Percutaneous support of the failing left and right ventricle—recommendations for the use of mechanical device therapy

Sven Möbius-Winkler¹ · Michael Fritzenwanger¹ · Rüdiger Pfeifer¹ · P. Christian Schulze¹

Published online: 30 July 2018

© Springer Science+Business Media, LLC, part of Springer Nature 2018

Abstract

Patients in cardiogenic shock and acute heart failure show high mortality and morbidity despite aggressive and invasive methods such as percutaneous coronary intervention and the use of mechanical support devices. Percutaneous implantation of active hemodynamic support is often the only option for hemodynamic stabilization of patients in cardiogenic shock. Therefore, current guidelines support the use of these devices. Standardized protocols and clinical algorithms for the use of these support devices decrease mortality in these patients. The aim of this review is an overview of current therapies of cardiogenic shock with special focus on mechanical support devices and the suggestion of a clinical algorithm for the differential use of current devices as well as the hemodynamic monitoring of such patients in order to reduce mortality in cardiogenic shock.

Keywords Shock · Heart failure · Mechanical support

Introduction

Patients in cardiogenic shock (CS) and acute heart failure (AHF) show high mortality and morbidity despite aggressive and invasive methods such as percutaneous coronary intervention and the use of mechanical support devices. Current mortality rates are still $\geq 50\%$ [1–4]. Percutaneous implantation of active hemodynamic support systems like Impella, TandemHeart, or extracorporeal life support (ECLS) is often the only option for hemodynamic stabilization of patients in CS. Therefore, current guidelines support the use of these devices with a class IIb indication [5, 6] (Figs. 1 and 2).

Besides the implementation of a specialized Cardiogenic Shock Team consisting of cardiologists, cardiac surgeons, perfusionists, and intensive care physicians as well as specialized nurses, the local expertise in the use of percutaneous support devices is a major factor for improvement of patient outcome. A standardized protocol and clinical algorithm for the use of these active support devices with a clear differentiation of the use of different devices is another way to decrease

complications. The aim of such a standardized protocol focuses on the following points:

- a) Early revascularization as aim to improve prognosis
- b) Early evaluation of hemodynamics in patients with suspected cardiogenic shock to be able to support these patients very early
- c) Early use of mechanical support devices
- d) Deferring to prevention of complications by use of standardized protocols
- e) Strict documentation of those patients for quality assessment

Therefore, the aim of this review is an overview of current therapies of CS with special focus on mechanical support devices and the suggestion of a clinical algorithm for the differential use of current devices as well as the hemodynamic monitoring of such patients in order to reduce mortality in cardiogenic shock.

Definition of cardiogenic shock

Cardiogenic shock is defined as a state of critical end-organ hypoperfusion (e.g., altered mental status, pulmonary congestion, oliguria, cold clammy skin, increased serum lactate) due to reduced cardiac output and persistent hypotension with

✉ Sven Möbius-Winkler
sven.moebius-winkler@med.uni-jena.de

¹ Department of Internal Medicine I, University Hospital Jena, Friedrich-Schiller-University Jena, Jena, Germany

Fig. 1 Mechanical support algorithm University Hospital Jena—acute phase support

systolic blood pressure < 90 mmHg despite adequate filling status [7]. Shock is also considered to be present if intravenous inotropes or mechanical support is needed to maintain systolic blood pressure above 90 mmHg.

Fundamentals of therapy of patients in cardiogenic shock

Coronary revascularization

Main focus of therapy for patients in CS due to myocardial infarction is the restoration of blood flow through the infarcted coronary artery to induce reperfusion of the infarcted myocardial area. The use of percutaneous coronary intervention and stent implantation as the first-line therapy in patients with myocardial infarction and cardiogenic shock was able to reduce mortality rates by 13.2% after 12 months [8]. The randomized SHOCK trial showed a significant decrease in mortality rates for patients younger than 75 years of age and myocardial infarction complicated by cardiogenic shock after 30 days of

follow-up [1] as well as in long-term follow-up after 1 and 6 years compared to patients without early revascularization; however, the primary endpoint of mortality from all causes at 30 days was not met in this trial [8–10].

According to this data, today a recommendation for early revascularization with PCI and stent implantation in patients with myocardial infarction complicated by CS was given for patients with myocardial infarction complicated by CS. This is true for patients in cardiogenic shock due to ST segment elevation myocardial infarction (ESC-Class I A recommendation) and also for patients without ST segment elevation (ESC Class I C recommendation) [5].

Cardiogenic shock emergency care in the USA and Europe

If a patient presents with STEMI, the patient should be transferred to the nearest center with PCI capability 24/7 according to the guidelines. In Europe, this is also true for most countries if the patient presents with a possible cardiogenic shock or with a proposed NSTEMI [11]. If a patient has the signs of shock in emergency medicine, American and European guidelines show some differences. In the US guidelines and

Fig. 2 Mechanical support algorithm University Hospital Jena—chronic phase support

scientific statements, a regional care system is proposed. In the case of cardiogenic shock, the patient should be transferred not to the nearest PCI center but to a PCI center with adequate ICU capabilities being familiar with the treatment of patients with cardiogenic shock. These “hub” centers are also able to implant temporal or durable mechanical cardiac support. In the case of unclassified shock, the patients should be stabilized in the nearest hospital. If the diagnosis is cardiogenic shock, the patient should be transferred to a “hub” center. This could be done by a mobile from the hub center with a specialized shock team [12].

Oxygen supply

Primary aim is to maintain normoxemia with a PaO₂ > 60 mmHg or a peripheral oxygen saturation (SO₂) of > 90% (class I C recommendation) [5, 7]. In cardiogenic shock, most patients develop pulmonary congestion due to elevated left ventricular filling pressures. In those cases, oxygen delivery should be performed through the use of oxygen flow masks, high-flow nasal cannula, non-invasive positive pressure ventilation, or endotracheal intubation and ventilatory support in order to reduce ventilator distress and increase oxygen supply to the failing heart. The

majority of patients with CS, however, will require invasive mechanical ventilation. There is insufficient evidence to recommend specific ventilation modes, strategies (including lung protective ventilation), or physiological end points in the CS population [12]. Periodical arterial blood gas assessment and continuous monitoring of the peripheral oxygen saturation is required (class I C recommendation) [7].

Maintaining arterial perfusion pressure and circulation by pharmacological agents

Patients with systolic blood pressure of > 90 mmHg should be evaluated for the treatment with a vasodilator-like nitrate or sodium-nitroprusside in order to reduce pre- and afterload and to increase the stroke volume of the heart (class II a recommendation) [7].

In patients suffering from systolic blood pressure < 90 mmHg and cardiogenic shock, an inotropic agent (dobutamine, dopamine, levosimendan*, milrinone, enoximone*) may be considered to increase cardiac output and blood pressure and to improve peripheral perfusion to maintain end-organ perfusion (class II b recommendation) [7] (*levosimendan and enoximone are not approved/available in the USA).

Mechanical support

In cases of inadequate response to PCI with stent implantation and medical therapy with inotropes and vasopressors, short-term mechanical support therapy should be considered. This is also true for patients with CS caused by decompensated chronic heart failure or acute myocarditis. There are different devices available to support hemodynamic depression in cases with a potential reversible cause of cardiogenic shock (bridge to recovery) or cases where a definite decision is delayed due to several reasons (bridge to decision). Also, in cases where a definite decision and treatment can be made later (such as heart transplantation, surgical implantable left/right ventricular assist device), short-term bridging with a mechanical percutaneous implantable assist system seems to be adequate (bridge to destination therapy).

Role of cardiogenic shock centers and multidisciplinary shock teams

Due to good experiences in non-cardiac and cardiac medicine (e.g., STEMI) current guidelines propose the building of CS centers. Within these centers, dedicated physicians work together within a multidisciplinary shock team consists of a cardiothoracic surgeon, interventional cardiologist, advanced heart failure specialist, critical care specialist, and trained health care professionals [12]. There is consensus that tertiary high-volume cardiovascular centers should take over CS patients from lower specialized sites if there is a need/chance for LVAD and or transplant or mechanical support systems not available within the initial hospital after careful evaluation by a shock team. Patients should be preferred treated by dual-trained cardiologist-intensivist within these centers while there are hints for a better outcome [12].

Types of mechanical cardiac support system

The selection of the mechanical support system used depends on several factors like local availability and expertise, hemodynamic situation, and patient specific comorbidities.

Intraaortic balloon pump Intraaortic balloon pump (IABP) was used for several decades to support patients in cardiogenic shock with unstable hemodynamics despite adequate volume status and inotropic/vasopressor support. Pathophysiologically, IABP offers a pulse-synchronic counterpulsation within the descending aorta leading to a blunting of the arterial pressure curve and to an increase in coronary perfusion and blood pressure. Simultaneously, there is a slight reduction in afterload.

The IABP Shock II trial by Thiele et al. showed that for patients with cardiogenic shock, the additional use of IABP support was unable to decrease mortality compared to patients without mechanical support [4]. Mainly due to this trial, the

current guidelines do not support the routine use of IABP in patients with cardiogenic shock [5, 7]. In patients with mechanical complications due to myocardial infarction, e.g., acute mitral regurgitation or ventricular septal defect, the use of IABP should be considered (class II a, recommendation, level of evidence C) despite the lack of solid data [5].

The IABP is contraindicated in severe peripheral vascular disease (PVD) of the aortoiliac and femoral arteries—due to increased risk of lower extremity ischemia if there is no other access (e.g., subclavian artery, axillary artery)—and severe aortic valve insufficiency (AI), because their AI will be worsened by the balloon pump, furthermore, aortic dissection and aortic aneurysm, aortic thrombus and coagulopathy.

Impella® microaxial pump The Impella system (Abiomed Europe, Aachen, Germany) is a microaxial, non-pulsatile, flow pump that pumps blood from the left ventricular cavity into the ascending aorta using the principle of Archimedes, not depending on ECG or pulsatile flow. Currently, there are 3 sizes available: the Impella 2.5 is a percutaneous implantable 14 Fr system that is able to reach flow rates of 2.5 L/min. The Impella CP is also percutaneous implantable that promotes up to 3.5 L/min blood flow. The Impella 5.0 is a surgically implantable device with a flow rate of 5.0 L/min. Flow rates of all three devices are adjustable. Impella 2.5 and Impella CP can be implanted via the femoral artery with a 14-Fr spliceable sheath. Over a 0.018 in. guidewire located within the left ventricular cavity, the device is advanced until the inflow cannula is located within the left ventricle. After removing the wire, the pump can be started immediately.

The Impella 5.0 is a 21-Fr system that is usually used after a surgical cut down and grafting from either the axillary position (A. axillaris or A. subclavian) or femoral position. The insertion sheath can be locked via two graft locks. The Impella 5.0 is frequently used as a bridge to recovery or bridge to LVAD tool in patients with CS or post cardiectomy syndrome and provides full hemodynamic support, LV unloading, and organ perfusion up to 5 L/min.

Due to the flow through the Impella pump, there is a continuously unloading of the left ventricle leading to a reduction in left ventricular dimension and wall tension and according to the principle of Frank and Starling to a decrease in myocardial oxygen demand and simultaneously to an increase in cardiac output and arterial mean pressure, leading to a decrease in left atrial pressure/pulmonary wedge pressure.

This is in comparison with ECMO/ECLS (see following chapter), a more physiological principle of support, whereas the ECMO/ECLS System leads to a retrograde blood flow within the aorta from the abdominal aorta to the thoracic aorta. This causes an increased afterload leading to increases in LVEDP, wall tension, and myocardial oxygen demand. The

blood flow within the coronaries or the supraaortic vessels depends on the amount of antegrade flow from the failing ventricle.

Furthermore, an increase in left ventricular end-diastolic pressure and pulmonary capillary wedge pressure is common leading to an impairment of the LV. Therefore, strategies for active LV unloading (e.g., additional implantation of an Impella–Ecmella) are discussed.

The ISAR Shock Trial [13] as well as the Euro Shock registry [14] revealed by comparison of Impella 2.5 vs. IABP that their use is associated with an increased cardiac index and improved lactate restoration as surrogate parameter of organ dysfunction. A non-randomized multicenter registry by Basir et al. showed in 273 patients with acute coronary syndrome complicated by cardiogenic shock that the early use of mechanical support by Impella (0.1–1.3 h) compared to the delayed use of the device (4.3–243 h) leads to a marked decrease in mortality from 74% in late use patients to 34% in early implanted patients [15]. Prospectively randomized trials comparing the use of Impella vs. conservative strategies without mechanical support as well as with other support devices (e.g., ECLS, TandemHeart) are lacking. The current guidelines therefore recommend the use of mechanical support devices under a class II b indication with a level of evidence C [5, 7].

The Impella is contraindicated for use with patients suffering from mural thrombus in the left ventricle, presence of a mechanical aortic valve or heart constrictive device, aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm² or less), moderate to severe aortic insufficiency (echocardiographic assessment graded as $\geq +2$), presence of an atrial or ventricular septal defect (including post-infarct VSD), left ventricular rupture, and cardiac tamponade. Patients suffering from severe PVD may be contraindicated if there is no other entry possible (e.g., subclavian artery).

The Impella ventricular support is approved for up to 6 days.

In cases of contraindications, the TandemHeart system or VA-ECMO can be discussed as an alternative.

Right ventricular support with Impella The Impella RP is an active support device for the right ventricle in patients with right ventricular failure or biventricular failure in combination with another LV support system (Bipella-Concept). The Impella RD is a 22-Fr device specially shaped to pump the blood from the V. cava inferior to the outflow area in the pulmonary trunk. The pump is position via the right femoral vein into the pulmonary trunk. The system is able to support the right ventricle with up to 4 L/min. The Impella RP is approved for up to 14 days of right ventricular support.

TandemHeart The TandemHeart System (Liva Nova; Cardiac Assist, Inc.; Pittsburgh, PA) is an extracorporeal cardiopulmonary bypass from the left atrium to the femoral artery. The inflow cannula (21 Fr) is placed via the femoral vein after a transseptal puncture within the left atrium and unloads oxygenated blood from the left atrium. The extracorporeal centrifugal blood pump (up to 7500 rpm) provides a support up to 5 L/min in the outflow cannula within the descending aorta. This might as well as with the ECMO/ECLS lead to an increase of the afterload. The TandemHeart is approved for temporary cardiopulmonary bypass up to 6 h.

Right ventricular support with the TandemHeart With the Protect duo cannula, a double lumen cannula, the TandemHeart centrifugal pump, is able to support the right ventricle by bypassing from the right atrium to the pulmonary artery. If needed, the system can be added by Tandem Lung—a blood oxygenator—to support also lung function. The system is approved for short-term right ventricular bypass of 6 h.

Extracorporeal life support ECLS systems as well as extracorporeal membrane oxygenation (ECMO) systems are derived from the heart lung machines used for cardiothoracic surgery. The implantation of these systems in cardiogenic shock is usually through the femoral artery and vein but access through other sites such as the subclavian vessels is possible. Venous arterial ECMO is used to support both the cardiovascular and respiratory systems and is frequently used in CS [12]. Venovenous ECMO is used in well-selected patients with isolated respiratory failure without impairment of cardiovascular systems.

Cannulation of the femoral vein is usually between 17 and 24 Fr whereas cannulation of the femoral artery depends on the diameter of the artery usually between 15 and 21 Fr. The systems extract venous blood from the V. cava/right atrium and, due to a extracorporeal circulation with or without membrane oxygenation, pump the blood into the abdominal aorta. Due to the size of the cannula, the maximal blood flow is around 5 L/min. An antegrade cannulation of the A. femoralis communis of the arterial cannulation side for antegrade perfusion of the leg is usually necessary to avoid ischemic complication of the leg. Due to the size of the cannulas, complications of the access site are common. A common issue related to peripheral insertion is the resulting increase in LV afterload, which may lead to inadequate unloading of the LV [12]. Furthermore, an increase in left ventricular end-diastolic pressure and pulmonary capillary wedge pressure is common leading to an impairment of the LV. Therefore, strategies for active LV unloading (e.g., additional implantation of an Impella–Ecmella) are discussed.

Today, there is no randomized clinical trial showing the effectiveness of the system compared to medical therapy only

or other mechanical support devices. There are limited registry data showing that even with ECLS support mortality in cardiogenic shock is between 33 and 70% [16, 17] with an excess mortality in the elderly of up to 100% in those above 75 years [18]. In a meta-analysis of several registries, the authors found no significant difference between the use of ECLS or Impella/TandemHeart in cardiogenic shock [17].

The current guidelines, therefore, recommend the use of mechanical support devices (ECLS, ECMO) under a class II b indication with level of evidence C [5, 7].

ECLS/ECMO is contraindicated in unrecoverable heart and not a candidate for transplant or VAD, advanced age, chronic organ dysfunction (emphysema, cirrhosis, renal failure), prolonged CPR without adequate tissue perfusion and contraindication for anticoagulation (relative contraindication) [19].

Standardized protocols for the use of mechanical assist devices in cardiogenic shock

Hemodynamics in cardiogenic shock are unstable and the maintenance of adequate systolic blood pressure of > 90 mmHg is challenging. In patients with acute coronary syndrome, as discussed above, an urgent revascularization is recommended. Due to the manipulation during PCI at the infarct-related artery, a further drop in blood pressure sometimes leading to a need of cardiac resuscitation can occur. O'Neill et al. reported of a retrospective analysis of patients in cardiogenic shock with a significant increase in survival from 52 to 59% by using the Impella pre-PCI ($n = 2450$) compared to the use of IABP or inotropes prior to PCI ($n = 3121$) [20]. In another publication, early initiation of mechanical support lead to a decrease in mortality by 24.4% from 65.1% vs. 40.7%, $P = 0.003$ in 154 patients [21]. This provided pilot data for the prospective “Detroit Cardiogenic Shock Initiative” which utilized a structured program for using mechanical support in cardiogenic shock patients. The aim was to establish an algorithm for the treatment of patients with cardiogenic shock due to acute coronary syndrome using an early implantation strategy using a cardiac support device before targeting the infarcted coronary vessel [20]. The authors were able to show that compared with a historic cohort, the survival to explant increased from 51 to 89%. The door-to-unloading of the left ventricle time was on average 89 min.

In another small monocentric trial, Schroeter et al. showed that delayed Impella implantation was an independent risk factor for higher long-term mortality with a hazard ratio of 2.2 after 1 year ($p = 0.04$) in patients suffering from ACS

complicated by cardiogenic shock. Within this registry, this was also true for patients older than 70 years [22].

Aim of the recommendation

Aim of the current recommendation is to propose a standardized protocol for use in experienced and unexperienced center for patients with acute coronary syndrome complicated by cardiogenic shock to achieve an optimized setting for performing PCI under maximal protection for the patient.

Stage-based recommendation of cardiogenic shock patients

As outlined in the current guidelines [7] patients with myocardial infarction complicated by cardiogenic shock should be immediately transferred to a catheter laboratory. The aim should be to reopen the infarcted vessel as quickly as possible.

Patients with cardiogenic shock (for definition, see Table 1) or at high risk for the development of cardiogenic shock during a procedure (e.g., lung edema, hypotension) should undergo a structured evaluation using right heart catheterization and echocardiography right before the coronary angiography starts for optimizing the further diagnostic and therapeutic steps (Tables 2 and 3).

Hemodynamic and echocardiographic evaluation may help to address the problem of the failing heart (e.g., right heart failure vs. left heart failure vs. biventricular failure) and identifies specific reasons for cardiogenic shock (e.g., acute mitral regurgitation, decompensated aortic stenosis, infarct-related VSD, etc.). Both methods can help to decide which support system should be used (e.g., LV Impella use when there is a large chronic insufficient LV vs. ECMO use in a failing heart with small, hypertrophic ventricle in decompensated aortic stenosis, etc.). Furthermore, with echocardiography, it is possible to identify several contraindications for the support devices (e.g., LV thrombus, high-grade aortic regurgitation, LV-RV shunts, etc.). Hemodynamic parameters such as the pulmonary artery pulsatility index (PAPi) score might have additional value in the evaluation of these patients.

Table 1 Diagnostic criteria for cardiogenic shock

1. Hypotension with systolic blood pressure < 90 mmHg or need for inotropes in the absence of hypovolemia
2. Signs of end organ hypoperfusion (1 criterium)
 - a) Centralization of perfusion: lactate > 2.0 or central venous O₂ saturation < 55%
 - b) Somnolence
 - c) Oliguria < 30 mL/h
 - d) Cold clammy skin/extremities
3. Congestion/lung edema

Table 2 Advanced invasive monitoring in patients with cardiogenic shock

1. Right heart catheterization (implementation of Swan Ganz Catheter): measure cardiac output, cardiac index, pulmonary capillary wedge pressure, pulmonary artery pressure, saturation within pulmonary artery
2. On-site echocardiography: measure left ventricular ejection fraction, left ventricular end-diastolic diameter, right ventricular end diastolic diameter, right ventricular function, heart valves

Selection of the ventricular support system

If there are no contraindications for the use of a support device (e.g., active bleedings, peripheral obstructive artery disease, malignancy without treatments options or sever reduction of life quality or life expectancy < 1 year, patients with cardiogenic shock should be evaluated for implantation of a mechanical support system. The aim of the assessment is to choose the device for a specific patient that is less invasive but most effective to treat the underlying heart disease.

Impella (CP) is the system of choice for patients in cardiogenic shock with a pulsatile aortic pressure and no need for external oxygenation. Also patients of older age where current data show that they do not have a mortality benefit from ECMO implantation should be evaluated for Impella support.

Depending on the center expertise and the stability of the patient, also surgically implanted Impella 5.0 or the transseptally implanted TandemHeart device can be an option. To our knowledge, the Impella CP is the support system that offers the fastest implantation and most efficient LV unloading support of the patient. The TandemHeart system requires distinct physician experience in transseptal puncture, whereas Impella 5.0 needs surgical support, often associated with some time delay from diagnosis to real hemodynamic support of the patient.

Patients with very low arterial pressure (< 70 mmHg systolic), recurrent cardiopulmonary reanimation, need for external oxygenation are candidates for the primary ECMO implantation.

Implantation of mechanical assist devices

Implantation of mechanical assist devices in CS should be done within the catheter laboratory usually by a trained interventional cardiologist. Members of the heart team may, if possible, support the implantation procedure (e.g., perfusionist, anesthetist), especially in cases where VA ECMO or Impella 5.0 needs to be used. The support systems should be stored within the cardiac catheterization laboratory to avoid long transport and waiting times and to achieve the recommended door to balloon/door to wire time.

Impella 2.5/CP implantation The Impella controller will be prepared by an unsterile nurse/technician as recommended by the manufacturer. For the implantation, access via the femoral artery is usually used. After a safe puncture of the femoral artery, heparin should be administered to achieve an activated clotting time of > 160 s. Via a stiff wire, different dilators can be used to implant the 14-Fr access sheath. A pigtail catheter is then used to get into the left ventricle. Importantly, the pigtail should lie freely within the ventricle, not trapped by papillary muscles, cords, etc. The Impella wire (alternatively a V18 wire) is then used to change the pigtail catheter against the Impella wire. The Impella device can now be advanced via the wire into the left ventricle. After angiographic control of the Impella position (marker should be at the aortic valve position), the device flow can be started. Then, the 14-Fr splitting/peeling sheath can be removed and the permanent introducer advanced within the femoral artery and fixed by sutures.

ECMO implantation The ECMO console should be prepared by a technician. After a safe puncture of the femoral artery and vein and administration of heparin to achieve an activated clotting time (ACT) of at least 160 s, a stiff wire should be introduced (e.g., Amplatz extra stiff). Now, a second arterial puncture towards the leg for antegrade perfusion should be performed and a cannula or sheath for antegrade leg perfusion should be advanced. After the use of several dilators, the arterial and venous cannula can be advanced. The size depends on patient's size and weight and diameter of femoral vessels. Usually, the venous sheath should be at least 21 Fr whereas the arterial cannula should be 17 to 21 Fr. After insertion, both cannulas should be clamped and connected with the ECMO console using a bubble-free wet-to-wet connection. Both cannulas should be sutured for stable fixation. The ECMO flow now can be started.

PCI Coronary intervention by standard techniques in cardiogenic shock should be done immediately after the mechanical support is started. Several registry studies imply that an early mechanical support pre-PCI might reduce mortality in cardiogenic shock patients [20, 22]. After successful PCI, another evaluation of hemodynamics using the Swan Ganz catheter (cardiac output, cardiac index, pulmonary capillary wedge pressure, pulmonary artery pressure, saturation within pulmonary artery) should be performed as well as echocardiographic re-evaluation.

In Impella-patients with persistent PA saturation below 55% despite FiO₂ of 100%, an additional ECMO implantation should be discussed.

Intensive care During ECMO/Impella use, a therapeutic anticoagulation should be given and ACT should be at least

Table 3 Differential use of mechanical assist devices

	Impella	ECMO
Age > 75	+++	(+)
Tako Tsubo	+++	+
Respiratory failure (pO ₂ < 60 mmHg)	+	+++
Need for epinephrine/high-dose norepinephrine for maintaining blood pressure	+	+++
CPR ≥ 2×	+	+++
Ongoing CPR	–	+

160 s. Fixation of the cannulas/Impella should be checked multiple times a day. Position control of the Impella catheter should be done by echo directly after patients transfer. Pulses of the legs should be regularly evaluated. Measurements of hemodynamic parameters should be done three times daily.

Weaning Aim of the structured weaning process is to stabilize the patients and get off catecholamine medications as soon as possible. After reduction of catecholamines, the weaning of the mechanical assist device should be done. Using echocardiography during a turn down or weaning protocol may help to decide if explanation is suitable.

Impella Main criteria for weaning is hemodynamic stabilization with a systolic blood pressure > 90 mmHg/mean blood pressure of 60 mmHg for at least 60 min without or only minimal catecholamine support and stable end-organ function. Reduction of Impella flow is every 3 h by reduction of one P level until the P2 Level on the controller is reached without changes in hemodynamics. (P-level means the power level of the Impella device which ranges from P0 (no rotation) to P8 (maximal rotation)). Thereafter, another hemodynamic and echocardiographic measurement should be done before explantation of the device. Closure of the puncture site can be done by compression or surgical techniques as well as closure devices (e.g., Proglide).

ECMO Main criteria for weaning is hemodynamic stabilization with a systolic blood pressure > 90 mmHg/mean blood pressure of 60 mmHg for at least 60 min without or only minimal catecholamine support and stable end-organ function.

ECMO flow should be reduced by 0.3 L every 6 h. Lung ventilation should be increased simultaneously and O₂ supply by ECMO should be reduced stepwise using blood gas analysis for control. At a reduced flow of the ECMO below 2 L/min, risk of thromboembolism increases; therefore, strict anticoagulation should be done. An echocardiography may help to decide if explanation is suitable. If the flow reaches 2 L/min, an explantation should be scheduled. In the most cases, this will be done surgically but especially if closure devices (e.g., Proglide, Abbot Inc., Angio Seal; Terumo) are

used the interventional approach of closing the implantation side should be preferred due to the less invasive character.

Conclusion

Patients in cardiogenic shock and acute heart failure show still a high mortality and morbidity. Mechanical support by different devices like Impella or ECMO seems to be tools that can help to gain time and/or reduce mortality and morbidity. Today, randomized trials even for Impella and ECMO are lacking but are under way. By having strict algorithms for the implantation of those devices, we are able to standardize procedures and gain experience and knowledge with those devices that can lead to a substantial improvement in the therapy of those patients.

Compliance with ethical standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants performed by any of the authors.

References

1. Aissaoui N, Puymirat E, Tabone X, Charbonnier B, Schiele F, Lefevre T, Durand E, Blanchard D, Simon T, Cambou J-P, Danchin N (2012) Improved outcome of cardiogenic shock at the acute stage of myocardial infarction: a report from the USIK 1995, USIC 2000, and FAST-MI French Nationwide Registries. *Eur Heart J* 33:2535–2543
2. Goldberg RJ, Spencer FA, Gore JM, Lessard D, Yarzebski J (2009) Thirty-year trends (1975 to 2005) in the magnitude of, management of, and hospital death rates associated with cardiogenic shock in patients with acute myocardial infarction: a population based perspective. *Circulation* 119:1211–1219
3. Jeger RV, Radovanovic D, Hunziker PR, Pfisterer ME, Stauffer JC, Erne P, Urban P (2008) Ten-year incidence and treatment of cardiogenic shock. *Ann Intern Med* 149:618–626
4. Thiele H, Zeymer U, Neumann F-J, Ferenc M, Olbrich H-G, Hausleiter J, Richardt G, Hennersdorf M, Empen K, Fuernau G, Desch S, Eitel I, Hambrecht R, Fuhrmann J, Bohm M, Ebelt H, Schneider S, Schuler G, Werdan K (2012) Intraaortic balloon support for myocardial infarction with cardiogenic shock. *N Engl J Med* 367:1287–1296
5. (2017) 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. *Eur Heart J* 1–66
6. Rihal CS et al (2015) 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care. *J Am Coll Cardiol* 65(19):2140–2141
7. (2016) 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J* 37(27):2129–2200
8. Hochman JS, Sleeper LA, White HD et al (2001) One-year survival following early revascularization for cardiogenic shock. *J Am Med Assoc* 285:190–192

9. Hochman JS, Sleeper LA, Webb JG, Sanborn TA, White HD, Talley JD, Buller CE, Jacobs AK, Slater JN, Col J, McKinlay SM, Picard MH, Menegus MA, Boland J, Dzavik V, Thompson CR, Wong SC, Steingart R, Forman R, Aylward PE, Godfrey E, Desvigne-Nickens P, LeJemtel TH (1999) Early revascularization in acute myocardial infarction complicated by cardiogenic shock. *N Engl J Med* 341:625–634
10. Hochman JS, Sleeper LA, Webb JG, Dzavik V, Buller CE, Aylward P, Col J, White HD, SHOCK Investigators (2006) Early revascularization and long-term survival in cardiogenic shock complicating acute myocardial infarction. *JAMA* 295(21):2511–2515
11. Werdan K, Ruß M, Buerke M, Engelmann L, Ferrari M, Friedrich I, Geppert A, Graf J, Hindricks G, Janssens U, Pieske BM, Prondzinsky R, Reith S, Trappe H-J, Zehender M, Zerkowski H-R, Zeymer U, Adams HA, Briegel J, Delle-Karth G, Schöndube FA, Schwaab B, Bode C, Christoph A, Erbel R, Fuhrmann JT, Strasser R, Figulla H-R, Gorge G, Schmitt D, Schuler G, Silber R-E, Tebbe U, Zwißler B (2011) Deutsch-österreichische S3-Leitlinie Infarktbedingter kardiogener Schock – Diagnose, Monitoring und Therapie. *Kardiologie* 5:166–224. <https://doi.org/10.1007/s12181-011-0349-8>
12. Van Diepen et al (2017) Contemporary management of cardiogenic shock; a scientific statement from the American Heart Association. *Circulation* 136. <https://doi.org/10.1161/CIR.0000000000000525>
13. Seyfarth M, Sibbing D, Bauer I, Fröhlich G, Bott-Flügel L, Byrne R, Dirschinger J, Kastrati A, Schömig A (2008) A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. *J Am Coll Cardiol* 52(19):1584–1588
14. Lauten A, Engström AE, Jung C, Empen K, Erne P, Cook S, Windecker S, Bergmann MW, Klingenberg R, Lüscher TF, Haude M, Rulands D, Butter C, Ullman B, Hellgren L, Modena MG, Pedrazzini G, Henriques JP, Figulla HR, Ferrari M (2013) Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. *Circ Heart Fail* 6(1):23–30
15. Basir MB, Schreiber TL, Grines CL, Dixon SR, Moses JW, Maini BS, Khandelwal AK, Ohman EM, O'Neill WW (2017 Mar 15) Effect of early initiation of mechanical circulatory support on survival in cardiogenic shock. *Am J Cardiol* 119(6):845–851
16. Pontallier M, Demondion P, Lebreton G, Golmard JL, Leprince P (2017) Experience with extracorporeal life support for cardiogenic shock in the older population more than 70 years of age. *ASAIO J* 63(3):279–284
17. Ouweneel DM, Schotborgh JV, Limpens J, Sjaauw KD, Engström AE, Lagrand WK, Cherpanath TG, Driessen AH, de Mol BA, Henriques JP (2016) Extracorporeal life support during cardiac arrest and cardiogenic shock: a systematic review and meta-analysis. *Intensive Care Med* 42(12):1922–1934
18. de Waha S, Graf T, Desch S, Fuernau G, Eitel I, Pöss J, Jobs A, Stiermaier T, Ledwoch J, Wiedau A, Lurz P, Schuler G, Thiele H (2017) Outcome of elderly undergoing extracorporeal life support in refractory cardiogenic shock. *Clin Res Cardiol* 106(5):379–385
19. Extracorporeal Life Support Organization (ELSO) Guidelines for Adult Cardiac Failure. <https://www.elseo.org/Portals/0/IGD/Archive/FileManager/e76ef78eabcusersshydocumentselsoguidelinesforadultcardiacfailure1.3.pdf>
20. O'Neill WW et al (2017) Outcomes for 15,259 US patients with acute MI cardiogenic shock (AMICS) supported with Impella; Oral presentation ACC
21. O'Neill WW, Schreiber T, Wohns DH, Rihal C, Naidu SS, Civitello AB, Dixon SR, Massaro JM, Maini B, Ohman EM (2014) The current use of Impella 2.5 in acute myocardial infarction complicated by cardiogenic shock: results from the USpella Registry. *J Interv Cardiol* 27(1):1–11
22. Schroeter MR, Köhler H, Wachter A, Bleckmann A, Hasenfuß G, Schillinger W (2016) Use of the Impella device for acute coronary syndrome complicated by cardiogenic shock –experience from a single heart center with analysis of long-term mortality. *J Invasive Cardiol* 28(12):467–472