The American College of Cardiology held its 59th Annual Scientific Session in conjunction with the Innovation in Intervention Summit in Atlanta, Georgia, from March 14 to March 16, 2010, presenting several breaking trials in the field of Interventional Cardiology that are summarized herein. The 59th Annual Scientific Session of the American College of Cardiology (ACC) was held in conjunction with the Innovation in Intervention (i2) Summit in Atlanta, Georgia, from March 14 to March 16, 2010, revealing several breaking trials in the field of Interventional Cardiology. A summary of the key breaking trials and registries in Interventional Cardiology is presented herein.

**FIR**

A meta-analysis of the FRISC (Framingham and Fast Revascularization During Instability in Coronary Artery Disease II) trial (1), ICTUS (Invasive versus Conservative Treatment in Unstable Coronary Syndromes) trial (2), and RITA (Randomized Intervention Trial of Unstable Angina 3) trial (3)—known as the FIR trial collaboration (4)—was initiated due to ambiguity about the long-term findings of the individual studies comparing a more aggressive routine-invasive strategy with a more conservative selective-invasive strategy among patients with non–ST-segment elevation acute coronary syndrome. The combination of the 3 trials totaled 5,467 patients, of whom 2,721 were randomized to the routine invasive strategy, and 2,746 were randomized to the selective-invasive strategy followed-up over 5 years. The study revealed that outcomes of nonfatal myocardial infarction (MI) alone and combined end points of cardiovascular death/MI and all-cause mortality/MI were significantly lower in the routine-invasive group compared with the selective-invasive cohort. The differences in MI began to diverge within the first 3 months and remained separated at 5 years. Moreover, patients in the highest-risk group seemed to benefit most from the routine-invasive strategy.

**EVEREST II**

The EVEREST (Endovascular Valve Edge-to-Edge Repair Study II) (5) compared the safety and efficacy of a percutaneous version of mitral valve repair with the traditional surgical repair in a selected patient population. The trial enrolled 279 patients with significant mitral regurgitation that were randomized 2:1 to percutaneous edge-to-edge repair with the MitraClip device (Abbott, Evanston, Illinois) or to surgical repair or replacement at the surgeon’s discretion. Primary end points of the study were major adverse events at 30 days and clinical success rate, defined as freedom from a combination of death, mitral valve surgery, or re-operation for mitral valve dysfunction and an improvement of at least 2 grades of mitral regurgitation at 12 months. Superior safety and noninferior efficacy with the device compared with surgery was demonstrated, with slightly more moderate regurgitation in the device group. These results will be discussed further in relation to possible regulatory approval of the studied device.

**JET STENT**

The JETSTENT (Comparison of AngioJet Rheolytic Thrombectomy before Direct Infarct Artery Stenting to Direct Stenting Alone in Patients with...
Acute Myocardial Infarction) trial (6) evaluated the use of rheolytic thrombectomy before direct stenting of the infarct-related artery in patients with acute MI. In contrast to the TAPAS (Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) (7), which showed improved reperfusion and clinical outcomes with the use of a mechanical aspiration catheter, the AiMI (AngioJet Rheolytic Thrombectomy in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction) study (8) previously showed that rheolytic thrombectomy with AngioJet (Medrad Interventional/Possis, Minneapolis, Minnesota) did not significantly reduce infarct size. The JETSTENT study, however, only included patients with angiographically visible thrombus, and thrombectomy was performed with a single-pass antegrade approach moving in a proximal-to-distal direction in an attempt to prevent embolization, and this was associated with better reperfusion defined by significantly greater achievement of 50% ST-segment resolution at 30 min and trends toward lower major adverse cardiac events at 30 days and 6 months. By contrast, no difference was documented in infarct size.

MAIN-COMPARE 5-Year

The MAIN-COMPARE (Revascularization for unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) registry (9) compares percutaneous coronary intervention (PCI) versus coronary artery bypass grafting (CABG) for patients with unprotected left main coronary artery disease. Recent trials, including the SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) trial (10) and registry data including 3-year results from MAIN-COMPARE (11) that have previously been published, demonstrate similar composite end points of death, MI, and stroke.

The study involved 2,240 patients with unprotected left main coronary artery disease who received either PCI (n = 1,102; bare-metal stents [BMS; n = 318]; drug-eluting stents [DES; n = 784]) or CABG (n = 1,138) and followed-up for 5 years. After propensity-score matching to reduce the effect of treatment selection bias, the end points of death and the combined risk of death, MI, or stroke were similar for PCI- and CABG-treated patients. However, the rate of target vessel revascularization (TVR) was significantly higher in the PCI group. Stent type (BMS vs. DES) did not significantly alter outcomes; TVR was 6% with DES and 11% with BMS.

PERSEUS

The PERSEUS (Prospective Evaluation of the Safety and Efficacy of the Taxus Element Paclitaxel-Eluting Coronary Stent System) trial (12) includes 2 parallel studies of the novel Taxus Element stent (Boston Scientific, Natick, Massachusetts), which is a paclitaxel-eluting stent over a platinum-enriched metal alloy platform with a thinner 81-μm strut for enhanced radio-opacity and improved deliverability.

The PERSEUS Workhorse study involved 1,262 patients with lesions in coronary arteries ranging from 2.75 to 4.0 mm in diameter and ≤28 mm in length, who were randomized 3:1 to receive either the new Taxus Element or the first generation Taxus Express paclitaxel-eluting stent. Target lesion failure rates at 1 year, average percent diameter stenosis at 9 months, and stent thrombosis (ST) at 1 year were similar in both stent groups.

The PERSEUS Small Vessel study enrolled 224 patients with lesions in coronary arteries, ranging from 2.25 to 2.75 mm in diameter and ≤20 mm in length, who received the Taxus Element stent. Because no DES were Food and Drug Administration–approved for small vessels when the PERSEUS trial began in 2007, the control group was a matched historical Express BMS group from the TAXUS V trial (13). At 9 months, the primary angiographic end point of in-stent late loss and the rate of ST were significantly lower in the TAXUS Element group (mean was 0.37 mm).

SORT OUT III

The SORT OUT III (Danish Organization for Randomized Trials with Clinical Outcome) study (14) is a prospective randomized comparison of 2 DES: the first-generation sirolimus-eluting stent (SES; Cypher, Cordis, Miami Lakes, Florida) versus the second-generation zotarolimus-eluting stent (ZES; Endeavor, Medtronic, Minneapolis, Minnesota). A total of 2,332 patients were randomized to receive either ZES (n = 1,162) or SES (n = 1,170) and were followed-up for 18 months. The primary end point, which was a composite of cardiovascular death, MI, and TVR, was significantly higher in the ZES group compared with SES. Secondary end points of all-cause mortality, cardiovascular death, MI, ST, and TVR were also significantly higher in the ZES group. The results from this trial differ from the ENDEAVOR III trial (15), where there were no significant differences in major adverse cardiovascular events between ZES and SES at up to 2 years. Some of the reasons for the discrepancy between the 2 trials note that SORT OUT III included all patients including complex lesions, such as bifurcations, ostial lesions, left main lesions, long lesions, chronic total occlusions, acute coronary syndromes, and ST-segment elevation MI. At the same time, the SORT OUT III study used administrative databases for follow-up and did not include early (up to 5 days after procedure) events; thus, event rates might appear lower than reality.
ISAR-TEST-2

The ISAR-TEST-2 (Intracoronary Stenting and Anti-thrombotic Regimen-Test Efficacy of Dual Drug-Eluting Stents) trial (16) evaluated a novel dual drug-eluting stent (DDES) on a new polymer-free platform that elutes both sirolimus and probucol, an antihyperlipidemic drug. The trial randomized 1,007 patients with de novo coronary lesions to stenting with the first-generation SES (Cypher, Cordis, Miami Lakes, Florida), ZES (Endeavor, Medtronic, Minneapolis, Minnesota), or the new DDES (Bavarian Research Foundation) and followed-up for 2 years. The new results show that the anti-restenotic benefits of the new DDES achieved at 1 year that were previously presented (17) were maintained out to 2 years, although there is some level of catch-up in binary restenosis and TLR in the SES group. The ZES group had higher event rates than the other stents at 1 year, but no increment was observed between 1 and 2 years.

Summary

The 2010 ACC Annual Scientific Session presented new data on breaking clinical trials and established follow-up data on previously initiated trials in Interventional Cardiology that have been summarized. Complete coverage of the ACC/i2 Summit 2010 can be accessed at the ACC Cardiosource website (18).

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