Percutaneous mechanical circulatory support in cardiogenic shock
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PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT VERSUS INTRA-AORTIC BALLOON PUMP FOR TREATING CARDIOGENIC SHOCK: META-ANALYSIS

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In patients with cardiogenic shock after acute myocardial infarction (AMI), mortality remains high despite advances in treatment. Short-term percutaneous circulatory support devices provide superior hemodynamic support compared with the intraaortic balloon pump (IABP). American guidelines have downgraded the recommendation for usage of the IABP from Class I to IIa, and European guidelines to Class III. Both American and European guidelines endorse usage of other mechanical assist devices that provide more hemodynamic support. The Impella platform (Abiomed, Danvers, Massachusetts) is a frequently used percutaneous circulatory support device providing from 2.5 to 5.0 l/min depending on the model used. A few randomized controlled trials have compared the Impella device with IABP. All trials were underpowered to adequately evaluate mortality. Therefore, we pooled the data from these trials to compare Impella with IABP on 30-day and 6-month all-cause mortality and left ventricular ejection fraction (LVEF) during follow-up. If the endpoint was not available in the original paper, the data was provided by the investigators. All measurements of LVEF closest to 6 months were included, independent of the imaging modality.

There were 3 randomized controlled trials comparing Impella with IABP in cardiogenic shock after AMI. Inclusion criteria of the 3 trials were slightly different, as the definition of cardiogenic shock was different in each trial. One trial aimed for inclusion of pre-shock patients, excluding full-blown cardiogenic shock; 1 trial applied the generally used SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial criteria; the other trial aimed for inclusion of mechanically ventilated severe shock patients. Two trials compared IABP with the Impella 2.5 (2.5 l/min), and 1 trial with the Impella CP (3.5 l/min).

A total of 95 patients were randomized to either Impella (n=49) or IABP (n=46). As reported in Figure 1, there was no difference in all-cause mortality between the patients treated with Impella or IABP at 30 days (relative risk [RR]: 0.99; 95% confidence interval [CI]: 0.62 to 1.58; p=0.95) and at 6 months (RR: 1.15; 95% CI: 0.74 to 1.48; p=0.53). Data on LVEF during follow-up was available in 47 patients. Seyfarth et al. measured LVEF by angiography at 6 months (not previously published), Ouweneel et al. reported cardiac magnetic resonance measurements at 4 months and Ouweneel et al. reported echocardiography after 2 months. There was no difference in LVEF between Impella and IABP-treated patients during follow-up (mean difference -2.6%; 95% CI: -9.1 to 3.8; p=0.42).

This meta-analysis of 3 randomized controlled trials comparing Impella with IABP shows no difference in 30-day and 6-month all-cause mortality. Also, no difference was observed in LVEF between surviving IABP- and Impella-supported patients. Although the Impella has repeatedly shown to provide more hemodynamic support than the IABP, this did not translate into improved clinical outcomes in these very sick patients who have a high mortality risk.
Our findings should be interpreted with caution. First, the studies included relatively unselected patients. To some extent, this may result in an almost “all-comer” shock population with the risk of underestimating the effect of increased circulatory support in patients that may benefit more than the relatively high number of resuscitated patients in all trials. It is possible that a subgroup of patients may benefit from support with the Impella device. Cohort studies have shown that earlier initiation of Impella support, even before revascularization of the occluded artery, is associated with reduced mortality\(^4\); this is supported by experimental studies that have shown that pre-revascularization Impella initiation is associated with reduced infarct size in improved left ventricular function.\(^5\) It is, therefore, important to note that the vast majority of patients enrolled in the studies were treated with mechanical support therapy after revascularization. How-

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**Figure 1** Meta-analysis showing the relative risk of 30-day and 6-month all-cause mortality with the use of Impella and IABP.

Relative risks and 95% confidence intervals are presented of the individual trials as well as the pooled analysis for (top) 30-day and (middle) 6-month all-cause mortality. (Bottom) Difference in left ventricular ejection fraction (LVEF) with 95% confidence intervals.
ever, large randomized controlled trials or large-scale observational studies are needed to show which patients may benefit from this therapy. Another contributing factor is the fact that cardiogenic shock after AMI is complex, and patients experience not only cardiac ischemia but also diminished organ perfusion, anoxic brain damage, and systemic inflammatory responses. Therefore, providing more hemodynamic support only may not be enough to save these very ill patients, and the addition of other therapies may yield better outcomes. This meta-analysis is limited by the relatively small number of included studies and patients and by the inclusion of studies with different inclusion criteria for the severity of the cardiogenic shock (from pre-shock to severe shock). Also, the studies differed in the usage of the kind of Impella device (Impella 2.5 and Impella CP). The Impella 2.5 has gone through several improvements and recently received U.S. Food and Drug Administration approval on the basis of data from the USpella registry.

In conclusion, although there is only limited data available, this meta-analysis shows no difference in mortality or LVEF in cardiogenic shock patients who are treated with Impella compared with IABP. A pooled analysis comprising undersized studies may mitigate the true effect, but in the absence of largescale, sufficiently sized trials, pooled data are the next best source of evidence.

REFERENCES


