The Impella system as a “bridge to recovery”: a case series of four ST-elevation myocardial infarction patients presenting with cardiogenic shock

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Introduction

Prognosis for ST-elevation myocardial infarction (STEMI) has improved significantly since primary percutaneous coronary intervention (PCI) has become standard of treatment [1]. Nevertheless, prognosis remains dismal for STEMI complicated by cardiogenic shock (CS). Despite prompt revascularization with primary PCI, in-hospital mortality rates for these patients are as high as 50% [2]. Besides re-establishing blood flow to the ischemic myocardium, mechanical circulatory support may promote myocardial recovery and thus improve clinical outcomes. The intra-aortic balloon pump (IABP) system was introduced in the 1960s [3] as the first minimally invasive system for mechanical circulatory support. Today, it is still the most widely used device and the current standard of treatment for patients with STEMI complicated by CS, according to both the American and European guidelines [4,5]. Nevertheless, in a recently published meta-analysis of IABP support in high-risk STEMI, no net effect of IABP treatment could be demonstrated, either with regard to mortality or left ventricular function [6]. Several other devices have been developed in addition to the IABP, including the Impella® system (Abiomed Europe GmbH), which is displayed in Figure 1. The Impella system is a catheter (9 Fr)-mounted micro-axial rotary blood pump designed for short-term mechanical circulatory support that is inserted through the femoral artery and positioned across the aortic valve into the left ventricle using fluoroscopy. The pump’s driving console allows management of pump speed (according to 9 gradations) and displays the pressure difference between inflow and outflow, which provides an indication for pump position. The Impella 2.5 device is 12 Fr in diameter, which enables it to be introduced through a percutaneous sheath. This device provides a maximum flow of 2.5 L/min at its maximal rotation speed of 51,000 rpm, by expelling blood from the left ventricle into the ascending aorta. The Impella 5.0 device is mounted on a 9-Fr catheter as well; however, the pump itself is 21 Fr in diameter. The device is inserted through a Dacron graft sewed onto the femoral artery. The subsequent positioning is similar to the Impella 2.5 placement; however, the 5.0 device is capable of generating a maximum flow of 5.0 L/min.

In the experimental setting, Impella treatment has been shown to reduce infarct size [7]. Furthermore, it has been shown to be safe and feasible both in the clinical setting of high-risk PCI [8,9] and STEMI without CS [10]. Impella treatment has been a part of routine care in our institution, especially in patients presenting with CS. The current case series describes the clinical history of three patients with severe CS who were all bridged to recovery with the Impella 5.0 device. However, each case illustrates a distinct course of clinical decision-making that eventually led to 5.0 implantation. In addition, we briefly describe the history of a patient with less severe CS (not...
requiring mechanical ventilation) who was bridged to recovery with an Impella 2.5 device.

Case A – Impella 5.0 treatment after initial pharmacological therapy
Case A concerns a 46-year-old man with no previous medical history. His risk factors for ischemic heart disease included smoking and a positive family history. He had contacted the ambulance service for acute severe upper back pain and collapsed subsequently; basic life support was initiated immediately. When the ambulance arrived, the ECG revealed ventricular fibrillation (VF), for which he was defibrillated once. After recovery of sinus rhythm, the ECG revealed ST-elevation and the patient was transferred to our institution for primary PCI. Upon arrival at the catheterization laboratory, he was already on mechanical ventilation. The ECG showed a sinus tachycardia of 115/min and left axis deviation, a right bundle branch block and ST-elevation in leads I and aVL (Figure 2). Blood pressure upon arrival was 85/60 mmHg. Coronary angiography (CAG) revealed a proximal occlusion of the left anterior descending coronary artery, which was successfully treated with balloon angioplasty and subsequent stenting (Figures 3a and b). During primary PCI, the patient was repeatedly defibrillated for recurrent VF. Baseline lab revealed a blood lactate level of 7.3 mmol/L and a pH of 7.05. After initiation of high-dose intravenous dobutamine and norepinephrine, the patient was transferred to the intensive care unit (ICU). However, as his clinical condition deteriorated overnight despite maximum pharmacologic therapy, we decided to implant an Impella 5.0 device the next morning. Echocardiography immediately after device implantation revealed a depressed left ventricular function. Peak CK-MB level was 1158 µg/L. After five days of full mechanical circulatory support, the patients’ clinical condition had improved and he could be weaned from Impella support. After pump removal, no pharmacological circulatory support was necessary. The ICU clinical course was additionally complicated by pneumonia and a brief episode of acute renal failure, both of which quickly resolved once treated. He was transferred to the nursing ward in stable clinical condition after one week, and discharged home two weeks later. Echocardiography before discharge showed a left ventricular ejection fraction (LVEF) of 35%. After three months, the patient had resumed all of his former activities. Recovery of left ventricular function was sustained, as a nuclear gated-synchronized acquisition (GSA) scan revealed an LVEF of 37%.

Case B – Impella 5.0 treatment after initial IABP implantation
A 58-year-old woman with no previous medical history was referred from a primary care hospital for treatment-refractory CS after primary PCI for left main coronary artery occlusion. During primary PCI, extensive cardiopulmonary resuscitation had been performed. Mechanical ventilation and high-dose intravenous inotropic therapy had been initiated and an IABP had been implanted. However, despite maximum conventional therapy, her haemodynamic status did not improve. She was transferred to our institution for further evaluation and treatment. Upon arrival at the catheterization laboratory, her blood pressure was 45/32 mmHg. The ECG revealed signs of a recent anterior myocardial infarction, with a sinus tachycardia of approximately 110/min, a left axis deviation and QS pattern in leads V1 and V2 (Figure 4). We decided to remove the IABP and implant an Impella 5.0 device. After Impella 5.0 implantation, the patient was transferred to the ICU. After five days of Impella support, her clinical condition had improved and the Impella was explanted after careful weaning. However, in the initial period

Figure 1. The Impella system

The position of the Impella 2.5 device in the heart; the pump inlet is located in the left ventricle, whereas the outlet is located just above the aortic valve.

Figure 2. Patient A – Baseline ECG

Patient A’s ECG upon arrival at the catheterization laboratory shows signs of an anterior STEMI, with a sinus tachycardia of 115/min and left axis deviation, a right bundle branch block and ST-elevation in leads I and aVL.
after device removal, she still required low-dose intravenous milrinone and norepinephrine to maintain adequate blood pressure. Furthermore, she had developed acute renal failure during ICU admission, for which haemodialysis was initiated. After two weeks, she was no longer inotrope-dependent. Although she still required dialysis, she was transferred to the ICU of the referring hospital. Eventually, renal failure recovered as well, and a few weeks later she was discharged home in good clinical condition.

**Case C - Impella 5.0 treatment after initial Impella 2.5 implantation**

A 48-year-old man presented to the ambulance service with a sudden episode of heavy chest pain and nausea during exercise. He had no previous medical history and no risk factors for ischemic heart disease. The ambulance ECG revealed ST-elevation, and he was transferred to the hospital immediately for primary PCI. Upon arrival at the catheterization laboratory, his blood pressure was immeasurable. The ECG showed signs of an anterior STEMI, including a sinus tachycardia of 102/min, a right bundle branch block with left axis deviation, ST-elevation in leads I, aVL and V1-V4 with reciprocal ST-segment depression in leads II, III and aVF (Figure 5). Coronary angiography (CAG) revealed a proximal left main coronary artery occlusion, which was promptly treated with balloon angioplasty (Figures 6a and b). Baseline lab studies revealed a blood lactate level of 10.9 mmol/L and a pH of 6.78. During angioplasty, several episodes of ventricular fibrillation occurred and the patient was defibrillated repeatedly. In addition, mechanical ventilation was initiated as well as intravenous inotropic therapy. An Impella 2.5 device was inserted as well. However, despite Impella 2.5 support and high-dose intravenous inotropes, haemodynamic status remained marginal. Therefore, an Impella 5.0 device was implanted. After device implantation, the patient was transferred to the ICU. Echocardiography after device implantation revealed an only moderately depressed left ventricular function, whereas the peak CK-MB level was 3496 µg/L. After three days of full mechanical support, recovery was sufficient to enable removal of the Impella. The further ICU clinical course was complicated by recurrent episodes of atrial fibrillation, as well as acute renal failure, for which dialysis was initiated. After five weeks, all remaining complications had resolved without sequelae.

**Figure 3a. Patient A – Baseline coronary angiography**

This figure displays the result of initial coronary angiography, which revealed a proximal occlusion of the left anterior descending artery (LAD).

**Figure 3b. Patient A – Coronary angiography after treatment**

This figure shows the coronary angiogram after successful balloon angioplasty and stenting of the proximal left anterior descending coronary artery (LAD) from a different viewpoint.
and the patient was transferred to the nursing ward in stable clinical condition. A GSA scan performed just before hospital discharge showed an LVEF of 26%. According to the ACC guidelines [4], an implantable cardioverter-defibrillator (ICD) was implanted. The patient was subsequently discharged home in good clinical condition. Nine months later, he had resumed all former activities, including light exercise. A repeat GSA scan demonstrated profound recovery of left ventricular function, with an LVEF of 38%.

**Case D – Sole Impella 2.5 treatment in less severe CS**

A 51-year-old man presented to the ambulance service after waking up from severe sustained chest pain and total malaise. He had no previous medical history except for subclinical diabetes mellitus. His risk factors for coronary heart disease included smoking and hypertension. The ECG upon hospital presentation revealed a sinus tachycardia with ST-elevations in leads I and aVL, a right bundle branch block and left axis deviation, consistent with an anterior myocardial infarction (Figure 8). The patient arrived at the catheterization laboratory in overt clinical severe CS and respiratory distress with a heart rate of 104/min and blood pressure of 60/44 mmHg. The CAG revealed an occlusion of the left main coronary artery (Figure 9a). To maintain haemodynamic stability during PCI, the operator placed an Impella 2.5 device, which allowed haemodynamic and respiratory stability throughout the procedure. Balloon angioplasty and stenting was subsequently performed for both the left main and the left anterior descending and circumflex coronary arteries (Figure 9b). After PCI, systolic blood pressure remained around 100 mmHg. No additional therapies were initiated and the patient was transferred to the coronary care unit. After eight days of Impella support, haemodynamic status had recovered and the device was removed. Echocardiography after device removal revealed a moderately depressed left ventricular (LV) function. The patient was transferred to a local hospital and eventually discharged home in good clinical condition.

**Discussion**

In three of the cases, the implantation of an Impella 5.0 device eventually served as a “bridge to recovery,” despite an adverse clinical condition upon hospital presentation. In the last case of less severe CS, Impella 2.5 treatment alone led to clinical recovery as well. These four cases illustrate different clinical pathways and treatment strategies that may be applied for patients presenting with CS, including the decision for Impella 5.0 implantation.

**Mechanical circulatory support**

As briefly mentioned above, mechanical circulatory support is an increasingly important treatment modality for patients in CS. Whereas the IABP is still the most widely used device in this setting (and which is currently endorsed by both the American and European STEMI guidelines [4,5]), evidence for its efficacy is limited. Given the passive circulatory support provided by the IABP, its dependency on native cardiac function and its limited contribution to cardiac output, several other mechanical circulatory support systems have been developed over the last decades. Although results of surgically implantable devices are encouraging [11] and although they are capable of delivering full circulatory support, their invasiveness limits their applicability in the acute setting. However, several less invasive systems have been developed as well, including the

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**Figure 4. Patient B – Baseline ECG**

This ECG was performed upon arrival at our catheterization laboratory, after percutaneous coronary intervention had been performed in the referring hospital. Signs of a recent anterior myocardial infarction are visible, with a sinus tachycardia of approximately 110/min, a left axis deviation and QS pattern in leads V1 and V2.

**Figure 5. Patient C – Baseline ECG**

This ECG shows a sinus tachycardia of 102/min and a right bundle branch block with left axis deviation. In addition, ST-elevation is visible in leads I, aVL and V1-V4 with reciprocal ST-segment depression in leads II, III and aVF. These signs are consistent with a large anterior myocardial infarction.
TandemHeart® (CardiacAssist, Pittsburgh, Pennsylvania), extracorporeal membrane oxygenation (ECMO) and Impella® systems. The TandemHeart system is a powerful device that can be inserted percutaneously. However, as the implantation procedure requires a transseptal puncture, it is associated with a significant learning curve. Importantly, implantation of the device takes 20 to 30 minutes, even in experienced hands. The ECMO system has been investigated in the setting of CS as well, both as a complication of STEMI [12] and in the setting of treatment-refractory postcardiotomy CS [13]. Although results seem favourable and although the ECMO is capable of delivering powerful support, applicability in the acute setting may be challenging, as the insertion procedure is rather complex. The Impella system (especially the 2.5 version) is a much less invasive device providing unloading of the left ventricle and circulatory support. Although a larger 5.0-version is available, surgical cut-down of the femoral artery is required for the implantation procedure, which is an important limitation in the acute setting. In addition, echocardiography is required before implantation to exclude LV thrombus, which may be a limitation as well. For daily clinical practice, it is important to understand that the delivered output of both versions of the Impella system is related to both pre- and afterloading conditions. Therefore, maximum delivered output may vary somewhat. Furthermore, there is a risk of limb ischemia and haemolysis; however, these risks apply to all mechanical circulatory support devices, including the IABP. Nevertheless, especially when considering the availability of two different versions of the system, the Impella device may still be the most suitable, and superior, alternative to an IABP in the acute setting.

Impella
As demonstrated in our pilot study in STEMI patients and in the ISAR-shock trial, the Impella 2.5 device provides an immediate increase in cardiac output of about 0.5-1.0 L/min [10,14]. Another main purpose of Impella 2.5 treatment is LV unloading, which may promote the recovery of stunned myocardium. This hypothesis is supported by evidence from animal studies, in which Impella treatment was shown to reduce infarct size [7]. In our pilot study of STEMI without CS, an increase in LVEF was observed as well, suggesting a potential beneficial effect of LV unloading on LV function. A randomized trial of

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**Figure 6a. Patient C – Baseline coronary angiography**

LM = left main coronary artery  
LAO = left anterior oblique  
CRA = cranial  
24.2 LAO 1.5 CRA = view settings

This figure shows a picture of the initial coronary angiogram, which was performed upon arrival at the catheterization laboratory. Only the most proximal part of the left main coronary artery is visible, whereas both the left anterior descending (LAD) and circumflex (LCX) coronary arteries are not visible. This image is consistent with a left main coronary artery occlusion.

**Figure 6b. Patient C – Coronary angiography after treatment**

LM = left main coronary artery  
LAD = left anterior descending coronary artery  
LCX = left circumflex coronary artery  
LAO = left anterior oblique  
CRA = cranial  
45.0 LAO 0.05 CRA = view settings

This figure shows the coronary angiogram after successful balloon angioplasty of the occluded left main coronary artery. Both the left anterior descending (LAD) and circumflex (LCX) coronary arteries are now visible.
IABP versus Impella 2.5 in STEMI with CS was performed by Seyfarth et al. [14] and showed superior circulatory support with Impella measured by cardiac index at 30 minutes after pump implantation. No mortality difference was demonstrated; however, this randomized trial was underpowered for mortality. Currently, an ongoing randomized trial of IABP versus Impella 2.5 in haemodynamically unstable STEMI patients at our institution is evaluating the difference in LVEF assessed by cardiac magnetic resonance imaging (CMR) at four-month follow-up (www.trialregister.nl; NTR1079). In patients presenting with profound and severe CS, the Impella 5.0 device is likely to be of additional value. Impella 5.0 treatment provides a considerable contribution to cardiac output and systemic circulation, in addition to the LV unloading effect.

Although comprehensive randomized evidence is not yet available, the preliminary results of Impella treatment are encouraging. In our institution, Impella treatment has become an important part of routine care [15] in a variety of clinical settings for patients presenting with poor haemodynamic conditions.

**Clinical implications**

Encouraged by the results of Impella treatment in CS patients in our institution, we developed a standardized treatment strategy for patients presenting with CS (Figure 7). All patients who do not respond to full conventional therapy (including revascularization (for STEMI patients), high-dose inotropic therapy and IABP implantation) could be potential candidates for Impella support. In fact, given the available evidence, it even makes sense to consider active unloading and circulatory support up front rather than as a “last resort” therapy. For patients who develop CS post-cardiac surgery, prompt Impella 5.0 implantation may be the most effective strategy. For STEMI patients on mechanical ventilation with profound CS, the Impella 5.0 is the preferred device as well. However, as immediate implantation may be challenging, patients may be bridged to 5.0 implantation with the Impella 2.5 device. For patients with STEMI and CS who are not mechanically ventilated, initial treatment with the Impella 2.5 is preferable. Nevertheless, these patients (who appear to be less ill) need careful monitoring as well, and if there is insufficient response to treatment, implantation of an Impella 5.0 device should be considered. In an estimated one-third of cases, circulatory support with the Impella 5.0 device will not be efficacious and patients will soon succumb to treatment-refractory CS. In another one-third of cases, patients may experience full recovery of cardiac function. The remaining patients may experience partial recovery of cardiac function; however, it may not be possible to wean them off of support. Especially in case of intact neurological status, those patients may eventually be eligible for implantation of a surgical left ventricular assist device (LVAD), although this treatment option is currently only available as a bridge-to-transplant in the Netherlands. Nevertheless, overwhelming evidence is available with regard to the efficacy of LVAD placement as destination therapy in patients with chronic heart failure [16].

**Figure 7.** The implemented Academic Medical Center (AMC) strategy for mechanical support in patients presenting with cardiogenic shock, based on observations from the current study.

**Figure 8.** Patient D – Baseline ECG

This ECG shows a sinus tachycardia of approximately 100/min and a right bundle branch block with left axis deviation. In addition, ST elevation is visible in leads I and aVL and reciprocal ST-segment depression in leads II, III and aVF. These signs are consistent with a large anterior myocardial infarction.
Importantly, although the standardized protocol can help in the general decision-making process, careful patient selection and patient-based modifications to the standard algorithm remain extremely important. Treatment of these severely ill patients remains challenging, both with regard to medical and ethical considerations. Therefore, in our institution, treatment decisions are made using a team-based approach, carefully considering all risks and benefits, including the patients’ chances for recovery and possibilities for bridging, as opposed to the risk of serious complications.

Conclusion
The Impella system seems to be a promising new technology for mechanical circulatory support in STEMI complicated by CS. Illustrated by the four aforementioned cases, the careful application of this new treatment modality, according to a pre-specified protocol, may lead to significant recovery of cardiac function in selected patients.
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References

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