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CARDIOLOGY 2017

NEWS AND TECHNOLOGY UPDATES FOR CARDIAC CARE

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The ESC Congress 2017

With 4,500 accepted abstracts, 600 sessions and 30,000 expected attendees, ESC Congress 2017 is undoubtedly the world's largest cardiovascular event. European Hospital correspondent Mélisande Rouger asked Dr Stephan Achenbach, Congress Program Committee Chairperson, for an overview of issues and events unfolding in Barcelona from August 26-30

During the Congress, explained Stephan Achenbach, the ESC issues guidelines on how to manage patients with cardiovascular disease. 'In 2017 the guidelines focus on how to treat ST myocardial infarction, valve disease, peripheral artery disease and dual antiplatelet therapy, which is very important in coronary intervention.

'The Hot Lines presentations are late clinical trials; we have very promising publications, especially in the field of prevention – both primary and secondary. 'We also commemorate the anniversary of percutaneous coronary intervention. Forty years ago, Andreas Grüntzig performed the first balloon angioplasty of coronary artery stenosis.

'This year, we'll learn a lot that's new about the connection between heart disease and inflammation, considering the huge amount of abstracts received on the topic.

'Many of our sessions are joint sessions with partners, for instance sister associations such as the American College of Cardiology, the American Heart Association, the Japanese circulatory society, and the Indian and Chinese cardiac societies. 'We will also have sessions with subspecialty societies, including European Society of Hypertension and the European Society of CardioVascular Surgery, but also with genetics cardiology, pediatric cardiology, etc.

'Last, but not least, we will have very interesting sessions with the New England Journal of Medicine, JAG and the Lancet.

'This is a new addition because digital health is really becoming important in cardiology. We're cooperating with Mobile World Capital Barcelona, a tremendously large congress on mobile technologies. We will have interactive lecturers sharing their experience of mobile technology in cardiology.'

'Our challenges arise from the opportunities. Today we have many more options to treat and prevent cardiovascular disease, but they are expensive and we need to find resources and to direct those resources to patients who really need it. I think that's the challenge. As our opportunities become more complex we have to ensure that they remain economically viable. European research focuses on many aspects, but mainly on the development of percutaneous valve disease

treatment, really advancing percutaneous catheter-based treatment of aortic stenosis and percutaneous treatment of other valve disease. Europe really has a leading role there.

'Personally I am also involved with imaging, in the context of these new valve treatments, to prepare and guide the procedure and to decide which strategy to use in which patient.

'Imaging is tremendously important to fix heart disease. There's a growing interest among cardiologists to use imaging and high-end imaging using computed tomography or magnetic resonance."

'Europe has this very wide spectrum of high and low-income countries, so the field is very heterogeneous. The ESC has to cater to all these countries. 'In terms of trends, Europeans are traditionally early adopters of new technologies, treatments and diagnostic methods. They need to make these strategies economically viable.'

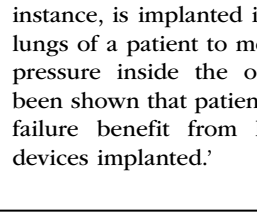
'Issues of data sharing and privacy, and selecting meaningful data are very important in cardiology as in any other field.

'The ESC has a working group on e-cardiology and the congress will feature sessions on e-cardiology and big data. Data is both a major opportunity and a problem.'

'The most important and promising indication for wearable devices use is screening for atrial fibrillation because it predisposes to stroke. Some research at the ESC will focus on that aspect.

'If you can find fibrillation early, you can prevent stroke, so this is a major opportunity for wearable technology, and it has not been looked at extensively yet. In the future there will be other indications, and there will be indications for cardiovascular risk factors such as diabetes and hypertension.

'There's also a new generation of devices that are implanted in patients to monitor physiological parameters. CardioMEMS, for instance, is implanted in one of the lungs of a patient to measure blood pressure inside the organ. It has been shown that patients with heart failure benefit from having such devices implanted.'



Stephan Achenbach MD graduated from the University of Erlangen Medical School in Germany in 1993. Today he is still there, as Professor of Medicine and chairman of its cardiology department. He has not only held posts in Erlangen, but also in Boston, Maryland, USA, and Giessen, Germany. With main clinical interests in interventional cardiology, general cardiology as well as cardiac imaging and intensive care medicine, Achenbach has authored around 550 publications listed in Medline. Between 2014-2016 he served as Vice President of the European Society of Cardiology (ESC) and is currently a Board Member and Chairperson of the ESC Congress Program Committee.

'We don't know how to control the monster we created'

Will software steal the heart of cardiology?

Celebrating 40 years of PCI, cardiologists fret over their future with big data, machine learning and robots, John Brosky reports

Software may replace cardiologists one day, but never the hands-on work of interventional cardiologists and their armatorium of hardware.

That was the curious consensus at the start of the 2017 EuroPCR congress, which saw the arrival of a robot performing catheter-based procedures and advances in computer-assisted diagnostic tools to aid guidewire operators with clinical decisions, such as whether to stent or not to stent.

This confident view among panellists at the conference came during a session dedicated to teasing out the 'Next Big Thing in Cardio-Vascular Medicine' at the largest European gathering of interventional cardiologists.

As with this year's congress of the European Society of Cardiology (ESC), the EuroPCR meeting celebrated the 40th anniversary of the first angioplasty procedure, which opened a new specialisation for interventional cardiology.

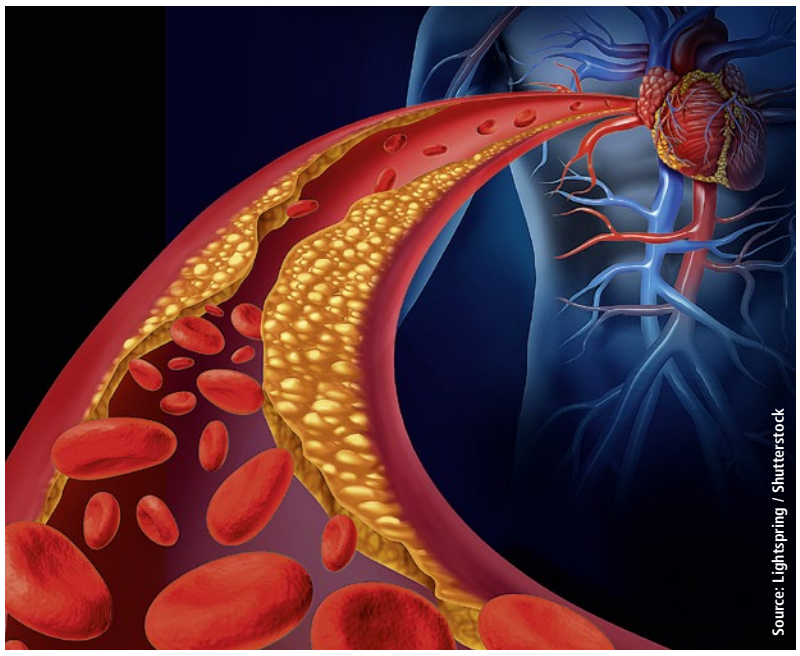
Many of the leading members of ESC are contemporaries of the pioneer for percutaneous coronary interventions (PCI), the German radiologist Andreas Grüntzig who re-opened a clogged artery using a hard wire catheter in 1977 at the University Hospital of Zurich.

Today there are almost 8,000 members of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), making this the second largest of the associations within the legal structure of the ESC, surpassed only by the Heart Failure Association.

By 2015 the worldwide market for PCI had grown to $6.3 billion according to the Dublin-based firm Research and Markets.

Grüntzig's primitive tool opened what EuroPCR keynote speaker Stephen Oesterle called the vascular highway that enables interventional cardiologists, 'to go anywhere you need to go in the body.'

The field today covers 30 procedures that can be performed over-the-wire to place stents or treat vessels with drug-eluting balloons. And this does not take into account the growing practice of structural valve repair that is also performed over-the-wire.



Source: Lightspring / Shutterstock

'Heart failure and mitral repair are two areas where developers are currently working to create catheter-based treatments,' he said.

Yet, we are still treating end-stage disease, he told colleagues, suggesting new catheter-based procedures could be developed for preventive strategies, such as implanting sensors to monitor blood pressure or glucose levels.

A practicing cardiologist for 25 years, Oesterle worked for 15 years

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The simple, efficacious technique that revolutionised cardiology

Coronary angioplasty is 40 years old

Report: Mark Nicholls

Coronary angioplasty is arguably the most revolutionary breakthrough in the history of cardiology.

While the technique is today performed on millions of patients worldwide, its origins can be traced back to the work of Dr Andreas Grüntzig in Zurich, Switzerland, in the late 1970s.

Tragically, Grüntzig never lived to see the impact of his research, having died in a plane crash in 1985. Yet, across the world, his work has an enduring legacy and changed the face of cardiology forever. Later this summer – on 16 September - the world of medicine will be marking the 40th anniversary of the first coronary angioplasty.

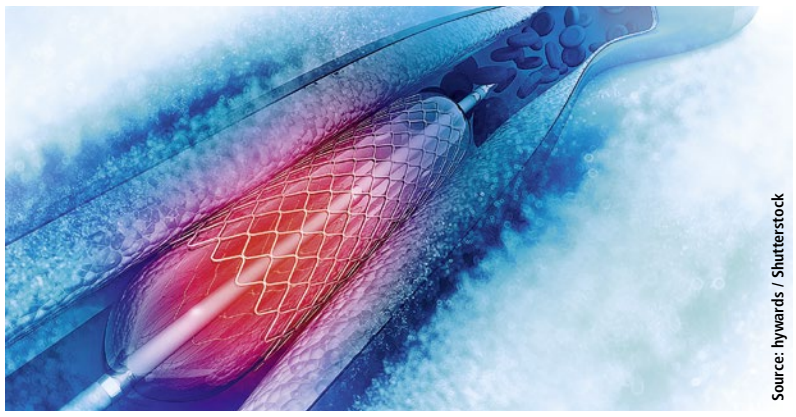
Before Grüntzig embraced the concept, others had experimented in the field. The technique of angiography was first developed in 1927 by the Portuguese physician Egas Moniz at the University of Lisbon for cerebral angiography while, in the 1960s, American interventional radiologist Charles Dotter pioneered angioplasty and the catheter-delivered stent, which were first used to dilate peripheral arteries by inserting sequential catheters with increasing diameters through the narrowing artery.

In 1958, Dr Mason Sones performed the first selective coronary angiogram and a few years later, Melvin Judkins introduced catheters shaped to reach the coronary arteries to perform selective coronary angiography.

It was this work that Grüntzig built on to perform the first successful percutaneous transluminal coronary angioplasty (PTCA) – or percutaneous coronary intervention (PCI) – on a human on 16 September 1977 at University Hospital, Zurich.

Born in 1939 in Dresden, Germany, Grüntzig studied medicine at Heidelberg University, graduating in 1964. He rotated through a series of internships in Mannheim, Hanover, Bad Harzburg, and Ludwigshafen, before moving to the department of Angiology at the University Hospital of Zurich in 1969.

His initial procedure used an expandable balloon based on balloons for use in peripheral arteries, created on a kitchen table in his apartment, helped by his assistant Maria Schlumpf. This was used on 38-year-old severe angina patient Adolph Bachman – the same age as Grüntzig. He successfully dilated a stenosed short non-branching section of the Left Anterior Descending (LAD) artery and presented the results of the procedure at the American Heart Association meeting two months later to widespread acknowledgement. Grüntzig performed coronary angioplasties on further patients in Zurich and taught the technique to other cardiologists, as the field evolved.



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Stent angioplasty procedure with placing a balloon

Contribution through example

Professor Tony Gershlick, consultant cardiologist at Leicester's Hospitals and Honorary Professor of Interventional Cardiology at the University of Leicester, reflects on Andreas Grüntzig's legacy…

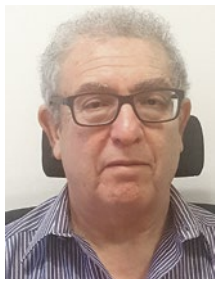
'Whilst not part of the original cohort who visited Grüntzig at the very beginning, my recollections of the procedure go back to an impressionable and formative age for me as a junior doctor at the National Heart Hospital in 1980, when Tony Rickards undertook what I believe to be the first UK balloon angioplasty patient.

'There was clearly a lot of excitement and undoubtedly something going on, so I decided I'd make a rare trip to the catheter laboratory. It was not possible… there were crowds of people.'

Inspired, Professor Gershlick became closely linked to the evolution of interventional cardiology, through the '90s – the decade of invention – and later was the first UK cardiologist to implant a drug eluting stent (DES) and first to implant a bio-absorbable stent. Awarded the inaugural British Cardiovascular Intervention Society (BCIS) Lifetime Achievement Career Award in January, recognising his 'outstanding contribution to the speciality of coronary intervention', he reflects on the door that Grüntzig opened. 'All of what we do now – radial day case intervention with great outcomes, especially in STEMI and even in complex surgical cases – would not be possible without Gruntzig's far-reaching insights. More important is the capturing of great minds and innovators by his original work. That legacy continues unabated today.

'He was a clinical scientist and his original studies taught us careful clinical studies, meticulous honest observations and robust reporting and interpretation of outcomes. Most importantly he never oversold the procedure.

'His contribution through example was and remains immense. Now, if by chance the first five patients had died - which was clearly a possibility considering the kit and lack of understanding regarding risk – then that would have been a completely different story. Maybe his real contribution was that in his hands, despite all, they didn't.'



Tony Gershlick is a consultant cardiologist at Leicester's Hospitals and Honorary Professor of Interventional Cardiology at the University of Leicester. For more than two decades he has been at the forefront of developments in interventional cardiology in the UK and was the first cardiologist in the UK to implant a drug eluting stent (DES) and a bio-absorbable stent. In January 2017 he was awarded the inaugural British Cardiovascular Intervention Society (BCIS) Lifetime Achievement Career Award in recognition of his outstanding contribution to the speciality of coronary intervention.

Naturally, there were complications, such as abrupt vessel closure after balloon angioplasty and restenosis but from the initial percutaneous balloon angioplasty; intracoronary stents were deployed in the mid-1980s.

Through the '90s and beyond, various incremental improvements in balloon and stent technology arrived, along with newer devices and medicine regimens resulting in the drug eluting stent, designed to help reduce in-stent restenosis. These also reduced the risk of stent thrombosis.

Coronary angioplasty is now the mainstay of cardiac care

One man who recalls those early procedures is Bernhard Meier, former Chairman and Professor of Cardiology and current Senior Consultant at the Swiss Cardiovascular Centre at Bern University Hospital. He worked with Grüntzig during the early development of the technique, and also 'found' the first patient to undergo the procedure.

Meier has been involved in coronary angioplasty as a specialist in interventional cardiology since the first case Grüntzig performed in Zurich 1977, having joined the team in 1976. 'I watched him doing peripheral angioplasty and helped him accumulate the respective data.

The former Chairman and Professor of Cardiology at the Swiss Cardiovascular Centre in Bern University Hospital, **Bernhard Meier** is currently Senior Consultant developing the centre into the most active for interventional cardiology in Switzerland. A close associate of Dr Andreas Grüntzig, Meier has been involved in coronary angioplasty as an interventional cardiology specialist since the first case in 1977. He was involved in the development of structural interventions such as closure of the patent foramen ovale (PFO) and the left atrial appendage (LAA), and in the introduction of transarterial aortic valve implantation (TAVI) in Switzerland.

I also suffered with him through more than a year of the desperate search for a patient suitable to become the first-in-man PCI recipient,' Meier recalled. 'Serendipity led me to find the first patient and assist Dr Grüntzig. Finding this patient when he was away and presenting the case to him upon his return was certainly one of my career highlights. 'I've been able to take care of this patient up to now. He's still doing extremely well, 40 years after his historical intervention, without ever needing coronary artery bypass surgery.'

When, in 1980, Grüntzig left Switzerland for the USA, Meier followed and spent three years with him in Atlanta, undergoing his cardiology training at Emory University.

Back in Switzerland, Meier further developed the technique as head of invasive cardiology at University Hospital, Geneva (1983-92). In 1992, he became chairman of the Cardiology Department at Bern University Hospital, turning it into the most active interventional cardiology centre in Switzerland.

Meier recalls Grüntzig (11 years his senior) as a role model: 'He was good looking, a sociable person, and full of great ideas with the necessary energy to pursue them even against a headwind from sceptics and envious – and sometime mischievous – colleagues and superiors.

'He also liked and lived simplicity as the basis of successful medicine. The balloon catheter to treat coronary artery stenosis is about as simple and as efficacious as it gets.

Will software steal the heart of cardiology?

Continued from page 1

with the medical device manufacturer Medtronic before joining the venture fund New Enterprise Associates, where he partnered Dr Scott Gottlieb who, in May 2017, was appointed new Commissioner of the USA's Food & Drug Administration.

Confounding the audience

When Oesterle shifted his talk from hardware to software he began to confound the audience.

The next big thing in the cardiovascular space, he said, is not in the room today – unless you count the smart phones in everyone's pocket.

The research and development budget at Apple is $17 billion annually, and what they are working on will make the future iPhone a healthcare companion, he said.

Google Life Sciences, now called Verily, has invested $4 billion over the past two years to create partnerships with Johnson & Johnson's surgical division and glucose monitoring specialist Dexcom, as well as several major pharmaceutical companies.

IBM has declared that healthcare is the future of the company, he said, and the Watson super-computer is not meant to play games, having already shown it can outperform radiologists.

Data analytics coupled with cognitive computing will take over healthcare, Oesterle predicted. 'We have come to a point where computing power is massive, it is fast and it is incredibly cheap. Your next-generation competitor will come from software.'

As a venture capitalist, he noted that less than 10 percent of private equity funding goes to medical technologies, that 20 percent goes to biotechnologies and '70 percent goes into the software that is going to disrupt our practice, just as it has disrupted other industries.'

'No one wants to back a new stent, distributed healthcare is where the money is going,' he said, adding that consumer-oriented medical technologies aim to pass up the clinician in order to go directly to the patient.

Vice President for Medical Affairs at Medtronic Vascular, Martin Rothman spoke up to say: 'I just can't see these next big things.' And he agreed the next big cardiovascular enterprise based on software would not be Medtronic. 'It's not our core skill. We do some software engineering but what we really do is micro-engineering and that is our skill.'

Then he added: 'When we talk about what will be the next big application in data handling, we quickly come to the important question: Where is the revenue? When we sell a stent or a TAVR [transcatheter aortic valve replacement], we get revenue. How do you get revenue when you sell a software click? How do you make that work? We don't understand it,' he said.

With the authority of his white-haired seniority, Eberhard Grube, the Chief of the Department of Cardiology and Angiology at the Heart Centre in Siegburg, Germany, followed up on these comments: 'We are speaking of things that may come in 20 years. It makes me dizzy talking about five billion here and 50 billion there.

'Perhaps,' he suggested, 'we are more down-to-earth.' Then he cautioned colleagues, 'We hear about an unlimited imagination in what software can do, and then we look at what happened with a hospital in the United Kingdom when it no longer had access to its data. We have created a monster we do not know how to control.'

Improved monitoring and raised quality of life

Intelligent shirts 'watch' cardiac patients

A pioneering study has certified that wearable technology produced better results in monitoring cardiac patients and improving their quality of life compared to conventional systems. European Hospital correspondent Mélisande Rouger spoke with Spanish cardiologist David Del Val MD, who led the study, before he presented his results at the European Congress of Cardiology held in Barcelona.

David Del Val: 'Medicine, and more particularly cardiology, is experiencing a real technological revolution. Many devices have been developed to improve diagnostic therapy efficiency and patients' quality of life. However, very few studies have actually measured the pertinence of these devices in real life. This study is a pioneering work because it compares efficiency in a new wearable device and conventional systems in clinical practice.

'The study was designed to compare monitoring efficiency in terms of perceived life quality benefits in patients using a wearable system developed by a company called Nuubo and conventional electrocardiographic monitoring systems.

'150 patients alternatively used intelligent shirts and a conventional ambulatory monitoring system to monitor their cardiac rhythm during 24 hours.

'Results showed that the effective monitoring time was higher with the new system using wearable technology compared to the conventional system. Questionnaires answered by patients also revealed that quality of life indices were higher in those who used a wearable device.

'Our cardiology department started work with Nuubo's technology five years ago. We have worked with the same company on other projects to evaluate prolonged electrocardiographic monitoring over a week and a month, and electrocardiographic monitoring on sportsmen during competitions. We obtained very positive results in both projects.

'Personally I have always been very interested in medical technology advances, especially for cardiology; that's why I seized the opportunity to lead the first clinical experiments with Nuubo's monitoring system.'

Are collected data then stored in the patient's electronic health record?

'The data generated by these devices is stored on a memory card and can be downloaded and analysed thanks to dedicated software. We write a report based on this data, which is kept in the patient's health record. Unfortunately, in our hospital, there isn't any system enabling connection and incorporation of this data directly into the electronic clinical history, which doubtlessly would be a great advance.'

Are you or your colleagues working on other wearable technology projects?

'For the moment, I'm not involved in other projects validating wearable technology, but I consider this to be a field with major projection for patients suffering chronic diseases.

'Our cardiology department is currently working on a cutaneous patch that enables continuous medication of different haemodynamic parameters, a system that can help to follow up patients more closely and anticipate the disease progression.

'The department also leads another project in which a toothbrush enables us, daily, to measure vital signs and various biomarkers in the saliva.'

'Wearable technology enables us to remotely follow up different key parameters early, to detect any worsening of a given pathology. Therefore, we can anticipate and plan our actions to fight the disease, initiate early treatment, avoid hospitalisation and reduce healthcare costs.

Cardiologist **David Del Val MD** is currently completing his fellowship in haemodynamics and interventional cardiology at Ramón y Cajal University Hospital in Madrid, Spain. Having gained his medical degree from Madrid Autonomous University his residency in cardiology was at Ramón y Cajal Hospital. Later, at Alcalá University, he specialised in scientific investigation methodology.

We must protect cardiologists from cancer risk

CorPath enters the vascular highway

Shielding cardiologists from harmful radiation is the goal for two systems capable of navigating the vascular highway, John Brosky reports

'We cannot continue to accept working in conditions that put our lives in danger,' says Alain Cribier, the pioneering cardiologist from the University Hospital of Rouen, who first implanted an aortic heart valve via a catheter in 2002. 'You don't feel anything; radiation is not painful, but there is an accumulation of dose when you do this for decades, day-in and day-out,' he explained.

A study, published by the American Heart Association in August 2016, demonstrated a direct relation between working in a catheterisation lab and developing radiation-induced cancer, cataracts and skin lesions.

According to the study, interventional cardiologists accumulate significant lifetime radiation exposure in the range of 50 milliseverts to 200 mSv, which corresponds to a whole body dose equivalent to 10,000 chest X-rays.

'I have lost several colleagues to brain cancer,' Alain Cribier told European Hospital. 'We all have musculoskeletal problems,' he said, bringing out of a closet the 12-kilo lead apron he wears during 12-hour work shifts that can result in aggravated orthopaedic maladies.

At EuroPCR in May 2017 in Paris, Cribier met with fellow cardiologists on the stand of Robocath, in his role as a key opinion leader for the company, which is also based in Rouen.

He discloses that he has no financial interest in the company but an enthusiasm for a system that can put a shielding wall between him and the irradiating X-ray projector that, as he points out, hovers just inches from his head during some time-long procedures.

The R-One system from Robocath is not the first remote stenting robot for cardiology.

Two systems approved by the USA's Food & Drug Administration are commercialised by Corindus, based in Waltham, Massachusetts, which during EuroPCR 2017 celebrated what it called a milestone for the 100th percutaneous coronary intervention (PCI) performed using the second generation CorPath GRX System.

Although Corindus systems hold a CE Mark, the company has yet to sell a CorPath robot in Europe.

Robocath is currently completing pre-clinical trials as part of its submission for a CE Mark approval that it hopes to receive in 2018. A submission of the device to the FDA is expected in 2019.

The results of a single-centre REMOTE-PCI [percutaneous coronary intervention] study sponsored by Corindus were published in the January 2017 edition of EuroIntervention, the journal of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and the European Society of Cardiology (ESC).

PCI was successfully performed on 19 of 22 target lesions using radial access, the first demonstration of the ability to perform PCI from outside the confines of the cath lab by using a combination of robotics and telecommunications.

The CorPath 200 cockpit to control the robot was installed in a separate room, roughly 17 meters from the patient table, isolating the operator but maintaining continuous video and audio contact with both the patient and any personnel in the lab.

Principal investigator Ryan Madder MD, a cardiologist and researcher with the Spectrum Medical Group based in Grand Rapids, Michigan, told European Hospital that, in addition to the stenting procedures, he has successfully utilised the CorPath robot to perform the diagnostic procedure of fraction flow reserve (FFR) to assess lesion severity.

Potentially, Madder said the remote robotic system can be installed anywhere there is a fluoroscopy suite, and that it suggests a potential for tele-stenting, an ability to perform procedures in regions where PCI is currently unavailable by utilising a robotic cockpit located in a distant expert centre.

'We are still very early in this study; there's a lot of work to be done,' he noted. 'We are ways off from deploying a system to community hospitals.'

Neuroradiologist Philippe Bencteux, is the founder of Robocath, based in Rouen, France.

Prof. Alain Cribier, MD, is head of Cardiology at the Charles Nicolle Hospital , in Rouen University, France.

Back at the R-One robotic system from Robocath, Cribier provided a demonstration. 'This is not a totally new idea,' he said. 'There are surgical robots, orthopaedic robots, robots for brain surgery. But it was not considered possible for cardiology. I was sceptical myself but, over 10 years, I have followed the progress step-by-step as they solved technical problems.'

At the patient table, Cribier feeds the catheter into a single-use cartridge, an integral part of the robotic mechanism that contains the graspers that advance and turn the guidewire.

Walking from the patient table to the control panel behind a radiation shield, he said, 'The robot does not perform anything itself, everything is controlled by the operator's hand,' he pointed out. 'I can do exactly the same things using the robot that I would do with my hands, advance the wire, retreat, rotate and push.'

At the controls he advances and rotates the guidewire simultaneously, pushing and turning, something the CorPath robot cannot do.

Cribier expects in a next step the robot can be applied to peripheral artery procedures as it uses the same sized wire. Corindus has already been granted an extended indication by the FDA to apply the CorPath for peripheral procedures.

As for the transcatheter aortic valve replacement procedures that he pioneered, Cribier said, 'There is no question the system can be adapted to accept these larger catheters. This system will allow physicians to go anywhere on the vascular highway.'

We must embrace the potential of digital data

Cardiologists must keep up

Tex vector / Shutterstock

Report: Mark Nicholls

Leading cardiologist and healthcare researcher Professor Harlan Krumholz has warned that medical practitioners must embrace the potential of digital data generated by patients if they are to avoid being left behind as the digital revolution moves forward at an ever-advancing pace.

As Professor of Medicine (Cardiology) at Yale School of Medicine, he delivered the prestigious Paul Wood Lecture at the June conference in Manchester, UK, of the British Cardiovascular Society on a theme of 'Personalised medicine and computational cardiology – enhancing cardiovascular care and health in the next era'.

'Data generated every day for a variety of practical purposes can serve as an inexhaustible source of knowledge to fuel learning in a healthcare system,' he said, but warned that if medicine wants to take advantage of technology, it has to catch up with the digital revolution. He pointed to statistics that show the average American spend 5.6 hours on digital devices every day, including those in older age groups, and that medicine has to recognise the power of this trend.

Krumholz also suggested that medicine has not learned to communicate as rapidly, effectively and simply with its audience in the way that other sectors, such as weather forecasters, retailers, and traffic bulletins, have. Medicine, he said, had been slow to find ways of integrating digital data into practice, pointing to the transition to electronic health records, where he feels health professionals in the USA were slow to get involved as hospitals made the transition - eased with $50bn of funding. In 2008, 9.4% of records were electronic health records (HER) but, by 2015, it was 83.8%.

He also felt patients should have access to their own record to share it in ways that can improve their care and augment research, being partners as 'citizen scientists'.

The most important element about precision medicine, Krumholz continued, is that it can be driven with patients as partners and that the doctors and researchers should recognise the value of patient reported outcome data that are generated from wearable

An exciting new approach for heart bypass surgery

Transforming veins into arteries

Raimondo Ascione is Professor of Cardiac Surgery and Translational Research at the University of Bristol, UK. He is also Academic Director of the pre-clinical Translational Biomedical Research Centre (TBRC), which bridges the gap between basic science research and the NHS to boost the translation of fundamental discoveries and emerging biomedical technologies to the bedside. Ascione is also Chief Investigator of clinical trials and experimental work aimed to protect adult high-risk patients from complications during cardiac surgery.

Report: Mark Nicholls

Scientists in the United Kingdom are investigating the potential of a new regenerative and tissue engineering technique that could transform veins into arteries to improve the outcomes for patients undergoing heart bypass surgery.

The research, at Bristol University, led by cardiac surgeon Professor Raimondo Ascione, alongside Professor Sarah George and Dr Jason Johnson, could revolutionise the approach to cardiac artery bypass surgery.

Presently, replacement arteries for bypass operations are limited, so surgeons use veins taken from the patient's leg to replace the blocked vessels of the heart.

Populating veins with artery-like cells

However, while arterial grafts can continue to work well for up to 20 years, up to half of vein grafts can become blocked within 5-10 years as the greater blood pressure of the artery environment damages the graft after implant. 'With the bypass surgery we are taking a piece of vein from the leg which has a thin wall with blood flowing at a very low pressure,' explained Professor Ascione, Chair of Cardiac Surgery and Translational Research at Bristol. 'But when put into the heart it has to support and sustain a much higher pressure because it is being put into an arterial system, a high pressure system, so this is what leads to problems with the vein.

'Currently, veins are used for approximately 80% of all grafts made during heart bypass surgery. They work well in the short-term, but they are not designed for the demands of working as an artery.'

This may result in the grafted vein thickening its wall and becoming blocked and, when this happens, the heart bypass operation may have to be repeated, or the patient may even suffer a heart attack.

The Bristol team aim to achieve the vein-to-artery transformation by 'washing' cells from the vein, stripping it back to leave a tube-like scaffold made from extracellular matrix. An artery can then be built on this framework by populating it with arterial-like cells. This will be done either before surgery, in a dynamic bioreactor that mimics the arterial environment, or after the surgical implant by the host's natural healing processes.

'With the old cells stripped out of the vein we are only left with the vascular skeleton, the actual framework of the vein,' Ascione explained. 'The vein goes from being "pinky" to like a white ghost colour. Then we can use this acellular skeleton of just vascular extracellular matrix and transform it into a high-pressure system and seed the arterial cells on this.

Tissue-engineered arterial grafts improve long-term outcomes

'By stripping back a vein and using it as the framework on which to build an artery, we hope to create in the lab tissue-engineered arterial grafts that are better able to cope with the demands of carrying blood from the heart.'

The professor has already demonstrated the feasibility of these approaches in pilot studies and is now leading a new project to find the best method to re-populate the tube-like scaffolds derived from veins with cells.

Plain and pre-populated scaffolds will be implanted into pigs at the new Translational Biomedical Research Centre (TBRC) co-funded by the British Heart Foundation (BHF) and the Medical research Council (MRC) to establish if they give a better result than the grafts that are currently used. If this proves successful, it could see a new approach to the way heart bypass surgery is performed. In future, the vision is that patients would be admitted to hospital a few weeks before their operation for veins to be taken from their leg and engineered in a laboratory into arteries.

The patient would return to hospital a few weeks later for bypass surgery operation with surgeons using the vein material that has been transformed into arterial-quality conduits.

'In terms of surgical technique, it would be pretty much the same,' Ascione added. 'Stitching and suturing these arterial-like grafts will be similar to those grafts surgeons are already used to, so no further training would be necessary.'

The technique could also benefit vascular surgeons who, for peripheral vascular grafting in patients with blocked arteries in their legs, can only use vein or synthetic material with poor mid-term outcome.

Around 17,000 coronary artery bypass operations are carried out in the United Kingdom each year, with many thousands more conducted internationally.

This approach could improve longer-term outcomes for heart bypass patients.

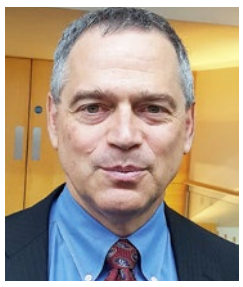
'Ultimately,' Ascione concluded, 'this research could mean that people receive longer-lasting grafts, improving their life expectancy while reducing their need for future surgery and use of hospital resources.'

devices and data collection mobile technologies.

Suggesting that data acquisition is an important new dimension to the way doctors approach medicine, Krumholz said: 'Medicine now is more than ever an information science and increasingly a digital information science.' Yet he harbours concerns about whether physicians are truly making the best use of available data unless they 'learn to use and develop new knowledge iteratively' and acquire 'smart enough' systems to process the data and utilise it.

Among his key concerns is that current medical research enterprises cannot keep pace with the information needs of patients, clinicians, administrators and policymakers. The digital revolution, tools and approaches, he pointed out, could augment and accelerate knowledge – producing a new paradigm of a learning healthcare system. 'Medicine needs to realise that we are in a new era,' he said. Health professionals, not the technicians, have to be the key, as they understand what patients need and the complexity of the problems that our patients face.

'The next generation must be deployed in a way that preserves the special nature of our profession but the advances in technology should help us be better, not replace the human touch. We should not be afraid of technology when it comes to health. It is better to embrace it - it can make us smarter than ever in looking after large populations.'



Cardiologist **Professor Harlan Krumholz** is a healthcare researcher at Yale University and Yale-New Haven Hospital, and the Harold H Hines, Jr. Professor of Medicine and Director of the Yale Center for Outcomes Research and Evaluation (CORE) – one of the America's most productive research units dedicated to producing innovations to improve patient outcomes and promote better population health. He is also a Director of the Robert Wood Johnson Foundation Clinical Scholars Program, which prepares especially talented physicians to become future healthcare leaders.

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New scan detects inflammation after heart attack

Exciting hyperpolarised MRI

Report: Mark Nicholls

A new type of scan that can detect cardiac inflammation may help tailor treatment for patients who have suffered a heart attack, according to research findings presented at the British Cardiovascular Society (BCS) conference in June. Developed in the UK, hyperpolarised MRI (h-MRI) enables cardiologists to see more detail of healthy and diseased hearts than conventional scans, including the level of inflammation post-myocardial infarction.

Detecting inflammation in the heart

Funded by the British Heart Foundation (BHF) the University of Oxford researchers now believe h-MRI could help scientists develop and monitor the effects of new, inflammation-targeting treatments that may improve the heart's healing process in heart attack patients.

The discovery could have significant benefits because the hearts of patients who have suffered a myocardial infarction (MI) can undergo continued inflammation even during the healing process, and despite receiving emergency treatment.

Yet research into why this may happen remains limited as conventional scans cannot detect or measure inflammation in the heart, whereas h-MRI can.

Conventional MRI measures how protons change position when exposed to a magnetic field, but h-MRI works by producing images from carbon molecules, which make up the energy sources needed to help the heart pump and can offer doctors a clearer picture of inflammation in the heart.

h-MRI as biomarker and pharmacological target

The Oxford University team used the hyperpolariser laboratory to investigate how the experimental drug 2-deoxyglucose (2-DG) may improve heart function after a heart attack

For the study, the team measured production of lactate in the damaged heart tissue of rats and found that after a heart attack immune cells within the injured heart muscle become active and are reprogrammed to make lactate, leading to inflammation in the heart. By monitoring how much lactate is produced in the damaged tissue, they were able to identify and measure the level of inflammation in the heart.

Following on from that, the team administered the experimental drug 2-deoxyglucose (2-DG) to the rats after the heart attack, to try and combat the inflammation.

Using h-MRI to monitor the heart's response, they found that 2-DG reduced lactate production and inflammation, and improved the heart's function.

The cutting edge scanning system

They showed that high hyperpolarised lactate signal in the days after myocardial infarction is caused by macrophage-driven inflammation, and reflects not just the number of inflammatory cells infiltrating the myocardium but also the inflammatory phenotype of those cells.

The Oxford scientists – one of the first groups to use h-MRI to study the human heart – believe that h-MRI will not only detect inflammation in damaged heart tissue but also could provide a novel method for the detection of myocardial inflammation with high translational potential as both a biomarker and novel potential pharmacological target.

'H-MRI is a cutting-edge scanning system which allows doctors to better understand the innermost workings of the heart non-invasively, and how they become abnormal in heart disease,' Dr Andrew Lewis, Specialist Registrar in Cardiology at the Great Western Hospital in Swindon, summed up. 'In this research, we used h-MRI imaging to capture the healing processes in experimental models after a heart attack, and also tested new treatments to improve the heart's recovery.

Andrew Lewis MD is a Specialist Registrar in Cardiology at the Great Western Hospital in Swindon, UK, and won the Young Investigator's Prize Competition at the British Cardiovascular Society conference in Manchester for his research into myocardial inflammation imaging.

More studies needed

'Our work has identified several forms of heart disease where this technique could be used to improve diagnosis and treatment,' Lewis added. This is incredibly exciting, and we intend to move forward with patient studies as quickly as possible.'

Lessons gained from an EHRA 2017 Symposium

Cardiac resynchronisation therapy improvements

Which CRT patients can be 'downgraded' from a CRT-D device with defibrillator function to a CRT-P with just a pacemaker function? This, with two further current CRT issues – chronotropic incompetence and telemonitoring of CRT patients – featured prominently at the Europace-Cardiostim Congress in Vienna.

For more than 20 years, cardiac resynchronisation therapy (CRT) has been a pillar in the treatment of chronic heart failure (CHF). CRT devices are either pacemakers (CRT-Ps) or implantable defibrillators (CRT-Ds), which are implanted in the patient's chest. These are connected to the heart with three leads, the third one linking to the left ventricle which pumps blood through the body. While both types of devices synchronise the heartbeat, CRT-Ps prevent the heart from beating too slowly and CRT-Ds prevent it from beating too quickly.

At a satellite symposium at the Europace-Cardiostim Congress (EHRA 2017) experts debated whether patients who respond well to a CRT-D and show improved heart function should receive a CRT-P in the next scheduled device replacement. The background: Many patients respond so well to CRT that their heart function markedly improves and a CRT-D might not be needed; indeed between 10-25% are so-called super-responders, i.e. their cardiac device restores a normal ejection fraction in the left ventricle, lowering the risk of sudden cardiac arrest to that of a healthy person.

At EHRA 2017, Dr. Jacques Mansourati from Brest University Hospital in France, presented a study investigating this very issue: The BioContinue study is observing 277 CRT patients in eight countries to determine which patients need a defibrillator. According to preliminary study data, 39% of patients who receive a CRT replacement do not need a defibrillator because the therapy increased the ejection fraction of the left ventricle by at least 40% and no ventricular tachycardia was reported. 'During a scheduled replacement of the device, responders and super-responders can be downgraded from a CRT device with defibrillator to one without this function,' Mansourati explained.

The second controversial issue in CRT is chronotropic incompetence: In 20-40% of all CRT patients, heart rate does not increase commensurate with increased physical activity. 'Chronotropic incompetence could be a major factor in patients who do not respond to CRT,' said Dr. Mattias Roser from Charité Berlin. In these cases, Roser points out, rate-adaptive pacing might provide a solution, as indicated by BioCreate, a pilot study conducted at Charité to investigate whether Closed Loop Stimulation in heart failure patients with chronotropic incompetence can improve clinical outcomes. This technology, developed by Biotronik, responds naturally to patients' physical and mental activity or stress, adapting heart rates physiologically.

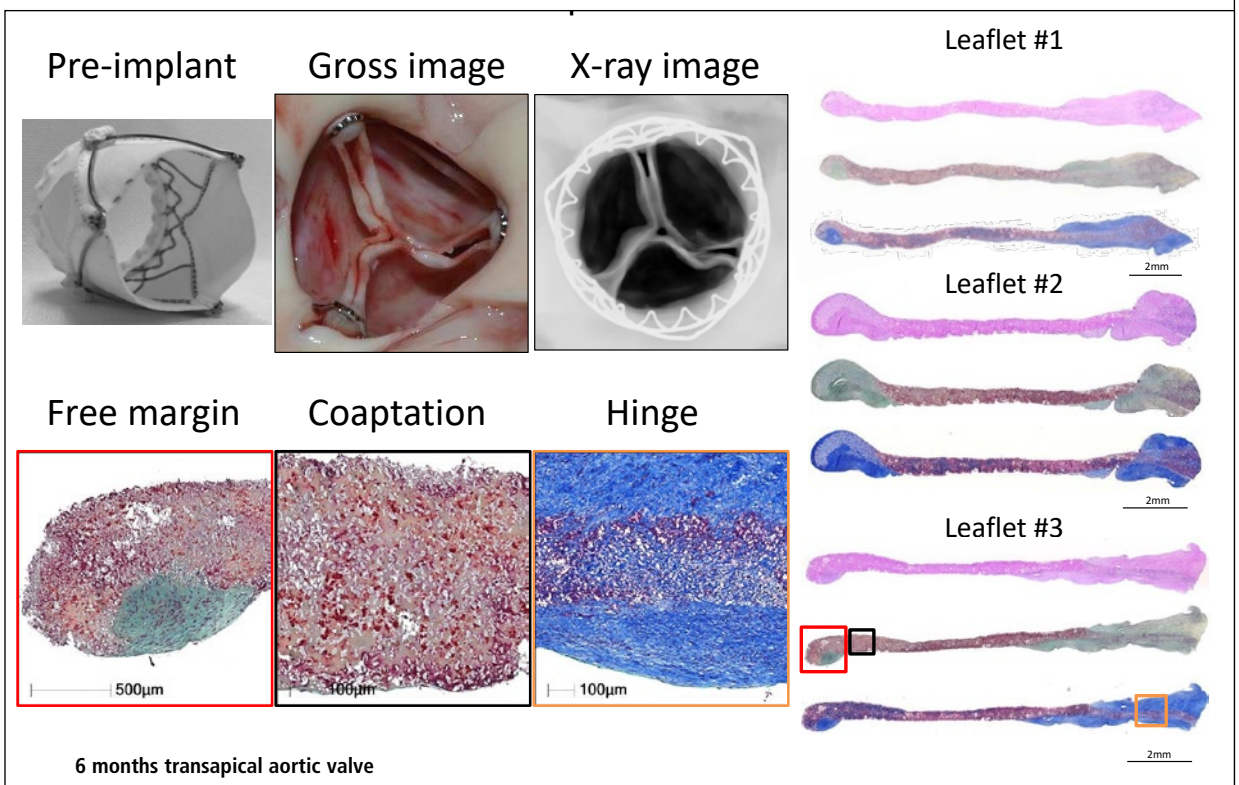
Roser is optimistic: 'We consider this a highly potential approach to significantly improve the treatment of CRT patients,' he said.

The third, but by no means least, important issue is remote monitoring of ICD patients. Ever since the IN-TIME study showed Biotronik Home Monitoring reduced mortality in heart failure patients, the use of this technology has been included in the clinical guidelines. However, data presented at EHRA 2017 indicate that not all tele-monitoring systems are created equal: they do offer different clinical outcomes. TRUECOIN, a meta-analysis, showed Biotronik Home Monitoring to reduce mortality in all types of ICD patients.

Where will material come from as demand grows?

Renewing the promise of bioabsorbable implants

Electrospun materials bring a spark of hope to a cardiovascular landscape darkened by setbacks for reabsorbable stents, John Brosky reports



6 months transapical aortic valve

It was famously said that implanting a device in a person to cure a disease is to implant a new disease. Simply put, the human body will continually fight against foreign materials, leading to chronic inflammations or repeated interventions. Which explains the recent excitement among cardiologists for a new generation of materials that can repair a diseased condition, and then disappear as the body absorbs the foreign material.

The earliest advances in this field were made with bio-reabsorbable stents (BRS), which have also delivered the greatest setbacks. Two- and three-year results for the leading stent, the Absorb BRS from Abbott Vascular, not only failed to demonstrate the promised benefits, but also in some trials showed a dangerous tendency for in-stent thrombosis. In the August 2017 issue of EuroIntervention, Editor-in-Chief Patrick Serruys noted the long-term follow-up data from randomised trials 'sometimes contradict themselves', and show that, 'we went from the best result to the worst result.'

With improved technology, he concluded, 'We will reach the promised land, which is not for tomorrow but for the day after.'

Beyond stents, which utilise a hardened bioabsorbable polymer, other cardiovascular applications for bioabsorbable materials have shown more promising long-term results with the first in-human trials.

The technology that may open a new path to the Promised Land is electrospinning, where an electrospray technique combined with the spinning of fibres creates a highly versatile soft fabric for implantation devices that the body can absorb over time.

While this technology has been known for 100 years, and for decades has been used to produce absorbable sutures for surgical closings, it is only recently that new devices using the materials have emerged.

According to Benoit Studlé, the CEO of Statice, which designs and manufactures these next-generation cardiac implants, the rediscovery of this technology is due to a progressive evolution in the savoir-faire for engineering unique chemical and mechanical properties.

'The medical need has been better defined, which has created a greater demand, and as a result, there is a market today. This is a great motivator,' he said, adding that there are multiple projects moving in the cardiology pipeline.

As a contract manufacturer, Studlé can not speak about projects being developed by innovative physicians and start-up entrepreneurs at Statice – except to say the company is a partner in a pan-European program TEH-TUBE, [tissue engineering of the right heart outflow tract by a biofunctionalised bioresorbable polymeric valved tube] and REVAMED, a €4 million program to develop implantable biosynthetic patches for drug delivery to aid with surgical closings, wound dressings and pain management.

Statice engineers are also creating electrospun fabrics for an aortic valve, but this is still in an early stage of development.

A Swiss firm that can speak publicly about its work in cardiovascular applications is Xeltis, which, during EuroPCR 2017, renewed the hopes for bioabsorbable implants in a crowded scientific session.

Xeltis presented the 24-month results for a pulmonary heart valve to correct or reconstruct right ventricular outflow tract in 10 children, as well as the first study results from the company's preclinical aortic valve program.

The prestigious panel of key opinion leaders would have been enough to pack the room, as it included presentations by Serruys, who is a professor of Cardiology Imperial College London; Thierry Carrel, from the University Hospital Bern Clinic, who also serves on the editorial board of several international journals; the internationally renowned cardiovascular pathologist Renu Virmani; and, Martin Leon, the director at the Center for Interventional Vascular Therapy at Columbia University Medical Center and New York-Presbyterian Hospital.

Elazer Edelman, who directs the Harvard-MIT Biomedical Engineering Center and is a member of the U.S. FDA's Science Board, chaired the session.

The Chief Technology Officer and co-founder of Xeltis, Martijn Cox, explained the principle of what his company calls endogenous tissue restoration using electrospun fabrics.

The human body colonises implanted scaffolding by creating proteins and collagen to build new tissue, while macrophages also attach to the structure and simultaneously dissolve the foreign material.

Serruys suggested the dynamic tension between the rate of destruction and the rate of construction would be the subject of debate for a long time.

'How sharp, how long, how fast? There may yet be surprises, we may discover new enemies,' he said.

Virmani showed that among the children implanted with the Xeltis valved conduit, the diameter of the valve is not only well-maintained after two years, it is enlarging, 'so that as the child will grow, this conduit will allow enlargement of the pulmonary trunk as well as the valve'.

Yet, a conduit is not an aortic valve, she said, showing histological evidence to demonstrate a critical inconsistency in the creation of new tissue at the hinge point of the aortic valve. 'We need to think completely differently about how colonisation and tissue formation is achieved,' she said. 'Unfortunately, we cannot learn this on the bench top

The promised land of synthetic implants that can heal is clearly not for tomorrow.

Yet, as Edelman noted, there is urgency in cardiovascular interventions. 'Today heart valves are made from the hide of a very small herd of animals in a very small part of the world. This forces us to consider where these materials are going to come from, as the demand grows greater,' Edelman pointed out.

According to Leon, in a summary statement: 'This innovative treatment approach has the potential to reduce complications, re-interventions and healthcare costs, while improving quality of life for patients with heart valve disease. This would represent a major leap forward in heart valve therapy.'

Supporting women in electrophysiology and cardiology

The EPIC Alliance

'We are now in an era where patients with implantable devices – not just pacemakers, but also cardioverter defibrillators – can undergo MRI scanning. Although there are still open questions, we no longer have to exclude these patients from this very important imaging technology,' said Seattle-based cardiologist Professor Jeanne E Poole, during the Europace-Cardiostim Congress (EHRA 2017) in Vienna. While discussing implantable devices and MRI is not unusual at a scientific congress, the satellite symposium 'Clinical Decision Making in Electrophysiology/Arrhythmias', chaired by Professor Poole, differed from other such events in one particular way: the panel was all-female. This symposium was organised by the Electrophysiologist International Community Alliance (EPIC Alliance).

Founded in 2010, the EPIC Alliance aims to advance career opportunities for women in electrophysiology and cardiology. The network currently includes 250 women electrophysiologists and cardiac device specialists internationally. 'It is focused on helping women achieve a pathway in electrophysiology equally as successful as men,' Poole pointed out.

First and foremost, the founders of the EPIC Alliance wanted to create a network for women working in electrophysiology and cardiology. 'Globally, we did not know each other; many of the female electrophysiologists and cardiac device specialists had not met women from other countries working in this field,' Poole explained during our interview.

Today, EPIC Alliance activities have moved far beyond the initial networking aspect to provide members with an array of professional development opportunities. Members are supported in submitting abstracts and organising symposia at conferences; experienced mentors share their knowledge and support young and upcoming physicians; the alliance also organises meetings and networking events for members to gather at global and local levels. 'The EPIC Alliance is the most successful organisation supporting women in our field, in which very few women work,' said Poole, estimating that only about 10 percent of all electrophysiologists and cardiac device specialists are female.

Women, she surmises, may be put off by the two to three years of additional training and by extremely long working hours, two factors that appear to be irreconcilable with motherhood and family. However, Poole herself provides a convincing example that a satisfactory work/life balance can be achieved. 'But,' she underlines, 'we do need role models and we must ensure women are visible at scientific congresses.'

Male colleagues, she added, would also benefit from a sustainable work/life balance: 'We are all just human beings working in a very exciting speciality.'

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Prof. Dr. med. Peter Luppa,
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