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ECPELLA 2.0—Minimally invasive biventricular groin-free full mechanical circulatory support with Impella 5.0/5.5 pump and ProtekDuo cannula as a bridge-to-bridge concept: A first-in-man method description

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Abstract

Background: Cardiogenic shock (CS) from biventricular heart failure that requires acute mechanical circulatory support (MCS) is associated with high mortality. Different MCS methods and techniques have emerged as a standard of care in CS. Nevertheless, the routine MCS approach carries multiple limitations such as limb ischemia, missing of left ventricular unloading and immobilization.

We describe a method to establish a groin-free full support MCS in patients with CS without the need for thoracotomy. This is the first report of the ECPELLA 2.0 concept, a peripheral groin-free biventricular MCS in patients with acute CS.

Methods and results: We discuss two patients in acute CS (INTERMACS I) treated with two peripheral MCS devices (Impella 5.0 or 5.5 surgically via an axillary artery and ProtekDuo cannula percutaneously via a right internal jugular vein) as a bridge before the implantation of a durable left ventricular assist device (LVAD).

Biventricular assist device (BIVAD)-support duration was 9 and 15 days and both of the patients were successfully bridged to a durable LVAD. As our BIVAD-concept is groin-free, the patients started full mobilization as early as they were weaned from the respirator 2 days after the BIVAD-implantation. ECPELLA 2.0 provides a high cardiac output, right and left ventricular unloading with end-organ recovery and a possibility of administration of a membrane oxygenator. There were no device-related complications.

Conclusion: The ECPELLA 2.0 biventricular support concept for patients suffering from an acute CS. Allows for rapid extubation, mobilization, and physical exercise while on full support. Additional application of a membrane oxygenator is easily feasible if required.

Arjang Ruhparwar and Alina Zubarevich contributed equally to this manuscript.

KEYWORDS
biventricular mechanical support, cardinogenic shock (CS), groin-free, heart failure (HF), Impella 5.5, ProtekDuo

1 | INTRODUCTION

Cardiogenic shock (CS) is a state in which ineffective cardiac output caused by a primary cardiac disorder results in both clinical and biochemical manifestations of inadequate perfusion.[1] CS with biventricular heart failure is a life-threatening condition with very high mortality.[2] Mechanical circulatory support (MCS) remains the only option if medical treatment fails to improve the hemodynamic condition and has continuously evolved over the last decade.[2] In general, three strategies of temporary MCS are applied: (a) bridge-to-recovery in case of a recovery potential, (b) bridge-to-bridge (or transplantation) if weaning from MCS fails, and (c) bridge-to-decision if acute MCS treatment has to be prioritized before the definite treatment is available.

Various MCS techniques are developing rapidly.[3,4] However, the classic extracorporeal life support (ECLS) in the heart failure setting carries certain limitations and risks. Frequently, bleeding complications occur after a certain time on ECLS. The pathophysiology of this altered coagulation is very complex and includes thrombocytopenia, loss of coagulation factors, adverse effects of anticoagulants, and hemolysis. If ECLS with left ventricular decompression is provided surgically, allowing antegrade full-flow support including left ventricle (LV)-unloading, thoracotomy is inevitable. This results in extended time on the respirator and contributes to higher bleeding rates due to the surgical approach. Both, central ECLS and peripheral ECLS prevent full mobilization, as the cannulas are either directly connected to the aorta or are placed into the groin vessels. These cannulation techniques not only prevent patient mobilization but also lead to limb ischemia.[5] Further complications are systemic inflammation, infections, and multiorgan failure that have to be taken into consideration. Infection (eg, groin cannulation site infections, sepsis, pneumonia) is one of the most common complications in ECLS occurring in up to 13% of adult patients.[6] Thrombotic or air embolism and bleeding may cause cerebrovascular accidents. Inadequate decompression of the failing LV causes a backlog of blood into the lung with subsequent pulmonary congestion and a failure of the right ventricle. Especially in the setting of a dilated, poorly contracting heart with severe systolic dysfunction, decompression by LV venting might be crucial for the recovery of myocardium.[7] To address LV unloading, the concept of Impella (2.5 or CP) system in combination with ECLS has already been described as *ECPELLA*. However, other ECLS limitations and complications persist.[8]

We present a novel approach to establish a full-flow MCS for patients in CS due to acute biventricular heart failure. ECPELLA 2.0 is a first-in-man concept of a groin-free MCS consisting of a full-flow axial flow pump (Impella 5.0/5.5) as left ventricular assist device (LVAD) in combination with the TandemHeart/ProtekDuo system as right ventricular assist device (RVAD) that allows full biventricular support with an option of an upgrade using an oxygenator that would facilitate rapid weaning from the respirator, mobilization, and physical exercise of the patient on full support. In both, our patients there was no need of using a membrane oxygenator.

2 | METHODS

Impella 5.0/5.5 heart pump (Abiomed, Danvers, MA) is an intravascular microaxial blood pump that delivers up to 5.5 L/min of antegrade blood flow from the LV into the ascending aorta, unloading the failing LV. The main indications for use of the Impella pump are CS and postcardiotomy syndrome. The transluminal placement of the pump crossing the aortic valve into the LV is performed via axillary artery access and under transesophageal echocardiography (TEE) and fluoroscopy guidance (Figure 2A).

The ProtekDuo cannula, in combination with any centrifugal pump, offers the advantage of minimally invasive percutaneous full right heart support.[9] The ProtekDuo cannula is a flexible, dual lumen and partially wire-reinforced cannula providing drainage of venous blood through the outer 29 Fr. lumen from the right atrium and output through the tip of the inner 16 Fr. cannula into the pulmonary artery, with optional lung support by adding an oxygenator into the circuit. The cannula can be combined with any centrifugal pump as a temporary RVAD.

Our one-stage implantation protocol includes initial Impella implantation followed by percutaneous implantation of the ProtekDuo cannula via the right internal jugular vein (IJV) under fluoroscopy and TEE guidance as previously described.[7] The ProtekDuo cannula crosses the tricuspid valve, right ventricle (RV) and pulmonary valve into the main pulmonary artery.

Heparin was applicated immediately before implantation (target activated clotting time [ACT] 240 seconds). On ECPELLA 2.0 the heparin purge fluid was applied and dosed by the Impella controller. The goal ACT was kept at 180 to 220 seconds as recommended by the manufacturer. Due to the design of the TandemHeart pump housing, continuous flushing with heparinized saline is mandatory.

The first patient was a 59-year-old male suffering from dilated cardiomyopathy (DCMP) admitted to our department in CS. Despite high-dose inotropic support, the patient remained in low cardiac output (INTERMACS I). Echocardiography showed severely reduced LV ejection fraction (EF) of 10%, mild aortic- and mitral valve regurgitation as well as depressed RV function with severe tricuspid regurgitation and an elevated pulmonary pressure (65/35/50 mm Hg). Additionally, the patient was suffering from acute kidney- and liver failure with spontaneous high international normalized ratio

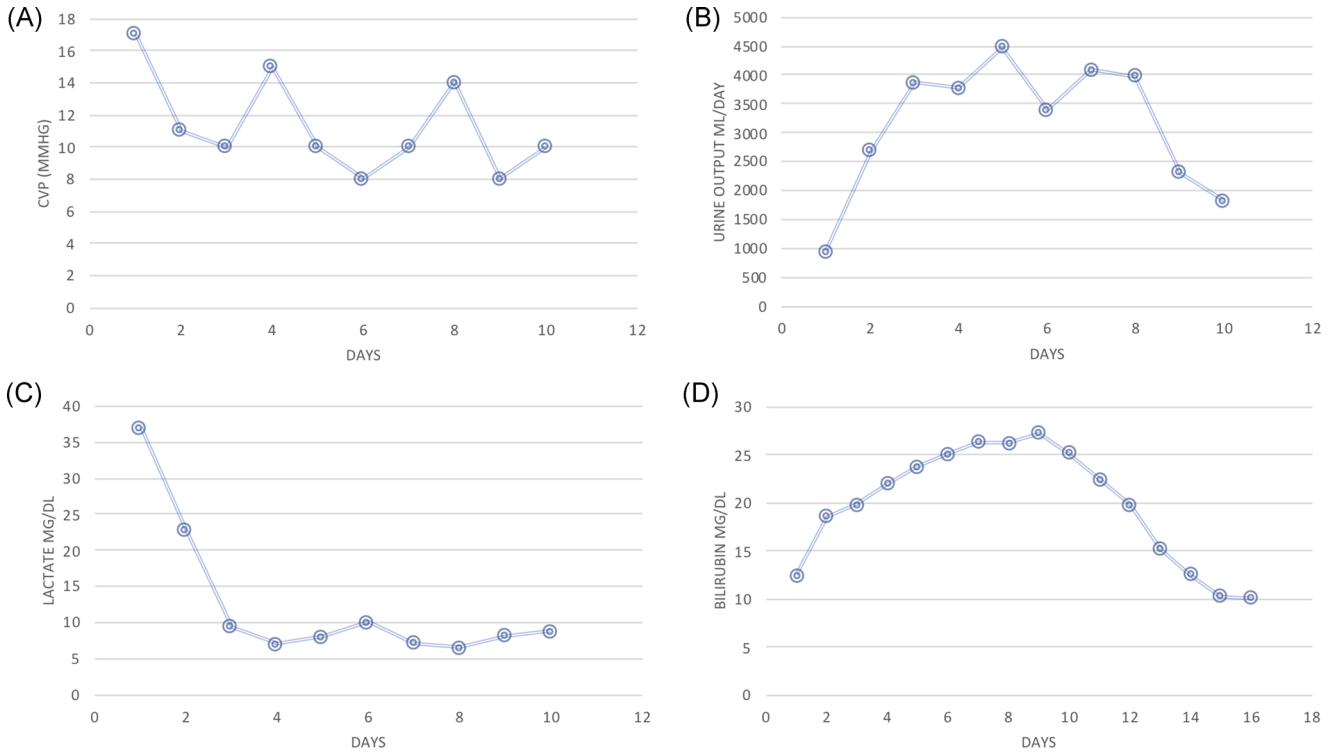

FIGURE 1 Course of CVP (A), urine output (B), lactate (C) and bilirubin (D) starting from ECPELLA 2.0 implantation until durable LVAD implantation. All parameters improved during bridge-to bridge support. CVP, central venous pressure; LVAD, left ventricular assist device

(INR)-levels and elevated bilirubin. Coronary angiography excluded stenotic coronary artery disease. Hence, the indication for biventricular support was given. We implanted an Impella 5.0 Pump via 10 mm Dacron-prosthesis following a minimally invasive surgical cutdown to the right axillary artery. To provide RV support, we implanted a ProtekDuo cannula percutaneously via the right IJV connected to a centrifugal pump. The Impella 5.0/5.5 and the temporary RVAD were set to deliver an estimated 4.3 to 4.5 L/min

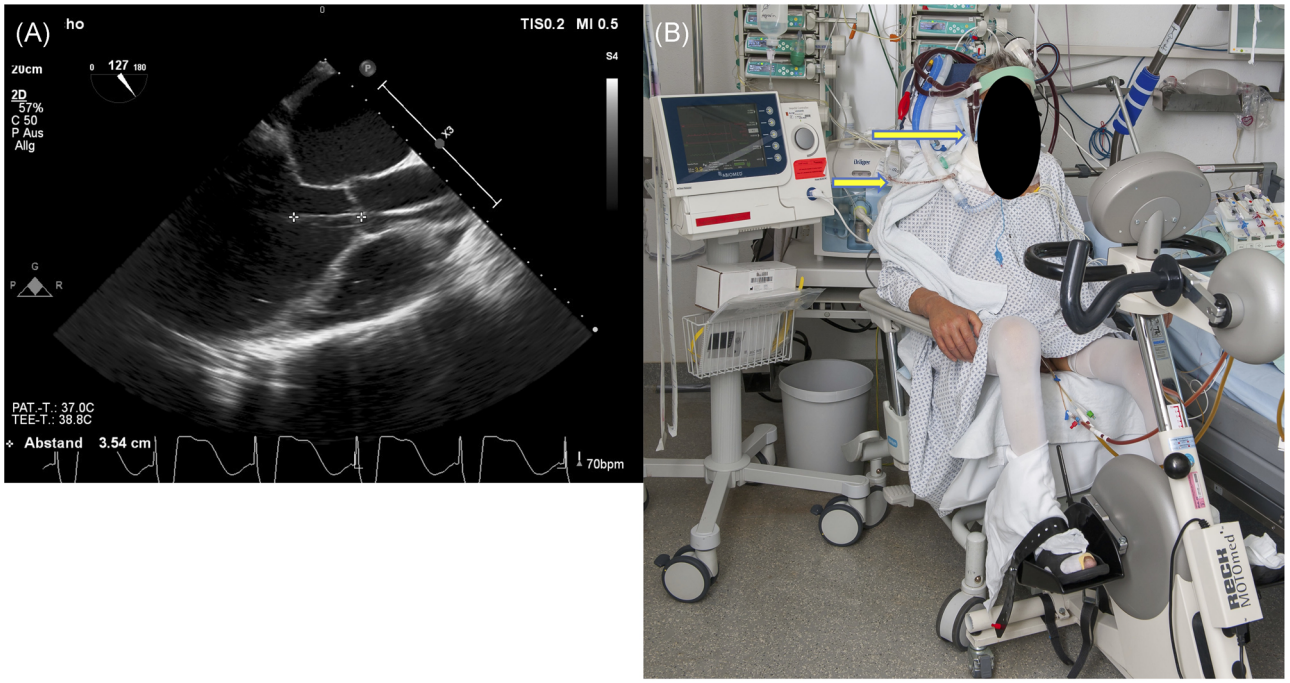

FIGURE 2 (A) TEE controlled positioning of the Impella—5.5 pump in the LV 35 mm beyond the aortic valve, (B) mobilization of the patient on ECPELLA 2.0 with bedside cycle exercise opportunity with insertions sites of the Impella pump and the ProtekDuo cannula (arrows). LV, left ventricular; TEE, transesophageal echocardiography

and 3.8 to 4.0 L/min flow, respectively (ECPELLA 2.0). Two days after implantation of the ECPELLA 2.0 the patient was weaned from the respirator and full mobilization started.

The fully mobilized patient was able to perform full-body bedside cycle exercise (Figure 2B) underwent successful LVAD (HeartMate 3) implantation 2 weeks later with explantation of the Impella 5.0 and leaving the temporary RVAD in situ. In the intraoperative TEE, the prior aortic regurgitation appeared to be mild-to-severe. We performed an aortic valve replacement as a concomitant procedure. On the first postoperative day (POD), the patient was weaned from the respirator and full mobilization continued. The temporary RVAD was weaned according to our protocols [10] and explanted at the bedside on POD 5.

The second patient was a 52-year-old male with a CS (INTERMACS I) due to ischemic cardiomyopathy with a history of multiple coronary interventions. Transthoracic echocardiogram showed severely reduced LV EF of 15%, mild mitral valve regurgitation and a failing RV with severe tricuspid valve regurgitation and elevated mean pulmonary pressure (65 mm Hg). Additionally, the patient was suffering from the progressive kidney- and liver failure and peripheral edema with an NT-proBNP level at 12200 ng/L.

We applied our ECPELLA 2.0 concept and inserted the Impella 5.5 pump and the ProtekDuo as described above. The systems were set to perform 4.0 to 4.2 L/min and 3.4 L/min flow, respectively. The patient was extubated on POD 2 and was mobilized. During the next days, the kidney and liver function improved significantly and regained function. On POD 9 the patient was successfully bridged to a durable LVAD leaving the TandemHeart in situ. On the first POD, our patient developed vasoplegia and an acute kidney failure with the need for intermittent hemodialysis. Three days after the LVAD implantation the patient recovered from vasoplegia receiving only low dose vasopressors was extubated and started mobilization, and physical therapy including full body bedside cycle exercise (Figure 2B). The temporary RVAD flow was weaned and explanted on the 22nd POD. Both patients signed informed consent to participate in this study.

3 | RESULTS

We treated two patients in severe CS (INTERMACS I) and multiorgan failure with a biventricular support using Impella 5.0/5.5 and temporary RVAD with a bridge-to-bridge intention to the durable LVAD.

Hemodynamics improved immediately after the initiation of the ECPELLA 2.0 MCS. Central venous pressure (CVP) dropped to normal levels (Figure 1A) resulting in a decompression of the severe venous congestion[11] while blood pressure and cardiac output improved to normal with no more inotropic support needed. ECPELLA 2.0 enabled support of up to 4.2 to 4.5 L/min LVAD flow and 3.8 to 3.9 L/min RVAD flow. As a result, urine output increased (Figure 1B) and the bilirubin levels decreased (Figure 1D) as a sign of a kidney- and liver recovery. Patients were extubated on POD 2. The patients were weaned off the MCS after hemodynamic and clinical parameters (mean arterial pressure >65 mm Hg, central venous oxygen saturation >65%, urinary output >0.5 mL·kg·$^{-1}$·h^{-1}, echocardiographic findings). Impella was removed surgically bedside. Both patients left the intensive care unit (ICU) to complete mobilization and full recovery process to receive outpatient care. As both patients were eligible for a heart transplant, the listing process was initiated.

The groin-free ECPELLA 2.0 concept allows for full mobilization on temporary BIVAD with no risk of limb ischemia or groin vessel injury. Moreover, this strategy enables advanced physical therapy, facilitating recovery in ICU. Support duration on the ECPELLA 2.0 was 9 and 14 days, respectively, before successful LVAD implantation was performed. Both patients are well and have been discharged from our department.

4 | DISCUSSION

CS refractory to medical therapy due to biventricular heart failure carries a high mortality and remains a medical challenge.[2] These patients may require MCS as a bridge-to-recovery or bridge-to-transplant. In both our cases the patients were referred to us in advanced CS with the failing end-organs (INTERMACS I). As previously shown, the outcome of the LVAD implantation in high-risk patients suffering from CS improves after the temporary use of peripheral MCS as compared to immediate durable LVAD implantation.[12] Hence, ECLS is considered a standard of care for these patients. Although the use of MCS carries a high rate of complications, the utilization increases rapidly.[2] Nevertheless, central and peripheral ECLS carries certain limitations that need to be addressed. These include bleeding, limb ischemia, prolonged intubation, immobilization, restricted time on ECLS-support due to bleeding and thromboembolic complications and cerebrovascular accidents.[3] As a consequence, our group developed an alternative concept of an interventional/minimally invasive ECPELLA 2.0. It provides LV unloading, full biventricular support, is completely groin-free allowing for immediate full mobilization of the patient. The very limited procedure trauma results in early extubation and prevention of ventilator-associated complications.[13] While left-sided short-term MCS is unable to relief systemic venous congestion, RV-dysfunction or failure is common in patients receiving LVAD.[9] Our strategy carries the advantage of leaving the RVAD in place during and after LVAD implantation to prevent RV-failure after durable LVAD implantation to explant the temporary RVAD during ICU course at the bedside.[10] Although none of the patients had lung failure, this concept preserves the opportunity to add an oxygenator in the RVAD circuit.

We kept our goal ACT between 180 and 220 seconds combining the recommended anticoagulation manufacturer protocols and had no bleeding or thrombotic complications.[9]

A major advantage of this concept is the combination of already available systems. Implantation may also be able to be performed in a cath lab by the heart team.[14] In the absence of cardiac surgeon

access to the axillary artery can be provided by a general or vascular surgeon.

5 | CONCLUSION

In summary, we report the first-in-man groin-free biventricular support "ECPELLA 2.0" for patients suffering from biventricular failure and CS (INTERMACS I), allowing for a full biventricular support with reliable LV unloading, the option for adding an oxygenator in the RVAD circuit an immediate early mobilization. ECPELLA 2.0 is an excellent concept that provides full-flow support and preconditioning for a potential durable ventricular assist device (VAD) without the need for a thoracotomy in the first line. In addition, ECPELLA 2.0 can also be used as a bridge-to-decision in acute situations, where the treatment concept cannot be determined immediately due to the complexity of a pathology. In conclusion, the ECPELLA 2.0 concept is an innovative treatment for acute CS with relevant advantages as compared to conventional ECLS therapy and up-to-date percutaneous concepts. As these patients often have a complicated postoperative course in ICU, it is imperative to provide swift physical therapy and exercise opportunities for muscle gain that will support recovery.[15] Further studies may follow to collect more data for this concept.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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