Optimal bail-out and complication management strategies in protected high-risk percutaneous coronary intervention with the Impella

Jan-Malte Sinning1*, Karim Ibrahim2, Jörg Schröder3, Davorin Sef4, and Francesco Burzotta5

1Department of Cardiology, St Vinzenz Hospital Cologne, Cologne, Germany; 2Department of Cardiology, Technische Universität Dresden (Campus Chemnitz), Klinikum Chemnitz, Chemnitz, Germany; 3Department of Cardiology, University Hospital RWTH Aachen, Aachen, Germany; 4Department of Cardiac Surgery and Transplant Unit, Royal Brompton & Harefield NHS Foundation Trust Harefield Hospital, Harefield, UK; and 5UOC Interventistica Cardiologica e Diagnostica Invasiva, Fondazione Policlinico Gemelli IRCCS and Università Cattolica del Sacro Cuore, Rome, Italy

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Despite the routine use of percutaneous mechanical circulatory support (pMCS) with the Impella heart pump, vascular and bleeding complications may occur during removal with or without pre-closure. To safely close the large-bore access (LBA), post-hoc selection of the appropriate treatment of vascular complications is critical to patient recovery and survival. Femoral artery access is typically utilized for LBA, and percutaneous axillary artery access is a common alternative, especially in the instance of severe peripheral artery disease. Optimization of patient outcomes and efficiency of pMCS can be achieved with adequate arterial access using state-of-the-art techniques. Impella removal techniques with or without pre-closure will be addressed as well as the management of large-bore femoral access complications. In addition, treatment strategies to manage patient deterioration during a protected high-risk percutaneous coronary intervention will be provided.

Introduction

Percutaneous mechanical circulatory support (pMCS) with the Impella heart pump is routinely used in cardiogenic shock and high-risk percutaneous coronary interventions (PCIs). Closing the large-bore access (LBA) post-hoc remains a challenge due to safety and feasibility of methods. Vascular and bleeding complications are the most frequent procedure-related complications that influence the recovery and survival of the patient.1,2

Femoral artery access remains necessary for numerous LBA procedures and is most used for pMCS.3,4 Percutaneous axillary artery access is typically considered as an alternative for the delivery of MCS, especially in patients with severe peripheral artery disease.

This article addresses the techniques for Impella removal with or without pre-closure and addresses further complication management of large-bore femoral access. In addition, we will discuss potential methods to consider in order to address a patient whose status deteriorates during a protected high-risk PCI.

Techniques for Impella removal in the catheterization laboratory, with or without pre-closure

Anatomical assessment of the iliofemoral axis using computed tomography (CT) angiography or digital subtraction...
Angiography is routinely conducted preoperatively to ensure proper selection of the arteriotomy site. Successful and safe large-bore femoral access is ensured by a single anterior puncture of the common femoral artery (CFA), avoiding areas of calcification as well as areas above the level of the inferior epigastric artery and near the superficial or profunda femoral artery. Fluoroscopy-guided femoral access requires the identification of anatomic landmarks and palpation of the femoral pulse. Ultrasonography is the current gold standard and should be used to puncture the Impella access site. Ultrasound-guided access enables central cannulation of the artery at an area without calcification and therefore provides good preparation for the application of vascular closure devices (VCDs) at the end of the procedure. Crossover angiography can be performed to assess the vascular access site and to provide guidance for the puncture of the CFA.

Table 1 provides a summary of current methods of Impella removal in the catheterization laboratory with and without pre-closure, which are described in detail below. Pre-closure of the access site can be performed with either one Prostar or two ProGlide devices (Abbott Vascular, Santa Clara, CA, USA) deployed in a 90- to 120° angle (positioned at 10 and 2 o’clock). Another option is to use a MANTA device, measuring the depth of the puncture site before insertion of the Impella device via the stiff wire. In most protected PCI cases, the Impella insertion sheath (14 French, Figure 1A) will remain in the circumflex artery for the ease of the procedure, although antegrade blood flow is compromised more than with the Impella repositioning sheath (9 French, Figure 1B), when the insertion sheath is removed.

In order to prevent vascular complications and maintain vessel patency, it is paramount to carefully remove the MCDs and large-bore arterial sheaths. After completion of the PCI and successful weaning in the catheterization laboratory, the insertion sheath allows removal of the Impella heart pump at the end of the procedure, while a regular 0.035-inch wire can be advanced to enable the additional deployment of an AngioSeal or ProGlide if the pre-closure with one ProStar or two ProGlide fails. This is especially important if the single-access technique (access for the guiding catheter up to 7 French via the Impella insertion sheath) has been used and a control angiography is not possible.

After closing the arteriotomy site with the two ProGlide™ devices, the access site can be evaluated using selective contralateral crossover angiography for the detection of vascular and/or bleeding complications and if necessary, an additional AngioSeal or ProGlide is used. Afterwards, bleeding prevention starts with haemostasis through additional manual compression for 5- to 10-min and subsequent application of a compression bandage for 12 h. In cases of relevant extravasation or persistent bleeding after manual compression on final crossover angiography, percutaneous transluminal angioplasty as a dry closure technique can be performed. If bleeding still persists or remains severe despite the implemented pre-closure techniques, a covered self-expanding nitinol stent graft can be implanted via contralateral femoral access and should be preferred over surgical repair depending on the status of the patient.

An alternative method is the use of a compression device such as the Femostop™ (Abbott Vascular). The transparent pneumatic dome is placed slightly proximal to the arteriotomy site before removal of the large-bore sheath. The compression device is held in place with a belt wrapped and tightened around the supine patient. For equipment removal, the pneumatic dome is inflated to approximately 60-80 mmHg. The sheath is then removed while keeping the rigid frame of the compression device in place to avoid any shifting away from the pneumatic dome. The pneumatic dome is inflated to approximately 20 mmHg higher than the systolic blood pressure of the patient for 20 min for initial haemostasis. Afterwards, the pneumatic dome is deflated to the mean arterial blood pressure of the patient and remains in situ for another 20 min, before being deflated to 30-40 mmHg for another 20 min. During the compression period, the patient must be monitored for bleeding, distal limb perfusion, and excessive pain at the compression site.

For patients supported with MCS during protected PCI (and cardiogenic shock) with the need to remain on support even after the PCI procedure, deployment of suture-based vascular (pre)-closure devices may not be ideal, since sterility of the closure system is difficult to ensure over days and the duration of support and time for recovery can be difficult to predict. In these patients, dedicated large-bore closure devices are gaining popularity and may offer solutions when delayed haemostasis is required. The available devices are the collagen-based MANTA, patch-based PerQseal and membrane-based InSeal devices. The current generation of repositioning sheaths of the Impella heart pump provide a side arm, which allows the insertion of a 0.035 inch wire. This can guide VCDs such as the MANTA system after Impella removal. In this situation, depth measurement is not possible and sonography might be helpful; thus, the implantation depth will rely on the operator’s discretion and experience. In most cases, an implantation depth of 5.5 cm is sufficient. In this scenario, a single 8 French AngioSeal VCD can be a safe and feasible (but off-label) option in the catheterization lab or even in the intensive care unit (ICU). After a clinically successful access site closure with a VCD, an angiography or ultrasound control is highly recommended to rule out any residual bleeding and to confirm vessel patency and distal limb perfusion. In select cases, protamine can be administered for heparin reversal. This situation is mostly restricted to delayed haemostasis in cardiogenic shock patients since protamine administration directly after a complex high-risk PCI might be deleterious. A gentle compression bandage for 6-12 h is recommended with the patients in a supine position. An institutional protocol to regularly document the control for bleeding, distal limb perfusion, and the final outcome is recommended. Regular clinical evaluation of the access site should be part of the post-procedural evaluation. If bleeding occurs around the Impella catheter, especially after removal of the peel-away sheath, partial ProGlide tightening can be effective. In case of prolonged support (>24 h) or doubts about VCD sterility, removal of the pre-implanted VCD and replacement with another one should be considered to avoid VCD infection.
Management of limb ischaemia during Impella support

The development of ipsilateral lower limb ischaemia during Impella support occurs in up to 12% of cases\textsuperscript{10,11} and can lead to serious complications, necessitating immediate action. A recent comparative study of pMCS in patients with acute myocardial infarction complicated by cardiogenic shock demonstrated a higher incidence of limb ischaemia with the Impella device (8 vs. 0%, $P = 0.06$) when compared with intra-aortic balloon pump.\textsuperscript{12} Ischaemia during Impella support may occur due to dissections in the iliac-femoral artery (potentially created during Impella crossing; \textit{Figure 2A}), iliofemoral thrombosis around the Impella catheter and sheaths (\textit{Figure 2B}), and distal embolization of the femoral arteries or their branches (from non-occlusive thrombus that may develop around the Impella sheath or catheter; \textit{Figure 2C}). All of these complications are facilitated by the presence of iliofemoral atherosclerosis, which could simultaneously occur and have an increased risk with the duration of support and the use of inotropes such as dobutamine or norepinephrine.\textsuperscript{13} On the other hand, the removal of Impella at the end of the PCI is associated with a reduced risk of limb ischaemia.\textsuperscript{11} In an individual patient, the mechanism causing lower limb ischaemia can be assessed by ultrasound if an experienced operator is available. Yet, if a definitive interpretation is required in order to plan the best management, peripheral angiography by another access point, usually the radial approach or contralateral femoral, is required in the majority of cases.

Once ipsilateral ischaemia is recognized, the Impella device should be promptly removed from the femoral artery and ischaemia should be treated before signs of limb necrosis develop.\textsuperscript{14} In the event that the Impella must be removed, the support will be interrupted. To safely accomplish the removal, a suitable alternative access (contralateral femoral or axillary artery) should be identified in case further MCS is needed, ideally to enable the

| Table 1 | Techniques for Impella removal in the catheterization laboratory, with and without pre-closure |
| --- | --- |
| **Closure strategy** | **Method** |
| Non-invasive | Manual compression  
Femoral compression devices  
- FemoStop™ (Abbott Vascular)  
- CompressAR® (Bisping) |
| Invasive, using VCD | Suture-based VCD  
- Prostar® XL  
- ProGlide® |
| Invasive | Collagen-based VCD  
- MANTA™  
Patch-based VCD  
PerQseal®  
Membrane-based VCD  
- InSeal  
- Surgical cut-down  
- Interventional with peripheral balloon compression  
- Interventional with covered stent implantation |
| | \textit{VCD}, vascular closure devices. |
new Impella to be inserted simultaneously while the first Impella is removed.

Treatment of acute limb ischaemia related to the Impella device includes medical management after removal of the Impella, open thrombectomy, percutaneous mechanical thrombectomy, and vascular surgery including amputation. Among the available options of Impella removal, blind removal followed by manual compression must be regarded as unsafe as this may worsen ischaemia, in which case the distal thrombus would dislodge and require the need for prolonged pressurized haemostasis to obtain entry-site haemostasis, respectively. On the other hand, urgent vascular surgery is the gold standard for Impella removal in conditions of limb ischaemia since direct exposure of the entry site can allow complete removal of the thrombus and thrombectomy in order to re-establish patency both proximally and distally to the entry site. This allows surgical haemostasis avoiding further blood stasis, however, the critical conditions of patients requiring such bail-out management make urgent vascular surgery extremely challenging. The risk may be prohibitive in many circumstances and, therefore, the interventional cardiologist must be able to recognize factors that may lead to potential vascular complications.

For these reasons, alternative techniques are increasingly adopted by multidisciplinary Shock Teams comprising a cardiologist, a cardiothoracic surgeon, an interventional cardiologist, and a cardiovascular ICU attending physician. As a general approach, the aim is to combine Impella removal with endovascular techniques to restore antegrade flow. Catheterization laboratories or hybrid theatres are usually preferred in order to provide full support to the critically ill patient and facilitate implantation of the MCS device. Ultrasound-guided femoral artery access may help to optimize access. For elective procedures, a baseline angiography of the iliofemoral arteries performed from a contralateral or radial access can be useful in patients with suspected peripheral artery disease. Furthermore, a detailed assessment of the specific vascular complication should be achieved by selective peripheral angiography (radial or contralateral femoral artery). In addition, a successful attempt of crossing the occluded artery with a guidewire might allow sealing dissection with a stent, removal of thrombus and thromboembolism with an extraction catheter, and eventually facilitate haemostasis with balloon inflation (Figure 2D). A post-procedural angiography should confirm the blood flow restoration in the ischaemic leg (as well as distal flow) and the achievement of entry-site haemostasis. In order to prevent such devastating vascular complications, management and monitoring of the Impella device requires a level of expertise and should be performed in high-volume tertiary centres with available cardiac and vascular surgery.

Procedural options for patient deterioration during Impella protected percutaneous coronary intervention

Percutaneous Impella may not be sufficient for adequate circulatory support in profound cardiogenic shock, e.g. developing during protected PCI. Similar to other left-ventricular assist devices, the blood flow generated by the Impella device can be limited by poor right-ventricular (RV) output and RV distention that shifts the interventricular septum towards the left ventricle in the case of RV failure. Haemodynamic management includes fluid balance and titration of inotropes, such as dobutamine or norepinephrine, depending on the mean arterial pressure, lactate levels, and/or TOE findings. Additional parameters, depending on the type of monitoring, are central venous pressure, pulmonary capillary wedge pressure, mixed central venous oxygen saturation, and pulmonary artery pulsatility index. Furthermore, a patient can deteriorate due to respiratory failure or profound cardiogenic shock.
with multi-organ failure despite Impella support. All of the above-mentioned causes might necessitate further escalation of MCS in order to improve gas exchange or provide better haemodynamic support. Interestingly, recent studies aimed to analyse the impact of periprocedural left-ventricular end-diastolic pressure (LVEDP) among several other findings but did not demonstrate that LVEDP was a reliable risk factor associated with periprocedural haemodynamic deterioration.

However, in the case of severe RV failure or profound cardiogenic shock, simultaneous use of venaarterial extracorporeal membrane oxygenation (VA-ECMO) with the Impella device as an unloading strategy (ECPella) is a popular MCS configuration. Depending on the underlying cause, other treatment options include escalation to the surgically implanted Impella (Impella 5.0 or 5.5) via the subclavian artery and the use of another right-sided percutaneous ventricular assist device (ProtekDuo; CardiacAssist Inc, Pittsburgh, PA, USA). A recent report in a cohort of patients in cardiogenic shock supported with Impella demonstrated that consecutive VA-ECMO implantation with Impella, provided rapid improvement in total blood flow and haemodynamic parameters, including lactate and mixed central venous oxygen saturation. VA-ECMO can be implanted percutaneously using the Seldinger technique via the contralateral femoral artery. In the case of clinical signs of limb ischaemia or a significant drop in oxygen saturation (>20%) in the lower limb during the ECMO support, the distal perfusion cannula can be inserted immediately into the superficial femoral artery. However, device-related complications are a major concern of ECPella use, including higher rates of bleeding complications, haemolysis, renal replacement therapy, and ischaemic complications. Therefore, it is

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**Figure 2** Potential mechanisms and management of ischemia during Impella support. Potential mechanisms and management of ischemia during Impella support. (A) Occurrence of dissections in the iliac-femoral artery; (B) iliofemoral thrombosis around the Impella catheter and sheaths; or (C) distal embolization of the femoral arteries or their branches. (D) The crossing of the occluded artery with a guidewire might allow sealing dissection with a stent, removal of thrombus and thromboembolism with an extraction catheter, and eventually facilitate haemostasis via balloon inflation.
paramount to ensure that each patient receives an individualized approach and that the Heart Team decides which patients will benefit from a particular MCS device in the catheterization laboratory.

Conclusion

Given that bleeding and vascular complications contribute to the increased mortality observed in LBA procedures, obtaining safe vascular access and closure is critical and essential to optimize outcomes and efficiency of pMCS in patients undergoing protected PCI with the Impella heart pump. The combination of ultrasound-guided vessel puncture, along with advanced imaging prior to the procedure, leads to safer LBA in most patients. Removal of the Impella device and large-bore arterial sheaths requires meticulous pre- and/or post-closure techniques to prevent vascular complications such as bleeding, retroperitoneal haemorrhage, vascular perforation, limb ischaemia, pseudoaneurysms, and to preserve vessel patency. In addition, operators should be familiar with an endovascular bail-out and complication management in order to optimize patient outcomes.

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