Continued from page 17

In subgroup analyses, neither postprandial TG level nor fasting TG level was associated with outcome in patients with impaired glucose tolerance. In the subgroup of patients with normal glucose metabolism, however, fasting TG as well as postprandial TG kinetics (area under the curve and the relative postprandial increase) was associated with the primary endpoint. They remained independent predictors in those patients in the highest tertile of TG versus the lowest after adjustment for baseline characteristics, metabolic parameters, and CV risk factors (fasting TG >150 mg/dL vs <106 mg/dL; HR, 3.10; 95% CI, 1.06 to 9.06; p=0.04; relative postprandial TG increase >210% vs <171%; HR, 4.45; 95% CI, 1.33 to 14.91; p=0.02).

The outcomes that were observed in the subgroup with normal glucose tolerance are generally consistent with a recently released scientific statement from the American Heart Association [Miller M. *Circulation* 2011], which states that TG levels appear to provide unique information as a biomarker of risk, especially when combined with low high-density lipoprotein cholesterol and elevated low-density lipoprotein cholesterol. The statement acknowledges the pivotal role that TG plays in lipid metabolism and reaffirms that it is not directly atherogenic due to its association with atherogenic remnant particles and apo CIII.

While overall this study did not show an association between postprandial TG level and outcome after adjustment for known risk factors, the authors noted that there is an association with CV events in the subgroup of patients with CAD and normal glucose tolerance. Commenting on the findings, Prof. Laufs observed, "It seems that glucose tolerance determines triglyceride pharmacokinetics." Fasting and postprandial TG values independently predicted CV events in patients with CAD and normal glucose tolerance.

Several important aspects of this trial should be noted when applying these findings in clinical practice, including a modest cohort size, a high rate of statin use (95%), a broad primary endpoint that includes diverse outcomes that may or may not be modified by TG level, and the use of a specific protocol for TG and glucose tolerance assessment. The interesting relationship of TG and outcomes in the subgroup of patients with normal glucose tolerance should be confirmed by independent outcome studies, though HCS is by far the largest study using a comprehensive metabolic test protocol to date. In summary, fasting TGs and – with superior risk prediction – postprandial TGs correlate with CV events in patients with CAD and normal glucose tolerance but do not independently predict CV outcomes in patients with impaired glucose metabolism.

EXAMINATION: Similar Outcomes with New-Generation DES Compared with BMS for Patients with Acute STEMI Undergoing PCI

Written by Anne Jacobson

For patients with acute ST elevation myocardial infarction (STEMI), outcomes with percutaneous coronary intervention (PCI) using a new-generation drug-eluting stent (DES) were similar after 1 year compared with a bare-metal stent (BMS), according to new findings from the Evaluation of Xience V Stent in Acute Myocardial Infarction trial [EXAMINATION; NCT00828087].

Manel Sabaté, MD, University Hospital Clinic, Barcelona, Spain, presented results from the multinational EXAMINATION study.

EXAMINATION included 1504 patients who presented with STEMI within 48 hours of symptom onset. All patients required emergent PCI and were required to have a target vessel diameter of 2.25 to 4.0 mm to accommodate currently available stents. The "all-comer" trial design resulted in a study population that was highly representative of real-world patients who are undergoing PCI for acute STEMI. The study enrolled 70% of all STEMI patients who presented to 12 study sites in Spain, Italy, and The Netherlands, including patients who presented within 12 hours of symptom onset (primary PCI), after successful thrombolysis, after failed thrombolysis (rescue PCI), and between 12 and 48 hours of symptom onset (latecomers).

Patients were randomly assigned, in a single-blind fashion, to intervention with an everolimus-eluting stent (EES; n=751) or a cobalt-chromium stent (n=747). Baseline and procedural characteristics were similar in the two treatment groups, including good compliance with antithrombotic medications at discharge and throughout the 1-year follow-up period (approximately 90% was on dual antiplatelet therapy [DAPT] at 1 year). Acute procedure-related outcomes were similar in the DES and BMS groups, with a low risk of TIMI bleeding and very low rate of device malfunction (0.5% vs 0.7%; p=NS). The primary composite endpoint was all-cause death, myocardial infarction (MI), and revascularization. The trial, as designed, had 86% power to detect a 30% reduction in the rate of the primary endpoint at 1 year for DES compared with BMS.

After 1 year, a similar proportion of patients in the DES and BMS groups remained free from the primary endpoint (87.8% vs 85.7%; p=0.20). Several individual endpoints were

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