Intra-aortic balloon pumps do not reduce infarct size in patients with STEMI without cardiac shock

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Intra-aortic balloon pump counterpulsation prior to PCI in patients with ST segment elevation MI does not reduce infarct size as measured by MRI, according to results from the Counterpulsation Reduces Infarct Size Acute Myocardial Infarction (CRISP AMI) trial.

Intra-aortic balloon counterpulsation is a procedure in which a balloon inserted in the aorta is timed to inflate at the start of diastole and to deflate before the start of systole. This increases diastolic pressure, which increases coronary perfusion and oxygen delivery to the myocardium, and facilitates ejection of blood from the left ventricle. There is evidence that LV unloading before reperfusion can reduce the extent of the infarct; infarct size has been shown to predict LV function after AMI.

Principal investigator Dr Manesh Patel from the Duke Clinical Research Institute of Duke University, Durham, USA, explained: "Animal studies had suggested that inserting a balloon pump before opening the vessel would reduce the heart's workload and, by doing so, could potentially reduce infarct size. However, having tested this observation in humans, we did not show similar results."

CRISP AMI was a multicentre, prospective, randomised trial in patients with acute ST segment elevation MI without shock. They were recruited within six hours of chest pain onset and planned primary PCI. Of the

337 patients enrolled, 161 were randomised to receive intra-aortic balloon counterpulsation (IABC) prior to primary PCI, and 176 to standard care (SOC, primary PCI without IABC support).

The primary efficacy endpoint of the trial was infarct size measured by cardiac MRI at 3-5 days post-PCI. The secondary clinical endpoint was the composite of major adverse clinical events including death, reinfarction, and heart failure at six months.

Results showed that mean infarct size was not significantly different between the IABC and SOC groups (42.1% vs. 37.5%, representing the percentage of left ventricle affected). At 30 days, major bleeding or transfusion had occurred in five (3.1%) of IABC patients and three (1.7%) of SOC patients. Major vascular complications occurred in seven IABC (4.3%) and two SOC (1.1%) patients. By six months, death had occurred in three (1.9%) of the IABC and nine (5.2%) of the SOC group.

While the study did not meet its primary endpoint, and was not powered to draw significant conclusions on clinical events, Dr Patel says the results nevertheless offer an insight into the treatment of STEMI patients. "The most striking observation is the excellent overall outcome for the highest risk patients within the context of this trial," he says. "The IABC group had less than 5% mortality, and it's difficult to improve that. We've become very good at treating AMI patients." In the USA acute mortality risk in AMI is between 6% and 15%; one-year mortality is estimated at 38% for women and 25% for men.

Dr Patel adds that 15 of the patients in the SOC group crossed over to receive IABC, and five patients crossed over prior to PCI and ten patients after PCI. "While this trial shows that the routine use of IABC cannot be recommended in STEMI, physicians should be vigilant about identifying those patients who are at risk for rapid deterioration and may

benefit from counterpulsation," he says.

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