

ACUTE CORONARY SYNDROMES

Percutaneous cardiac support devices for cardiogenic shock: current indications and recommendations

Dagmar M Ouweneel, José P S Henriques

► Additional references are published online only. To view these references please visit the journal online (<http://heart.bmj.com/content/98/16.toc>).

Department of Cardiology, Academic Medical Center, Amsterdam, The Netherlands

Correspondence to

Dr José P S Henriques, Academic Medical Center, University of Amsterdam, Department of Cardiology, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands; j.p.henriques@amc.uva.nl

Cardiogenic shock (CS) is a physiological state in which inadequate tissue perfusion results from cardiac dysfunction, most commonly following acute myocardial infarction. Non-ischaemic causes include myocarditis, end-stage cardiomyopathy or sustained arrhythmias.

The use of reperfusion therapy has substantially reduced 30-day mortality in acute ST-segment elevation myocardial infarction (STEMI) patients.^{w1–w3} Currently, the optimal reperfusion therapy is timely primary percutaneous coronary intervention (PCI). The improvement in clinical outcome has been mostly observed in STEMI patients without cardiogenic shock. Despite reperfusion therapy, approximately 6–10% of STEMI patients develop cardiogenic shock during initial hospitalisation.^{1 2 w4} The large multicentre Should we Emergently Revascularise Occluded Coronaries for Cardiogenic Shock? (SHOCK) trial and registry demonstrated that early revascularisation, including PCI or coronary artery bypass grafting, in cardiogenic shock patients improves clinical outcome, but the overall 6-month mortality of cardiogenic shock patients remained 50%⁵ in accordance with other reports.^{1 w4} Despite reperfusion by primary PCI, cardiogenic shock remains the leading cause of death for hospitalised STEMI patients.^{1 w5}

Cardiogenic shock after STEMI is mostly a consequence of decreased myocardial contractility due to the infarction, resulting in a cascade of decreased cardiac output, hypotension and decreased coronary blood flow (CBF), which will further reduce contractility and cardiac output. This vicious circle may not only lead to further myocardial ischaemia, but also to diminished organ perfusion and may ultimately result in multiple organ failure and death. Additional aggravation of the downward spiral is caused by a systemic inflammatory response and excess nitric oxide synthesis induced by the myocardial infarction, which further induces vasodilatation.²

Clinically, cardiogenic shock is characterised by hypotension and defined by a systolic blood pressure of less than 90 mm Hg for at least 30 min or the need for supportive measures to maintain a systolic blood pressure of 90 mm Hg, heart rate of more

than 60 beats/min and end-organ hypoperfusion with cool extremities or a urine output of less than 30 ml/h. Haemodynamic criteria for cardiogenic shock include cardiac index less than 2.2 l/min per square metre and a pulmonary capillary wedge pressure (PCWP) of at least 15 mm Hg.^{3 4}

There are currently two therapeutic options for patients with cardiogenic shock to support the circulation: pharmacological inotropic and/or vasopressor therapy and mechanical support. The recently updated 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guidelines for PCI recommend the use of a haemodynamic support device for patients with cardiogenic shock who do not quickly stabilise with pharmacological therapy.⁵

PHARMACOLOGICAL INOTROPIC SUPPORT

Inotropic and vasopressor agents can be used to improve the haemodynamic parameters rapidly in cardiogenic shock. They are generally administered under the assumption that short-term clinical recovery will be facilitated by enhancement of cardiac output or vascular tone.^{w6} Although these agents all increase myocardial oxygen consumption and can cause ventricular arrhythmias, contraction band necrosis and infarct expansion, the haemodynamic benefits are perceived to outweigh the specific risks of inotropic therapy because hypotension itself also compromises myocardial perfusion.^{w6} The increased myocardial oxygen consumption and vascular tone may have detrimental consequences that may negatively impact clinical outcome, such as impairment of peripheral organ perfusion and an increase in myocardial ischaemia. Although survival in the case of acute myocardial infarction has improved, many patients are left with sizeable infarcts and organ dysfunction, which limits long-term survival and quality of life despite good short-term outcomes. The use of pharmacological inotropic circulating support is recommended, although inotropes and vasopressors have not been shown to improve patient outcomes in randomised controlled studies.

MECHANICAL SUPPORT

The aim of mechanical cardiac assistance is to support the endangered circulation by providing increased systemic blood flow to prevent organ hypoperfusion and allow organ recovery. In addition to haemodynamic support, mechanical cardiac assistance may also provide myocardial protection by unloading the ventricle. It is hypothesised that this left ventricular unloading may result in infarct size reduction and increased left ventricular recovery.⁶

Haemodynamic support

In patients with cardiogenic shock, the maintenance of haemodynamic stability is the primary objective of cardiac support. This includes appropriate mean arterial pressure (MAP) and cardiac output to ensure adequate organ perfusion at the tissue level. The SHOCK trial investigators have shown that cardiac power output (CPO) is the best haemodynamic parameter to predict mortality in the case of cardiogenic shock.⁷ CPO can also be used to predict worsening heart failure in patients with heart failure or pre-shock.^{w7 w8}

$$CPO = \frac{MAP * CO}{451}$$

The parameter takes both the systemic flow, cardiac output and the MAP into account and is divided by a conversion factor of 451 to get the CPO in Watts, assuming that cardiac output alone is necessary but not sufficient for end-organ perfusion and also adequate blood pressure is required. The ideal device would be able to maintain both cardiac output and blood pressure without concomitant vasopressor or inotrope therapy and thereby avoid the possible cardiotoxicity and long-term morbidity of these agents.

Myocardial protection

To protect the myocardial tissue, the optimal device should be able to reduce oxygen demand and increase oxygen delivery to prevent (further) myocardial damage. Myocardial tissue depends exclusively on aerobic metabolism, extracting most of the oxygen provided by the coronary system. Because oxygen extraction cannot substantially be increased, the oxygen supply can only be increased by augmentation of the CBF. CBF is related to the pressure difference between the proximal and distal vascular bed and is inversely related to myocardial microvascular resistance. Coronary flow occurs mainly during diastole, when coronary vascular resistance is minimal due to extravascular compression during systole. The pressure gradient is the MAP in diastole minus the downstream pressure, which is related to the end-diastolic filling pressure. Myocardial microvascular resistance is related to the wall tension, which is also closely related to the end-diastolic filling pressure. To increase the oxygen supply, the CBF can be increased by decreasing the end-diastolic pressure

and thereby affecting both the microvascular resistance and the perfusion pressure.

Reducing the oxygen demand is another way to protect the cardiac tissue. The pressure-volume area (PVA) is the parameter that correlates with the oxygen consumption per beat. The PVA is the area of the pressure-volume loop bounded by the end-diastolic pressure volume relation, the end-systolic pressure volume relation and the systolic portion of the loop, and has been considered to represent the total mechanical energy generated by the left ventricle.^{w9 w10} The ideal device decreases preload and unloads the ventricle, which results in shifting of the pressure-volume loop downwards and to the left, reducing the PVA and therefore the oxygen consumption.

In conclusion, devices that affect both the oxygen supply by increasing CBF and decrease the oxygen consumption simultaneously will have the best advantage by providing myocardial protection.

MECHANICAL ASSIST DEVICES

Many left ventricular support devices have been developed over the past decades. Surgical ventricular assist devices may improve clinical outcome in STEMI patients with cardiogenic shock.^{w11 w12} However, during an acute critical presentation, only those assist devices allowing percutaneous access are suitable due to the invasiveness of surgical devices. The ideal device should enable both haemodynamic support and myocardial protection. Also, a percutaneous approach is preferable to provide for a quick and easy deployment. In addition, the ideal device should be associated with a low complication rate, as complications may sometimes outweigh the potential beneficial effect. Complications associated with any (percutaneous) left ventricular assist device (LVAD) may include limb ischaemia, embolisation of atherosclerotic and/or thrombotic material, stroke, infection and haemolysis.

INTRA-AORTIC BALLOON PUMP

The intra-aortic balloon pump (IABP) is a percutaneous cardiac assist device that is most frequently used and has been broadly available in clinical practice since its introduction in 1968.^{w13} The IABP is inserted percutaneously in the femoral artery and the balloon is positioned in the descending thoracic aorta distal to the left subclavian artery and proximal to the renal artery branches. The balloon is synchronised to the cardiac cycle and is rapidly inflated during diastole and rapidly deflated immediately before systole, aiming for augmentation of the CBF and systemic blood flow during diastole. Immediately before or during early systole the balloon rapidly deflates, decreasing afterload and thereby increasing cardiac output, decreasing ventricular wall tension and reducing myocardial oxygen demand. The IABP generates an increase in cardiac output up to approximately 0.3–0.5 l/min. Also the IABP is assumed to increase CBF due to

increased diastolic pressure and reduction of left ventricular end-diastolic pressure, and a decrease in oxygen demand by decreased afterload and decreased ventricular wall tension.^{8 w14 w15} However, the Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction (CRISP AMI) randomised trial concluded that in 337 anterior segment STEMI patients without shock, IABP therapy complementing PCI alone did not result in reduced infarct size.⁹ Also, a small randomised trial recently reported no significant difference in cardiac index and acute physiology and chronic health evaluation II score using IABP therapy.¹⁰

There are several limitations to the IABP aside from the limited proof of effectiveness. The augmentation of cardiac output of approximately 0.3–0.5 l/min is likely to be insufficient for patients with severe cardiogenic shock. Additional use of possible deleterious vasoactive agents might be necessary to maintain adequate CPO. Also, the function of the IABP relies on synchronisation with the cardiac cycle, which might not be reliable in the case of cardiac arrhythmia in the critically ill patient and it requires a certain level of left ventricular function.

There are only a few relatively small randomised clinical trials that have studied IABP therapy in STEMI complicated by cardiogenic shock. A meta-analysis published in 2009 of cohort studies of STEMI patients showed no improved outcome in patients treated with IABP.¹¹ A recently published Cochrane individual patient data meta-analysis of randomised controlled trials on patients with myocardial infarction complicated by cardiogenic shock included six eligible and two ongoing studies with a total of 190 patients.¹² This study concluded that the small number of randomised trials that were available were not able to show convincing evidence, for either benefit or harm, supporting the use of IABP-therapy. A large randomised trial, IABP–SHOCK II, started in 2009 and is expected to be completed early in 2012 with reporting late in 2012.

LEFT VENTRICULAR ASSIST DEVICES

Several efforts have been made to develop cardiac assist devices with more haemodynamic support, but as non-invasive as the IABP. They can be used as a bridge to recovery for several days or as a bridge to surgery when no recovery occurs. Currently, three percutaneous devices are commonly used, TandemHeart (Cardiac Assist Inc, Pittsburgh, Pennsylvania, USA), extracorporeal membrane oxygenation (ECMO) and Impella (Abiomed Europe GmbH, Aachen, Germany). These devices differ in the insertion technique and working mechanism (table 1).

TandemHeart

The TandemHeart is a trans-septal ventricular assist device that can be inserted in the catheterisation laboratory under fluoroscopy. This device is

inserted via the femoral vein and right atrium into the left atrium via an atrial septum puncture (figure 1). The outflow cannula is inserted through the femoral artery and positioned at the level of the aortic bifurcation. It has a continuous flow centrifugal pump with a maximal rotation speed of 7500 revolutions/min, which can deliver up to 4 l/min. The haemodynamic effects of the TandemHeart are an increase in cardiac output and MAP and a decrease in PCWP, central venous pressure and pulmonary artery pressure, which results in reduced filling pressures in the left and right ventricle, reduced cardiac workload and reduced oxygen demand.^{13 14 w16} However, it should be noted that without direct left ventricular unloading, increases in MAP translate to increases in the left ventricular afterload, which partly offset the potential cardiac workload benefits. Thiele *et al*¹³ also found an increase in the cardiac power index of 0.15 W/m². Kar *et al*¹⁵ implanted the TandemHeart in 117 patients with severe refractory cardiogenic shock refractory to IABP and vasopressor support resulting in a significant improvement in haemodynamic values, mixed venous oxygen saturation and urine output. Two randomised controlled trials in patients with STEMI complicated by cardiogenic shock confirmed the superior improvement of haemodynamic parameters with TandemHeart support compared with IABP therapy.^{13 w16} However, complications such as severe bleeding, arrhythmias and limb ischaemia occurred more often using the TandemHeart than IABP. Although both studies were not powered to detect differences in mortality, no difference in mortality was found.

In conclusion, the TandemHeart provides both haemodynamic support and myocardial protection in patients with STEMI complicated by cardiogenic shock, although several complications such as severe bleeding and limb ischaemia can occur when using this invasive treatment. Also, the insertion procedure is complex.

Impella

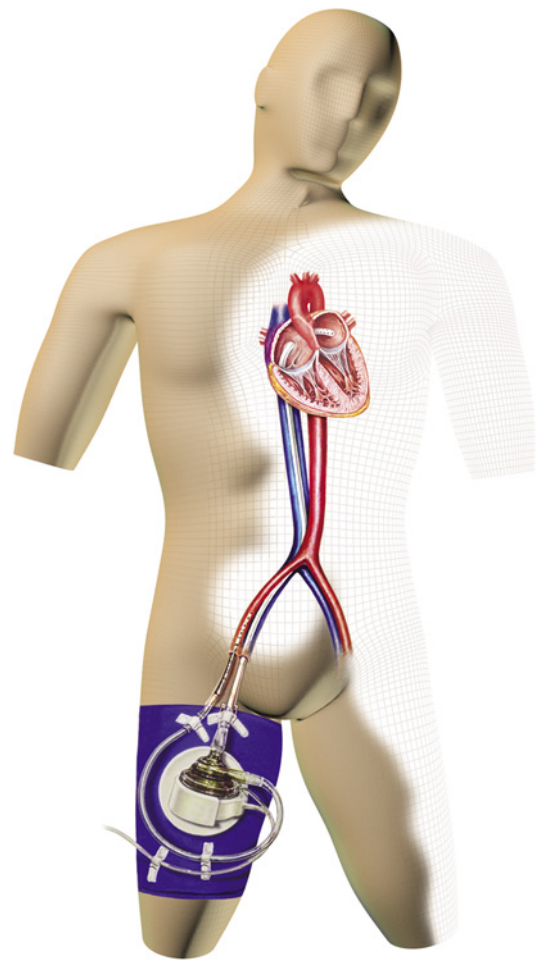
The Impella is a micro-axial rotary pump that is placed across the aortic valve expelling aspirated blood from the left ventricle into the ascending aorta (figure 2). Two versions of the Impella system are currently available. The Impella 2.5 can provide up to 2.5 l/min and can be percutaneously inserted. The Impella 5.0 can deliver up to 5.0 l/min but requires a surgical cutdown of the femoral or axillary artery. Maximum flow in the Impella 2.5 and 5.0 is generated at a maximal rotational speed of 50 000 and 33 000 revolutions/min, respectively. The device has a pigtail-catheter at the tip to ensure stable positioning in the left ventricle and to avoid adhering to the myocardium.

Several studies have demonstrated that the Impella device is feasible and safe in STEMI and high-risk PCI patients,^{16 17 w17} but in cardiogenic shock patients, only a few studies have been reported. Meyns *et al*¹⁸ showed initial safety and feasibility in six patients with severe cardiogenic shock after maximal inotropic support and IABP

Table 1 Comparison of devices

	IABP	ECMO	TandemHeart	Impella 2.5	Impella cVAD	Impella 5.0
Pump mechanism	Pneumatic	Centrifugal	Centrifugal	Axial flow	Axial flow	Axial flow
Cannula size	7–9 Fr	18–21 Fr inflow; 15–22 Fr outflow	21 Fr inflow; 15–17 Fr outflow	13 Fr	14 Fr	22 Fr
Insertion technique	Descending aorta via the femoral artery	Inflow cannula into the right atrium via the femoral vein, outflow cannula into descending aorta via the femoral artery	21 Fr inflow cannula into left atrium via femoral vein and trans-septal puncture and 15–17 Fr outflow cannula into the femoral artery	12 Fr catheter placed retrogradely across the aortic valve via the femoral artery	14 Fr catheter placed retrogradely across the aortic valve via the femoral artery	Surgical cutdown 21 Fr catheter placed retrogradely across the aortic valve via a surgical cutdown of the femoral artery
Haemodynamic support	0.5 l/min	>4.5 l/min	4 l/min	2.5 l/min	3.7 l/min	5.0 l/min
Implantation time	+	++	++++	++	++	++++
Risk of limb ischaemia	+	++	+++	++	++	++
Anticoagulation	+	+++	+++	+	+	+
Haemolysis	+	++	++	++	++	++
Requires stable heart rhythm	Yes	No	No	No	No	No
Post-implantation management complexity	+	++	+++	++	++	++

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump.

**Figure 1** The TandemHeart ventricular assist device, which is placed in the left ventricle using a trans-septal cannula.

therapy. They showed decreased PCWP and blood lactate levels and increased MAP and cardiac output. The ISAR-SHOCK randomised trial compared IABP with Impella 2.5 in cardiogenic shock patients.¹⁹ They found increased cardiac index, cardiac output and MAP in patients treated with Impella compared with IABP-treated patients. Also, they found the overall cardiac power index was slightly higher in Impella patients but the endogenous cardiac output of the left ventricle was significantly lower at all time points because of the additional work of the device. Serum lactate levels were lower in the Impella group than the IABP group. No difference in mortality, major bleeding, distal limb ischaemia, arrhythmias and infections was found. The long-term effects of the Impella are only described by usage after PCI by STEMI and showed no aortic valve abnormalities.²⁰ Also, the Impella group patients showed more left ventricular ejection fraction recovery compared with control patients.

The IMPRESS in STEMI trial, comparing mechanical support by IABP versus Impella 2.5 in STEMI patients with signs of pre-shock, has recently been stopped because of a low inclusion rate due to the targeted pre-shock population,

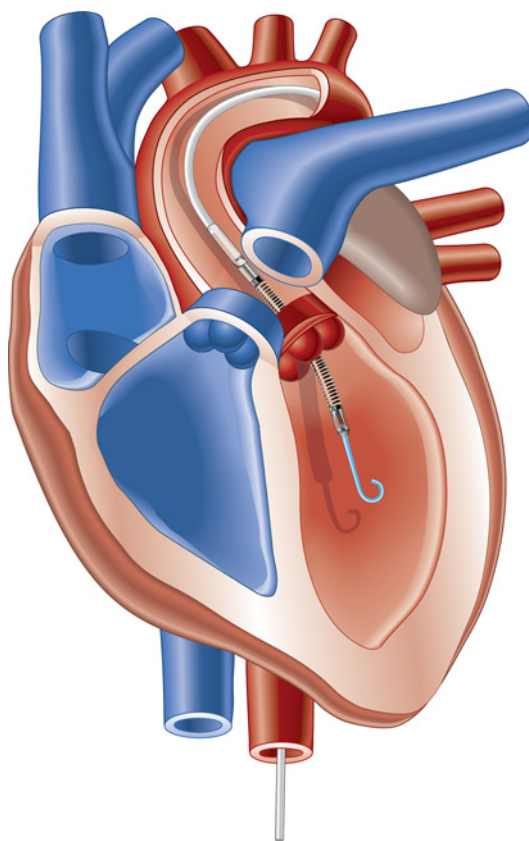


Figure 2 The Impella 2.5 is inserted percutaneously and positioned across the aortic valve in the left ventricle.

which is not an easily assessed clinical condition.^{w18} Also the RECOVER II trial, comparing IABP and Impella 2.5 in haemodynamically unstable STEMI patients, has been terminated due to insufficient patient enrolment.^{w19}

The direct unloading of the left ventricle is an important feature of the Impella. The unloading effect is demonstrated by reduced end-diastolic wall stress and an immediate decrease in PCWP by using the Impella 2.5.^{21 w20} There is also an increase in coronary perfusion pressure and coronary flow.^{w21} Measured pressure volume loops show a decreased PVA, which indicates a reduced oxygen consumption of the myocardium.^{w21} The Impella-induced increase in coronary flow probably results from both an increased perfusion pressure and a decreased left ventricular volume-related intramyocardial resistance. In an experimental setting in sheep, the Impella support has been demonstrated to reduce infarct size.¹⁸ The Impella 5.0 should result in even larger unloading due to the substantially larger contribution to overall circulation.

In severe cardiogenic shock, the Impella 5.0 may result in superior haemodynamic support. Engstrom *et al*²² described the experience with the use of the Impella 2.5 and 5.0 and suggested that Impella 5.0 placement should be considered for profound cardiogenic shock patients. Either immediate insertion or quick upgrade, after initial Impella 2.5 to Impella 5.0 may be considered in cases with severe shock without signs of recovery. Also, in patients with post-cardiotomy low-output

syndrome with a residual cardiac function of 1 l/min a significant reduction in mortality was observed with Impella 5.0 support.^{23 w22}

In conclusion, the less invasive Impella 2.5 support is able to unload the ventricle, improves coronary circulation and gives haemodynamic support up to 2.5 l/min with a low complication rate. However, the Impella 2.5 may not be sufficient to provide enough cardiac output to preserve or restore organ perfusion in the case of severe and profound cardiogenic shock. In these cases, the Impella 5.0 may be able to provide additional support although a drawback of this device is the requirement of femoral artery surgical cutdown. In 2012, the Impella cVAD is expected to be clinically available. The Impella cVAD is smaller than the Impella 5.0 (14 Fr pump vs 21 Fr) and can deliver at least 3.7 l/min. Due to its smaller size, it can be inserted percutaneously like the Impella 2.5. A randomised controlled trial using the Impella cVAD should give more insight into the feasibility of the Impella cVAD in cardiogenic shock. The IMPRESS in Severe Shock Trial using the Impella cVAD is planned to start as soon as the Impella cVAD is clinically available.

Percutaneous ECMO

ECMO can be achieved percutaneously and is a modified heart–lung machine, which can be used for several days. The ECMO system generally consists of a centrifugal pump, a heater and an oxygenator. Via the femoral artery, venous blood flows from the right atrium into a centrifugal pump and oxygenator and is guided via an outflow cannula into the descending aorta via the femoral artery (figure 3). The usage of percutaneous ECMO in cardiogenic shock has been described in post-cardiotomy,^{w23} STEMI^{w24} and myocarditis.^{w25} ECMO is the only percutaneous assist device that also oxygenates the blood. It can give haemodynamic support more than 4.5 l/min depending on the cannula size. Complications associated with ECMO use are a systemic inflammatory response, renal failure, limb ischaemia and bleeding complications. Although ECMO can provide substantial haemodynamic support, it also increases both afterload and preload of the left ventricle, increasing the oxygen demand and impeding myocardial protection.^{w26}

However, the European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines recommend consideration of ECMO implantation for temporary support in patients who continue to deteriorate after IABP implantation and adequate circulation cannot be maintained.²⁴ This strong recommendation is, however, not substantiated by any robust clinical evidence and should therefore be re-evaluated.

PERCUTANEOUS LVAD VERSUS IABP

A meta-analysis compared the safety and efficacy of percutaneous LVAD with IABP in patients with cardiogenic shock²⁵ using two TandemHeart studies^{13 14} and one Impella study,¹⁹ and concluded

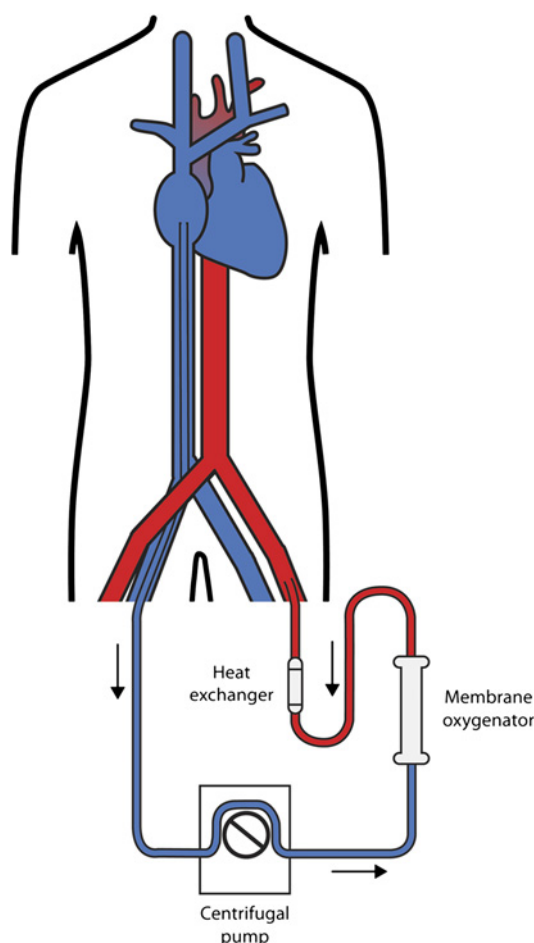


Figure 3 A percutaneous veno-arterial access. The venous access is connected to an extracorporeal membrane oxygenation (ECMO) system with an integrated centrifugal pump and membrane oxygenator (artificial lung) and connected to the arterial inflow access.

that LVAD patients had a higher cardiac index and MAP and lower PCWP compared with IABP patients. Although none of the included studies was powered to detect mortality differences, the authors reported similar mortality and incidence of leg ischaemia, but more bleeding in LVAD patients compared with patients treated with IABP.

In the case of cardiogenic shock, especially full-blown cardiogenic shock, haemodynamic support is the main concern, to prevent organ dysfunction. In these patients, the Impella 2.5 may be insufficient and the TandemHeart or Impella 5.0 device would be superior to increase CPO to avoid organ failure, despite the longer implantation time and higher complication rates. Of note, the Impella 2.5 clearly improves various clinical parameters when compared with IABP therapy in a variety of clinical conditions.¹⁹ A more complete review on the technical details between the TandemHeart and Impella devices is described by Naidu.²⁶

Guidelines

The ESC/EACTS guidelines on myocardial revascularisation recommend early reperfusion as well as

haemodynamic support to prevent end-organ failure.²⁴ The use of an IABP is recommended only in the presence of haemodynamic impairment. Although not supported by evidence, insertion is recommended before angiography. It is also stated that after failure of initial therapy including reperfusion and revascularisation to stabilise haemodynamics, temporary mechanical support using an extracorporeal membrane oxygenator should be considered.

The recently updated 2011 ACCF/AHA/SCAI guidelines for PCI for cardiogenic shock recommend PCI as soon as possible if the patient is a suitable candidate.⁵ A haemodynamic support device, specifically including the IABP, Impella and TandemHeart, is recommended if the patient does not stabilise quickly with pharmacological therapy, although it is mentioned that no data support a reduction in mortality rates when using the IABP or percutaneous LVAD. An overview of recommendations of using mechanical assist devices is shown in table 2.

FUTURE PERSPECTIVES

Despite prompt revascularisation, pharmacological treatment and the use of IABP therapy, the mortality in cardiogenic shock patients remains high. Currently available percutaneous LVADs are promising and safety and feasibility is encouraging in patients with cardiogenic shock. The experience in LVAD therapy is expanding rapidly. The indications include not only acute cardiogenic shock patients, but also prophylactic support during high-risk PCI or as a bridge to transplant in advanced heart failure patients. Therefore, in the forthcoming years, the development and usage of percutaneous LVADs will increase and haemodynamic support will be used more frequently as an additional treatment in several patient groups. In patients with cardiogenic shock, mechanical cardiac assistance can provide immediate circulatory support to prevent organ failure and to provide time to await myocardial recovery. Also, if myocardial recovery is not expected to occur rapidly, percutaneous LVAD may select patients who may benefit from long-term (surgical) LVAD therapy. In STEMI patients with cardiogenic shock, mechanical circulatory support may even become as equally important as opening the occluded artery. In the future, the focus of these patients may therefore shift from door-to-balloon time to door-to-circulatory support time.

However, large randomised trials need to be performed to show the effect of different LVADs and IABP on hard clinical endpoints and preferably on survival. Future developments need to focus on minimising insertion point-related complications such as limb ischaemia and severe bleeding by reducing the device size while maintaining sufficient haemodynamic support. Also thromboembolic complications should be reduced and the associated morbidity needs to be minimised.

As described before, the amount of cardiogenic support and ventricular unloading varies between

Table 2 Guideline recommendations on mechanical assist devices

Indication	Assist device	ESC/EACT guidelines ²⁴	ACC/AHA/SCAI guidelines ^{5 27}
Cardiogenic shock	IABP	Class I (level of evidence C)	Class I (level of evidence B) A haemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilise with pharmacological therapy
	TandemHeart	Class III (level of evidence B)	
	Impella	No recommendation	
	ECMO	No recommendation	No recommendation
High-risk PCI	IABP	Class III (level of evidence B)	Class IIb (level of evidence C) Elective insertion of an appropriate haemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients
	TandemHeart	Class III (level of evidence B)	
	Impella	No recommendation	
	ECMO	No recommendation	No recommendation
Unstable angina/NSTEMI	IABP	Class I (level of evidence C)	Class IIa (level of evidence C) IABP counterpulsation is reasonable in UA/NSTEMI patients for severe ischaemia that is continuing or recurs frequently despite intensive medical therapy, for haemodynamic instability in patients before or after coronary angiography, and for mechanical complications of MI
	TandemHeart	Class IIa (level of evidence C)	
	Impella	No recommendation	
	ECMO	No recommendation	No recommendation
CABG	IABP	Class IIa (level of evidence C)	Class IIa (level of evidence B) In the absence of severe, symptomatic aorto-iliac occlusive disease or peripheral artery disease, the insertion of an intra-aortic balloon is reasonable to reduce mortality rate in CABG patients who are considered to be at high risk (eg, those who are undergoing reoperation or have LVEF <30% or left main CAD)
	TandemHeart	Class IIa (level of evidence C)	
	Impella	No recommendation	
	ECMO	No recommendation	No recommendation

ACC/AHA/SCAI, American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions; AHA, advanced heart failure; CABG, coronary artery bypass grafting; CAD, coronary artery disease; ECMO, extracorporeal membrane oxygenation; ESC/EACT, European Society of Cardiology/European Association for Cardio-Thoracic Surgery; IABP, intra-aortic balloon pump; LVADs, left ventricular assist devices; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; UA, unstable angina.

Percutaneous cardiac support devices for cardiogenic shock: key points

- ▶ Despite reperfusion therapy, approximately 6–10% of STEMI patients develop cardiogenic shock.
- ▶ The overall 6-month mortality of cardiogenic shock patients is 50%.
- ▶ The aim of mechanical cardiac assistance is to support the endangered circulation by providing increased systemic blood flow to prevent organ hypoperfusion and allow organ recovery.
- ▶ The IABP is a percutaneous cardiac assist device that is most frequently used. However, IABPs have failed to improve clinical outcome in randomised trials.
- ▶ Several percutaneous LVADs have been shown to improve haemodynamics in cardiogenic shock. However, the effectiveness on mortality has not yet been shown.
- ▶ The ESC/EACTS guidelines on myocardial revascularisation recommend early reperfusion and the use of an IABP in the presence of haemodynamic impairment. If the patient does not stabilise, the use of ECMO is recommended but without robust clinical evidence.
- ▶ The ACCF/AHA/SCAI guidelines for PCI recommend a haemodynamic support device if the patient does not quickly stabilise with pharmacological therapy.
- ▶ In the future, large randomised trials need to show the effect of different percutaneous LVADs and IABPs on mortality.

different mechanical support systems. The choice of support system may depend on the amount of support needed. In consequence, subgroups of patients have to be defined regarding the severity of cardiogenic shock to allow a better discrimination between patient groups and devices to detect beneficial or harmful effects on outcome in different subgroups. Whether device therapy will ultimately prove beneficial and whether one device is superior to the other in each situation remains to be seen. The usage of percutaneous right ventricular assist devices in the case of right ventricular failure is in development and only little experience is available. Developments of both the TandemHeart

and Impella systems are in progress and a percutaneous right ventricular assist device might become clinically available in the future.^{w27}

There is a critical need for studies regarding the optimal timing of percutaneous cardiac support device implantation, which may prevent the need for potentially deleterious pharmacotherapy. Intuitively, by placing the assist device early in the course of cardiogenic shock, systemic perfusion may be preserved while unloading the heart, resulting in less myocardial damage and multi-organ failure. This would be expected to improve survival although evidence is currently lacking.

CONCLUSION

In conclusion the experience and usage of percutaneous cardiac assist devices in cardiogenic shock has increased over the past years. The ideal device generates sufficient haemodynamic support to prevent end-organ failure, but also myocardial protection to prevent myocardial ischaemia, and has a low complication rate. In the future, mechanical circulatory support may even become equally important as opening the occluded artery in STEMI patients with cardiogenic shock. Eventually, the focus of these patients may therefore shift from door-to-balloon time to door-to-circulatory support time but only in the light of clinical evidence.

Contributors Both authors participated in the literature search and writing the article. Both authors gave approval for the final version to be published.

Competing interest In compliance with EBAC/EACCME guidelines, all authors participating in Education in Heart have disclosed potential conflicts of interest that might cause a bias in the article. JPSH received honoraria/speaking fees and an unrestricted research grant from Abiomed Europe GmbH (Aachen, Germany). DMO has no conflicts of interest to declare.

Provenance and peer review Commissioned; internally peer reviewed.

You can get CPD/CME credits for Education in Heart

Education in Heart articles are accredited by both the UK Royal College of Physicians (London) and the European Board for Accreditation in Cardiology—you need to answer the accompanying multiple choice questions (MCQ). To access the questions, click on **BMJ Learning: Take this module on BMJ Learning** from the content box at the top right and bottom left of the online article. For more information please go to: <http://heart.bmj.com/misc/education.dtl>

- ▶ **RCP credits:** Log your activity in your CPD diary online (<http://www.rcplondon.ac.uk/members/CPDdiary/index.asp>)—pass mark is 80%.
- ▶ **EBAC credits:** Print out and retain the BMJ Learning certificate once you have completed the MCQ—pass mark is 60%. EBAC/EACCME Credits can now be converted to AMA PRA Category 1 CME Credits and are recognised by all national accreditation authorities in Europe (<http://www.ebac-cme.org/newsite/?hit=men02>).

Please note: The MCQ are hosted on BMJ Learning—the best available learning website for medical professionals from the BMJ Group. If prompted, subscribers must sign into Heart with their journal's username and password. All users must also complete a one-time registration on BMJ Learning and subsequently log in (with a BMJ Learning username and password) on every visit.

REFERENCES

1. **Goldberg RJ**, Spencer FA, Gore JM, *et al*. 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* 2009;**119**:1211–19.
2. **Reynolds HR**, Hochman JS. Cardiogenic shock: current concepts and improving outcomes. *Circulation* 2008;**117**:686–97.
3. **Hochman JS**, Sleeper LA, Webb JG, *et al*. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. SHOCK Investigators. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock. *N Engl J Med* 1999;**341**:625–34.
- ▶ **Large randomised controlled trial in patients with acute myocardial infarction complicated by cardiogenic shock comparing early revascularisation and initial medical stabilisation in the setting of acute myocardial infarction complicated by cardiogenic shock.**
4. **Menon V**, Hochman JS. Management of cardiogenic shock complicating acute myocardial infarction. *Heart* 2002;**88**:531–7.
5. **Levine GN**, Bates ER, Blankenship JC, *et al*. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation* 2011;**124**:e574–651.
6. **Mejns B**, Stolinski J, Leunens V, *et al*. Left ventricular support by catheter-mounted axial flow pump reduces infarct size. *J Am Coll Cardiol* 2003;**41**:1087–95.

7. **Fincke R**, Hochman JS, Lowe AM, *et al*. Cardiac power is the strongest hemodynamic correlate of mortality in cardiogenic shock: a report from the SHOCK trial registry. *J Am Coll Cardiol* 2004;**44**:340–8.
8. **Scheidt S**, Wilner G, Mueller H, *et al*. Intra-aortic balloon counterpulsation in cardiogenic shock. Report of a co-operative clinical trial. *N Engl J Med* 1973;**288**:979–84.
9. **Patel MR**, Smalling RW, Thiele H, *et al*. Intra-aortic balloon counterpulsation and infarct size in patients with acute anterior myocardial infarction without shock: the CRISP AMI randomized trial. *JAMA* 2011;**306**:1329–37.
10. **Prondzinsky R**, Lemm H, Swyter M, *et al*. Intra-aortic balloon counterpulsation in patients with acute myocardial infarction complicated by cardiogenic shock: the prospective, randomized IABP SHOCK Trial for attenuation of multiorgan dysfunction syndrome. *Crit Care Med* 2010;**38**:152–60.
11. **Sjaauw KD**, Engstrom AE, Vis MM, *et al*. A systematic review and meta-analysis of intra-aortic balloon pump therapy in ST-elevation myocardial infarction: should we change the guidelines? *Eur Heart J* 2009;**30**:459–68.
 - ▶ **Meta-analysis evaluating the use of IABP in STEMI patients with and without cardiogenic shock.**
12. **Unverzagt S**, Machemer MT, Solms A, *et al*. Intra-aortic balloon pump counterpulsation (IABP) for myocardial infarction complicated by cardiogenic shock. *Cochrane Database Syst Rev* 2011;(7):CD007398.
13. **Thiele H**, Sick P, Boudriot E, *et al*. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. *Eur Heart J* 2005;**26**:1276–83.
 - ▶ **Randomised controlled trial comparing TandemHeart and IABP in patients with cardiogenic shock after an acute myocardial infarction, showing improved haemodynamic parameters, similar 30-day mortality but a higher complication rate with TandemHeart.**
14. **Burkhardt D**, Cohen H, Bruckhorst C, *et al*. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. *Am Heart J* 2006;**152**:469.e1–8.
 - ▶ **Randomised controlled trial comparing TandemHeart and IABP in patients with cardiogenic shock after an acute myocardial infarction, showing improved haemodynamic parameters with TandemHeart but similar 30-day mortality and severe adverse event rates.**
15. **Kar B**, Gregoric ID, Basra SS, *et al*. The percutaneous ventricular assist device in severe refractory cardiogenic shock. *J Am Coll Cardiol* 2011;**57**:688–96.
 - ▶ **The largest registry study of the TandemHeart in cardiogenic shock (n=117) showing improved haemodynamic parameters in patients refractory to IABP and vasopressor support.**
16. **Henriques JP**, Remmelink M, Baan J Jr, *et al*. Safety and feasibility of elective high-risk percutaneous coronary intervention procedures with left ventricular support of the Impella Recover LP 2.5. *Am J Cardiol* 2006;**97**:990–2.
17. **Dixon SR**, Henriques JP, Mauri L, *et al*. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (the PROTECT I Trial): initial U.S. experience. *JACC Cardiovasc Interv* 2009;**2**:91–6.
18. **Mejns B**, Dens J, Sergeant P, *et al*. Initial experiences with the Impella device in patients with cardiogenic shock—Impella support for cardiogenic shock. *Thorac Cardiovasc Surg* 2003;**51**:312–17.
19. **Seyfarth M**, Sibbing D, Bauer I, *et al*. 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* 2008;**52**:1584–8.
 - ▶ **Prospective, randomised controlled trial comparing Impella 2.5 and IABP in patients with cardiogenic shock after an acute myocardial infarction, showing improved haemodynamic parameters with Impella 2.5 but similar 30-day mortality.**
20. **Engstrom AE**, Sjaauw KD, Baan J, *et al*. Long-term safety and sustained left ventricular recovery: long-term results of percutaneous left ventricular support with Impella LP2.5 in ST-elevation myocardial infarction. *EuroIntervention* 2011;**6**:860–5.
21. **Sjaauw KD**, Remmelink M, Baan J Jr, *et al*. Left ventricular unloading in acute ST-segment elevation myocardial infarction patients is safe and feasible and provides acute and sustained left ventricular recovery. *J Am Coll Cardiol* 2008;**51**:1044–6.
22. **Engstrom AE**, Cocchieri R, Driessen AH, *et al*. The Impella 2.5 and 5.0 devices for ST-elevation myocardial infarction patients presenting with severe and profound cardiogenic shock: the Academic Medical Center intensive care unit experience. *Crit Care Med* 2011;**39**:2072–9.
 - ▶ **Retrospective evaluation of Impella 2.5 and 5.0 in patients with severe cardiogenic shock.**
23. **Siegenthaler MP**, Brehm K, Strecker T, *et al*. The Impella Recover microaxial left ventricular assist device reduces mortality for postcardiotomy failure: a three-center experience. *J Thorac Cardiovasc Surg* 2004;**127**:812–22.
24. **Wijns W**, Kolh P, Danchin N, *et al*. Guidelines on myocardial revascularization. *Eur Heart J* 2010;**31**:2501–55.
25. **Cheng JM**, den Uil CA, Hoeks SE, *et al*. Percutaneous left ventricular assist devices vs. intra-aortic balloon pump counterpulsation for treatment of cardiogenic shock: a meta-analysis of controlled trials. *Eur Heart J* 2009;**30**:2102–8.
 - ▶ **Meta-analysis comparing TandemHeart and Impella 25 with IABP in cardiogenic shock patients using three randomised trials.**
26. **Naidu SS**. Novel percutaneous cardiac assist devices: the science of and indications for hemodynamic support. *Circulation* 2011;**123**:533–43.
27. **Hillis LD**, Smith PK, Anderson JL, *et al*. 2011 ACCF/AHA guideline for coronary artery bypass graft surgery: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Thorac Cardiovasc Surg* 2012;**143**:4–34.



Percutaneous cardiac support devices for cardiogenic shock: current indications and recommendations

Dagmar M Ouweneel and José P S Henriques

Heart 2012 98: 1246-1254

doi: 10.1136/heartjnl-2012-301963

Updated information and services can be found at:

<http://heart.bmj.com/content/98/16/1246.full.html>

These include:

Data Supplement

"Supplementary Data"

<http://heart.bmj.com/content/suppl/2012/08/08/heartjnl-2012-301963.DC1.html>

References

This article cites 26 articles, 9 of which can be accessed free at:

<http://heart.bmj.com/content/98/16/1246.full.html#ref-list-1>

Article cited in:

<http://heart.bmj.com/content/98/16/1246.full.html#related-urls>

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections

Articles on similar topics can be found in the following collections

[Acute coronary syndromes](#) (49 articles)
[Education in Heart](#) (468 articles)
[Acute coronary syndromes](#) (2409 articles)
[Drugs: cardiovascular system](#) (7607 articles)
[Interventional cardiology](#) (2580 articles)
[Epidemiology](#) (3084 articles)
[Hypertension](#) (2581 articles)
[Clinical diagnostic tests](#) (4243 articles)
[Percutaneous intervention](#) (844 articles)

To request permissions go to:

<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:

<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:

<http://group.bmj.com/subscribe/>

Notes

To request permissions go to:
<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:
<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:
<http://group.bmj.com/subscribe/>