also similar, including freedom from cardiac death (96.7% vs 97.1%; p=0.68), recurrent MI (98.6% vs 97.9%; p=0.30), and repeat revascularization (91.6% vs 89.2%; p=0.10).

Although the comparison of the primary endpoint was neutral, there were reductions in key secondary endpoints with DES compared with BMS, including reductions in the rates of definite or probable stent thrombosis (0.9% vs 2.6%; p=0.01) and definite stent thrombosis (0.5% vs 1.9%; p=0.01).

The results of this study support the 2010 European Society of Cardiology guideline preference for DES over BMS in patients who have no contraindications to prolonged DAPT. More specifically, the findings of the EXAMINATION trial are consistent with the existing literature that demonstrates the safety and efficacy of DES for use in patients with STEMI. A particular strength of this study is the inclusion of all-comer STEMI patients, resulting in a cohort that is generalizable to clinical practice. In addition, it is one of the first trials that have evaluated EES, a newer-generation DES, in such a broad population.

The observation of a reduction in definite and definite or probable stent thrombosis in this modestly powered single-blind trial requires validation. In applying results to clinical practice, it should be noted that there was high utilization (90%) of DAPT through 1 year.

IABP Do Not Reduce Infarct Size in Patients with STEMI without Cardiac Shock: The CRISP AMI Trial

Written by Rita Buckley

Intraaortic balloon pump counterpulsation (IABP) prior to percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction (STEMI) does not reduce infarct size, as measured by magnetic resonance imaging (MRI), according to results from the Counterpulsation Reduces Infarct Size Acute Myocardial Infarction trial. Manesh Patel, MD, Duke University, Durham, North Carolina, USA, reported outcomes from the study [Patel MR et al. *JAMA*. 2011; CRISP AMI; NCT00833612].

CRISP AMI was an open-label, multicenter, randomized, controlled trial that included 337 patients with STEMI that involved the anterior wall who presented within 6 hours of chest pain onset and without cardiogenic shock. Patients were randomly assigned to receive IABP, which was placed prior to PCI and continued for at least 12 hours, or primary PCI with IABP used as "bailout," if necessary.

The objective of the study was to determine if routine IABP placement prior to reperfusion in patients with anterior STEMI without shock reduces myocardial infarct size. The primary outcome was infarct size, expressed as a percentage of left ventricular (LV) mass, as measured by cardiac MRI that was performed 3 to 5 days after PCI. Secondary endpoints included all-cause death at 6 months, rates of vascular complications, major bleeding, and transfusions at 30 days.

A total of 337 patients were randomized to either IABP prior to PCI (n=161) or standard PCI with "bailout" IABP if necessary (n=176). PCI was successfully performed in 94% of patients, and the left anterior descending artery was the target vessel in 97.6%. The crossover rate (patients in the standard PCI group who required IABP due to hemodynamic instability) was 8.5% (n=9).

Mean infarct size was not statistically significantly different between the patients in the IABP plus PCI group and in the standard PCI group (42.1% [95% CI, 38.7% to 45.6%] vs 37.5% [95% CI, 34.3% to 40.8%], respectively; p=0.06). Results were similar in the subgroup of patients with proximal left anterior descending disease and TIMI flow scores of 0 or 1 (46.7% [95% CI, 42.8% to 50.6%] vs 42.3% [95% CI, 38.6% to 45.9%], respectively; p=0.11).

At 30 days, there were no significant differences between the treatment groups with respect to major vascular complications (4.3% [95% CI, 1.8% to 8.8%] vs 1.1% [95% CI, 0.1% to 4.0%]; p=0.09) and major bleeding or transfusions (3.1% [95% CI, 1.0% to 7.1%] vs 1.7% [95% CI, 0.4% to 4.9%]; p=0.49) for IABP plus PCI versus standard PCI. At 6 months, there was no significant difference in outcomes, including mortality (p=0.12) and the composite of death, MI, or congestive heart failure (p=0.15).

Overall, this trial showed no benefit in terms of infarct size reduction in the use of routine IABP prior to PCI in patients with anterior STEMI. In addition, no significant differences between the IABC plus PCI group and the standard PCI group were observed in clinical endpoints. The authors concluded that the routine use of IABC in patients with anterior wall STEMI without cardiogenic shock does not lead to a reduction in infarct size at Days 3 to 5 or to an improvement in clinical outcomes at 6 months.

New Observations from STICH

Written by Anne Jacobson

Mitral valve (MV) repair during coronary artery bypass grafting (CABG) may be associated with improved survival compared with CABG alone in patients with low left

ventricular ejection fraction (LVEF) and moderate to severe mitral regurgitation (MR), according to new findings from the Surgical Treatment for Ischemic Heart Failure trial [STICH; NCT00023595].

Marek A. Deja, MD, Medical University of Silesia, Katowice, Poland, reported results from a subanalysis of the STICH trial in patients with MR.

In the STICH study, 1212 patients with LVEF <35% who were suitable candidates for CABG were randomly assigned to CABG (n=610) or medical therapy alone (n=602). In the primary analysis, there was no difference in all-cause mortality between CABG and medical therapy alone (36% vs 41%; HR, 0.86; 95% CI, 0.72 to 1.04; p=0.12). While the primary result was neutral, CABG was associated with reductions in some secondary endpoints, including the risk of cardiovascular (CV) death (28% vs 33%; HR, 0.81; 95% CI, 0.66 to 1.00; p=0.05) and the composite endpoint of all-cause mortality or CV hospitalization (58% vs 68%; HR, 0.74; 95% CI, 0.64 to 0.85; p<0.001) [Velazquez EJ et al. *N Engl J Med* 2011].

At baseline, MR was present in 64% of patients and classified as mild, moderate, and severe in 46%, 15%, and 3% of the patients who were randomized in STICH, respectively, underscoring the high prevalence of MR in candidates for CABG. The decision of whether or not to treat MR was left to the surgeon. In the current analysis, investigators examined the relationship of MR severity and survival and compared outcomes in patients with moderate–severe MR who received mitral repair versus those who did not.

In patients who were randomized to medical treatment, mortality was higher in patients with increasingly more severe MR (30% with no/trace MR, 47% with mild MR, 55% with moderate–severe MR). Compared with patients with no or trace MR, patients with moderate or severe MR had nearly double the risk of death from all causes (HR, 1.97; 95% CI, 1.37 to 2.83), while those with mild MR had a 60% increase in all-cause mortality (HR, 1.60; 95% CI, 1.18 to 2.18).

After 6 years of follow-up, CABG was not associated with decreased mortality relative to medical therapy alone in patients with no or trace MR (28% vs 30%; HR, 0.87; 95% CI, 0.61 to 1.24); however, CABG was associated with a reduced risk of death in patients with mild MR (31% vs 47%; HR, 0.64; 95% CI, 0.48 to 0.85).

In the small subgroup of patients with moderate or severe MR (n=195), there was no survival advantage with CABG compared with medical therapy alone (HR, 0.86; 95% CI, 0.57 to 1.29) or with CABG and mitral repair (HR vs medical therapy 1.13, 95% CI, 0.69 to 1.86). However, after adjustment for baseline prognostic variables, the combination of CABG and MV repair was associated with a lower hazard of mortality compared with CABG alone (HR, 0.45; 95% CI, 0.23 to 0.90) and was associated with a trend toward lower mortality compared with medical therapy alone (HR, 0.66; 95% CI, 0.40 to 1.11).

The authors conclude that in patients with severe left ventricular dysfunction and mild MR, CABG alone improves survival, while in patients with moderate–severe MR, adding mitral repair to CABG tends to decrease perioperative risk and increase survival compared with CABG alone or medical therapy alone.

ASCOT-LLA: Statin Legacy Felt with Reduced Non-CV Death Eight Years After Trial End?

Written by Anne Jacobson

Prior treatment with atorvastatin is associated with a reduction in the risk of all-cause mortality compared with placebo 8 years after the early termination of the Anglo-Scandinavian Cardiac Outcomes Trial—Lipid-Lowering Arm (ASCOT-LLA) and 11 years after initial randomization, according to new findings from a long-term follow-up study.

In 2003, an interim analysis of ASCOT-LLA showed that atorvastatin significantly reduced the risk of coronary heart disease (CHD; RRR 36%) and stroke (RRR 27%) compared with placebo in patients with hypertension who were also receiving antihypertensive treatment, leading to an early termination of the trial [Sever PS et al. *Lancet* 2003]. The subgroup of patients who were enrolled in the United Kingdom (UK) cohort of ASCOT-LLA was then followed for an additional 8 years after trial termination on open-label therapy, as selected by the local health care provider. Peter S. Server, MD, FRCP, Imperial College, London, UK, presented mortality results for the entire 11-year follow-up period since initial randomization in ASCOT-LLA.

In the ASCOT-LLA randomized trial, 10,305 patients with hypertension and a total cholesterol level of ≤6.5 mmol/L (250 mg/dL) were randomly assigned to atorvastatin 10 mg or placebo. After a median follow-up of 3.3 years, the trial was terminated due to overwhelming benefit with atorvastatin, with a reduction in the primary endpoint of nonfatal myocardial infarction (MI) and fatal CHD of 36% compared with placebo (HR, 0.64; 95% CI, 0.50 to 0.83; p=0.0005). At that time, there was no significant difference between groups in terms of either all-cause mortality (HR, 0.87; 95% CI, 0.71 to 1.06) or cardiovascular (CV) mortality (HR, 0.90; 95% CI, 0.66 to 1.23).