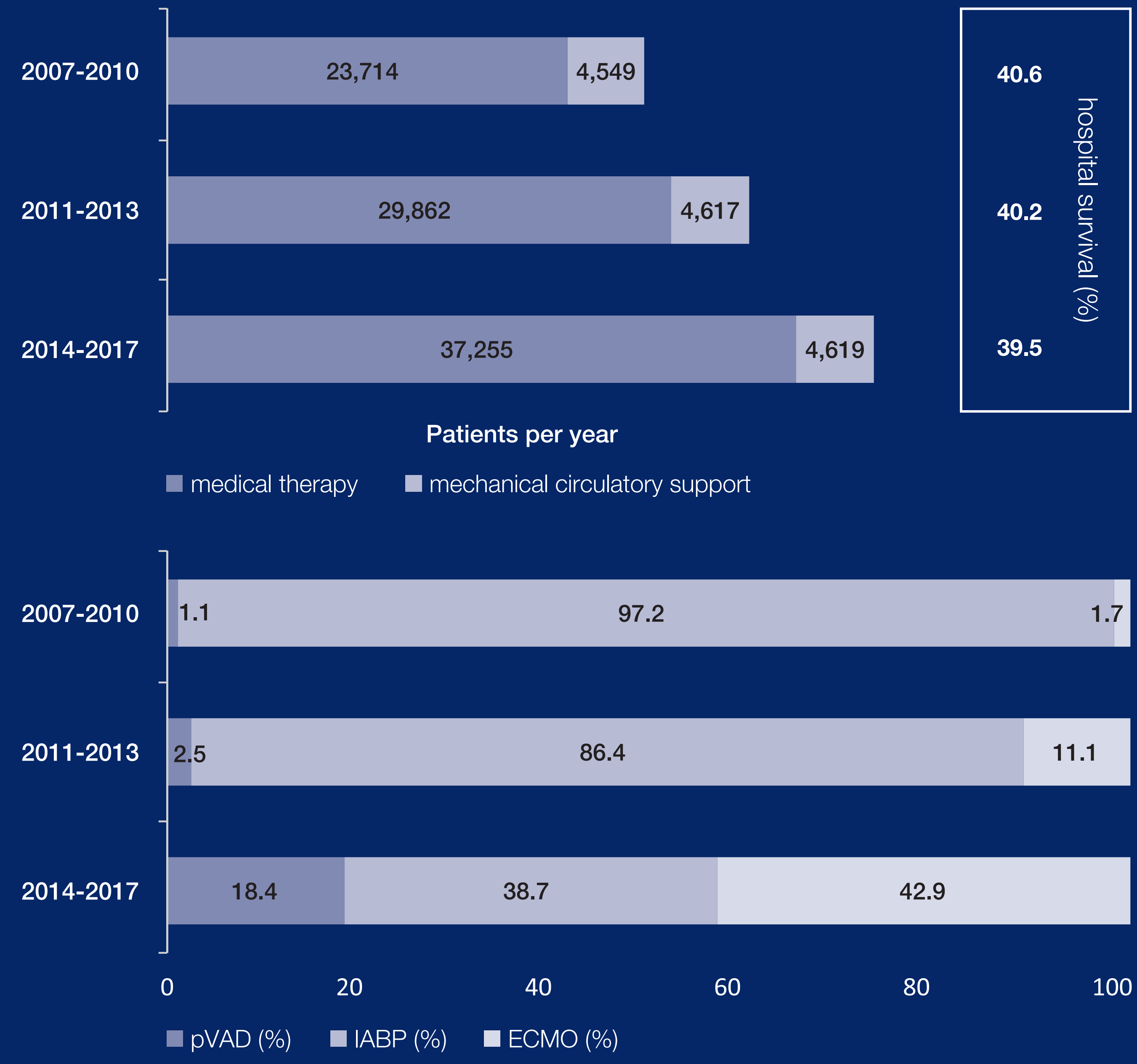


Diagram modified from [30]

Analysis of data collected from hospitalized CS patients in Germany between 2007 and 2017 demonstrates that the management of CS patients has changed over time. The use of VA ECMO and percutaneous ventricular assist device (pVAD) has increased whereas the use of intra-aortic balloon pump (IABP) has decreased. In 383,983 cardiogenic shock patients the overall hospital survival was 40.2 %.[30]

Evidence for ECMO in cardiogenic shock

Under optimal conditions and with timely hospitalization, 90% of patients survive myocardial infarction. However, with complicating CS, survival is reduced to ~50%.[29]

Being suitable for patients with biventricular failure, ECMO has become an important temporary circulatory support system for CS. However, clinical evidence from RCTs is needed to assess benefits of different temporary circulatory support systems in CS management.[31] Several RCTs are currently in progress.[32,33,34]

Scientific reviews and meta-analyses showed that CS mortality is still high after ECLS treatment. One-month survival ranges from 34% to 79% in nine studies including 1,998 patients with CS after AMI.[35] In patients with post-cardiotomy shock, mortality after ECMO was ~67%.[36] Patients with phaeochromocytoma-induced CS[37] and CS in Takotsubo syndrome[38] may have better survival chances (87% and 95%), indicating that the underlying condition may determine mortality[39].

Highly discussed is also the combination of ECMO with left ventricular assist devices to compensate the increased left ventricular afterload from retrograde VA ECMO reperfusion.

Mechanical circulatory support in patients with cardiogenic shock not secondary to cardiotomy: a network meta-analysis[40]

A Bayesian network meta-analysis including seven RCTs and 17 non-RCTs involving 11,117 patients compared the efficacy and safety of different MCS devices in CS. Compared with patients that did not receive MCS, ECMO treated patients had a reduced 30-day mortality. This was not observed for treatment with Impella or IABP. But an even greater reduction in mortality was observed with the ECMO+IABP and ECMO+Impella treatment combinations than with ECMO alone. However, publication bias in the included non-RCT studies may have led to an overestimation of the observed benefits. Nevertheless, the authors conclude:

“Favoring ECMO and, to a greater extent, its combinations with an unloading-dedicated device, our results prove that times would be ripe to test these strategies in adequately powered RCTs.”[40]

Left ventricle unloading with veno-arterial extracorporeal membrane oxygenation for cardiogenic shock. Systematic review and meta-analysis[41]

This meta-analysis included studies from 2000-2019 with 7,581 patients instituted for refractory CS of which 44% received left ventricle/left ventricular (LV) unloading together with VA ECMO. An overall in-hospitality of 59% was reported. A lower risk of mortality compared to ECMO alone was observed in patients that received additional left ventricular unloading. The patient subgroup with underlying AMI profited the most from additional LV unloading while the subgroup with underlying myocarditis did not profit.

“During veno-arterial extracorporeal membrane oxygenation, the increase of left ventricular afterload can negatively impact the recovery from cardiogenic shock. In this meta-analysis including 7581 patients on VA ECMO support, the adjunct of left ventricular unloading was associated with 35% higher probability of weaning and 12% lower risk of mortality.”[41]

Extracorporeal life support during cardiac arrest and cardiogenic shock: a systematic review and meta-analysis[42]

In this meta-analysis, data of 13 studies (nine studies cardiac arrest patients; four studies CS patients after myocardial infarction (MI)) were pooled and analyzed. Evaluation of the data revealed that ECLS increased chances of 30-days survival in cardiac arrest patients by 13% compared to patients who did not receive ECLS. Moreover, the rate of neurological outcomes at 30 days improved. Patients with CS could also benefit from ECLS. Their 30-days survival rate was 33% higher compared to patients treated with IABP, but in terms of survival ECLS was not superior compared to TandemHeart/Impella.

“In the setting of refractory cardiac arrest, the meta-analysis showed increased survival and favorable neurological outcomes in the ECLS-treated patients. In the setting of cardiogenic shock there was an increased survival with ECLS compared with IABP.”[42]

Basics of ECMO treatment

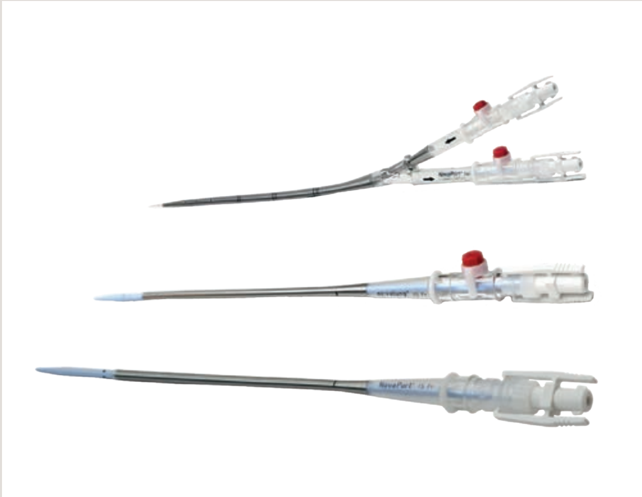
Types of cannulation[1,2,43]

There are different ways of accessing the major vessels for ECMO:

- Surgical central cannulation
- Surgical peripheral cannulation
- Percutaneous cannulation

Venous cannulation sites include the internal jugular veins, femoral veins and the right atrium.
Arterial cannulation sites are the femoral, aorta and carotid arteries.

Find more information about our cannula portfolio in our NovaPort brochure.



The principle of gas exchange

Gas exchange is carried out by the gas exchanger with a semi permeable membrane:

- Blood flows across one side while a "sweep" gas moves in opposite direction
- Blood flow and sweep gas flow determine gas exchange[44]

Find more information about our patient kits portfolio in our disposable brochures: Novalung kits, iLA activve iLA kit, iLA activve iLA kit IPS

Transport

The ELSO has recently published a new guideline on transport of ECMO patients, addressing many technical aspects of transportation.[45]
We provide equipment for the fixed ground transport.

Find more information about the transport system in our Xenios console brochure or MultiSupport GROUND technical data sheet.

Abbreviations

A(MI)	(acute) myocardial infarction
ARDS	acute respiratory distress syndrome
ATS	American Thoracic Society
BTB	bridge to bridge
BTD	bridge to decision
BTR	bridge to recovery
CESAR	Conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure
CPR	cardiopulmonary resuscitation
CS	cardiogenic shock
DGAI	Deutsche Gesellschaft für Anästhesiologie & Intensivmedizin
DGK	Deutsche Gesellschaft für Kardiologie- Herz- und Kreislaufforschung e.V.
ECHO	echocardiogram
ECLS	extracorporeal life support
ECMO	extracorporeal membrane oxygenation
ELSO	Extracorporeal Life Support Organization
EOLIA	ECMO to Rescue Lung Injury in Severe ARDS
ESICM	European Society of Intensive Care Medicine
FiO_2	Fraction of inspired oxygen
IABP	Intra-aortic balloon pump
ICS	Intensive Care Society
ICU	Intensive care unit
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
LV	left ventricle/left ventricular
MCS	mechanical circulatory support
PaO_2	arterial oxygen partial pressure
PEEP	positive end-expiratory pressure
pVAD	percutaneous ventricular assist device
RCT	randomized controlled trial
SCCM	Society of Critical Care Medicine
VA	veno-arterial
VV	veno-venous

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