angiography reduces the overall length of stay in the hospital and also allowed for the direct discharge from the emergency room. At the same time, there was no decrease in the overall cost of care and increased radiation exposure.

Now putting these results in proper perspective, the patients of ROMICAT II had an average age of 54 years, 47% were women, all had normal ECG's and all had normal troponin levels. With all these parameters, the probability of occurrence of coronary artery disease itself is so low that whether one needs to do further testing at all in these patients can be questioned and most definitely cannot be recommended as a general policy for all. Most of us would probably not ask for any investigations beyond a few hours of observation, some serial ECGs and a troponin level at the end of it all!

If you want to consider this from country wise perspective then for a country like the USA where even one missed coronary event can lead to a lawsuit, protective medicine will probably result in this study leading to CTA becoming part of the emergency room protocols for chest pain. This type of protective medicine fortunately is not yet practiced in India.

If we look at the cost of care of chest pain (excess of Rs 2 lakhs!), then perhaps a CTA within a few hours of admission cutting down the cost of admission could be one new way of looking at this issue but then this was not the question addressed in this study.

At the same time one should not discount the utility of coronary CT angiography in select situations in the emergency room, where you want to be very confident about the coronary anatomy (e.g. VIP or faculty colleague or relative) or where a patient keeps coming back and will not be convinced without a normal report, then a CTA is the answer.

So, in conclusion, in most situations especially as a public policy, simple observation and clinical testing would be better than CTA, though a CTA should always be available for selected situations.

Sandeep Seth*
Additional Professor, Department of Cardiology, All India Institute of Medical Sciences, New Delhi 110029, India

Namit Gupta
Senior Research Officer, Department of Cardiology, All India Institute of Medical Sciences, New Delhi 110029, India

**Corresponding author*. Tel.: +91 11 26594970.
E-mail address: drsandeepseth@hotmail.com

H. Thiele, U. Zeymer, F.J. Neumann, et al. Intraaortic balloon support for myocardial infarction with cardiogenic shock. N. Engl. J. Med. (2012)10,1056/NEJMoa1208410

"By failing to prepare you are preparing to fail." — Benjamin Franklin

Intra-aortic balloon counter-pulsation (IABP) is one of the most commonly used haemodynamic support device in the setting of haemodynamic instability complicating myocardial infarction. IABP support gets class I recommendation for this condition even though the evidence for such recommendation is scarce. In the IABP SHOCK II trial 600 patients with acute myocardial infarction and cardiogenic shock undergoing early revascularization were randomised to IABP and no IABP. IABP use was not associated with any significant difference in the 30-day mortality or hospital stay. At 30 days, 39.7% of the IABP patients and 41.3% of controls had died ($p = 0.69$). Interestingly, there was no IABP related side effects in the IABP group. Most of the patients (86.6%) received IABP immediately after the procedure and 10% patients in no IABP arm crossed over to IABP arm. There was no difference in the primary end point of mortality among the various subgroups of age, gender, type of MI and blood pressure.

Major limitations in this study as discussed in the accompanying editorial were a relatively smaller sample size and a lower mortality rate as compared with other contemporary trials. This makes it a relatively moderate risk group where benefit of IABP may be lower than in high risk patients. A 10% crossover rate is another limiting factor, although on treatment analysis after accounting for the crossover, also failed to prove benefit for IABP use.

Perspective

Fifty years after first technical demonstration of the utility of IABP at the Cleveland clinic, several serious questions are being raised regarding the efficacy of IABP. Although IABP is a class I recommendation for refractory cardiogenic shock as per ACC/AHA and ESC guidelines, the evidence for the use of IABP is mainly from small randomised studies or retrospective analysis. The basic haemodynamic principle of IABP is improvement in diastolic coronary perfusion and systolic unloading of the heart. Intuitively this principle appears quiet promising in the setting of STEMI with cardiogenic shock but has failed on clinical grounds. A meta-analysis published in 2009 also failed to show any benefit for IABP in the setting of primary PCI with cardiogenic shock.

Two more trials published recently have failed to show any benefit for IABP in the setting of anterior wall STEMI and complex PCI. Counter-pulsation to Reduce Infarct Size Pre-PCI-Acute Myocardial Infarction (CRISP-AMI) trial randomised 337 patients with stable AWSTEMI who underwent primary PCI with/without IABP support. There was no difference in the 30-day and 6 months death or MI rates between the two groups. Assessment of infarct size by cardiac MRI 4 days after MI was also not different. Second trial, Balloon-Pump Assisted Coronary Intervention Study (BCIS)-1 randomised patients with low EF and undergoing PCI, to IABP and no IABP. It had shown no difference in the risk of major adverse cardiac and cerebrovascular events (MACCE) at the time of hospital discharge among patients treated with IABP when compared with those who did not receive counter-pulsation. However, long term results of this study after a median follow up of 51 months have shown a 34% reduction in the mortality.

The three trials mentioned earlier have studied the utility of IABP in complex PCI, STEMI and cardiogenic shock, with none of them supporting the use of IABP in these conditions. Registry data from Cath-PCI registry has shown no difference

in the outcomes among the hospitals with frequent use of IABP for complex PCI versus hospitals with less use of IABP. This registry has analysed data from more than 180,000 patients who underwent complex PCI with use of IABP in about 19,000 (10.5%) procedures.

Although, believers of IABP may have one or other criticism for these trials but the fact remains that these are (especially IABP SHOCK II) large randomised trials and they have failed to show benefit of IABP use consistently. These results will have impact on the IABP usage in the coming years and researchers will have to look for new protocols/algorithms to decide about the need for IABP in a particular patient. The only comforting point for IABP use is that there were no IABP related complications. This will give IABP users some leverage to use it on a case to case basis as it is not doing any harm.

Neeraj Parakh
Assistant Professor of Cardiology, All India Institute of Medical Sciences, New Delhi, India
E-mail address: neerajparakh@yahoo.com

Anouar Belkacemi, Pierfrancesco Agostoni, Hendrik M. Nathoe, Michiel Voskuil, ChunLai Shao, Eric Van Belle, Thierry Wildbergh, Luigi Politi, Pieter A. Doevendans, Giuseppe M. Sangiorgi, Pieter R. Stella. First results of the DEB-AMI (drug eluting balloon in acute ST-segment elevation myocardial infarction) trial: a multicentre randomized comparison of drug-eluting balloon plus bare-metal stent versus bare-metal stent versus drug-eluting stent in primary percutaneous coronary intervention with 6-month angiographic, intravascular, functional, and clinical outcomes. J. Am. Coll. Cardiol. 59 (2012) 2327–2337

Objectives: The goal of this study was to compare angiographic, intravascular imaging, and functional parameters, as well as the clinical outcomes of patients treated with drug-eluting balloon (DEB) plus bare-metal stent (BMS) versus BMS versus drug-eluting stent (DES) for ST-segment elevated acute myocardial infarction (STEMI).

Background: Concerns remain regarding the long-term safety of DES in STEMI. DEB could provide an attractive alternative in order to achieve potentially similar effectiveness but limiting the long-term hazards related to late-acquired stent malapposition and thus stent thrombosis.

Methods: In this randomized, international, 2-center, single-blinded, 3-arm study, STEMI patients were randomly assigned to group A: BMS; group B: DEB plus BMS; or group C: DES after successful thrombus aspiration. The primary endpoint was 6-month angiographic in-stent late-luminal loss. Secondary endpoints were in-stent binary restenosis, major adverse cardiac events (MACE: cardiac death, myocardial infarction, target vessel revascularization). In a subgroup of patients, stent (mal) apposition (by optical coherence tomography) and endothelial function (by acetylcholine infusion) was assessed.

Results: Overall, 150 patients were randomized. Procedural success was achieved in 96.7%. In groups A, B, and C, respectively, late-luminal loss was 0.74–0.57 mm, 0.64–0.56 mm, and 0.21–0.32 mm (p–0.01); binary restenosis was 26.2%, 28.6%, and 4.7% ($p - 0.01$); and MACE rates were 23.5%, 20.0%, and 4.1% ($p - 0.02$), respectively. The median percentage [25th–75th interquartile range] of uncovered and malapposed stent struts per lesion was 0 [0–0.35], 2.84 [0–6.63], and 5.21 [3.25–14.5] ($p - 0.01$). Significant paradoxical vasoconstriction was seen in groups B and C.

Conclusions: In STEMI patients, DEB followed by BMS implantation failed to show angiographic superiority to BMS only. Angiographic results of DES were superior to both BMS and DEB. Moreover, DEB before implantation induced more uncovered and malapposed stent struts than BMS, but less than after DES.

Perspective

The main findings of this randomized, multicentre study are: 1) DIOR DEB failed to demonstrate angiographic superiority over BMS, with similar late-luminal loss and binary restenosis rates; 2) DES showed significantly better angiographic and clinical results compared with both DEB and BMS; and 3) DEB had significantly more combined uncovered and malapposed struts compared with BMS, but less compared with the DES group.

DEB appeared to be an attractive option in the treatment of STEMI in combination with a BMS because of the following theoretical advantages: 1) homogeneous distribution of the drug to the vessel wall, especially at the area of the culprit plaque, whereas the DES delivers the drug only in the proximity of its struts; 2) better angiographic results, and hence less need for TLR; 3) less malapposition, with potentially less stent thrombosis with respect to DES; 4) preservation of endothelial function with respect to DES; and 5) possibly less prone to the potential clinical consequences in case of shortened dual antiplatelet duration, or in patients incapable of adhering to 12-month dual antiplatelet therapy. Notwithstanding these potential advantages, the DEB used in this study failed to prove superior angiographic outcomes.

Moreover the percentage of uncovered and malapposed struts as seen on OCT suggest that there is a drug effect induced by DEB that shows morphological changes compared with BMS alone. The DES group showed even more pronounced morphological changes. These results may suggest that the DEB did induce some effects on neointimal proliferation as demonstrated by OCT; however, they were insufficient to cause enough inhibition of the process to reduce late-luminal loss as compared with the BMS group.

Also, the acetylcholine testing findings in the present study point toward a drug effect in DEB-treated patients. After incremental acetylcholine infusions, paradoxical vasoconstriction occurred in the DEB- and DES-treated patients, with insignificantly more pronounced vasoconstriction in DEB compared with DES. By contrast, endothelial function in the BMS group was stable after incremental acetylcholine concentrations.

Our opinion

Primary PCI with DES has been shown to be better than BMS in reducing TLR without an increased risk of stent thrombosis in