International Journal of Cardiology 274 (2019) 254–256

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Editorial

Left ventricular support with Impella for high risk percutaneous coronary intervention. The demonstration of the hemodynamic benefit in daily practice

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ARTICLE INFO

Article history:
Received 13 August 2018
Received in revised form 29 August 2018
Accepted 31 August 2018
Available online 6 September 2018

The complexity and risks of Percutaneous Coronary Intervention (PCI) have risen over time due to the expansion of indications for more complex anatomies in a context of technological advances and enhanced life expectancy that increases the number and the average age of patients treated with PCI. Accordingly, patients with more complex coronary artery disease involving multiple vessels, total occlusions, left main lesions, and/or decreased ventricular function are being treated with PCI more frequently. These complex procedures may require multiple and prolonged balloon inflations or additional devices like rotablator, which increases the exposure of at-risk myocardium to ischemia, exacerbation of ventricular dysfunction, and the potential for hemodynamic collapse [1]. In spite of this clear increase in the risk of PCI procedures, there is a lack of consensus of what defines a high-risk PCI. A recent publication proposes a simple definition based on clinical, anatomical and hemodynamic criteria [2] that can simplify this question.

Several efforts have been made in an attempt to reduce the risk of the procedures. In order to protect the myocardium at risk and improve results, a series of left ventricular assist devices were developed in the past decades. Furthermore, thanks to technological improvements, these devices can be inserted percutaneously (percutaneous Left Ventricular Support Devices, pLVSD), avoiding the complications of a central assist device. A recent consensus document regarding the best strategy for decreasing the risk of PCI in high risk patients, suggests the use of left ventricular support devices during these procedures [3].

Intra-Aortic Balloon Pump (IABP) was the first device introduced in 1968. Its physiologic benefits in improving coronary perfusion and reducing afterload were believed to enhance survival in patients with high-risk PCI or cardiogenic shock. The value of IABP in high-risk PCI was assessed in the BCIS-1 (Balloon Pump-Assisted Coronary Intervention Study-1). This randomized trial evaluated patients undergoing elective high-risk PCI (unprotected left main disease, severe LV dysfunction, or large area of myocardium supplied by the target vessel) and reported that elective IABP did not significantly decrease all-cause mortality at 6 months compared to PCI without elective IABP. However, 51-month follow-up data of the BCIS-1 trial showed significant long-term mortality benefit [4]. This data should be interpreted with caution, since all-cause mortality was not the primary end-point and the trial was not designed to address all-cause mortality.

Tandem Heart (TH) is another pLVSD that offers an increased hemodynamic support in comparison with IABP. The value of TH comes from small randomized trials in the setting of cardiogenic shock after an acute myocardial infarction, and although the primary end point was reached (improvement in hemodynamic status: increase in cardiac output and decrease in pulmonary arterial pressure), the clinical end point was not met due to side effects: critical limb ischemia, bleeding, and vascular complications [5].

Impella is a pLVSD that offers potential benefits due to its design. It is a device that can be easily inserted percutaneously with a good balance between safety and efficacy [6]. The data on non-emergent high-risk PCI derived from the randomized trial PROTECT II (Prospective Randomized Clinical Trial of Haemodynamic Support with Impella 2.5 versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention) is the largest randomized comparison of Impella and IABP [7]. The primary composite endpoint of major adverse events (MACE) at hospital discharge or 30 days (whichever came sooner) was similar in both arms. At 90 days, there was a non-significant trend towards a lower MACE rate for the Impella. A redefinition of the endpoint was made, excluding small elevation of biomarkers since it has been shown that they did not influence in the long term prognosis [8], and the results showed a clear benefit in terms of MACE both in the intention-to-treat or per-protocol treatment arm [9]. Furthermore, multivariate analysis showed that treatment with an Impella device was one of the independent factors for a lower MACE at 90 days of follow-up.

DOI of original article: https://doi.org/10.1016/j.ijcard.2018.07.064.
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https://doi.org/10.1016/j.ijcard.2018.08.105

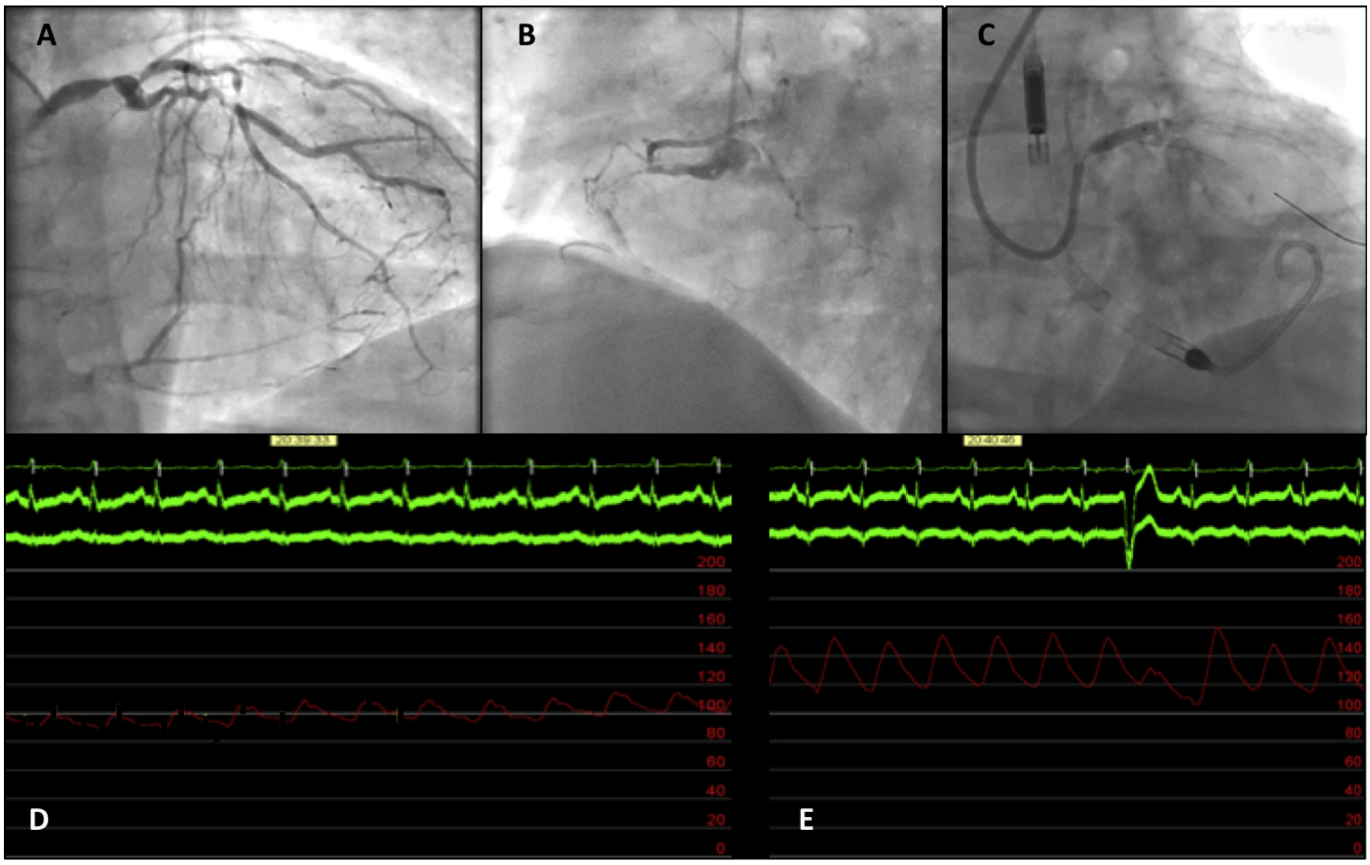

Fig. 1. Example of hemodynamics in a high-risk PCI of an 82 year old patient with left ventricular dysfunction (Ejection Fraction 35%). A: Left coronary angiography showed a severe and calcified lesion in a bifurcated left main trunk, severe lesion in mid segment of left anterior descending artery, and moderate lesions in marginal branch. B: Total occlusion of a dominant right coronary artery. C: PCI was performed with Impella CP support, and this picture shows the balloon dilation of left main. D: Hemodynamics during left main balloon inflation. A decrease on arterial pulsatility is clearly seen, but mean pressure is over 100 mm Hg. E: Image 73 s after the previous one, that shows a recovery of hemodynamics.

In the current issue, an interesting paper from Russo et al. [10], showed the effect of the Impella during the whole PCI procedure, analyzing the internal data of the console in a series of 37 patients with high-risk PCI. The authors extracted some interesting conclusions; first, no malfunction of the Impella was detected. Second, only 10% of the patients experienced critical systemic blood pressure drops during PCI, and these were related to higher jeopardized myocardium and left ventricular diastolic volumes. And third and more important, although significant systemic blood pressure decreases occurred, pressure was systematically maintained at levels warranting vital organ perfusion. These results explain the effect of the Impella device, protecting the myocardium from the deleterious effect of ischemia induced during PCI. The final result is a marked stability of the patient during the whole PCI procedure, data of special relevance in high risk procedures with left ventricular dysfunction.

In our personal experience, the highest efficacy of the Impella device is observed in patients with high-risk PCI, which are in stable hemodynamic condition at the beginning of the procedure. The device keeps the patient in this stable situation every time that an ischemic insult occurs, maintaining a mean arterial pressure during these ischemic periods and avoiding the hypotension induced by the transient episodes of left ventricular dysfunction. During the procedure, when ischemia is produced by balloon inflation or stent implantation, a reduction in aortic wave pulsatility is detected, but with a small decrease in mean aortic pressure (Fig. 1), and a rapid recovery in a few seconds. This stability allows a more complete treatment of the patients (increasing the degree of revascularization) that leads to a decrease in the MACE rate during follow-up.

In conclusion, it is important to recognize which patients are at high-risk before undergoing the procedure in order to reduce it with left ventricular support devices. In this context, the Impella device has a good safety-efficacy profile that makes it a device that can be easily used in the catheterization laboratory to treat patients with high-risk PCI. But, well-designed trials are needed to define the role of pLVSD in this scenario.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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