Cardiovascular health takes centre stage in Brussels

The first-ever Cardiovascular Health Week in the European Parliament took place in Brussels, November 2013

The first-ever Cardiovascular Health Week was an awareness-raising activity on the theme ’Mind Your Heart – for a Heart Healthy Europe’. The initiative was organized by the Members of the European Parliament (MEPs) Heart Group, under the auspices of the European Parliament and supported by the European Society of Cardiology (ESC) and the European Heart Network (EHN).

The MEP Heart Group held meetings with European experts discussing pressing issues of cardiovascular health. Other activities included cardiopulmonary resuscitation training, free cardio fitness classes in the European Parliament Sports Centre, and heart healthy meals in the main European Parliament restaurant.

In addition, MEPs had cardiovascular screening of blood pressure and cholesterol measurements that will be used to predict their 10-year risk of mortality from heart attack and stroke. They then received advice on how to adopt a more heart healthy lifestyle.

Staffan Josephson, President of the EHN, said: ‘We hope this will show MEPs that there is a lot they can do to help protect EU citizens if CVD-friendly policies are in place, such as banning smoking in public places and making healthy food affordable’.

In anticipation of the European Parliament elections in May 2014, MEPs were encouraged to support with a ‘Pledge for Cardiovascular Health’, committing them to consider the impact of cardiovascular health when voting on European Union (EU) legislation and support national strategies to promote cardiovascular health.

Ms Linda McAvan MEP and Co-Chair of the MEP Heart Group, commenting on the importance of this far-reaching endeavour, said: ‘Cardiovascular disease (CVD) is the number one killer in Europe, causing 1.9 million deaths every year, yet there is no dedicated policy on CVD at EU level. The MEP Heart Group is pleased to encourage the engagement of EU policymakers to make the EU a force for protecting and promoting cardiovascular health’.

The opening ceremony was attended by high-level keynote speakers including the European Commissioner for Health Tonio Borg, Lithuanian Minister of Health Dr Vytenis P. Andriukaitis, and Dr Roberto Bertollini, chief scientist and World Health Organization (WHO) Representative to the EU.

Warmly welcoming the initiative, Tonio Borg said: ‘As the primary cause of death and disability in Europe, cardiovascular diseases deserve great attention at EU level. This awareness week is a big step towards putting CVD higher on the EU agenda and generating an environment that is conducive to cardiovascular health, for the good of European citizens’.

Dr Andriukaitis said: ‘Cardiovascular Health Week represents a unique opportunity for policymakers to show EU citizens in their Member States that they care about their health. The Lithuanian Presidency is part of this endeavour - for instance, I am personally spearheading a first-reading adoption of the Tobacco Products Directive, as we know that smoking causes 28% of CVD deaths in adult men and 13% in women of the same age’.

Expressing WHO’s support for the initiative, Dr Bertollini said: ‘MEPs can promote heart healthy lifestyles in their own countries by calling for and supporting WHO and EU policies that discourage smoking and encourage a healthy diet and physical activity. By 2030 more than 23 million people will die annually from CVDs including heart disease and stroke. This is despite the fact that CVD is largely preventable through control of risk factors such as high blood pressure’.

Panagiotis E. Vardas, President of the ESC, concluded: ‘This is the first time the European Parliament has dedicated a week to cardiovascular disease. As a medical doctor, I see this high-level engagement of EU policymakers as a major contribution in striving for optimal prevention and treatment. These will fall short if they are not supported by a strong political commitment’.

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American College of Cardiology/American Heart Association release new guideline for assessing cardiovascular risk in adults

Broader assessment may improve identification of at-risk patients and focus on prevention strategies

The American College of Cardiology (ACC) and the American Heart Association (AHA) recently released a new clinical practice guideline to help primary care clinicians better identify adults who may be at high risk for developing atherosclerotic cardiovascular disease and potentially serious cardiovascular conditions, who may benefit from lifestyle changes or drug therapy.

The guideline—last updated in 2004—has been broadened to include assessment for the risk of stroke as well as heart attack, and provides new gender-and ethnicity-specific formulas for predicting risk in African-American and white women and men. The recommendations also help clinicians and patients look beyond traditional short-term (10-year) risk estimates to predict an individual’s lifetime risk of developing heart disease and having a stroke.

Donald M. Lloyd-Jones, MD, ScM, Senior Associate Dean, Chair and Professor of Preventive Medicine at Northwestern University Feinberg School of Medicine, who was co-chair of the working group that developed the new guidelines, said ‘We must do a better job of prevention. For example, that means being smarter in our approach to determine who should get medications’.

Roughly one in three US adults who have not yet been diagnosed with heart disease and have not had a heart attack or stroke is at high enough risk that they could benefit from primary prevention with medications, including statins. A primary goal of the new guideline is to help ensure preventive treatments including lifestyle changes and drug treatments are used in those most likely to benefit without undue risk or harm. To do this, the new guideline developed high-quality risk assessment methods that use risk factors known to lead to atherosclerosis—such as age, cholesterol levels, blood pressure, smoking, and diabetes—that primary care providers can easily collect. This information is then integrated into a risk score to guide care and prompt risk discussions with patients.

‘The vast majority of heart attacks and strokes could be prevented if people knew their risk and did the things we know are effective in reducing that risk, but patients and doctors alike often underestimate cardiovascular disease risk, especially when considered over the lifespan’, said David C. Goff, Jr., MD, PhD, Dean and Professor, Colorado School of Public Health, and co-chair of the working group. ‘This document offers clinicians the most up-to-date, comprehensive guidance about assessing that risk, so they can work with their patients to prevent heart attack and stroke’.

Inclusion of stroke risk

In the past, cardiovascular risk assessment included only coronary heart disease. Yet, stroke is the fourth leading cause of death in US women, and African-Americans, in particular, are at much greater risk for stroke.

The risk for chronic heart failure was not included in the current algorithm because existing data were insufficient to allow development of a high-quality risk equation for this complex condition.

Development of sex- and race-specific formulas to more accurately quantify risk

The report includes new pooled-cohort risk equations to better represent the effect of atherosclerosis risk factors for specific gender and ethnicities. Risk equations recommended in the past were based on data only from non-Hispanic whites. These new formulas are derived from a broad group of existing data sets including the Framingham Heart Study, the Atherosclerosis Risk in Communities Study, the Cardiovascular Health Study, and the Coronary Artery Risk Development in Young Adults study—all National Heart, Lung, and Blood Institute-sponsored community-based cohort studies.
'There is some evidence that the risk factors we know about—age, smoking, high cholesterol, blood pressure and diabetes—have somewhat different effects in women and men, and certainly in whites and African-Americans', said Dr Lloyd-Jones. 'These equations also allow us to be selective and smart about whom we identify as being at high enough risk for cardiovascular disease that it would merit starting drug therapy to help prevent it'.

As such, the authors recommend the new equations be used to assess risk in non-Hispanic whites and African-Americans aged 40–79 years. The hope is that these formulas will be incorporated into electronic health records, helping clinicians to automatically and easily calculate a patient’s risk and discuss individualized options for lowering that risk.

Assessing lifetime risk

Because the risk for developing atherosclerosis accrues over time and is a function of lifelong exposure to risk factors, the authors say it is really never too early to focus on determining risk. The guideline provides additional methods for determining a patient’s lifetime risk that are particularly intended to help younger adults to understand how they can reduce their risk of heart disease and stroke.

Weighing in on the usefulness of newer risk measures

Four markers stood out as potentially helpful to use when patients or providers are uncertain about risk-based treatment after—the quantitative risk has been calculated using the pooled equations.

These measures include family history of premature cardiovascular disease, coronary artery calcium score, high-sensitivity C-reactive protein levels, and blood pressure ankle–brachial index. ‘These showed the greatest promise, and may help inform treatment decision-making when patients or providers are on the fence after quantitative risk assessment’, Dr Goff said.

Authors say more research is needed to better understand the optimal means for using short- and long-term cardiovascular risk assessment in all race/ethnic groups, across different ages, and between men and women.

The expert panel that wrote the report was convened by the National Heart, Lung, and Blood Institute of the National Institutes of Health. At the invitation of the NHLBI, the American Heart Association and American College of Cardiology assumed the joint governance, management, and publication of the guideline in June 2013. Committee members volunteered their time and were required to disclose all healthcare-related relationships, including those existing 1 year before the initiation of the writing project.

The full report, ‘2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk’, is available online at the ACC website (http://content.onlinejacc.org/article.aspx?doi=10.1016/j.jacc.2013.11.005) and the AHA (http://circ.ahajournals.org/lookup/doi/10.1161/01.cir.0000437741.48606.98), as well as in print issues of the Journal of the American College of Cardiology (JACC) and the American Heart Association Journal, Circulation.

Andros Tofield
American Heart Association late-breaking clinical trials 2013

STREAM 1-year follow-up
Presented by Dr Peter R. Sinnaeve

Although timely primary PCI (pPCI) is recommended as the preferred reperfusion strategy, many STEMI patients worldwide do not present at a cathlab-capable hospital and do not receive pPCI within guideline-recommended timelines. In the STREAM trial, 1892 STEMI patients presenting within 3 h after the onset of symptoms and unable to undergo primary PCI within 1 h were randomized to a pharmaco-invasive (PI) strategy or standard pPCI according to local practice. The PI approach consisted of bolus tenecteplase, clopidogrel, and enoxaparin with dose adjustments in the elderly. The primary combined endpoint of death, shock, congestive heart failure, and re-infarction at 30 days was nominally lower in PI patients.

As pre-specified by the protocol, 1-year mortality data were acquired for all patients surviving the first 30 days. At 1 year, all-cause (6.7 vs. 5.9%) as well as cardiac (4.0 vs. 4.1%) mortality rates were similar for PI- and pPCI-treated patients. We observed a small and non-significant excess in non-cardiac (11 vs. 6) but not cardiac mortality in the PI arm after Day 30. Taken together, at 1 year, the PI strategy used in STREAM was similar to pPCI and offers an alternative reperfusion therapy to a substantial proportion of patients worldwide.

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ASPIRETENSION II Trial
Presented by Tobias N. Bonten MD

What is already known. Aspirin is used for cardiovascular disease (CVD) prevention by millions of patients on a daily basis. Previous studies in hypertensive subjects suggested that aspirin intake at bedtime reduces blood pressure compared with intake on awakening. This has never been studied in patients with CVD. Moreover, platelet reactivity and CVD incidence is highest during morning hours and bedtime aspirin intake may attenuate morning platelet reactivity. This clinical trial examined the effect of aspirin intake at bedtime compared with intake on awakening on 24 h ambulatory blood pressure measurement (ABPM) and morning platelet reactivity in patients using aspirin for CVD prevention. What we did—In this randomized, open-label, cross-over trial, 290 patients were randomized to take 100 mg aspirin on awakening or at bedtime during two periods of 3 months. At the end of each period, ABPM and morning platelet reactivity were measured. Main results. Aspirin intake at bedtime did not reduce blood pressure compared with intake on awakening. However, platelet reactivity during morning hours was significantly reduced with bedtime aspirin intake. Implications. This study showed that the intake of aspirin at bedtime compared with intake on awakening does not reduce blood pressure of patients with CVD. However, bedtime aspirin reduced morning platelet reactivity, which might reduce excess cardiovascular events during high-risk morning hours.

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TAC-HFT Trial
Dr Joshua M. Hare presented the ‘Transendocardial Autologous Mesenchymal Stem Cells and Mononuclear Bone Marrow Cells for Heart Failure Trial’ (TAC-HFT Trial). This is a phase I/II randomized, blinded, placebo-controlled study with a primary objective of demonstrating the safety of transendocardial stem cell injection with autologous MSCs and BMCs in patients with ischaemic cardiomyopathy. A total of 65 patients with left ventricular dysfunction due to ischaemic cardiomyopathy were enrolled at the University of Miami Hospital. Patients received 200 million mesenchymal stem cells or mononuclear bone marrow cells or placebo, injected into 10 left ventricular sites using the Biocardia Helical Infusion Catheter. Transendocardial stem cell injection with autologous MSCs or BMCs appeared to be safe in patients with chronic ICM and LV dysfunction. MSCs significantly improved quality of life and functional status, evaluated with the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and 6-min walk distance test, respectively. Cardiac magnetic resonance imaging revealed decreased scar size and improved regional wall motion at the site of cell injection. Bone marrow cells improved the MLHFQ. Together, the safety profile and the findings of scar reduction, and improved quality of life and functional capacity, provide the basis for larger studies to provide further assessment of safety and efficacy of this new therapeutic approach.

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Eating fish and atrial fibrillation

Moderate intake appears to be a key when it comes to eating fish and avoiding atrial fibrillation

An observational study presented at the EHRA EUROPACE Congress in Athens, Greece, found a U-shaped association between consumption of marine n-3 polyunsaturated fatty acids (n-3 PUFAs) and the risk of developing atrial fibrillation (AFib). People who have both low and high intakes were found to suffer more from AFib than those with median intakes. The lowest risk of AFib was found in those who consumed \( \sim 0.63 \) g marine n-3 PUFA per day, which corresponds to about two servings of fatty (oily) fish per week.

Earlier studies had reported that regular consumption of fish can exert beneficial effects in preventing the development of AFib. In the Cardiovascular Health study with 4815 participants, a 28% lower risk of AFib was observed among people who consumed fish one to four times per week compared with those who ate fish less than once per month. However, such observed associations have not been confirmed in all cohort studies.

In the current study, Dr Thomas A. Rix and colleagues from Aalborg University Hospital in Denmark examined the hypothesis that a negative association exists between the development of AFib and consumption of n-3 PUFAs. ‘Since AFib is present in over six million people in Europe and associated with considerable morbidity, mortality and economic costs, preventing AFib by achievable dietary changes would be of major public interest’, said Dr Rix.

The investigators made use of the Danish Diet, Cancer and Health cohort, which between 1993 and 1997 enrolled a total of 57,053 Danish participants aged 50–64 years. The study, funded by the Danish Cancer Society, had been initiated with the primary objective of exploring the role of diet in the development of cancer. Baseline data recorded for the study included a semi-quantitative food frequency questionnaire with detailed questions about the consumption of fish and food products containing fish that enabled the calculation of average n-3 PUFA intakes.

Follow-up of AFib events in the population was undertaken using the Danish National Patient Registry, which recorded discharge diagnoses from hospital admissions, emergency rooms, and outpatient clinics. The registry was facilitated by the Danish practice of identifying every citizen with a unique personal identification number that enables cross-links to be made between different national registries.

Altogether, a total of 3425 incident cases of AFib were registered during 13.6 years of follow-up. Data were analysed in a multivariate Cox regression model.

‘A 13% observed lower risk of AFib was seen at moderate intakes of marine n-3 PUFA compared with low intakes which may be related to a reduction in ischemic heart disease and anti-inflammatory effects in addition to direct anti-arrhythmic effects’, said Dr Rix. He noted that, in one study, treatment with 1.8 g n-3PUFA/day in patients with low intakes of fish resulted in prolongation of the atrial effective refractory period and less inducible AFib, both in subjects with AFib and subjects without AFib.

‘The biological mechanisms behind the higher risk of AFib observed for high intakes of n-3 PUFA compared to moderate intakes were more difficult to explain’, said Dr Rix. ‘We can only speculate that the balance between AFib inhibiting and AFib promoting effects can change according to co-morbidities and intakes of marine n-3PUFA. This is the first time that such an association has been shown and it needs to be explored in further studies. However, it may help explain some of the contradictory results obtained in earlier studies’.

Andros Tofield

Clinical Research I

Research failure can result in lost lives