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Impella ventricular support in clinical practice

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Review

Impella ventricular support in clinical practice: Collaborative viewpoint from a European expert user group

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ABSTRACT

Mechanical circulatory support represents an evolving field of clinical research and practice. Currently, several cardiac assist devices have been developed but, among different institutions and countries, a large variation in indications for use and device selection exists. The Impella platform is an easy to use percutaneous circulatory support device which is increasingly used worldwide.

During 2014, we established a working group of European physicians who have collected considerable experience with the Impella device in recent years. By critically comparing the individual experiences and the operative protocols, this working group attempted to establish the best clinical practice with the technology. The present paper reviews the main theoretical principles of Impella and provides an up-to-date summary of the best practical aspects of device use which may help others gain the maximal advantage with Impella technology in a variety of clinical settings.

1. Background

The use of percutaneous mechanical support has increased over the last decade. Given the recent data on the questionable value of intra-aortic balloon pump (IABP) particularly in acute post-infarction shock [1–4], leading to a downgrade in the ESC guidelines for routine use (class III A), an expectation of the possible clinical value of newer devices which afford greater circulatory support has increased. Among the most common of these are the extracorporeal systems, either left atrium to aorta (TandemHeart) or right atrium to aorta (Extracorporeal Membrane Oxygenation (ECMO)) and the Impella transaortic intraventricular pump. The Impella device was approved in Europe (2005), Canada (2006), Latin and South America (2008) and recently in China (2013) for a variety of indications including high risk percutaneous coronary intervention (PCI) and cardiogenic shock. It is estimated that in

the last eight years, over 8000 patients have been supported outside the United States of America (US). In the US, the device has been used since 2006 in the Protect I FDA trial for high risk PCI and was granted 510(k) clearance in 2008 [5]. Currently, more than 800 US hospitals have supported over 20,000 patients.

Although first introduced in Europe, there is remarkable variation in indications for use and type of devices used among different countries (Fig. 1). The reasons for such disparity may be partially due to different reimbursement conditions across the region but also uncertainty on best applications for the various devices in different clinical scenarios. This working group, whose members jointly represent an experience of over 1000 European Impella implants, aims to give a state-of-the-art overview, enabling better understanding of the basic fundamentals of the Impella technology and application.

2. Impella technical data

Impella technology is based upon a miniaturized axial pump built on a 9 F catheter. The inlet cage allows for blood to be aspirated from the

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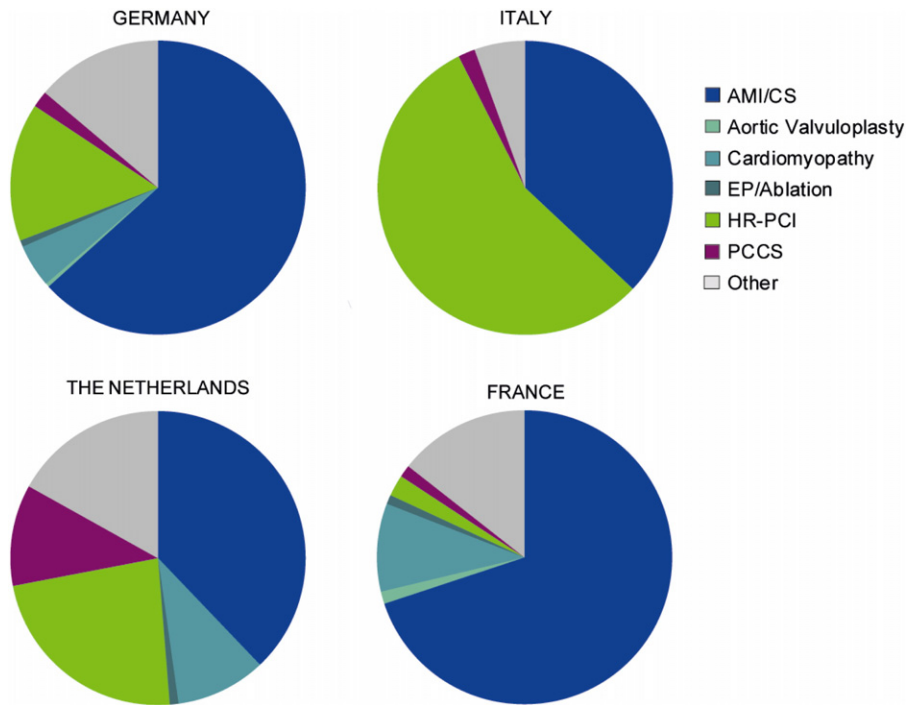 E-mail address: j.p.henriques@amc.uva.nl (J.P.S. Henriques).

Fig. 1. Geographic distribution of Impella per indication comparing Germany, France, The Netherlands and Italy.

left ventricle (LV) into the cannula portion of the pump and then expelled above the aortic valve into the ascending aorta. The power connections for the pump motor and sensors are contained in the 9 F guiding catheter. The end of the catheter is connected to an external console which consists of an integrated controller for the pump and purge system (Fig. 2) The different Impella catheter models vary in size, insertion technique and maximum flow capabilities. These pump characteristics are listed in Table 1.

3. Physiology of Impella support

There are three key physiologic effects of left sided Impella support. First and foremost, the Impella unloads the left ventricle, reducing LV end diastolic pressure and LV wall tension and, consequently, decreasing LV work and myocardial oxygen demand [4]. The characteristic change of the left ventricular pressure volume curve predicted by computational physiology is shown in Fig. 3 and corresponds well to physiologic observations.

Secondly, Impella operation results in an increase in mean arterial pressure, diastolic pressure, cardiac output and thus cardiac power output, leading to improved systemic perfusion and increased coronary flow. Impella support has been found to improve coronary perfusion through the combined mechanism of increased aortic pressure working synergistically with LV unloading and decreased wall tension [4,6].

Third, Impella leads to a decrease in pulmonary capillary pressure and a secondary reduction in right ventricular afterload.

4. Impella support and therapeutic effect

Impella technology is load dependent but not rhythm dependent which leads to a number of physiologic implications. Pump flow is afterload sensitive in that forward flow through the pump decreases with increasing ventriculo-aortic pressure gradient. This sensitivity accounts for the characteristic phasic motor current fluctuations during the cardiac cycle with highest pump flow and motor current achieved during systole when the gradient between LV and aorta is minimal.
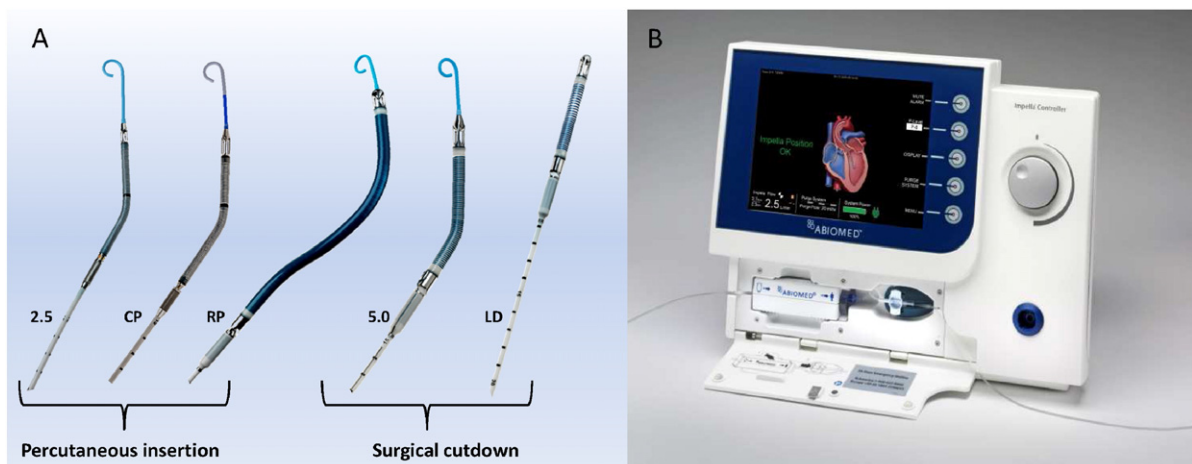

Fig. 2. The Impella (a) Catheter pumps and (b) Automated Impella Controller.

Table 1
Pump characteristics.

	Impella 2.5	Impella CP	Impella 5.0/LD	Impella RP
Access	Percutaneous, femoral	Percutaneous, femoral	Surgical, axillary/fem or ascend aorta	Percutaneous, femoral vein
Output (max)	2.5 L/min	4.0 L/min	5.0 L/min	4.6 L/min
Guiding catheter size	9 F	9 F	9 F	11 F
Motor size	12 F	14 F	21 F	22 F
Introducer size	13 F peel away	14 F peel away	Dacron graft 10 mm recommended	23 F peel away
RPM (max)	51,000	46,000	33,000	33,000
EU approval	5 days CE Mark	5 days CE Mark	10 days CE Mark	14 days CE Mark

This characteristic phasic flow pattern is reported as maximum and minimum flows on the Automated Impella Controller (AIC). The phasic motor current is also used in the positioning monitoring algorithm and allows for precise flow calculation. Furthermore, pump flow is preload dependent because the pump needs sufficient inflow for normal pump output. In patients with acute hemodynamic distress due to left ventricular failure, preload is normally sufficient for normal pump action. Yet, extremely impaired inflow may be observed in situations where LV filling pressure is low, the left ventricular cavity is small or severe right ventricular function impairment is present. Finally, pump performance is independent of cardiac rhythm which is a major distinguishing difference with IABP.

5. Patient selection

Pre-procedural visualization of the LV excluding the presence of thrombus is advisable when circumstances allow time for cardiac echo. The most common result of an Impella ingesting a clot in the LV is that the device will stop. The likelihood of clot ingestion resulting in embolization of clot is extremely unlikely but a mobile thrombus represents a risk for systemic embolization with any LV catheter placement.

Similarly, severe aortic regurgitation (AR) is a relative contraindication. A competent valve separating the LV and aorta enables optimal Impella mediated forward flow. A patient exhibiting decompensating hemodynamics due to AR will be poorly served by Impella support since the increased aortic pressure may increase AR and worsen aortic and LV dilatation.
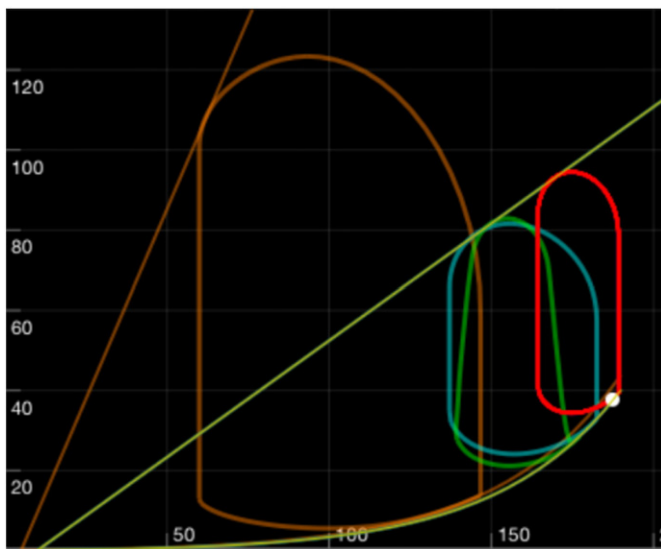
Fig. 3. Pressure–volume loop: Normal conditions (brown), Acute Heart Failure without hemodynamic support (blue), with Impella CP support (green) and with ECMO support (red). The loop area is an estimate of the mechanical work performed by the ventricle. Note the area reduction (work reduction) by the Impella device and the characteristic oblique vertical lines in the latter, indicating continuous emptying of the ventricle even in the "isovolumic" phases.
Data from the Basel Heart Simulator Project, P. Hunziker.

Peripheral vascular disease is not an absolute contraindication but its presence and severity should be assessed before insertion of the device's sheath and Impella catheter implantation attempt. Thus, depending on the clinical situation, selection of alternative accesses or pre-implantation peripheral vascular intervention should be considered before Impella placement in patients with significant peripheral artery disease.

6. High risk intervention

Percutaneous coronary intervention (PCI) can be an alternative revascularization option for patients in critical conditions that are refused coronary artery bypass grafting (CABG) due to unacceptably high risk of complications or death [6]. Nevertheless, these same patients when undergoing PCI are also exposed to peri-procedural complications including hemodynamic collapse and potentially lethal rhythm disturbances. However, timely and effective circulatory support initiated prior to intervention may allow complex PCI without abrupt circulatory deterioration during coronary occlusion facilitating more complete revascularization.

High risk clinical presentation is determined by both the degree of complexity of the coronary artery disease and clinical co-morbidities such as LV dysfunction, advanced age, diabetes, renal dysfunction and prior procedural history. Complex procedures usually require long procedural times, challenging techniques such as rotational atherectomy, and are more prone to acute vessel occlusion, low-flow or distal embolization, and myocardial necrosis. Extensive stenting may be required to achieve a good final result. The use of Impella support in high risk interventions has been studied in a prematurely discontinued randomized controlled trial [7,8] in which at the primary endpoint of 30 day MACE no major difference was observed but at 90 days the Impella group showed a significant reduction in MACE. Also, Impella support may be a cost effective therapy in the US [9] and EU [10] compared with IABP counterpulsation. This consensus group is aware of the current limitation of the available evidence for peri-procedural mechanical support in planned high-risk PCI but knows from clinical experience that there are patients that benefit from support in certain circumstances. Although, there are no evidence based criteria, we recommend assessing the risk benefit ratio according to some of the items included in Fig. 4.

7. Cardiogenic shock

Cardiogenic shock (CS) occurs in ~8–10% of patients admitted to the hospital with ST-elevation myocardial infarction (STEMI). Since the IABP has shown not to be associated with improved outcome in CS, more potent devices, such as Impella have been explored and more recently there is a growing body of (nonrandomized) clinical data that these devices may improve myocardial function in this condition [11–15].

The acute and critical decrease in cardiac output (CO) seen in cardiogenic shock can potentiate myocardial ischemia and cause cell death in the infarct border zone and in the remote zone. Immediate revascularization relieves ischemia but does not immediately improve CO or left ventricular ejection fraction. Inotropic agents and vasoconstrictors

Issues to be considered during patient selection for Impella support in high risk PCI		
Coronary Disease and Treatment Considerations	**Clinical Considerations**	**Hemodynamic Considerations**
MVD or unprotected LM disease Anticipated PCI related ischemic risk Extensive revascularization intended Number of balloon inflations, use of adjunctive devices	Comorbidities and cardiac conditions affecting the tolerance to myocardial ischemia and low output states (e.g. advanced age, diabetes, heart failure, peripheral vascular disease, etc.)	Depressed Left Ventricular Function Unstable Angina

MVD = multivessel disease; LM = left main; PCI = percutaneous coronary

Fig. 4. Patient selection in high-risk PCI.

temporarily improve CO and peripheral perfusion but do not interrupt (and may accelerate) the vicious cycle of decline [16].

Hemodynamic parameters like cardiac power, and stroke work index have been established as powerful short-term prognostic data [17]. Nevertheless, there has been a decline in pulmonary artery (PA) catheter (Swan–Ganz) use likely due to the controversy sparked by a prospective observational study that suggested that PA catheters were associated with poor outcome. The authors feel that Swan–Ganz catheterization should be seriously considered to assess the severity of CS especially when mechanical cardiac assistance devices like Impella are selected. Of note, the timing of Impella support initiation is a critical factor in the treatment of refractory cardiogenic shock. Data from the USpella cohort study reported that in STEMI and NSTEMI CS patients, initiation of Impella support prior to PCI was associated with improved survival rates and a higher degree of complete revascularization [11]. This consensus group is aware of the current limitation of the available evidence for mechanical support in patients with cardiogenic shock but there is a wide clinical experience with these devices in severe cardiogenic shock. This consensus group recommends usage of Impella in cardiogenic shock patients, but not without individual assessment of risk versus benefit, using some of the criteria depicted in Fig. 5.

8. Impella support for other indications

In addition to its application in high risk PCI and cardiogenic shock complicating acute myocardial infarction, Impella has been successfully employed in a wide variety of clinical scenarios requiring percutaneous left ventricular support.

Among these clinical scenarios, fulminate myocarditis is a setting where Impella support has been used successfully [13,18] to maintain cardiac output in the acute phase at a time when ventricular function decreases profoundly. Successful use in post-cardiotomy cardiogenic shock (PCCS) has also been reported. In one study, 30-day survival rates in PCCS patients treated with Impella were comparable to studies evaluating surgically implanted LVADs [19].

Although severe aortic stenosis is considered a relative contraindication for Impella support, a growing number of investigators have reported successful and safe use to support high-risk aortic valvuloplasty and PCI

Issues to be considered during patient selection for Impella support Cardiogenic Shock		
Coronary Disease and Treatment Considerations	**Clinical Considerations**	**Hemodynamic Considerations**
Large LAD or CX related STEMI Adequate peripheral access Preferable initiate Impella support before PCI	≤ 75 years of age Lactate >3 mmol/L Low/moderate bleeding risk (ACT of 160-180 s)	SBP < 90 mmHg or inotropic/pressure dependence Heart rate > 100 bpm Signs of poor peripheral perfusion Signs of end organ dysfunction (e.g. low urine output)

LAD = left anterior descending; CX = circumflex; PCI = percutaneous coronary intervention; ACT = activated clotting time; SBP = systolic blood pressure; bpm = beats per minute

Fig. 5. Patient selection in cardiogenic shock.

Table 2
Checklist upon arrival at the ICU.

- At arrival check that Tuohy-Borst valve on Impella catheter is locked.
- When patient has been installed in ICU perform echocardiography to ensure optimal Impella position.
- Disable Autoflow feature on console and switch to P-level mode with as high support as possible (P8). Disable suction control.
- Transfer the purge system to "standard configuration".
- Ensure that roller clap on pressure bag is open.
- Verify pressure bag pressure is 300–350 mm Hg.
- Secure Impella catheter to the inner aspect of patient's leg.

[20–23]. Further, Impella has been deployed following acute circulatory collapse post transaortic valve replacement (TAVR) to immediately support the failing left ventricle [24].

Another growing indication for Impella support is during ablation of ventricular tachycardia (VT) enabling the procedure to be performed under relatively stable conditions despite the induction of otherwise hemodynamically intolerable VT [25–29].

9. Combined Impella use with other devices and escalation of support

According to the anticipated degree of support needed, the Impella 2.5, Impella CP, or Impella 5.0 may be implanted [19,30,31]. This choice is centered around both the size of the patient which characterizes the native hemodynamic "burden" as well as the degree of hemodynamic compromise. It is important to understand that the pre-insertion native CO is not simply added to intended Impella flow to obtain a total cardiac output. The native output will be unloaded with the device pumping at an optimal target. Thus a patient with a pre-insertion cardiac output of 3 L/min who had an Impella CP placed and pumping 3.5 L/min, would not be expected to have a total cardiac output of 6.5 L/min. Rather the patient's native heart would be unloaded to a degree bringing the native contribution down to, for example, 1.8 L/min resulting in a total "CO" of 5.3 L/min [6]. In patients with profound compromise a large Impella pump (Impella CP or 5.0) might unload the native LV to the point of continuous aortic valve closure resulting in a non-pulsatile arterial curve on the monitor.

Patients in cardiogenic shock may often have both right and left ventricular compromise [32]. In cases with right ventricular heart failure (e.g. biventricular failure), acute lung congestion or multi-organ dysfunction syndrome, several reports have demonstrated combined use of veno-arterial extracorporeal membrane oxygenation (VA-ECMO) and Impella [30,33,34]. In cases of severe left ventricular failure, VA-ECMO increases left ventricular load due to retrograde aortic blood return via the arterial cannula and therefore may not be able to decompress the left ventricle, resulting in LV distension and delayed LV recovery [35]. Combined use with the Impella device unloads the LV while on ECMO support. Further, the Impella device allows earlier and expeditious weaning from ECMO. According to our experience with the combined use of Impella and ECMO support, the performance level of the Impella device should be reduced to a level that provides sufficient unloading of the LV and adequate hemodynamic support.

For patients with severe right heart failure, the recently CE approved percutaneous right ventricular-assist device Impella RP may represent another valuable option. The Impella RP is currently available in EU and first experiences with the percutaneous right ventricular Impella are promising especially in patients with RV failure after surgical LVAD implantation and heart transplantation as well as in post AMI CS including its combined use with left sided percutaneous support [36,37].

There have been several clinical reports suggesting the combined use of Impella with IABP [38,39]. However, this combination decreases Impella forward flow during diastole due to diastolic pressure augmentation from the IABP. In addition, there are multiple device interactions leading to misinterpretation of alarms, potential position issues, and perhaps most importantly, the fact that the IABP induced momentary flow reductions through the Impella prolong red cell transit times thus increasing shear stress possibly leading to hemolysis. Since maintaining adequate forward flow and cardiac output in order to perfuse vital organs is essential in cardiogenic shock and consistent with the manufacturer's recommendations, we do not recommend the systematic simultaneous use of the Impella device with an IABP.

10. Access site management

Meticulous attention should be paid to the selection and management of the access site for Impella support in order to reduce complications seen with larger sheaths [40].

When Impella implantation is planned in an elective situation, the access site selection and the implantation/removal technique should take into account the patient's anatomy and the operator's experience. Percutaneous insertion through the common femoral artery is highly advisable for the Impella 2.5 and CP, whereas axillary artery access is preferred for the Impella 5.0 (via surgical technique). The suitability of the arterial access can be easily screened by angiographic assessment. While closure devices such as Perclose have been successfully used with Impella, longer term implants for several days should not be treated with percutaneous preclosure techniques due to infection risk. Arterial flow disruption can be avoided by removal of the peel away sheath and use of the repositioning sheath on the Impella catheter. Manual compression is almost always sufficient but direct surgical closure may also be considered. Although rare, arterial insufficiency must be promptly investigated and treated appropriately.
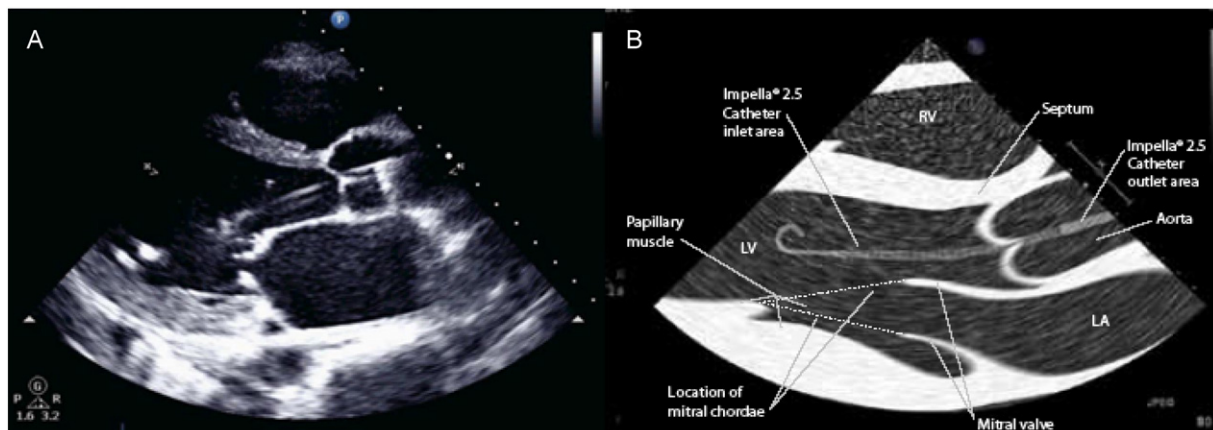
Fig. 6. Echo presentation of Impella in position, (a) clinical image and (b) schematic drawing.

Table 3
Most common console alarms.

Alarm condition	Frequency	Interpretation	Clinical picture	Treatment
Position wrong	Common	Inlet and outlet in the same chamber (both in LV or both in AO)	May occur during the start-up phase and transportation	Re-position under echo or fluoroscopic guidance
Position unknown	Common	Difference between max and min pressure on aortic pressure curve <20 mm Hg.	Frequently due to low native heart pulsatility	Re-position under echo or fluoroscopic guidance
Suction	Common	Above normal motor current necessary for set performance level.	Device too deep or low volume status. Frequently due to high resistance in Impella inflow when in contact with LV wall or papillary muscle	Re-position under echo or fluoroscopic guidance
Low volume/Suction	Common	Reduction of flow due to insufficient volume. Flow lower as expected for set performance level. Either due to suction or due to high afterload.	May cause hemolysis if positioned wrong. Check free hemoglobin (>40 mg/dl)	Optimize volume status. RV failure?
High purge pressures	Rare	Increased pressure (>1100 mm Hg) at purge system due to increase resistance anywhere along the purge lumen necessary to prevent blood entry in the motor compartment.	After long term support. Catheter kink or blood ingress into motor. May precede motor stop if extreme.	Place a new purge cassette when longer support is needed.
Sudden pump stop	Very rare	Most likely clot ingestion.	Possible systemic emboli.	Exclude LV thrombus. Adequate anticoagulation (ACT 180–200 s)

Multiple studies have documented the low risk of significant arterial complications (similar to IABP) with Impella support when good access management techniques were employed [7,41,42].

11. Device management in the CCU/ICU

11.1. Impella placement and position during long-term support

Accurate Impella placement is essential during all phases of Impella support but it is particularly important for long term support. Correct placement across the aortic valve is critical to avoid complications including hemolysis, suction episodes and inadequate hemodynamic support. Attention to the positioning of the device begins in the catheterization laboratory or operating room by preventing migration into the LV. This is best accomplished by removing excess slack from the catheter in the ascending aorta or transverse aortic arch. With the Impella set at P8 (high thrust condition) the excess slack is removed so that the Impella catheter lies along the inner curve of the aorta and that the positioning marker is approximately at the aortic valve. The aim is to place the inlet approximately 3.5 cm distal to the aortic valve. Care should be taken during insertion to avoid wire placement in areas other than the LV apex, avoiding the subannular position or any position that interferes with the anterior mitral leaflet or entrains the catheter into the papillary muscles. Careful attention to positioning alarms and to potential loss of position after patient movement is critical to success. To ensure proper positioning after transition to the ICU/CCU, a close cooperation between trained ICU physicians, ICU nursing staff and cardiologists with understanding of percutaneous circulatory support is needed. It is recommended that upon arrival in the ICU a check list is completed as listed in Table 2.

11.2. Echocardiography

Bedside echocardiography should be available on a 24 hour basis for evaluation of placement with transthoracic (TTE) or transesophageal echocardiography (TEE). Images obtained with TTE in the parasternal long-axis view (Fig. 6) produce the optimal view. In this view, effort should be made to identify the inlet of the device, ideally located in the LV cavity approximately 3.5 cm from the aortic valve. The best TEE study is usually obtained in the mid esophageal view with a 120–130 degree rotation. Manipulation of the catheter should be done during continuous echocardiographic guidance since, due to "slack", movement of the catheter in the aorta does not necessarily translate into the desired movement of the pump. Heavy turbulence with aliasing of colors makes color flow mapping difficult to interpret, yet the "mosaic" of colors associated with the outflow of the device should appear above the aortic valve when Impella is properly positioned. Echocardiography should also address right ventricular function (tricuspid annular excursion) and volume status (size and respiratory variability in inferior vena cava size) and should be performed amidst any suspicion of device displacement.

11.3. Anticoagulation

Two separate and distinct anticoagulation solutions are required during Impella support:

1. Systemic anticoagulation titrated using standard techniques and,
2. Anticoagulant added to the purge fluid to prevent blood entrance into the motor chamber and to maintain patency of the purge solution channel. If the amount of UFH in the purge fluid leads to undesired systemic anticoagulant effects as measured by ACT or PTT, the concentration of UFH in the purge fluid can be reduced.

The device is approved to be used with systemic anticoagulation, with a suggested activated clotting time (ACT) of 160–180 s or locally adjusted activated partial thrombin-time (aPTT) values with a target ACT of 160–180 s. In most clinical situations, the purge heparin flowing at 4 to 8 cm^3/h will not be sufficient to achieve desired systemic anticoagulation. In the case of (suspected) heparin induced thrombocytopenia (HIT), it is possible to replace both the anticoagulant in the

Table 4
Most common clinical complications.

Complications	Frequency[*]	Symptoms	Treatment
Access site bleeding	17.5%	Bleeding including hematoma	Local control/surgical repair
Access site infection		Erythema, fluctuance	Drainage/antibiotics
Limb ischemia	<4%	Pain, pulselessness, paresthesia, pallor, paralysis	Distal extra-anatomic bypass, thrombectomy
Hemolysis[**]	<10%	Hematuria	Check device position
Stroke	<2%	Paralysis	According to local protocol

[*] Frequencies given for during long term support. Complications during elective high-risk procedures very low and comparable to IABP.
[**] Free hemoglobin >40 mg/dL.

Setting up an Impella program in your hospital

⇩

Preferably start with high risk PCI procedures (3-5 cases)

⇩

Involve all disciplines during the initial phase:
Cardiologists: staff, fellows, (non)interventional
Cardiothoracic surgeons
Intensive Care Physicians
Nursing staff (catheterization laboratory, and CCU/ICU)
Perfusionists

⇩

Identify a group of Impella specialists for console alarms
(eg perfusionists, nurses)

⇩

Refrain from device usage in crash and burn cases until after initial (elective) case experience

⇩

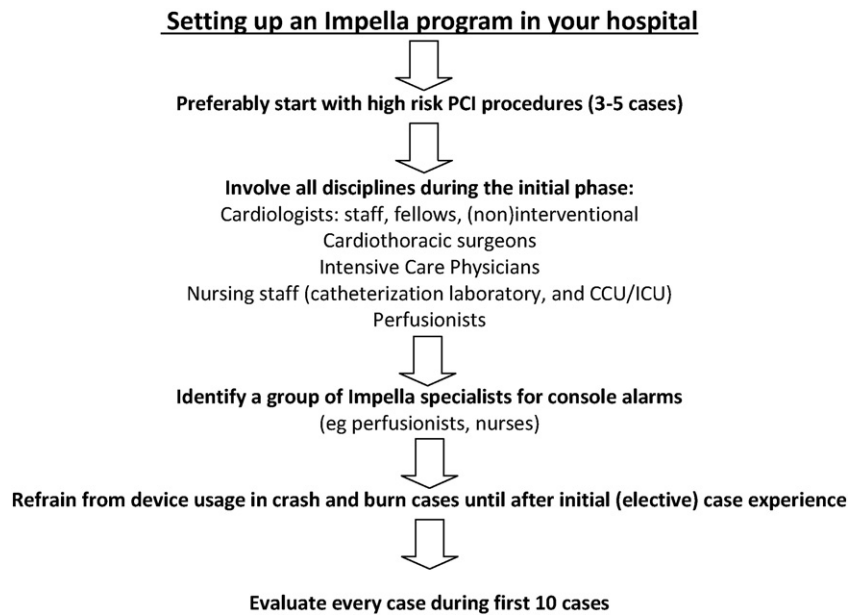**Evaluate every case during first 10 cases**

Fig. 7. Preferred strategy to start an Impella program.

purge fluid and systemic anticoagulation by direct thrombin inhibitors (DTI) such as Argatroban or Bivalirudin.

11.4. Weaning

Patients should be supported until hemodynamics are stable and no more than a small dose of pharmacological inotropic support is required. Initial screening for myocardial recovery can be accomplished using short weaning trials during echocardiographic observation. During final weaning from Impella, the performance level is gradually decreased over 4–6 h until support is at approximately 1–1.5 L/min. Echocardiography is recommended to ensure recovery of LV function and stability of cardiac index. The SVO$_2$, lactate and arterial pH should be monitored during the weaning period. Once the decision to explant has been made, the catheter can be pulled back into the descending aorta and the systemic UFH can be discontinued allowing the ACT to fall into the ≤150 s range. After 30 min, the Impella can be turned off and removed with subsequent manual compression (minimum 30 min) to achieve hemostasis.

11.5. Most common complications and console alarms

Complication rates are low and most complications are related to bleeding mainly during longer usage. These complications require careful patient selection where potential benefit is higher compared to increased risk of complications for specific patients as listed in Figs. 4 and 5. Most common console alarms and clinical complications are depicted in Tables 3 and 4 and usually require individual decision making.

12. Starting your Impella program

Once you have decided to begin an Impella or any advanced circulatory support program, there are several important points to consider. First, make sure that all segments and stakeholders have access to training from the beginning. This should include catheterization lab personnel and administration, nurses and physicians from the ICU and CCU, surgeons and operating room personnel, intensivists, and perfusion services. Local protocol development is important and enables uniform care regardless of which physician is on call.

Finally, we recommend that the first cases undertaken in any program should be elective high risk interventional cases (PCI) rather than cardiogenic shock cases. Although there is a temptation to use the system for patients in extremis, this increases the chances or errors during insertion and repetitive use in such patients with associated poor outcomes can be demoralizing for the staff and may result in a high perceived mortality rate for patients treated with any technology in this situation. Elective high risk cases can be predicted with some accuracy and will allow your mentors and clinical representatives to be present. This allows reinforcement of training in a non-threatening environment which is important with technology that is not used on a daily basis. A PROTECT 2 trial subanalysis showed that a learning curve however small does exist [43]. Supporting the elective high risk procedures allows the staff to build confidence in providing circulatory support in the catheterization laboratory so that when the STEMI shock patient arrives in the off hours, they are able to seamlessly provide the required Impella and other supportive measures (Fig. 7).

13. Conclusion and summary

This report attempts to relate best practices with the Impella circulatory support system from a group of European experienced users of the Impella device with some of the recommendations being applicable to percutaneous mechanical support in general. Through collaboration and professional review, we believe that the information compiled herein can offer the new center and physician useful and important best practices for use of the Impella system. An understanding of the device variations, clinical application, and physiologic impact of device usage as well as an understanding of the alarms and potential risks are all important when considering a patient for percutaneous circulatory support.

In the current absence of evidence based from randomized clinical trials, this consensus group acknowledges that there are patients that could benefit from mechanical support and has aimed to guide clinical usage with a set of recommendations based on a vast experience with the Impella technology.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

Acknowledgments

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