Percutaneous assist devices vs. intra-aortic balloon pump for cardiogenic shock: evidence under construction vs. expert opinion

With great interest, we read the meta-analysis by Cheng et al.1 The authors evaluated percutaneous left ventricular assist device (pLVAD) therapy vs. intra-aortic balloon pump (IABP) therapy in cardiogenic shock (CS). The authors found that pLVADs provided superior haemodynamic support when compared with the IABP. However, no benefit could be demonstrated with regard to 30-day mortality.

From the results of the present meta-analysis, the authors conclude that pLVAD therapy should not be the first choice of treatment in CS and it should not replace IABP therapy. These statements are in accordance with the current American and European ST-elevation myocardial infarction (STEMI) guidelines. However, some issues may need to be addressed with regard to these conclusions.

First of all, in a recently published meta-analysis of available evidence for IABP usage, both in the setting of high-risk STEMI and CS, no benefit could be demonstrated with regard to mortality or left ventricular function.2 In fact, more complications were observed in patients treated with IABP.

Another issue with respect to the current meta-analysis is the fact that two very different pLVADs are compared. The majority of patients (74 of 100) were randomized to TandemHeart vs. IABP. As emphasized by the authors, complication rate is high in TandemHeart-treated patients. Contrariwise, complication rate as reported in the current analysis is much lower with the Impella LP2.5, confirming previous safety and feasibility results.3

Finally, an important issue is the sample size of the current meta-analysis, as acknowledged by the authors. Although randomized trials are included in this meta-analysis, it is underpowered with regard to mortality. When including 100 patients, absolute mortality difference would have to be 28% to obtain significance. To detect an absolute 10% decrease in mortality, almost 800 patients would have to be included in a randomized trial when assuming 80% power and α = 0.05.

Several randomized trials are currently ongoing to evaluate mechanical circulatory support. One trial compares IABP support with medical therapy alone for STEMI with CS (www.clinicaltrials.gov NCT00491036). In another trial, the Impella LP2.5 is compared with IABP therapy in STEMI patients with cardiogenic pre-shock (www.trialregister.nl NTR 1079).

As stated by the authors, the currently available evidence shows that pLVADs provide superior haemodynamic support when compared with IABP, although there is no evidence for a beneficial effect on survival. Therefore, we agree with the authors that currently, pLVADs cannot be recommended for first line circulatory support. Nevertheless, this conclusion holds true for IABP usage as well.

Currently, there is no clinical evidence supporting the use of any mechanical device, including the IABP, in the setting of STEMI with haemodynamic compromise. Therefore, the use of any device may be considered on the basis of expert opinion while awaiting randomized evidence.

References

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Percutaneous assist devices vs. intra-aortic balloon pump for cardiogenic shock: evidence under construction vs. expert opinion: reply

We thank the colleagues from Amsterdam for their interest in our meta-analysis on the safety and efficacy of mechanical assist devices in cardiogenic shock.1 They raised some important issues, which we address below.

First, although current American and European ST-elevation myocardial infarction guidelines supported the use of IABP counterpulsation as method of first choice for mechanical assistance in cardiogenic shock, we agree with the authors that evidence supporting the use of IABP is somewhat fragile, as was demonstrated by their recent meta-analysis.2

This lack of evidence especially holds for patients with cardiogenic shock from acute myocardial infarction who undergo primary percutaneous coronary intervention. Our meta-analysis clearly showed that the use of a percutaneous LVAD provides superior haemodynamic support relative to IABP. However, the benefit on haemodynamics associated with the use of a percutaneous LVAD did not translate into improved 30-day survival, possibly by higher complication rates. Therefore, we concluded that, at the moment, percutaneous LVADs cannot be recommended for routine clinical practice. Because much more experience has been obtained using IABPs,3 and taking into account the very high costs of percutaneous LVADs, we argue to stick to the IABP in the time coming while awaiting further studies.

Second, we agree with the authors that complications rates of the TandemHeart should not be mixed up with those of the

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