

Intra-aortic balloon pump applications and coronary revascularization in cardiovascular clinics.

Author's reply

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Dear Dr. Engin and Dr. Guvenç,
Thank you very much for your interest in our article entitled "Hemodynamic effects of larger volume intra-aortic balloon pump during high-risk percutaneous coronary intervention" [1]. We respond to your questions with great pleasure.

This was a single-center, prospective, and randomized study. We used an online randomization tool (using multiple permuted blocks) to assign the consecutive high-risk patients scheduled by the local Heart Team for percutaneous coronary intervention (PCI) to one of the three study groups with the following interventions: a) PCI without hemodynamic support; b) PCI with a standard volume intra-aortic balloon pump (IABP) and finally c) PCI with a larger volume balloon. Since some patients did not meet all our inclusion and exclusion criteria (as shown in Supplementary material, *Figure S1*) but still their PCIs were deemed high-risk, we performed these interventions according to the protocol without a support device and only in a few cases with a larger balloon and included this cohort for final per-treatment analysis.

We know that the IABP is a relatively weak hemodynamic support device and accordingly, it does not affect short-term mortality in high-risk PCI [2]. But in our view, contrary to cardiogenic shock, in elective high-risk PCI, mortality is not a good efficacy marker. For the operator, it is important to have stable patient hemodynamics to be able to perform all the planned interventions and optimization, which might affect long-term rather than early major adverse cardiovascular events, as was shown in the 5-year results of the

BICIS-1 trial [3]. Indeed, in our previous work concerning the same cohort, we were able to show that MEGA balloon use was associated with a reduction in composite hemodynamic endpoint [4]. So, we think, that excluding extreme patients, an IABP of larger volume might be a good (and cheaper) alternative to Impella devices.

Peripheral arterial disease was an exclusion criterion only if we knew that severe ilio-femoral disease was previously diagnosed. In some cases, we were unable to place an IABP because of severe lesions that were not diagnosed before randomization. At present, our daily practice is to have in all patients some form of visualization (preferably computed tomography angiography). We did not use peripheral intervention to facilitate placement of an IABP.

We did not use the axillary route for IABP placement. In Poland, there is experience in some centers with an Impella placed percutaneously via the axillary artery with very good results and low complication rates in cases when peripheral access is unavailable [4, 5].

The heart failure definition was clinical. Although majority of patients had low (<35%) ejection fraction, they were not classified as heart failure if their predominant symptom was angina instead of dyspnea or fatigue. We agree that EuroScore II was very high in our cohort, which means that the patients had a high surgery risk. On the other hand, the SYNTAX Score was also high denoting high PCI risk. In every case, we asked for a Heart Team consultation, and it was the cardiac surgeon who decided if a patient was not suitable for coronary artery bypass grafting. This is our de-

fault strategy to have an agreement between a cardiologist and a cardiac surgeon before complex and high-risk PCI.

We hope our explanation has answered your questions. Once more. thank you for your interest in our study.

Article information

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