The 67th Annual Scientific Session and Expo of the American College of Cardiology (ACC) were held at the Orange County Convention Center, Orlando, from March 10–12, 2018. This meeting offered 2,700 accepted abstracts presented in oral and poster sessions by 2,100 experts and 37 Late-Breaking Clinical Trials and Featured Clinical Research presentations. This report introduces the key presentations and highlights from the ACC 2018 Scientific Session.

**Key Words:** American College of Cardiology; Late-Breaking Clinical Trials; Scientific Sessions

**Opening Showcase**

The ACC Scientific Session started with singing of the national anthem. Next, ACC President Mary Norine Walsh, MD, FACC, welcomed thousands of cardiovascular professionals from around the world to ACC.18 in Orlando as part of the Opening Showcase Session on March 10 (Figure 1C). Walsh began her announcement with, “The College’s 67th Annual Scientific Session promises to be better than ever.” She noted the hundreds of leaders, staff, cardiovascular society partners, industry sponsors and other stakeholders involved in the planning and implementation of the meeting. Walsh’s presidential address focused on her father’s heart disease experience and the importance of advocacy in cardiovascular care. She highlighted three ways attendees can advocate each day, with the most obvious being advocacy on behalf of patients. “Our ACC Core Values now explicitly call out that we be patient-centered,” she said. “We are the future of cardiovascular healthcare and the protectors of our patients.” Walsh also stressed the need for cardiovascular professionals to advocate for each other to prevent burnout, encourage diversity in the profession, improve team care, and more. A third way to advocate was to “be quality and professional leaders nationally and at our own institutions,” she said. “We are lucky in cardiology. We have reams of quality data to back us up. We have more randomized controlled trials and guidelines than any other field of medicine and our registries. We can advocate for quality by using data to innovate.”

Walsh closed by challenging attendees when they returned to work on Tuesday morning, enriched by the new science and technology, practice development, and networking at this fantastic meeting, to continue to advocate and surmount barriers. “Let’s not take no for answer,” she said. “Let’s take care of each other. Let’s advocate.”

**LBCTs**

There were 20 LBCTs presentations in 5 LBCT sessions (Figure 2A), included the joint ACC/Journal of American College of Cardiology, the joint ACC/Journal of the American Medical Association and the joint ACC/New England Journal of Medicine. Featured Clinical Research presentations also included 17 LBCTs in 3 sessions. Among them, 16 LBCTs are reported here.
VEST trial evaluated whether a wearable cardioverter-defibrillator (WCD) could reduce sudden cardiac death (SCD) occurrence in the immediate post-MI period (<90 days) in patients with reduced left ventricular ejection fraction (LVEF), as a bridge to evaluation for an implantable cardioverter-defibrillator. A total of 2,302 patients with acute MI and LVEF ≤35% were randomized 2:1 at 108 sites in 4 countries to receive guideline-directed medical therapy plus a WCD (n=1,524) or guideline-directed medical therapy alone (n=778) within 7 days of hospital discharge. The primary outcome was SCD and death from ventricular arrhythmias. The mean follow-up was 84.3 days. There was no significant difference in the primary outcome between the WCD and control groups (1.6% vs. 2.4%, P=0.18). Total mortality was 3.1% in the WCD group and 4.9% in the control group (P=0.04).

NOTION trial compared the primary composite outcome of all-cause death, stroke and MI 5 years post surgery for 139 lower-risk patients (82% with Society of Thoracic Surgery risk score <4%) aged 70 years and over who underwent transcatheter aortic valve replacement (TAVR) and 135 who underwent surgical aortic valve replacement (SAVR). Secondary outcomes were safety and efficacy and echocardiographic outcomes. The rate of the primary outcome

levels ≥100mg/dL or apolipoprotein B ≥80mg/dL after 2–16 weeks of intensive or maximally tolerated statin therapy. Patients were randomized to either subcutaneous injections of alirocumab 75 or 150mg every 2 weeks (n=9,462) or placebo (n=9,462). The target LDL-C level was 25–50mg/dL. The primary efficacy endpoint was the time to first occurrence of coronary artery disease (CAD) death, nonfatal myocardial infarction (MI), unstable angina requiring hospitalization or ischemic stroke. After a median follow-up of 2.8 years, LDL-C levels were 53.3mg/dL in the alirocumab group compared with 101.4mg/dL in the placebo group, for an absolute reduction of 54.7%. The primary efficacy endpoint was significantly lower in the alirocumab group vs. the placebo group (9.5% vs. 11.1%; hazard ratio [HR], 0.85; 95% confidence interval [CI]: 0.78–0.93; P=0.0003). Although the rate of all-cause death was significantly lower by 15% with alirocumab vs. placebo (3.5% vs. 4.1%; HR, 0.85; 95% CI: 0.73–0.98; P=0.026), there was no significant difference between the groups for CAD death (2.2% vs. 2.3%) and cardiovascular death (2.5% vs. 2.9%). Among patients with baseline LDL-C levels ≥100mg/dL, alirocumab reduced the primary efficacy endpoint by 24% (absolute risk reduction 3.4%) and all-cause death by 29% (absolute risk reduction 1.7%) compared with placebo.
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was 39.2% of TAVR patients and 35.8% of SAVR patients (P=0.78). Undergoing TAVR was associated with higher rates of aortic regurgitation (AR), with 52.9% of TAVR patients having mild AR and 8.2% having moderate AR, compared with 77.4% of SAVR patients not experiencing AR. The patients with new pacemaker implantation after TAVR tended to be associated with increased mortality than those without new pacemaker (38.2% vs. 21.7%, P=0.07).

SECURE-PCI
This trial compared the safety and efficacy of 2 loading doses of atorvastatin (80mg) given early among patients presenting with ACS for whom an early invasive approach was planned. The researchers randomized 4,191 patients with ACS in 58 sites in Brazil scheduled for percutaneous coronary intervention (PCI) to receive a loading dose of atorvastatin 80mg followed by an additional 80mg atorvastatin or matching placebo within 7 days of the planned PCI. All patients in both groups received atorvastatin 40mg for the next 30 days. The primary outcome was the rate of major adverse cardiovascular events (MACE) at 30 days, defined as a composite of all-cause death, nonfatal acute MI, nonfatal stroke and unplanned coronary revascularization. There was no significant difference in MACE between the atorvastatin loading group and the placebo group (6.2% vs. 7.1%, P=0.27). Among patients who underwent PCI, there was a significant difference in the primary outcome, which occurred in 6% of those who received the loading dose vs. 8.2% of patients who received placebo (P=0.02).

COMPASS
This substudy of the COMPASS trial analyzed outcomes in 6,391 patients with lower extremity peripheral artery disease (PAD) who were randomized to receive either a low-dose rivaroxaban and aspirin combination, rivaroxaban alone, or aspirin alone. Researchers investigated whether hospitalizations, MACE, amputations and deaths were higher after the first episode of major adverse limb events (MALE). They also studied the effect of treatment with low-dose rivaroxaban and aspirin compared with aspirin alone on the incidence of MALE, peripheral vascular interventions, and all peripheral vascular outcomes over a median follow-up of 21 months. The incidence of MALE was highest (3.8%) in PAD patients with prior revascularization, amputation or critical limb ischemia. A total of 128 patients experienced MALE, putting them at signifi-
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CANTOS
Canakinumab is a monoclonal antibody targeting interleukin-1β. At the European Society of Cardiology Congress 2017, the CANTOS trial showed that canakinumab was superior to placebo at preventing adverse cardiac events. The 2 subanalyses from the CANTOS trial were presented at the ACC.18 Scientific Session.

CANTOS Diabetes
This analysis evaluated the effect of canakinumab on the risk of new-onset type 2 diabetes in patients with prediabetes. A total of 4,960 patients with prediabetes at trial entry received canakinumab for a median of 3.7 years. Significant, dose-dependent reductions from baseline in inflammatory markers were observed in patients with prediabetes receiving canakinumab vs. placebo. Despite these reductions, canakinumab did not reduce the rate of new-onset diabetes. In the 50, 150, and 300 mg dose groups, the incidence of new-onset diabetes was 4.24, 4.35 and 4.12, respectively, compared with 4.20 in the placebo group. Combined analysis of the 3 dose groups found no significant difference compared with placebo.

CANTOS CKD
The other subanalysis evaluated the benefits of canakinumab among patients with moderate to severe chronic kidney disease (estimated glomerular filtration rate 30–60 mL/min/1.73 m²). Results showed those who achieved on-treatment high-sensitivity C-reactive protein levels <2 mg/L after the first dose of canakinumab had a 31% reduction in MACE (P=0.004), a 34% reduction in cardiovascular death (P=0.02), and a 24% reduction in all-cause death (P=0.05). Canakinumab had neither clinically meaningful benefit nor substantive harm with respect to adverse clinical renal events.

CVD-REAL 2
CVD-REAL 2, a large-scale and real-world study, evaluated the relationship between the initiation of sodium glucose cotransporter-2 inhibitors (SGLT-2i) vs. other glucose-lowering drugs and a broad range of cardiovascular outcomes (all-cause death, hospitalization for heart failure, MI and stroke) in patients with type 2 diabetes from Japan, South Korea, Singapore, Israel, Australia and Canada. Initiation of SGLT-2i was associated with a lower risk for all of the cardiovascular outcomes. Compared with the other glucose-lowering drugs, SGLT-2i reduced all-cause death (HR, 0.51; 95% CI: 0.37–0.70), hospitalization for heart failure (HR, 0.64; 95% CI: 0.50–0.82), MI (HR, 0.81; 95% CI: 0.74–0.88) and stroke (HR, 0.68; 95% CI: 0.55–0.84).

CARES
The aim of this trial was to demonstrate that major cardiovascular event rates with febuxostat were noninferior to allopurinol in patients with gout and cardiovascular disease. Rates for the composite primary endpoint of cardiovascular death, nonfatal MI, nonfatal stroke, or unstable angina with urgent revascularization were 10.8% on febuxostat and 10.4% on allopurinol (P=0.002 for noninferiority) in the modified intent-to-treat population of 6,190 gout patients. However, febuxostat significantly raised the risk of all-cause death (7.8% vs. 6.4%; HR, 1.22; 95% CI: 1.01–1.47) and cardiovascular death (4.3% vs. 3.2%; HR, 1.34; 95% CI: 1.03–1.73). The increased risk of death was consistent across subgroups. Among patients receiving febuxostat, there was a higher risk of death in the patients who did not regularly take aspirin and those who regularly took nonsteroidal anti-inflammatory drugs, compared with those taking aspirin or not taking nonsteroidal anti-inflammatory drugs.

Blood Pressure Reduction in Black Barbershops
In this interesting study, researchers recruited 319 African-American men whose baseline systolic blood pressure (SBP) was higher than 140 mmHg from 52 Los Angeles Country barbershops. The barbershops were randomly assigned to a pharmacist-led intervention (in which barbers encouraged meetings in barbershops with specialty-trained pharmacists who prescribed drug therapy under a collaborative practice agreement with the participants’ doctors) or to an active control approach (in which barbers encouraged lifestyle modification and doctor appointments). Both the primary and secondary outcome was reduction in systolic and diastolic BP at 6 months. After 6 months, 64% of the men in the pharmacist-led intervention group had BP in the normal range, compared with just 12% of the control group (P<0.001). In the intervention group, SBP decreased from 153 mmHg at baseline to 126 mmHg, and DBP decreased by 18 mmHg. In contrast, in the active control approach group, SBP decreased from 155 mmHg to 145 mmHg, and DBP dropped by 4 mmHg.

POISE
The POISE trial was a randomized controlled trial exploring the effect of perioperative β-blockers on cardiac death, nonfatal MI, and nonfatal cardiac arrest. The 30-day results showed that perioperative extended-release metoprolol reduced the risk of MI (HR, 0.73; 95% CI: 0.60–0.89) but increased the risk of stroke (HR, 2.17; 95% CI: 1.26–3.74) and death (HR, 1.33; 95% CI: 1.03–1.74). To better understand the longer-term effect of perioperative β blockade, secondary outcomes were evaluated 1 year after surgery. At 12 months of follow-up, MI was significantly lower in the metoprolol group vs. the placebo group (5% vs. 6.2%; HR: 0.78; 95% CI: 0.65–0.94; P=0.008). All-cause death was significantly higher in the metoprolol group vs. the placebo group (9.8% vs. 8.5%; HR, 1.16; 95% CI: 1.01–1.34; P=0.036), as was non-cardiovascular death (6% vs. 5%; HR, 1.22; 95% CI: 1.01–1.48; P=0.043). There was no significant difference in cardiovascular death. Stroke was significantly higher in the metoprolol group vs. the placebo group (2.0% vs. 1.4%; HR, 1.52; 95% CI: 1.09–2.12; P=0.014).

TRIUMPH
The aim of this trial was to assess whether a strategy of initial or early treatment with fixed low-dose triple combination therapy would safely achieve better BP control, compared with usual care. At the time of enrollment, average BP was 154/90 mmHg, and 59% of participants were not receiving treatment for high BP. A total of 700 patients were randomly assigned to receive either usual care in which their physician selected their medication or the...
combination “Triple Pill,” consisting of telmisartan (20 mg), amlodipine (2.5 mg) and chlorthalidone (12.5 mg). The primary outcome was the proportion of patients who achieved BP ≤140/90 mmHg at 6 months. The Triple Pill was associated with greater achievement of BP target levels compared with usual care (70% vs. 55%; relative risk, 1.23; 95% CI: 1.09–1.39; P=0.0007). For patients receiving the Triple Pill, the average BP reduction was 8.7 mmHg, compared with 4.5 mmHg for those receiving usual care. After 6 months, 83% of the Triple Pill group was still taking the combination pill, while one-third of the usual-care group were taking at least two BP-lowering drugs. There was no significant difference in adverse events between the groups (38.7% vs. 34.7%, P=0.31).

**GWTG-HF Registry**

The study evaluated the association between hospital performance, based on 30-day risk-standardized mortality rates (RSMR), and long-term survival in 106,304 heart failure patients older than 65 who were hospitalized in 317 GWTG-HF participating sites between 2005 and 2013. The primary exposure variable was 30-day RSMR and 5-year all-cause death. The 30-day RSMR ranged from 8.6% in the highest-performing quartile to 10.7% in the lowest-performing quartile. Among 30-day survivors, high-performing hospitals had a 5-year mortality rate of 73.7% vs. 76.8% for low-performing hospitals. Median survival in the high-performing vs. low-performing hospitals was 717 days vs. 579 days. In the adjusted analysis, the 5-year mortality rate in the lowest-performing hospitals was 22% higher than in the highest-performing hospitals. Based on the findings, the researchers concluded that 30-day RSMR may be a useful heart failure performance metric to incentivize quality care and improve long-term outcomes.

**DEFENSE-PFO**

This trial evaluated whether the benefit from device closure of a patent foramen ovale (PFO) can be determined on the basis of the morphologic characteristics of the PFO. A total of 120 patients with high-risk PFO were randomized to receive transcatheter PFO device closure plus medical therapy or medical therapy alone. High-risk PFO was defined as PFO with atrial septal aneurysm, hypermobility or PFO size ≥2 mm. Medical therapy included anticoagulants or antiplatelet drugs as determined by the patients’ physicians. The primary endpoint was a composite of stroke, vascular death or major bleeding during the 2-year follow-up. All PFO closures were successful without fatal complications. No primary endpoint events occurred in the device closure group during follow-up, compared with 6 events (2-year event rate, 12.9% 95% CI: 3.2–22.6; standard error, 5.0) in the medical therapy alone group (log-rank P=0.013). Procedural complications in the PFO closure group included atrial fibrillation (n=2), pericardial effusion (n=1) and pseudoaneurysm (n=1).

**SMART-DATE**

The aim of this trial was to investigate whether a 6-month duration of dual antiplatelet therapy (DAPT) would be non-inferior to the conventional 12-month or longer duration of DAPT after implantation of drug-eluting stents in ACS patients. A total of 2,712 patients were randomized to 6-month DAPT (n=1,357) or 12-month DAPT (n=1,355) with aspirin and clopidogrel. The primary endpoint was major adverse cardiac and cerebrovascular events (MACCE) at 18 months after the index procedure. The secondary endpoints were assessed by the rate of stent thrombosis and Bleeding Academic Research Consortium type 2–5 bleeding. At 18 months of follow-up, at least 1 MACCE occurred in 4.7% of the 6-month DAPT group and in 4.2% of the 12-month DAPT group, demonstrating the non-inferiority of 6-month DAPT. There was no significant difference in the individual endpoints of all-cause death (2.6% vs. 2.9%; HR, 0.90; 95% CI: 0.57–1.42; P=0.90), stent thrombosis (1.1% vs. 0.7%; HR, 1.50; 95% CI: 0.68–3.35; P=0.32), and bleeding (2.7% vs. 3.9%; HR, 0.69; 95% CI: 0.45–1.05; P=0.09) between the 6-month and 12-month DAPT groups. However, the risk of MI was significantly 2.4-fold higher in the 6-month DAPT group vs. the 12-month DAPT group (1.8% vs. 0.8%; HR, 2.41; 95% CI: 1.15–5.05; P=0.02).

**ANNEXA-4**

Andexanet alfa is a specific reversal agent for all direct and indirect factor Xa inhibitors. Researchers assessed the efficacy of this drug in terms of reduction in anti-factor Xa inhibitor activity and achievement of clinical hemostasis within 12h of administration. All study patients presented with acute major bleeding within 18h of taking one of 4 factor Xa inhibitors (apixaban, rivaroxaban, edoxaban or enoxaparin). Excellent or good clinical hemostasis was achieved in 83% of patients. Safety of andexanet was assessed in all 227 patients. At 30 days, 27 patients (12%) had died and 24 patients (11%) had a thrombotic event. The rates of death and thrombotic events were consistent with expectations given the high-risk profile of the patients.

**Closing Remarks**

The ACC Scientific Sessions is one of the largest cardiology meetings in the world, providing the newest findings, relevant information, and updated guidelines. The ACC’s 68th Annual Scientific Sessions and Expo will hold in New Orleans from March 16–18, 2019. We hope this brief report gives the latest knowledge in cardiology and inspires young Japanese cardiologists to attend future ACC Scientific Sessions.

**References**


