Report of the American Heart Association (AHA) Scientific Sessions 2013, Dallas

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The American Heart Association (AHA) Scientific Sessions were held in Dallas on November 16–20, 2013. The meeting is one of the most leading conferences of cardiology in the world, with over 18,000 professional attendees from more than 105 countries. There were 315 invited sessions and 443 abstract sessions, comprising more than 5,000 presentations. The sessions were expanded to 26 program tracks, which included and integrated basic, translational, clinical, and population science. In the series of late-breaking sessions, updates of results from 20 clinical trials were disclosed. Japanese scientists submitted the second most abstracts to the Scientific Sessions in 2013. We appreciate the significant contribution to the sessions by Japanese cardiologists as well as the Japanese Circulation Society. (Circ J 2014; 78: 51–56)

Key Words: American Heart Association; Japanese Circulation Society; Late-breaking clinical trials; Scientific Sessions

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Late-Breaking Clinical Trials

Updates of results from the most recent clinical trials were the highlight of the AHA Scientific Sessions 2013, with 20 LBCTs in the sessions (Figure 3B). Another 19 clinical trials were presented in the clinical science sessions. Among them, several are summarized as follows.

TTM

The Targeted Temperature Management (TTM) trials were designed to compare 2 target temperatures for therapeutic hypothermia, and 939 patients with return of spontaneous circulation after CPR were assigned to targeted temperature management at either induced hypothermia (33°C) or a near-normal temperature (36°C) after cardiac arrest. There was no significant difference between groups in survival and a good neurologic outcome at 180 days. In unconscious survivors of out-of-hospital cardiac arrest of presumed cardiac cause, hypothermia at a targeted temperature of 33°C did not confer a benefit as compared with a targeted temperature of 36°C.6
Figure 1. The American Heart Association (AHA) Scientific Sessions 2013 were held at the Dallas Convention Center (A,B) in downtown Dallas (C).

Figure 2. The American Heart Association (AHA) Scientific Sessions 2013 acknowledged the major international societies of cardiology for their contribution to the International Sessions (A). Professor Kyoichi Mizuno, Congress Chairperson of the 77th Annual Scientific Meeting of the Japanese Circulation Society, overviewed the meeting held in Yokohama on March 15–17, 2013 (B).
ROSE AHF
In the multicenter, double-blind placebo-controlled randomized Renal Optimization Strategies Evaluation in Acute Heart Failure (ROSE AHF) trial, it was investigated whether the addition of low-dose dopamine (2 μg/kg/min) or low-dose nesiritide (0.005 μg/kg/min) to optimally-dosed diuretic therapy improved renal function and decongestion in 360 patients with AHF and renal dysfunction (estimated glomerular filtration rate of 15–60 ml/min/1.73 m²). Co-primary endpoints were cumulative urinary volume from randomization through 72 h (decongestion endpoint) and change in serum cystatin-C from randomization to 72 h (renal function endpoint). There was no difference in 72-h urinary volume and change in cystatin-C between low-dose dopamine and placebo. There was also no difference in 72-h urinary volume and change in cystatin-C between low-dose nesiritide and placebo.7

CTSN
No conclusive evidence for superiority of mitral valve repair or replacement for patients with severe ischemic mitral regurgitation (MR) is specified in current guidelines. The Cardiothoracic Surgery Clinical Trials Network (CTSN) conducted a multicenter randomized clinical trial of severe ischemic MR treatment (CTSN trial). In this study, 251 patients with severe ischemic MR were allocated to mitral valve repair or chordal-sparing replacement. The primary endpoint was the degree of left ventricular (LV) reverse remodeling assessed by LV end-systolic volume index (ESVI) using transthoracic echocardiography at 12 months. There were no significant differences in the primary endpoint and clinical outcomes at 30 days and 1 year, including mortality, major adverse cardiac events, serious adverse events, and quality of life (Figure 4). However, the frequency of moderate or severe recurrent MR at 1 year was significantly higher in patients who underwent repair than in those who had replacement, and LVESVI at 1 year in patients who had repair with recurrent MR was significantly greater than in those who had repair without recurrent MR. This study showed that chordal-sparing mitral valve replacement is at least equally effective for severe ischemic MR and may be preferable based on the significantly lower incidence of recurrent MR as compared with mitral valve repair.8

TOPCAT
In the international multicenter, double-blind, placebo-controlled randomized Treatment Of Preserved Cardiac function heart failure with an Aldosterone antagonist (TOPCAT) trial, the effect of treatment with spironolactone on clinical outcomes in 3,445 patients with HF and preserved left ventricular ejection fraction (HFpEF) was investigated. The primary endpoint was a composite of cardiovascular mortality, aborted cardiac arrest, or hospitalization for the management of HF. Mean follow-up was 3.3 years. Spironolactone did not alter the primary endpoint compared with placebo, but it significantly reduced hospitalization for HF (12% vs. 14.2%).8
and hypertension or CKD.

**EU-PACT**
The European Pharmacogenetics of Anticoagulant Therapy (EU-PACT) is a multicenter single-blind randomized control trial aiming to evaluate genotype-guided warfarin dosing in 455 patients with AF or venous thromboembolism. Genotyping for...
CYP2C9*2, CYP2C9*3, and VKORC1 was performed. For patients assigned to the genotype-guided group, warfarin doses were prescribed according to pharmacogenetic-based algorithms for the first 5 days. Patients in the control (standard dosing) group received a 3-day loading-dose regimen. The genotype arm, the mean percentage of time in the therapeutic range (%TTR) of 2.0–3.0 for the international normalized ratio (INR) was higher and the median time to reach a therapeutic INR was shorter. There were significantly fewer cases of excessive anticoagulation (INR ≥4.0) in the genotype-guided group.12

COAG
The Clarification of Optimal Anticoagulation through Genetics (COAG) is a multicenter double-blind randomized control trial aiming to evaluate pharmacogenetic-guided warfarin dosing in 1,015 patients with AF, deep-vein thrombosis or pulmonary embolism. The algorithms for the genotype-guided dosing strategy included clinical variables and genotype data for CYP2C9*2, CYP2C9*3, and VKORC1. The algorithms for the clinically-based dosing strategy included clinical variables only. At 4 weeks, the mean %TTR was 45.2% in the genotype-guided group and 45.4% in the clinically-guided group. There was, however, a significant interaction between dosing strategy and race. Approximately 1 in 4 patients in the study was African-Americans, and among them, the mean %TTR was less in the genotype-guided group than in the clinically guided group.13

ENGAGE AF-TIMI48
The Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation–Thrombolysis in Myocardial Infarction 48 (ENGAGE AF-TIMI 48) is a randomized, double-blind, double-dummy trial comparing 2 once-daily doses of edoxaban (60 mg or 30 mg) with warfarin in 21,105 patients with moderate-to-high-risk AF (median follow-up, 2.8 years). The mean CHADS2 score was 2.8 (CHADS2 score 0 and 1 were excluded). The median %TTR was 68.4% in the warfarin group. The annualized rate of the primary endpoint (stroke and systemic embolic events) during treatment was 1.50% with warfarin. Compared with warfarin, the hazard ratio and annualized rate of the primary endpoint for patients on edoxaban 60 mg and 30 mg were 0.79 and 1.18% (P<0.001 for noninferiority), and 1.07 and 1.61% (P=0.005 for noninferiority), respectively. In the intention-to-treat analysis, there was a trend favoring high-dose edoxaban vs. warfarin and an unfavorable trend with low-dose edoxaban vs. warfarin. In a subgroup analysis, edoxaban at both doses was significantly better than warfarin for hemorrhagic stroke, but not for ischemic stroke in the 30-mg once-daily group. Major bleeding events, fatal bleeding or intracranial hemorrhage, and death from cardiovascular causes were significantly less in patients on any dose of edoxaban compared with warfarin.14

**Closing Remarks**
The AHA Scientific Sessions 2013 were successfully held in Dallas on November 16–20, 2013. The sessions continue to evolve and improve with the input from the attendees as well as promoting mutual networking. We appreciate the significant contribution to the sessions by Japanese cardiologists as well as the highly sophisticated Japanese Circulation Society. We hope the present report will generate interest among many
young Japanese cardiologists to submit abstracts and attend the AHA Scientific Sessions 2014 to be held in Chicago on November 15–19, 2014.

References