Handling high-risk patients in the catheterization laboratory

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KEYWORDS
Protected PCI; Vascular access; Cardiac output; Cardiac index; Pulsatility; Impella CP Smart Assist

Protected percutaneous coronary intervention is considered a life-saving procedure for high-risk patients. Therefore it is important that the interventional cardiology team is prepared, the procedure is planned, and potential complications, as well as bail out strategies are considered. Throughout the procedure, it is critical to monitor the patient to identify any early signs of deterioration or changes in patient well-being to avoid any potential complications.

Preparing the catheterization laboratory and team for protected percutaneous coronary intervention

Protected percutaneous coronary intervention (PCI) is a life-saving procedure for high-risk patients with acute and chronic coronary syndromes. It is used when percutaneous revascularization is essential, and the option to implement standard procedure is not indicated due to a patients higher risk for adverse cardiovascular and cerebrovascular events, including all-cause death and myocardial infarction. Impaired left ventricular ejection fraction (LVEF <40%) is the most relevant clinical indication to identify patients who will benefit from protected PCI. Patients with anatomical conditions such as the presence of coronary multivessel disease, intervention on the left main coronary artery, extensive revascularization, as well as previous coronary artery bypass surgery are also selected for protected PCI. When the risk of vascular injury or severe bleeding—especially in conjunction with decreased haemoglobin level <8 g/dL—is high, the cardiac interventionist should be careful when starting mechanical circulatory support.

A standardized protocol should be established in each hospital that is performing protected PCI. As such, an essential part to effective treatment for high-risk patients is the proper set up of the catheterization laboratory and preparedness of the cardiac team. Specifically, both the physician and nursing teams must be experienced in performing coronary interventions and using the respective necessary tools and devices (including atherectomy, imaging, etc.). This includes the team’s awareness of any potential adverse effects of using the Impella. These complications include arrhythmias, bleeding, cardiac tamponade, haemolysis, perforation, valve injury, renal failure, or changing of the device position. Thus, prior to any procedure each patient case should be discussed and coronary artery disease treatment strategy outlined.
Handling high-risk patients

Among team members. Once a treatment plan has been derived and approved, any necessary baseline blood laboratory tests should be performed before procedure initiation. During the procedure, vital signs and echocardiogram (ECG) must be continuously monitored so if any adverse side effects do arise, the team is able to react immediately. Additionally, anticoagulation is crucial to achieve activated clotting time (ACT) $>$250 s and must be monitored and recorded at fixed intervals. Furthermore, the patient should be protected with emergency rescue equipment, the option to perform echocardiography, and packed red blood cells should be available for transfusion in the event any excessive or uncontrolled bleeding occurs during the intervention.\(^7\)

Early in the procedure, when performing the right heart catheterization (RHC), a central venous line should be inserted. To prevent unnecessary bleeding at the vascular access site, it is recommended to micropuncture at a 30–45° angle and use ultrasound and fluoroscopy to optimize access. Similarly, choosing the best technique during vascular closure helps avoid adverse effects at the end of the procedure. In unstable patients, haemodynamic monitoring might be necessary. The most readily available method is transpulmonary thermodilution which provides information about adequate tissue oxygenation, cardiac index, preload, volumetric response, pulmonary oedema, and necessary vasopressor therapy.\(^8\) In more severe cases, especially those with refractory cardiogenic shock or right ventricular involvement, the Swan-Ganz catheter can be used.\(^9\)

Given the serious condition of patients requiring protected PCI, the team must be prepared for respiratory decompensation and to provide emergent adequate respiratory support. In patients with acute myocardial infarction, use of non-invasive ventilation to prevent hypoxaemia during PCI procedures has been shown to improve oxygen pressure in the arterial blood within 1 h after the procedure completion.\(^10\) While acute decrease of systemic perfusion and ventilation is the main indication for invasive mechanical ventilation during the procedure, this support may also be used to address pulmonary oedema or cardiogenic shock.\(^11\) Moreover, intubation is more often preferred rather than laryngeal mask airway usage in this group of patients.\(^12\) In cases of haemodynamic instability, patients may be sedated with midazolam and/or fentanyl while percutaneous interventions are performed. Irrespective of procedural approach, the cardiac surgery team must be ready to respond to any and all mechanical complications that may arise during the surgical intervention.

In addition to a central venous catheter, a 7F sheath via the femoral vein should be inserted to provide secure venous access throughout the procedure. Insertion of a 7F sheath also provides the possibility, if needed, of placing a temporary pacemaker without delay. In some patients, the use of a urinary catheter might also be reasonable, particularly if a procedure is expected to have a long duration. Furthermore, urine output can be measured as an early sign for the beginning stages of cardiogenic shock, providing additional useful information of overall well-being of the patient during the intervention.

Monitoring patient condition during the procedure

The primary objective of protected PCI is to maintain stable haemodynamic conditions throughout the entire procedure and avoid insufficient organ perfusion and/or the development of cardiogenic shock. However, further monitoring of additional parameters has proven useful.

The novel Impella CP SmartAssist offers many additional options such as measurement of cardiac output (CO) and registration of left ventricular end-diastolic pressure (LVEDP) to observe patient trends. Use of this ‘new’ version of Impella is increasing worldwide, particularly in patients that require higher flow rates than the Impella 2.5 is able to provide.

Use of transthoracic echocardiography monitoring during procedure

Every patient undergoing protected PCI should undergo a detailed transthoracic echocardiography (TTE) that includes evaluation of left ventricular (LV) function, LV wall thickness, valve function, calcifications, absence of LV thrombus, as well as function of the right side of the heart. This is especially important information in patients with severe aortic stenosis, given that regurgitation may impede the insertion of an Impella device. Reduced LV function is prerequisite for the use of the Impella in protected PCI and as a result, right heart function is often neglected or overlooked. However, some of the challenges during protected PCI could be based on sequential right heart failure. Therefore, a standardized echocardiography is recommended by the European Association of Cardiovascular Imaging and should be available in the catheterization laboratory throughout the entire procedure\(^13\) (see Box 1).

### Box 1. Pre-procedural echocardiography (excerpt)

- Left ventricular diameters and volumes
- Left ventricular wall thickness
- Left ventricular ejection fraction (LVEF)
- Diastolic function
- Left atrium size and volume
- Ascending aorta (Annulus, Sinus of Valsalva, sinotubular junction, proximal ascending aorta)
- Right ventricle diameter
- Right ventricular outflow tract diameter
- Tricuspid annular plane systolic excursion
- Fractional area change
- Right atrium diameters

Changes in LV and right ventricular function, as well as complications during the intervention can be identified using TTE. As such, a TTE should be performed when there are no obvious reasons for deterioration of the patient. This allows for the immediate detection of...
potential complications such as cardiac tamponade, right heart failure, mitral valve regurgitation, and papillary muscle dysfunction.

Right heart catheterization

While RHC is commonly used in cardiogenic shock, its use in protected PCI is rare. Nevertheless RHC in patients with severely depressed LV function, high pulmonary artery pressures, or pre-existing right heart failure may be beneficial. Before beginning a PCI, a brief assessment of the following important parameters should be performed: (i) pulmonary arterial pressures (systolic/diastolic), (ii) pulmonary artery saturation, (iii) right atrial pressure (RAP), and (iv) pulmonary capillary wedge pressure (and/or LVEDP). Assessment of each of these parameters is associated with lower in-hospital mortality in cardiogenic shock. Right heart function can be determined when combined with arterial haemodynamics, the CO/CI (continuous or according to Fick’s method), pulmonary and systemic vascular resistance index, and pulmonary arterial pressure index. With the Impella CP SmartAssist, it is possible to enter the CO in the automated Impella controller and achieve continuous information throughout the procedure (see Box 2).

Box 2. Haemodynamic parameters

| Parameter                  | Formula                                                                 |
|----------------------------|-------------------------------------------------------------------------|
| CO (native)                | $\text{CO} = \text{CO}_{\text{Impella}}$                                  |
| CO (measured using RHC)    | $\text{CO} = \frac{\text{PAP} - \text{PADP}}{\text{RAP}} \times \frac{\text{MAP}}{451}$ |
| VS₀                        | $\text{CO} = \text{CO} \times \text{MAP}/451$                          |
| PAPi                       | $\text{PAPi} = \frac{(\text{PASP} - \text{PADP})}{\text{RAP}}$         |

Arterial pressure monitoring during the procedure

Arterial pressure monitoring should be maintained throughout the entire procedure. The initial arterial pressure curve provides information about the average blood pressure of the patient in stable rest conditions. Typically, the blood pressure in patients with chronic heart failure on optimal medical therapy and severely depressed LV function is low [mean arterial pressure (MAP) about 65 mmHg]. The systolic upstroke and decline may change during the procedure, indicating an early sign of patient deterioration. According to a German registry of left main stem, additional severe calcifications with the need of atherectomy or complete occlusion requiring revascularization were present in most cases of protected PCI. During the intervention, the most frequent haemodynamic complication was hypotension, even with the use of the Impella device. Long-lasting episodes of hypotension may lead to cardiogenic shock, emphasizing the importance of precise haemodynamic monitoring.

Echocardiogram monitoring during the procedure

ECG monitoring is mandatory during every protected PCI to detect arrhythmia, bradycardia, tachycardia, and ventricular fibrillation. If shockable tachycardia is detected, an electric cardioversion should be performed immediately. Although LV devices such as Impella maintain the CO even during ventricular fibrillation for long periods of time, consecutive right heart failure has to be taken into consideration. It is important to note that sometimes the patient is stable, enough to ‘watch and wait’ and administer anti-arrhythmic drugs. More often than not, however, electrical shock is warranted, which requires patient sedation.

Blood chemistry analysis prior to and during the procedure

Each patient should have arterial blood gas analysis performed at the initiation of the procedure and at fixed intervals throughout the procedure to detect any potential changes that could lead to deterioration of the patient condition (e.g., increase of lactate levels). Furthermore, an ACT should be determined after administration of intravenous unfractionated heparin or bivalirudin according to the clinical standard of care. Other anticoagulation regimens are adapted from the prescribing information and are discussed in more detail in the third manuscript of this supplement.

Left heart failure

During left main stem or proximal left anterior descending artery balloon inflation, it is not uncommon for blood pressure to drop. Typically, the arterial pulsatility will decrease with minimal drop of MAP. After deflating the balloon, restoration of pulsatility is an important sign of left ventricle recovery. These drops in blood pressure are predictable and occur frequently. With a LV Impella device in place, restoration of pulsatility occurs much faster than without assist device.

More difficult to detect are subtle deteriorations of the CO that are not accompanied by a significant drop in arterial blood pressure. This occurs in ischaemic cardiac conditions with compensation of arterial blood pressure due to release of endogenous catecholamines. In these cases, continuous monitoring of CO helps to detect this condition. This can be done indirectly by monitoring changes in arterial blood gas levels (e.g., lactate or increase in negative base excess) or pulmonary artery saturation levels, which are reflective of CO.

With the Impella CP SmartAssist, continuous monitoring of CO (native plus Impella) is possible which allows
for changes in native CO to be detected early. A number of reversible 'mechanical' problems might be solved easily, such as wedge-position of the guiding catheter or low-reflow during interventions. If there is no possibility to restore native CO, further considerations must be made such as escalation of LV support (Impella 5.5 or ECMO) or surgical support in cases of mechanical complications. The time from onset of haemodynamic degradation to restoration is essential and affects the outcome. Therefore, a drop in the native CO should always be cause for concern. In general, the use of inotropes should be avoided, as the mechanical assist device provides cardiac blood flow and decreases oxygen consumption of the left ventricle. Nonetheless, the use of vasopressors might be required to preserve adequate MAP due to a drop in systemic vascular resistance during the procedure.

Another advantage of the Impella CP SmartAssist is the calculation of the Cardiac Power Output (CPO), a strong predictor for mortality in cardiogenic shock patients. In brief, CPO is calculated as CO multiplied by MAP divided by 451 (see Box 2). A CPO above 0.6 should be maintained throughout the procedure. If the CPO drops below 0.6, the volume status has to be checked and right heart failure has to be excluded. Whether assessment of CPO may also improve the outcome in protected PCI is still unknown and warrants further investigation.

Right heart failure

The identification of right heart failure may be more difficult, as it occurs less frequently in protected PCI. However, in interventions of the proximal right coronary artery or in patients with pre-existing reduced right ventricular function (due to pulmonary hypertension) right heart failure may develop. In the beginning, the reduced CO of the right ventricle will result in a volume deficit of the left ventricle. In consequence, the MAP will drop and the Impella flow may be impaired. With the Impella CP SmartAssist, both the native and the Impella CO will drop and trigger a suction alarm. In this case, a volume deficiency of the left ventricle must be ruled out either by echocardiography or RHC.

With a continuous measurement of pulmonary and RAPs, the pulmonary artery pulsatility index (PAPI) might help to detect right heart failure early. In brief, the PAPI is calculated as the difference between pulmonary artery systolic pressure (PASP) and diastolic pulmonary artery pressure (PADP) divided by the RAP: PAPI = (PASP−PADP)/RAP (see Box 2). A PAPI below 0.9 is regarded as right heart failure. Right heart support must be considered if no concrete reversible reason for right heart failure can be detected. In all instances, the use of TTE is advisable. An overview of differences in left and right ventricular failure is shown in Figure 1.

Weaning strategies in the catheterization laboratory

In protected PCI cases, the removal of the Impella should occur inside the catheterization laboratory at the end of the procedure. Data from a German registry demonstrated that Impella devices could be explanted in 87% of the cases in the catheterization laboratory. Therefore, after completion of the coronary intervention, the Impella performance level should be reduced by four levels, careful not to fall below Level 2. Changes in haemodynamics must be recorded and the performance adapted when necessary. After 5−10 min without deterioration of patient performance, Level 1 or 2 may be selected and withdrawal of the Impella initiated from the left ventricle into the aorta. Afterwards, Level 0 is selected and the Impella is removed completely. Since the 14F sheath remains in the femoral artery throughout the entire procedure, the withdrawal of the device should not be problematic.

In cases of haemodynamic instability, the Impella should be maintained and the patient transferred to a cardiac critical care unit. The weaning procedure should be initiated as soon as the haemodynamic conditions of the patients are stable. In these cases, the performance level of Impella should be reduced by two levels every 10−15 min while closely monitoring the cardiac function. Once performance Level 2 has been reached, the Impella can be removed as described above.

Some centres routinely remove the pump in a cardiac critical care unit to allow prolonged ventricular unloading and therefore reduce cardiac damage. Currently, no data exists to confirm a clear benefit of longer support in protected PCI. However, a possible disadvantage of this approach is the risk of infection when using vascular closure devices (VCDs) as well as dislocation of the pump during transport.

Access site closure

Safe removal of the percutaneous left ventricular assist device (pLVAD) and access site closure is of utmost importance since bleeding and vascular complications are associated with worse outcomes in patients with cardiogenic shock and in patients undergoing pLVAD-supported high-risk PCI. Successful access site closure is defined by both haemostasis and patency of the vessel and adequate distal limb perfusion. Manual compression, use of compression devices, interventional and surgical techniques, as well as dedicated percutaneous VCDs can be utilized for safe access site closure. The approach should be selected according to patient characteristics and experience of the cardiology team.

![Figure 1](image-url)
Non-invasive access site closure strategies

Manual compression is a non-invasive strategy for access site closure and can be utilized as a first-line option; however, it is time-consuming, labour-intensive, strenuous, and bleeding control can be challenging, especially in patients with obesity. The quality of manual compression is dependent on the experience of the cardiac team, and while this might not be the preferred closure method, training of manual compression skills is highly recommended for all interventional cardiologists since it is an important bail out method in the event of any VCD failure.  

The use of compression devices, such as FemoStop™ (Abbott Vascular), should be considered in patients with peripheral artery disease and severe calcifications at the access site since these factors are associated with an increased risk of percutaneous closure device failure, subsequent bleeding, and vascular complications. The transparent pneumatic dome of the FemoStop™ allows adapted compression and visual control of the puncture site. However, the correct position of the device needs to be adequately monitored, particularly in patients with obesity. Implementing an institutional monitoring protocol is recommended to ensure proper positioning, adequate compression pressures, distal limb perfusion, as well as to minimize bleeding and pain of patients during the procedure.

Invasive access site closure strategies using vascular closure device

VCDs can be divided into suture-, collagen-, patch-, and membrane-based systems. While planning the application of VCDs, the approach of use is important. A pre-closure strategy, such as placing sutures prior to sheath introduction, is advisable during pLVAD-assisted high-risk PCI. However, this approach might be difficult in patients supported with pLVAD for cardiogenic shock. These patients require delayed haemostasis and the deployment of suture-based vascular pre-closure devices, which is not ideal since sterility of the closure system cannot be ensured and the duration of support is difficult to predict, although the technical feasibility has been documented. The latest generation of sheaths for femoral Impella CP provides a side arm, allowing the introduction of a 0.035-inch wire that facilitates the application of VCDs as a post-closure strategy.

The most effective VCD approach for large-bore vascular closure is with suture- and collagen-based devices, which are mostly needed for transcatheter aortic valve implantation (TAVI) and endovascular aneurysm repair procedures. Percutaneous suture-based VCD include the Prostar® XL and ProGlide® device (Abbott Vascular). While the Prostar® XL does not play a significant role for access closure related to pLVAD, the ProGlide® device is primarily used as a pre-closure technique with option to be utilized as a post-closure VCD as well. The ProGlide® strategy typically requires two devices for large-bore vascular closure with the devices deployed at the 10- and 2 o’clock position prior to sheath introduction. Use of one single ProGlide® deployed strictly at 12 o’clock is also possible when used in combination with an ultrasound-guided puncture of the anterior vessel wall. After the procedure, the introducer sheath is removed and the preformed knots are tied by the help of a knot pusher. The closing procedure can be performed with a safety wire in place to enable the use of additional VCDs if haemostasis is not achieved. Suture-based VCDs have also been successfully applied for closure of axillary and subclavian access sites. According to data collected from an Italian multicentre registry, ProGlide® is associated with a reduced rate of the composite end-point cardiovascular mortality, bleeding, and vascular complications at 30 days in patients undergoing TAVI (13.8% vs. 20.5%, respectively; multivariate adjusted odds ratio, 0.80 (95% CI: 0.65–0.99); P = 0.043) compared with Prostar® XL. In the setting of pLVAD-associated access site closure, the ProGlide® VCD has been successfully used in both pre- and post-closure strategies. The MANTA™ VCD (Teleflex) is a collagen-based closure device consisting of a poly-lactic-co-glycolic toggle that is connected to a bovine collagen plug. A stainless-steel lock secures the sliding suture knot pushing the collagen and toggle together so that it is sandwiched to the arterial wall. Accurate tension is indicated by the appearance of a green marker on the device handle. This is also a helpful landmark for future interventions, although the toggle and collagen plug is completely absorbed within 6 months. The MANTA™ VCD comes in two sizes: 14 Fr version for 10-14 Fr devices/sheaths (maximum outer diameter 18 Fr) and 18 Fr version for 14-22 Fr devices/sheaths (maximum outer diameter 25 Fr). The MANTA™ VCD has also been used for closure of percutaneous axillary access sites after TAVI. Use of the MANTA™ VCD has also been evaluated in pivotal clinical trials of percutaneous cardiac or peripheral procedures with the use of large-bore (10-18F) interventional devices. Based on this data, the MANTA™ VCD is a viable option for access site closure of patients requiring Impella™ support. For example, it can be used in the setting of pLVAD-supported HR-PCI with adequate depth measurement of the punctured vessel prior to sheath introduction. Or in the post-closure setting, in which a second operator provides gentle manual compression during depth measurement and maintenance during the initial steps of MANTA™ VCD application. Other novel dedicated large-bore closure devices include the PerQseal® (Vivasure Medical) and the InSeal (InSeal Medical) VCD but only limited data are available.

Additional access site closure strategies

Although no longer prioritized, surgical methods to obtain access may be necessary in individual cases, especially in the case of severe calcification or complete occlusions, which can be treated in one session. In addition, interventional methods can be used to achieve haemostasis. For example, a peripheral balloon can be inflated proximal to the puncture site via the...
contralateral side until safe haemostasis is achieved. This dry closure technique can be used as a bail out strategy, especially in the event of closure system failure and is further described in Sinning et al. 13

Acknowledgements
This manuscript is one of eight manuscripts published as a Supplement to address best practices for Impella protected PCI. JetPub Scientific Communications, LLC, supported by funding from Abiomed Europe GmbH, provided editorial assistance to the authors during preparation of this manuscript.

Funding
This work has been supported by the Abiomed Europe GmbH to cover publication costs as well as professional language editing of each manuscript. No individual fees were paid to the authors in the generation of this publication. This paper was published as part of a supplement financially supported by Abiomed GmbH.

Conflict of interest: J.L. has received research funding that was paid to the institution from Shockwave Medical Inc, and payment or honoraria from AstraZeneca and Boston Scientific. N.M. has received consulting fees from Abiomed, B. Braun, Biotronik, Boston Scientific, Pfizer, and Sanofi Genzyme, payment or honoraria from Abbott, Abiomed, AstraZeneca, Bayer, B. Braun, Biotronik, Boston Scientific, Edwards Lifescience, Medtronic, Novartis, Pfizer, and Sanofi Genzyme, and was National PI for the PROTECT IV Trial from Abiomed. N.W. has received support for the present manuscript from Abiomed, grants or contracts from Shockwave and Abiomed, payment or honoraria from Abiomed, Boston Scientific, and Shockwave, support for attending meetings and/or travel from Medtronic, Edwards, and Abiomed, and participated on a data safety monitoring board or advisory board from Cingular. K.I. reports consulting fees, speaking fees, and travel support from Abiomed. A.T. has received payment honoraria for lectures from Bayer, Servier, AstraZeneca, Bi, Krka, and Novartis, and ESC congress fee and accommodation. Other authors declared no conflict of interest.

Data availability
The data underlying this article will be shared on reasonable request to the corresponding author.

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