WEDNESDAY

American Heart Association®
SCIENTIFIC SESSIONS 2013

# DAILY NEWS

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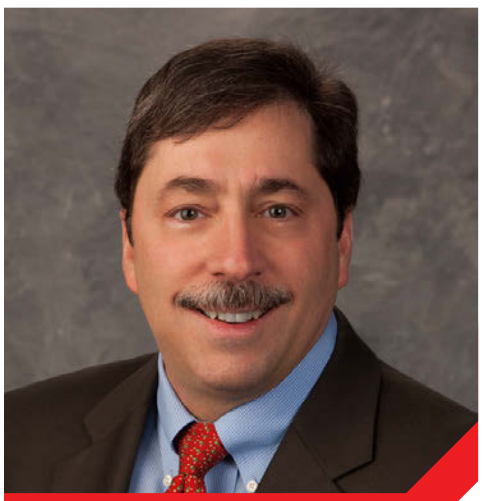
# Discussion of new prevention guidelines set for final day of Scientific Sessions

The new clinical practice prevention guidelines released by the American Heart Association and American College of Cardiology will be presented and discussed in detail during a plenary session Wednesday.

The guidelines, issued Nov. 12, provide comprehensive guidance for physicians about obesity, cholesterol, risk assessment and lifestyle risk factors for preventing cardiovascular diseases and stroke.

The prevention guidelines are critical tools for physicians, considering about one-third of U.S. adults have elevated levels of bad cholesterol and nearly two-thirds have high blood pressure or prehypertension. Fully 60 percent likely will have a major vascular event before they die.

"It's an exciting and rare opportunity to present these new, lifesaving guidelines at an event as important as Scientific Sessions," said former American Heart Association President Gordon F. Tomaselli, MD, FAHA, who co-chaired the Subcommittee on Prevention Guidelines for the ACC/AHA Task Force.



Gordon F. Tomaselli, MD, FAHA

"We're raising the bar on providing clinicians with the tools they need to help their patients with known cardiovascular diseases and stroke risk factors," said Tomaselli, the Michel Mirowski, MD, Professor of Cardiology and Chief of the Division of Cardiology and a Professor of Medicine at Johns Hopkins.

The Scientific Sessions plenary session is scheduled from 9 a.m. to noon at the Omni Hotel Dallas (Ballrooms D-H).

Wednesday's three-hour session includes ample discussion time and will be moderated by leaders from the AHA and the ACC, who are collaborating on the peer-review and dissemination of the guidelines supported by the evidence-review process of the National Heart, Lung, and Blood Institute, said Robert Harrington, MD, FAHA, FACC, and Program Chair on the Committee on Scientific Sessions.

"This major plenary is all about the global prevention agenda and is really a cornerstone of this year's Scientific Sessions," Harrington said. "It's a rare chance to get a comprehensive view on the challenges, strategies and successes in promoting cardiovascular health as a way to improve the world's leading cause of mortality and morbidity."

GUIDELINES continued on page 19

# COAG, EU-PACT trials evaluate value of genetics in guiding warfarin dosage

A pair of Late-Breaking Clinical Trial sessions addressed the power of genetics to determine the therapeutic warfarin dose in patients, and results can differ greatly depending on the strategy used.

Both studies used similar intervention arms: a validated, pharmacogenetic algorithm based on genetic and clinical factors, revised for dosing on days four and five. Information for the same genotypes commonly known to affect warfarin metabolism were used in both studies — *CYP2C9*2*, *CYP2C9*3*, *VKORC1*. After day five, warfarin doses were managed based on common clinical practice.

Stephen Kimmel, MD, MSCE

Stephen Kimmel, MD, MSCE, presenting on behalf of the Clarification of Optimal Anticoagulation through Genetics (COAG) investigators said, "The COAG trial does not support the hypothesis that genetic information provides added benefit above and beyond clinical information on anticoagulation control over the first four weeks of warfarin therapy. There was no effect of pharmacogenetic-based dosing in those expected to have benefit based on predicted dose differences."

For the primary outcome of percent time in the therapeutic INR range (PTTR) at 28 days, there was no difference in PTTR: 45.2 percent for the genotype-guided dosing vs. 45.4

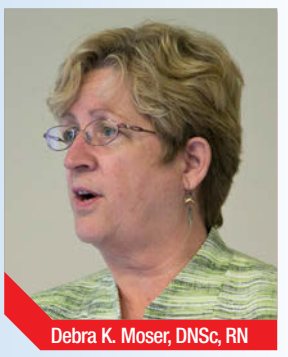
TRIALS continued on page 18

# Self-care CV risk reduction program effective in rural areas

Self-care interventions that overcome environmental and personal barriers to reducing cardiovascular disease risk factors could be successful in rural, socioeconomically disadvantaged areas of the country and possibly other communities at high risk of cardiovascular disease, according to a two-phase study presented Tuesday.

University of Kentucky cardiovascular researchers conducted the study in a rural area of Kentucky's Appalachian region with high rates of persistent poverty and unemployment and low literacy rates. The region also has populations without health insurance or with inadequate insurance and poor access to medical care, especially preventive care.

Phase 1 of the study was a randomized, controlled trial of the efficacy of a 12-week self-care cardiovascular disease risk-reduction program focused on reducing environmental and personal barriers to reducing CVD risks. It involved 425 adults with two or more CVD risk factors who were randomized to either immediate intervention or a wait-list control group.



Debra K. Moser, DNSc, RN

In phase 2, 756 adults in four Kentucky communities participated in the same self-care intervention and were followed for six months after participating in the risk-reduction program to assess the effectiveness and sustainability of the intervention.

The 12-week program in phase 1 was a one-on-one, culturally appropriate CVD risk-factor management education and support program. The program also involved a referral strategy whereby patients were referred to an identified provider for risk management supplemented by CVD risk-reduction guidelines. Participants were encouraged to eat a healthy diet, be more

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## TODAY AT SESSIONS

Don't miss today's highlighted presentations and events. For a complete schedule, see the Final Program or view it online at **scientificsessions.org**.

**9–10:15 a.m.**
*The Cardiovascular Health and Prevention Agenda: 2013-2030*
Ballrooms C1 & C2

**9–10:15 a.m.**
*The Legacy of Cardiovascular Disease for Cancer Survivors*
Room C147

**9–11:55 a.m.**
*Clinical Practice Guidelines for Prevention: Next Steps*
Dallas Ballroom D-H, Omni Dallas Hotel

**10:45 a.m.–12 p.m.**
*Future Strategies and Targets for Heart Failure*
Room C147

**10:45 a.m.–12:15 p.m.**
*Clinical Science: Special Reports IV – Advanced Cardiovascular Disease: Complications and Challenges*
Ballrooms C1 & C2


## Attendee feedback

Scientific Sessions attendees can access online meeting evaluation surveys at **learn.heart.org**. The American Heart Association uses these attendee surveys for feedback on programming, location, networking and CME credits. Attendees must complete the survey to receive CME/CE credit.

Attendees who are not claiming CME/CE credit are invited to fill out a non-CME survey, which will be emailed Friday, Nov. 22.

Responses are anonymous and will be used only to evaluate and build educational and networking opportunities at future Scientific Sessions. ▼

# Highlights from the Program Chair

By Robert Harrington, MD, FAHA, FACC, Committee on Scientific Sessions Program Chair

**It's the last day of AHA Scientific Sessions 2013,** but there's still plenty to cover. One long-awaited session takes place this morning at the Omni Dallas Hotel (Ballrooms D-H), with a plenary devoted to the new cardiovascular guidelines for prevention. Leaders from the AHA and the ACC – who are collaborating on the peer-review and dissemination of the guidelines supported by the evidence-review process of the NHLBI – will moderate the session. Today's sessions will focus on each of the four guidelines released Nov. 12: cholesterol, cardiovascular risk assessment, lifestyle interventions and obesity. There will be ample time for discussion among a panel featuring experts from the AHA, ACC and the NHLBI. (For more on this session, see story on page 1.)

We'll also have other educational activities focusing on prevention and cardiovascular health, in keeping with the AHA's 2020 Strategic Impact Goals.

Today's major plenary looks at the global prevention agenda, with presentations highlighting the challenges, strategies and successes in promoting cardiovascular health as a way to improve the world's leading cause of mortality and morbidity.


Robert Harrington, MD, FAHA, FACC

Special Sessions today highlight the challenges in understanding the cardiac issues among cancer survivors as well as further targets and opportunities in caring for heart failure patients. The final Clinical Science Special Report of this year's program looks at advanced cardiovascular disease and will include a presentation on a first-in-man use of a tissue-engineered vascular graft.

The entire Committee on Scientific Sessions Programming hopes you enjoyed this year's meeting. Safe travels home, and we hope to see you in Chicago for AHA Scientific Sessions 2014. ▼

## Clinical Science: Special Reports — CS.04

10:45 a.m.–12:15 p.m. Wednesday | Ballrooms C1 & C2
**Advanced Cardiovascular Disease: Complications and Challenges**

| TRIALS | DESCRIPTIONS |
|---|---|
| The Incidence of Kidney Injury for Patients Treated with Intensive versus Less Potent Statin Therapy after an Acute Coronary Syndrome | The current analysis examined the incidence of kidney injury for patients on potent versus less intensive statin therapy after ACS. |
| First-in-Man Clinical Evaluation of a Novel Tissue Engineered Vascular Graft | This preclinical trial was designed to support the initiation of clinical trials for human acellular vascular grafts in hemodialysis vascular access, and clinical trials are now underway. |
| Dedicated ICD Programming Reduces the Number of Inappropriate Therapies in a Real World Primary Prevention ICD Population: The DECREASE - Trial | The trial was designed to show a significant reduction of inappropriate ICD therapy by changing detection settings in primary prevention ICD patients. |
| A Multicenter, Randomized Study Assessing the Efficacy of Left Ventricular Augmentation with Algisyl-LVR in the Treatment of Advanced Heart Failure Patients with Ischemic and Non-ischemic Cardiomyopathy: Interim Results of the AUGMENT-HF Study | This study evaluates the concept that in patients with advanced heart failure intramyocardial Alginate hydrogel implants into the free wall of the failing LV will reduce LV wall stress, reverse remodel the failing LV and improve functional capacity. |

# High CHADS2 score may predict dementia risk in AFib patients

A CHADS2 score greater than 2 in atrial fibrillation (AFib) patients predicts an increased risk of new-onset dementia, suggests a retrospective longitudinal observational study presented Tuesday that was based on data from the National Health Insurance Research Database of Taiwan.

Scoring systems predicting dementia risk have been developed for different populations, but presenting author Min-Tsun Liao, MD, an Attending Cardiologist at the National Taiwan University Hospital in Hsinchu City, said this was the first study showing that a high CHADS2 score can predict new-onset dementia specifically in patients with AFib.

Liao and his colleagues enrolled 5,224 patients with AFib and no history of dementia from the national database between 1997 and 1998 and followed them for a mean of 10.9 years. They calculated CHADS2 scores for each patient. The investigators found new-onset dementia in 163 patients (3.1 percent). The mean incidence of new-onset dementia in these AFib patients was 2.86 per 1,000 patient-years.

Among those with the lowest CHADS2 score of 0, the incidence was 1.09 per 1,000 patient-years, but among patients with a CHADS2 score greater than 2, the incidence increased significantly, to 4.04 per 1,000 patient-years. After the researchers adjusted the results for gender and other confounders, the incidence was still significantly increased in AFib patients with higher CHADS2 scores, Liao said. A Kaplan-Meier curve also demonstrated the relationship of new-onset dementia with the CHADS2 score ($p>0.001$).

CHADS2 scores have proved effective in predicting future strokes in AFib patients. Several meta-analyses have demonstrated that AFib is independently associated with an increased risk of dementia. The goal of this study was to evaluate whether the CHADS2 score could predict the incidence of new-onset dementia in AFib patients.

"We found that the higher the CHADS2 score, the higher the incidence of new-onset dementia. The risk of new-onset dementia increased about fourfold from a CHADS2 score of 0 to a CHADS2 score more than 2," he said. "As a cardiologist, I think it's easy to use the CHADS2 score to predict future stroke. And maybe dementia should also be kept in mind in these patients. We do our best to prevent stroke with anticoagulation therapy, and we also have to prevent dementia in these patients. Both of them will affect patients' quality of life."

A large prospective, randomized study must take place to confirm the predictive value of the CHADS2 scoring system and whether it is really a useful tool for risk stratification of new-onset dementia, Liao said.

"If we pay attention to this issue, maybe we can give these patients a better quality of life," he said. ▼

# Obesity increases heart failure risk, but fitness helps lower the threat

As body mass index (BMI) increases, the long-term risk of heart failure increases significantly, but improved fitness levels can attenuate risk of heart failure, according to a study of the relationship between midlife obesity, cardiorespiratory fitness and risk of heart failure using Cooper Center Longitudinal Study data.

William K. Cornwell III, MD, a Postdoctoral Cardiology Research Fellow at the University of Texas Southwestern Medical Center in Dallas, presented the abstract Tuesday, reporting that research showed that the risk of heart failure increases by approximately 10 percent for each kg/m2 increase in BMI. Fitness, however, substantially reduces this danger.

"This study emphasizes the importance of fitness, particularly in obese populations," Cornwell said. "Weight loss is always emphasized in middle-aged obese individuals, but weight loss and fitness are not the same thing. While control of an individual's weight is an important consideration, we need to counsel patients on the importance of fitness if we want to reduce the long-term risk of cardiovascular disease."

The AHA recommends 40 minutes of moderate to vigorous aerobic exercise three to four times a week for most people. This study shows that even in obese individuals, the risk of heart failure can be substantially reduced by overall fitness.


William K. Cornwell III, MD

Researchers linked participant data from the Cooper Center Longitudinal Study with Medicare claims files for 19,476 individuals who received Medicare health insurance coverage from 1999 to 2009. They estimated fitness level in metabolic equivalents of tasks (METs) using the Balke treadmill test.

By applying a proportional hazard model to the treadmill test data, they assessed the associations among BMI status, fitness level and hospitalizations for heart failure in participants 65 or older. They further analyzed a subgroup of 7,589 participants using measurements of obesity other than BMI (waist-hip ratio, waist circumference and percent of body fat) to evaluate the association of these measures with subsequent heart failure.

After 25.5 years of follow-up, the researchers found 1,051 heart failure events among participants. After adjusting the data for multiple heart failure risk factors (age, sex, systolic blood pressure, diabetes, total cholesterol and smoking), they discovered that the association of BMI with heart failure was attenuated by adjusting for fitness, revealing a strong inverse association between midlife fitness and subsequent heart failure later in life but no association between heart failure and the other measures of obesity.

"In this study we evaluated BMI and fitness levels during middle age — the average age in our study was 50 years," Cornwell said. "However, our outcome of interest was a diagnosis of heart failure in later life, when subjects were eligible for Medicare. Thus, this study emphasizes the importance of midlife fitness for long-term reduction of heart failure."

The Cooper Center Longitudinal Study contains more than 250,000 health records from almost 100,000 individuals and the largest storehouse of information on fitness in the world. ▼

## CAREER PROGRESSION: ALAN TALL

For Alan Tall, MD, attending Scientific Sessions is like pulling up a chair at an immense intellectual buffet or shopping at a grand marketplace of knowledge.

"Because the meeting is so big and has so much to offer, you may feel you've walked away from the buffet line with a plate that's too full. You have to understand the challenge," said Tall, director of the Division of Molecular Medicine at Columbia University's College of Physicians & Surgeons.

"One finds oneself running around, trying to get to as many places as possible. It's like a bazaar of information. Some of the information you're picking up in the hallways, some at great talks, some in seminars going on at 8 o'clock at night, some over a drink with colleagues.

"One comes back feeling exhausted but stimulated."

Tall, who also headed Columbia's Cardiovascular Research Initiative, has regularly attended Scientific Sessions for 30-plus years. One he remembers well is the Sessions in Anaheim, Calif., just two months after the Sept. 11 terrorist attacks.

"The American Heart Association actively encouraged people to go, and it wasn't an easy sell," he said. "I live in New York and I have to admit I was a little apprehensive flying out. I remember that once we were there, people were glued to the television sets because there was some incident in New York that ended up not being terrorism-related.

"Still, we were able to get on with business and establish some semblance of normalcy. That's what we needed."

Ten years later, in Orlando, Fla., Tall had a very different Sessions experience, having been selected to give the Robert I. Levy Memorial Lecture. Renowned for research that linked cholesterol with heart disease and a longtime AHA volunteer, Dr. Levy died in 2000.

"Delivering that lecture meant a lot to me because I knew Bob Levy personally," Tall said. "I remember giving the lecture and being touched that various colleagues told me I did a good job."

Like Levy, Tall has spent much of his professional life researching the connection between cholesterol and heart disease.

Tall moved from his native Australia to Boston in 1973 and became a New Yorker in 1978 when he joined Columbia as an assistant professor. Shortly thereafter, his relationship with the American Heart Association began.

"I was very fortunate to receive the grant-in-aid from the AHA that helped me establish my independent laboratory at Columbia," he said. "A few years later, I got the Established Investigator award and have remained involved with the American Heart Association ever since."

He has served on various committees and currently is an associate editor of *Circulation Research*. He especially valued his time on the Research Committee – "an interesting, stimulating job in which we would help to make policy decisions about how the AHA would use its resources to promote research and other initiatives."

Tall is thrilled that the American Heart Association has been such an ardent supporter of the next generation of researchers.

"I benefited from that, and the AHA has only strengthened its program in more recent years," he said. "The Scientist Development Grants have really helped a lot of young researchers launch their careers, and the Established Investigator Awards have become even more prestigious.

"We all should be thankful that the AHA plays a vital role in filling the gaps in career development that are not adequately covered by federal grants." ▼

*Each day in this spot, we will profile an investigator in various career stages, from early career to distinguished veteran.*

## MEMBER SPOTLIGHT

**Kiran Musunuru, MD, PhD, MPH**
*Assistant Professor of Stem Cell and Regenerative Biology, Harvard University*

**How long have you been an AHA/ASA Professional Member?**
I first became a member in 2006 when I was starting my cardiology fellowship.

**Why did you join?**
I actually had my first opportunity to attend the AHA Scientific Sessions while I was still in medical school. I was so impressed by the science and the sense of community at the conference that when I made the decision to specialize in cardiology, the choice to join was a no-brainer. (To learn more about his path to becoming a FAHA, see the cover article on FAHAs in the Saturday edition of the *Daily News*.)

**Are you involved in any AHA councils?**
I serve on the Leadership Committee and various subcommittees of the Council on Clinical Cardiology and the Interdisciplinary Council on Functional Genomics and Translational Biology.

**What do you enjoy most about these roles?**
Despite being relatively new to the field, my ideas are taken very seriously by my senior colleagues in the AHA. My early career colleagues and I have been able to make meaningful contributions to Council activities and have been encouraged to take the lead in starting a variety of efforts including: a mentorship program, a minority travel grant program, a blog and podcast series, an online educational video series and a review series for one of the AHA journals. I also greatly enjoy getting to know and work with a diverse group of people from around the country and the world with whom I otherwise would never had the chance to interact, despite being in the same profession. Volunteering for the AHA has really broadened my horizons.

**How else are you involved with AHA?**
I have been involved in the planning of the Early Career Day at AHA Scientific Sessions and I serve on the Committee on Science Operations.

**Why is membership valuable to you?**
For me, it's about being part of communities. The AHA is such a diverse organization, with its 16 Councils that cover every conceivable aspect of cardiovascular/stroke medicine and science. As a physician-scientist, this is very important to me. With respect to my research interest in cardiovascular genetics, the Council on Functional Genomics and Translational Biology has provided a scientific home for me and enabled me to develop a much larger network of senior members in the field and peers who are in their early careers. As a clinical cardiologist, my involvement with the Council on Clinical Cardiology allows me to remain engaged in the clinical world and well-acquainted with the latest developments relevant to clinical practice. Participating in young investigator award competitions has also provided a boost at a critical phase in my career.

**What message would you like to convey to your colleagues about being an AHA member?**
I would especially like to reach out to colleagues who are in their training years or just getting started in their careers. The AHA is particularly good about engaging early career members in its activities, from organizing and moderating sessions at the AHA Scientific Sessions, to judging scientific abstract submissions and award/grant competitions, to participating in writing groups and contributing to AHA publications. I urge interested fellows-in-training and young investigators to join! ▼

# Individually tailored intervention helps lower sodium intake in patients with uncontrolled hypertension

A new study of a behavioral educational intervention tailored to lower sodium intake in adults with uncontrolled hypertension found that intervention matched to patients' readiness to change their dietary sodium intake significantly reduced salt intake.

Sundar Natarajan, MD, MSc, staff physician with the VA New York Harbor Healthcare System and Associate Professor of Medicine at the affiliated New York University School of Medicine, presented the study results Tuesday.

The randomized, controlled trial involved 533 patients. It used measures of urinary sodium to evaluate the effectiveness of two active educational interventions designed to change dietary sodium intake in patients with uncontrolled hypertension and compared the results with a control group under usual care. All patients had been receiving antihypertensive medications for at least six months prior to entering the trial.

Both interventions involved monthly phone calls to the participants for six months, with

Sundar Natarajan, MD, MSc

education provided about the importance of changing dietary salt intake to lower blood pressure.

The most effective intervention was tailored to the participants' readiness to follow a low-sodium diet, as assessed by a questionnaire and simple algorithm. After being told what a low-sodium diet was, participants were asked if they were following such a diet, and if so, for how long. If they were not following a low-sodium diet, they were asked to state their intention to change and the date when they hoped to do so.

In the monthly phone calls, trained health counselors, mostly psychologists, guided the individuals according to a transtheoretical (stages-of-change) model shown to be effective in changing smoking and other unhealthy behaviors. For example, for those in the pre-contemplation-to-change stage, the counselors talked about the risks associated with a high-sodium diet and worked to increase the participants' willingness to change their diets. In addition, counseling also was tailored to self-efficacy and decision-making.

In the non-tailored intervention, the counselors talked to the participants once a month about the importance of a low-sodium diet in lowering their blood pressure and advised them to follow American Heart Association recommendations for dietary salt intake and to look at food labels to avoid high-salt foods.

The usual care group did not get monthly phone calls but did receive printed information about hypertension self-care and low-sodium diets. All groups were assessed at six months for their blood pressure and urinary sodium levels compared with baseline.

"At baseline, the three groups were similar to one another in terms of sodium intake," Natarajan said. "At six months, we found that the tailored intervention group had significantly lower sodium intake than the usual care group. Sodium intake in the non-tailored intervention group was a little lower, but not significantly lower, than in the usual care group."

At six months, the median sodium-to-creatinine ratio was 7.99 for the tailored intervention group, 8.76 for the non-tailored intervention group and 9.39 for the usual care group. The baseline measures were 9.28 for the tailored intervention group, 10.08 for the non-tailored intervention group and 8.99 for the usual care group.

"This trial provides promising evidence that counseling that is matched or tailored to an individual can actually have long-term impact and change behavior," Natarajan said. "In this case, we showed that a tailored intervention could help patients consistently reduce their salt intake."

He believes that in light of the current healthcare shift to providing personalized care in a patient-centered medical home (PCMH), physicians will be working more and more in transdisciplinary teams with phone-based follow-up as an integral part of care to help patients adhere to treatment recommendations.

This study shows the value of theory-based telephone care and provides an additional tool for the healthcare team to improve care for hypertension, Natarajan said. ▼

# Distinguished Science Lecturer: New cholesterol agents coming


Scott M. Grundy, MD, PhD

While statins can help some patients reduce cholesterol and lower the risk of cardiovascular disease, recent discoveries are already pointing toward a next generation of cholesterol-lowering agents, Distinguished Science Lecturer Scott M. Grundy, MD, PhD, said Tuesday.

"Statins are not the last word in cholesterol reduction," said Grundy, Director of the Center for Human Nutrition and Professor of Internal Medicine at the University of Texas Southwestern Medical Center and Assistant Chief for Research at the Veterans Affairs Medical Center in Dallas. "New pathways and new agents are coming."

During his talk, "Hypercholesterolemia and Metabolic Syndrome: Mischievous Partners," Grundy described the development of current agents and strategies for the reduction of atherosclerotic cardiovascular disease. His research into the mechanisms of atherosclerotic cardiovascular disease has helped transform cardiovascular disease prevention from dream to reality.

"The major emphasis of my research has been cholesterol," Grundy said. "I started from the knowledge that cholesterol levels and death from heart disease are directly related. There were two basic research questions: What causes elevated cholesterol, and how to lower elevated cholesterol?"

Four decades later, Grundy still works on those two basic questions. Along the way, he has developed methods to measure the cholesterol balance and secretion of biliary lipids in humans; identified the metabolic causes of cholesterol gallstones; defined the metabolic effects of saturated and unsaturated fats, especially monounsaturated fats such as olive oil, on cholesterol and lipoprotein metabolism; identified the metabolic defects in hypercholesterolemia, hypertriglyceridemia and hypoalphalipoproteinemia; and defined the mechanisms of actions of several classes of lipid-lowering drugs, most notably statins.

Grundy also was among the first to explore what has become a key factor in the development of cardiovascular disease: obesity. Obesity increases cholesterol synthesis, which elevates cardiovascular risk. Obesity is among several factors in the metabolic syndrome that not only elevate cholesterol synthesis but also are independent risk factors for atherosclerotic cardiovascular disease.

The increased risk lies with two lipoproteins, LDL and VLDL cholesterol. Together, the two constitute non-HDL cholesterol, a value that has been recognized as a more useful predictor of risk than LDL alone.

"In populations and individuals having very low levels of non-HDL cholesterol, atherosclerotic cardiovascular disease is quite rare," Grundy said. "In individuals with severe elevations of non-HDL cholesterol, these lipoproteins can initiate atherogenesis and precipitate ASCVD in the absence in other risk factors."

It has long been known that LDL and VLDL cholesterol are synthesized in the liver, he said. The discovery of the LDL receptor was a game changer. Once researchers knew the cycle of LDL synthesis and absorption, they could design or discover potential therapeutic agents to disrupt the cycle.

The discovery that individuals with familial hypercholesterolemia have a genetic defect in the LDL receptor that reduces LDL clearance helped encourage researchers to look for agents that might enhance LDL clearance.

The first statin, compactin, discovered in Japan in 1976, inhibits cholesterol synthesis and showed great promise in early clinical trials. Merck followed with a second statin, lovastatin, which also showed promising results in early clinical trials by enhancing LDL clearance from plasma. But when researchers found that compactin could cause cancer in dogs, statin development came to a halt worldwide.

"Fortunately, the FDA was still highly enamored of statins and granted two experimental licenses," Grundy said. "We got one and found that statins increase LDL receptors to enhance LDL clearance. We also found the combination of statins plus bile acid resins can doubly lower LDL levels."

The first Adult Treatment Panel (ATP I) of the National Cholesterol Education Program identified LDL cholesterol as the primary target of lipid-lowering therapy in 1988. In 2001, ATP III added metabolic syndrome as a risk factor that can, and must, be controlled.

"The metabolic syndrome basically doubles the risk of cardiovascular disease compared to individuals without the syndrome," Grundy said. "We expected that adding the metabolic syndrome would help draw attention to an important risk factor that works with LDL to increase risk. We think it has worked. In 2000, there were about 500 papers published that mentioned the metabolic syndrome. In 2012, there were more than 5,000."

The next step in LDL treatment probably will involve agents that act directly on LDL receptors. Mutations in the PCSK9 protein can dramatically reduce the incidence of coronary heart disease by enhancing LDL receptors. That finding has pushed drug developers to develop inhibitors of PCSK9 to similarly enhance LDL receptors.

"PCSK9 inhibitors open the LDL receptor pathway and reduce LDL levels," Grundy said. "This opens a therapeutic pathway beyond the statins. Stay tuned for further developments." ▼

# Sessions Walking Challenge

## CONGRATULATIONS,

Walking Challenge participants. You've already logged enough steps to walk from the Dallas Convention Center to McCormick Place in Chicago, the site of next year's Scientific Sessions … and back … several times over!

As of 7:30 p.m. Tuesday, Walking Challenge participants had logged a grand total of 8,882,382 steps. Using 3 feet as an average stride length, that comes out to more than 5,046 miles. The driving distance between the Dallas and Chicago convention halls is 926 miles, so that's headed toward three round trips.

The Walking Challenge was a fun new addition this year, along with Tuesday being "Sneakers Day." They were a reminder of the importance of physical activity, a theme further emphasized by this year's Global Congress on Physical Activity.

Hopefully you even saw yourself on the leaderboards displayed throughout the convention center. The scroll included the top 20 steppers, and the top five councils. As of 7:30 p.m. Tuesday, CVSA held a slight lead over PVD and 3CPR. ▼

# RURAL continued from page 1

physically active and to identify and try to overcome their environmental and personal barriers.

Compared to baseline measures, the intervention resulted in a significant decrease in low-density lipoprotein among the participants from an average 110.5 mg/dL to 95.8 mg/dL (p=0.01), an increase in high-density lipoprotein in men from 34.5 mg/dL to 39.8 mg/dL (p=0.03) and in women from 49.6 mg/dL to 55.7 mg/dL (p>0.001), and a decrease in total cholesterol from 190 mg/dL to 180 mg/dL (p>0.001).

Before the intervention, 21 percent of the participants engaged in moderate physical activity for 30 minutes a day at least four days a week, but after the intervention, 60 percent of them did (p>0.001). In addition, body mass index decreased from an average 32.6 to 28.4 (p>0.001).

Phase 2 involved intervention reinforcement through the community, especially local churches. It resulted in a significant 10 percent or greater reduction in cardiovascular risk factors, said presenting author Debra K. Moser, DNSc, RN, professor and Gill Endowed Chair of Cardiovascular Nursing at the University of Kentucky College of Nursing in Lexington.

"People in this rural area were very open to participating in this study," Moser said. "People flocked to the opportunity to be in it, and they stayed in the study, too. The intensive intervention program concentrated on self-management."

In the long term, she believes this sort of intervention is sustainable.

"We were careful not to just give a special diet for weight loss," she said. "Instead, we talked about how people should live every day to minimize not only their risk of heart disease but all chronic diseases, about how to adapt what they eat to eat better, and about how to be more active given where they live."

Success depends on relying on the individual to self-manage risk factors, especially in areas with poor access to preventive medical care, and getting the local community involved in supporting behavior change, Moser said. ▼

# Telomere length might predict atherosclerosis

Researchers studying telomere length in American Indians with no cardiovascular disease or atherosclerotic plaque in their carotid arteries at baseline found that short leukocyte telomere length significantly predicts the incidence and progression of carotid plaque independent of known coronary risk factors, and that telomere length could serve as a predictive marker for atherosclerosis.

Presenting author Shufeng Chen, PhD, a Postdoctoral Fellow in Epidemiology at Tulane University School of Public Health and Tropical Medicine in New Orleans, shared study results Tuesday.

The investigators enrolled 3,665 American Indians, ages 14 to 93, living in Arizona, North Dakota, Oklahoma and South Dakota into the Strong Heart Family Study and followed them for an average 5.5 years. They assessed carotid atherosclerosis and the presence of atherosclerotic plaque through ultrasound evaluation. Quantitative polymerase chain reaction technology measured telomere length in leukocytes.

Among the participants, 2,091 had no cardiovascular disease and carotid plaque at baseline. During the 5.5 years of follow-up, 357 (17.1 percent) developed new carotid plaque. Researchers compared the results in three tertiles of telomere length, from shortest to longest, after controlling for traditional cardiovascular risk factors.

"This is the first study providing initial evidence that shorter leukocyte telomere length could be used as a prognostic biomarker in predicting carotid atherosclerosis," said Jinying Zhao, MD, PhD, Associate Professor of Epidemiology at Tulane and principal investigator of the study.

"Among participants with no carotid plaque and overt cardiovascular disease at baseline, those with shorter telomere length (in the lowest telomere tertile) were over 50 percent more likely to develop carotid plaque compared with those with longer telomere length (in the highest telomere tertile) after about six years of follow-up."


Jinying Zhao, MD, PhD


Shufeng Chen, PhD

Telomere length shortens progressively with cell division and declines significantly with age, making it a useful biomarker for cellular aging and age-related disorders, including atherosclerosis.

She said this study provides novel insights into the pathophysiology of telomere shortening, or biological aging, and how it affects atherosclerosis. The study also provides useful information that could be used to identify individuals at higher risk of atherosclerosis. ▼

# Scientific Sessions 2013 educational materials still available


## Highlights OnDemand app (Atrial Fibrillation)

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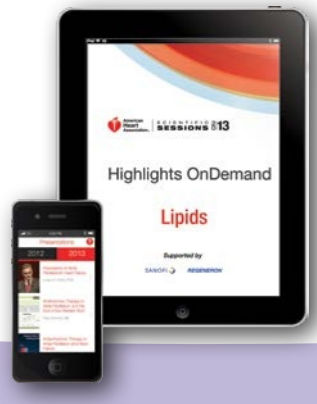


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PAID

## BRILINTA® *(ticagrelor)* Tablets

**WARNING: BLEEDING RISK**

- **BRILINTA, like other antiplatelet agents, can cause significant, sometimes fatal bleeding [see WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS].**
- **Do not use BRILINTA in patients with active pathological bleeding or a history of intracranial hemorrhage [see CONTRAINDICATIONS].**
- **Do not start BRILINTA in patients planned to undergo urgent coronary artery bypass graft surgery (CABG). When possible, discontinue BRILINTA at least 5 days prior to any surgery [see WARNINGS AND PRECAUTIONS].**
- **Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention (PCI), CABG, or other surgical procedures in the setting of BRILINTA [see WARNINGS AND PRECAUTIONS].**
- **If possible, manage bleeding without discontinuing BRILINTA. Stopping BRILINTA increases the risk of subsequent cardiovascular events [see WARNINGS AND PRECAUTIONS].**

**WARNING: ASPIRIN DOSE AND BRILINTA EFFECTIVENESS**

- **Maintenance doses of aspirin above 100 mg reduce the effectiveness of BRILINTA and should be avoided. After any initial dose, use with aspirin 75-100 mg per day [see WARNINGS AND PRECAUTIONS and CLINICAL STUDIES (14) in full Prescribing Information].**

### BRIEF SUMMARY of PRESCRIBING INFORMATION:

For full Prescribing Information, see package insert.

### INDICATIONS AND USAGE

#### Acute Coronary Syndromes

BRILINTA is a $P2Y_{12}$ platelet inhibitor indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). BRILINTA has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis [*see Clinical Studies (14) in full Prescribing Information*]. BRILINTA has been studied in ACS in combination with aspirin. Maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Avoid maintenance doses of aspirin above 100 mg daily [*see Warnings and Precautions* and *Clinical Studies (14) in full Prescribing Information*].

### DOSAGE AND ADMINISTRATION

Initiate BRILINTA treatment with a 180 mg (two 90 mg tablets) loading dose and continue treatment with 90 mg twice daily. After the initial loading dose of aspirin (usually 325 mg), use BRILINTA with a daily maintenance dose of aspirin of 75-100 mg. ACS patients who have received a loading dose of clopidogrel may be started on BRILINTA. BRILINTA can be administered with or without food. A patient who misses a dose of BRILINTA should take one 90 mg tablet (their next dose) at its scheduled time.

### CONTRAINDICATIONS

**History of Intracranial Hemorrhage** BRILINTA is contraindicated in patients with a history of intracranial hemorrhage (ICH) because of a high risk of recurrent ICH in this population [*see Clinical Studies (14) in full Prescribing Information*].

**Active Bleeding** BRILINTA is contraindicated in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage [*see Warnings and Precautions (5.1)* and *Adverse Reactions (6.1) in full Prescribing Information*].

**Severe Hepatic Impairment** BRILINTA is contraindicated in patients with severe hepatic impairment because of a probable increase in exposure, and it has not been studied in these patients. Severe hepatic impairment increases the risk of bleeding because of reduced synthesis of coagulation proteins [*see Clinical Pharmacology (12.3) in full Prescribing Information*].

**Hypersensitivity** BRILINTA is contraindicated in patients with hypersensitivity (e.g. angioedema) to ticagrelor or any component of the product [*see Adverse Reactions (6.1) in full Prescribing Information*].

### WARNINGS AND PRECAUTIONS

#### General Risk of Bleeding

Drugs that inhibit platelet function including BRILINTA increase the risk of bleeding. BRILINTA increased the overall risk of bleeding (Major + Minor) to a somewhat greater extent than did clopidogrel. The increase was seen for non-CABG-related bleeding, but not for CABG-related bleeding. Fatal and life-threatening bleeding rates were not increased [*see Adverse Reactions (6.1) in full Prescribing Information*]. In general, risk factors for bleeding include older age, a history of bleeding disorders, performance of percutaneous invasive procedures and concomitant use of medications that increase the risk of bleeding (e.g., anticoagulant and fibrinolytic therapy, higher doses of aspirin, and chronic nonsteroidal anti-inflammatory drugs [NSAIDS]). When possible, discontinue BRILINTA five days prior to surgery. Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, PCI, CABG, or other surgical procedures, even if the patient does not have any signs of bleeding. If possible, manage bleeding without discontinuing BRILINTA. Stopping BRILINTA increases the risk of subsequent cardiovascular events [*see Warnings and Precautions (5.5)* and *Adverse Reactions (6.1) in full Prescribing Information*].

**Concomitant Aspirin Maintenance Dose** In PLATO, use of BRILINTA with maintenance doses of aspirin above 100 mg decreased the effectiveness of BRILINTA. Therefore, after the initial loading dose of aspirin (usually 325 mg), use BRILINTA with a maintenance dose of aspirin of 75-100 mg [*see Dosage and Administration* and *Clinical Studies (14) in full Prescribing Information*].

**Moderate Hepatic Impairment** BRILINTA has not been studied in patients with moderate hepatic impairment. Consider the risks and benefits of treatment, noting the probable increase in exposure to ticagrelor.

**Dyspnea** In PLATO, dyspnea was reported in 14% of patients treated with BRILINTA and in 8% of patients taking clopidogrel. Dyspnea was usually mild to moderate in intensity and often resolved during continued treatment, but occasionally required discontinuation (0.9% of patients taking BRILINTA versus 0.1% of patients taking clopidogrel). If a patient develops new, prolonged, or worsened dyspnea during treatment with BRILINTA, exclude underlying diseases that may require treatment. If dyspnea is determined to be related to BRILINTA, no specific treatment is required; continue BRILINTA without interruption. In the case of intolerable dyspnea requiring discontinuation of BRILINTA, consider prescribing another antiplatelet agent. In a substudy, 199 patients from PLATO underwent pulmonary function testing irrespective of whether they reported dyspnea. There was no significant difference between treatment groups for $FEV_1$. There was no indication of an adverse effect on pulmonary function assessed after one month or after at least 6 months of chronic treatment.

**Discontinuation of BRILINTA** Avoid interruption of BRILINTA treatment. If BRILINTA must be temporarily discontinued (e.g., to treat bleeding or for elective surgery), restart it as soon as possible. Discontinuation of BRILINTA will increase the risk of myocardial infarction, stent thrombosis, and death.

**Strong Inhibitors of Cytochrome CYP3A** Ticagrelor is metabolized by CYP3A4/5. Avoid use with strong CYP3A inhibitors, such as atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin and voriconazole [*see Drug Interactions (7.1)* and *Clinical Pharmacology (12.3) in full Prescribing Information*].

**Cytochrome CYP3A Potent Inducers** Avoid use with potent CYP3A inducers, such as rifampin, dexamethasone, phenytoin, carbamazepine, and phenobarbital [*see Drug Interactions (7.2)* and *Clinical Pharmacology (12.3) in full Prescribing Information*].

### ADVERSE REACTIONS

#### Clinical Trials Experience

The following adverse reactions are also discussed elsewhere in the labeling:

- Dyspnea [*see Warnings and Precautions (5.4) in full Prescribing Information*]

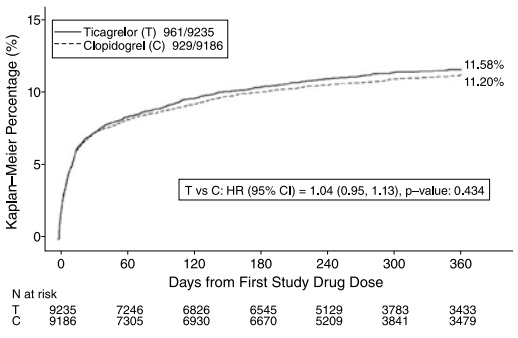
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. BRILINTA has been evaluated for safety in more than 10000 patients, including more than 3000 patients treated for more than 1 year.

Bleeding PLATO used the following bleeding severity categorization:

- Major bleed – fatal/life-threatening. Any one of the following: fatal; intracranial; intrapericardial bleed with cardiac tamponade; hypovolemic shock or severe hypotension due to bleeding and requiring pressors or surgery; clinically overt or apparent bleeding associated with a decrease in hemoglobin (Hb) of more than 5 g/dL; transfusion of 4 or more units (whole blood or packed red blood cells (PRBCs)) for bleeding.
- Major bleed – other. Any one of the following: significantly disabling (e.g., intraocular with permanent vision loss); clinically overt or apparent bleeding associated with a decrease in Hb of 3 g/dL; transfusion of 2-3 units (whole blood or PRBCs) for bleeding.
- Minor bleed. Requires medical intervention to stop or treat bleeding (e.g., epistaxis requiring visit to medical facility for packing).
- Minimal bleed. All others (e.g., bruising, bleeding gums, oozing from injection sites, etc.) not requiring intervention or treatment.

Figure 1 shows major bleeding events over time. Many events are early, at a time of coronary angiography, PCI, CABG, and other procedures, but the risk persists during later use of antiplatelet therapy.

**Figure 1 Kaplan-Meier estimate of time to first PLATO-defined 'Total Major' bleeding event**




Annualized rates of bleeding are summarized in Table 1 below. About half of the bleeding events were in the first 30 days.

**Table 1 Non-CABG related bleeds (KM%)**

| | BRILINTA N=9235 | Clopidogrel N=9186 |
|---|---|---|
| Total (Major + Minor) | 8.7 | 7.0 |
| Major | 4.5 | 3.8 |
| Fatal/Life-threatening | 2.1 | 1.9 |
| Fatal | 0.2 | 0.2 |
| Intracranial (Fatal/Life-threatening) | 0.3 | 0.2 |

As shown in Table 1, BRILINTA was associated with a somewhat greater risk of non-CABG bleeding than was clopidogrel. No baseline demographic factor altered the relative risk of bleeding with BRILINTA compared to clopidogrel. In PLATO, 1584 patients underwent CABG surgery. The percentages of those patients who bled are shown in Table 2. Rates were very high but similar for BRILINTA and clopidogrel.

# G-protein receptor may offer novel target for hypertension therapy

A G-protein-coupled receptor found in the heart known as GPR37L1 is a possible novel target for treating hypertension and subsequent cardiovascular disease, a study presented Tuesday showed.

Previous studies have indicated that GPR37L1 is downregulated in heart failure patients and is associated with profoundly elevated blood pressure and left-ventricular hypertrophy in GPR37L1 knockout mice. This receptor also has been shown to be downregulated in the left ventricles of mice subjected to thoracic-aortic constriction, angiotensin II infusion or transgenic overexpression of myosin heavy chain.

To gain insights into the potential therapeutic relevance of GPR37L1, researchers in Australia generated stable, doxycycline-inducible cells expressing human GPR37L1 tagged with C-terminal-enhanced yellow fluorescent protein. Nicola J. Smith, PhD, a senior research fellow at Victor Chang Cardiac Research Institute in Sydney, Australia, presented the study results Tuesday.

In confocal microscopy and cell-surface biotinylation experiments, investigators showed that wild type GPR37L1 enhanced with yellow fluorescent protein reached the surface of the cells but resided primarily in intracellular vesicles, suggesting activation and internalization of the receptor. A western blot analysis revealed that the receptor is cleaved in a region of 18 amino acids within the N-terminus in a manner that can be entirely blocked by broad-spectrum matrix metalloprotease inhibitors.


Nicola J. Smith, PhD

Looking at human heart tissue as well as mouse tissue, investigators found that the GPR37L1 receptor all but disappears in the heart in various types of cardiovascular disease, Smith said.

"There is something about cardiovascular disease that causes the receptor to disappear," she said. "In a mouse model with the receptor knocked out, there are massive increases in blood pressure. Linking those two facts together suggests that this receptor is an important target in modifying blood pressure and, in particular, pathological hypertension."

In an effort to understand the pharmacologic properties of the receptor, Smith and her colleagues found that it is an orphan receptor, meaning it has yet to be paired with its endogenous hormone. In the absence of its ligand, it is permanently turned on, undergoes novel proteolytic cleavage and has its N-terminus clipped off by metalloproteases.

"We know that high blood pressure and cardiovascular disease lead to an increase in metalloproteases, so it looks like the body is turning off the expression and the activity of the receptor in the setting of cardiovascular disease," Smith said. "We hypothesize that turning off the activity of the receptor further drives the pathology of high blood pressure."

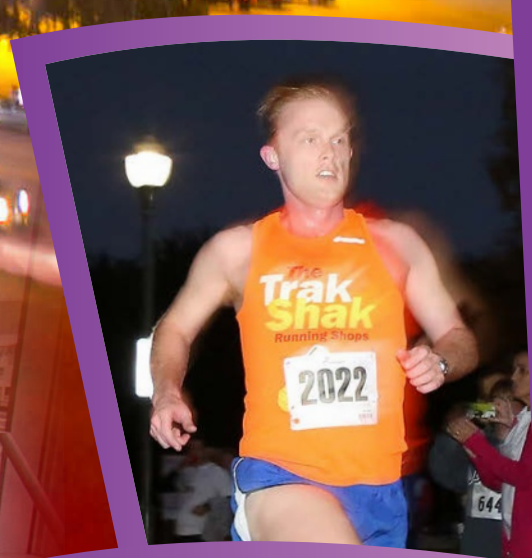
Investigators think this orphan receptor could offer a valid mechanistic target for the treatment of hypertension and cardiovascular disease secondary to high blood pressure, and it represents an entirely new class of antihypertensive medications. More studies are necessary.

Current therapies such as diuretics and angiotensin blockers act to reduce blood volume or vessel diameter but do not target the underlying causes of hypertension. Smith said that this orphan protein has the potential to be a new way to treat an underlying cause.

She added that researchers should think about new paradigms for the management of high blood pressure.

"Many of the current treatments for hypertension are not effective for a small proportion of the population," she said. "Some people are on three or four medications, and their blood pressure is still not controlled sufficiently. This condition has a significant impact on their likelihood of developing major morbidity or mortality." ▼

# SCENES FROM SESSIONS




## CELEBRATING RESEARCH

Current and past American Heart Association research awardees gathered Monday for a group photo. The AHA has funded more than $3.5 billion in research of heart disease, stroke and other cardiovascular diseases, more than any organization outside the federal government. The organization has funded 13 Nobel Prize winners and lifesaving research advancements such as the first artificial heart valve, cholesterol-inhibiting drugs, heart transplantation, and CPR techniques and guidelines.

# Fun Walk/Fun Run

Hundreds of runners and walkers arrived at Reverchon Park before dawn Tuesday to take part in the 21st Fun Walk/Fun Run. Jack Health (pictured above center with bib 2022) was the first to cross the finish line, needing only 17:40.48 to complete the 5k run. Marilia Santos was the first female finisher in 21:13.94. Congratulations and thanks to all participants. For results and more photos, visit **scientificsessions.org** and click on the link to the Fun Walk/ Fun Run page, or simply scan the QR code.

# 2013 POSTER WINNERS

Early career work is extremely important to the American Heart Association.

Truly, the future of cardiovascular science is in the hands of these healthcare professionals and scientists. That's why it's so important to the AHA that we continue to fund their work through research awards and provide meaningful learning and mentoring opportunities. In fact, we devoted a full day to early career programming Saturday during Scientific Sessions.

But the importance of those early in their careers wasn't just emphasized Saturday; their work is showcased throughout Scientific Sessions. The Poster Sessions include many examples of some of the important work being done by this group. Here is a look at the Poster Winners from Scientific Sessions 2013, all of whom are early career professionals:

**Core 1. Cardiovascular Imaging**

**Kunihiro Matsushita**

*The Association of Kidney Disease Measures With Left-Sided Cardiac Structure and Function: The Atherosclerosis Risk in Communities (ARIC) Study*

Board 1017

**Core 2. Epidemiology and Prevention of CV Disease: Physiology, Pharmacology and Lifestyle**

**Mary Helen Black**

*Hypertensive Disorders First Identified in Pregnancy Increase Risk for Incident Prehypertension and Hypertension in the Year After Delivery*

Board 2037

**Core 3. Genetics, Genomics and Congenital CV Disorders**

**Sekar Kathiresan**

*Rare Loss-of-Function Mutations in the Apolipoprotein C-III gene, Plasma Triglycerides, and Risk for Coronary Heart Disease*

Board 3029

**Core 4. Heart Rhythm Disorders and Resuscitation Science**

**Pasquale Santangeli**

*Pulmonary Vein Antrum Isolation in Patients With Paroxysmal Atrial Fibrillation: A Decade of Follow-Up*

Board 4076

**Core 5. Myocardium: Function and Failure**

**Derk Frank**

*Transgenic Mice Overexpressing The ID Protein Myozap Are Sensitized To Pressure Overload And Develop A Progressive Protein-aggregate Associated Cardiomyopathy*

Board 9006

**Core 6. Catheter-Based and Surgical Interventions**

**Julien Magne**

*Postoperative Outcome in Primary Mitral Regurgitation: Impact of Preoperative Exercise Pulmonary Hypertension*

Board 6081

**Core 7. Vascular Disease: Biology and Clinical Science**

**Vahagn Ohanyan**

*Mouse Model of Takotsubo Cardiomyopathy: The Role of Coronary Metabolic Blood Flow Regulation in Apical Ballooning*

Board 9025

# Physical inactivity may cause twice as many deaths as obesity

Increasing physical activity may be more effective than eliminating obesity in reducing premature deaths, according to results of a multicenter European study presented Tuesday that looked at the effects of physical activity and obesity on all-cause mortality.

Ulf Ekelund, PhD

The study's investigators measured body mass index (BMI) and waist circumference in 334,161 men and women from nine countries in Europe and followed them for 12.4 years to determine all-cause mortality. They examined independent and combined associations between physical activity, BMI, waist circumference and all-cause mortality.

"Physical inactivity is theoretically responsible for twice as many deaths as obesity in this population," said presenting author Ulf Ekelund, PhD, professor of physical activity epidemiology in the department of sport medicine at the Norwegian School of Sport Sciences in Oslo.

The investigators assessed physical activity using a validated questionnaire and categorized the participants into four activity groups cross-categorized with three BMI groups (<25 kg/m$^2$, 25 to 30 kg/m$^2$, >30 kg/m$^2$) and two abdominal obesity groups (waist circumference >102 cm for men and >88 cm for women). They analyzed life tables to estimate gains in life expectancy associated with physical activity, BMI and waist circumference.

The researchers examined the combined associations between physical activity, general and abdominal obesity and all-cause mortality using Cox proportional hazards models. At 12.4 years of follow up, 11,086 men and 10,352 women had died.

After adjusting for confounders (age, sex, education, smoking and alcohol intake), researchers found that compared to active and normal-weight individuals, the risk of premature death was similar and almost 50 percent higher in the active and obese individuals.

Individuals who were active and abdominally obese had a similar risk of premature death as those who were inactive and of normal weight, but they had a 44 percent higher risk of premature death compared with those who were active and of normal weight, Ekelund said.

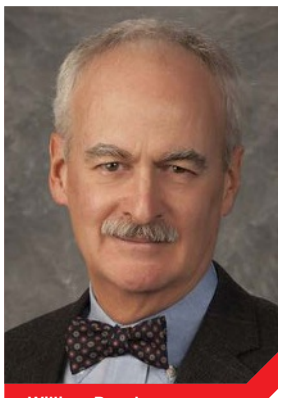
"Increasing physical activity levels in all individuals regardless of obesity status would have significant health benefits," Ekelund said. "The greatest reductions in mortality risk were observed between the inactive and the moderately active groups, suggesting that efforts to encourage even small increases in physical activity in inactive individuals could have major public health benefits."

A stronger emphasis on promoting physical activity for health rather than focusing on body weight may have important public health implications, he noted.

"Our challenge is to shift the focus from body-weight loss to changing lifestyle behaviors and look beyond the weight scale in individuals and populations," Ekelund said. ▼

# Voices for Healthy Kids taking action to prevent obesity

A new advocacy collaboration called Voices for Healthy Kids is mobilizing people across the nation to improve the health of their communities and reverse the childhood obesity epidemic.



William Roach

The need is critical considering that nearly one-third of American children and adolescents are overweight or obese.

"By advocating for public policies that will help reduce childhood obesity, Voices for Healthy Kids will help improve the health of generations of Americans," said William Roach, former AHA chairman of the board and chair of the Strategic Advisory Committee for Voices for Healthy Kids. "To raise healthy kids and reverse the childhood obesity epidemic, we must ensure that the places where our children live, learn and play make the healthy choice the easy choice."

Voices for Healthy Kids, a collaboration between the American Heart Association and the Robert Wood Johnson Foundation, launched in July. It targets six major areas:

- Improving the nutritional quality of snack foods and beverages in schools
- Reducing consumption of sugary beverages
- Protecting children from unhealthy food marketing
- Increasing access to affordable healthy foods
- Increasing access to parks, playgrounds, walking paths, bike lanes and other opportunities to be physically active
- Helping youth-serving programs increase children's physical activity levels.

Because childhood obesity doesn't affect all communities equally, Voices for Healthy Kids is committed to reaching minorities and lower-income areas.

## Fighting food deserts

Voices for Healthy Kids works to increase access to healthy food in underserved neighborhoods where people often can't get to or afford healthy foods.

One in five Americans live in "food deserts," areas where it's difficult to buy fresh food. Low-income ZIP codes have 25 percent fewer chain supermarkets than middle-income ZIP codes. As a result, access to fresh produce, dairy and other staples is extremely tough or not an option. These areas suffer worse diet-related health outcomes, including obesity, heart disease, diabetes, cancer and premature death.

Healthy Food Financing is a policy initiative that helps bring supermarkets to rural and urban communities to provide more access to fruits and vegetables, low-fat dairy, whole grains, seafood and lean meats.

Voices for Healthy Kids is mobilizing communities across the country to advocate for these public policy changes. Voices for Healthy Kids is also working on policies to make healthy foods and beverages more readily available in schools, promote physical activity and give kids better access to play programs and spaces.

Health professionals and researchers can get involved with Voices for Healthy Kids. Learn more and join at **voicesforhealthykids.org.** ▼

# Genders differ in mortality risk based on fitness, study finds

A study of men and women enrolled in the FIT Project who had no known coronary artery disease (CAD) or heart failure showed that gender plays an important role when interpreting the prognostic importance of cardiorespiratory fitness on mortality risk, according to a study presented Tuesday.

Researchers from Henry Ford Hospital in Detroit and Johns Hopkins University in Baltimore evaluated the effects of gender and fitness on mortality among 55,124 patients without CAD or heart failure who completed a routine symptom-limited treadmill exercise test between 1991 and 2009.

Cardiorespiratory fitness was measured by the estimated metabolic equivalent of task (MET) value. Men had a higher fitness level, with a median of 10.1 METs, compared with women, who had a median of 8.2 METs ($p<0.001$).

In a multivariable Cox regression analysis, METs were shown to have a marked inverse association with all-cause mortality, and this inverse relationship was stronger in men than in women (interaction $p<0.001$).

"We found that fitness differs by gender," said presenting author Mouaz H. Al-Mallah, MD, MSc, FAHA. "In the cohort, 35 percent of men and only 10 percent of women achieved the highest fitness level, with more than 12 METs. However, only 8 percent of men versus 18 percent of the included women were in the lowest level of fitness, with 6 METs or less."

To determine all-cause mortality, the investigators searched the Social Security Death Index in April 2013 for the names of study participants. During a median follow-up period of 10 years, they found 3,375 deaths among the 29,470 men in the study and 2,486 deaths among the 25,727 women participants. A decrease in exercise capacity as measured by METs was associated with an increase in mortality in both men and women.

Researchers also found that across the spectrum of patients, the higher the fitness, the better the outcome for both men and women, said Al-Mallah, a cardiologist at Henry Ford Hospital and Head of Cardiac Imaging at King Abdul-Aziz Cardiac Center in Riyadh, Saudi Arabia.

"It appears that the benefit of fitness plateaus at a certain point, and that point is different for men and women," he said. "For men, it appears to be around 12 METs. For women, it appears to be closer to 8 METs. Men continue to benefit from increasing levels of fitness until the fitness level plateaus at a much higher level compared to women."

Mouaz H. Al-Mallah, MD, MSc, FAHA

However, men with a lower level of fitness have worse outcomes than women who have the same level of fitness, the researchers found. For example, if someone from both genders had a fitness level of 6 METs, men would have higher mortality rates than women. Biological differences between men and women in exercise endurance may help explain these outcome differences, Al-Mallah said.

From the long-term clinical perspective, physicians must encourage all patients to increase their fitness level.

"The more fit they are, the less chance they have of developing heart disease and subsequent mortality," he said. "However, fitness always has to be interpreted in the context of gender. Women at 10 METs are highly fit, but men need to do better than that to be considered highly fit."

Al-Mallah serves as principal investigator for the FIT Project, an initiative that combines prospectively collected exercise data elements with retrospectively collected EMR-based data to study the implications of physical fitness on cardiovascular outcomes and all-cause mortality. FIT followed a gender and racially diverse cohort of 69,885 consecutive adults who underwent physician-referred treadmill stress testing at Henry Ford Hospital between 1991 and 2009. ▼

# Program makes cooking healthy, affordable for families

Although many families put nutritious eating on the back burner, you can help your patients learn about easy, affordable, heart-healthy cooking with the American Heart Association's Simple Cooking with Heart program.

How affordable are these meals? The program features many recipes that can feed four people for less than $10.

Simple Cooking with Heart is funded by a grant from the Walmart Foundation for the third year. It provides online how-to videos, tips and free downloadable kits to make it easier for people to host cooking demonstrations or parties with family, friends and neighbors.

"With busy, on-the-go lifestyles, many Americans have lost touch with their kitchens and thrown in the towel on eating healthy, which is key to prevention of heart disease and stroke," said Rachel Johnson, PhD, MPH, RD, FAHA, Chair of the American Heart Association's Nutrition Committee and Professor of Nutrition and Medicine at the University of Vermont in Burlington. "We've developed diverse, nutritious recipes that are very budget-conscious and heart-healthy."

Traditional, home-cooked meals are becoming increasingly rare as more two-income families work more hours with longer commutes. Less than one-third of Americans cook their meals from scratch. Research has shown that away-from-home meals account for at least half of all U.S. food expenditures, and take-out meals usually have more saturated fat, trans fat, cholesterol, sodium, added sugars and calories than home-cooked meals.

Rachel Johnson, PhD, MPH, RD, FAHA

With nearly seven out of 10 American adults overweight or obese, experts project that, by 2015, 75 percent of adults will be overweight, with 41 percent of them obese. Simple Cooking with Heart aims to teach that healthy home cooking is achievable for all families.

The program has a bit of everything families need to get started, including basic cooking terms, healthy substitutions for common foods and help stocking a heart-healthy pantry. Participants can pick up all sorts of helpful tips, such as learning that a package of dry beans stretches into more meals than canned beans.

Simple Cooking with Heart is based on the Socioecological Model and Social Cognitive Theory of behavior change, both proven to be successful in diet and lifestyle interventions. It primarily targets low-income families, especially moms ages 29 to 54.

A third-party evaluation measured the program's impact and showed positive changes, including an increase in fruits, vegetables and whole grains consumption.

To share the information with your patients, send them to **heart.org/simplecooking**. ▼

# NMR lipid testing found to be better for adolescents and young adults

Nuclear magnetic resonance (NMR) imaging to determine the number and size of lipoprotein particles in blood may be more sensitive than traditional lipid values in evaluating the risk for changes in vascular structure and function in adolescents and young adults, according to an abstract presented Tuesday.

In adults, dyslipidemia has been associated with higher carotid intima media thickness and arterial stiffness, common risk factors for cardiovascular events. In adolescents and young adults, however, the correlations between cholesterol levels and vascular structure and function have been less consistent.

"We wondered if the type of cholesterol testing we were doing did not adequately reflect the true atherogenic burden in adolescents and young adults," said presenting author Elaine M. Urbina, MD, MS, Director of Preventive Cardiology at Cincinnati Children's Hospital. "We hypothesized that nuclear magnetic resonance imaging would provide a better feel for the actual atherogenic potential of the lipoprotein particles than just the cholesterol concentrations measured in traditional blood tests."

Researchers used NMR imaging to measure the number and size of low-density lipoprotein (LDL), high-density lipoprotein (HDL) and very low-density lipoprotein particles in the blood of a cohort of 674 patients with a mean age of 18 years. They designed the study to evaluate the effects of obesity and type 2 diabetes on cardiovascular structure and function when compared with lean individuals.

Elaine M. Urbina, MD, MS

Urbina and colleagues constructed general linear models that included age, race, sex, group (lean, obese or diabetic), body mass index, blood pressure, fasting glucose, insulin, hemoglobin A1c levels, C-reactive protein and either traditional or NMR lipid parameters.

"When we performed more sensitive NMR lipid testing, we were able to demonstrate an independent relationship between atherogenic lipoprotein particles and vascular structure and function even after adjusting for traditional risk factors," Urbina said. "Whereas, when we looked at traditional cholesterol blood tests after adjusting for other risk factors, such as obesity and blood pressure, the relationship was lost."

She believes that NMR lipid testing shows this relationship in adolescents and young adults because of the shorter duration of exposure to atherogenic lipoprotein particles. Older adults develop more atherosclerosis because they have been exposed to atherogenic lipoprotein particles for a longer time, and less sensitive routine blood tests for cholesterol are sufficient to identify atherosclerosis.

"Because adolescents have a shorter duration of exposure, they haven't developed as much atherosclerosis, so the less-sensitive blood tests are unable to show the relationship," she said.

Although lean subjects had better lipid levels than both the obese and diabetic groups regardless of which test was used, traditional LDL concentrations were the same in the obese subjects as in those with type 2 diabetes. However, LDL size was smaller (worse) in the diabetic group.

"The long-term clinical implications of our results are that, in the future, it may be useful for high-risk adolescents and young adults with borderline lipid values to have NMR lipid testing to predict their atherosclerotic risk," Urbina said. "But I would never suggest using NMR lipid testing for all kids, just specifically for borderline lipid values in very high-risk kids based on family history and other risk factors, such as obesity, hypertension treated with medication, diabetes, kidney disease or a solid organ transplant." ▼

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"These educational offerings provide critical information for patients regarding diseases, treatments and heart-healthy lifestyle changes," said Kathleen Grady, PhD, APN, FAHA, FAAN, the Administrative Director at the Center for Heart Failure and Associate Professor in the Department of Surgery at the Feinberg School of Medicine at Northwestern University.


Kathleen Grady, PhD, APN, FAHA, FAAN

A recent patient survey showed that recipients believe the information has increased their knowledge, confidence and ability to take action toward better heart health.

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### *Heart Insight*

Another patient education product the AHA offers is *Heart Insight*, a free, quarterly, award-winning consumer magazine that focuses on managing and preventing cardiovascular diseases and related conditions. Articles feature patients and caregivers who have firsthand experience dealing with these issues.

"*Heart Insight* is a wonderful resource for patients and their caregivers," said Grady, who also is an AHA volunteer. "Heartwarming and motivational stories about heart disease and treatment are shared by celebrities and people from all walks of life. The magazine focuses on issues that are pertinent to patients, strategies on how to implement Life's Simple 7 and wonderful heart-healthy recipes."

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Readers can access *Heart Insight* online at **heartinsight.com**. It's also available through a free iPad app and readers can sign up to receive a monthly e-newsletter. Bulk copies are available free to cardiologists for distribution in their offices. To order or change the quantity you are receiving, email heartcirc@wolterskluwer.com or call (866) 440-7557. ▼

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## TRIALS continued from page 1

percent for the clinical-guided dosing.

Approximately 1 in 4 patients in the study was African-American. For this patient subset, the COAG study showed that genotype-guided dosing was much worse for determining the initiating dose of warfarin — in keeping with information that the genotypes used in the study do not work well for predicting a warfarin dose in these patients.

Munir Pirmohamed, MD, PhD

For more detailed coverage of Tuesday's Late-Breaking Clinical Trials, scan here to visit AHA's *Science News*.

COAG used a clinically validated algorithm to determine warfarin doses at start for the clinically guided arm. A revised algorithm was used for days four and five of therapy. The algorithm was derived from clinical information such as age, body surface area and medications used. COAG was a double-blind study that randomized 1,015 patients indicated for warfarin use. Patients had deep-vein thrombosis, pulmonary embolism, atrial fibrillation (AFib), among other conditions that warranted warfarin use.

The EU Pharmacogenetics of Anticoagulant Therapy (EU-PACT) Warfarin study tested a different strategy.

"Genetic testing done before starting warfarin therapy can increase patients' being in the therapeutic range by 7 percent while reducing the need for warfarin dose adjustments," said presenting author Munir Pirmohamed, MD, PhD.

Researchers designed this single-blind, randomized trial of 455 patients to determine whether genotype-guided dosing was superior to standard clinical care over three months in AFib or venous thromboembolism patients who had not previously received warfarin. Patients in the control arm of the study used a fixed loading dose of warfarin based on standard clinical management in the United Kingdom and Sweden.

After three months, PTTR was 67.4 and 60.3 percent for patients in the genotype and clinical arms, respectively. The 7-percent difference was statistically significant ($p<0.001$).

Genotyping also reduced over-anticoagulation by 69 percent; reduced the time required to reach therapeutic INR by about 28 percent; improved the time required to reach stable dose by 25 percent; and reduced the number of warfarin dose adjustments by 9 percent.

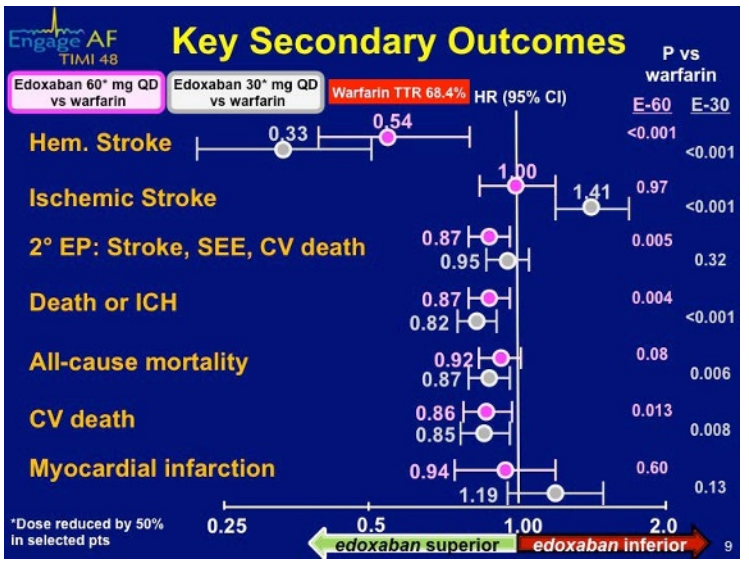
"Although significant, the trial evaluated a surrogate endpoint, but did not have power to assess clinical events of bleeding and thrombosis," which were determined to be similar between the two arms, Pirmohamed said.

Both studies were published in *The New England Journal of Medicine* to coincide with Tuesday's presentations.

Discussant Patrick Ellinor, MD, PhD, Associate Professor at the Harvard Medical School, advocated the use of a clinical algorithm at warfarin initiation.

"We shouldn't be using a fixed dose at warfarin initiation," he said. "We certainly shouldn't rely only on genetic data for warfarin initiation in African-Americans."

In 2010, 25 million prescriptions were written for warfarin. Having warfarin users in the INR 2.0-3.0 range is significant due to complications that arise outside it. Below the INR, patients are at risk for thrombotic events. Over an INR of 4.0, patients are at risk for bleeding.




## Edoxaban vs. warfarin

Data from the ENGAGE AF-TIMI 48 study showed edoxaban to be non-inferior to warfarin in preventing strokes and systemic embolic events (SEE), meeting the primary endpoint of the study.

After 2.8 years, compared with warfarin, hazard ratios for stroke/SEE for patients on edoxaban 60 mg QD and 30 mg QD were 0.79 and 1.07, respectively, with the 97.5 percent confidence limits well within the prespecified limit of 1.38. In a subgroup analysis, edoxaban at both doses was shown to be significantly better for patients compared with warfarin for hemorrhagic stroke, but not ischemic stroke (for the 2 mg QD dose). In addition, patients on any dose of edoxaban were significantly less likely to experience any major bleeding event, fatal bleeding or intracranial hemorrhage.

"Compared to well-managed warfarin (PTTR 68.4 percent) once-daily edoxaban was non-inferior for stroke/SEE and significantly reduced major bleeding, intracranial hemorrhages, hemorrhagic stroke and cardiovascular death," said Robert Giugliano, MD, SM, FAHA, FACC, presenting on behalf of the ENGAGE AF-TIMI 48 collaborators.

The large, double-blind, double-dummy trial randomized 21,105 patients with AFib and a CHAD2 score of at least 2 to receive warfarin (INR 2.0-3.0), edoxaban 60 mg QD, or edoxaban 30 mg QD.

"This is the largest of the AFib trials, which enrolled medium- to high-risk patients with a mean $CHADS_2$ of 2.8," said discussant Elaine Hylek, MD, MPH, Professor of Medicine at Boston University School of Medicine. "Most patients had hypertension and 28 percent of patients had prior stroke."

Hylek said that edoxaban 30 mg QD lacked efficacy for prevention of ischemic stroke, increasing the risk by approximately 40 percent compared to warfarin.

Given the availability of three other oral anticoagulant therapies in clinical practice, discussion Tuesday concentrated on where edoxaban fits into the clinical management of patients. While available agents could not be directly compared due to the lack of head-to-head studies, the dosing regimen, risk profile of patients and how well patients are managed on warfarin will decide which patients may be appropriate for each available agent.

The study was simultaneously published in *The New England Journal of Medicine.*

## High-frequency source ablation for AFib

Targeted, high-frequency source ablation (HSFA) was as safe and effective as standard treatment for paroxysmal AFib after one year, according to data from the Radiofrequency Catheter Ablation of Drivers vs. Circumferential Pulmonary Vein Isolation in Patients with Atrial Fibrillation (RADAR-AF) study. RADAR-AF provided 232 patients with paroxysmal or persistent AFib with either standard therapy (CPVI) for AFib or HSFA, which uses computer mapping to single out abnormal heart tissue followed by ablation with a high-frequency source.

In patients with paroxysmal AF, the study did not meet its non-inferiority endpoint for freedom from AFib six months after the procedure. After one year, however, and after more than one procedure, 79 and 82 percent of patients undergoing CPVI and HSFA, respectively, were free from AFib ($p=0.008$ for noninferiority).

"Improved computer systems can analyze the electrical activity of the heart, localize them and, through ablation, eliminate those areas faster," said presenting author Felipe Atienza, MD, PhD, Senior Electrophysiologist at Hospital Gregorio Marañón in Madrid, Spain.

For patients with persistent AFib, however, the combination of HSFA+CPVI was not superior to CPVI alone.

When discussing the algorithms used in RADAR-AF, Mark Link, MD, of Tufts University Medical School said, that in this trial, HFSA did not improve outcomes in patients with paroxysmal or persistent AFib, "but the fact that HFSA treatment was equivalent to CPVI in paroxysmal AFib keeps the AFib substrate and trigger argument alive." ▼

## GUIDELINES continued from page 1

The new guidelines are based on rigorous, comprehensive, systematic evidence reviews originally sponsored by the NHLBI. The AHA and ACC worked with a number of professional organizations in the process of finalizing these guidelines, and multiple stakeholder organizations were invited to review and endorse the final documents.

### A closer look at the guidelines

**The 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults** recommends managing and treating obesity like a disease.

Included in the obesity guidelines is a first-of-its-kind roadmap to help patients lose weight and keep it off by finding out who would benefit from weight loss by calculating patients' body mass index at least once per year. Patients with a BMI of 30 or higher are considered obese and need treatment. In the U.S., nearly 78 million adults are obese.

**The 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk** recommends maintaining an overall heart-healthy dietary pattern is more important than avoiding occasional indulgences, and just 40 minutes of moderate to vigorous aerobic exercise three to four times a week – even a brisk walk – should be sufficient for most people. They also recommend dietary patterns that emphasize fruits, vegetables, whole grains, low-fat dairy products, poultry, fish and nuts.

The average American adult consumes 3,600 milligrams of sodium a day. The new guideline says adults with hypertension would benefit from lowering their sodium consumption to no more than 2,400 milligrams daily. Further reduction to 1,500 milligrams a day is desirable because it is associated with an even greater reduction in blood pressure.

**The 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults** and the **2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk** for the first time include a new risk calculator to determine 10-year risk for heart attack and stroke. It's intended to be a tool to help physicians converse about risk with their patients who are between the ages of 40 and 79.

The calculator uses an updated equation developed from community-based populations that for the first time includes African-Americans in addition to other factors such as gender, age, total cholesterol, HDL cholesterol, blood pressure, use of blood pressure medication, diabetes status and smoking status.

The guideline suggests that patients who have a 7.5 percent or higher risk for a heart attack or stroke within the next 10 years may require medical intervention or lifestyle modification.

Some questions have been raised in the media about how the cohort groups used in creating the new guideline could cause the calculator to overestimate risk. AHA and ACC experts who worked on the guidelines support its validity and point out that the calculator is designed for large populations. Tomaselli said it's important to understand that the calculator score is meant to encourage physician-patient conversations, not put more people on statins.

"The risk calculator is a primary driver for all the other conversations," he said. "That's why it is foundationally important to the rest of the documents."

Wednesday's plenary should encourage ongoing discussions, which the guidelines deserve, said Sidney Smith, MD, FAHA, FACC, Director of the Center for Cardiovascular Science and Medicine at the University of North Carolina at Chapel Hill and a former AHA President. Smith was Chair of the Subcommitee on Prevention Guidelines for the ACC/AHA Task Force.

"I think the prevention guidelines, which have been developed over five years and accurately reflect the latest views of scientific and medical experts, are a fitting way to end Scientific Sessions 2013," he said. "I'm reassured that we've done a good job and I look forward to hearing more during the plenary." ▼

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