



## Debate: Mechanical circulatory support in relation to coronary intervention. Cardiologist's perspective from the cardiac intensive care unit

### *A debate: Soporte circulatorio en relación al intervencionismo coronario. Perspectiva del cardiólogo de la unidad de críticos*

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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:** The IABP-SHOCK II<sup>1</sup> did not show any benefits in the 30-day mortality rate or major complications rate when the IABP was compared to conventional therapy in patients with post-infarction cardiogenic shock undergoing primary percutaneous coronary intervention (PCI). No differences were found either in the mortality rate or quality of life of survivors in the studies conducted at 12-month<sup>2</sup> and 6 year-follow-up.<sup>3</sup>

European guidelines<sup>4</sup> downgraded the systematic use of IABP to a class IIIb level of evidence leaving the indication IIa for the management of infarct related mechanical complications. This decreased the use of IABP in the routine clinical practice. However, it is still used in critical care units because it is easy to use, can be implanted quickly, and is cheaper compared to other devices.

Taking into account the limitations of these studies and although we do not use it systematically in our center like we used to years ago, we still implant it as the first-line strategy for the management of infarct related mechanical complications. Also, in patients with extensive acute myocardial infarction (IAM) and hemodynamic instability because it improves coronary perfusion and increases the cardiac output.

**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 observational registries revealed a higher rate of adverse events, and higher costs associated with the use of the Impella device compared to the IABP. However, they have some

limitations: they mixed different types of Impella devices (2.5, CP, and 5) and different etiologies of cardiogenic shock. Also, in most of the patients the device was implanted after the primary percutaneous coronary intervention. In one of these registries that would later be published in *Circulation*,<sup>5</sup> patients implanted electively with the Impella device in the cardiogenic shock setting were also included.

We have been getting more and more data that the management of cardiogenic shock through the creation of specialized units, invasive hemodynamic monitorization, and implantation of the Impella CP device prior to the PCI improves the results of revascularization and reduces the size of the infarction and the 30-day mortality rate in patients with post-infarction cardiogenic shock. Some studies like the Detroit shock initiative<sup>6</sup> and the national cardiogenic shock initiative<sup>7</sup> have already discussed this theory.

Currently, several randomized clinical trials are trying to come to terms with this hypothesis: the Danger shock trial<sup>8</sup> (support with Impella CP prior to the PCI vs conventional therapy in the management of post-infarction cardiogenic shock), the RECOVER IV (Impella before PCI vs PCI without Impella in the management of infarction related cardiogenic shock), and the STEMI DTU (ClinicalTrials.gov NCT03947619) (Impella CP and PCI delayed 30 min. vs immediate PCI in patients with ST-segment elevation acute myocardial infarction of anterior location without shock). The latter is based on the results from a pilot study on safety and feasibility. The DTU-STEMI pilot trial<sup>9</sup> proved that it is safe and feasible to perform a PCI 30 min. after LV (left ventricular) unloading with the Impella CP device in patients with anterior AMI without shock.

Regarding high-risk PCIs, the PROTECT-II trial<sup>10</sup> that randomized 452 patients who underwent high-risk PCIs with IABP or Impella 2.5 support showed no differences in the cardiovascular events occurred at the 30- and 90-day follow-up. However, fewer

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adverse events were seen at the 90-day follow-up in the Impella 2.5 group.

The PROTECT IV study is underway (Impella as support for high-risk PCI vs PCI without hemodynamic support). It will start in 2021 and it will be part of the clinical evidence for the class I recommendation for the Impella device in high-risk PCIs.

The results of the studies currently underway are promising because I think it is LV unloading prior to the PCI that will certainly improve the mortality of post-infarction cardiogenic shock. To this day and until proven wrong, I strongly believe that the Impella CP implanted prior to the PCI is the device of choice for the management of post-infarction cardiogenic shock.

Until we have more data available, I think high-risk PCIs should be handled individually based on the characteristics of the patients and the experience of the heart teams with these devices and in the management of complex PCIs.

**Q.:** Is your center savvy in the use of extracorporeal membrane oxygenation (ECMO)? What evidence exists for its use in the management of cardiogenic shock in patients with infarction? What studies would be needed in this context to consolidate its indication?

**A.:** Some of the advantages of the ECMO device are that it is easy to use and can be implanted quickly. Its main hemodynamic effect is an increased mean arterial blood pressure that is higher compared to other devices. However, this advantage is precisely the cause for its most important limitation: the problem of LV unloading in relation to an increased afterload. This increases myocardial oxygen demand and produces deleterious effects on the size of the infarction and its potential recovery. From the pathophysiological point of view, it is not a good device for the management of post-infarction cardiogenic shock.<sup>11</sup> Its basic role rests in its hemodynamic effect and improved organ perfusion; that is, it is indicated for patients in INTERMACS 1 situation. To overcome the limitation of inadequate LV unloading, the best option is to add an Impella device that is capable of producing the most powerful hemodynamic effect for LV unloading in ECMO.<sup>12</sup>

Our center is highly experienced in the use of ECMO for the management of cardiogenic shock of any known etiology. We use it for the management of patients with post-infarction deep cardiogenic shock (INTERMACS 1) in the coronary care unit before or after the primary percutaneous coronary intervention. In these patients we initially implant the IABP to improve LV unloading. If the balloon is insufficient, the next step is to add an Impella device.

There are no randomized studies available on the use of ECMO for the management of post-infarction cardiogenic shock. We'll have to wait for the results from other devices. If the hypotheses formulated prove right, ECMO will play a significant role in the management of patients with AMI in whom the Impella device is insufficient or in hospitalized patients with hemodynamic compromise used in combination with the Impella device to overcome the limitation of inadequate ventricular unloading.

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

**A.:** I think the first thing to do is to include cardiogenic shock in specialized units experienced in the management of these patients and use of this type of devices. The right selection of patients, invasive hemodynamic monitorization, and use of inotropes for

stabilization purposes is of paramount importance until early device implantation.

With the current data and taking into account the costs of the different devices and the complications associated there are different considerations to be made when choosing one device over the other:

- Patients with extensive infarction and pre-shock, mechanical complications or ventricular arrhythmias: IABP.
- Patients without deep shock (INTERMACS 2): Impella CP prior to the percutaneous coronary intervention and, if not enough support is achieved, add ECMO.
- Patients in deep shock (INTERMACS 1): ECMO combined with balloon or Impella device if there are problems unloading the left ventricle.

## CONFLICTS OF INTEREST

None reported.

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