

# Congress News

Wednesday 29 August 2018

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## Challenging conventional thinking on a healthy diet: Data from PURE



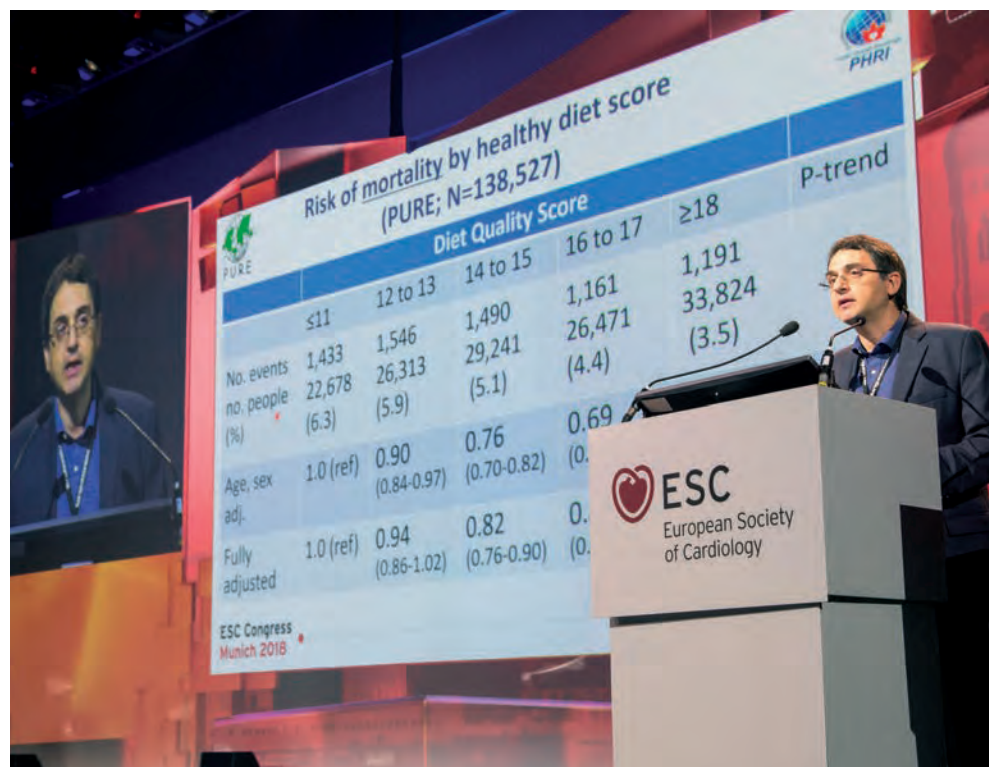
**Dr. Andrew Mente**

In a Hot Line session yesterday, **Doctor Andrew Mente (Hamilton Health Sciences and McMaster University, Hamilton, Ontario, Canada)** presented the results of an analysis in 218,000 people from over 50 countries based on four large international studies to clarify the type of modern, international diet that promotes cardiovascular (CV) health and longevity.

"Contrary to what has been believed for decades," says Dr. Mente, "the Prospective Urban Rural Epidemiology (PURE) study revealed that a high-carbohydrate diet increases the risk of mortality but that fats are associated with a lower risk of total mortality and stroke.<sup>1</sup> It also established that the protective effect of fruit, vegetables and legumes extends globally.<sup>2</sup>"

The PURE cohort includes over 138,000 individuals without cardiovascular disease (CVD) from 21 countries in five continents. In order to clarify the constituents of a healthy diet, intake was recorded using country-specific food frequency questionnaires at baseline and patients were followed for a median of 8.1 years. "Dietary quality scores were based on foods associated with a lower risk of mortality, such as fruit, vegetables, legumes, nuts, fish, dairy products and unprocessed meat," Dr. Mente says, explaining, "The association between diet and CVD was first examined in the PURE cohort and then validated in 79,478 patients in a prospective study in vascular disease (ONTARGET/TRANSCEND) and two case-control studies in first myocardial infarction (MI) (INTERHEART) and first stroke (INTERSTROKE)."

There were 5,466 major CV events—death from CV causes, non-fatal MI, stroke and heart failure—and 6,821 total deaths. After adjusting for confounding factors, higher-quality diets ( $\geq 18$  points) were associated with a lower risk of major CV events (hazard ratio [HR] 0.89;



$p=0.0193$ ), stroke (HR 0.83;  $p=0.0402$ ), CV mortality (HR 0.71;  $p<0.0001$ ), non-CV mortality (HR 0.74;  $p<0.0001$ ) and total mortality (HR 0.75;  $p<0.0001$ ) than lower-quality diets ( $\leq 11$  points). Similar results were found in the studies in patients with vascular diseases.

**"Higher-quality diets were associated with lower risks of major CV events and mortality—CV, non-CV and total—in the prospective study and in MI and stroke in the case-control studies."**

"PURE confirms that a diet emphasising fruit, vegetables, nuts, legumes, fish, dairy products and unprocessed meat is the best for CV health and reduces the risk of early death," says Dr. Mente.

1. Dhegghan M, et al. Lancet 2017;390:2050-2062.
2. Miller V, et al. Lancet 2017;390:2037-2049.

**Read more about the PURE study and the relationship between nutrition and heart disease in the article on page 6 of this issue.**

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## Thank you!

**You have made ESC Congress 2018 the third largest in the ESC's history: more than 32,850 participants from a record 156 countries.**

**This really is the world summit of cardiovascular medicine.**

# News from the General Assembly 2018

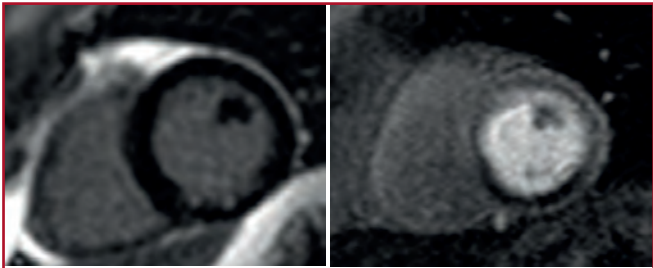
Yesterday's General Assembly began with a summary of the financial and annual report by Professor Ian Graham (ESC Secretary/Treasurer) and the good news that, despite the difficult economic and regulatory environment, results for the fiscal year 2017-2018 compare favourably with the budget and are higher than the previous year, in part due to additional congresses.

The Audit Committee Chair, Luciano Respini, highlighted important progress in the Declaration of Interest policy and provided some future recommendations, including a general review of existing ESC Statutes, which have been in place for many years, to enable the ESC "to effectively operate in today's world and provide state-of-the art governance practice."

ESC's President 2016-2018, Professor Jeroen Bax, provided an overview of resolutions and results from the Ordinary General Assembly. He noted two approved resolutions that represent "important steps forward for the Society": the creation of the Association of Cardiovascular Nursing and Allied Professions (ACNAP) and the new Council of Cardio-Oncology. He also welcomed Uzbekistan as the 57th National Cardiac Society.

Professor Fausto Pinto performed his last task as Past President (2016-2018) when he announced the results of the ESC Board 2018-2020 elections, naming Professor Stephan Achenbach as President Elect. Prof. Bax presented Prof. Pinto with a commemorative plaque in grateful recognition of his dedication, inspiration and leadership.

Speaking of his time as ESC President, Prof. Bax said, "I have enjoyed a great ride and a fantastic adventure." He warmly thanked members of the 2016-2018 ESC Board members for their distinguished service and honoured them with ESC Silver Medals. Prof. Bax then handed over the presidency to Professor Barbara Casadei, ESC's President for 2018-2020. Prof. Casadei described the "emotional moment" of accepting the presidency and in her first task, presented Prof. Bax with an ESC Gold Medal in recognition of his dedication and leadership to the Society. In an inspirational address, Prof. Casadei then outlined her vision, saying, "To maintain high standards and the legacy of the present, we must continually evolve to be fit for the future." Read more about Prof. Casadei's plans in the article opposite.



## What's Your Diagnosis?

BROUGHT TO YOU BY THE EUROPEAN ASSOCIATION OF CARDIOVASCULAR IMAGING (EACVI)

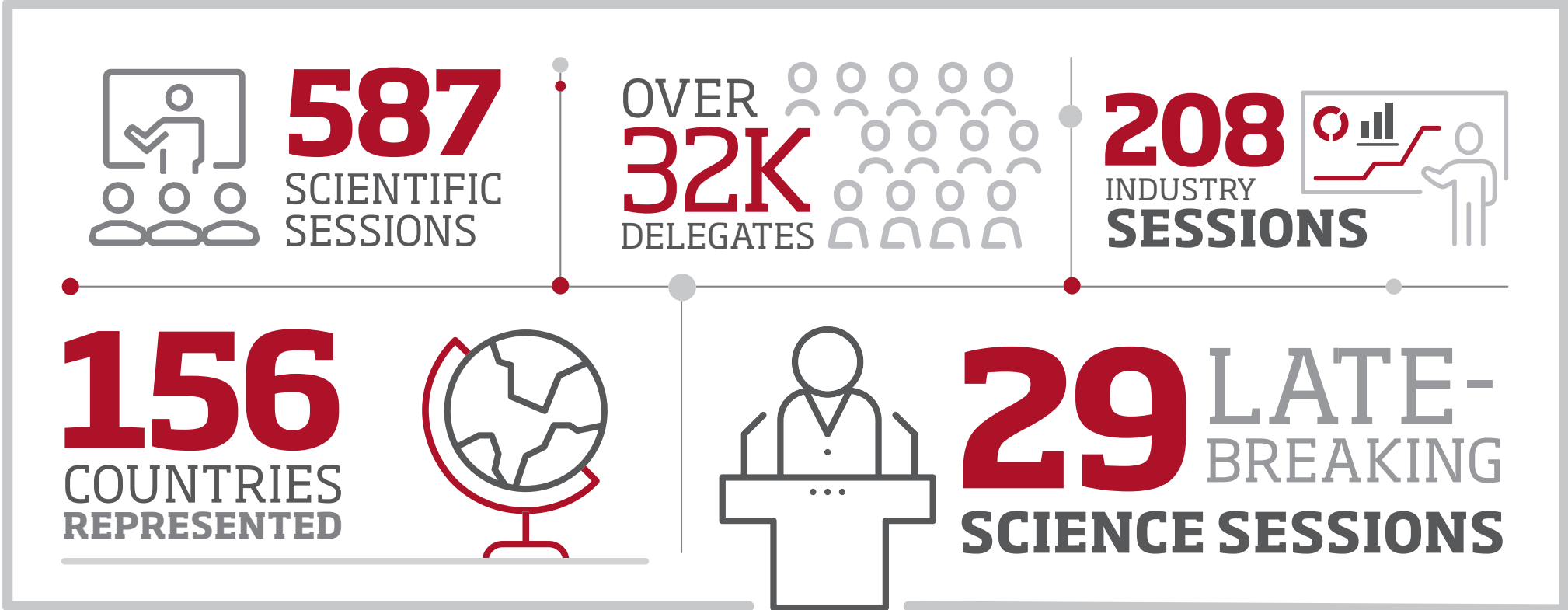
Cardiovascular magnetic resonance (CMR) late gadolinium enhancement image (left) and stress perfusion image (right) in a 65-year-old male with stable angina.

Iwan Harries & Chiara Bucciarelli-Ducci, Bristol Heart Institute, Bristol, UK



Answer on page 11.

# ESC Congress 2018 - Facts & Figures



## Collaboration 2019

ESC President 2018-2020 Barbara Casadei and World Heart Federation President David Wood announce "ESC Congress 2019 - Special Edition" in Paris

[www.escardio.org/ESC2019](http://www.escardio.org/ESC2019)



# Incoming ESC President Barbara Casadei

## talks priorities for the next two years



**Prof. Barbara Casadei**

**Professor Barbara Casadei first became involved in the ESC some 30 years ago when she received an ESC Fellowship to train at the University of Oxford in the United Kingdom. Since then, she has been an active volunteer—particularly within the scientific Working Groups and Councils—a FESC, and today she becomes its President.**

For Prof. Casadei, the priority in this new role is to modernise and expand ESC's reach. "I would like to firmly establish patients in the framework of the ESC and to be able to

develop policies that are also informed by their personal experience of cardiovascular disease," she explains.

"It is hard for me to hear patients saying that they are grateful for their care, but that if they want help in how best to cope with cardiovascular disease they need to talk to other patients, often via websites. I want to bridge this gap in the Society—to advocate for patients as well as for investment in cardiovascular health and our needs as professionals in the current challenging environment."

**"We need to improve our communication with patients and the public; I want the ESC to be seen as a trustworthy hub of news and reliable information that has an impact on public health."**

"I would also like to strengthen the ESC registry programme to make it fit to assess quality of care across Europe," continues Prof. Casadei. "Collecting health data to inform and refine our practice is a 'must'," she highlights, giving the example of Sweden's nation-wide registry SWEDEHEART, which has the dual purpose of providing doctors with a means to evaluate and improve quality of care, and of serving as a platform for pragmatic clinical trials. "This is very important to the ESC, as such infrastructure, underpinned by research, will maintain European cardiology at the forefront for years to come."

What challenges might the presidency hold? "The key will be managing the balance between advancing our traditional activities whilst making the Society 'bigger' in term of aspirations, inclusivity, achievement and impact," says Prof. Casadei. I want to stay focused on the big battles that need to be fought."

As Vice President for Scientific Affairs and Chair of the ESC Research Strategy and Cardiovascular Roundtable, Prof. Casadei says that she has been able to discuss her ideas widely and plan well for her new role as President. Having a sense that the membership feels aligned with the mission and values of the ESC will amount to success for Prof. Casadei. "A membership that embraces the pursuit of quality of care, unbiased education, excellence in research and the need for transparency and trustworthiness is key for winning our battle with cardiovascular disease, for improving the lives of our patients, and for asserting our profession—being true to these values will make the ESC fit for the future," she emphasises. "I exhort cardiovascular patients, health professionals and scientists to engage with the ESC and help our Society fulfil its mission to reduce the burden of cardiovascular disease."

# Fractional flow reserve-guided percutaneous coronary intervention: When to use it?



**Prof. Gilles Rioufol**

**Late-breaking abstract presentations of further analyses of two prematurely halted trials provided valuable information about the utility of fractional flow reserve (FFR) measurement to guide treatment decisions in different patient populations with multivessel disease.**

On Saturday, Professor Gilles Rioufol (Hospices Civils de Lyon, Lyon, France) spoke about the prematurely halted Functional Testing Underlying Coronary Revascularization (FUTURE) trial. FUTURE was conducted at 31 centres in France with a planned enrolment of over 1,700 patients with multivessel disease. Stable all-comer coronary artery disease (CAD) patients referred for coronary angiography with at least two-vessel disease including the left anterior descending coronary artery, left main coronary artery or three-vessel disease, were randomised to management according to FFR guidance or to control angiographic guidance. In the FFR group, each  $\geq 50\%$  stenosis by visual estimation was tested for FFR. Any stenosis with  $\text{FFR} \leq 0.80$  was considered for revascularisation either by percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), while stenoses with  $\text{FFR} > 0.80$  were excluded from the revascularisation plan.

Prof. Rioufol explains, "After enrolment of just over 900 patients, the data safety monitoring and steering committee advised stopping the trial in view of a more than



**Dr. Stephane Fournier**

two-fold increase in overall mortality in the FFR group. Of note, the one-year outcome data available for nearly 800 patients did not show a significant difference in the composite primary endpoint of all-cause mortality, myocardial infarction (MI), stroke or unplanned coronary revascularisation." When Prof. Rioufol presented these findings at American Heart Association Scientific Sessions 2016,<sup>1</sup> there was much speculation as to why mortality was increased—at ESC Congress 2018, he provided final results and further insight.

The safety analysis confirmed a higher mortality in the FFR group compared with the control group at one year (hazard ratio 2.39;  $p=0.038$ ). "However," says Prof. Rioufol, "in the intention-to-treat analysis, there was no difference in the incidence of the primary endpoint between the FFR and the control group at one year (14.4% vs 14.6%;  $p=0.94$ ). The mean Syntax score was higher in the FFR group compared to the control group when revascularisation with PCI was chosen ( $19 \pm 7$  vs  $17 \pm 7$ ;  $p=0.007$ ). Notably, patients with a Syntax score  $\geq 32$  had a higher risk of adverse outcomes in the FFR group compared to the control group ( $p=0.02$ )."

He explains, "Using FFR to select a revascularisation strategy in this subset of complex patients appears to increase mortality in patients with a Syntax score  $\geq 32$  by lowering their functional ischaemic severity. Our results suggest caution

when using FFR in patients with complex multivessel disease not obviously amenable to PCI."

**"This analysis of FUTURE is reassuring for FFR. It's not a device-related problem but is more linked to strategy."**

Commenting on the results, Prof. Rioufol observes, "FUTURE was a trial questioning if FFR could help to improve revascularisation strategy in patients with multivessel disease. It absolutely did not challenge the role of FFR for PCI-eligible patients." He continues, "We observed that FFR decreased the rate of revascularisation with a two-fold increase of medical treatment only, and these patients fared very well. This is a good news. We also observed that PCI was the dominant choice of revascularisation (only 12% for CABG) and that was quite a surprise because inclusion criteria left room for the options of PCI or CABG. In that specific context, with the choice of treatment decided centre by centre according to local practices, we observed that PCI remained the dominant strategy, even when anatomy was very complex according to the Syntax score and these patients had a worse outcome."

Yesterday, Doctor Stephane Fournier (Cardiovascular Center Aalst, Aalst, Belgium) presented results from a sub-analysis of the Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME 2) trial. FFR was measured in all stenoses in patients with stable CAD for whom PCI was being considered.<sup>2</sup> Patients with at least one stenosis measuring  $\text{FFR} \leq 0.80$  were randomised to FFR-guided PCI or medical therapy alone. The primary endpoint was a composite of death, MI or urgent

revascularisation. Recruitment was halted prematurely after randomisation of 888 patients because of a significant between-group difference. Dr. Fournier explains, "The original analysis showed that in patients with stable CAD and functionally significant stenoses, FFR-guided PCI decreased the need for urgent revascularisation compared with medical therapy alone. Here we investigated outcomes in 98 participants with silent ischaemia—which is thought to have particularly poor outcomes—compared with the remaining symptomatic patients."

"Among patients receiving medical therapy alone, the rate of death or MI was significantly higher in silent compared with symptomatic ischaemia (31.1% vs 14.4%, respectively;  $p=0.002$ )," he says, continuing, "However, in patients receiving PCI, there was no significant difference in this endpoint between silent and symptomatic ischaemia (9.4% vs 12.2%;  $p=0.497$ )." Dr. Fournier notes that, "Death or MI were significantly lower in patients with silent ischaemia who were randomised to PCI compared with medical therapy alone (9.4% vs 31.1%;  $p=0.003$ )."

**"The excess in adverse outcomes in patients with silent ischaemia appears to be abolished by FFR-guided PCI."**

"Symptomatic patients randomised to medical therapy alone more often cross over to PCI, which presumably protects them from death or MI," he adds.

1. Rioufol G, et al. Presented at: American Heart Association Scientific Sessions 2016. November 14, 2016. New Orleans, LA.
2. Xaplanteris P, et al. N Engl J Med 2018;379:250-259.

# A major step forward for cardiovascular nurses and allied health professionals – a new Association is born!

If you're one of the 806 cardiovascular nurses or allied professionals attending ESC Congress, then you'll be particularly pleased to know that at yesterday's General Assembly, the ESC voted to elevate the long-standing ESC Council of Cardiovascular Nursing and Allied Professions (CCNAP) to an Association, one of only seven within the ESC.

The ESC CCNAP was officially launched in Barcelona in 2006. Current Chair, Associate Professor Ekaterini Lambrinou (Cyprus University of Technology, Limassol, Cyprus) said, "With more than 3,000 members worldwide, the mission of our organisation has been to support both research-active and clinical nurses and allied health professionals to deliver the best possible care to patients with cardiovascular disease and their families. This is an exciting era for international cardiovascular nursing, but our mission remains the same."

Since its inception, the CCNAP has made significant strides, including: the creation of the highly informative annual congress, EuroHeartCare; the top-ranking *European Journal of Cardiovascular Nursing*; development of educational resources, such as the Core Curriculum and the Comprehensive Guidelines Implementation Toolkit; and many career enhancement and mentorship programmes.

Vice-Chair, Doctor Tina Birgitte Hansen (Zealand University Hospital, Denmark) explained, "Nurses and allied health

professionals play a pivotal role in cardiac care. Evolution of the CCNAP to the Association of Cardiovascular Nursing and Allied Professions (ACNAP) gives further strength to our growing community. It will allow us to collaborate and contribute at an equal level with other subspecialties and associations within the ESC so that we can play an even greater role in the delivery of optimal cardiovascular care."

**"Creation of the ACNAP reflects the continued growth and increasing recognition of the important part that nurses and allied health professionals have to play in cardiac care."**

While plans for the new ACNAP are in development, Dr. Hansen described important areas for the future, "We would like to increase our focus on targeting ACNAP activities at allied professionals, engage more nurses working in clinical practice in ACNAP activities, continue to stimulate research and participate even more actively in partnerships with external stakeholders and across professions."

Nurses and allied health professionals—we welcome you to join the new ACNAP.



## Young Investigator Awards

Winners from this year's Young Investigator programme received their awards from ESC President (2016-2018) Prof. Jeroen Bax and Congress Programme Committee Chair Prof. Stephan Achenbach.

## Globally largest registry with clinical outcomes for bioresorbable scaffolds – findings from the European ABSORB Consortium



**Prof. Holger Nef**

In a late-breaking abstract presentation yesterday, Professor Holger Nef (University of Giessen, Giessen, Germany) presented data from the European ABSORB Consortium (EAC) in patients undergoing percutaneous coronary intervention (PCI) with the ABSORB bioresorbable vascular scaffold (BVS).

**The EAC is the globally largest prospective registry of bioresorbable vascular scaffold use in PCI.**

"Entering the European market in 2011, the ABSORB BVS was considered to be opening up a new era in stent technology," says Prof. Nef. "However, it became beset by technical issues and safety concerns. In 2017, three-year data from the randomised ABSORB study in just over 2,000 patients revealed higher event rates with the BVS than with metallic drug-eluting stents, with statistically significantly more instances of target vessel myocardial infarction (MI) and scaffold thrombosis.<sup>1</sup> In September of the same year, sales of ABSORB BVS were halted, but physicians were still allowed to implant existing stock and patients in clinical trials continued to be monitored according to plans<sup>2</sup>"

Within the EAC—which is made up of five European registries: GABI-R, UK Registry, ABSORB France, RAIRegistry and REPARA—patients are followed up systematically by scheduled telephone interview and clinical outcome data are collected and adjudicated by an independent clinical event committee. The primary clinical endpoint is 12-month target lesion failure (TLF) (cardiac death, MI and target lesion revascularisation [TLR]) with secondary endpoints including death, TLR and definite/probable stent thrombosis (ST).

"Between 2013 and 2016, 10,312 patients underwent BVS implantation and had a

12-month follow-up," reports Prof. Nef. "The TLF rate was 3.6% and the rates of death and cardiac death were 1.2% and 0.6%. Target vessel MI, TLR and target vessel revascularisation (TVR) were reported in 1.8%, 2.6% and 3.2% of cases, respectively." These real-world data show that BVS is associated with acceptable clinical outcomes, thinks Prof. Nef. "Particularly noteworthy is the TLF rate, which is comparable to registry data gained with second-generation drug-eluting stents (DES) a number of years ago." He notes, "In this, the largest pooled data set globally to date, we found a 1.6% rate of definite/probable ST."

**The rate of definite/probable stent thrombosis depends on the implantation protocol.**

The cumulative incidence curve of definite/probable Academic Research Consortium-defined ST showed an initial steep rise: about 60% of cases were observed within the first 30 days. "To exclude a learning curve," says Prof. Nef, "we compared patients who were implanted before and after 2015. This particular cut-off was chosen because the instructions for use were changed by the manufacturers in November 2014 with regard to implantation technology." Although not adjusted for confounding factors, most notably, the composite endpoints for target vessel failure (TVF) and TLF were reduced. "Moreover, the ST rate was somewhat lower in the population implanted in the more recent period—1.8% to 1.4% after 12 months, without reaching statistical significance," says Prof. Nef.

He concludes, "The EAC reports large-scale, real-world clinical outcome data for BVS. Outcome seems to depend on implantation protocols and BVS technology. This includes ST, which remains high in this registry."

1. Kereiakes DJ, et al. J Am Coll Cardiol 2017;70:2852-2862.  
2. [www.vascular.abbott/us/products/coronary-intervention/absorb-bioresorbable-scaffold-dissolving-stent.html](http://www.vascular.abbott/us/products/coronary-intervention/absorb-bioresorbable-scaffold-dissolving-stent.html).

## ESC announces NEW ESC Council of Cardio-Oncology



The ESC General Assembly yesterday voted to create a new ESC Council on Cardio-Oncology. The goal: to guide and support physicians tackling an increasing number of patients developing cardiovascular complications following cancer treatments.

The chairperson of the new Council, Doctor Riccardo Asteggiano (Turin, Italy), says, "Advances in treatment have led to a dramatic improvement in the survival of patients with cancer; however, their cardiovascular adverse effects are relatively frequent and there's increasing concern about the potential of premature cardiovascular-related morbidity and mortality among cancer survivors."

**In the coming years, there may be a cardio-oncology 'epidemic' due to the growing population of cancer survivors and to the high frequency of cardiovascular diseases as complications of cancer treatment.**

Cardio-oncology is a field with many unmet needs and gaps in knowledge. In 2016, an ESC task force published a position paper, under the auspices of the ESC

Committee for Practice Guidelines,<sup>1</sup> to support physicians in the difficult task of monitoring and decision-making related to cancer treatment and cardiovascular toxicity. The creation of a council is the next step by the ESC to further address this issue. Dr. Asteggiano says, "Faster progress is required and this can only be achieved through multidisciplinary teams among cardiology subspecialties, oncologists and specialists in related fields, such as haematologists and radiotherapists."

Cardiologists have specific challenges and responsibilities in this emerging, interdisciplinary alliance and the ESC is focussed on providing a coordinated approach. "Together we need to identify the deficiencies and create effective initiatives," says Dr. Asteggiano.

Cardiologists from all subspecialties are welcome to join the new ESC Council of Cardio-Oncology. As with the six established ESC Councils, the aim of the Council of Cardio-Oncology is to encourage research, education and the sharing of knowledge to contribute to the ESC's overall mission of reducing the burden of cardiovascular diseases.

1. Zamorano JL, et al. Eur Heart J 2016;37:2768-2801.

# Late-breaking abstract presentations reveal new information on TAVI



**Prof.  
Martine Gilard**

**Transcatheter aortic valve implantation (TAVI), or transcatheter aortic valve replacement (TAVR), is an established treatment for patients with severe aortic stenosis considered to be at high risk for surgical valve replacement. A number of late-breaking TAVI registry abstract presentations yesterday provided long-term data in high-risk patients and data on the use of this approach in lower-risk patients.**

Professor Martine Gilard (Hospital Cavale Blanche, Brest, France) reported 5-year follow-up data from the FRANCE-2 registry, which included all consecutive high-risk patients (n=4,201) who underwent a CoreValve or Edwards TAVI procedure at 34 centres in France between January 2010 and January 2012.<sup>1</sup>

"At five years, the all-cause mortality rate was 60.8%," she notes. "Most cardiovascular events occurred within the month after valve implantation, remaining low (<2%/year) thereafter. The exception was heart failure, which decreased over time to <5%/year from 14.3% at one year." In terms of the valve, the mean gradient, valve area and aortic valve regurgitations remained stable over time. "We found that moderate haemodynamic structural valve deterioration (SVD) increased from 6.9% at one year to 13.3% at five years, but that it was severe in only 1.4% and 2.5% of cases, respectively," she says.

**The data from FRANCE-2 represent the largest long-term dataset available for TAVI in a high-risk population and support the long-term efficacy of the approach in this population.**

"The FRANCE-2 registry is the largest cohort of consecutive TAVI patients with available late follow-up, and with 459 patients having echocardiographic evaluation at five years providing unique information with regard to valve durability," says Prof. Gilard. "Haemodynamic SVD was defined according



**Prof.  
Raffi Bekerredjian**

to the European Association of Percutaneous Cardiovascular Interventions (EAPCI) consensus statement. The low rates of severe haemodynamic SVD and good New York Heart Association (NYHA) functional status maintained up to five years support the long-term efficacy of TAVI with the two types of transcatheter prostheses used in these in high-risk patients."

Although TAVI is a standard approach for high-risk patients, interest in this treatment option for lower-risk patients is growing. Two registries reported on its use in this patient type.

Professor Raffi Bekerredjian (Robert-Bosch Hospital, Stuttgart, Germany) presented results of an analysis of the German Aortic Valve Registry (GARY), comprising patients with a Society of Thoracic Surgeons' (STS) risk score of <4%, comparing patients undergoing isolated TAVI (n=6,062) with those receiving surgical aortic valve replacement (SAVR; n=14,487) between 2014 and 2015. "While all patients had an STS score of <4%, the two treatment groups differed significantly in their baseline characteristics. For example, TAVI patients were older (79 vs 67 years, p<0.0001) and had a higher mean STS score (2.86 vs 1.79, p<0.0001) and European System for Cardiac Operative Risk Evaluation score (EuroSCORE) (12.9 vs 5.9, p<0.0001). There are no guidelines recommending TAVI as a treatment for low-risk patients and these differences at least partly reflect the heart teams' decisions in selecting the patients most suitable for TAVI."

**Short-term survival rates were higher with TAVI than SAVR, but there was no difference between the groups in the number of patients surviving at one year.**

"Using a weighted propensity score model, the survival rates for TAVI and SAVR were 98% vs 97%, for both the in-hospital (p=0.003) and 30-day (p=0.014) time periods," says Prof. Bekerredjian. "The 12-month survival rates were 90% with TAVI and 91% with SAVR (p=0.158), showing non-inferiority." This pattern was consistent for transvascular TAVI.



**Prof.  
Ron Waksman**

"The results from GARY," he says, "provide convincing evidence to support the benefits of TAVI in low-risk patients."

The Low Risk TAVR (LRT) trial is the first FDA-approved, prospective, multicentre clinical trial of TAVI in low-risk patients in the USA.<sup>2</sup> "The study investigated the safety and feasibility of TAVR in 200 elderly patients with an STS score ≤3%, using all-cause mortality as the primary endpoint," says Professor Ron Waksman (MedStar Washington Hospital Center, Washington DC, USA). "As would be expected, these low-risk patients, who had a ≤3% 30-day STS-predicted risk of mortality, were younger than those observed in previous intermediate-risk studies, with a mean age of 73.8 years," he says. The 30-day clinical outcomes support the safety and efficacy of TAVI in low-risk patients. "All-cause mortality was 0% at 30 days," says Prof. Waksman, "and rates of secondary Valve Academic Research Consortium (VARC)-2 safety signals were low. Among 194 patients available for subclinical leaflet thrombosis assessment, hypoattenuated leaflet thickening was observed in 15.8% taking antiplatelet therapy and 7.7% receiving anticoagulants."

Patients in the LRT trial underwent a propensity score-matched comparison with a historical control of 719 patients who underwent SAVR at the same institutions between January 1 2013 and December 31 2017. The primary endpoint was all-cause mortality at 30 days. "The zero 30-day all-cause mortality in the TAVR group compared with 1.7% mortality in the SAVR group," comments Prof. Waksman, continuing, "Also, there were zero in-hospital strokes in the TAVR group vs 0.6% stroke in the SAVR group." Permanent pacemaker implantation rates were similar between TAVI and SAVR patients (5.0% vs 4.5%). The rate of new onset atrial fibrillation (3.0%) and length of hospital stay (2.0±1.1 days) were low in the TAVI group. One TAVI patient had >mild paravalvular leak and 14% of TAVI patients had evidence of subclinical leaflet thrombosis at 30 days.

"The results of LRT are a strong signal that expansion of the indication of TAVR for low-risk patients is just a matter of time," concludes Prof. Waksman.

1. Didier R, et al. Circulation 2018;August 28;doi:10.1161/CirculationAHA.118.036866.
2. Waksman R, et al. J Am Coll Cardiol 2018;doi:10.1016/j.jacc.2018.08.1033.

### Sessions of the day

9:00	Congress Condensed - 2018 Clinical Practice Guidelines
Munich	
Centre Stage	Congress Condensed General Cardiology
Bach	Congress Condensed Basic Science
Beethoven	Congress condensed Valvular Heart Disease
10:15	
Munich	ESC Congress Highlights

## ESC Congress 2019 awaits!

As this highly successful congress draws to a close, the ESC is already looking ahead to ESC Congress 2019.

It is fitting that next year, the summit of cardiovascular medicine will be held in Europe's largest conference complex, the newly opened, centrally-located Paris Convention Centre. In response to the increasing size and impact of ESC Congress, the 2019 meeting will for the first time have two chairs: Professor Silvia Priori (University of Pavia, Pavia, Italy) and Professor Marco Roffi (University Hospital of Geneva, Geneva, Switzerland).

**ESC has a big responsibility to organise the world’s largest cardiology congress—clinicians and scientists are coming from all over the world to attend and are looking at ESC congresses as the place to help them strive for excellence in patient care and to present their best research.**

For Prof. Priori, the main aim of the congress is to assist general and subspecialty cardiologists in daily patient care. “Sessions on clinical practice updates and case-based discussions will be strengthened and more physicians will be able to present the case they always wanted to share. Attendees will also have the opportunity to talk with experts to address practical aspects of routine and complex cardiac procedures,” she says.

Another important congress aim is the first presentation of the very latest and most innovative research, not only at Hot Line sessions or Late-Breaking Science sessions but also in highly interactive discussion forums. In addition, ESC Congress 2019 wants to stimulate increased dialogue between clinical cardiology and basic science, by more closely connecting these two areas, and to encourage young physicians to drive clinical medicine forward from basic science backgrounds.

The reason for selecting ‘Global Health’ as the main spotlight for ESC Congress 2019 is explained by Prof. Roffi. “We decided to focus on this theme because non-communicable diseases—which include cardiovascular disease—are now also becoming the main cause of death and disability in lower-/middle-income countries. The scope for intervention and the impact of improved care are potentially huge and the ESC has chosen to take on the challenge to help affiliated cardiac societies in reducing the burden of cardiovascular disease, which is the very mission of ESC,” he says, adding, “The spotlight also fits perfectly with the fact that next year the ESC congress and the World Congress of Cardiology of the World Heart Federation will be held together. What a great opportunity!”

# The PURE study: Understanding the relationship between nutrition and heart disease



Prof. Salim Yusuf

**Results from the Prospective Urban Rural Epidemiology (PURE) study published last year have shaken up the field of nutrition sciences and could have a significant impact on global dietary guidelines.**

Findings from this large, epidemiological cohort study involving 135,335 individuals aged 35 to 70 years from 18 low-, middle- and high-income countries (across North America, Europe, South America, the Middle East, South Asia, China, South East Asia and Africa) suggest that high carbohydrate intake increases total mortality, while high fat intake is associated with a lower risk of total mortality and has no association with the risk of myocardial infarction or cardiovascular disease-related mortality. Furthermore, a higher saturated fat intake appeared to be associated with a 21% lower risk of stroke.<sup>1</sup> Why might these results be in such contrast with current dietary advice? “The conclusion that low fat intake is protective is based on a few very old studies with questionable methodology,” explains Professor Salim Yusuf (McMaster University, Hamilton, Ontario, Canada), senior investigator for the PURE study. “The problem is that poorly designed studies performed 25-30 years ago were accepted and championed by various health organisations when, in fact, there are several recent studies using better methods, which show that a higher fat intake has a neutral effect,” he continues, citing the example of the Women’s Health Initiative trial conducted by the National Institutes of Health in 49,000 women that showed no benefit of a low-fat diet on heart disease, stroke or cardiovascular disease.<sup>2</sup>

**“We need greater investment in nutritional sciences to reach more reliable conclusions. We need to question established dogma and to look at the evidence more objectively”**

So, what can be done to address the disconnect between current dietary guidelines and findings from the PURE study? “Nutrients are not like tobacco, an external toxin for which it’s clear that any level is bad. Most nutrients are essential to health—too little is bad, too much is bad, so there is an optimal level or ‘sweet spot’ for consumption of most nutrients. We need a fresh look at the evidence, which is difficult given the current dogma. Careful evaluation in well-designed, large randomised trials of food patterns, conducted in different settings, is required.” At a time when the field of nutritional sciences is undergoing an evolution—perhaps even revolution—what is clear is that greater investment is needed to improve the quality of the evidence we have. “Reliance on surrogate outcomes (such as blood pressure or LDL-cholesterol) alone can be misleading as diet is incredibly complex, and so their effects cannot be captured by the effects on a single biomarker,” advises Prof. Yusuf. “Furthermore, studies need to be population- and culture-specific as the levels and patterns of consumption of various nutrients vary in different societies. The impact of reducing salt is likely to vary based on the levels of consumption of sodium or potassium,” he says.

The PURE study is one of the largest dietary studies in the world. In addition, it has global relevance having been conducted in 21 countries across five continents. It provides a unique opportunity to examine the impact of diet on total mortality and on cardiovascular disease in some settings where over-nutrition is common and others where poverty is widespread and under-nutrition is of greater concern. “I have worked with over 1,500 investigators across many countries and a significant portion of these colleagues have become close friends,” says Prof. Yusuf. “I am passionate about preventing cardiovascular disease both globally and also in low- and middle-income countries. I am proud of the collaborations that we have built with other researchers who are collectively inspired to tackle the big, relevant questions and raise the necessary funds that are needed for their studies.”

1. Dehghan M, et al. Lancet 2017;390:2050-2062.  
2. Howard BV, et al. JAMA 2006;295:655-666.

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# Pointers for oral anticoagulants and antiplatelet therapy use in patients with atrial fibrillation: News from GARFIELD-AF



Prof. John Camm

The Global Anticoagulant Registry in the FIELD-Atrial Fibrillation (GARFIELD-AF) is the largest multinational prospective registry in AF. Late-breaking abstract presentations yesterday reported new studies from this registry looking at the comparative effectiveness of oral anticoagulants (OACs) and adverse outcomes following combination OACs plus antiplatelet therapy.

Professor John Camm (St George's University of London, London, UK) reported results of a study comparing the use of OACs vs no OACs—and, within this, a comparison of non-vitamin K antagonist oral anticoagulants (NOACs) vs vitamin K antagonists (VKAs)—in patients with AF and a high risk of stroke (CHA2DS2-VASc score  $\geq 2$ , including gender). “We know from clinical trials that OACs can prevent strokes and extend the lives of patients with AF, and guidelines recommend OACs for men and women with CHA2DS2-VASc scores of 1 and 2, respectively,” begins Prof. Camm. “GARFIELD-AF gives us the opportunity to look at the effects of OACs, and to compare different types of agents, in the context of real-world, daily clinical practice.”

The analysis included patients who were receiving OACs with or without antiplatelet



Prof. Keith Fox

therapy and who were enrolled consecutively onto the registry between April 2013 and September 2016. “This is the time that NOACs became available in many countries,” observes Prof. Camm. A total of 20,564 patients receiving OACs (NOACs [n=10,380] and VKAs [n=10,184]) and 7,608 patients not receiving OACs were included and followed up for two years. Most of the patients not receiving OACs were on antiplatelet therapy (83.3%). “The 24-month survival rate was 91.8%,” reports Prof. Camm. “Slightly more deaths were non-cardiovascular vs cardiovascular related and the main known causes were congestive heart failure and cancer, at 12% each.”

### There was a clear survival benefit for OAC use.

“Compared with no OAC use, OAC use was associated with reductions in all-cause mortality (hazard ratio [HR] 0.83; 95% confidence intervals [CI] 0.75-0.93; p=0.002) (Figure) and stroke/systemic embolism (SE) (HR 0.79; 95% CI 0.64-0.97; p=0.028),” he says. “In terms of the type of OAC, NOACs were superior to VKAs for all-cause mortality (HR 0.81; 95% CI 0.71-0.92; p<0.001) but were not associated with significant reductions in stroke/SE. The survival benefits associated with OACs and NOACs persisted after adjustment for baseline variables.” As expected, the risk of major bleeding was significantly higher in the OAC vs the non-OAC

group (HR 1.41; 95% CI 1.04-1.91; p=0.029). However, the risk was not significantly different between NOACs and VKAs.

Prof. Camm concludes that, “The results associated with OAC use in this real-world setting support observations from clinical trials and highlight the benefits of OACs for patients with AF in everyday clinical practice. GARFIELD-AF results confirm that oral anticoagulation in real-world experience reduces stroke and mortality, but trends to increase major bleeding. Stroke and major bleeding trend towards being less with NOACs compared with VKAs, but mortality is significantly reduced.”

The results of a study evaluating the risks vs the benefits of combination OAC/antiplatelet therapy initiated at the time of AF diagnosis were reported by Professor Keith Fox (University of Edinburgh, Edinburgh, UK). “OAC use is standard for AF patients at a high risk of stroke,” explains Prof. Fox, “but, because of the increased risk of bleeding, the addition of antiplatelet agents is generally recommended only when prevention of coronary or peripheral artery thrombosis is required, such as in patients having a myocardial infarction (MI) or those with peripheral artery disease (PAD). However, we don’t really have a clear idea of the level of risk vs benefit for this type of combination therapy in AF patients without a clear indication for it.”

A total of 25,815 newly diagnosed patients receiving OACs (OACs plus antiplatelet therapy [n=3,133] and OACs alone [n=22,682]) were included in the study. “While most patients receiving combination

therapy had a higher prevalence of coronary artery disease (CAD), acute coronary syndrome and stroke,” says Prof. Fox, “1,743 patients had neither CAD nor PAD.”

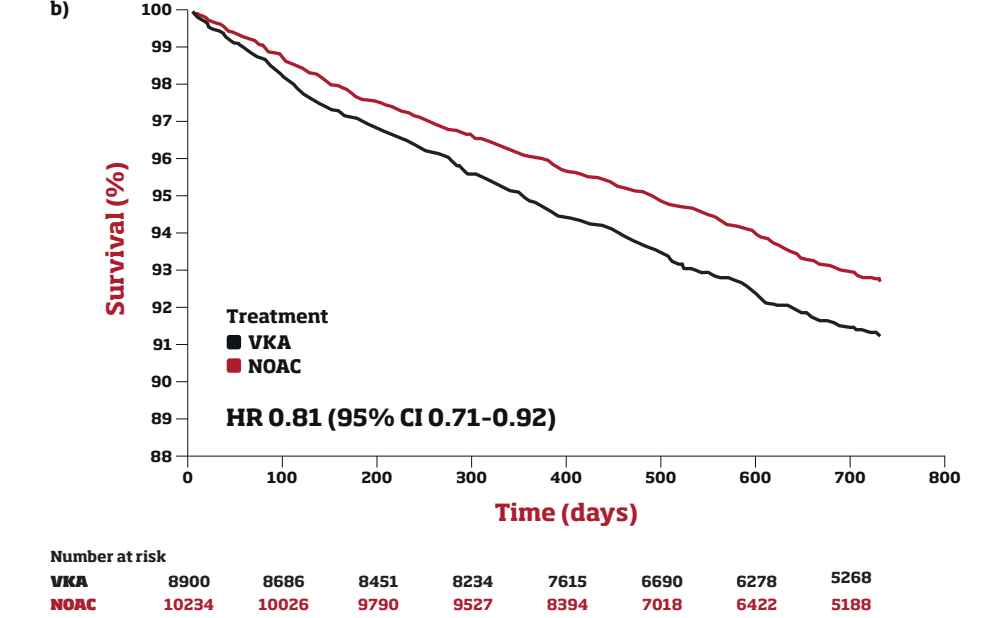
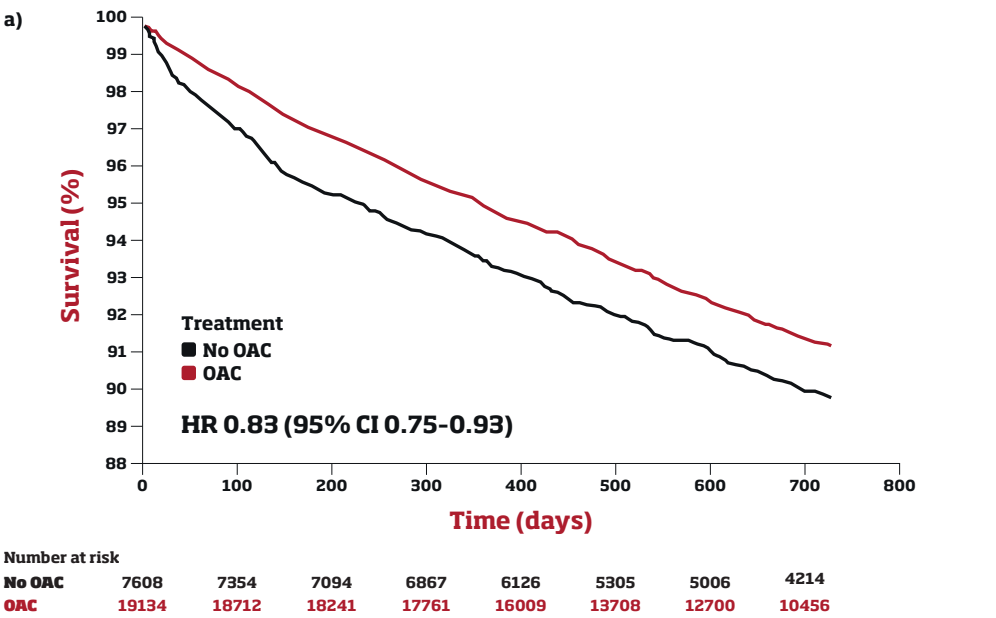
### Overall, the use of combination OAC/antiplatelet therapy was associated with an increased risk of major bleeding (HR 1.45; 95% CI 0.94-2.23) and all-cause mortality (HR 1.31; 95% CI 1.05-1.62) and no reduction in the risk of stroke (HR 1.60; 95% CI 1.08-2.35).

Prof. Fox reports that the risks of mortality, stroke and major bleeding were generally greater in patients treated with anticoagulation plus antiplatelet therapy, without CAD or PAD. “Even after excluding those with prior PAD or CAD, the HR for all-cause mortality with OAC plus antiplatelet therapy vs OAC alone was 1.48 among those without CAD/PAD and 1.31 for all patients,” he notes, “and hazard increases were also observed for stroke and major bleeding. The increased risk remained even after propensity score matching.”

Summing up, Prof. Fox says, “Patients receiving combined OAC/antiplatelet therapy at the time of AF diagnosis have a worse prognosis than those receiving OACs alone, and this appears to be particularly true for patients without a clear indication for antiplatelet therapy. The findings challenge the addition of antiplatelet therapy to full oral anticoagulation unless there is a good indication for using the combination.”

1. Kirchhof P, et al. Eur Heart J 2016;37:2893-2962.

## 24-month Nelson-Aalen-adjusted survival curves comparing a) OACs vs no OACs and b) NOACs vs VKAs





# Does high-sensitivity cardiac troponin I evaluation improve outcomes in patients with suspected acute coronary syndromes?



Prof. Nicholas Mills

In a Hot Line presentation yesterday, Professor Nicholas Mills (University of Edinburgh, Edinburgh, UK) revealed one-year outcomes data from the High-Sensitivity Troponin in the Evaluation of patients with Acute Coronary Syndrome (High-STEACS) trial.<sup>1</sup>

This was a stepped-wedge cluster randomised controlled trial that evaluated the implementation of the ARCHITECT<sub>STAT</sub> high-sensitivity cardiac troponin I (hs-cTnI) assay using the sex-specific 99th centile (34 ng/L for men, 16 ng/mL for women) as a diagnostic threshold in 48,282 consecutive patients with suspected acute coronary syndrome from 10 secondary and tertiary care hospitals across Scotland. The primary endpoint of myocardial infarction (MI) or cardiovascular death at one year was compared in patients reclassified as having

myocardial injury by the hs-cTnI assay before and after implementation.

Prof. Mills says, “The trial found that implementation of a high-sensitivity cTnI using the 99th centile as the diagnostic threshold increased the frequency of patients with myocardial injury; but only a third had a diagnosis of MI, and implementation was not associated with lower rates of subsequent MI or cardiovascular death at one year.” He continues, “The findings were surprising. But it was encouraging that there was no evidence of misdiagnosis, inappropriate treatment, excess bleeding or harm. Indeed, the length of stay across the trial population was reduced by almost a third suggesting that use of the high-sensitivity test increased the confidence of clinicians to rule out heart disease, with benefits for health service providers.” When discussing next steps, Prof. Mills concludes, “These results are controversial because they suggest that the Universal Definition of Myocardial Infarction needs to move away from a binary threshold to diagnose and guide treatment for MI. It is now up to the research community to find a superior approach.”

1. Shah ASV, et al. Lancet 2018;August 28:doi:10.1016/S0140-6736(18)31923-8.

# Partial oral treatment of endocarditis – does it work?



Prof. Henning Bundgaard

In a Hot Line session yesterday, Professor Henning Bundgaard (Rigshospitalet, Copenhagen, Denmark) presented eagerly awaited late-breaking data from the Partial Oral Treatment of Endocarditis (POET) study.<sup>1</sup>

Explaining the rationale for the trial, Prof. Bundgaard notes “Guidelines for the treatment of left-sided infective endocarditis recommend up to 6 weeks of intravenous antibiotics. We hypothesised that a shift from intravenous to oral antibiotics in clinically stabilised patients could have similar efficacy as continued intravenous antibiotics but with reduced side effects and shortened length of hospital stay.”

Previously, evidence supporting partial oral therapy as an alternative to the routine continued parenteral therapy was scarce and limited to observational data.

In a prospective, open-label non-inferiority study, 400 stable patients with streptococcal, *Enterococcus faecalis*, *Staphylococcus aureus* or coagulase-negative staphylococcal infection of the mitral valve or the aortic valve who had received a minimum of 10 days’ intravenous treatment were randomised to oral therapy (n=201) or unchanged intravenous therapy (n=199), which was received for a median of 18 days. Patients were followed up for 6 months after completion of antibiotic therapy, with a primary composite endpoint of all-cause mortality, unplanned cardiac surgery, embolic events and relapse of positive blood cultures with the primary pathogen. Prof. Bundgaard explains the main finding, “The primary endpoint occurred in 10.5% of patients with a non-significant difference in favour of oral treatment. This means that the non-inferiority criterion was met and a change to oral treatment was as efficient and safe as the conventional continued intravenous treatment for the whole period.” He concludes, “Shifting to oral antibiotic treatment in stabilised patients with endocarditis was as effective and safe as continued intravenous antibiotic treatment and was given during half the antibiotic treatment period. These novel findings may have a significant impact on future clinical practice for the management of patients who are stable.”

1. Iversen K, et al. N Engl J Med 2018;August 28:doi:10.1056/NEJMoa1808312.

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# Thank you from the ESC Congress News Editors!

With ESC Congress 2018 drawing to a close, we would like to take this opportunity to thank everyone involved in developing five great editions of ESC Congress News. The newspaper was produced with the excellent medical writing support of TMC Strategic Communications.

We hope you have enjoyed reading the articles and the fresh design. It was our aim to keep you informed of what was going on and to represent the large and diverse congress programme. Have a safe trip home and see you all in Paris!

Left to right: Stephan Achenbach, Steen Dalby Kristensen, Kurt Huber and Freek W. A. Verheugt.



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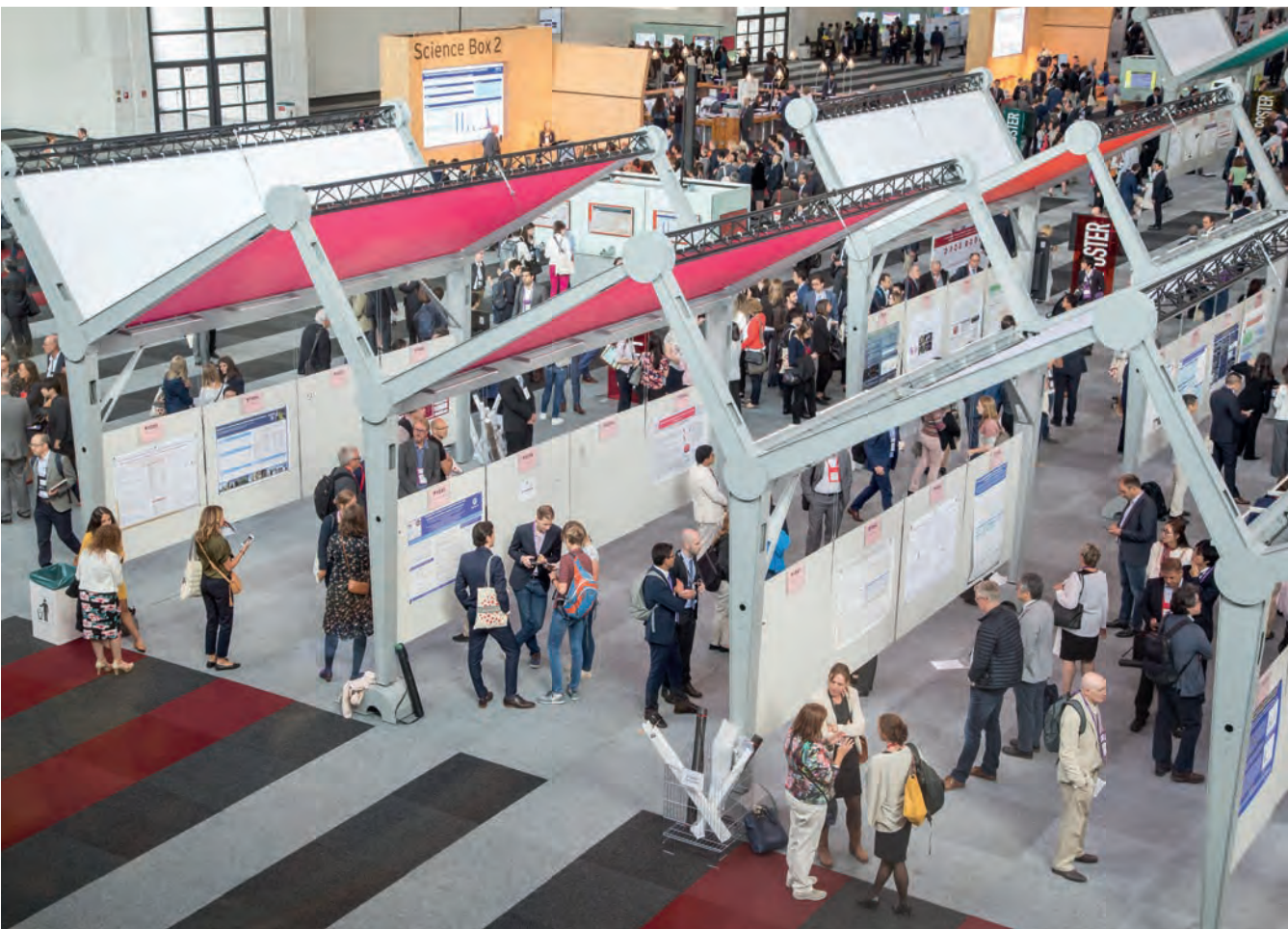
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# ESC Congress 2018 in pictures



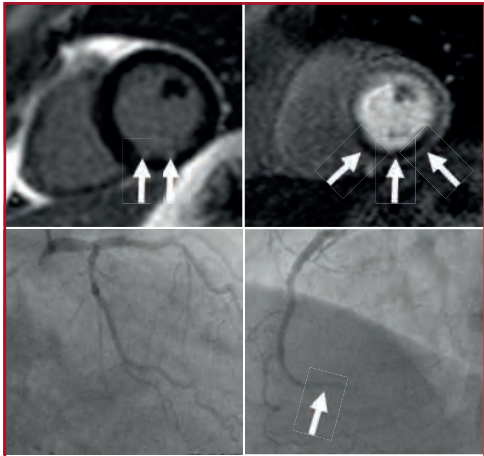
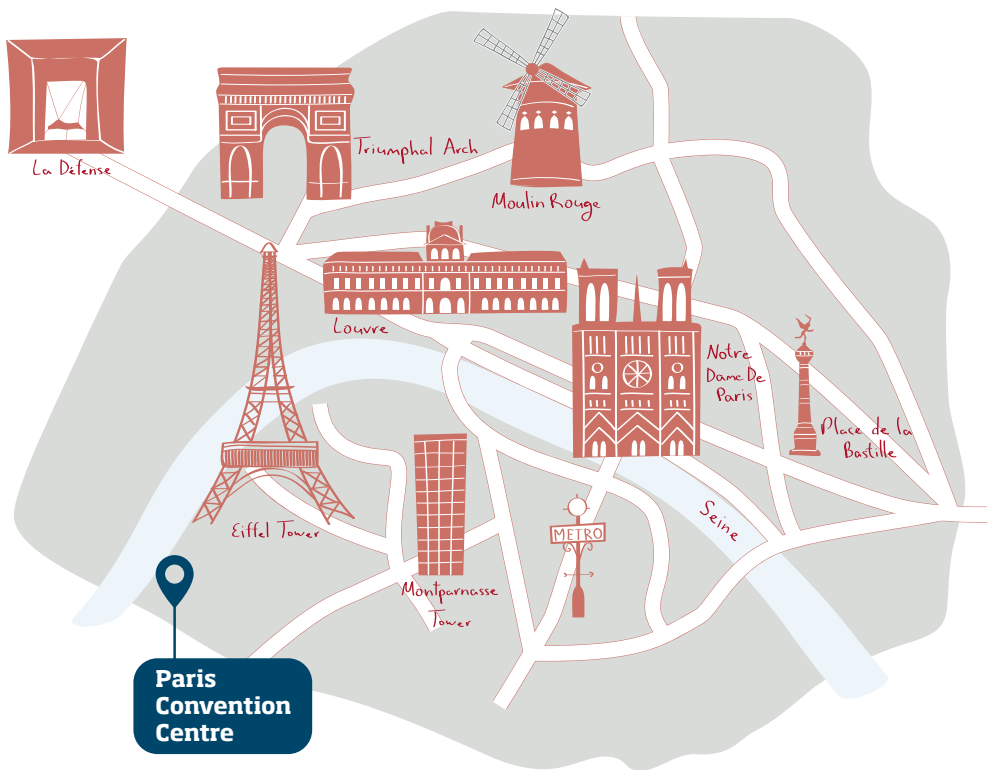
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Iwan Harries, Bristol Heart Institute, Bristol, UK  
Chiara Bucciarelli-Ducci, Bristol Heart Institute, Bristol, UK

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