Special article

Summary of the Clinical Studies Reported in the Annual Scientific Sessions of the American College of Cardiology (San Diego, United States, March 14-16, 2015)

Resumen de los ensayos clínicos presentados en las Sesiones Científicas Anuales del American College of Cardiology (San Diego, Estados Unidos, 14-16 de marzo de 2015)

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INTRODUCCIÓN

Following our priority policy to reinforce continuing medical education for our readers, we present the results of the clinical trials that were presented in special sections (Late-breaking Clinical Trials) in the American College of Cardiology 2015 Congress, held in San Diego. As in previous editions,1,2 we briefly outline the main objective, methods, and results, in line with the oral presentations. The information we offer should be considered preliminary because many of these studies have not yet been published in their final version.

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The potential benefit of dual antiplatelet therapy

The two ticagrelor doses each reduced, as compared with placebo, the rate of the primary efficacy end point, with Kaplan–Meier rates at 3 years of 7.85% in the group that received 90 mg of ticagrelor twice daily, 7.77% in the group that received 60 mg of ticagrelor twice daily, and 9.04% in the placebo group (hazard ratio for 90 mg of ticagrelor vs placebo, 0.85; 95% confidence interval [CI], 0.75 to 0.96; P = .008; hazard ratio for 60 mg of ticagrelor vs placebo, 0.84; 95%CI, 0.74 to 0.95; P = .004). Rates of TIMI major bleeding were higher with ticagrelor (2.60% with 90 mg and 2.30% with 60 mg) than with placebo (1.06%) (P < .001 for each dose vs placebo); the rates of intracranial hemorrhage or fatal bleeding in the three groups were 0.63%, 0.71%, and 0.60%, respectively.

Conclusions. In patients with a myocardial infarction more than 1 year previously, treatment with ticagrelor significantly reduced the risk of cardiovascular death, myocardial infarction, or stroke and increased the risk of major bleeding.

OSLER 1 and 2: Effect of the PCSK9 Inhibitor Evolocumab on Cardiovascular Outcomes

Presented by Marc Steven Sabatine, Boston, Massachusetts, United States.

Background. Evolocumab, a monoclonal antibody that inhibits proprotein convertase subtilisin–kexin type 9 (PCSK9), significantly reduced low-density lipoprotein (LDL) cholesterol levels in short-term studies. We conducted two extension studies to obtain longer-term data.

Methods. In two open-label, randomized trials, we enrolled 4465 patients who had completed 1 of 12 phase 2 or 3 studies ("parent trials") of evolocumab. Regardless of study group assignments in the parent trials, eligible patients were randomly assigned in a 2:1 ratio to receive either evolocumab (140 mg every 2 weeks or 420 mg monthly) plus standard therapy or standard therapy alone. Patients were followed for a median of 11.1 months with assessment of lipid levels, safety, and (as a prespecified exploratory analysis) adjudicated cardiovascular events including death, myocardial infarction, unstable angina, coronary revascularization, stroke, transient ischemic attack, and heart failure. Data from the two trials were combined.

Results. As compared with standard therapy alone, evolocumab reduced the level of LDL cholesterol by 61%, from a median of 120 mg per deciliter to 48 mg per deciliter (P < .001). Most adverse events occurred with similar frequency in the two groups, although neurocognitive events were reported more frequently in the evolocumab group. The risk of adverse events, including neurocognitive events, did not vary significantly according to the achieved level of LDL cholesterol. The rate of cardiovascular events at 1 year was reduced from 2.18% in the standard-therapy group to 0.95% in the evolocumab group (hazard ratio in the evolocumab group = 0.47; 95% confidence interval, 0.28 to 0.78; P = .003).

Conclusions. During approximately 1 year of therapy, the use of evolocumab plus standard therapy, as compared with standard therapy alone, significantly reduced LDL cholesterol levels and reduced the incidence of cardiovascular events in a prespecified but exploratory analysis.
EMBRACE-STEMI: Safety, Tolerability and Efficacy of Intravenous Bendavia\textsuperscript{TM} on Reperfusion Injury in Patients Treated With Standard Therapy\textsuperscript{a}

Presented by C. Michael Gibson, Boston, Massachusetts, United States.

**Background.** Although significant efforts have been made to improve ST-segment elevation myocardial infarction (STEMI) outcomes by reducing symptom-onset-to-reperfusion times, strategies to decrease the clinical impact of ischemic reperfusion injury have demonstrated limited success. Bendavia, an intravenously administered mitochondrial targeting peptide, has been shown to reduce myocardial infarct size and attenuate coronary no-reflow in experimental models when given before reperfusion. EMBRACE-STEMI is testing the hypothesis that Bendavia, in conjunction with standard-of-care therapy, is superior to placebo for the reduction of myocardial infarction size among patients with first-time, acute, anterior wall STEMI who undergo successful reperfusion with primary PCI and stenting.

**Methods.** The EMBRACE STEMI study is a phase 2a, randomized, double-blind, placebo-controlled trial enrolling patients with a first-time anterior STEMI and an occluded proximal or mid-left anterior descending artery undergoing primary percutaneous coronary intervention (PCI) within 4 hours of symptom onset to either Bendavia 0.05 mg/kg/hr (n = 58) or placebo (n = 60). The primary end point is infarct size measured by the area under the creatine kinase-MB enzyme curve calculated from measurements from the central clinical chemistry laboratory obtained over the initial 72 hours after the primary PCI procedure, and the major secondary end point is infarct size calculated by the volume of infarcted myocardium (late contrast gadolinium enhancement) on the day 4 ± 1 cardiac magnetic resonance imaging.

**Results.** Patient characteristics: Mean patient age: 60 years, females 28%, diabetics 10%, ischemia time: 151 minutes, left anterior descending artery (LAD) area at risk: 85%, aspiration thrombectomy prior to percutaneous coronary intervention (PCI): 68%. The primary outcome was similar in the bendavia and placebo arms: 217.4 vs 266.6 (no significant difference, [NS]). Secondary outcomes: AUC troponin I at 6 hours, 144.6 vs 139.3 (NS); complete ST-segment resolution immediately post-PCI: 14.6% vs 22%; P > 0.05; infarct volume at day 4, 43.1 vs 48.4 (NS); left ventricular ejection fraction at day 4, 44.0% vs 41.9% (NS); infarct volume at day 30, 30.1 vs 31.5; left ventricular ejection fraction at day 30, 44.8% vs 46.1% (NS); complete ST-segment resolution immediately after PCI, 14.6% vs 22% (NS); or at 24 hours 53.6% vs 50.9% (NS); TIMI 3 flow after PCI, 88.3% vs 87.1% (NS); death/new-onset chronic heart failure rehospitalization at 30 days, 22.4% vs 28.3% (NS); and at 6 months: 25.9% vs 28.3% (NS). In the 8 hours during / following Bendavia administration, there was a trend towards reduced symptomatic heart failure (8.6% vs 18.3%; P = 0.18).

**Conclusions.** The results of this trial indicate that Bendavia, a novel agent to prevent mitochondrial dysfunction, and thus potentially reperfusion injury, does not reduce infarct size compared with placebo in patients with anterior STEMI due to proximal/mid occlusion of the LAD. Further phase 3 trials are ongoing. The hypothesis generating data that demonstrated a trend toward a favorable reduction in CHF symptoms in the 8 hours during/following Bendavia administration is being prospectively evaluated at comparable and higher doses in an ongoing trial of patients with systolic heart failure (HFREF).

SCOT-HEART: Computed Tomography Coronary Angiography in Patients With Suspected Angina Due to Coronary Heart Disease\textsuperscript{a}

Presented by David E. Newby, Edinburgh, United Kingdom.

**Background.** The benefit of CT coronary angiography (CTCA) in patients presenting with stable chest pain has not been systematically studied. We aimed to assess the effect of CTCA on the diagnosis, management, and outcome of patients referred to the cardiology clinic with suspected angina due to coronary heart disease.

**Methods.** In this prospective open-label, multicentre trial, we recruited patients aged 18–75 years referred for the assessment of suspected angina due to coronary heart disease from 12 cardiology chest pain clinics across Scotland. We randomly assigned (1:1) participants to standard care plus CTCA or standard care alone. Randomisation was done with a web-based service to ensure allocation concealment. The primary endpoint was the diagnosis of angina secondary to coronary heart disease at 6 weeks. All analyses were intention to treat, and patients were analysed in the group they were allocated to, irrespective of compliance with scanning.

**Results.** Between Nov 18, 2010, and Sept 24, 2014, we randomly assigned 4146 (42%) of 9849 patients who had been referred for assessment of suspected angina due to coronary heart disease. 47% of participants had a baseline clinic diagnosis of coronary heart disease and 36% had angina due to coronary heart disease. At 6 weeks, CTCA reclassified the diagnosis of coronary heart disease in 558 (27%) patients and the diagnosis of angina due to coronary heart disease in...
In patients with suspected angina due to coronary heart disease, CTCA clarifies the diagnosis, enables targeting of interventions, and might reduce the future risk of myocardial infarction. Our findings show that TAVR as an alternative to surgical AVR resulted in significantly lower mortality compared with surgical AVR at 1 year in patients who were at increased risk for surgery. Long-term outcomes following TAVR with the self-expanding CoreValve are necessary to further validate this survival advantage.

**Conclusions.** In stable patients with new chest pain, CTA strategy improved efficiency of use of invasive evaluation. But despite lower testing costs for CTA compared with functional tests, net effect was to drive a small (< $500), statistically non-significant increase in cost.

**Late-Breaking Clinical Trials III**

**PARTNER 1: Five-year Outcomes**

*Presented by Michael Mack, Plano, Texas, United States.*

**Background.** The Placement of Aortic Transcatheter Valves (PARTNER) trial showed that mortality at 1 year, 2 years, and 3 years is much the same with transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR) for high-risk patients with aortic stenosis. We report here the 5-year outcomes.

**Methods.** We did this randomised controlled trial at 25 hospitals, in Canada (2), Germany (1), and the United States (23). We used a computer-generated randomisation sequence to randomly assign high-risk patients with severe aortic stenosis to either SAVR or TAVR with a balloon-expandable bovine pericardial tissue valve by either a transfemoral or transapical approach. Patients and their treating physicians were not masked to treatment allocation. The primary outcome of the trial was all-cause mortality in the intention-to-treat population at 1 year, we present here predefined outcomes at 5 years. The study is registered with ClinicalTrials.gov, number NCT00530894.

**Results.** We screened 3105 patients, of whom 699 were enrolled (348 assigned to TAVR, 351 assigned to SAVR). Overall mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 11.7%. At 5 years, risk of death was 67.8% in the TAVR group compared with 62.4% in the SAVR group (hazard ratio = 1.04; 95% confidence interval, 0.86–1.24; P = .76). We recorded no structural valve deterioration requiring surgical valve replacement in either group. Moderate or severe aortic regurgitation occurred in 40 (14%) of 280 patients in the TAVR group and two (1%) of 228 in the SAVR group (P < .0001), and was associated with increased 5-year risk of mortality in the TAVR group (72%-4% for moderate or severe aortic regurgitation vs 56.6% for those with mild aortic regurgitation or less; P = .003).

**Conclusions.** Our findings show that TAVR as an alternative to surgery for patients with high surgical risk results in similar clinical outcomes.

**CoreValve US Pivotal High Risk Trial: 2-Year Outcomes**

*Presented by Michael J. Reardon, Houston, Texas, United States.*

**Background.** The randomized CoreValve trial demonstrated that transcatheter aortic valve replacement (TAVR) resulted in significantly lower mortality compared with surgical AVR at 1 year in patients who were at increased risk for surgery. Longer-term outcomes following TAVR with the self-expanding CoreValve are necessary to further validate this survival advantage.

**Methods.** We included patients with severe aortic stenosis at increased surgical risk with NYHA functional class II or greater. The primary endpoint was all-cause mortality at 2 year.
Results. Median patient follow-up of 24 (TAVR, 24.4; surgical AVR, 24.2) months. All-cause mortality (22.2% vs 28.6%; Log-rank, \( P = .04 \)) and all stroke (10.9% vs 16.6%; Log-rank, \( P = .05 \)) was lower in the TAVR group compared to the surgical AVR group. There were no differences in major stroke (6.8% TAVR vs 9.8% surgical AVR). MACCE was significantly lower in the TAVR group compared to the surgical AVR group (29.7% vs 38.6%; \( P = .01 \)).

Conclusions. At 2 years for patients with symptomatic severe AS at increased risk of surgery, the survival superior seen at 1 year for TAVR over surgical AVR is maintained. All stroke was less with TAVR over surgical AVR but major stroke showed no difference and MACCE was significantly lower with TAVR compared to surgical AVR.

Early Clinical and Echocardiographic Outcomes With the SAPIEN 3 Transcatheter Aortic Valve Replacement System in Inoperable, High-risk and Intermediate-risk Aortic Stenosis Patients12

Presented by Susheel Kodali, New York, New York, United States.

Introduction. The SAPIEN 3 TAVR system is the newest iteration of balloon-expandable valve designed with an external fabric skirt to minimize paravalvular regurgitation (PVR). Two non-randomized registries were embedded in the PARTNER II trial to evaluate valve performance.

Methods. From October 2013 to September 2014, 1661 patients with aortic stenosis (583 high-risk or inoperable [S3-HR], 1078 intermediate risk [S3-I]) were treated via the transfemoral (TF) (n = 1450; 87%), transapical or transaortic (n = 211; 13%) access route at 57 sites. Procedural outcomes and 30-day clinical events were assessed in the DEFLECT III trial. (n = 1450; 87%), transapical or transaortic (n = 211; 13%) access route was positioned across all 3 cerebral vessels) protection compared with previous transcatheter valves.

Methods. Multicenter prospective single-blind randomized controlled trial at 13 sites, including 86 patients (exploratory study for the design of a pivotal RCT). Primary Safety Endpoint (ITT population): In-hospital composite of death, stroke, life-threatening or disabling bleeding, AKI (2/3), and major vascular complications (VAREC-2). Secondary Performance outcome: successful positioning (complete 3-vessel coverage verified by angiography) and retrieval without TAVR interference. Secondary Efficacy: Frequency, number, and average single, maximal, and total lesion volumes by DW-MRI at 4 days (range 2-6 days). Neurocognitive assessment was performed by Montreal Cognitive Assessment scores.

Results. There were not important baseline characteristic differences between both groups. CoreValve (Medtronic) was employed in about a third of patients, with a Sapien device (Edwards LifeSciences) being used in the rest. Fluoroscopy time was longer with the TriGuard (28.2 vs 18.6 minutes; \( P < .001 \)). 29% and 34% of study and control patients, respectively, were lost to follow-up over 30 days for reasons including stroke, refusal, permanent pacemaker implantation, or death. Technical success was achieved in 87% of the study group (6 patients lost complete coverage), and TAVR success did not differ between the study arms. The primary safety endpoint and its individual components were comparable between both groups. At 30 days, 73% of the TriGuard group and 88% of controls had no lesions on diffusion-weighted MRI (4.5 and 4.0 new lesions per patient, respectively). TriGuard reduced single and maximum lesion volumes: 16% and 17%, respectively, in the intention-to-treat analysis, and 41% and 45% in the per-treatment analysis. Only 12.5% of controls had zero total lesion volume. National Institutes of Health (NIH) stroke scale score, improved or stays the same at 30 days for the majority of patients in both the study (97.4%) and control arms (87.9%). Montreal Cognitive Assessment scores improved in the TriGuard arm and worsened in the control arm.

Conclusions. In this exploratory clinical trial, use of the TriGuard was safe and provided complete cerebral coverage in 87% of cases, it increased the proportion of patients completely free of ischemic brain lesions and it reduced single and maximum lesion volume.

Outcomes of the Initial Experience With Commercial Transcatheter Mitral Valve Repair in the United States14

Presented by Paul Sorajja, Minneapolis, Minnesota, United States.

Background. Degenerative MR is common, affecting ~600 000 persons in the United States. Surgery is the standard of care, and is indicated for patients with symptoms or left ventricle (LV) dysfunction. However, there are patients in whom the risk of surgery is prohibitive. The MitraClip system received commercial approval in October 24, 201, being indicated for symptomatic patients with primary MR ≥ 3 and prohibitive surgical risk. Our objective was to analyze and report the initial commercial experience with the MitraClip System in the United States.

Methods. This study shows all commercial transcatheter mitral valve repair (TMVR) cases with MitraClip enrolled in the registry through August 31, 2014 for 564 participants across 61 health care centers in the United States. The in-hospital and 30-day outcomes for procedure success, complications, and device-related events, were examined. Procedure success was considered if post-implant MR grade ≤ 2, without CV surgery and without in-hospital mortality. Other definitions were procedure complications (cardiac perforation,
major bleeding, stroke, myocardial infarction, mitral injury, or death) and device-related adverse events (single leaflet device attachment, complete clip detachment, device thrombosis, device or delivery component embolization).

**Results.** Clip implantation occurred in 94% of the cases, and procedural success was achieved in 91.8%. Variables related with procedural success were: smaller left ventricular end-diastolic diameters, less severe baseline mitral regurgitation, A2-P2 clip location and case volume (×2). Procedure complications and device-related adverse events rates were 7.8% and 2.7%. Mortality was 2.3% in-hospital, and 5.8% at 30-days.

**Conclusions.** In this first report of the US commercial experience with TMVR, procedure success, clinical outcomes, and adverse events were favourable in comparison to pre-approval studies and other national registries. These data demonstrate effectiveness and safety of TMVR with MitraClip for the treatment of prohibitive risk patients with symptomatic MR.

**JOINT AMERICAN COLLEGE OF CARDIOLOGY/NEW ENGLAND JOURNAL OF MEDICINE LATE-BREAKING CLINICAL TRIALS**

**AATA: Ablation Versus Amiodarone for Treatment of Persistent Atrial Fibrillation in Patients With Congestive Heart Failure and an Implanted Device**

*Presented by Luigi Di Biase, Austin, Texas, United States.*

**Background.** Catheter ablation (CA) represents a valid treatment option in patients with drug-refractory symptomatic atrial fibrillation (AF). The majority of catheter ablation trials have mainly enrolled patients with preserved LVEF and paroxysmal AF. However, a significant number of patients with AF also have heart failure (HF) and rhythm control with antiarrhythmic drugs has not shown satisfactory results in randomized trials both in patients with or without HF. Whether CA is superior to amiodarone for the treatment of persistent AF in patients with HF is unknown.

**Methods.** This was an open-label, randomized, parallel-group, multicenter study. Patients with persistent AF, dual-chamber ICD or CRT-D, NYHA II–III and LVEF < 40% within the last 6 months were randomly assigned (1:1 ratio) to undergo CA for AF (group 1 = 102 patients) or receive amiodarone, (group 2 = 101 patients). The main goal of the ablation procedure was pulmonary vein antrum isolation. Recurrence of AF was the primary endpoint. Recurrence of AF was the primary endpoint.

**Results.** Baseline characteristics were not different between groups. At 26 ± 8 months follow-up, 71 (70%) patients in group 1 were free of recurrences after average 1.4 ± 0.6 procedures as compared to 34 (34%) in group 2 (log-rank, P < .001). Success rate of CA in the different centers after a single procedure ranged from 29% to 61%. After adjusting for covariates in multivariable model, patients on amiodarone therapy were found to be 2.5 times more likely to fail (HR = 2.5; 95% confidence interval [95%CI], 1.5-4.3; P < .001) compared to CA. Over the 2 year follow-up, hospitalization rate was 31% (32 patients) in group 1 and 57% (58 patients) in group 2 (P < .001), showing 45% relative risk reduction (RR = 0.55; 95%CI, 0.39-0.76). A significant lower mortality was observed in CA [8 [8%] versus AMIO [18 [18%]; P = .037].

**Conclusions.** This multicenter randomized study shows that CA of AF is superior to amiodarone in achieving freedom from AF at long-term follow-up and reducing hospitalization and mortality in patients with heart failure and persistent AF.

**Effectiveness of Surgical Ablation of Atrial Fibrillation During Mitral Valve Surgery**

*Presented by A. Gillinov, New York, New York, United States.*

**Background.** Among patients undergoing mitral-valve surgery, 30 to 50% present with atrial fibrillation, which is associated with reduced survival and increased risk of stroke. Surgical ablation of atrial fibrillation has been widely adopted, but evidence regarding its safety and effectiveness is limited.

**Methods.** We randomly assigned 260 patients with persistent or long-standing persistent atrial fibrillation who required mitral-valve surgery to undergo either surgical ablation (ablation group) or no ablation (control group) during the mitral-valve operation. Patients in the ablation group underwent further randomization to pulmonary vein isolation or a biaarial maze procedure. All patients underwent closure of the left atrial appendage. The primary end point was freedom from atrial fibrillation at both 6 months and 12 months (as assessed by means of 3-day Holter monitoring).

**Results.** More patients in the ablation group than in the control group were free from atrial fibrillation at both 6 and 12 months (63.2% vs 29.4%; P < .001). There was no significant difference in the rate of freedom from atrial fibrillation between patients who underwent pulmonary-vein isolation and those who underwent the biaarial maze procedure (61.0% and 66.0%, respectively; P = .60). One-year mortality was 6.8% in the ablation group and 8.7% in the control group with ablation, (HR = 0.76; 95% confidence interval, 0.32 to 1.84; P = .55). Ablation was associated with more implantations of a permanent pacemaker than was no ablation (21.5 vs 8.1 per 100 patient-years; P = .01). There were no significant between-group differences in major cardiac or cerebrovascular adverse events, overall serious adverse events, or hospital readmissions (figure 2).

**Conclusions.** The addition of atrial fibrillation ablation to mitral-valve surgery significantly increased the rate of freedom from atrial fibrillation at 1 year among patients with persistent or long-standing persistent atrial fibrillation, but the risk of implantation of a permanent pacemaker was also increased.

**LEGACY: Long-term Effect of Goal Directed Weight Management on an Atrial Fibrillation Cohort**

*Presented by Rajeev K. Pathak, Adelaide, Australia.*

**Background.** Obesity and atrial fibrillation (AF) are dual epidemics that frequently coexist. Weight-loss reduces AF burden; however, whether this is sustained, has a dose effect or is influenced by weight-fluctuation is not known. The aim was to evaluate the long-term impact of weight-loss and weight-fluctuation on rhythm control in obese individuals with atrial fibrillation.

**Methods.** Of 1415 consecutive patients with AF, 825 had BMI ≥ 27 kg/m² and were offered weight management. After screening for exclusion criteria, 355 were included in this analysis. To determine a dose-response, weight-loss was categorized as: Group-1 (> 10%); Group-2 (3–9%); and Group-3 (< 3%). Weight trend/fluctuation was determined by yearly follow-up. We determined the impact on AF severity scale and 7-day ambulatory monitoring.

**Results.** There were no differences in baseline characteristics or follow-up duration between the groups (NS); At follow-up, AF burden and symptom severity decreased more in Group-1 compared to Group-2 and 3 (p 10% resulted in a six-fold (95% confidence interval, 3.4-10.3; P < .001) greater probability of arrhythmia-free survival compared to other two groups. Greater than 5% weight-fluctuation partially offsets this benefit with a two-fold (95% confidence interval, 1.0-4.3; P = .02) increased risk of arrhythmia recurrence.
Conclusions. Long-term sustained weight-loss is associated with significant reduction of AF burden and maintenance of sinus rhythm. Weight-loss and avoidance of weight-fluctuation constitute important strategies for reducing the rising burden of AF.

References.

