Cardiogenic shock: to pump or not to pump?

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This editorial refers to ‘A systematic review and meta-analysis of intra-aortic balloon pump therapy in ST-elevation myocardial infarction: should we change the guidelines?’†, by K.D. Sjauw et al. on page 459

Cardiogenic shock complicating acute myocardial infarction still has a grim prognosis, with a mortality rate of ∼50%.1,3 Over the last 10 years a steady reduction in mortality has been observed, which is mainly attributed to the increase of percutaneous coronary intervention (PCI) for reperfusion.2 Another method considered to improve mortality is the use of intra-aortic balloon pumping (IABP) for mechanical assistance, with a class IC recommendation in the current European Society of Cardiology guidelines and a class IB recommendation in the American College of Cardiology/American Heart Association Guidelines.4,5

Despite the high class recommendation, the rate of IABP use in cardiogenic shock patients is only 20–30% as an international average.2,6 Assuming a 5–8% incidence of cardiogenic shock of all hospitalized acute myocardial infarctions, this translates into ∼40 000–50 000 cases per year in the USA and ∼60 000–70 000 cases in Europe.8 Thus, altogether 70 000–96 000 cardiogenic shock patients per year do not receive IABP although it is recommended by guidelines. This is mainly influenced by reimbursement policies and by the fact that many cardiologists believe: ‘There is little evidence from randomized, controlled, clinical trials for the clinical benefit of IABP in cardiogenic shock.’ The treatment with IABP is a typical example of adoption of a treatment based on a concept which becomes clinical practice. The principle reason for the lack of evidence is that IABP was introduced prior to the strong regulations by the regulating authorities, namely the FDA. In the absence of such requirements, studies to demonstrate the safety and clinical utility of an assist device are typically not performed because they are very costly, and after introduction such a study is difficult to perform because any negative result might be thought to jeopardize the current profit arising from this product despite the overwhelming potential.

Sjauw et al. have comprehensively reported the current evidence on IABP support for ST-elevation myocardial infarction without and with cardiogenic shock in two separate meta-analyses.9 The first meta-analysis including seven randomized trials (n = 1009) showed neither a 30-day survival benefit nor improved left ventricular ejection fraction with IABP use, while being associated with higher stroke and bleeding rates. Interestingly, the indication for IABP use in high-risk ST-elevation myocardial infarction without cardiogenic shock is not mentioned in current guidelines, which is supported by the results of this meta-analysis.4,5 The second meta-analysis including nine cohorts of patients with cardiogenic shock after acute myocardial infarction (n = 10 529) revealed mixed results. In patients treated with fibrinolysis, IABP was associated with a significant 18% decrease in 30-day mortality. However, the younger age and the significantly higher PCI rate in IABP patients compared with patients without IABP support might be relevant confounders explaining these results. In contrast, patients treated with primary PCI had a 6% higher mortality at 30 days, which is mainly influenced by the results of the National Registry of Myocardial Infarction-2.6 The different effects of IABP with different reperfusion regimens in this meta-analysis clearly show that there must be other confounders and selection bias in the decision to use the IABP. Although Sjauw et al.9 performed careful analyses to ensure that their results are not influenced by publication bias and provided useful explanations for the different observed effect, unequivocal evidence for the use of IABP in cardiogenic shock is still lacking.

Irrespective of the type of guideline recommendation, IABP use has become a mature technology four decades after its introduction. It improves peak diastolic pressure and lowers the end-systolic pressure, which translates into a reduction of afterload and improved coronary perfusion with concomitant increase in myocardial oxygen supply. Owing to the ease of percutaneous implantation, the relatively low cost, and the beneficial haemodynamics at a low complication rate, it has become the most common mechanical cardiac assistance method in intensive care medicine. As long as we do not have any other evidence from randomized, controlled, clinical trials we should not change our current practice because the beneficial haemodynamic effects of the IABP should outweigh any potential hazard.

Randomized clinical trials in cardiogenic shock are difficult to perform and are costly. However, as acute myocardial infarctions

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† doi:10.1093/eurheartj/ehn602
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are frequent and cardiogenic shock is inherited with high mortality, any intervention which reduces mortality is likely to have major public health implications and should be thoroughly tested.

In the era of evidence-based medicine, such trials are therefore of paramount importance to achieve a break-through in the treatment of cardiogenic shock complicating acute myocardial infarction. Recently, trials have been published showing improved haemodynamics for tilarginine and also for active circulatory assist devices without effects on outcome. Therefore, we have to realize that an improved haemodynamic status might not be a suitable surrogate marker for survival. Future studies assessing any mechanical assist device or drug need therefore to be judged according to their clinical efficacy. This is true for the IABP and for any other ventricular assist device. Due to rapid developments in ventricular assist device technology, several percutaneous implantable assist devices have become available and are being used more and more. However, as underscored by the IABP meta-analysis by Sjauw et al., for these new devices too we need evidence from properly powered, randomized, controlled clinical trials with regard to their effect on outcome, before they are heralded as a new therapeutic option.

Based on a small randomized pilot study, which showed beneficial effects on brain natriuretic peptide with similar effects on the change in the APACHE-2 score, a large properly powered, randomized, clinical trial has recently started (www.clinicaltrials.gov: NCT00491036) which will hopefully give us the answer to whether IABP treatment is beneficial for the treatment of cardiogenic shock in addition to PCI.

In conclusion, Sjauw et al. are to be commended for performing this important analysis which summarizes the current (small) evidence for IABP use. Taking the limitations of this meta-analysis into account, these observations are credible but should not have clinical implications unless data from large randomized controlled clinical trials are published.

Conflict of interest: H.T. received lecture fees from Dataspase, Germany.

References


