First successful bridge to recovery with the Impella Recover 100 left ventricular assist device for fulminant acute myocarditis

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A patient with septic and cardiogenic shock secondary to acute fulminant myocarditis was successfully treated by mechanical offloading of the left ventricle using the Impella® Recover 100, a new implantable micro-axial blood pump designed for short-term circulatory support (for a maximum of 7 days). The possibility of implanting this device without using cardiopulmonary bypass allowed us to manage the septic shock, to reverse cardiac and hepatorenal failure and to wean the patient off treatment after 18 days of support. At 3 months the left and right ventricular function was satisfactory. The widespread application of this kind of support depends on the availability of an inexpensive "mini-invasive" blood pump, appropriate weaning protocols and emerging strategies to promote sustainable myocardial recovery.

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Introduction

Fulminant myocarditis can cause rapid and irreversible cardiac failure, resulting in death or requiring cardiac transplantation. Besides symptomatic treatment with inotropes, diuretics and vasodilators, immunosuppression has been attempted in this condition[1] with controversial results. The mortality remains high. The availability of mechanical ventricular support might improve the prognosis of fulminant myocarditis[2]. The Impella® Recover 100 is an intravascular micro-axial blood pump designed for short-term circulatory support (up to 7 days) (Fig. 1). So far, it has been used in conditions of reduced left ventricular function due to postcardiotomy low output syndrome or to cardiogenic shock after acute myocardial infarction. To our knowledge, this is the first case of a young man with cardiogenic shock secondary to acute myocarditis, which was successfully supported using the Impella® Recover 100, thus allowing patient recovery and weaning from the device.

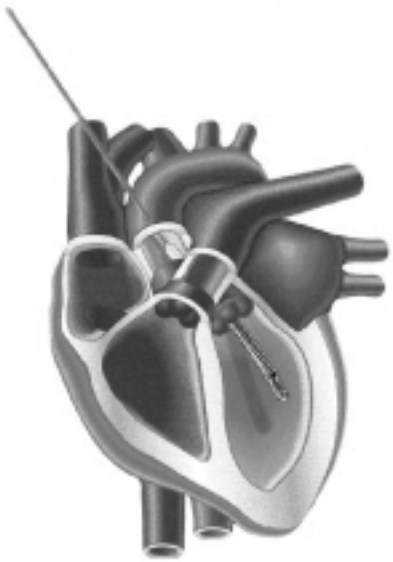


Figure 1. *The figure shows the position of the Impella® Recover 100. The device is inserted into the ascending aorta through a 10 mm Dacron graft (not shown) and advanced into the left ventricle across the aortic valve.*

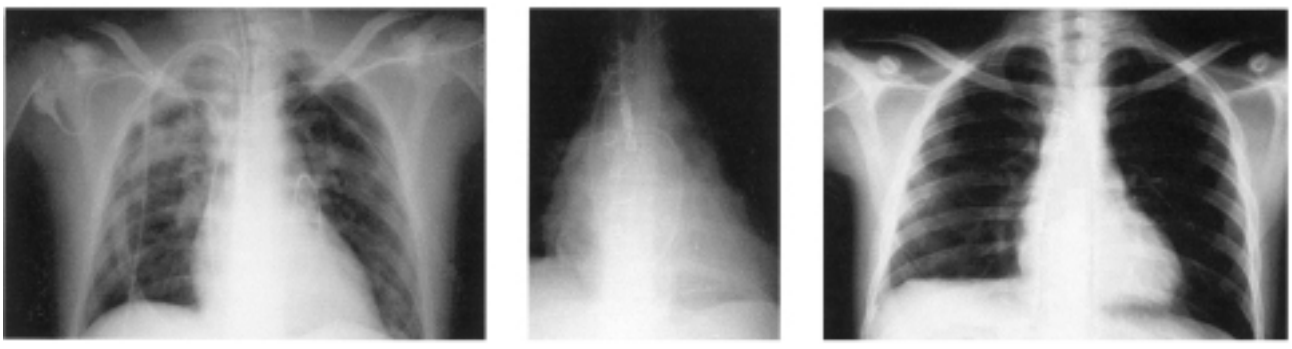
Case report

An otherwise healthy 30-year-old male (body weight 80 kg) had a history of tonsillitis with fever lasting 1 week that resolved with medical treatment. Ten days later the patient presented to the local hospital for a new episode of fever with chest pain and moderate dyspnea. The electrocardiogram showed widespread ST-segment elevation, and the patient was admitted with an initial diagnosis of pericarditis. At admission there were no signs of left ventricular dys-

function, but during the following days the patient developed acute respiratory failure and became progressively hypotensive and oliguric. An echocardiogram revealed a normal heart chamber size and severe global biventricular hypokinesia with a very low ejection fraction (20%). At chest X-ray bilateral inflammatory infiltrates were appreciated (Fig. 2A). The hemodynamic status deteriorated progressively and the patient was transferred to our institution for mechanical support with profound hypotension (his arterial pressure was 70/50 mmHg), respiratory failure and anuria. Mechanical ventilation and inotropic support with high-dose dopamine and dobutamine were instituted. Blood analysis showed leukocytosis (the white blood cell count was 18 000/mm^3) and hepatic and renal failure (total bilirubin 4.18 mg/dl; blood urea nitrogen 162 mg/dl; creatinine 3.86 mg/dl), while blood cultures revealed gram-positive sepsis. As the patient was in cardiogenic and septic shock, left ventricular assist device (LVAD) support was urgently instituted. The Impella® Recover 100 was implanted via a median sternotomy on the beating heart, inserted through a 10 mm Dacron graft sutured end-to-side to the ascending aorta and advanced in the left ventricle across the aortic valve (Fig. 2B). The blood pump itself contains an impeller that rotates at a maximum speed of 33 000 rpm. The pump has a low-flow (10 ml/hour) infusion system of glucose solution that contains heparin to provide both fluid dynamic hydraulic bearing surfaces and local anticoagulation within the pump. With a pump flow of 3.8 l/min and epinephrine infusion to improve the right ventricular ejection, circulatory support was started, followed by rapid improvement of the patient's hemodynamics and peripheral perfusion. Transesophageal echocardiography showed the correct position of the device across the aortic valve and unloading of the left ventricle. All the same, intra-aortic balloon pump (IABP) support was continued to optimize the diastolic pressure and coronary perfusion. After 24 hours the device was found to be displaced and replaced with a smaller one. The patient was still pyretic, and blood culture showed *Staphylococcus capitis* sepsis; continuous veno-venous hemofiltration was instituted for progressive oliguria. During the following days there was a gradual hemodynamic improvement, while as documented at X-ray (Fig. 2C) the pulmonary infiltrates resolved. As the Impella is intended for short-term use only (≤ 7 days), on day 8 the device was replaced with a new one; a right ventricular endomyocardial biopsy was performed showing moderate myocardial fibrosis with an inflammatory infiltrate. Echocardiography showed a moderate improvement of the left ventricular performance (ejection fraction 35%). On day 11, the patient's clinical and hemodynamic status worsened due to bleeding and tamponade and new surgery was performed for hemothorax. The IABP was again inserted to achieve better support and improve coronary flow and myocardial recovery. The patient finally showed a slow but progressive improvement and could be weaned off the Impella on day 18. On day 15 the patient was no longer pyretic, and on day 23 he was extubated. The patient was discharged from the hospital 16 days after discontinuing left ventricular support. One month after device removal, transthoracic echocardiography revealed a left ventricular ejection fraction of 42%.

Discussion

Acute myocarditis is a disease with an unclear pathophysiology and etiology, an uncertain diagnosis and variable presentation. Most cases remain subclinical with cardiac signs and symptoms overshadowed by systemic manifestations of fever, myalgia, muscle tenderness, and fatigue. Cardiac symptoms of congestive heart failure, arrhythmias and chest pain generally follow a viral prodrome. The management of acute heart failure for acute myocarditis includes sodium restriction, digitalis, diuretics, vasodilators and the aggressive use of inotropic agents and the IABP when needed. Less frequently, the patient's course is more fulminant, leading to hemodynamic decompensation requiring mechanical ventricular support[2,3]. Myocarditis is a rare indication for mechanical support, accounting for less



A B C

Figure 2. A: *chest X-ray performed at admission showing a significantly enlarged mediastinal shadow and bilateral lung inflammation.* B: *chest X-ray showing the correct position of the device.* C: *chest X-ray at discharge showing resolution of the pulmonary edema and normal dimensions of the heart.*

than 5% of devices implanted in most databases[2]. A high mortality ranging between 50 to 75% was reported in acute myocarditis patients with abrupt-onset and progressive congestive heart failure, including pulmonary vascular congestion and a cardiac index < 2.1 l/min/m^2 [4]. For most patients with acute myocarditis, support has normally included either extracorporeal devices or extracorporeal membrane oxygenation with peripheral cannulation. Intracorporeal LVAD have been used less frequently with disappointing overall success rates. The Novacor LVAD has been implanted in 20 patients with acute myocarditis with an overall survival of 30% (Device Tracking Registry, Novacor LVAS, Worldheart Corporation, Ottawa, Canada), while 23 patients with acute myocarditis were on TCI support with an overall survival of 47% (Device Tracking Registry, TCI Heartmate, Thoratec Corporation, Pleasanton, CA, USA). In our experience, including this case, we supported 6 patients with acute myocarditis (1 with Biomedicus, 1 with Thoratec, 3 with Medos, and 1 with Impella), 4 as a bridge to transplant and 2 as a bridge to recovery, with an overall survival of 67%. The present patient represented a very challenging case in that the need of advanced mechanical circulatory support due to the low output syndrome with hepatorenal failure was complicated by the need to manage the septic shock. The sepsis forced us to reconsider the possibility of implanting a traditional LVAD, principally due to the necessity of cardiopulmonary bypass for ventricular assist device implant and removal and to the requirement of systemic anticoagulation. Moreover, ventricular assist device implantation is expensive and time-consuming. The choice of mechanical support for this previously healthy patient who presented with rapid-onset hemodynamic instability of non-ischemic origin which progressed to cardiogenic shock, was dictated by the likelihood of a diagnosis of fulminant acute myocarditis even in the absence of histology at the time of operation. The recent report from the Johns Hopkins Hospital[5] strongly suggests that these patients, unless they have giant cell myocarditis, have an excellent prognosis for a complete long-term recovery if they are supported aggressively. Since sepsis was a major determinant of immediate survival in this patient, we implanted the Impella as a short-term LVAD to minimize the surgical trauma, the surface in contact with blood and the systemic anticoagulation. Moreover, since a bridge to recovery was expected, the use of a device that does not require apical cannulation was appealing. As circulatory support was started and the diagnosis of fulminant myocarditis was confirmed at endomyocardial biopsy, the patient's ventricular function was strictly monitored by means of daily echocardiography, and slowly but progressively improved to recovery. A controversial point in this phase was the interaction of the Impella and the IABP. We stopped IABP support immediately after the Impella support was started, as we thought that the simultaneous use of a "pulsatile support" such as the IABP and of a continuous flow pump would have resulted in an impaired pump performance. We then found some evidence in the literature, in the articles by Meyns et al.[6], about the interaction between the IABP and the continuous flow pump. They suggest that, in spite of a slightly reduced pump performance, the IABP determines a good improvement of the coronary flow and consequently a more marked improvement of myocardial recovery than the device alone. For this reason, we decided to insert the IABP again on day 10, when bleeding and tamponade caused significantly impaired hemodynamics, and we now think that the synergy between unloading the left ventricle (due to LVAD) and the improvement in coronary blood flow (due to the IABP) played an important role in the healing process of the heart. In most cases of fulminant acute myocarditis ventricular recovery necessitates several weeks[7]. The average duration of ABIOMED support was about 10 days (Device Tracking Registry, ABIOMED). Patients supported by ECMO were usually weaned off in less than 1 week, although some were supported successfully for up to 3 weeks[8]. Our case confirmed these experiences and even the duration of support (18 days), considering the particularly compromised status at admission, is in line with these data. All the same, it is interesting to notice that the Impella was effective in stabilizing the patient during the critical phase of septic shock, so that, should myocardial recovery not have occurred, the patient could have undergone an elective implant of a traditional LVAD, as a bridge to heart transplantation (bridge to bridge). Furthermore, another issue of this device concerns the weaning process. Weaning from mechanical assistance is a complex process because, owing to the possibility of clotting, the ventricular assist device cannot be turned off for a sufficiently long period (several hours) to evaluate the heart function[9]. As Impella® Recover 100 does not need systemic anticoagulation and its flow and performance levels are easily controllable, we were able to explore, by means of echo, the response of both ventricles to a temporary reduction in the Impella pump flow and thus monitor changes in the ejection fraction, left ventricular diameters and volumes, right ventricular function, and left ventricular filling during the weaning process.

The Impella® Recover 100 is attractive as it efficiently supports and unloads the heart, is easy to install, and does not require cardiopulmonary bypass. It is implantable, which should reduce the infection rate, and has an original local heparin delivery system that should prevent bleeding complications.

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