**WEDNESDAY 31 AUGUST**

**Efficacy of drug-eluting stents fails to top bare metal in RCT**

‘Patients treated with DES do not live longer’

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**A new anticoagulant option around cardioversion for AF**

Edoxaban is an effective and safe alternative to anticoagulation therapy for AF patients undergoing electrical cardioversion, according to the ENSURE-AF study presented in a Hot Line yesterday. The findings were published simultaneously in *The Lancet*.

ENSURE-AF is the largest prospective randomised trial to date of anticoagulation for cardioversion in patients with AF. Principal investigator Andreas Goette said the advantage of this new approach was ‘very convenient and very fast’.

‘At a practical level, our study results show that newly diagnosed non-anticoagulated AF patients can start edoxaban as early as two hours prior to cardioversion if they have access to transoesophageal echocardiography or three weeks prior to that,’ said Goette, from St Vincent’s Hospital, Paderborn, Germany.

Current guidelines for AF patients having cardioversion recommend three weeks of therapeutic anticoagulation prior to the procedure. This is followed by continuation of anticoagulation for four weeks - or longer in patients at risk of AF recurrence or those with stroke risk factors present.

VKAs have traditionally been used successfully as oral anticoagulants around cardioversion. However, they have major

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**THE LARGEST STENT trial ever has found no significant differences in death from any cause or non-fatal MI in patients receiving drug-eluting stents (DES) and bare-metal stents (BMS). The investigator-initiated NORSTENT study, reported in a Hot Line session yesterday, was published simultaneously in the *New England Journal of Medicine*.

‘Patients treated with DES do not live longer and they do not live better than patients treated with BMS,’ said study presenter Kaare Bonaa from the University of Tromso, Norway. Both contemporary DES and BMS, he added, may be similarly recommended for coronary revascularisation.

‘Although ESC guidelines recommend new DES over BMS as default for coronary revascularisation, this recommendation,’ he said, ‘may need to be modified in light of the NORSTENT findings.’

Aware that findings for bare-metal stents have improved with new stent designs, different metal composition and thinner struts, the NORSTENT investigators felt a re-examination against second-generation DES was needed. The study took place in all eight centres in Norway performing PCI.

Between September 2008 and February 2011, the Norwegian Coronary Stent Trial (NORSTENT), funded by the Norwegian Research Council, randomised 903 patients with stable or unstable CAD to PCI with either contemporary drug-eluting stents (n=4504) or bare-metal stents (n=4509). In the DES group 96% received everolimus or zotarolimus-eluting stents.

Results at six years showed that the rates of the primary outcome (a composite of death from any cause and non-fatal MI) were 16.0% in the DES group and 17.7% in the BMS group. Additionally no differences were found between the two groups for all-cause mortality.

However, the six-year rates of any repeat revascularisation were 16.5% in the DES group and 19.8% in the BMS group (HR 0.76, 95% CI 0.69 to 0.85; P<0.001).

Results from the Seattle Angina Questionnaire show that no differences were found between DES and BMS groups for physical limitation, angina frequency and quality of life.

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Andreas Goette described a new anticoagulant option before cardioversion.

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Continued on page 2
Decoy protein reverses anticoagulant bleeding

**HOT LINE SESSION RESULTS**

**Comparative effects in bare metal vs drug-eluting stents trial**

Continued from page 1

Bonaa disclosed that on the basis of these results 30 patients would need to be treated with DES to prevent just one repeat revascularisation.

‘As expected, the need for repeat revascularisation was lowered by DES, but this effect was less than anticipated,’ said Bonaa, adding that in some studies it was found to be around half this level.

An accompanying Lancet editorial described the observations as ‘important because they balance the claim by some observers that there is no longer any role for bare-metal stents in PCI because of the superiority of their drug-eluting counterparts in these outcomes’. The editorial added that the trial results ‘should increase confidence’ in choosing bare-metal stents if clinical indications favour that.

**Anticoagulation around cardioversion in AF**

Continued from page 1

Limitations in that VKAs require regular monitoring to ensure target INR range of 2.0-3.0. This can delay cardioversion sometimes for several weeks.

Trials have suggested that NOACs could be a role for bare-metal stents in PCI because of the feasibility treatment option for patients undergoing cardioversion.

The phase 3b study involved 239 study sites in 19 countries in Europe and the US, with 2,199 patients with documented non-valvar AF recruited. All were scheduled for electrical cardioversion after anticoagulation therapy.

A total of 1095 were randomised to edoxaban, and 1004 to enoxaparin/warfarin with dosing depending on patient characteristics. A total of 90.2% (n=988) were cardioverted spontaneously, some with TEE.

The study’s primary efficacy objective was to compare incidences of the composite endpoint of stroke, MI and CV death between the two groups at day 28 (ITT analysis).

The endpoint occurred at a comparable rate in both groups, that is in 0.5% in the edoxaban arm versus 1.0% in the enoxaparin/warfarin arm (OR=0.46; 95% CI, 0.12-1.43).

The primary safety outcome was a composite endpoint of major and clinically relevant non-major bleeding events at 30 days. This also occurred at a comparable rate of 1.5% and 1.9% respectively.

Overall, edoxaban had similar rates of major bleeding and thromboembolism compared to well-managed optimised enoxaparin/warfarin therapy. Results were also similar whether TEE-guidance was used or not, whether patients had received prior anticoagulation or not, and in patients with a broad range of associated comorbidities.

Professor Goethe said: ‘Results suggest that edoxaban is an effective and safe alternative to standard enoxaparin/warfarin VKA therapy.’
A CLINICAL DECISION RULE can help clinicians choose which female patients can safely discontinue anticoagulants by identifying those at low-risk of VTE recurrence. The REVERSE II trial, presented yesterday, showed that the HERDOO2 rule can be applied to women after a first unprovoked VTE, making it the only validated rule to do this, according to study investigator Marc Rodger, Ottawa Hospital Ottawa, Canada.

The number considered low-risk based on HERDOO2 criteria was 622, and the majority discontinued anticoagulant therapy. Most of the 591 high-risk women continued anticoagulants.

The primary outcome was recurrent blood clots in low-risk women who discontinued anticoagulants. The rate was 8.1% in high-risk patients who discontinued, and for high-risk patients who continued it was 1.6%.

This is an important finding, as using our rule, over half of women with unprovoked VTE can safely discontinue anticoagulants and be spared the burdens, costs, and risks of lifelong anticoagulation,” said Rodger, from the Ottawa Hospital and University of Ottawa, Ontario, Canada.

Test for recurrent VTE in women on anticoagulants

The HERDOO2 rule in a multinational study. A total of 2779 patients (mean age 54.4 years) with a first unprovoked VTE were enrolled after completing at least five and up to 12 months of anticoagulant therapy.

CORONARY BIFURCATIONS – a type of coronary artery narrowing - are best treated with Culotte stenting as opposed to Tandem- and protrusion (TAP) stenting, when there is a need for side-branch stenting, according to the BBKII trial presented yesterday. The trial, published simultaneously in the European Heart Journal, represents the first ever head-to-head comparison of the two most commonly used techniques in side branch stenting with anatomy considered suitable for both techniques.

‘Interventional cardiologists can now use Culotte stenting with more confidence knowing that this technique is associated with a very low angiographic restenosis rate and lower rate of TLR as compared with TAP stenting,’ said study presenter Miroslav Ferenc, from the University Heart Center, Freiburg, Bad Krozingen, Germany, ‘even though it is slightly more challenging and requires appropriate training.’ In coronary bifurcation lesions side branch stenting is necessary in 5-36% of patients for optimal results.

In the Bifurcations Bad Krozingen (BBKII) study, 380 patients with stable or unstable angina were deemed amenable to both stenting techniques and were randomised to either TAP stenting (n=150) or Culotte stenting (n=150).

Results at nine months showed that the primary endpoint of maximal in-stent diameter stenosis of the bifurcation lesion (assessed by follow-up quantitative coronary) was 27% for Culotte stenting versus 20% for TAP stenting.

The difference in the primary endpoint was driven almost entirely by differences in the side branch, where the mean percent diameter stenosis was 16% in the Culotte arm versus 22% in the TAP stenting arm.

Other important differences favouring Culotte stenting included a highly significant difference in binary in-stent restenosis at the bifurcation lesion, which occurred in 6.5% of the Culotte arm and 17% of the TAP arm as well as the target lesion rate of bifurcation lesion revascularization rate at one year, which occurred in 6% of the Culotte arm versus 12.5% of the TAP arm.

‘Given the clear results of this trial together with the same trend for hard clinical endpoints, Culotte stenting has now to be seen as the preferred approach for coronary bifurcations, when stenting of the site branch is needed,” concluded Ferenc.

European Heart Academy extends postgraduate education programmes

RAISING standards and harmonising training for cardiologists is a cornerstone of the ESC’s mission to improve patient care. To that end, the ESC has developed a range of grants for healthcare professionals.

Professor Francesco Cosentino, Chair of the ESC Credentials Committee, which evaluates grant applications, says: ‘The ESC recognises that in today’s environment access to funding can be challenging. ESC Grants Fellowships are designed to support those who have little or no access to training or to carry out research in centres of excellence outside their own country.’

In 2016, 28 grants worth 1.9 million Euros were awarded to individuals to support their projects and advance cardiovascular research. In addition, 25 ESC grants worth 625,000 Euros were awarded to support clinical practice training.

In 2009 Alexander Kharlamov from Russia was awarded an ESC Research Grant. He says: ‘The ESC Grant was a truly dramatic step forward. It upgraded my level of knowledge and experience in cardiology, and enabled me to join a translational cardiovascular team at Radboud University Hospital at Nijmegen in the Netherlands under the mentorship of Professor Paul Smits. This inspired me to take part in further projects with another renowned expert in interventional cardiology, Professor Patrick Serrays at Erasmus MC in Rotterdam. I’ve never looked back.’

Professor Cosentino, who trained outside his own country as a young cardiologist, adds: ‘Moving abroad to advance your career is a must for anyone who really wants to grow, not only in their field of interest but as a human being. Young physicians have to take the opportunity and identify an academic institution that is really top in what they want to pursue. This is a great opportunity to develop yourself, to produce results and to acquire the necessary skills to return home with.’

Find out more about ESC grants and fellowships at www.escardio.org/grants

Grants for training and research available from ESC

More information on the Academy programmes can be found at the ESC Plaza and on www.EuropeanHeartAcademy.org.
New European guidelines on CVD prevention follow the close collaboration of ten societies

**European data resource collated in the ESC Atlas of Cardiology**

**Making sure that cardiologists have a say in EU research funding**

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**European data resource collated in the ESC Atlas of Cardiology**

Despite many advances in healthcare, there are still serious disparities in cardiovascular systems and outcomes in Europe. In addition, there remain significant problems in healthcare management in many countries. European policymakers need extensive, reliable data to solve these problems and further document cardiovascular disease as the number one health priority throughout the continent. The ESC Atlas of Cardiology aims to do just that.

The Atlas is a unique, ambitious project that provides essential evidence to improve decision-making and patient care, and bridge the gap between policies and realities. It is a comprehensive data collection project of 350 variables. It is also the first project ever to combine socio-demographic, economic, health outcomes, risk factors, healthcare system structure and policies data derived from international sources (WHO, World Bank and the Organisation for Economic Co-operation and Development) and cardiovascular data provided by ESC Member National Cardiac Societies.

This phenomenal resource maps the status of European healthcare systems from a cardio-epidemiological perspective, revealing trends, disparities, gaps and associations between fundamental variables and provides the answers to questions such as:

- **What do European countries compare with each other?**
- **What explains the disparities between them?**
- **What is the optimal level of service provision?**
- **Which factors are responsible for better outcomes?**
- **Where should health systems invest?**

The next steps for the ESC will be to use the robust data and analyses from the Atlas to provide national and international decision-makers with evidence-based policy recommendations. The ultimate goal is to shape cardiovascular policy and regulation; influence allocation of funds for prevention, treatment, education and research to harmonise standards of care for healthier, longer lives.

The E-Atlas of Cardiology is now available to all ESC National Cardiac Societies who participated in the project; demonstrations are available at the ESC stand.

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**Making sure that cardiologists have a say in EU research funding**

Research needs funding—and funds can be hard to come by. But there are ways. Each year the ESC and the European Commission hold a joint session at ESC Congress to discuss EU funding and networking opportunities. These practical sessions focus on where to find relevant information, how to prepare a successful project proposal and an overview of managing EU-funded research projects. Ensuring researchers know what opportunities are available and how to make the most of them is one part of the ESC’s work. Another is ensuring that such funds are available in the first place.

The ESC’s advocacy programme works with European institutions to emphasise the need for funding and advise where EU funds should be used in cardiovascular research. In short, ensuring that scientists have a say on where and how the money should be spent.

To achieve this, the ESC has also teamed up with 20 other leading medical societies within the framework of the Alliance for Biomedical Research in Europe (BioMed Alliance) of which the ESC is a founding member. The BioMed Alliance has made significant inroads to ensure that scientists are consulted by decision-makers when deciding on research policies. This includes the creation of the Scientific Panel for Health—a unique body created within the European Commission under the Horizon 2020 programme—that brings together 30 experts and has been mandated to formulate recommendations to policymakers.

Supporting excellence in research is one of five focus areas for the ESC in the coming years. Another is advocacy, to shape a policy and regulatory environment favourable to improving cardiovascular health. Find out more on www.escardio.org

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* Videos and slides from the ESC/EU sessions are available at www.escardio.org and http://www.escardio.org/Home-Escardio/beta/Research/Research-Funding/eu-funding-for-organisations
Despite guidelines, SCD in hypertrophic cardiomyopathy rarely linked to exercise

SUDDEN DEATH IN patients with hypertrophic cardiomyopathy (HCM) is rarely associated with exercise, according to study results presented by cardiologist Gherardo Finocchiaro from St George’s University of London, UK. Speaking at a press conference earlier this week, he explained that almost 80% of patients in the study had no symptoms and only one in five had been diagnosed with HCM before their death.

As background to his report Finocchiaro explained that HCM is an inherited heart muscle disease with variable clinical expression and natural history. It is characterised by hypertrophy of the left ventricular walls (‘thick heart muscle’). Sudden cardiac death (SCD) is a relatively common cause of mortality in patients with HCM, caused by fatal arrhythmias which can be effectively treated with ICDs.

‘Exercise is considered a trigger of fatal arrhythmias,’ said Finocchiaro, ‘and international recommendations advise patients with a clear phenotypic expression of HCM to avoid competitive sports. It is unclear, however, if SCD occurs more frequently at rest or during exercise in these patients.’

This study investigated the circumstances and demographics of SCD in 184 HCM patients enrolled from 1994 to 2014 at St George’s Hospital. All had a detailed post-mortem examination to confirm the diagnosis. However, only 20% had had a previous diagnosis of HCM. Just 22% of patients had exhibited cardiac symptoms such as dyspnoea, syncope and chest pain.

SCD occurred at various ages, with the highest prevalence in the third and fourth decades of life. The majority of patients (almost 80%) died during rest, 12% during sleep. SCD during exertion occurred more frequently in young male patients; 11% were recreational or competitive athletes.

Finocchiaro said: ‘Our findings are relatively new and are based on a large sample size. We showed that SCD in HCM occurs relatively rarely during sport activity, but more often at rest and sometimes during sleep.’

However, even if treated with an ICD, the risk of sudden death, however slight, may not be wholly removed, for another study described at the same press conference suggested that the risk of traffic accidents is around 50% higher in ICD patients than in age and gender matched controls.

‘Driving after ICD implantation is an area of great debate and concern for both doctors and patients,’ said first author Jenny Bjerre from Herlev and Gentofte University Hospital, Copenhagen. ‘Our study provides contemporary data suggesting that the risk of motor vehicle accidents is in fact higher following ICD implantation than in controls.’

Using national registers, the researchers identified all Danish residents who received a first ICD for primary or secondary prevention between 2008 and mid-2012. Motor vehicle accidents were recorded from national records on accidents and deaths. The study included 4874 ICD patients and a control group of 9748 subjects matched by age and gender. Participants were 63 years old on average.

During an average follow-up period of 2.5 years, 2.3% of ICD patients were in contact with a hospital following a motor vehicle accident, compared to only 1.7% of the controls. Over time, this translated into a 51% higher risk of motor vehicle accident in ICD patients than in controls. There was no difference in accident risk between primary and secondary prevention ICD patients.

Nevertheless, the overall rate of motor vehicle accidents in ICD patients was low (1.0 to 1.4% within the first year after implantation), and the researchers in this study observed no traffic accident deaths in those with an ICD.

Huge mortality benefits from Mediterranean diet

While a Mediterranean diet has been linked to a wide range of health benefits for a wide range of people, rarely has a study specifically found a lower risk of death. Yet this was the conclusion of the Molli-Sani project, a prospective epidemiological study of 25,000 randomly recruited adults living in the Italian region of Molise. Among them were 1197 with a history of CVD at the time of enrolment.

During a median follow up of 7.3 years there were 208 deaths. A 2-point increase in the Mediterranean Diet Score was associated with a 21% reduced risk of death after controlling for age, sex and other variables. The highest MDS score (6–9) was associated with a 37% lower risk of death than the bottom category (0–3).

Investigator Giovanni de Gaetano (below) from the Neuromed Institute in Pozzilli, Italy, said: ‘The major contributors to mortality risk reduction were a higher consumption of vegetables, fish, fruits, nuts and monounsaturated fatty acids.’
Reviewing his vision for the ESC, incoming President Jeroen Bax said that his aim is ‘to provide continuity of action that stabilises, fosters, protects and further develops the ESC’. Professor Bax will be ESC president from 2016 to 2018. Describing the Society as ‘a big ship’ he said that subtle adjustments can be made to a course that is set, but, ‘if you shift it more than one degree there is a danger that the organisation could sink’. Professor Bax, from Leiden University Medical Center in the Netherlands, said the five-year strategic plan for the ESC had been formed to help steer the ESC course, taking into account a changing environment and focusing on advocacy, research, education, congress and membership. The ESC will look to stimulate research rather than carry it out, and in education the successful ESCel programme will focus on general cardiology as well as the subspecialties. Guidelines, he added, are based on trials that may not be representative of daily clinical practice. ‘So we need to integrate our registries and use this feedback to change the guidelines.’ ESC Congress, which had a record-breaking attendance in 2016, will continue to provide the highest scientific and educational content, and the concept of ESC 365, in which sessions are online after the meeting, will be expanded.

There will also be changes to membership, said Professor Bax, with a need to develop the concept of ‘personalised membership’, which, much like personalised medicine, will be tailored to the needs of individual members.

In his outgoing address, Professor Fausto Pinto described his Presidency as a ‘real privilege’. It had, he said, ‘enriched his knowledge’ of different countries and bodies. Among his achievements of the past two years, he highlighted the new membership scheme and the expansion of research and training. ‘We can provide more for a younger generation which has been one of our priorities, and provide more support for the younger society,’ he said. Research, education and membership are among the five pillars which continue to support the ongoing success of the ESC, along with advocacy - such as a strong European Heart Agency - and ESC Congress. He attributed the ESC’s success in disseminating knowledge and guidelines to the Society’s global nature. One novelty implemented between 2014 and 2016 was the ESC ethics committee. ‘Strong governance,’ he said, ‘makes our Society very strong.’

Thanking his fellow board members, Professor Pinto described them as ‘outstanding people, outstanding colleagues’ who had ‘dedicated a substantial part of their lives for the good of our society’. saying: ‘I’m really deeply grateful and you will all remain in our hearts.’ ESC chief executive officer Isabel Bardinet was singled out for special thanks - ‘I’ve learned a lot from her. We have an excellent relationship.’ He also applauded the seven ESC Silver Medal award winners who were this year recognised for their outstanding contribution.

On a personal note, Professor Pinto thanked his family too for the sacrifices they had made during his time as President. ‘They were a group of people who did suffer a little bit - my wife and my five children. I missed them and many times I was missing at home.’ He completed his term of office by wishing Jeroen Bax the best of luck for 2016 to 2018.

The following members have been elected to the ESC board for 2016 to 2018

President Elect: Barbara Casadei
Vice Presidents: Bela Merkely, Lina Badimon
Stefan Anker
Secretary/Treasurer: Ian Graham
Councillors: Hector Bueno, Cecilia Linde
Sarah Clarke, Christophe Lederer
Donna Fitzsimmons, Franz Wiedinger
Audit Committee: Jose Lopez Sendon
Nominating Committee 2016-2018
Representatives of National Societies:
Keith Fox, Frans Van De Werf, Martin Borggreve
Kurt Huber, Eva Swahn, Helène Eltchaninoff
Representatives of Associations, Working Groups and Councils:
Patrizio Lancellotti, Antonio Pelliccia
Andrew Coats, Christie Deaton
Petar Seferovic, Martine Gilard

Papal cart now in place at ESC Congress

The Pope will arrive at 12:15 today, driven slowly along the Passarella in his Papal cart. Buses will drop off delegates at the West entrance only. All delegates should arrive by 11:00. Entrances will be closed shortly afterwards and remain closed until the end of the Pope’s visit by 13:15.

There will be no restrictions on leaving Fiera Roma after 11:00. There will be airport-style security at the entrance, with designated fast-lanes for delegates with only hand luggage.

Those with suitcases should leave them at the Cloakroom after clearing security. ESC will be providing a bus service to the airport from the main parking area outside Fiera Roma near the train station. This service will be free of charge and run between 11:00 and 15:00. If you wish to return to the city, please take a taxi or train.
Missed a session? Just catch up at home

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These resources are only accessible to certified healthcare professionals, associated press, industry representatives and other qualified stakeholders in the science, management and prevention of cardiovascular disease.

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Click on the ESC Congress 365 logo on the upper left corner to return to the home page.

WHAT IS ‘YOUR 365 SELECTION’?
‘Your 365 selection’ is the selection of all the presentations you tagged as ‘Favourite’ with the star button.

WHY DO SOME PRESENTATIONS NOT HAVE SLIDES AND/OR VIDEOS
Most of the resources on ESC Congress 365 were available within 24 hours of the presentation’s delivery in Rome. However, ESC Congress 365 only features resources for which the speakers and/or presenters have granted the ESC the rights to use for educational purposes.

• In early September one ‘best of’ presentation from each of the Congress’s 10 main topics will be summarised in a brief 10-minute presentation.

• More than 1 million visits (since 2013)
• More than 27 500 presentations
• More than 150 cardiovascular topics

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What's your take-home message from Rome?

John Camm
General cardiologist
London

I was particularly interested in the DANISH trial's neutral result, which showed that the use of ICDs in patients with non-ischaemic systolic heart failure did not deliver benefits. This trial reflects a general need to reassess therapies that were originally investigated many years ago against the background of modern treatments. But there can be difficulties in persuading ethics committees to reinvestigate something that seems to be proven from the past. There have concerns about depriving patients. I believe that the providers of health care and the payers have a particular interest in encouraging these kind of studies.

Bojidara Borissova
Head nurse
Sofia, Bulgaria

Doctors and nurses should be one team. I deal with cardiac patients and those with vascular disease so it’s important to be team working to ensure patients get the best results. I’ve worked in cardiac surgery and collaboration is especially important there in the heart teams. Nurses have a vital role to play but where I am from in Bulgaria there is a lack of nurses. Maybe small salaries are a factor, as well as the psychological impact of the job which is emotionally draining. A lot of young people study and then when they finish they go off to other countries. We need to do more to make them stay.

Sakis Themistoclakis
Electrophysiologist
Venice, Italy

I was particularly interested in the new ESC guidelines on atrial fibrillation. In the past our usual practice was to use ablation techniques as second line after drug therapies to control rhythm and rate. Now, the new guidelines give ablation a far more prominent role and suggest there’s now a real possibility to offer our patients ablation up front instead of drugs. For me the guidelines offer confirmation of strategies we have already been following for some time in our clinical practice, and ones which we’ve found that our patients generally prefer.

Peter Lynn
Preregistration pharmacist
Glasgow, UK

For me, the take home message is team working and sharing knowledge. I work with adult congenital heart problems and we really lack evidence from randomised controlled trials. Of course, it’s really difficult to do these trials because of the heterogeneous population - but that’s the challenge for us. Many of our practices are based on expert opinion and consensus because of the small numbers of patients. Most of our patients have been engaged since a young age and they want to benefit from any breakthroughs. I attended a meeting on Tetralogy of Fallot and it emphasised for me just how much there’s a need for collaborative research across country and centre.

HEART FAILURE: No. 1 reason for hospitalizations

We can make a difference