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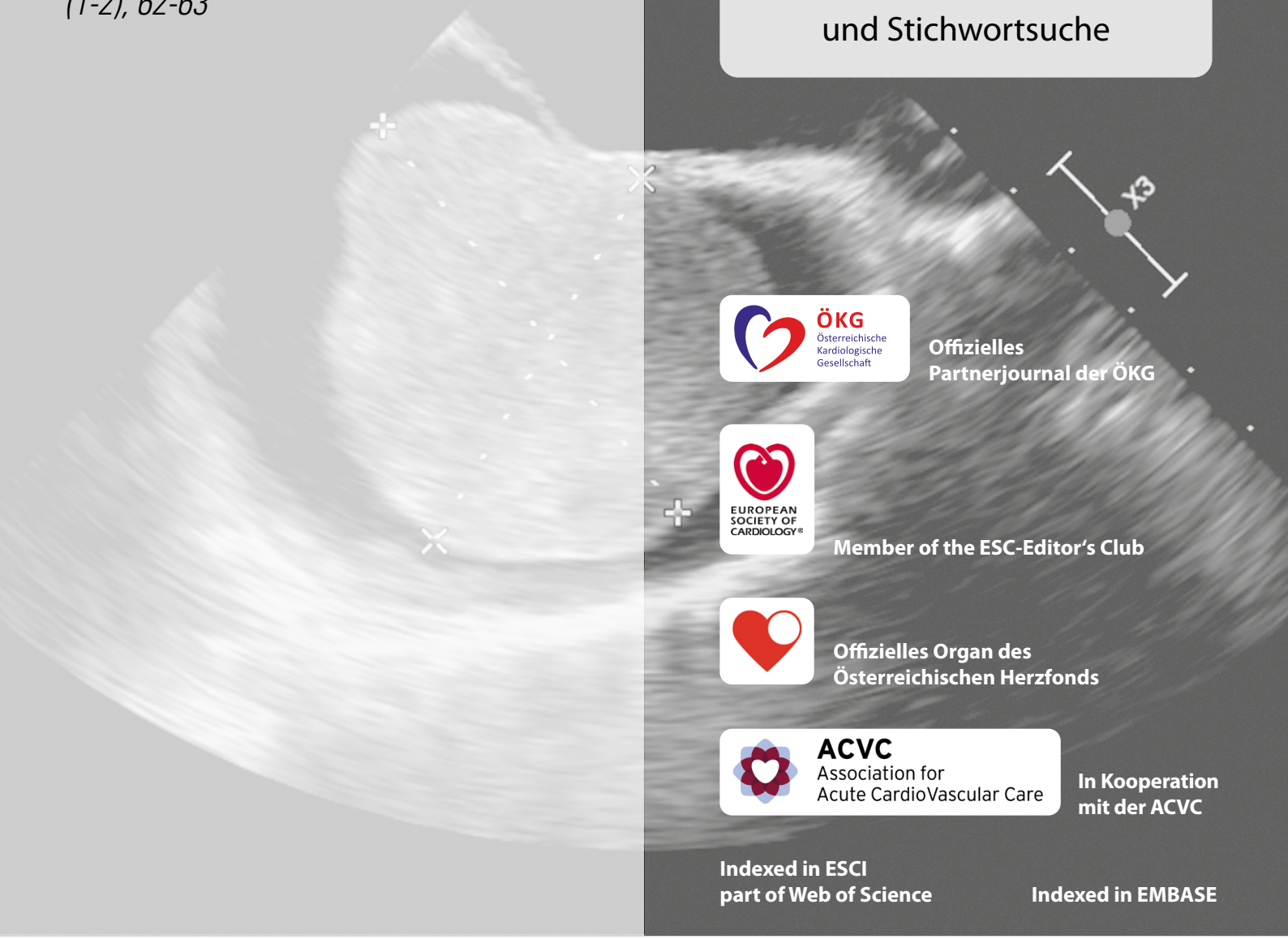

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Acute Cardiovascular Care: Intraaortic balloon support for myocardial infarction with cardiogenic shock*

Holger Thiele, MD; on behalf of the IABP-SHOCK II Trial Investigators

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Acute Cardiovascular Care Association ACCA
A Registered Branch of the ESC

Approximately 5–10% of patients after an acute myocardial infarction present with cardiogenic shock. In Europe approximately, 60,000 to 70,000 patients present with cardiogenic shock each year. In the last decade the mortality of cardiogenic shock patients could be reduced mainly by early revascularization. Nevertheless, mortality of these patients is still extremely high with approximately half of the patients dying within the first 30 days.

Since 1968 intraaortic balloon counterpulsation is used to support the failing heart in cardiogenic shock. This intraaortic balloon pump (IABP) is the most widely used support device in cardiogenic shock and since its introduction in 1968 the IABP has been used in several million people. However, currently there is only limited proof of evidence that such an IABP, one of the oldest medical products in cardiology, is beneficial for the patient. There are only some registry studies and also some trials which have shown that the IABP can improve the blood pressure and also the perfusion of the coronary arteries. Based on these studies, international guidelines recommended using an IABP in patients with cardiogenic shock with a class IB in the American and class IC in the European guidelines. However, because cardiologists are not entirely convinced by the device it is currently only used in 25–40% of shock patients.

Therefore, the IABP-SHOCK II trial was started and it aimed to show that the IABP can improve mortality if used in conjunction with optimal medical therapy and early revascularization.

In this IABP-SHOCK II trial altogether 600 patients were randomly assigned to either support with the IABP or conventional optimal medical treatment alone. With 600 included patients the IABP-SHOCK II trial is currently the largest trial in cardiogenic shock that has been performed, so far. Because of its importance the trial was supported by the German Research Foundation, the German Heart Research Foundation, the German Cardiac Society, the "Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte", and also partly funded by unrestricted grants from Maquet Cardiopulmonary AG, Hirrlingen, Germany and Teleflex Medical, Everett, MA, USA.

Figure 1. Participating centres in Germany.

Patients with cardiogenic shock were enrolled in 37 centres in Germany (see Figure 1) within the last 2 and half years. This trial was a German multicenter trial which was led be the lead investigator Professor Dr. Holger Thiele, from the University of Leipzig – Heart Centre in Germany. The hypothesis of the lead investigators was that the IABP could reduce mortality within 30 days.

Against the initial assumption, there was no reduction in 30-day mortality in the IABP group in comparison to a group without IABP treatment. Several subgroups were also evaluated and there was no clear benefit for any of the subgroups studied. The IABP could also not show an improvement in blood pressure, a reduction in the length of treatment at the intensive care unit or in the length or the dose of drugs for the support of the heart. Also on organ perfusion and tissue hypoxemia as measured by serial serum lactate measurements there were no improvements with the IABP in comparison to the control group. On the other hand, the trial results showed that the IABP did not induce complications. It was a safe device.

* Nachdruck aus http://www.escardio.org/communities/ACCA/publications/top-stories/Pages/intraaortic-balloon-support-cardiogenic-shock.aspx – 1. ACCA Newsletter der European Society of Cardiology, TOP Story, mit freundlicher Genehmigung von E. Delaveau, ACCA Administrator der ESC.

In conclusion, the IABP-SHOCK II trial is the largest clinical trial in cardiogenic shock ever perwformed. The current trial could not show a benefit for the currently most widely used mechanical supporting device in cardiogenic shock.

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Pro Comment by Prof. Marco Tubaro, MD FESC, San Filippo Neri Hospital, Rome, Italy

In many studies, intra-aortic balloon pumping (IABP) showed to improve the haemodynamic parameters in patients with acute myocardial infarction (AMI) and cardiogenic shock (CS): cardiac index and mean arterial pressure increased and systemic vascular resistance decreased with IABP [1]. Complete reversal of systemic hypoperfusion with IABP was linked to mortality at 30 days and 1 year. Prophylactic IABP can prevent reocclusion of the infarct-related artery and improve overall clinical outcome, without an increase of major bleedings. In 1999, the AHA STEMI guidelines gave a class I indication for IABP in CS.

As mortality is concerned, already in the year 2000 the SHOCK Trial Registry demonstrated that a wide application of IABP (86% of the patients) and of an invasive strategy reduced significantly 6-month and 1-year mortality rates [2]. With thrombolytic therapy, IABP consistently showed a sinergistic effect, both in the SHOCK Registry and in the data from the National Registry of Myocardial Infarction (NRMI)-2 [3]. The Benchmark Registry [4] confirmed the synergistic effect of IABP and reperfusion, with a reduced mortality with PCI (18.8%) or CABG (19.2%), in comparison with medical therapy (33.2%).

IABP can be particularly useful in hospitals without primary PCI facilities, to improve cardiac haemodynamics during patients' transfer to a tertiary care cardiac centre. In case of a long transfer time, a strategy of thrombolysis and IABP, followed by an immediate transfer for PCI/CABG, may be appropriate.

IABP was studied also in patients with AMI without CS: in the CRISP-AMI trial, even if the infarct size (evaluated with cardiac magnetic resonance) was not reduced by IABP application, both mortality and combined end-point at 6 months were reduced in patients with anterior AMI treated with IABP [5]. About 8.5% of patients in the study crossed over from the non-IABP group to the IABP group: this could support a "stand-by" strategy of IABP application only when needed, in comparison with a routine IABP use.

Moreover, IABP showed very good results in BCIS-1 trial [6] on patients with ischaemic cardiomyopathy and severe CAD. The 6-month mortality risk showed a 34% relative risk reduction (RRR) with IABP (HR 0.66; 95%-CI: 0.44–0.98).

In the recent metanalysis of Sjauw et al. [7], 3 out of 4 groups of patients with STEMI and CS showed favourable results with IABP: patients treated with thrombolysis, patients without reperfusion therapy and the overall group. As the primary PCI group is concerned, in which no benefit was shown, it is well possible that confounding factors have curtailed a possible IABP beneficial effect: the study was not a randomized controlled trial (RCT) and it is not possible to exclude that the worse patients have been assigned to primary PCI treatment.

Even in the latest RCT on AMI patients with CS (IABP-SHOCK II trial) [8], the group randomized to IABP support presented an absolute risk reduction of death at 30 days of 1.4% (RRR 4.1%), without any increase in complications (major bleeding, peripheral ischaemia, stroke, sepsis). Moreover, being the IABP-SHOCK II population a group with CS at moderate risk (40% global mortality at 30 days), it may well be possible that better results could be achieved in higher risk cohorts.

Finally, in comparison with a left ventricular assist device (LVAD) like the Tandem Heart, IABP presented the same mortality rate, with a reduced incidence of severe bleeding and limb ischaemia [1].

The current STEMI guidelines give to IABP in STEMI patients with CS a class IIaB indication in USA and a class IIbB indication in Europe. Even if a reduction of mortality has not been demonstrated with IABP in association with primary PCI, the bulk of evidence and the everyday clinical practice are in favour of the use of IABP as haemodynamic support in patients with AMI and CS non immediately responsive to volume expansion and inotropic stimulation. The same use of IABP in case of AMI mechanical complications as a bridge to intervention is clearly indicated.

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Con Comment by Prof. Uwe Zeymer, Klinikum Ludwigshafen, Germany

Early revascularization therapy has been shown to improve outcome of patients with acute myocardial infarction complicated by cardiogenic shock, but mortality in these patients re-

mains high. Current ESC guidelines recommend the use of IABP in patients with cardiogenic shock with an IIb indication [1]. In clinical practice in Europe the utilization rate of IABP is low (15–30%) [2]. However, one reason for the overall low utilization rate of IABP might be that interventionalists are not fully convinced about the beneficial effect of IABP on top of early revascularization therapy. This scepticism is supported by a recent randomized trial, the IABP-Shock II study [3]. The largest randomized trial in patients with cardiogenic shock so far found no benefit of the IABP in patients with STEMI complicated by cardiogenic shock treated with primary PCI. Although IABP use was safe and not associated with an increase in complications such as sepsis, vascular complications or bleedings neither mortality nor any secondary endpoints were improved with IABP use. Secondary endpoints included hemodynamic parameters (blood pressure and heart rate) pre and post revascularization, serum lactate levels measured every 8 h for 48 h, inflammatory markers, Simplified Acute Physiology Score-II (SAPS-II) measured daily during intensive care treatment, and serial creatinine-level and creatinine-clearance using the Cockcroft-Gault-formula. Furthermore, process of care outcomes such as time to hemodynamic stabilization, dose and duration of catecholamine therapy, requirement for renal replacement therapy, length of intensive care unit stay, requirement and length of mechanical ventilation, and requirement for active (percutaneous or surgical) left ventricular assist device implantation or heart transplantation were assessed and did not differ between the two groups. Therefore in highly experienced centers the use of IABP was safe but did not improve outcome. The small 1.4% difference in mortality in favour of IABP was far from reaching statistical significance and given the negative results in all secondary endpoints it is highly unlikely that 6- or 12 months results will show a significant benefit for IABP.

The results are supported by a recent meta-analysis [4] and finding from registries [2, 5–7]. If anything than IABP as adjunct to primary PCI was associated with an adverse outcome. In experimental models and human experience IABP increased myocardial perfusion and improved hemodynamics. But these factors seem not to be crucial in patients with early PCI for cardiogenic shock. The multi-organ distress syndrome induced by the shock seems to play a more important role once successful reperfusion has been achieved by PCI or CABG. IABP clearly is not beneficial in this respect.

What indications remain for IABP. With any doubt the use is indicated in patients with mechanical complications as bridge to surgery. It might be beneficial in combination with fibrinolysis. However, since fibrinolysis is only recommended if primary PCI is not available, one can hardly imagine a situation where PCI is not available but only an IABP. The finding the younger patients might benefit from IABP in the IABP-Shock II trial [3] is hypothesis generating, and should be replicated in a dedicated prospective trial. So far IABP might be considered in selected younger patients without hemodynamic improvement after successful revascularization.

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