

## Special article

# Summary of the Clinical Studies Reported in the Annual Scientific Sessions of the American College of Cardiology (New Orleans, LA, USA, April 2-5, 2011)

Resumen de los ensayos clínicos presentados en las Sesiones Científicas Anuales del American College of Cardiology (Nueva Orleans, Luisiana, Estados Unidos, 2-5 de abril de 2011)

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Following its policy of disseminating scientific information to the cardiology community,<sup>1-10</sup> the *Revista Española de Cardiología* offers a selection of the most relevant studies presented at the Scientific Sessions of the American College of Cardiology 2011 in New Orleans, Louisiana, specifically the *Late Breaking Clinical Trials*.

A summary of each selected study is presented, briefly outlining the objectives, methods, and results based on what was presented orally or simultaneously published in scientific journals in electronic format. Given that most of these studies have yet not been published in their final version, the information offered should be interpreted as preliminary.

## SUMMARY BY TOPIC

### Interventional Cardiology

PARTNER: Transcatheter Aortic Valve Implantation versus Surgical Aortic Valve Replacement in "High Risk" Patients with Aortic Stenosis.

PRECOMBAT: Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease.

EVEREST II: Randomized Clinical Trial: Two-Year Outcomes.

ISAR-CABG: Long-term Outcomes after Use of Drug-Eluting Stents and Bare Metal Stents for the Treatment of Saphenous Vein Graft Lesions.

RIVAL: A Randomized Comparison of Radial versus Femoral Access for Coronary Angiography or Intervention in Patients with Acute Coronary Syndromes.

RESOLUTE US: One-Year Clinical Outcomes.

PLATINUM: A Prospective, Randomized Investigation of a Novel Platinum Chromium Everolimus-Eluting Coronary Stent.

EXCELLENT: The Randomized Comparison of 6-Month versus 12-Month Duration of Dual Antiplatelet Therapy after Implantation of Drug Eluting Stent.

### Heart Failure

STICH: Medical Therapy With or Without Coronary Artery Bypass Graft Surgery in Patients With Ischemic Cardiomyopathy.

STICH viability: Influence of Myocardial Viability on Outcome of Patients With Coronary Artery Disease and Left Ventricular Dysfunction Undergoing Medical Therapy With and Without Surgical Revascularization.

### Cardiac Surgery

RAPS: Radial Artery and Saphenous Vein Patency More Than Five Years After Coronary Artery Bypass Surgery.

### Prevention

OSCAR: The Comparison of High-Dose Angiotensin II Receptor Blocker (ARB) Monotherapy versus Combination Therapy of ARB with Calcium Channel Blocker on Cardiovascular Events in Japanese Elderly High-Risk Hypertensive Patients.

NAGOYA HEART: Comparison between Valsartan and Amlodipine Regarding Cardiovascular Morbidity and Mortality in Hypertensive Patients with Glucose Intolerance.

### Miscellanea

REMEDIAL II: Renal Insufficiency Following Contrast Media Administration Trial II: Renalguard System in High-Risk Patients For Contrast-Induced Acute Kidney Injury.

PARTNER (cohort B): Lifetime Cost Effectiveness of Transcatheter Aortic Valve Implantation Compared with Standard Care Among Inoperable Patients With Severe Aortic Stenosis.

MAGELLAN: Rivaroxaban Compared With Enoxaparin for the Prevention of Venous Thromboembolism in Acutely Ill Medical Patients.

PROTECTION-AMI: Selective Inhibition of Delta Protein Kinase C to Reduce Infarct Size after Primary Percutaneous Intervention for Acute Myocardial Infarction.

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## INTERVENTIONAL CARDIOLOGY

### Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in "High Risk" Patients With Aortic Stenosis: The Randomized PARTNER Trial<sup>11</sup>

*Presented by Craig R. Smith, New York, New York, United States.*

**Background and aims.** As many as one-third of patients with severe aortic stenosis (AS) are high-risk surgical candidates and are conservatively managed. However, nonsurgical management of symptomatic AS is associated with a median survival of about 2 years. The results of the PARTNER trial (cohort B) comparing medical therapy to transfemoral transcatheter aortic valve implantation (TAVI) in inoperable patients demonstrated a significant mortality benefit with TAVI over medical therapy. The current trial (cohort A) sought to compare outcomes between TAVI (either transfemoral or transapical) versus surgical aortic valve replacement (AVR) in patients who were high risk.

**Material and methods.** High-risk AS patients with adequate femoral/iliac vessel diameter ( $\geq 7$  mm for #23 mm valve, and  $\geq 8$  mm for #26 mm valve) were randomized in a 1:1 fashion to either transfemoral TAVI or surgical AVR. Those with inadequate femoral/iliac vessel diameter were randomized in a 1:1 fashion to either transapical TAVI or surgical AVR. A total of 699 patients were randomized, 492 to the transfemoral randomization (TAVI = 244, AVR = 248), and 207 to transapical (TAVI = 104, AVR = 103).

**Results.** The mean Society of Thoracic Surgeons (STS) score was 11.7%. Most patients had severely symptomatic AS, with a mean valve area of  $0.7 \text{ cm}^2$  and a mean gradient of 43 mm Hg. About 75% had coronary artery disease, 28% had cerebrovascular disease, 43% had undergone prior coronary artery bypass grafting, 42% had peripheral vascular disease, and 43% had chronic obstructive pulmonary disease. Porcelain aorta and chest wall radiations were reported in <1% of patients, and about 16% of patients were considered "frail".

All-cause mortality was noninferior between TAVI and surgical AVR (24.2% vs 26.8%, hazard ratio [HR] 0.93, 95% confidence interval [CI] 0.71-1.22,  $P$  for noninferiority = 0.001,  $P$  for superiority = 0.62). When the two access routes were separately assessed, transfemoral TAVI was noninferior compared with AVR (22.2% vs 26.4%, HR 0.83, 95% CI 0.60-1.15,  $P$  for noninferiority = 0.002). The comparison between transapical TAVI versus AVR was underpowered (29.0% vs 27.9%, HR 1.22, 95% CI 0.75-1.98,  $P$  = 0.41).

There was 1 procedural death in the AVR arm, and 3 in the TAVI arm. There were 5 conversions from TAVI to surgical AVR, and 5 valve embolizations in the TAVI arm. Thirty-day mortality was similar between TAVI and AVR (3.4% vs 6.5%,  $P$  = 0.07). Vascular complications at 30 days (17.0% vs 3.8%,  $P$  < 0.01) and at 1 year (18.0% vs 4.8%,  $P$  < 0.01) were higher with TAVI, but major bleeding at 30 days (9.3% vs 19.5%,  $P$  < 0.01) and at 1 year (14.7% vs 25.7%,  $P$  < 0.01) was lower in the TAVI arm. The need for new permanent pacemaker was similar at 30 days (3.8% vs 3.6%,  $P$  = 0.89) and at 1 year (5.7% vs 5.0%,  $P$  = 0.68). All strokes were higher with TAVI at 30 days (5.5% vs 2.4%,  $P$  = 0.04), and at 1 year (8.3% vs 4.3%,  $P$  = 0.04), but not major strokes ( $P$  > 0.05 at both time points). The 6-minute walk test was superior for TAVI at 30 days ( $P$  = 0.002), but not at 1 year.

Mean echo gradients at 1 year were clinically similar, but statistically lower with TAVI (10.2 mm Hg vs 11.5 mm Hg,  $P$  = 0.008). Paravalvular aortic insufficiency was greater with TAVI at all time points ( $P$  < 0.05).

**Conclusions.** PARTNER is a landmark trial in the field of structural heart disease and in the management of patients with severe AS. The results of cohort A of the PARTNER trial presented here comparing TAVI (transfemoral or transapical) to AVR demonstrated noninferiority for all-cause mortality at 1 year, with transfemoral

TAVI individually demonstrating noninferiority as well. Thirty-day mortality was also significantly lower with TAVI (3.4% in a cohort with an expected mortality of >11%). As noted in cohort B, vascular complications and all strokes were higher with TAVI. The incidence of permanent pacemaker implantation was similar between TAVI and AVR.

These preliminary results are very encouraging and, although not yet Food and Drug Administration (FDA) approved, highlight the emerging importance of TAVI in the management of AS patients. Final full results are eagerly awaited. Future studies will likely assess the utility of TAVI in lower-risk patients, as well as compare outcomes between transfemoral and transapical TAVI.

### Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients With Left Main Coronary Artery Disease (PRECOMBAT) Trial<sup>12</sup>

*Presented by Seung-Jung Park, Seoul, South Korea.*

**Background and aims.** Percutaneous coronary intervention (PCI) is increasingly used to treat unprotected left main coronary artery stenosis, although coronary artery bypass grafting (CABG) has been considered to be the treatment of choice.

**Material and methods.** We randomly assigned patients with unprotected left main coronary artery stenosis to undergo CABG (300 patients) or PCI with sirolimus-eluting stents (300 patients). Using a wide margin for noninferiority, we compared the groups with respect to the primary composite end point of major adverse cardiac or cerebrovascular events (death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 1 year. Event rates at 2 years were also compared between the 2 groups.

**Results.** The primary end point occurred in 26 patients assigned to PCI as compared with 20 patients assigned to CABG (cumulative event rate, 8.7% vs 6.7%; absolute risk difference, 2.0 percentage points; 95% confidence interval [CI], -1.6 to 5.6;  $P$  = 0.01 for noninferiority). By 2 years, the primary end point had occurred in 36 patients in the PCI group as compared with 24 in the CABG group (cumulative event rate, 12.2% vs 8.1%; hazard ratio with PCI, 1.50; 95% CI, 0.90 to 2.52;  $P$  = 0.12). The composite rate of death, myocardial infarction, or stroke at 2 years occurred in 13 and 14 patients in the 2 groups, respectively (cumulative event rate, 4.4% and 4.7%, respectively; hazard ratio, 0.92; 95% CI, 0.43 to 1.96;  $P$  = 0.83). Ischemia-driven target-vessel revascularization occurred in 26 patients in the PCI group as compared with 12 patients in the CABG group (cumulative event rate, 9.0% vs 4.2%; hazard ratio, 2.18; 95% CI, 1.10 to 4.32;  $P$  = 0.02).

**Conclusions.** In this randomized trial involving patients with unprotected left main coronary artery stenosis, PCI with sirolimus-eluting stents was shown to be noninferior to CABG with respect to major adverse cardiac or cerebrovascular events. However, the noninferiority margin was wide, and the results cannot be considered clinically directive.

### EVEREST II Randomized Clinical Trial: Two-Year Outcomes<sup>13</sup>

*Presented by Ted Feldman, Evanston, Illinois, United States.*

**Background and aims.** Mitral valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

**Material and methods.** We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+) mitral regurgitation in a

2:1 ratio to undergo either percutaneous repair or conventional surgery for repair or replacement of the mitral valve. The primary composite end point for efficacy was freedom from death, from surgery for mitral valve dysfunction, and from grade 3+ or 4+ mitral regurgitation at 12 months. The primary safety end point was a composite of major adverse events within 30 days.

**Results.** At 12 months, the rates of the primary end point for efficacy were 55% in the percutaneous-repair group and 73% in the surgery group ( $P = 0.007$ ). The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ( $P < 0.001$ ). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

**Conclusions.** Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

#### Long-term Outcomes after Use of Drug-Eluting Stents and Bare Metal Stents for the Treatment of Saphenous Vein Graft Lesions: Results of the Randomized ISAR-CABG Trial<sup>14</sup>

*Presented by Julinda Mehilli, Munich, Germany.*

**Background and aims.** Although drug-eluting stents (DES) have been shown to be superior to bare-metal stents (BMS) in reducing in-stent restenosis and target lesion revascularization (TLR) in native coronary arteries, data comparing their performance in saphenous vein grafts are limited. The current trial sought to compare outcomes between DES and BMS in saphenous vein graft (SVG) lesions.

**Material and methods.** Patients with de novo SVG lesions were randomized to receive either DES (sirolimus-eluting stents or paclitaxel-eluting stents) or BMS. All patients received 500 mg of aspirin and 600 mg clopidogrel. In addition, all patients received 75 mg twice daily till discharge, followed by 75 mg daily for a minimum of 6 months. Aspirin 200 mg daily was continued indefinitely. In total, 610 patients were randomized, of which 303 received DES and 307 BMS.

**Results.** Baseline characteristics were fairly similar between the two arms. About 36% had diabetes, 56% had prior myocardial infarction (MI), and the mean SVG age was 13.5 years. Most patients presented with stable angina (61%), and 15% presented with acute MI. Multilesion PCI was performed in 23% of the patients, and 4% had more than one SVG intervention. The mean vessel diameter was 3.37 mm, and the total stented length was about 27 mm. About 17% of patients had aorto-ostial disease, 25% had proximal SVG disease, 27% had medial disease, and 16% had distal disease. About 5% of patients had TIMI 0 flow at the start of the procedure. Major adverse cardiac events (MACE) at 30 days was lower in DES compared with BMS (2.6% vs 5.9%,  $P = 0.05$ ), but not all-cause mortality (0.7% vs 1.0%,  $P = 0.57$ ) or MI (2.0% vs 4.6%,  $P = 0.07$ ). MACE at 1 year, the primary end point, was significantly lower in the DES arm compared with BMS (15.4% vs 22.1%, relative risk 0.65, 95% confidence interval 0.45–0.96,  $P = 0.03$ ), driven predominantly by a reduction in ischemia-driven target lesion revascularization (TLR) (7.2% vs 13.1%,  $P = 0.02$ ). No difference was noted in death (4.7% vs 5.2%,  $P = 0.82$ ), MI (4.2% vs 6.0%,  $P = 0.27$ ), or stent thrombosis (0.7% vs 0.7%,  $P = 0.99$ ).

**Conclusions.** The results of the ISAR-CABG trial indicate that DES (first generation stents, PES and SES) are superior to BMS in reducing MACE at 1 year, mainly due to a reduction in ischemia-driven TLR, but not death, MI, or stent thrombosis. These results are similar to those

noted by the SOS trial, and parallel those noted in native coronary vessels. Long-term follow-up data are awaited.

#### Rival Trial: A Randomized Comparison of Radial versus Femoral Access for Coronary Angiography or Intervention in Patients With Acute Coronary Syndromes<sup>15</sup>

*Presented by Sanjit S. Jolly, Hamilton, Canada.*

**Background and aims.** Small trials have suggested that radial access for percutaneous coronary intervention (PCI) reduces vascular complications and bleeding compared with femoral access. We aimed to assess whether radial access was superior to femoral access in patients with acute coronary syndromes (ACS) who were undergoing coronary angiography with possible intervention.

**Material and methods.** The Radial Vs femoral access for coronary intervention (RIVAL) trial was a randomized, parallel group, multicenter trial. Patients with ACS were randomly assigned (1:1) by a 24-hour computerized central automated voice response system to radial or femoral artery access. The primary outcome was a composite of death, myocardial infarction, stroke, or non-coronary artery bypass graft (non-CABG)-related major bleeding at 30 days. Key secondary outcomes were death, myocardial infarction, or stroke; and non-CABG-related major bleeding at 30 days. A masked central committee adjudicated the primary outcome, components of the primary outcome, and stent thrombosis. All other outcomes were as reported by the investigators. Patients and investigators were not masked to treatment allocation. Analyses were by intention to treat.

**Results.** Between June 6, 2006, and November 3, 2010, 7021 patients were enrolled from 158 hospitals in 32 countries. In total, 3507 patients were randomly assigned to radial access and 3514 to femoral access. The primary outcome occurred in 128 (3.7%) of 3507 patients in the radial access group compared with 139 (4.0%) of 3514 in the femoral access group (hazard ratio [HR] 0.92, 95% CI 0.72–1.17;  $P = 0.50$ ). Of the 6 prespecified subgroups, there was a significant interaction for the primary outcome with benefit for radial access in highest tertile volume radial centers (HR 0.49, 95% CI 0.28–0.87;  $P = 0.015$ ) and in patients with ST-segment elevation myocardial infarction (0.60, 0.38–0.94;  $P = 0.026$ ). The rate of death, myocardial infarction, or stroke at 30 days was 112 (3.2%) of 3507 patients in the radial group compared with 114 (3.2%) of 3514 in the femoral group (HR 0.98, 95% CI 0.76–1.28;  $P = 0.90$ ). The rate of non-CABG-related major bleeding at 30 days was 24 (0.7%) of 3507 patients in the radial group compared with 33 (0.9%) of 3514 patients in the femoral group (HR 0.73, 95% CI 0.43–1.23;  $P = 0.23$ ). At 30 days, 42 of 3507 patients in the radial group had large hematoma compared with 106 of 3514 in the femoral group (HR 0.40, 95% CI 0.28–0.57;  $P < 0.0001$ ). Pseudoaneurysm needing closure occurred in 7 of 3507 patients in the radial group compared with 23 of 3514 in the femoral group (HR 0.30, 95% CI 0.13–0.71;  $P = 0.006$ ).

**Conclusions.** Radial and femoral approaches are both safe and effective for PCI. However, the lower rate of local vascular complications may be a reason to use the radial approach.

#### One-Year Clinical Outcomes from the Pivotal Multicenter RESOLUTE US Study<sup>16</sup>

*Presented by Martin B. Leon, Boston, Massachusetts, United States.*

**Background and aims.** The R-ZES releases zotarolimus over a 6-month period in order to achieve optimal clinical effectiveness and safety. The RESOLUTE US (R-US) trial is a prospective,

observational study designed to evaluate the clinical effectiveness of the Resolute zotarolimus-eluting stent (R-ZES) in a United States population.

**Material and methods.** The R-US trial recruited patients with de novo native coronary lesions suitable for 1- or 2-vessel treatment with stents from 2.25 to 4.0 mm in diameter. In the main analysis cohort (2.5- to 3.5-mm stents and single-lesion treatment), the primary endpoint was 12-month target lesion failure (TLF) defined as the composite of cardiac death, myocardial infarction (MI), and clinically-driven target lesion revascularization (TLR), compared with data from Endeavor zotarolimus-eluting stent (E-ZES) trials, adjusting for baseline covariates through propensity scores.

**Results.** Overall, 1402 patients were enrolled with a mean reference vessel diameter of  $2.59 \pm 0.47$  mm and diabetes prevalence of 34.4%. In the main analysis cohort, TLF was 3.7% at 12 months compared with historical E-ZES results (TLF = 6.5%). The R-ZES met the 3.3% margin of noninferiority (rate difference = -2.8%, upper 1-sided 95% confidence interval: -1.3%,  $P < 0.001$ ). The overall TLF rate was 4.7%, and rates of cardiac death, MI, and TLR were 0.7%, 1.4%, and 2.8%, respectively. The 12-month rate of stent thrombosis was 0.1%.

**Conclusions.** The R-ZES achieved a very low rate of clinical restenosis while maintaining low rates of important clinical safety events such as death, MI, and stent thrombosis at 1-year follow-up.

#### **A Prospective, Randomized Investigation of a Novel Platinum Chromium Everolimus- Eluting Coronary Stent: The PLATINUM Trial<sup>17</sup>**

*Presented by Gregg W. Stone, New York, New York, United States.*

**Background and aims.** Randomized trials have demonstrated an excellent safety and efficacy profile for the cobalt chromium everolimus-eluting stent (CoCr-EES). The platinum chromium everolimus-eluting stent (PtCr-EES) uses the identical antiproliferative agent and polymer but with a novel platinum chromium scaffold designed for enhanced deliverability, vessel conformability, side-branch access, radiopacity, radial strength, and fracture resistance. We sought to evaluate the clinical outcomes with a novel PtCr-EES compared with a predicate CoCr-EES in patients undergoing percutaneous coronary intervention (PCI).

**Material and methods.** A total of 1530 patients undergoing PCI of 1 or 2 de novo native lesions were randomized at 132 worldwide sites to CoCr-EES ( $n = 762$ ) or PtCr-EES ( $n = 768$ ). The primary end point was the 12-month rate of target lesion failure (TLF), the composite of target vessel-related cardiac death, target vessel-related myocardial infarction (MI), or ischemia-driven target lesion revascularization (TLR) in the per-protocol population (patients who received 1 assigned study stent), powered for noninferiority.

**Results.** The 12-month rate of TLF in the per-protocol population occurred in 2.9% versus 3.4% of patients assigned to CoCr-EES versus PtCr-EES, respectively (difference: 0.5%, 95% confidence interval: -1.3% to 2.3%,  $P$  noninferiority = 0.001,  $P$  superiority = 0.60). By intention-to-treat, there were no significant differences between CoCr-EES and PtCr-EES in the 12-month rates of TLF (3.2% vs 3.5%,  $P = 0.72$ ), cardiac death or MI (2.5% vs 2.0%,  $P = 0.56$ ), TLR (1.9% vs 1.9%,  $P = 0.96$ ), or Academic Research Consortium definite or probable stent thrombosis (0.4% vs 0.4%,  $P = 1.00$ ).

**Conclusions.** In this large-scale, prospective, single-blind randomized trial, a novel PtCr-EES was noninferior to the predicate CoCr-EES for TLF, with nonsignificant differences in measures of safety and efficacy through 12-month follow-up after PCI.

#### **The Randomized Comparison of Six-Month versus 12-Month Duration of Dual Antiplatelet Therapy after Implantation of Drug Eluting Stent: From Comparison of Everolimus- versus Sirolimus-Eluting Stents for Coronary Revascularization (EXCELLENT) Trial<sup>18</sup>**

*Presented by Hyeon-Cheol Gwon, Seoul, South Korea.*

**Background and aims.** The goal of the trial was 1) to compare treatment with an everolimus-eluting stent (EES) versus sirolimus-eluting stent (SES), and 2) to compare treatment with 6 months of dual antiplatelet therapy versus 12 months of dual antiplatelet therapy after percutaneous coronary intervention (PCI).

**Material and methods.** Korean patients undergoing PCI were randomized by factorial design to 1) EES versus SES, and 2) 6 months of clopidogrel ( $n = 722$ ) versus 12 months of clopidogrel ( $n = 721$ ).

**Results.** Overall, 1443 patients were randomized. For the analysis of clopidogrel duration, the primary outcome of target vessel failure at 12 months occurred in 4.7% of the 6-month clopidogrel group versus 4.4% of the 12-month clopidogrel group ( $P$  for noninferiority = 0.0031). Among patients who received an EES, the primary outcome was 5.2% versus 5.1% ( $P$  for noninferiority = 0.0029), and among patients who received an SES, the primary outcome was 5.0% versus 2.2% ( $P$  for noninferiority = 0.27), respectively, for 6 months versus 12 months of clopidogrel. Cardiovascular death was 0.3% versus 0.4% ( $P = 0.65$ ), myocardial infarction (MI) was 1.8% versus 1.1% ( $P = 0.28$ ), and target vessel revascularization was 3.1% versus 3.2% ( $P = 0.87$ ), respectively. Stent thrombosis was 0.8% versus 0.4% ( $P = 0.32$ ), and TIMI major bleeding was 0.3% versus 0.6% ( $P = 0.41$ ), respectively.

**Conclusions.** Among Korean patients undergoing PCI, 6 months of clopidogrel was noninferior to 12 months in regard to target vessel failure. There appeared to be effect modification by stent type, such that 6 months of clopidogrel was noninferior to 12 months among recipients of an EES.

In contrast, noninferiority to duration of clopidogrel was not demonstrated in the SES group. This leaves open the possibility that 12 months of clopidogrel therapy after an SES might result in superior outcomes; however, 6 months of clopidogrel after an EES may be adequate.

#### **HEART FAILURE**

#### **Medical Therapy With or Without Coronary Artery Bypass Graft Surgery in Patients With Ischemic Cardiomyopathy: Results of the Surgical Treatment of Ischemic Heart Failure Trial<sup>19</sup>**

*Presented by Eric J. Velazquez, Durham, North Carolina, United States.*

**Background and aims.** The role of coronary artery bypass grafting (CABG) in the treatment of patients with coronary artery disease and heart failure has not been clearly established.

**Material and methods.** Between July 2002 and May 2007, 1212 patients with an ejection fraction of 35% or less and coronary artery disease amenable to CABG were randomly assigned to medical therapy alone (602 patients) or medical therapy plus CABG (610 patients). The primary outcome was the rate of death from any cause. Major secondary outcomes included the rates of death from cardiovascular causes and of death from any cause or hospitalization for cardiovascular causes.

**Results.** The primary outcome occurred in 244 patients (41%) in the medical-therapy group and 218 (36%) in the CABG group (hazard ratio with CABG, 0.86; 95% confidence interval [CI], 0.72 to 1.04;  $P = 0.12$ ). In total, 201 patients (33%) in the medical-therapy group and 168 (28%) in the CABG group died from an adjudicated cardiovascular



cause (hazard ratio with CABG, 0.81; 95% CI, 0.66 to 1.00;  $P = 0.05$ ). Death from any cause or hospitalization for cardiovascular causes occurred in 411 patients (68%) in the medical-therapy group and 351 (58%) in the CABG group (hazard ratio with CABG, 0.74; 95% CI, 0.64 to 0.85;  $P < 0.001$ ). By the end of the follow-up period (median, 56 months), 100 patients in the medical-therapy group (17%) underwent CABG, and 555 patients in the CABG group (91%) underwent CABG.

**Conclusions.** In this randomized trial, there was no significant difference between medical therapy alone and medical therapy plus CABG with respect to the primary end point of death from any cause. Patients assigned to CABG, as compared with those assigned to medical therapy alone, had lower rates of death from cardiovascular causes and of death from any cause or hospitalization for cardiovascular causes.

### **Influence of Myocardial Viability on Outcome of Patients With Coronary Artery Disease and Left Ventricular Dysfunction Undergoing Medical Therapy With and Without Surgical Revascularization: Results of the Surgical Treatment for Ischemic Heart Failure Trial<sup>20</sup>**

*Presented by Robert O. Bonow, Durham, North Carolina, United States.*

**Background and aims.** The assessment of myocardial viability has been used to identify patients with coronary artery disease and left ventricular dysfunction in whom coronary artery bypass grafting (CABG) will provide a survival benefit. However, the efficacy of this approach is uncertain.

**Material and methods.** In a substudy of patients with coronary artery disease and left ventricular dysfunction who were enrolled in a randomized trial of medical therapy with or without CABG, we used single-photon-emission computed tomography (SPECT), dobutamine echocardiography, or both to assess myocardial viability on the basis of prespecified thresholds.

**Results.** Among the 1212 patients enrolled in the randomized trial, 601 underwent assessment of myocardial viability. Of these patients, we randomly assigned 298 to receive medical therapy plus CABG and 303 to receive medical therapy alone. A total of 178 of 487 patients with viable myocardium (37%) and 58 of 114 patients without viable myocardium (51%) died (hazard ratio for death among patients with viable myocardium, 0.64; 95% confidence interval [CI], 0.48 to 0.86;  $P = 0.003$ ). However, after adjustment for other baseline variables, this association with mortality was not significant ( $P = 0.21$ ). There was no significant interaction between viability status and treatment assignment with respect to mortality ( $P = 0.53$ ).

**Conclusions.** The presence of viable myocardium was associated with a greater likelihood of survival in patients with coronary artery disease and left ventricular dysfunction, but this relationship was not significant after adjustment for other baseline variables. The assessment of myocardial viability did not identify patients with a differential survival benefit from CABG, as compared with medical therapy alone.

## **CARDIAC SURGERY**

### **Radial Artery and Saphenous Vein Patency More than Five Years Following Coronary Artery Bypass Surgery: Results from the Randomized Multicenter Radial Artery Patency Study (RAPS)<sup>21</sup>**

*Presented by Stephen E. Fremes, Toronto, Canada.*

**Background and aims.** The goal of the trial was to evaluate the angiographic patency of radial-artery grafts compared with

saphenous-vein grafts at 1 year, and again at 5 years, in patients undergoing coronary artery bypass grafting (CABG).

**Material and methods.** Patients were randomized in the operating room to undergo surgery according to one of two strategies: 1) radial-artery grafting to the circumflex territory and saphenous-vein grafting to the right coronary artery, or 2) radial-artery grafting to the right coronary artery and saphenous-vein grafting to the circumflex territory. Each patient served as his or her own control because the randomization was conducted within each patient. The internal thoracic artery was used to bypass the left anterior descending coronary artery. Follow-up angiography was performed at 1 year, and was repeated in a subgroup at 5 years.

**Results.** A total of 561 patients were enrolled, of which 529 had clinical follow-up and 501 had angiographic follow-up. Patients received an average of 3.8 distal anastomoses. Angiography was performed in 440 patients at 1-year follow-up. The primary end point of graft occlusion was higher in saphenous-vein grafts compared with radial-artery grafts (13.6% vs 8.2%,  $P = 0.009$ ), a relative risk reduction of 40%. Diffuse narrowing of the graft (ie, the angiographic "string sign") was more frequent in radial-artery grafts than saphenous-vein grafts (7.0% vs 0.9%,  $P = 0.001$ ). In an analysis restricted to patients with patent study grafts, presence of some angiographic stenosis at the proximal anastomosis was higher in radial-artery grafts compared with saphenous-vein grafts (21.4% vs 11.1%,  $P < 0.001$ ), but presence of stenosis in the graft body was lower in radial-artery grafts (5.7% vs 12.3%,  $P = 0.003$ ), with no difference in presence of stenosis at the distal anastomosis (14.0% for radial-artery grafts vs 17.7% for saphenous-vein grafts). There was no difference in perfect graft patency (ie, TIMI flow grade 3) by graft type (87.7% for radial vs 85.7% for saphenous). Five-year angiographic follow-up was available for 269 patients. In this subgroup, functional graft occlusion (TIMI grade flow 0-2) was still lower in the radial-artery grafts compared with the saphenous-vein grafts (12.0% vs 18.8%, odds ratio [OR] 0.64, 95% confidence interval [CI] 0.41-0.98,  $P = 0.05$ ), as was total graft occlusion (TIMI grade flow 0) (8.9% vs 17.8%, OR 0.50, 95% CI 0.32-0.80,  $P = 0.004$ ). There was no difference in proximal or distal anastomotic stenosis between the two grafts, but stenosis in the body of the graft was more common with saphenous-vein grafts (15.2% vs 6.7%,  $P = 0.02$ ). Mortality was 0.4% within 30 days, and 10% over the total period of follow-up. Only 0.4% of patients required redo-CABG, while 4.5% required PCI.

**Conclusions.** Among patients undergoing CABG, the rate of graft occlusion at 1 year was lower in radial-artery grafts compared with saphenous-vein grafts. This benefit appeared to be sustained at 5 years, at least in the subgroup that underwent repeat angiography.

## **PREVENTION**

### **The Comparison of High-Dose Angiotensin II Receptor Blocker (ARB) Monotherapy versus Combination Therapy of ARB With Calcium Channel Blocker on Cardiovascular Events in Japanese Elderly High-Risk Hypertensive Patients: Olmesartan and Calcium Antagonists Randomized (OSCAR) Study<sup>22</sup>**

*Presented by Hisao Ogawa, Fukuoka, Japan.*

**Background and aims.** Although the benefits of high-dose angiotensin-receptor blocker (ARB) therapy in patients with diabetic nephropathy and congestive heart failure (CHF) are well known, it is unclear if this is true for high-risk patients with hypertension as well. The current trial sought to compare outcomes with high-dose ARB versus low-dose ARB, along with a calcium channel blocker (CCB), in elderly Japanese patients with at least one cardiovascular (CV) risk factor.

**Material and methods.** All patients underwent a run-in period during which they received 20 mg olmesartan daily. Patients were then randomized to receive either olmesartan 40 mg daily, or olmesartan 20 mg daily plus a CCB (either azelnidipine or amlodipine).

**Results.** In total, 1217 patients were randomized, of which 1164 patients were evaluable. Of these, 578 received high-dose ARB and 586 received low-dose ARB plus CCB. Baseline characteristics were fairly similar between the two arms, except for body mass index, which was slightly higher in the high-dose ARB arm. The average blood pressure (BP) was 158/85 mm Hg, with a heart rate of 73 bpm. About 70% had a history of CV disease, including 3% with myocardial infarction, 8% with CHF, and 18% with stroke. About 54% of the patients had type 2 diabetes.

At 3 years, both systolic BP and diastolic BP were reduced in both arms, but to a larger extent in the low-dose ARB plus CCB arm than the high-dose ARB arm. Systolic BP and diastolic BP were 136 mm Hg/133.4 mm Hg, and 74.6 mm Hg/73.1 mm Hg in the high-dose ARB versus low-dose ARB plus CCB arms, respectively ( $P < 0.05$ ). The primary composite end point of fatal and nonfatal CV events and non-CV death was similar between the high-dose ARB and low-dose ARB plus CCB arms (10.0% vs 8.2%, hazard ratio [HR] 1.31, 95% confidence interval [CI] 0.89-1.92,  $P = 0.17$ ). Similarly, fatal and nonfatal CV events (8.5% vs 6.3%,  $P = 0.09$ ), cerebrovascular disease (4.2% vs 2.6%,  $P = 0.08$ ), CHF (2.1% vs 1.4%,  $P = 0.33$ ), and diabetic complications (0.3% vs 0.7%,  $P = 0.47$ ) were similar between the two arms.

On subgroup analysis, the incidence of the primary composite outcome was higher in the high-dose ARB arm in patients with established CV disease (12.6% vs 8.4%, HR 1.63, 95% CI 1.06-2.52,  $P = 0.03$ ). In the subgroup with type 2 diabetes and no other comorbidities, there was a trend toward benefit for the primary end point in the high-dose ARB arm ( $P = 0.14$ ). Serious adverse events were similar between the two arms (8.1% vs 8.7%,  $P = 0.75$ ).

**Conclusions.** The results of the OSCAR trial indicate that there is no difference in clinical outcomes between high-dose ARB and low-dose ARB plus CCB in elderly Japanese patients with at least one CV risk factor, despite a greater reduction in BP in the low-dose ARB plus CCB arm. However, in patients with established CV disease, low-dose ARB plus CCB was superior to high-dose ARB alone.

#### Comparison between Valsartan and Amlodipine Regarding Cardiovascular Morbidity and Mortality in Hypertensive Patients With Glucose Intolerance (NAGOYA HEART Study)<sup>23</sup>

*Presented by: Toyoaki Murohara, Nagoya, Japan.*

**Background and aims.** The goal of the trial was to compare treatment with valsartan compared with amlodipine among patients with hypertension and diabetes (or impaired glucose tolerance).

**Material and methods.** Japanese patients with hypertension and diabetes (or impaired glucose tolerance) were randomized to valsartan ( $n = 575$ ) versus amlodipine ( $n = 575$ ). Study medications were up-titrated to achieve target blood pressure  $<130/80$  mm Hg.

**Results.** Overall, 1150 patients were randomized. In the valsartan group, the mean age was 63 years, 34% were women, mean body mass index was 25 kg/m<sup>2</sup>, mean blood pressure was 145/82 mm Hg, and mean glycated hemoglobin was 7.0%. Over the follow-up period, there was no difference in blood pressure or glycated hemoglobin between the groups. At a median of 3.2 years, the composite cardiovascular outcome occurred in 9.4% of the valsartan group versus 9.7% of the amlodipine group (hazard ratio 0.97, 96% confidence interval 0.66-1.40). Individual outcomes were similar between the groups; however, heart failure admission occurred in 0.5% of the valsartan group versus 2.6% of the amlodipine group ( $P = 0.01$ ).

**Conclusions.** Among Japanese patients with hypertension and diabetes, there was no difference in composite outcomes for a valsartan-based treatment of hypertension versus an amlodipine-based treatment of hypertension. The only individual outcome which favored the use of valsartan was heart failure admission.

#### MISCELLANEA

#### Renal Insufficiency Following Contrast Media Administration Trial II: RenalGuard System In High-risk Patients For Contrast-Induced Acute Kidney Injury (REMEDIAL II)<sup>24</sup>

*Presented by Carlo Briguori, Milan, Italy.*

**Background and aims.** The goal of the trial was to evaluate hydration with sodium bicarbonate compared with the RenalGuard hydration system among patients at elevated risk for contrast-induced nephropathy.

**Material and methods.** Patients at elevated risk of contrast nephropathy were randomized to sodium bicarbonate hydration ( $n = 147$ ) versus RenalGuard hydration ( $n = 147$ ). Patients in the sodium bicarbonate group received sodium bicarbonate at 3 ml/kg intravenously 1 hour before and 1 ml/kg/h intravenously for 6 hours after the procedure. Patients in the RenalGuard group received normal saline and furosemide 0.25 mg/kg to achieve a urine flow of at least 300 ml/h prior to initiation of the procedure. Patients in both groups received periprocedural N-acetylcysteine. At baseline, use of an angiotensin-converting enzyme inhibitor was 48%, angiotensin-receptor blocker 29%, calcium channel blocker 25%, beta-blocker 63%, and statin 74%.

**Results.** Overall, 294 patients were randomized. In the RenalGuard group, the mean age was 76 years, 39% were women, 98% had hypertension, 69% had diabetes, mean body mass index was 28 kg/m<sup>2</sup>, mean blood pressure was 152/77 mm Hg, mean left ventricular ejection fraction was 46%, mean estimated glomerular filtration rate (eGFR) was 32 ml/min/1.73 m<sup>2</sup>, 73% had a contrast risk score of 11-15, and mean volume of contrast exposure was 135 ml. Urine volume at 24 hours was greater in the RenalGuard group compared with the bicarbonate group ( $P < 0.001$ ). The primary outcome, serum creatinine increase  $>0.3$  mg/dl at 48 hours, occurred in 11% of the RenalGuard group versus 20.5% of the bicarbonate group ( $P = 0.025$ ). Serum creatinine increase  $\geq 0.5$  mg/dl at 48 hours occurred in 6% versus 15% ( $P = 0.003$ ), and major adverse events at 30 months occurred in 6.8% versus 9.6% ( $P = 0.52$ ), respectively.

**Conclusions.** Among patients at high risk for contrast-induced nephropathy, hydration with the RenalGuard system plus furosemide prevented serum creatinine increase more effectively post-procedure compared with sodium bicarbonate hydration. This system achieved high urine flow volume. Major adverse events (death, dialysis, or pulmonary oedema) were not significantly reduced in the RenalGuard group.

#### Lifetime Cost Effectiveness of Transcatheter Aortic Valve Implantation Compared With Standard Care Among Inoperable Patients With Severe Aortic Stenosis: Results from the Randomized PARTNER Trial (cohort B)<sup>25</sup>

*Presented by Matthew R. Reynolds, Boston, Massachusetts, United States.*

**Background and aims.** A full accounting of the costs and cost-effectiveness of TAVR in PARTNER Trial (Cohort B) has not yet been reported. The aims of the investigation were: 1) To compare the short and long-term costs of the TAVR strategy with those of standard care

in patients with inoperable aortic stenosis, 2) To project the long-term differences in overall and quality-adjusted life expectancy between these groups, and 3) To estimate the lifetime cost-effectiveness of TAVR compared with standard therapy based on the PARTNER trial results.

**Material and methods.** The primary end point was lifetime incremental cost-effectiveness Ratio (\$/LYG) and the secondary end point was lifetime incremental costs per quality-adjusted life year gained (\$/QALY).

**Results.** The total procedural cost of TAVI, excluding MD fees, was \$42 806 (all values in 2010 USD), while the total index admission cost was \$78 540. On 12-month follow-up, total costs were significantly lower with TAVI compared with medical therapy: \$29 352 vs \$52 724,  $P < 0.001$ . Increased life expectancy of about 1.9 years was noted with TAVI. Cost-effectiveness analyses demonstrated an incremental cost-effectiveness ratio of \$50 212 per life-year gained, which is close to the \$50 000 life-year gained that is commonly used for evaluation of newer technologies.

**Conclusions.** For patients with severe aortic stenosis who are unsuitable for surgical AVR, TAVR significantly increases life expectancy at an incremental cost per life-year gained, well within accepted values for commonly used cardiovascular technologies.

### Rivaroxaban Compared With Enoxaparin for the Prevention of Venous Thromboembolism in Acutely Ill Medical Patients (MAGELLAN)<sup>26</sup>

*Presented by Alexander Cohen, Leverkusen, Germany.*

**Background and aims.** The optimal duration of thromboprophylaxis and the acutely ill patient population most likely to benefit from extended thromboprophylaxis is not well characterized. The current trial sought to compare different durations of rivaroxaban with enoxaparin in these patients.

**Material and methods.** Patients were randomized to receive either subcutaneous enoxaparin 40 mg daily for  $10 \pm 4$  days and oral placebo for  $35 \pm 4$  days, or oral rivaroxaban 10 mg daily for  $35 \pm 4$  days and subcutaneous placebo for  $10 \pm 4$  days. The active treatment period for the enoxaparin arm was from day 1 to day  $10 \pm 4$  and for the rivaroxaban arm was from day 1 to day  $35 \pm 4$ .

**Results.** In total, 8101 patients were randomized, of which 3997 received rivaroxaban and 4001 received enoxaparin/placebo. Baseline characteristics were fairly similar between the two arms. The mean weight was 77.4 kg, and the mean duration of hospitalization was 11 days. About 22% had a creatinine clearance  $<50$  ml/min. The underlying medical conditions were congestive heart failure (CHF) (33%), active cancer (7%), acute infectious diseases (46%), and acute respiratory insufficiency (28%); about 31% had  $\geq 2$  underlying medical conditions.

The primary efficacy outcomes (asymptomatic proximal deep-vein thrombosis [DVT] detected by mandatory ultrasonography, symptomatic DVT, symptomatic nonfatal pulmonary embolism [PE], and venous thromboembolism [VTE]-related death) were similar between the rivaroxaban and enoxaparin arms (2.7% vs 2.7%, relative risk [RR] 0.97, 95% confidence interval [CI] 0.71-1.33,  $P$  for noninferiority = 0.0025). The individual components were similar as well, including asymptomatic proximal DVT (2.4% vs 2.4%), symptomatic lower extremity DVT (0.2% vs 0.2%), and VTE-related death (0.1% vs 0.2%) ( $P > 0.05$  for all). In addition, the primary outcome favored rivaroxaban at 35 days over enoxaparin (4.4% vs 5.7%, RR 0.77, 95% CI 0.62-0.96,  $P = 0.02$ ), mainly due to a reduction in asymptomatic proximal DVT (3.5% vs 4.4%). Clinically relevant bleeding, the primary safety end point at 10 days (major + nonmajor clinically relevant bleeding), was higher in the rivaroxaban arm compared with enoxaparin (2.8% vs 1.2%,  $P < 0.0001$ ), as was major bleeding (0.6% vs 0.3%,  $P = 0.03$ ). Similarly, clinically relevant bleeding at 35 days was

higher in the rivaroxaban arm (4.1% vs 1.7%,  $P < 0.0001$ ), as was major bleeding (1.1% vs 0.4%,  $P = 0.0004$ ). Other clinical outcomes including any cardiovascular event (1.8% vs 1.6%) and all-cause mortality (5.1% vs 4.8%) ( $P > 0.05$  for both) were similar.

**Conclusions.** The results of the MAGELLAN trial indicate that rivaroxaban is noninferior to enoxaparin at 10 days for efficacy, but superior at 35 days. This is, however, tempered by a significant increase in major and nonmajor clinically relevant bleeding at both time points, as compared with enoxaparin. Further studies are needed to identify patient subsets that may derive the most benefit with rivaroxaban without a significant increase in bleeding.

### Selective Inhibition of Delta Protein Kinase C to Reduce Infarct Size After Primary Percutaneous Intervention for Acute Myocardial Infarction (PROTECTION-AMI Phase IIb)<sup>27</sup>

*Presented by A. Michael Lincoff, Cleveland Clinic, Cleveland, Ohio, United States.*

**Background and aims.** A novel protein kinase C inhibitor, KAI-9803 (delcasertib), has previously been shown to be safe for use in the treatment of patients with ST-segment-elevation MI (STEMI) undergoing PCI, as well as having a favorable impact on multiple biomarkers of reperfusion success. The aim of the study was to assess KAI-9803 safety and efficacy to reduce infarct size in STEMI patients treated with PCI.

**Material and methods.** This trial tested the intravenous administration of three doses of delcasertib—50 mg/hour, 150 mg/hour, and 450 mg/hour—in 908 patients with anterior STEMI undergoing planned primary PCI, including those randomized to placebo. In addition, investigators randomized 150 patients with inferior STEMI to placebo or to delcasertib 450 mg/hour.

**Results.** Treatment with the various doses of delcasertib in the anterior and inferior MI groups had no effect on CK-MB area under the curve (AUC), the study's primary end point, when compared with placebo, and had no effect on peak CK-MB, a secondary end point. In addition, other markers of reperfusion success, such as ECG ST-recovery AUC and time to stable ST recovery, were not significantly improved compared with placebo. A subgroup analysis of patients based on prePCI TIMI flow revealed a trend toward improvements in patients with TIMI 0/1 flow.

**Conclusions.** A novel protein kinase C inhibitor, KAI-9803 (delcasertib), failed to prevent reperfusion injury following acute MI.

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