



Debate: Mechanical circulatory support in relation to coronary intervention. The interventional cardiologist perspective

A debate: Soporte circulatorio en relación al intervencionismo coronario. Perspectiva del cardiólogo intervencionista

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QUESTION: After the IABP-SHOCK II clinical trial, which would you say is the utility of the intra-aortic balloon pump (IABP)?

ANSWER: In my opinion and yet despite the results of the IABP-SHOCK II,¹ the intra-aortic balloon pump (IABP) still plays a significant role in the management of acute myocardial infarction (AMI) and complex percutaneous coronary intervention (PCI) with risks higher than normal.

In high-risk PCIs there is evidence of the benefits derived from using left ventricular assist devices. In the first place, the IABP has shown late benefits in the BCIS-I trial.² This study randomized patients treated with high-risk PCI—defined as a left ventricular ejection fraction < 30% and > 40% of the lesion related myocardium with intention-to-treat—assessed using scores ≥ 8 in the Jeopardy score. The early study found no significant differences in the primary endpoint at the 28-day follow-up. In the secondary endpoint a numerical difference was found in the mortality rate at the 6-month follow-up, although it was not statistically significant (4.6 in the IABP vs 7.4% in the control group; $P = .32$) probably due to the low number of patients included (301). However, at the 51-month follow-up,³ the mortality rate was significantly higher in the control group: 38% (12.1/100 patients/year) vs 27.8% (7.9/100 patients/year). The Kaplan-Meier curves showed a significant difference with a hazard ratio of 0.66 [95% confidence interval, 0.44-0.98; $P = .039$]. In our routine clinical practice, patients undergoing high-risk PCI (left main coronary artery with occluded right coronary artery, multivessel disease with depressed left ventricular function) without a technically complex lesion are treated with IABP support.

On the other hand, in the management of AMI there is no doubt that in the presence of mechanical complications like acute mitral regurgitation or interventricular communication, the IABP improves

the patient's condition as long as he is not in a situation of deep cardiogenic shock. This stabilizes the patient until he is in a better condition to undergo definitive surgery.

In the management of AMIs complicated with cardiogenic shock, the role of the IABP would be limited when the shock has already occurred. However, it may be useful for the early management of those stages when the patient is in a high-risk situation and is starting to show hemodynamic impairment (certain degree of hypotension and tachycardia, but no signs of poor target organ perfusion) to achieve an early stabilization. This is so because it is easy to implant in any critical care unit without having to transfer the patient, and thanks to its safety profile confirmed by its low rate of complications.

Q.: In the congress held by the American Heart Association back in 2019 several observational registries showed more adverse events and higher costs compared with the use of the Impella device compared to the IABP. However, these results may be due to the effect of multiple biases. What do you think of all this?

A.: These studies have been published in *JAMA* and provide different data on the management of patients with post-infarction cardiogenic shock in a retrospective registry.⁴ This was a very large registry of patients with different baseline characteristics despite the fact that propensity score matching was used. After a thorough reading and analysis of the final outcomes, the mortality rate of the group treated with IABP was clearly lower compared to the one reported by randomized studies on the management of AMI with cardiogenic shock. This is indicative of an early selection bias since it was not a randomized study. However, the group treated with a micro-axial pump had a similar mortality rate compared to the one described by the studies.

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We should mention that neither one of the 2 devices showed clinical benefits in this situation compared to standard treatment. This means that the only information provided by that registry is that the least critically ill patients receive an IABP while the most critically ill ones receive a micro-axial flow device. The final outcome shows this early selection bias.

Q.: What is the evidence available on the use of the Impella device in high-risk interventional cardiac procedures? What is the routine clinical practice in your center? And in patients with infarction and cardiogenic shock?

A.: The Impella device has proven useful for the management of high-risk PCIs in the PROTECT II trial.⁵ This study randomized patients undergoing high-risk PCIs—defined as left main coronary artery disease or last patent vessel disease with an ejection fraction $\leq 35\%$ or 3-vessel disease with an ejection fraction $\leq 30\%$ —eligible to receive an IABP circulatory support device or an Impella 2.5 device. Regarding major cardiovascular events (all-cause mortality, myocardial infarction, stroke or new revascularization), the Impella 2.5 device obtained better results and even showed preventive properties in a multivariate study. If we analyze the study data thoroughly, we can see that its greatest advantage was the lower rate of new revascularizations in part due to the fact that with the Impella device we can treat more complex lesions during the index procedure.

In light of the results from these studies our indications for ventricular support in patients undergoing elective or high-risk PCIs (severe ventricular dysfunction with left main coronary artery disease plus right coronary artery occlusion or 3-vessel disease) are:

- Technically easy lesion: intra-aortic balloon pump.
- Technically complex lesion: Impella 2.5 device.

Q.: What escalation of mechanical circulatory support do you recommend in hemodynamically compromised patients or patients with post-infarction cardiogenic shock?

A.: The definition and fast detection of patients who have suffered an AMI is very important. In this sense, the Society for Cardiovascular Angiography and Intervention (SCAI) proposed a new classification of patients after AMI with a series of clinical, analytic, and hemodynamic criteria.⁶ This classification in stages has proven that there is a clinical correlation with the mortality rates shown by these patients.⁷ Thus, the stages of hemodynamic impairment can be described as:

- A (At risk): without hemodynamic impairment.
- B (Beginning): hypotension and tachycardia, without hypoperfusion.
- C (Classic): hypoperfusion without general impairment.
- D (Deteriorating): hypoperfusion with impairment, non-refractory.
- E (Extremis): refractory shock.

Currently, there are different types of hemodynamic support with different characteristics regarding the mechanism of action and the effects it has on the heart and coronary circulation.⁸ Every device

offers different hemodynamic support and is associated with a different rate of complications. That is why the risk-benefit ratio should be taken into consideration depending on each patient's hemodynamic impairment. In my view, the different devices may be indicated for the following stages:

- Intra-aortic balloon pump: stages A and B.
- Impella 2.5 device: stage B.
- Impella CP device, 5.0: stage C.
- Extracorporeal membrane oxygenation (ECMO): stages D and E.

In general, the degree of support required may be defined in a different way:

- Coronary support (refractory ischemia): intra-aortic balloon pump.
- Ventricular support (pulmonary edema): Impella device.
- Circulatory support (correct hypotension): ECMO.

CONFLICTS OF INTEREST

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