

Impella 5.0 supported oncological surgery as bridge to LVAD

Andrea Montisci^{1,2*}, Giancarlo Micheletto^{3,4}, Serena Sibilio², Francesco Donatelli^{2,5}, Maurizio Tespili⁶, Carlo Banfi^{2,5}, Francesco Casilli⁶, Daniele Cosseta¹, Antonio Miceli⁷, Silvia Cirri¹ and Federico Pappalardo^{8,9}

¹Department of Anesthesia and Intensive Care, Cardiothoracic Centre, Istituto Clinico Sant'Ambrogio, Milan, Italy; ²Chair of Cardiac Surgery, Postgraduate in Cardiac Surgery, University of Milan, Milan, Italy; ³Department of General Surgery, Istituto Clinico Sant'Ambrogio, Milan, Italy; ⁴Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy; ⁵Department of Cardiac Surgery, Cardiothoracic Centre, Istituto Clinico Sant'Ambrogio, Milan, Italy; ⁶Department of Interventional Cardiology, Cardiothoracic Centre, Istituto Clinico Sant'Ambrogio, Milan, Italy; ⁷Department of Minimally Invasive Cardiac Surgery, Cardiothoracic Centre, Istituto Clinico Sant'Ambrogio, Milan, Italy; ⁸Advanced Heart Failure and Mechanical Circulatory Support Program, San Raffaele Scientific Institute, Milan, Italy; ⁹Vita-Salute San Raffaele University, Milan, Italy

Abstract

We describe the case of a 58-year-old man presenting with myocardial infarction complicated by cardiogenic shock, treated with Impella CP which was escalated to an axillary 5.0 due to lack of cardiac recovery. Weaning from Impella 5.0 failed, and the patient was evaluated for heart transplantation (HTx) or left ventricular assist device (LVAD). HTx was excluded because of a rectal adenocarcinoma. The patient underwent colorectal surgery while on Impella. Perioperative course was uneventful. After 61 days of Impella, when the LVAD implantation was scheduled, the patient died due to *K. pneumoniae* infection.

Keywords Mechanical circulatory support; Cancer; Left ventricular assist device; Myocardial infarction; Cardiogenic shock

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*Correspondence to: Montisci Andrea, Department of Anesthesia and Intensive Care, Cardiothoracic Center, Istituto Clinico Sant'Ambrogio, Milan, Italy. Email: montisci.andrea@yahoo.it

Introduction

Malignancies concomitant with advanced heart failure (HF) are not rare, due to the sharing of some risk factors. The availability of new systems of mechanical circulatory support made possible the treatment of such patients, previously excluded from therapeutic perspectives.

Case report

A 58-year-old man, current smoker and suffering from arterial hypertension, was admitted to our emergency room with an anterior ST-elevation myocardial infarction (STEMI) complicated by cardiogenic shock (CS). The patient underwent percutaneous transluminal coronary angioplasty and drug eluting stent implantation on the proximal tract of the left anterior descending (LAD) artery and a plain old balloon angioplasty of the LAD distal tract and IABP implantation. Right and circumflex coronary arteries were chronically totally occluded Figure 1ABC. Left ventricular ejection

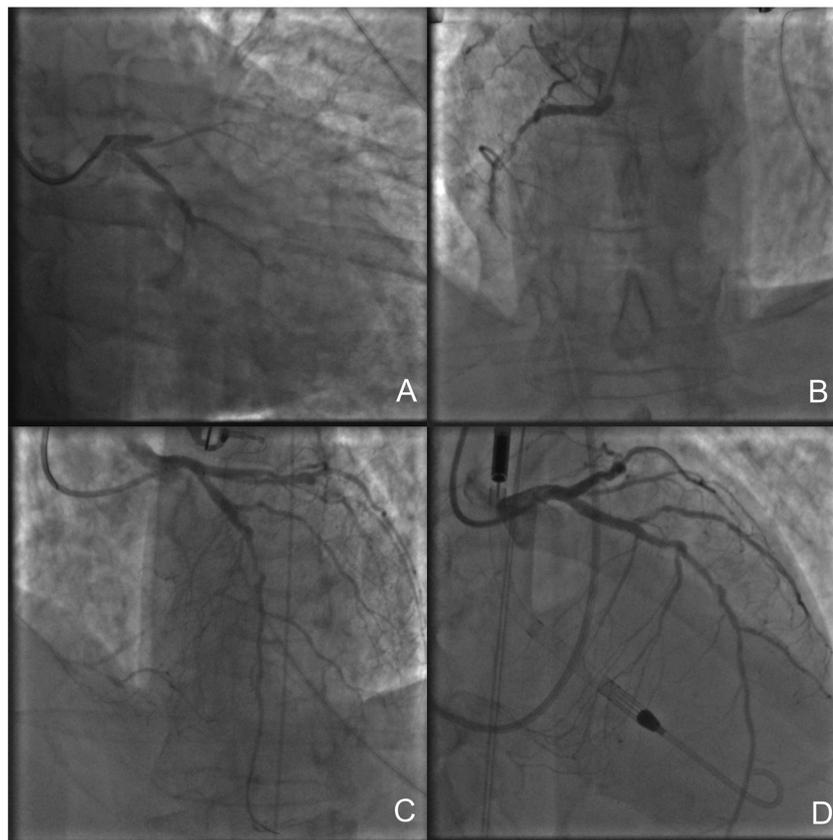
fraction was 25%, mitral regurgitation was moderate whereas right ventricular function was normal.

Six hours later, no reversal of CS was observed, and the patient underwent Impella CP implantation from right femoral artery Figure 1D. The patient received double antiplatelet therapy (DAPT) with acetylsalicylic acid and ticagrelor associated with bivalirudin with an activated partial thromboplastin time target of 60 s.

In 1~week, the patient was weaned from inotropes and mechanical ventilation, but showed no recovery of the heart with signs of HF, prompting Impella 5.0 implantation through the right axillary artery, to ensure full hemodynamic support and extended LV unloading. End-organ damage quickly recovered. After 15 days, no cardiac recovery was noted, and three weaning attempts failed due to acute pulmonary oedema at a still high level (P5) of support.

The patient was then evaluated for heart transplantation (HTx) or left ventricular assist device (LVAD). A colonoscopy was performed after an episode of rectal bleeding, demonstrating an ulcerating lesion with rolled and everted edges 10 cm above the anal orifice, suspected for malignancy. Endoscopic biopsy showed a well-differentiated adenocarcinoma,

Figure 1 (A) basal coronary angiography. (B) Chronic total occlusion of right coronary artery. (C) After left anterior descending revascularization. (D) After Impella CP implantation.



ruling out HTx candidacy. Total-body, contrast-enhanced computed tomography (CT) scan excluded metastases.

After a multidisciplinary discussion, taking into account the risks to proceed to LVAD implantation vs. radical surgery on Impella support, the patient underwent low anterior rectal resection with total mesorectal excision with termino-terminal anastomosis using the Knight–Griffen technique and diverting loop ileostomy.

DAPT was stopped 1 week before and bivalirudin 2 hours before surgery. Intraoperative course was uneventful, with a blood loss <1000 mL and no Impella-related adverse events. Bivalirudin was restarted 4 hours later. Sampled nodes were free from disease. In the following weeks, diurnal spontaneous ventilation, mobilization, and oral feeding were re-established. After 28 days, CT scan and endoscopy showed integrity of the colorectal anastomosis and the patient underwent loop ileostomy closure. LVAD implantation was delayed to allow a full weaning from mechanical ventilation (MV). Unfortunately, on the 58th day of Impella support, the patient presented with high fever, with blood cultures, and bronchoalveolar lavage positive for multi-resistant *K. pneumoniae*. The patient died on the 61th day of Impella support.

Discussion

To the best of our knowledge, this is the first case of major surgery for cancer performed in a patient supported with Impella 5.0.

We faced two main clinical dilemmas, related to the timing of LVAD implantation and the need for long-term Impella support.

LVAD before or after oncologic surgery

In patients listed for HTx, the prevalence of malignancies is up to 6%.¹ In patients with active cancer, LVAD implantation has been described in a limited number of cases.²

International Society of Heart and Lung Transplantation (ISHLT) Guidelines recommend that in patients with active malignancy, LVAD implantation could be considered as a destination therapy after oncologic evaluation and a life expectancy >2 years.³ In our case, CT scan documented the absence of metastases and a low probability of nodes involvement, but the risk of inadequate regional staging was still present, as pelvic nuclear magnetic resonance was not

performed.⁴ Moreover, the patient's clinical status played against LVAD implantation: active intestinal bleeding, which would be further worsened by the detrimental interaction with LVAD hemodynamic and coagulation milieu and the high risk of driveline infection due to the probable need for colostomy or ileostomy.

These considerations convinced us to postpone LVAD implantation, tying the definitive decision about LVAD candidacy with the feasibility of enteric anastomosis and final pathological staging.

The uncomplicated perioperative course for both surgical procedures suggests the feasibility of major surgery during Impella support, with an excellent hemodynamic stability. The perioperative management should be focused on the timing of withdrawal and restart of anticoagulation drugs. In our institution, all patients on mechanical circulatory support receive bivalirudin as anticoagulant therapy. Bivalirudin has no antagonists but a very short and predictable half-life, if renal function is normal.⁵

Length of Impella support

Impella 5.0 received CE mark for a maximum of 10 days of support, but many studies described longer runs, with a maximum of 71 days with Impella 5.0.⁶ Our patient was supported for 61 days, during which all our efforts were directed towards physical rehabilitation, mobilization—promoted by the axillary arterial access—weaning from MV and restart of oral feeding.

No Impella-related adverse events were observed. Specifically the degree of hemolysis was limited, neither pump

displacement nor pump malfunctioning episodes occurred. We did not report any site complication at the axillary arterial access. Our controversial decision to stop DAPT without any bridging therapy raised from the balance between the higher bleeding risk after abdominal surgery and the risk of stent thrombosis in light of the lack of cardiac recovery after weeks of satisfactory cardiac unloading.

Our experience provides some considerations. First, coronary artery disease and many malignancies share some risk factors, making concomitant cancer a concrete possibility.

Second, strict anticoagulation management and continuous evaluation of the pump performance are essential for a safe long Impella run, allowing for thorough evaluation of comorbidities and their treatment in a de novo presentation of advanced HF; indeed, VA ECMO would not be applicable to this scenario.

Third, a high level of attention should be addressed to common causes of death in ICU. The patient presented with several risk factors for nosocomial infection, such as MV, long ICU-stay, immunosuppression, and frailty condition, and his final cause of death was septic shock.

Fourth, IABP implantation as a first line of mechanical support could be criticized as no longer recommended. In the real world, however, the rate of IABP implantation is still high and often left to the physician's discretion, as it still represents the fastest and easiest tool in dealing with CS at its onset.⁷ Our experience suggests new horizons for the use of Impella in patients requiring mechanical support during non-cardiac surgery and the feasibility of prolonged support with Impella 5.0 as bridge to decision in STEMI patients (PROPELLA concept).^{8–10}

References

1. Beaty CA, George TJ, Kilic A, Conte JV, Shah AS. Pre-transplant malignancy: an analysis of outcomes after thoracic organ transplantation. *J Heart Lung Transplant* 2013; **32**: 202–211.
2. Samuels L, Casanova Ghosh E, Domsky S, Droogan C, Samuels M, DeNittis A, Ali Z. Beyond the means of natural selection: a case of end stage heart failure and advanced esophageal cancer successfully treated with an implantable left ventricular assist device (LVAD) and aggressive chemoradiation therapy. *Cardiovasc Disord Med* 2017; **2**: 1–3.
3. Feldman D, Pamboukian SV, Teuteberg JJ, Birks E, Lietz K, Moore SA, Morgan JA, Arabia F, Bauman ME, Buchholz HW, Deng M, Dickstein ML, el-Banayosa A, Elliot T, Goldstein DJ, Grady KL, Jones K, Hryniewicz K, John R, Kaan A, Kusne S, Loebe M, Massicotte MP, Moazami N, Mohacsi P, Mooney M, Nelson T, Pagani F, Perry W, Potapov EV, Eduardo Rame J, Russell SD, Sorensen EN, Sun B, Strueber M, Mangi AA, Petty MG, Rogers J. International Society for Heart and Lung Transplantation. The 2013 International Society For Heart And Lung Transplantation Guidelines for mechanical circulatory support: executive summary. *J Heart Lung Transplant* 2013; **32**: 157–187.
4. Glynne-Jones R, Wyrwicz L, Tiret E, Brown G, Rödel C, Cervantes A, Arnold D. on behalf of the ESMO Guidelines Committee Rectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol* 2017; **28**: 22–40.
5. Van De Car DA, Sunil V, Rao E. Magnus Ohman (2010) Bivalirudin: a review of the pharmacology and clinical application. *Expert Rev Cardiovasc Ther* 2010; **8**: 1673–1681.
6. Batsides G, Massaro J, Cheung A, Soltesz E, Ramzy D, Anderson MB. Outcomes of Impella 5.0 in cardiogenic shock: a systematic review and meta-analysis. *Innovations (Phila)* 2018; **4**: 254–260.
7. Helleu B, Auffret V, Bedossa M, Gilard M, Letocart V, Chassaing S, Angoulvant D, Commeau P, Range G, Prunier F, Sabatier R, Filippi E, Delaunay R, Boulmier D, Le Breton H, Leurent G. Current indications for the intra-aortic balloon pump: the CP-GARO registry. *Arch Cardiovasc Dis* 2018; **12**: 739–748.
8. Tschöpe C, Van Linthout S, Klein O, Mairinger T, Krackhardt F, Potapov EV. Mechanical unloading by fulminant myocarditis: LV-IMPELLA, ECMELLA, BI-PELLA, and PROPELLA concepts. *J Cardiovasc Trans Res* 2019; **12**: 116–123.
9. Bernhardt AM, Zipfel S, Reiter B, Hakmi S, Castro L, Söffker G, Kluge S, Lubos E,

Rybczinski M, Grahn H, Schrage B, Becher PM, Barten MJ, Westermann D, Blankenberg S, Reichenspurner H. Impella 5.0 therapy as a bridge-to-decision option for patients on extracorporeal life support with unclear

neurological outcomes. *Eur J Cardiothorac Surg* 2019; **6**: 1031–1036.

10. Basir MB, Kapur NK, Patel K, Salam MA, Schreiber T, Kaki A, Hanson I, Almany S, Timmis S, Dixon S, Kolski B, National Cardiogenic Shock Initiative

Investigators. Improved outcomes associated with the use of shock protocols: updates from the National Cardiogenic Shock Initiative. *Catheter Cardiovasc Interv* 2019; **7**: 1173–1183.