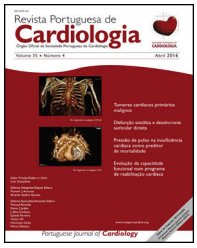
Revista Portuguesa de Cardiologia 40 (2021) 863–864

Portuguese Society of CARDIOLOGY

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org



EDITORIAL COMMENT

Impella support – Over- or underused?

Suporte ventricular com Impella – Sobre ou subutilizado?

Holger Thiele

Heart Center Leipzig at University of Leipzig, Department of Internal Medicine/Cardiology and Leipzig Heart Institute, Leipzig, Germany

In cardiogenic shock complicating acute myocardial infarction the only evidence-based treatment strategy proved to reduce mortality is revascularization of the infarct-related coronary artery.[1–3] Intensive care specialists and interventionalists are searching for additional ways to reduce the persistently high mortality in these cases, which is still in the range of 40-50%.[4] Since intra-aortic balloon pump (IABP) support fails to reduce mortality,[5–7] the next step is the increasing use of more potent active mechanical circulatory support devices, including microaxial left ventricular assist devices such as the Impella family, in the treatment of cardiogenic shock.

The Impella devices draw blood from the left ventricle and pump it into the ascending aorta and thus generate forward blood flow from the left ventricle to the aorta. The devices unload the left ventricle and theoretically improve forward blood flow. In general, this is appealing, as mechanical circulatory support can improve the perfusion of critical organs such as the heart, brain, and kidneys and may thereby reduce mortality. However, any invasive measure is also associated with complications.

Since sufficiently powered randomized trials of mechanical circulatory support devices are scarce,[8] large-scale registry studies with propensity matching represent an important data source and a way to provide additional evidence. However, these propensity-matched studies have also failed to show a mortality benefit with the Impella device. One comparison did not show a mortality reduction – while showing more complications – between Impella-treated patients and propensity-matched patients derived from the IABP-SHOCK II trial.[9] Furthermore, two other US reports matching Impella patients to IABP patients even showed a mortality increase with Impella versus IABP, once again accompanied by more complications such as major bleeding in Impella-treated patients.[10,11]

In this issue of the *Journal*, Brandão et al. report findings from a single-center retrospective observational study using Impella support for cardiogenic shock treatment and also for support during high-risk percutaneous coronary intervention (PCI).[12] In line with previous reports, in-hospital, 30-day and one-year mortality in cases of cardiogenic shock were high at 58.3%, 66.6% and 83.3%, respectively. The same was true for high-risk PCI, for which one-year mortality reached 20%.

These data should prompt discussion as to whether appropriate patient selection has been performed in this analysis and also previous analyses. Still, patient selection is key and no objective criteria are available to classify patients into those who do not need mechanical circulatory support

DOI of original article: https://doi.org/10.1016/j.repc.2020.12.012
E-mail address: holger.thiele@medizin.uni-leipzig.de

because they would survive anyway, those who will derive benefit, and those in whom the situation is futile and even the best device in the world will be unable to change the outcome.[4]

The study by Brandão et al. questions the approval of such devices without showing evidence for improvement in outcomes and challenges the increasingly frequent use of these Impella devices. The conflicting and insufficient evidence for active mechanical circulatory support in cardiogenic shock as well as in high-risk PCI supports the need for large clinical trials to more definitively assess this important issue. Several ongoing clinical trials are currently examining the use of mechanical circulatory devices, including the Danish-German cardiogenic shock trial (DanGer), n=360 (NCT01633502)[13]; the Extracorporeal Life Support in Cardiogenic Shock (ECLS-SHOCK) trial, n=420 (NCT03637205)[14]; the Assessment of ECMO in Acute Myocardial Infarction Cardiogenic Shock (ANCHOR) trial, n=400 (NCT04184635); and the Testing the Value of Novel Strategy and Its Cost Efficacy in Order to Improve the Poor Outcomes in Cardiogenic Shock (EUROSHOCK) trial, n=428 (NCT03813134).[15] For high-risk PCI the PROTECT IV trial, n=1252 (NCT04763200), is under way.

The results of these trials will hopefully help to define the appropriate use of mechanical circulatory support devices in cardiogenic shock and also during high-risk PCI. However, until reliable evidence from randomized trials is available, the study by Brandão et al., together with other registry studies, give reasons to restrict the use of these devices.

Conflicts of interest

The author has no conflicts of interest to declare.

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