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The ESC Textbook of Intensive and Acute Cardiovascular Care (2 ed.)

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Latest update

This online textbook has been comprehensively reviewed for the February 2018 update, with revisions made to 28 chapters. Find out more about the updates made.

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Portable (short-term) mechanical circulatory support

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Added new Figure 30.6; revised “Right-sided circulatory failure” and “Right ventricular support”

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Summary

Mechanical circulatory support can be used to resuscitate patients, as a stabilizing measure for angiography and prompt revascularization, or to buy time until more definite measures can be taken. In addition, there is experimental evidence that ventricular unloading of the left ventricle can significantly reduce the infarct size. Different systems for mechanical circulatory support are available to the medical community. Treatment options for mechanical circulatory support must be tailored to each patient in order to maximize the potential benefits and minimize the risk of detrimental effects.

Intra-aortic balloon pumping is still the most widely used mechanical circulatory support therapy. The relative ease and speed with which this device can be applied to patients with a rapidly deteriorating haemodynamic picture have led to its widespread use as a first-line intervention among critically unstable patients. Where intra-aortic balloon pumping is inadequate, an immediate triage to a more advanced percutaneous (short-term) mechanical circulatory support may be warranted. Despite their extensive use, the utility of mechanical circulatory support devices in acute heart failure syndromes and cardiogenic shock remains uncertain. This chapter concentrates on the application of mechanical circulatory support relevant to the interventional cardiologist and cardiac intensive care physician.

Contents

Introduction

CAD has emerged as the dominant aetiologic factor in acute heart failure syndromes (AHFS) and CS (see also Chapters 49 and 51). The *invasive management* of the complex cardiac patient with advanced (decompensated) heart failure, CS, and/or potential haemodynamic compromise during and/after PCI has become the remit of specialized myocardial intervention centres. Such centres provide state-of the art facilities for PCI, including experienced senior operators and critical care physicians who are available 24 hours per day, 7 days per week, with immediate access to cardiac surgery and *mechanical circulatory support* (MCS) systems.

There are two primary indications for (short-term) MCS:

- To *resuscitate* patients: ensure end-organ perfusion in the event of failure of the heart to meet the metabolic demands of the body (see Chapter 53), to buy time until definitive intervention(s) to reverse the underlying pathology are performed, and hence potentially improve survival
- As a *stabilizing measure* for angiography and (prompt) revascularization: to withstand transient derangements in organ perfusion and allow the original cardiac function to resume post-procedure or immediately thereafter (72 hours)

Moreover, *there is ample experimental evidence* that unloading of the LV can significantly *reduce the infarct size* and influence myocardial remodelling after an MI. Mechanical offloading of the myocardium during ischaemia and reperfusion has been shown to reduce LV pressure work and myocardial O_2 consumption. A reduction in the infarct size was related to the degree of pressure unloading of the LV.

General considerations

The intra-aortic balloon counterpulsation device (IABP) is one of the most versatile support devices used in the management of patients suffering from the complications of acute cardiovascular disease (CVD). The relative ease and speed to which this device can be applied to patients with a rapidly deteriorating haemodynamic picture have led to its use as a mainstay intervention among critically unstable patients. The main limitations of the IABP include the lack of active cardiac support, the need for accurate synchronization with the cardiac cycle, the requirement of a certain level of left ventricle (LV) function, and the limit of support provided. In many patients with severe depression of cardiac function and/or persistent (tachy-) arrhythmias, haemodynamic support and LV unloading derived from IABPs may be insufficient to maintain end-organ tissue perfusion. In these circumstances, an immediate triage to more advanced percutaneous (or implanted) (see Chapter 31) mechanical circulatory support (MCS) modalities may be warranted.

The aims of advanced MCS include increasing myocardial O_2 supply and improving oxygen delivery to dependent organ systems, thereby preventing multiple organ dysfunction and subsequent death. A minimal flow rate of 70 mL/kg body weight per minute (representing a cardiac index of at least 2.5 L/m^2) is generally required to provide adequate organ perfusion. This flow is the sum of the percutaneous MCS output and the residual cardiac function. A number of devices exists, the choice of which depends upon the underlying pathology, the expertise of the institution, and the required level of support. In addition, several other considerations exist, applicable to all types of MCS.

Design, performance requirements, and safety issues

The main considerations when choosing portable MCS include patient safety, deliverable flow rate, durability, device and cannula size, and ease of handling. The safety of the patient is the pre-eminent concern, with the main considerations outlined in the following sections and contraindications listed in Table 30.1.

Table 30.1 Complications during IABP use (Benchmark Registry)

Severe access site-related bleeding	1.4%
Vascular injury	0.7%
Major limb injury	0.5%
Amputation	0.1%

Bowel, renal, spinal cord infarcts	0.1%
Infection	0.1%
Stroke	0.1%
Venous thrombosis	0.1%
Death	0.05%

From Cohen M, Urban P, Christenson JT, et al. Intra-aortic balloon counterpulsation in US and non-US centres: results of the Benchmark Registry. Eur Heart J 2003;24: 19 1763–70 with permission from Oxford University Press.

Peripheral vascular disease

In patients with established coronary artery disease (CAD), potential peripheral artery disease should be a concern [1–2]. The requirement for large-bore cannulation of the femoral circulation is an important limitation of most portable MCS therapies. To make percutaneous insertion feasible, the diameters of cannulae are generally downsized to a maximum of approximately 10F. However, since the MCS device flow is limited by the size of the arterial cannula, in cardiogenic shock (CS), larger cannula sizes (13–17F) are required to achieve adequate organ perfusion.

Strategies aimed at reducing femoral artery access site complications, such as the use of pre-insertion abdominal and iliofemoral angiography and vascular ultrasound to guide femoral access (see Chapter 21), have been introduced and implemented in practice [3]. In cases of emergency in patients with severe atherosclerotic disease, angioplasty (percutaneous transluminal angioplasty, PTA) of the femoral artery or direct surgical cutdown may be performed.

Thromboembolism and bleeding

The occurrence of thromboembolic events depends on a number of factors, including the type of device, the duration of support, and the location and number of cannulation sites. Numerous physical factors must also be considered, including mechanical trauma, blood temperature, and blood flow. Embolization may occur during device insertion, function, and removal. The rate of thromboembolic events is relatively low with a heparin anticoagulation regimen. Heparin therapy remains the mainstay of anticoagulation during MCS, monitored using activated clotting time (ACT) and/or activated partial prothrombin time (aPTT) and/or heparin level. An ACT of 160–200 s is usually recommended. There is no evidence for the benefit of additional antiplatelet therapy in MCS. Regional anticoagulation (within the device) may reduce the systemic anticoagulation and reduce the risk of bleeding, although systemic anticoagulation is the norm.

Valvular heart disease

Abnormalities of the cardiac valves have important consequences in patients being considered for MCS, depending on the device selection and site of cannulation. In cases where LV assistance is initiated with left atrial (LA) to aortic cannulation, the presence of an even mild to moderate aortic valve insufficiency may result in LV ballooning in the presence of significant LV dysfunction. Conversely, in cases of severe mitral valve stenosis and impairment in LV filling, LA to aortic cannulation may become the access route of choice (see Chapter 59).

Right-sided circulatory failure

An adequate right heart function is required to maintain LV preload. Acute right ventricular (RV) failure occurs in multiple settings, including acute myocardial infarction (MI), fulminant myocarditis, acute decompensated heart failure, acute pulmonary embolism, decompensated pulmonary hypertension, following cardiac transplant, and in post-cardiotomy shock and is a major determinant of survival. Anatomic and physiologic determinants of RV function are distinct from the left ventricle. The management of RV failure and cardiogenic shock should be tailored accordingly.

In patients who fail to respond to first line interventions and develop refractory cardiogenic shock secondary to right ventricular (RV) failure, options for escalation of care are limited.

However, in selected patients where it is felt that there is prospect for recovery and survival, temporary mechanical circulatory support devices may provide an attractive rescue option (see further sections).

Portable devices for short-term percutaneous mechanical support

This section focuses on devices and modalities of blood flow generation available. It is important to understand that the device *never operates in a vacuum*. Understanding the interaction of the patient–device circuit is the cornerstone of proper monitoring, troubleshooting, and assessment of device performance.

Intra-aortic balloon pump

The IABP is currently the most widely used of all portable devices for short-term circulatory support. Its action is based on the concept of *counterpulsation*, with the assumption that the reduction in end-diastolic pressure improves the LV function. Counterpulsation improves LV performance by favourably influencing myocardial O_2 balance. It increases myocardial O_2 supply by diastolic augmentation of coronary perfusion and decreases myocardial O_2 requirements through a reduction in the afterload component of cardiac pressure work (see Figure **30.1**). However, the effects on cardiac output are only modest and may be limited to patients with a low cardiac output [6]. The reduction of LV afterload may be particular helpful in patients with acute mitral valve insufficiency or VSD. The haemodynamic effects of the IABP are dependent on several factors (see Table 30.2).

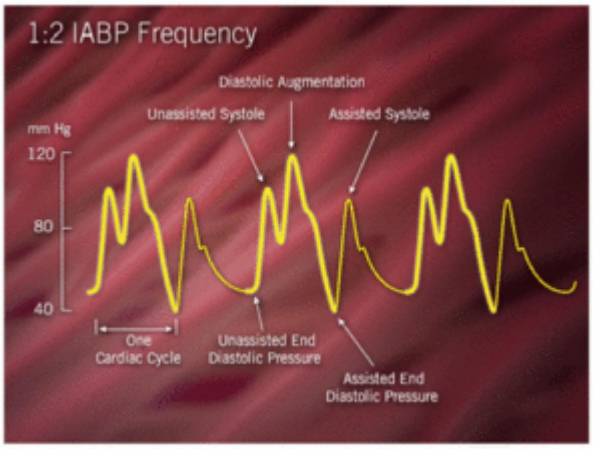

Figure 30.1
Correct timing and pitfalls in the timing of inflation and deflation of the IABP balloon. The balloon is inflated in diastole, concurrently with the closure of the aortic valve, and is held in inflation until the onset of the next ventricular systole. The balloon is then rapidly deflated. The inflation of the balloon displaces blood in the aorta (by an amount equal to the volume of the balloon) toward the coronary tree, thereby increasing (augmenting) the coronary perfusion pressure (CPP) and blood flow. The collapse of the balloon creates a reduction in impedance of the LV ejection and decreased afterload, and consequently reduces LV work.
With permission from Maquet Getinge Group.

Table 30.2 Conditions interfering with the haemodynamic effects of IABP
Position of the balloon in the aorta
Heart rate and rhythm
Size and volume of the balloon
Compliance of the aorta (aortic pressure/volume relation)

After almost four decades of use, the IABP has become a mature technology. The IABP therapy consists of inflating and deflating a Durathane (Maquet, Fairfield, NJ, USA) balloon catheter in synchrony with the patient's cardiac cycle. Different sizes are currently available, allowing the tailoring of the balloon size to patient length. The balloon catheter is commonly inserted through a femoral arteriotomy into the thoracic aorta. Figure **30.2** shows the correct positioning of the intra-aortic balloon tip in the proximal descending aorta. Smaller catheter diameter sizes and the option for a sheathless insertion should improve the distal limb blood flow and further contribute to a reduction of vascular complications, especially in patients with heavy arterial calcification, iliofemoral disease, or obesity.

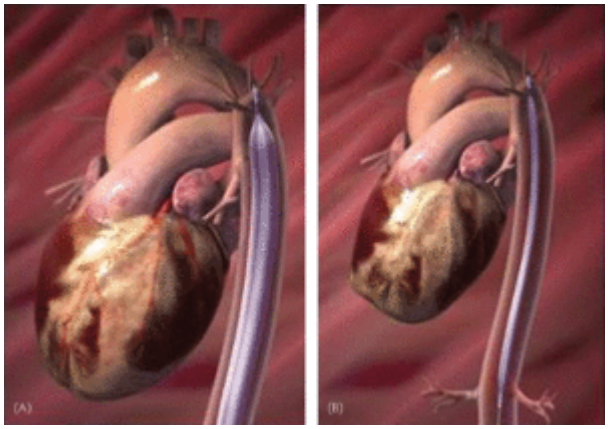

Figure 30.2
Proper positioning of the intra-aortic balloon catheter in the descending aorta: balloon inflation/deflation. Diagrammatic representation of IABP inflation and deflation and its effects on blood flow, as timed by the cardiac cycle. (A) During diastole, the IABP is inflated, increasing the diastolic pressure, thus augmenting the flow not only into the coronary arteries, but also into the great vessels and the renal arteries. (B) During systole, the IABP is deflated, creating a void where the inflated balloon was thus increasing the forward flow into the aorta and to the periphery.

Maquet.

Accurate timing of the intra-aortic balloon inflation and deflation is crucial. Timing errors typically produce characteristic pressure waveform changes that can easily be recognized. (see Figure **30.1**) Early recognition is crucial, as errors can be potentially life-threatening or lead to an ineffective cardiovascular support. The pumping chamber, which is activated by helium, is usually synchronized with the heart by signals from the electrocardiogram (ECG) or the central aortic pressure transducer. The implementation of fibreoptic pressure signal transmission to a patient monitor results in a faster signal acquisition and time to therapy. If paced, then pacing spikes can be used to detect cardiac cycle events. An internal trigger mode is available for asystolic arrested patients. Extreme tachycardia and cardiac arrhythmias may affect the efficiency of IABC. Pressure trigger is not recommended in patients with atrial fibrillation (AF).

Absolute contraindications for the IABP include severe aortic valve insufficiency and (acute) aortic dissection. The presence of an aortic aneurysm, severe iliofemoral vascular disease, and a history of aortic surgery are relative contraindications. Complications associated with IABP are less common in the modern era; the prevalence ranges up to 2.7% [7].

The indications and applications for IABP have come a long way since the early days of counterpulsation (see Table 30.3). The use of the IABP in the adjunctive treatment of CS is widely accepted, even on a guideline level. The joint American Heart Association (AHA)/American College of Cardiology (ACC) guidelines on revascularization of ST-segment elevation myocardial infarction (STEMI) and the joint ESC/European Association on Myocardial Revascularization attributed the use of IABP in the coronary revascularization of patients with CS a class 1B and class 1C recommendation, respectively [8–10]. Despite this, the actual evidence supporting the routine use of IABP adjunctive to primary percutaneous coronary intervention (PCI) in CS is limited and may be challenged [11–12]. Of note also, the routine use of IABP prior to angioplasty in patients with acute, potentially large anterior MIs—as measured by ECG—does little to limit the infarct size or improve clinical outcomes [13].

Table 30.3 Indications for implementation of IABP

	Guidelines	
	ESC/ EACTS	**AHA/ ACC**

STEMI/NSTE-ACS		
Complicated by CS	IC	IB
Mechanical complications (acute mitral insufficiency due to papillary muscle rupture, ventricular septum rupture) for preoperative stabilization	+	+
With hypotension (systolic blood pressure (BP) <90 mmHg or 30 mmHg below baseline BP, not responding to other interventions)		IB
With low output states		IB
In addition to medical therapy in cases of recurrent signs and/or symptoms consistent with myocardial ischaemia and haemodynamic instability, poor LV function, or a large area of myocardium at risk. As support to the emergent revascularization procedure		IC
With refractory polymorphic tachycardia to reduce myocardial ischaemia		IIa/B
With refractory pulmonary congestion		IIb/C
Acute decompensated heart failure (ADHF)		
Reversible myocardial depression		
♦ Acute myocarditis ♦ Drug-induced myocardial dysfunction ♦ Myocardial contusion ♦ Post-cardiac arrest syndrome (PCAS) ♦ Anorexia nervosa		
With haemodynamic instability		
During PCI		

♦ Haemodynamic instability ♦ Severely depressed LV function ♦ Left main disease (selected cases)		
During cardiac surgery		
Preoperative		
♦ Unstable clinical syndromes ♦ Poor LV function ♦ High-risk coronary anatomy ♦ Acute mitral insufficiency		
Intraoperative		
♦ Haemodynamic instability ♦ Difficult weaning from CBP		
Bridge to permanent MCS/transplantation		
High-risk non-cardiac surgery (selected cases)		
Severe LV depression with sepsis (selected cases)		

The IABP is a typical example of a *treatment based on a concept*. The relative ease and speed at which this device can be applied to patients with a rapidly deteriorating haemodynamic picture have led to its use as a first-line intervention among critically unstable patients.

Advanced mechanical circulatory support

Although each device has its own characteristics, the available advanced short-term portable MCS can be classified into two types: axial flow and centrifugal pumps. The use of advanced MCS in patients with acute heart failure syndrome (AHFS), CS complicating ACS, and ACS that do not respond to standard treatment, including IABP, has a level of evidence IIa and a class C recommendation in the recent ECS/European Association of Cardio-Thoracic Surgery (EACTS) guidelines [8]. Published randomized

trials failed to demonstrate any outcome benefit for advanced MCS over IABP in AHFS and CS [14].

Intracardiac axial flow pumps: the Impella platform (short-term, axial)

The Impella 2.5 (diameter 12 F) (Abiomed, Danvers, Massachusetts) is a catheter-mounted intracardiac axial flow pump for short-term use (up to 5 days) that is usually implanted across the aortic valve using a femoral access. It incorporates an impeller—a rotor with helical blades that curves around a central shaft, driven by an electrical motor. The spinning of the impeller draws blood from the cannula positioned into the LV cavity, through the device, to the outflow of the cannula in the ascending aorta. The device has a pigtail catheter at its tip to ensure a stable position in the LV and to prevent adherence to the myocardium (see Figure **30.3**). As with all axial pumps, its performance depends on the rotary speed (maximum 2.5 L/min at 51 000 rpm) and the 'pressure head' (aortic pressure minus LV pressure, continuously monitored). Although the rotary speed is held constant (to the user selection), variation in the pressure head during the cardiac cycle results generally in a pulsatile flow pattern.

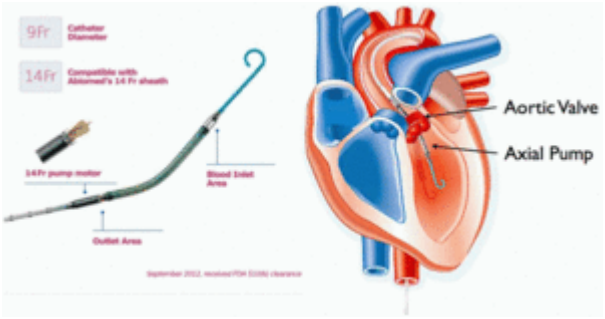

Figure 30.3
The Impella 2.5 System is a micro-axial flow, catheter-based left ventricular assist system (LVAS), designed for percutaneous insertion into the femoral artery and positioned across the aortic valve.
Reproduced with permissions from Abiomed.

This device operates in a way similar to a previous device (Hemopump 14 F, Medtronic, Minneapolis, MN, USA), which was shown to reduce the risk of cardiac arrest during high-risk PCI and provide superior unloading, compared IABP [15, 16]. Whether the 2.5 L/min of additional mechanical support provided by the smaller Impella 2.5 will be sufficient for patients with circulatory collapse still needs to be established [17].

More promising in this regard is the Impella CP and Impella 5.0, the latter capable of delivering a continuous flow of up to 5 L/min [18]. In a sheep infarction model, the Impella 5.0 was shown to reduce myocardial O_2 demand and reduce infarct size [19]. The Impella 5.0 is implanted

most frequently via the subclavian artery which allows for patient ambulation, although a minority of implants are accomplished through the femoral approach. A stable and correct position of the device across the aortic valve provides an efficient and a safe unloading of the LV and prevents haemolysis which is usually related to a suboptimal or an unstable position of the inlet in the LV or close to the aortic valve.

Indeed, limitations of axial support devices are related to the position across the aortic valve, such that the presence of a mechanical aortic prosthesis or aortic stenosis (AS) or of a significant aortic regurgitation (AR) is a contraindication to implantation. Because of the high rotation speed of the impeller, it can also provoke significant haemolysis [20].

Centrifugal pumps

Centrifugal pumps operate in a fashion similar to that of some cardiopulmonary bypass (CPB) pumps [21]. They typically consist of a cone-shaped rotor contained within a plastic or metal housing. Blood flows into the pump at the apex of the cone and exits at the edge of the base. The spinning of the rotor creates a centrifugal force that is imparted to the blood, generating a constant, non-pulsatile flow. Femoral arterial access is provided by large-bore arterial (ranging from 12 up to 17 F) and venous cannulae. Bilateral femoral cannulation using smaller sized cannulae may be an option in small patients. Limb ischaemia caused by femoral cannulation can be prevented by distal leg perfusion with a small catheter (5 F) placed in the distal artery.

Cardiopulmonary bypass

CPB incorporates a centrifugal pump and an extracorporeal oxygenator. The percutaneous technique for the initiation of femoro-femoral cardiopulmonary bypass support (percutaneous cardiopulmonary bypass support, PCPS), using the Bard portable percutaneous cardiopulmonary support system, has been described as far back as 1990 [22]. Blood is aspirated by a centrifugal pump from the right atrium through a long 18–20 F bypass cannula in the femoral vein and is returned by means of a heat exchanger membrane oxygenator to a femoral artery cannula; flow rates of up to 6 L/min may be obtained, providing nearly complete respiratory and circulatory support, independent of the intrinsic cardiac rhythm or ventricular function (see Figure **30.4**). The pump provides a continuous flow with the maintenance of a pulsatile arterial pressure, unless the circulation is completely supported by the CPB device.

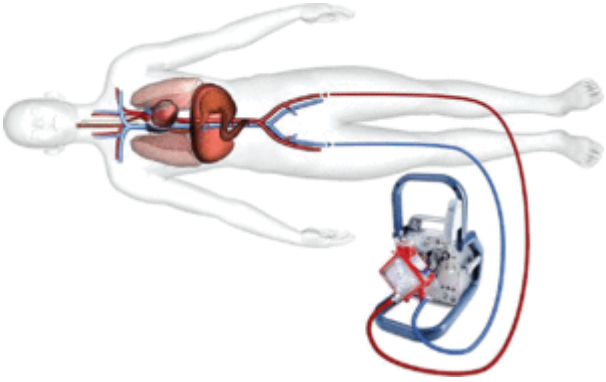

Figure 30.4
The Cardiohelp. The Cardiohelp veno-arterial extracorporeal life support replaces or supports the patient's circulation and respiration.
Maquet.

The initial experience with CPB has been hampered by: the relatively complex system set up, necessitating a specialized team, including perfusionists; the high morbidity rate by a high rate of associated complications; the need for extracorporeal circulation and a membrane oxygenator, with subsequent activation of cellular elements; and the limited support time (usually <6 hours) due to severe haematological and pulmonary complications. Extended use, up to several weeks, was made possible by incorporating a coated circuitry and biocompatible oxygenators designed for a prolonged perfusion incorporating a highly plasma-resistant fibre technology. However, significant complications related to anticoagulation and infection, in addition to an insufficient unloading of the LV, still remain as major problems.

A rapid percutaneous institution of CPB remains the most potent means of haemodynamic support in patients suffering from CS, cardiac arrest, and complicated coronary angioplasty [23]. In the specific setting of CS, the revival of extracorporeal circuitry and hardware that can provide both extended respiratory and/or circulatory support to patients for periods up to several weeks may be of particular interest. The clinical impact of newer and less complicated, smaller portable devices, such as the Cardiohelp System (Maquet Cardiopulmonary AG, Hirrlingen, Germany) remains to be assessed in future trials.

Percutaneous left atrial to femoral artery left ventricular support device (short-term, centrifugal)

In contrast to CPB, closed chest left heart bypass keeps the patient's lungs as its own ventilator and may be used to support the patient for prolonged periods of time (up to 18 days). The TandemHeart™ (Cardiac Assist INC, Pittsburgh, USA) incorporates a new generation of low-speed

centrifugal continuous flow pump with a low blood surface contact area, resulting in reduced potential for haemolysis and thromboemboli.

Oxygenated blood from the patient's LA is supplied to the pump, via a 21 F trans-septal cannula, and then returned to the patient's systemic circulation via an arterial cannula in the femoral artery (17 F in most patients) to the lower abdominal aorta (see Figure **30.5**). Successful deployment of this device requires a team of trained operators, including an operator familiar with the trans-septal puncture [24]. The system can deliver up to 3.0, 4.0, and 4.5 L of blood flow per minute, depending on the size of the arterial cannula and the filling conditions of the LA, while operating at a relatively low speed (7500 rpm). As with any left-sided assist device, the preload to the pump, and therefore the flow, is dependent on an adequate right heart function.

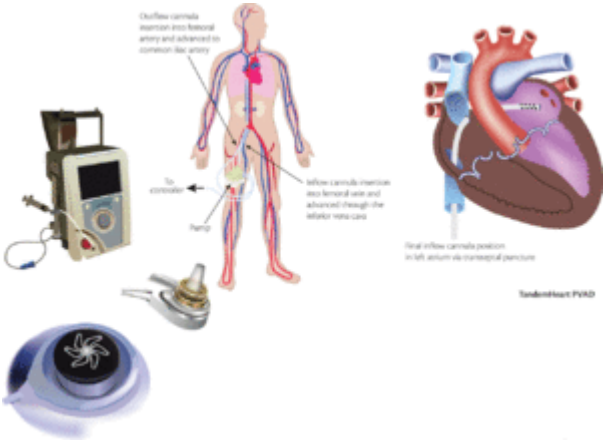

Figure 30.5
The TandemHeart. The TandemHeart PVAD is a percutaneous left atrial to femoral artery LV support device. Oxygenated blood from the patient's LA is supplied to a small extracorporeal pump by a 21 F trans-septal cannula, with a large end hole and 14 side holes, and then returned to the patient by the femoral route. The close-up shows the centrifugal pump.
Tandemheart.

There is mounting evidence that this device may be sufficient to prevent, or even reverse, organ dysfunction in CS patients. A recent single centre study on a 'step-up' therapy with the TandemHeart™ in patients with severe refractory CS despite standard therapy, including IABP, showed a remarkable 6-month mortality rate of 45.3% [25].

Right ventricular support

Several approaches for RV support have been described:

One option for percutaneous RV support is the Abiomed's Impella RP system (Figure **30.6**) . This device utilizes a catheter-mounted microaxial flow pump with the inflow just below the right atrium-inferior vena cava

junction and the outflow into the pulmonary artery after insertion via the femoral vein. It is shaped differently than the left heart Impella devices to accommodate the right ventricular anatomy. Its impeller flow is also reversed from Impella LV devices to pump blood from the right atrium into the pulmonary artery toward the lungs. It includes a 22 French outflow. Due to the design of the system, internal jugular placement and ambulation are not possible.

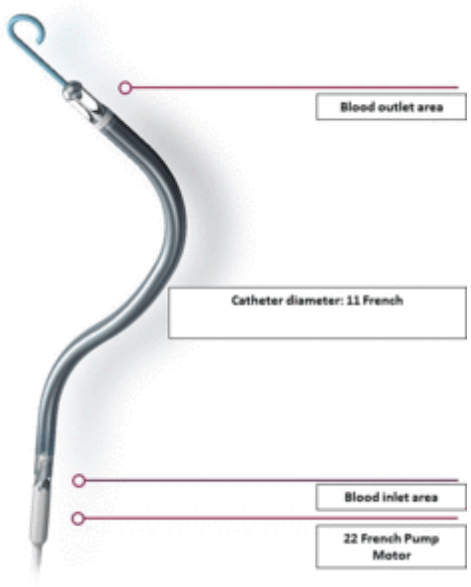

Figure 30.6
Impella ® RP system (Abiomed, Inc.)
Reproduced with permission from Abiomed, Inc.

Another option involves placing two cannulas—typically either two femoral venous cannulas or one femoral and one internal jugular venous cannula—with one cannula positioned in the right atrium and another in the pulmonary artery. This strategy employs an extracorporeal centrifugal pump with the inflow from the right atrial cannula and outflow to the pulmonary artery. Several different centrifugal flow pumps have been used with this cannulation strategy. As an alternative, a novel dual-lumen co-axial cannula flexible enough to be positioned with its distal tip in the pulmonary artery from internal jugular insertion can be used with a centrifugal flow pump to achieve a percutaneous RVAD. Because of its internal jugular cannulation site, this configuration allows for ambulation during the period of support. Removal is typically via a pursestring suture at bedside

Conclusion

The implementation of a portable advanced MCS holds great promise; yet the paucity of evidence supporting the use of these devices at this time is notable. The available devices differ in terms of the

insertion procedure, mechanical properties, and mode of action. Whether this heterogeneity translates into a haemodynamic and clinical meaningful difference in effects remain to be investigated. In all cases, the key requirements for success are appropriate patient selection and care in cardiothoracic centres of excellence.

Personal perspective

The use of percutaneous short-term MCS to support patients with AHFS and/or CS holds great promise and may herald the next major advance in cardiovascular therapeutics. Technology will ultimately solve many of the problems in applying MCS therapy to a wider spectrum of patients with AHFS and CS.

However, the paucity of evidence supporting their use today is notable. MCS devices are employed with increasing frequency in Europe and elsewhere, without yet having undergone rigorous testing and evaluation. It is now time to perform meaningful clinical investigations that are adequately powered to examine clinical endpoints.

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