

# CARDIOLOGY 2016

NEWS AND TECHNOLOGY UPDATES FOR CARDIAC CARE

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## The virtual-heart arrhythmia risk predictor

Researchers have developed a personalised 3-D virtual heart that can help predict the risk of sudden cardiac death. Mark Nicholls reports



**Natalia Trayanova PhD** is the John Hopkins University's inaugural Murray B. Sachs Professor of Biomedical Engineering in the Department of Biomedical Engineering and Institute for Computational Medicine. She received her doctorate at the Bulgarian Academy of Sciences in Sofia (1986) and post-doctoral training in biomedical engineering at Duke University. Her research focuses on understanding the normal and pathological electrophysiological and electromechanical behaviour of the heart.

Research by a team at John Hopkins University (JHU) in Baltimore, USA highlights the patients who are most likely to face lethal arrhythmias.

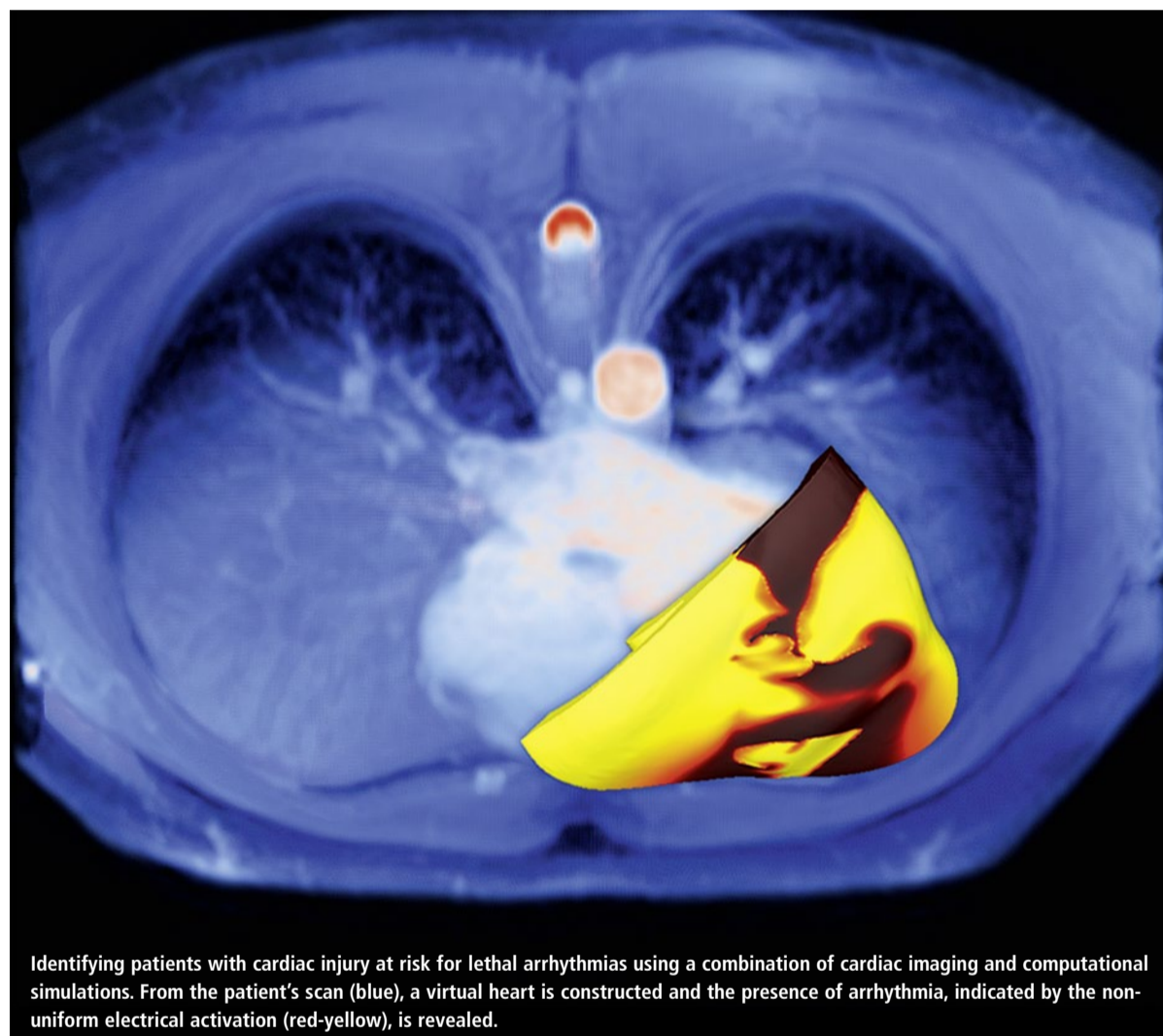
When patients suffer arrhythmia, cardiologists often respond by fitting a small defibrillator implant to sense the onset of arrhythmia and jolt the heart back to a normal rhythm. However, the question remains over how they decide which patients need the implant and the invasive surgery needed to fit it.

Aiming to address this, a team from the Department of Biomedical Engineering and Institute for Computational Medicine at JHU has developed a non-invasive 3-D virtual heart assessment tool to help doctors determine which patients face the highest risk of a life-threatening arrhythmia and would benefit most from a defibrillator implant.

Early evidence suggests the new digital approach yielded more accurate predictions than the current blood pumping measurement used by most physicians.

'Our virtual heart test significantly outperformed several existing clinical metrics in predicting future arrhythmic events,' Professor Natalia Trayanova, the university's inaugural Murray B. Sachs Professor of Biomedical Engineering, said. 'This non-invasive and personalised virtual heart-risk assessment could help prevent sudden cardiac deaths and allow patients who are not at risk to avoid unnecessary defibrillator implantations.'

A pioneer in developing personalised imaging-based computer models of the heart, she has worked on the project with cardiologist Katherine C Wu, associate professor in the Johns Hopkins School



Identifying patients with cardiac injury at risk for lethal arrhythmias using a combination of cardiac imaging and computational simulations. From the patient's scan (blue), a virtual heart is constructed and the presence of arrhythmia, indicated by the non-uniform electrical activation (red-yellow), is revealed.

of Medicine, whose research has focused on MR resonance imaging approaches to improving cardiovascular risk prediction.

For the study, Trayanova's team formed its predictions by using the distinctive magnetic resonance imaging (MRI) records of patients who had survived a heart attack

but were left with damaged cardiac tissue that predisposes the heart to deadly arrhythmias. The study involved data from 41 patients who had survived a heart attack and had an ejection fraction – a measure of how much blood is being pumped out of the heart – of less than thirty-five percent.

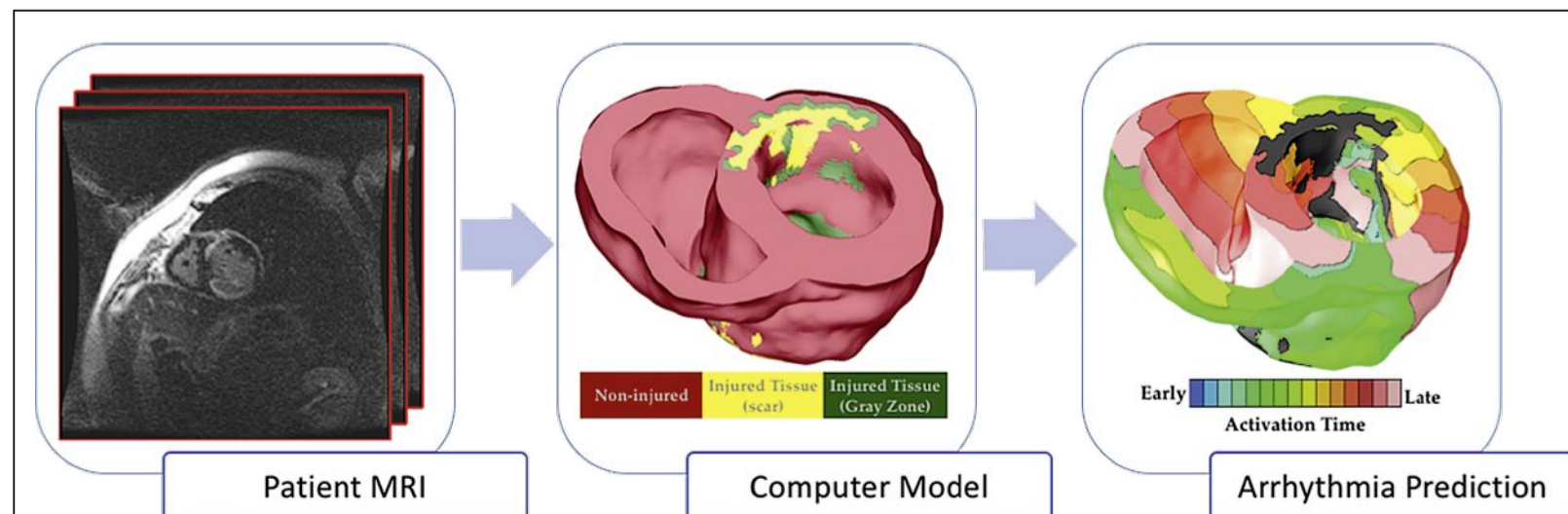
Patients in this range are usually recommended implantable defibrillators, however, with the JHU team concerned about this measuring score system, they invented an alternative to these scores by using pre-implant MRI scans of the recipients' hearts to build patient-specific digital replicas of the organs.

Using computer-modelling techniques developed in Trayanova's lab, the geometrical replica of each patient's heart was brought to life by incorporating representations of the electrical processes in the cardiac cells and the communication among cells. In some cases, the virtual heart developed an arrhythmia, and in others it did not.

The new non-invasive way to gauge the risk of sudden cardiac death due to arrhythmia has been named the VARP (virtual-heart arrhythmia risk predictor). Subsequent tests showed that patients who tested positive for arrhythmia risk by VARP were four times more likely to develop arrhythmia than those who tested negative. VARP predicted arrhythmia occurrence in patients four-to-five times better than the ejection fraction and other, invasive and non-invasive, existing clinical risk predictors. 'We demonstrated that VARP is better than any other arrhythmia prediction method out there,' Trayanova confirmed. 'By accurately predicting which patients are at risk of sudden cardiac death, the VARP approach will provide the doctors with a tool to identify those patients who truly need the costly implantable device, and those for whom the device would not provide any life-saving benefits.' Wu said that the early results indicate the more nuanced VARP technique could be a useful alternative to the one-size-fits-all ejection fraction score.

Trayanova is hopeful the new risk prediction methodology could also be applied to patients who had prior heart damage, but whose ejection fraction score did not target them for therapy under current clinical recommendations.

The next step is to conduct further tests involving larger groups of heart patients.



The virtual heart arrhythmia risk predictor. Patient-specific heart models are constructed from clinical imaging data. A virtual-heart model is then used to predict the patient risk of lethal arrhythmias.



Cardiac MRI adds crucial data on acute in-patient diagnoses

# CMR should complement echocardiography

MRI increasingly helps to diagnose cardiac disease, yet its role in clinical decision-making of acutely hospitalised patients has hardly been explored. ESC delegates will have a glimpse at how cardiac MRI (CMR) can add information, and sometimes change diagnosis in patients with acute conditions requiring hospitalisation, when Estefania De Garate presents the results of a study that could potentially impact on future cardiac clinical practice.

Report: Mélisande Rouger

In the study, one of the first to observe the role of CMR in this setting, De Garate and Dastidar (Figure) compared the value of echocardiography and CMR in a cohort 231 acutely hospitalised patients. They found that CMR confirmed the echo diagnosis in 11% of these patients, but interestingly added significant new information in 41% and changed the diagnosis made on echo in 30% of the cases.

'CMR is increasingly used in out-patients and our results now show the promising role of this technique in sicker hospitalised patients in whose diagnosis and management can be changed by having a CMR,' Chiara Bucciarelli-Ducci, who directed the study, told European Hospital.

The study also compared the level of agreement between echocardiography and CMR in the assessment of left ventricular (LV) function. 'We found that the level of agreement in patients with severe dysfunction was very good but in patients with mild and moderate dysfunction the agreement was only fair.

'If the heart works normally or really badly the two techniques appear to perform equally well, but when there are mild-moderate abnormalities, CMR has the advantage of higher spatial resolution and can distinguish subtler abnormali-



Estefania De Garate and Amardeer Ghosh Dastidar, the first co-author of the paper

ties', De Garate explained.

In a paper currently in submission, they explain in depth the potential use of CMR in the acute setting. The session is likely to attract a lot of interest and, as the abstract was among the top scored, it will be presented in the 'Cardiac MRI-Advances in Science' session at the ESC 2016 congress.

'We believe our results could be of interest to a wider cardiac audience. This work shows how CMR has an increasing role in cardiology and clinical practice, and can be a really useful tool for clinicians to guide management and decision-making in hospitalised patients.

Echocardiography continues to be the first line imaging test and our study does not want to suggest that it should be replaced by CMR. Quite the opposite, that CMR should be considered and used as an additional test to complement echocardiography when necessary' Bucciarelli-Ducci said.

The Bristol Heart Institute at the University Hospitals Bristol NHS Trust is a tertiary centre in the SouthWest of England. The CMR Unit performs around 3,000 CMRs a year, an impressive number – as Bucciarelli-Ducci said: 'The UK is the leading country worldwide where the highest number of CMR

scans are performed clinically by a community that is also very active scientifically.'

In the rest of Europe, Italy, Switzerland, the Netherlands, Germany and Spain are significantly active communities with an increasing number of clinical CMR activity per year.

Few factors can limit the use of CMR in clinical cardiology include a significant training in image interpretation. Access to equipment and elevated costs remain as major drawbacks to wider distribution. Examination time usually takes about an hour, but it can be shortened depending on the needs of the patient, and on the information required by the physician. 'We can tailor the CMR protocol according to the clinical question,' she said, 'and give you an answer in 10 minutes when needed.'

De Garate and Bucciarelli-Ducci hope the results of the study will contribute to clarify the role and the use of CMR in daily practice even in sicker patients. 'The mandate of the scientific CMR community is to generate and diffuse the evidence on the clinical use of CMR in daily practice.'

'This piece of work hopefully will contribute to incentivise colleagues,' said Bucciarelli-Ducci, adding that it will also get the attention of healthcare policy makers and scientific societies to consider CMR in the guidelines.

# Algorithm for prosthetic heart valves

Cardiologists have highlighted the importance of echocardiography and cardiac CT – to evaluate the condition of prosthetic heart valves and make recommendations.

Report: Mark Nicholls

With prosthetic heart valves recognised as the best treatment for the majority of patients with severe symptomatic valvular cardiac disease, the new algorithms will help clinicians diagnose and quantify prosthetic heart valve dysfunction.

Latest figures suggest that heart valve disease affects up to 6% of over 65-year-olds, with about 850,000 prosthetic heart valves expected to be implanted annually in western countries by 2050.

As the number of prosthetic valve implants continues to rise, the European Society of Cardiology (ESC) felt it was important to establish recommendations for assessing the condition of the implants using multimodality imaging.

Professor Patrisio Lancellotti, head of the intensive care cardiology unit at the Liège University Hospital Centre and Professor of Clinical Medicine at Liège University, led the ESC initiative. 'The guidelines are designed to underline the incremental value of all imaging modalities to evaluate prosthetic heart valves.'

The ESC recommendations include first-line imaging with 2-D transthoracic echocardiography; 2-D and 3-D TTE and trans-oesophageal echocardiography for complete evaluation; cinefluoroscopy to evaluate disc mobility and valve ring structure; cardiac CT to visualise calcification, degeneration, pannus, thrombus; cardiac MRI to assess cardiac and valvular function.

Weekend admissions of AF patients raises future death risk

# Cardiac records highlight an emergency

Two new studies have focused on the impact of weekend care and discharge on heart patients within the NHS in England. In one, patients suffering atrial fibrillation (AF) who were admitted to a National Health Service (NHS) hospital over the weekend faced a higher risk of dying within five years than patients admitted during normal hours.

In a second study, researchers found that HF patients discharged from hospitals in some parts of England at weekends were at an increased risk of dying than those sent home during regular weekday hours.

The new AF research on patients was led by Dr Rahul Potluri, founder of the Algorithm for Comorbidities, Associations, Length of Stay and Mortality (ACALM) study unit at Aston University's Medical School, in Birmingham, and focusing on 42,687 patients with one of the most common forms of abnormal heart rhythm.

The study found that atrial fibrillation patients admitted outside normal operating hours (9am-5pm, Monday-Friday) had a ten percent

increased risk of dying within the next five years.

The research was adjusted to account for external factors that



Rahul Potluri PhD is founder of the ACALM (Algorithm for Comorbidities, Associations, Length of stay and Mortality) study unit at Aston University in Birmingham. His clinical epidemiology research identified a link between high cholesterol and breast cancer and other prominent studies include health service research evaluating differences in death rates from weekend admission and discharge from UK hospitals, ethnic variations and the interplay between cardiovascular disease and mental health.

could influence death rates, such as age, gender, ethnic group, and the most common causes of mortality in the UK.

It is believed that AF affects about a million people in the UK, though many more may be undiagnosed and are unaware that they have the condition. In a separate study, the researchers looked at 31,760 atrial fibrillation patients discharged from hospitals in the north of England at weekends, finding a thirty-two percent increased chance of dying over the next five years compared to those sent home during regular weekday hours.

Across the UK there are more than 500,000 people diagnosed with HF. 'This study shows that the weekend effect is very much a reality for those suffering two of the most prevalent heart conditions in the UK,' Potluri pointed out. 'These patients are, quite simply, more likely to die if admitted or discharged outside regular hours, and that trend is particularly noticeable at the weekend.'

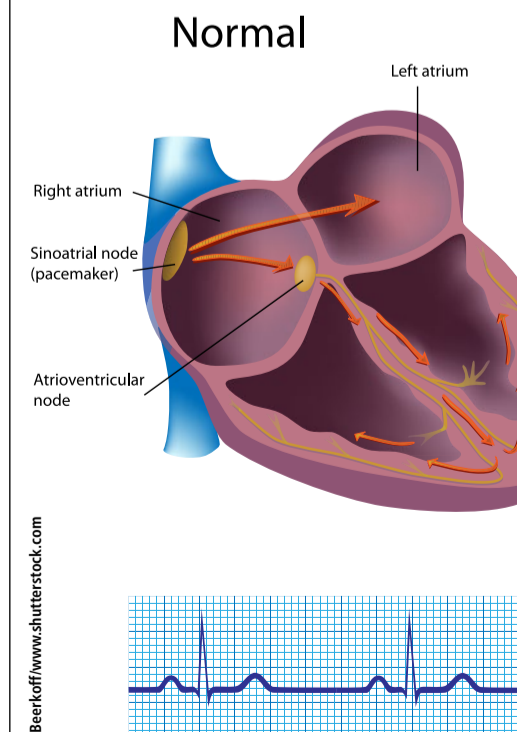
The researchers said they were not in a position to comment on

the underlying reasons for this from their study but did say it suggested that the level of support provided at weekends, from all teams involved in healthcare – in the hospital and in the community – should be addressed.

'What this research shows is that the weekend effect is not a universal phenomenon,' Potluri added. 'Across the two conditions we studied, its impact was varied, suggesting it can't be tackled effectively by blanket improvements to care.'

'Our findings suggest that the weekend effect is very complex and further research is urgently needed to assess what the implications of the weekend effect are for individual conditions, before any costly changes to services are implemented.'

\* The research involved the records of 929,552 patients (42,687 admitted with atrial fibrillation and 31,760 discharged following heart failure) between the first of January 2000 and 31 March 2013 across a number of North of England hospitals. Data was analysed according to the ACALM study protocol.



AF-patients who were admitted to an NHS hospital over the weekend had a ten percent increased risk of dying within the next five years than others.



Multimodality imaging assessment

# Algorithms define Prosthetic valve dysfunction

...ance of all imaging modalities – including  
...ate prosthetic heart valves in a new series



**Patrizio Lancellotti** is head of the intensive care cardiology unit at the University of Liège Hospital Centre and Professor of Clinical Medicine at the University of Liège. A pioneer in cardiac imaging techniques, his research has led to significant progress in the care of patients suffering functional mitral insufficiency. A former president of the European Association of Cardiovascular Imaging (EACVI) and the author of 330 peer-reviewed publications, he was also co-chair of the Task Force that drafted the ESC Guidelines for endocarditis, promoting the need for an approach based on a multimodal imaging.

‘Nuclear imaging currently has very limited application in the evaluation of PHV, other than in the setting of suspected infective endocarditis,’ Lancellotti explained.

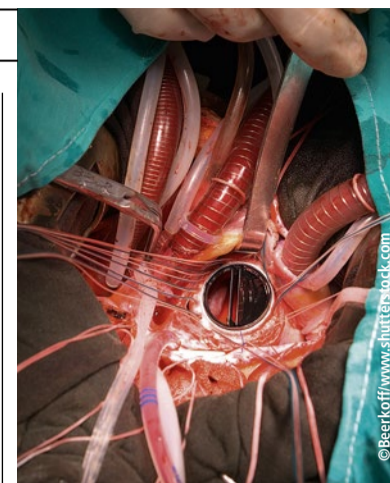
The Chinese Society of Echocardiography, the Inter-American Society of Echocardiography and the Brazilian Department of Cardiovascular Imaging have already endorsed the recommendations in

the document, which brings a series of tables providing parameters, criteria, and new algorithms. ‘Although relatively rare, valve dysfunction does occur with prosthetic heart

valves in the forms of structural valve deterioration or non-structural problems,’ he explained. ‘Though often challenging, establishing the exact cause of PHV dysfunction is

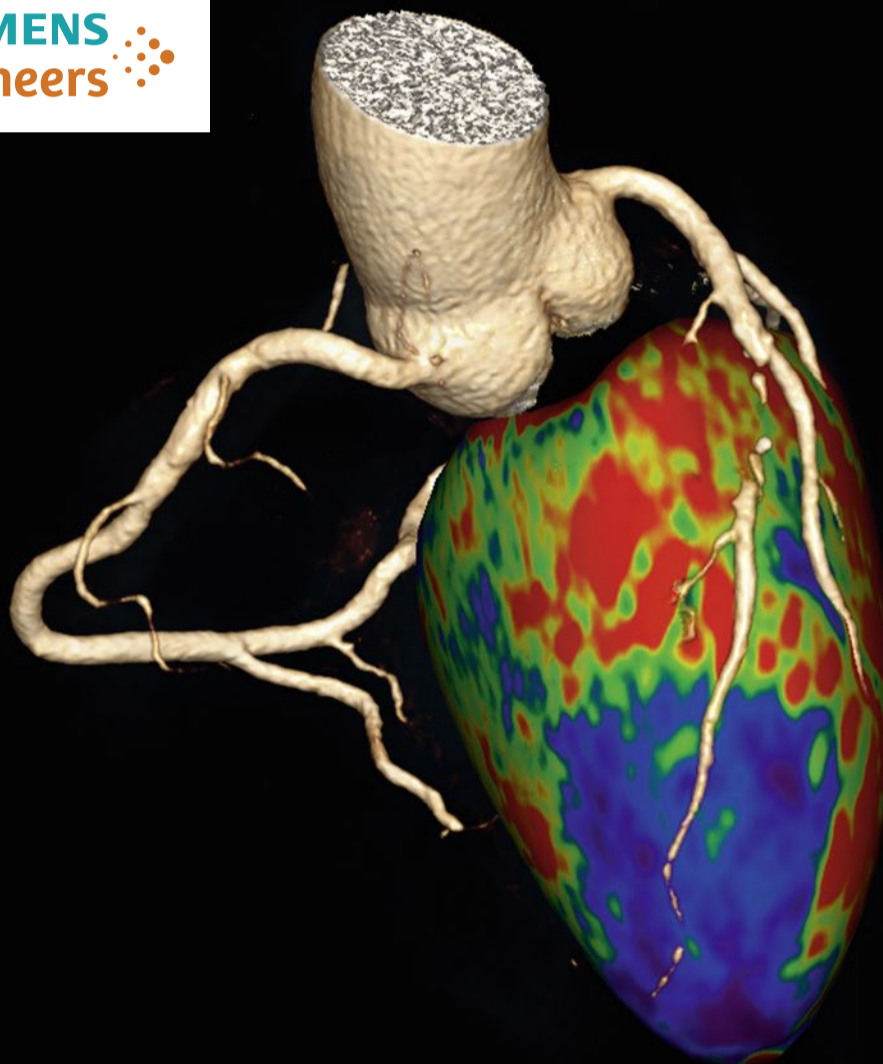
essential to determine the appropriate treatment strategy. The new algorithms to help clinicians diagnose and quantify prosthetic valve dysfunction are easy to use.’

‘In clinical practice, a comprehensive approach that integrates several parameters of valve morphology and function assessed with echocardiography is key to appropriately detect and quantitate PHV dysfunction. Other imaging modalities are complementary tools for the diagnosis and management of PHV complications.’



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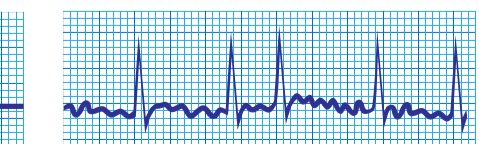
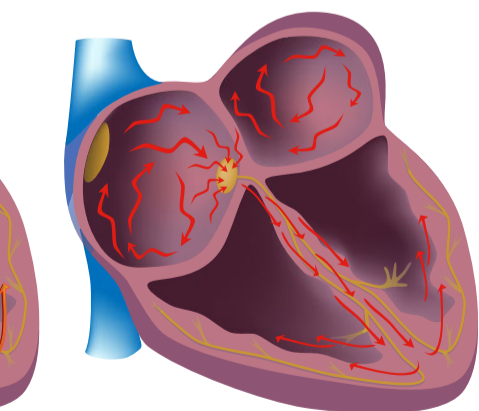
With its evaluation of dynamic myocardial perfusion, syngo.CT Myocardial Perfusion takes you to a new level in measuring the myocardial blood flow and allows you to use actual quantitative assessment for the hemodynamic relevance of intermediate stenoses of the coronaries.<sup>2</sup> This enables you to choose the right diagnostic approach for every patient.

<sup>1</sup> Optional application

<sup>2</sup> Rossi A, Pugliese F et al., Eur Heart J Cardiovasc Imaging. 2014 Jan;15(1):85-94.

# migma

Atrial Fibrillation



er the weekend faced a higher risk of dying over the

# A new technique for dilated

UK researchers are working on a more precise imaging technique for dilated cardiomyopathy that may lead to more effective treatments, Mark Nicholls reports

A study from the University of Oxford Centre for Clinical Magnetic Resonance Research (OCMR), part of the Division of Cardiovascular Medicine at the university, has demonstrated how the next generation of MRI scanners can work to measure heart conditions in dilated cardiomyopathy cases.

Oxford's new 7 tesla MRI scanner increased the phosphocreatine (PCr) signal-to-noise ratio by two-and-a-



Chris Rodgers is an Associate Professor of Biomedical Imaging in the Division of Cardiovascular Medicine at the University of Oxford and a Supernumerary Fellow and Stipendiary Lecturer in Physical Chemistry at Merton College, Oxford. His research – funded by his Sir Henry Dale Fellowship from the Wellcome Trust and the Royal Society – focuses on developing new methods for <sup>31</sup>P magnetic resonance spectroscopy and using Oxford's new 7-Tesla scanner and 3-T.

half times compared to values from a typical 3-Tesla MRI scanner. This means that 7-T scans provide a more precise reading of the energy supply in a patient's heart.

The study leader Chris Rodgers, Associate Professor of Biomedical Imaging at the University of Oxford, explained that the latest work builds on findings from Professor Stefan Neubauer, the head of the Division of Cardiovascular Medicine, who showed in the 1990s that dilated cardiomyopathy is associated with depleted energy reserves inside the muscle cells of the heart.

Neubauer measured this using phosphorus magnetic resonance spectroscopy on a 1.5-T MRI scanner.

More recently, the Oxford unit took delivery of an MRI scanner operating at a magnetic field-strength of 7-T – only the second 7-T system in the UK, and the only cardiac-capable 7-T system in the country – made by Siemens Healthineers. This was used in conjunction with a radiofrequency coil made by Rapid Biomedical GmbH.

'Our study was designed to show the feasibility of scanning cardiac patients in this new machine, and to show that we have much greater ability to monitor the phosphorus metabolites in the heart responsi-

ble for energy delivery,' Rodgers explained. 'This is part of a programme of work to deliver cutting-edge methods to monitor cardiac metabolism, primarily using the Oxford 7-T MRI scanner.'

'We intend to use these methods in forthcoming clinical studies of

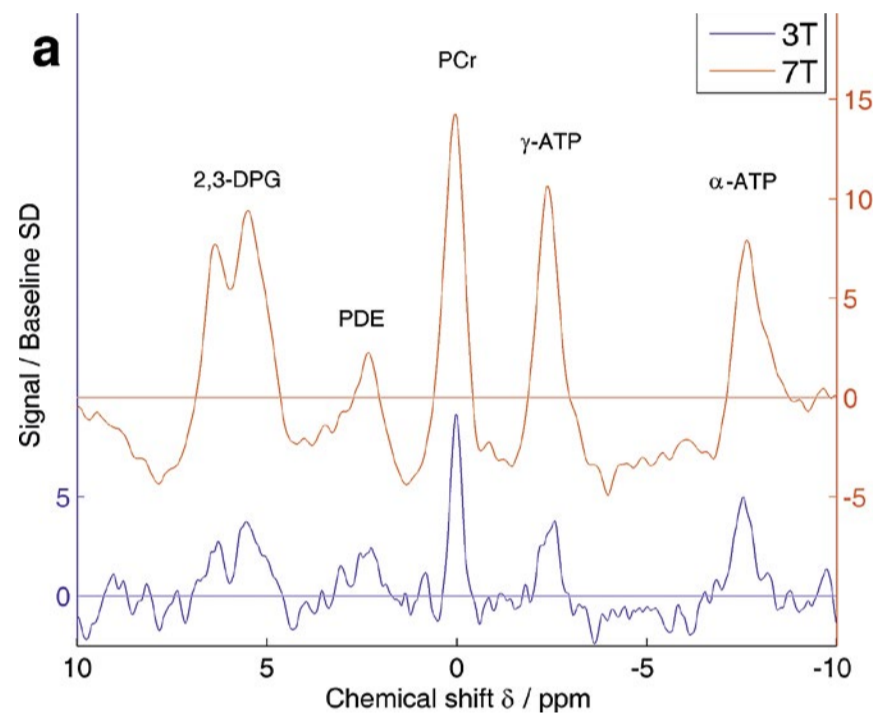
other cardiomyopathies, diabetes, and to monitor the effects of new drugs designed to treat heart failure.'

His team performed phosphorus magnetic resonance spectroscopy to record the concentrations and rates of generation/consumption of phosphate metabolites in ~60mL volumes at regular intervals across the chest.

Taking less than an hour in an MRI scanner equipped with special hardware for phosphorus measurements, the 7-T scans showed a marked improvement against 1.5-T and 3-T results, whose quality has previously prevented the wider uptake of phosphorus spectroscopy methods.

'We have seen a 2.6 times improvement in data quality at 7-T com-

Figure A, Graph shows comparison of spectra in a typical patient (57-year-old woman) at 3 T and 7 T. These spectra have had a matched filter applied and have been normalized to mean baseline noise, so the PCr peak height is, by definition, the PCr SNR. Increase in SNR at 7 T is readily apparent. B, Corresponding mid-short axis localizer image acquired at 7 T. C, Corresponding four-chamber localizer image acquired at 7 T. The spectroscopy matrix is overlaid in red, and the voxel plotted in A is highlighted. The yellow-shaded region denotes the regional saturation slab used to suppress signal from overlying skeletal muscle.



Changing research approaches as well as cardiac patient care

# Plumbing the depths of big data

Big Data has the potential to turn the approach to science and research on its head, according to leading expert Professor Viktor Mayer-Schönberger. In the future, he believes, researchers could adopt a position where they 'start with the data and then come up with the question.'

'They will be thinking about the hypothesis as the answer to the question,' he explained. 'That's because big data captures all the data from a scenario, often data that we did not expect it to scoop up. That has immense potential, particularly within the world of medicine and scientific research. With Big Data, we can ask questions of it that we did not think of when we collected the data.'

This is significant, he pointed out, because scientists traditionally start with a hypothesis and then collect the data to answer the questions they have posed.

Though as Professor of Internet Governance and Regulation at the Oxford Internet Institute, University of Oxford, he emphasised, 'this requires us to ask the right question.'

Speaking to cardiologists at the opening lecture of the recent British Cardiovascular Society conference

in Manchester, he posed the question 'Big Data: a big deal for cardiology?' outlining the role and impact big data can have in highlighting trends in disease and illness prediction and, consequently, how it may offer the opportunity to prevent it; he also warned that clinicians and researchers need to be responsible

and trustworthy in how they use it. Big Data, he suggested, first had an impact in the sphere of public health with the discovery of the H1N1 virus in 2009 as its spread alarmed health authorities across the world because of the lack of vaccine. The Centre for Disease Control and Prevention (CDC) sought to

constrain the spread and was able to monitor outbreaks but with a two-week delay.

However, by monitoring what people were searching for online from its five billion daily search requests, Google found a correlation to CDC data from what people were seeking.

'The remarkable element in how this gave a prediction was about time,' said Professor Mayer-Schönberger. 'Google could do that in real time. This is precisely what big data is all about – about understanding the world through data.'

He said the world is 'at the beginning of a wave of data', pointing to data having grown 100-fold from 1987-2007 and is now doubling every 18-20 months.

'In the year 2000, three-quarters of data was analogue, whereas today it is less than one percent,' he said. 'Within half a generation we have moved from the analogue world to the digital world.'

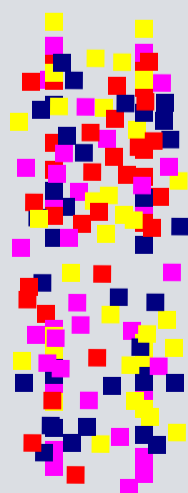
'The promise of big data is that we can take a quantity of data and, with new quality, gain new insights. It is a paradigmatic change.'

Professor Mayer-Schönberger said big data moves medicine 'beyond the average' and helps clinicians with improved decision making, particularly when data is re-used in terms of personalised medicine. 'Data re-use is key to the big data future, but there is a dark side,' he warned his audience of cardiologists. 'You have to understand that big data can only work if there is trust and responsibility among those who use data. Patients will only volunteer that valuable data to you if they can trust you.'

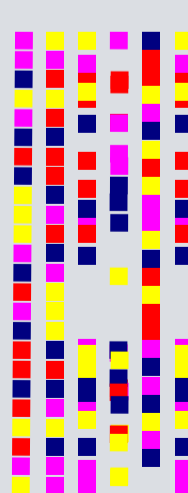
'In the future, big data is going to change the way you, as cardiologists, not only attend to your patients with individual diagnosis and suggestions for treatment, but how to discover and make those predictions.'

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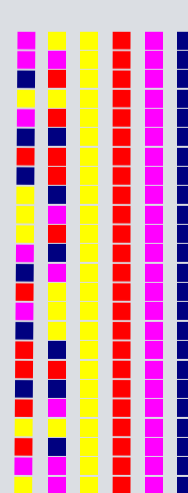
## BIG DATA



## ANALYTICS



## DECISIONS



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r with 7-T magnetic field-strength

# cardiomyopathy

pared to 3-T,' the professor added. 'This translates into being able to acquire the same quality data in five minutes that previously took 30 minutes, or into being able to use a finer spatial resolution, or into being able to measure other metabolites, such as inorganic phosphate which occur at lower concentrations in the body and were not visible in our scans.'

In the healthy heart, the concentration ratio of phosphocreatine (PCr) – the primary energy buffer of heart muscle cells – to adenosine triphosphate is approximately 2:1.

'In the failing heart,' Rodgers added, 'the concentration ratio drops to around 1.5:1. We measured this change in our group at 3-T and

7-T. The more sensitive 7-T experiment, in theory allowed us to detect changes in less severe cases of dilated cardiomyopathy than in the cohort we studied.'

Whilst still at the basic research stage, Rodgers believes the primary impact on patient treatment is that these more sensitive measurements

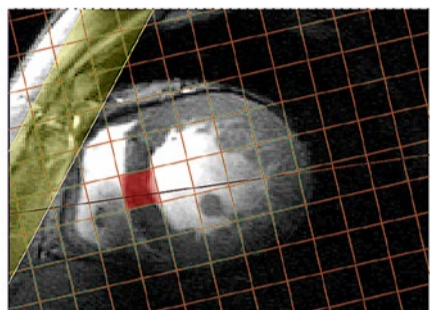
facilitate trials of new treatments such as new drugs, devices, or lifestyle modifications, because the imaging can detect smaller improvements or deteriorations in the heart's metabolic status than were previously visible.

'It ought to be possible to detect earlier improvement in response to treatment, and to quantify the relative merits of different treatments more accurately,' he said. 'We are also planning studies to understand the interplay between heart disease and disease in other organs, e.g.

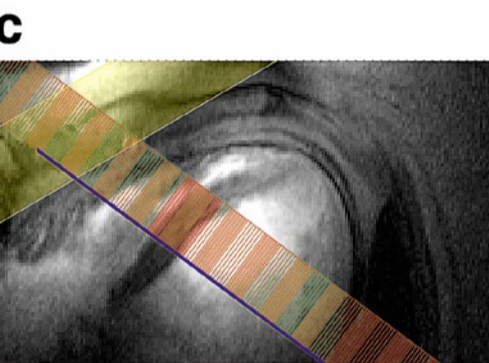
type II diabetes, or obesity.

'Having treatments that have been based on a more rigorous understanding of the heart's biochemistry will hopefully mean they will be more effective at treating heart disease.'

Research centres and teaching hospitals will also benefit, with the new approach helping improve understanding of the heart's metabolism in clinical studies.



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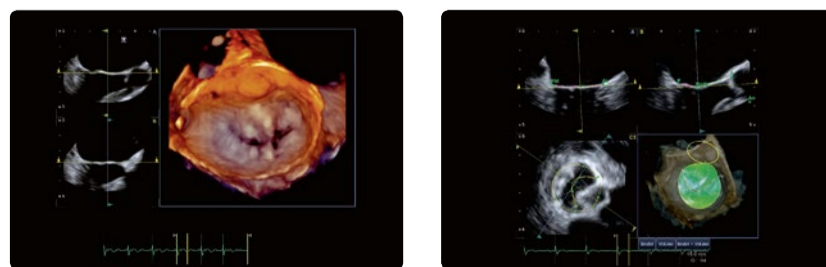


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Austrian Viktor Mayer-Schönberger, Professor of Internet Governance and Regulation at the Oxford Internet Institute, University of Oxford, England, founded Ikarus Software in 1986, which focuses on data security. Given his interest in 'big data', he researches the role of information in a networked economy. He has authored numerous articles and seven books including 'Delete: The Virtue of Forgetting in the Digital Age'.



Big Data: A Revolution That Will Transform How We Live, Work, and Think by Viktor Mayer-Schönberger and Kenneth Cukier; Published by Hodder & Stoughton, UK 2013; Price 7,99 Euro. ISBN: 9781848547926



The 2016 British Cardiovascular Society conference

# Prediction and prevention

Big data, the genetic basis of coronary artery disease and sudden cardiac death in the young were among key subjects for British cardiologists at their 2016 annual conference, Mark Nicholls reports

Within the theme 'Prediction and Prevention', the 2016 British Cardiovascular Society annual conference held in Manchester this June, featured innovative and interactive presentations, sessions, workshops, panel discussions, debate and a fas-

inating scientific programme.

The keynote speech, 'Big data: a big deal for cardiology?' delivered by Professor Viktor Mayer-Schoenberger, Professor of Internet Governance and Regulation at Oxford University's Internet Institute,

focused on the role of information in a networked economy.

The BCS Lecture 'Elucidating the genetic basis of coronary artery disease; implications for prediction, prevention and treatment' was delivered by Professor Sir Nilesh Samani, British Heart Foundation (BHF) Chair of Cardiology at Leicester University, who was knighted in 2015 for his services to medicine and medical research.

Professor Cliff Garratt, Chair of the Programme Committee and BCS Vice-President (Education & Research): 'Over the last few years, Professor Samani's group has led large-scale studies that have identified multiple genetic loci that affect risk of coronary artery disease. This presentation will present the current state of the discovery process, discuss what we have learned and illustrate the clinical translation potential of the findings.'

Prediction and prevention in acute coronary syndromes, the title of the BHF Bench-to-Bedside session - consisting of presentations (basic, translational or clinical) focused on a particular clinical condition - focused on the work of the BHF Centre for Cardiovascular Science at the University of Edinburgh.

'Over the last 30 years, this Edinburgh unit has led the way in describing new underlying causes of coronary heart disease, improving the identification of those at greatest risk, and ultimately demonstrating several innovative ways to treat coronary heart disease,' explained Professor Garratt.

The Sir Thomas Lewis Lecture saw Professor Michael Ackerman from the Mayo Clinic focus on prediction and prevention of sudden cardiac death in the young, while clinical anatomist, author and broadcaster Professor Alice Roberts discussed what embryology of the heart and other organs has taught us about our evolutionary origins.

In recent years, the BCS conference has gained recognition for offering 'something completely different' and, following on from the year's well-received presentation on Music and the Cardiovascular System, the focus for the popular Tuesday afternoon Auditorium session was Photography and the Heart. The conference also provided coverage of all the new developments in cardiology and cardiovascular science in training, a dedicated imaging track, arrhythmias with sessions on AF ablation and on first-line management of cardiac arrhythmias; intervention with sessions on acute coronary syndromes, myocardial infarction and percutaneous management of structural heart disease; heart failure; and adult congenital heart disease.

Sessions also included clinical science and translational research, basic science and hot topics, the Young Investigator's Prize, resuscitation, education for revalidation (E4R) and international sessions in association with the European Society of Cardiology and the American College of Cardiology.

An area for interactive education included 100+ Hot Topic sessions,



Cliff Garratt is Professor of Cardiology at the Institute of Cardiovascular Sciences, Professor of Cardiology at Manchester University and Hon. Consultant Cardiologist at Central Manchester University Foundation Trust. A clinical academic with an interest in arrhythmias and clinical cardiac electrophysiology, his research and clinical interests focus on the mechanisms and management of atrial fibrillation and familial sudden cardiac death syndromes.

poster sessions, simulator training, and an imaging Village with interactive, supervised CT, MRI, echo and nuclear imaging work-stations.

Garratt said the conference, again held with the British Heart Foundation, has attracted progressively increasing numbers of delegates over recent years. 'There is little doubt that there's an increasing - rather than decreasing - need for today's cardiologists to have a broad understanding of all the major subspecialist areas. The British Cardiovascular Society Annual Conference is uniquely positioned to facilitate this in one meeting.'

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#### SEARCH



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Smaller and more effective insertable cardiac monitors

## Device sensitivity and versatility increase

Remote monitoring through smaller, more effective, insertable cardiac monitors is playing a significant role in delivering care improvements for heart patients.

Greater sensitivity and versatility of devices, as well as more patient-friendly implantation options, were issues outlined at the CardioStim 2016 EHRA Europace world congress on cardiac electrophysiology, held in Nice, France.

The 'Improving Patient Outcomes in Arrhythmia Management' scientific session focused on Biotronik Home Monitoring systems, during which experts from Australia, Switzerland and the USA discussed the latest research on how remote monitoring systems and insertable cardiac monitors (ICMs) can improve patient outcomes.

In highlighting the rising importance of using remote monitoring via ICMs to enable earlier diagnosis and prevention in patients who have arrhythmias (but are not yet indicated for a pacemaker or ICD), the senior cardiologists also outlined how home monitoring is reducing mortality, hospitalisation and healthcare costs.

During the congress, Berlin-based cardio and endovascular medical technology specialist Biotronik also unveiled findings of the first-in-human trials of its new BioMonitor 2 ICM device to delegates with

experts. Covering 30 patients, this pilot study revealed high R-wave amplitudes and a 93.8 percent success rate for daily home monitoring transmissions from a device that can be inserted in as little as two minutes.

'For ICMs to have a significant impact on early arrhythmia diagnosis, reliable detection including sensing, data quality and transmission

is critical,' lead investigator Dr Sze-Yuan Ooi, from Sydney, explained. 'This study shows promising results for BioMonitor 2 in all of these fields. The high transmission success rate is key because we need robust, high-integrity data for our patients to derive the maximum benefit.'

BioMonitor 2 has an extended sensing vector with the combination of the rigid (55mm long) and flexible (33mm) part allowing adjustment to the shape of the body.

Sensitive to changes in heart rhythm with the automated detection of atrial fibrillation, bradycardia, sudden rate drop or high ventricular rate, this device can make up to six ECG transmissions a day.

Ooi described the BioMonitor 2 as a 'big step forward' in terms of technology, design and implantation technique, compared to the first generation Biotronik Biomonitor device.

'The pilot study showed that the R-wave amplitude is greater than the original Biomonitor device, the implantation process was easy, straightforward and quick and the other important finding out of all this was the





More at risk patients will become candidates for LAA closure

# Device trial could benefit stroke patients

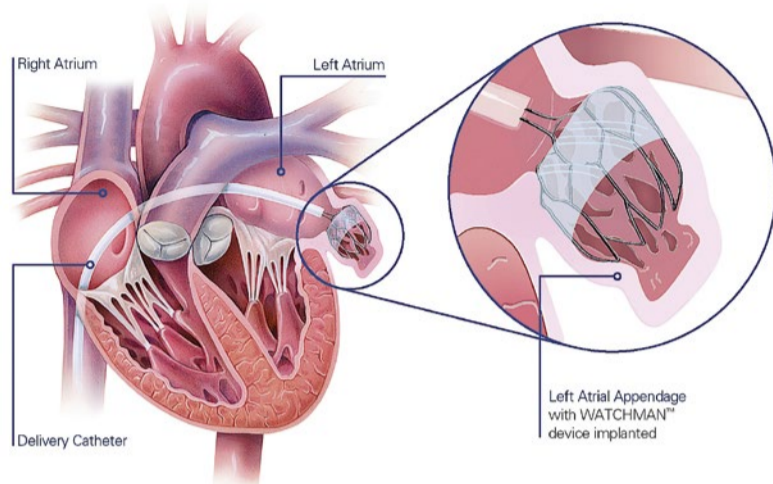
In the fast-evolving field of left atrial appendage closure a new study has delivered data that could benefit thousands of patients at risk of stroke. Led by Professor Martin Bergmann, head of Interventional Cardiology at Cardiologikum Hamburg in Germany, the EWOLUTION study was conducted to evaluate the Watchman Left Atrial Appendage (LAA) closure device from manufacturer Boston Scientific.

'The LAA field is evolving very quickly for stroke protection, mainly in the elderly,' Professor Bergmann explained. 'Anti-coagulants are a great step forward yet have left many patients with bleeding complications, so these drugs are not the solution for all patients.'

The LAA is believed to be the source of more than 90% of stroke-causing clots that come from the left atrium in people with non-valvular atrial fibrillation.

In recent years LAA closure has been seen as an alternative, though progress has been held back because of hesitancy among GPs, neurologists and non-interventional cardiologists to refer patients for the procedure because there was no clear data on success rates.

However, the recently published three-month results from the EWOLUTION registry found that LAA closure with the Boston Scientific Watchman device has a



LAA with WATCHMAN device

high success rate in complete LAA closure with low peri-procedural risk. 'We can now say that, irrespective of post procedural drug regimen, the risk of thrombus on the device is quite low, even in patients that have not received any oral anticoagulation because of their bleeding risk,' Bergmann confirmed.

The success of the trial, he added, will see more patients becoming candidates for LAA closure.

In Europe, two LAA closure devices are currently available - each with a different approach - but Bergmann said the Watchman device - which is anchored in the distal part of the LAA and closes LAA right at the entrance leaving the ridge to the pulmonary vein free - is the only one now underpinned by prospective data.

Watchman is a catheter-delivered heart implant designed to close the left atrial appendage to prevent the migration of blood clots from the

LAA, and thus, reduce the incidence of stroke and systemic embolism for higher risk patients with non-valvular AF.

Many patients are still being denied anticoagulation, he pointed out, because there are compliance issues, leaving them with a high stroke risk. However, he added: 'Ewolution should pave the way in Europe to solidly establish LAA closure in routine practice as one of the options that is available.'

Dual antiplatelet therapy (DAPT) following the implant also appears to be safe.

Data from the prospective multi-centre registry show that the implant procedure was successful in 98.5% of cases; 99% of implanted devices presented no or minimal peri-device leakage at the first follow-up, assessed by peri-procedural trans oesophageal echocardiogram (TEE); device or procedure related serious adverse events (SAE) rates at

92 days were similar if patients were treated with warfarin or DAPT; rates for bleeding SAE were also similar if warfarin or DAPT was used post-implantation (4.8% vs. 3.6%, respectively).

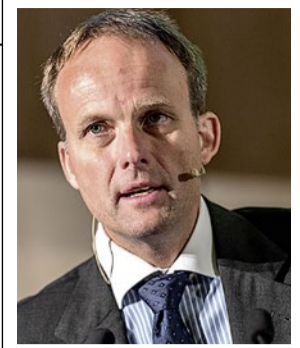
Following Watchman implantation, Bergmann added, 6% of patients received no anticoagulation, 27% received oral anticoagulation (16% warfarin and 11% novel oral anticoagulants - NOACs), 60% received dual antiplatelet therapy (DAPT) and 7% of patients were on single antiplatelet therapy.

Stroke (0.4%) and bleeding (4.1%) rates were low overall and did not vary by post-implantation medication.

The study, the professor said, is a significant step forward in the treatment of such patients and in the field of stroke prevention. 'We especially see the procedure being adapted in rising numbers in the interventional field because we see a lot of patients who have no indication for pulmonary vein isolation but have a problem with stroke prevention based on atrial fibrillation.'

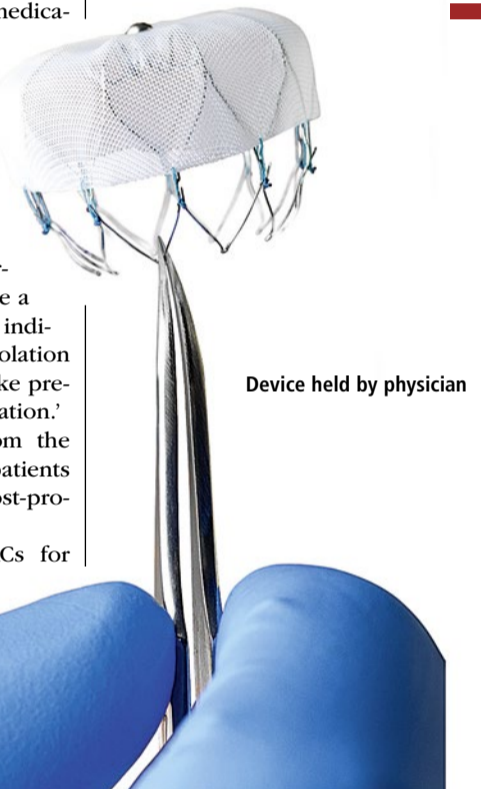
One factor to emerge from the trial was with the 11% of patients treated with NOACs, who post-procedurally had the best data.

'To be able to use NOACs for this therapy, which has the advantage of very short



An interventional cardiologist, **Professor Martin Bergmann MD** heads Interventional Cardiology at Cardiologikum Hamburg in Germany, a high volume PCI centre. His focus is on structural heart work including TAVI, mitral clip, LAA, PFO and ASD procedures. More than 1,000 patients are part of the EWOLUTION registry across 45 centres.

half-life,' Bergmann added, 'means that it may be even better than dual anti-platelet therapy, but this is something we will have to test in randomised trial or larger numbers.'



Device held by physician



**Sze-Yuan Ooi MD** is a coronary interventionist and cardiac device implanter at the Eastern Heart Clinic and Prince of Wales Hospital in Sydney, Australia. His research interests include new coronary stents and implantable device technology, coronary inflammation, coronary physiology and pressure wire technology.

transmission success rate of 93.8pc, which is really exceptional.

'Biotronik has invested heavily over the years in its Home Monitoring System and that is borne out in this trial. The most important aspect with the devices is the ability to make a diagnosis, that comes first and foremost, as well as the implantation procedure being not too invasive,' Ooi pointed out.

Biotronik Home Monitoring transmits patient heart data automatically on a daily basis, rapidly detecting deterioration in a patient's clinical status.

Early detection of clinically relevant events, in particular paroxysmal and asymptomatic arrhythmias, such as atrial fibrillation, enables the physician to adapt patient therapy at a very early stage.

Continued on page 8

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The dedicated stroke session at ESC 2016

# Imaging in intra-arterial interventions

ESC session highlights the cardiologist's role in stroke treatment and how imaging techniques can help them to carry out catheter based IA interventions correctly.

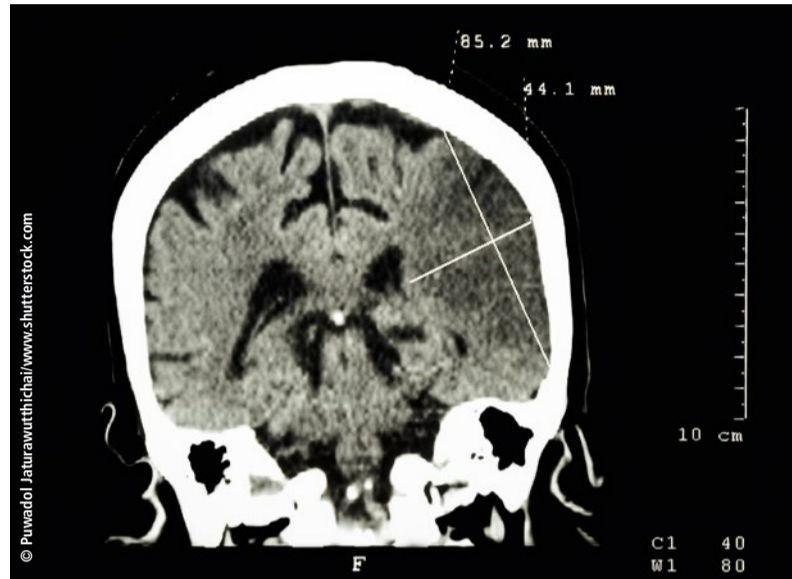
Report: Melisande Rouger

Stroke patients will first undergo a CT scan as they enter the hospital. Before any further imaging scan is carried out, the medical team must decide whether they need to intervene intra or extra cranially. 'Imaging enables you to see which pathology you are dealing with and helps you select patients for either recanalisation or revascularisation or, in some cases, occlusion by embolisation,' according to Dr Andreas Schwartz, Director of the Neurological Department of Hannover Hospital.

The cause of stroke can often be found in the vessel, intimal flaps, or inflammation of the endothelium – and atheroma or plaque intersection in the vessel wall can also trigger an event. Calcification, aneurysm or the presence of a tumour around the vessel could also lead to an arterio-embolic event.

Ultrasound is the best modality to detect defects in the vessel-lumen itself, in particular a moving intimal flap, according to Schwartz. 'You have to see moving pictures in this case, and US will help you better than any other modalities,' he believes. Alternatively, one can use digital angiography by injecting a contrast product in the catheter.

Endothelium inflammation is also best identified with ultrasound, because it enables measurement of the endothelium thickness. The alternatives are high-resolution 3-T MRI and cross sectional imaging. MRI and cross sectional imaging are also good to find out whether the problem is intramural, or if it is caused by the presence of atheroma in the vessel wall. 'If you just do conventional CTA you won't find all these pathologies,' Schwartz under-



Cerebral infarction at left hemisphere (CT-scan)

lines. 'Ultrasound is a prerequisite in stroke units all around Europe.'

Because ultrasound is easily movable around the hospital, all patients will undergo an ultrasound scan of the head and neck vessels within 24 hours of their arrival if CT shows no bleeding.

CTA or MRA will be preferred in plaque pathology imaging. To visualise plaque dissection, it is best to carry out a special type of MRI in a cross sectional mode. '3-D reconstruction doesn't tell you anything, you need cross sectional imaging to know what is in the vessel wall because you wouldn't see it in the angiography scan. You would fail in finding the dissection type,' he explained.

However an angiogram, CTA or MRA scan combined with 3-D reconstruction will help locate a tumour if it is compressing vessels.

For intracranial treatment, everything depends on whether one

looks at the anterior or posterior part of the circulation. 'If you are in the posterior part of the circulation of the brain vertebral artery, or basilar artery, you depend on the intra-arterial angiogram. CTA or MRA will not help, you will need to perform an angiogram by catheter, an invasive method. But in the anterior part of the circulation, you can use the angiogram with MRI or CT,' he explained.

Only a neuroradiologist will be able to conduct intracranial examinations, and it is recommended to have both a neurologist and an interventional neuroradiologist perform revascularisation, recanalisation and embolisation in a stroke unit. However, only large hospitals can afford such specialists and, at the moment, they are fairly rare across Europe. Germany has about 160 stroke units but not the same number of neuro interventionists, said Schwartz, who has worked on



Andreas Schwartz is Director of the Neurological Department of Hannover Hospital and Associate Professor of Neurology at Heidelberg University in Germany. His main research interests are cerebrovascular diseases, neuroradiology with special interest in MR and angiography, multiple sclerosis and Parkinson's disease. He has over 180 publications in international journals and is a full member of a number of national and international societies (ENS, AAN, RSNA, ANSR, ESNR) in the neurological field. Since 1996, he has also served as a regional representative of the German Stroke Foundation.

certifying stroke units in Europe as part of his long-term involvement with the German Society of Neuroradiology.

Cardiologists, who have performed thrombolysis in coronary heart disease since the 1970s, are the most suited professionals to carry out extra cranial investigations when no other specialist is available, he believes. 'There are not enough neuro interventionists around. That's why cardiologists have performed stenting and carotid endarterectomy for so many years. They can and should do it, but only in small hospitals, and they need imaging to do so,' he said.

Sending an interventional radiologist to stroke units when needed could be another solution, but equipment would remain a problem, because not every hospital has all the necessary machines and catheters. 'That would be a problem. I don't think it could work as a long-term solution,' he said.

Expertise should come first and before turf battles between medical disciplines. 'In the end it all comes down to this: You have to choose the professional with the most experience,' he concluded.

# Advancing cardiac dysfunction

Cardiologists have highlighted the importance of echocardiography and cardiac CT – to evaluate the impact of recommendations.

Report: Mark Nicholls

An innovative cardiac monitoring system that delivers continuous resynchronisation to patients, has shown a 35% risk reduction of hospitalisation for heart failure (HF) patients.

The finding comes from the RESPOND-CRT (cardiac resynchronisation therapy) clinical trial, which was designed to investigate the clinical efficacy and safety of device-based optimisation using the SonR cardiac contractility sensor in patients with advanced heart failure.

The proprietary SonR sensor from global medical technology and innovation company LivaNova delivers individualised therapy to heart patients by allowing for cardiac resynchronisation to be continuously adapted to the individual's needs.

The trial, led by renowned cardiologists Professor Josep Brugada and Dr Jagmeet Singh, compared optimisation with SonR to optimisation using echocardiography – widely considered to be the gold standard approach. Speaking at the CardioStim 2016 EHRA Europace world congress on cardiac electrophysiology, held in Nice, France, Professor Brugada said the overall positive response to CRT reached in



Dr Jagmeet Singh from Massachusetts General Hospital, Boston, is the Associate Chief of the Cardiology Division and Professor of Medicine at Harvard Medical School. He is the Founding Director of the Resynchronisation and Advanced Cardiac Therapeutics Programme.

Mobile digital X-ray units for hospitals and more...

# Wireless radiography on the move

With clients worldwide, the 20-year-old imaging and digital radiography solutions firm medical ECONET provides mobile radiography systems to hospitals, ambulance and mobile home care services, military clinics in conflict zones, as well as medical facilities on sea-going vessels.

With clients worldwide, the 20-year-old imaging and digital radiography solutions firm medical ECONET provides mobile radiography systems to hospitals, ambulance and mobile

home care services, military clinics in conflict zones, as well as medical facilities on sea-going vessels.

To that end, the firm's radiography solutions are equipped with a unique hybrid-powered technology.

The firm describes its mobile X-ray system POX-100BT as 'an ideological designed foldable device, which allows the user to work completely without any cables and without dependence to electricity due to its integrated high-performance Lithium-ion battery. With one full charge it is possible to make up to 1,000 images, which allows a complete unrestricted workflow in many different scenarios without any external power source.'

'The POX-100BT is highest mobility due to lightweight carrying bag for DR system

quickly installable and smooth to move, due to the big inflated wheels. The power output of 5 kW enables examinations of all human body parts without limitations.'

The firm's wireless Digital Radiography (DR) detector meX+1417WCC has an imaging size of 36 x 43cm, beneficial when mobile.

'Due to the wireless file transfer and automatic exposure detection (AED) of the detector, the user can work in a most comfortable way without any disturbing cables. With only 3kg weight, the flat panel is very easy to handle and provides brilliant image quality within few seconds after the exposure. The equipped meX+ Image Acquisition Software allows the optimisation and full diagnosis of images and external provision by patient CD, e-mail or teleradiography.'

The best image results are achieved by combining a UHD resolution notebook, the device manufacturer advises.

Device sensitivity an

Continued f





Continuous cardiac resynchronisation reduces hospitalisation

# ng AF and renal ion care

ce of all imaging modalities – including  
ate prosthetic heart valves in a new series



**Professor Josep Brugada** is medical director of the Cardiovascular Institute, at Hospital Clinic, University of Barcelona, Spain, and a past president of the European Heart Rhythm Society. With his brothers, Pedro and Ramon, he identified Brugada Syndrome, a genetic disease characterised by abnormal electrocardiogram (ECG) findings and an increased risk of sudden cardiac death.

history of AF and renal dysfunction, and optimisation, using the SonR contractility sensor, showed significant reduction of 35% in rates of heart failure hospitalisation during long-term follow up.'

Implanted cardiac resynchronisation devices resynchronise the contractions of the ventricles of the heart by sending tiny electrical impulses to the heart muscle, helping the

heart to pump blood more efficiently throughout the body. The SonR sensor uses measurements of cardiac contractility to optimise cardiac resynchronisation therapy.

Singh, from Massachusetts General Hospital, Boston, explained that although echo-guided optimisation was considered the gold standard in terms of reducing the number of non-responders to CRT, it was not widely used because of the commitment of time and resources it requires, as well as patients needing to attend the clinic. He added that

the SonR can optimise AV and VV intervals on a daily basis and on weekly basis for both rest as well as for exercise so patient do not have to come into the clinic or have echo guided optimisation.

'The device using the sensors can automatically optimise the heart, overcoming the inadequacies of existing optimisation strategies and logistical issues with echo-guided optimisation strategies.'

Respond-CRT was a prospective, multicentre, randomised, double-blind study designed to evaluate

the safety and efficacy of the SonR system. 1,039 patients were enrolled at 125 sites in Europe, the USA and Australia, who were implanted with a CRT-D (cardiac resynchronisation therapy and defibrillation) device, which combines the function of an implantable cardiac defibrillator (ICD) with cardiac resynchronisation therapy (CRT).

Patients were randomised 2:1 to receive either AV or VV optimisation with SonR or echocardiography, with the study meeting all of its primary safety and efficacy end points. ■

the group of patients treated with SonR was 75%, compared to 70.4% in the echo group. It also emerged that optimisation with SonR resulted in a significant improvement in clinical response for patients with atrial fibrillation and renal dysfunction.

Professor Brugada from the Cardiovascular Institute, Hospital Clinic, University of Barcelona, said: 'In order to deliver the very best CRT treatment to our heart failure patients, there has been a real need for an optimisation solution that is both automatic and efficient.'

'The results of the RESPOND-CRT trial have shown that SonR perfectly meets this need. The high rates of responders together with the beneficial improvements in clinical outcomes indicate a significant advancement in CRT therapy, one that will allow us to better treat a larger number of heart failure patients.'

'Automatic optimisation with SonR was as effective as echo-guided optimisation - 75% v 70.4% - so the primary efficacy end point was met, that a clinical response was in favour of SonR but especially patients with

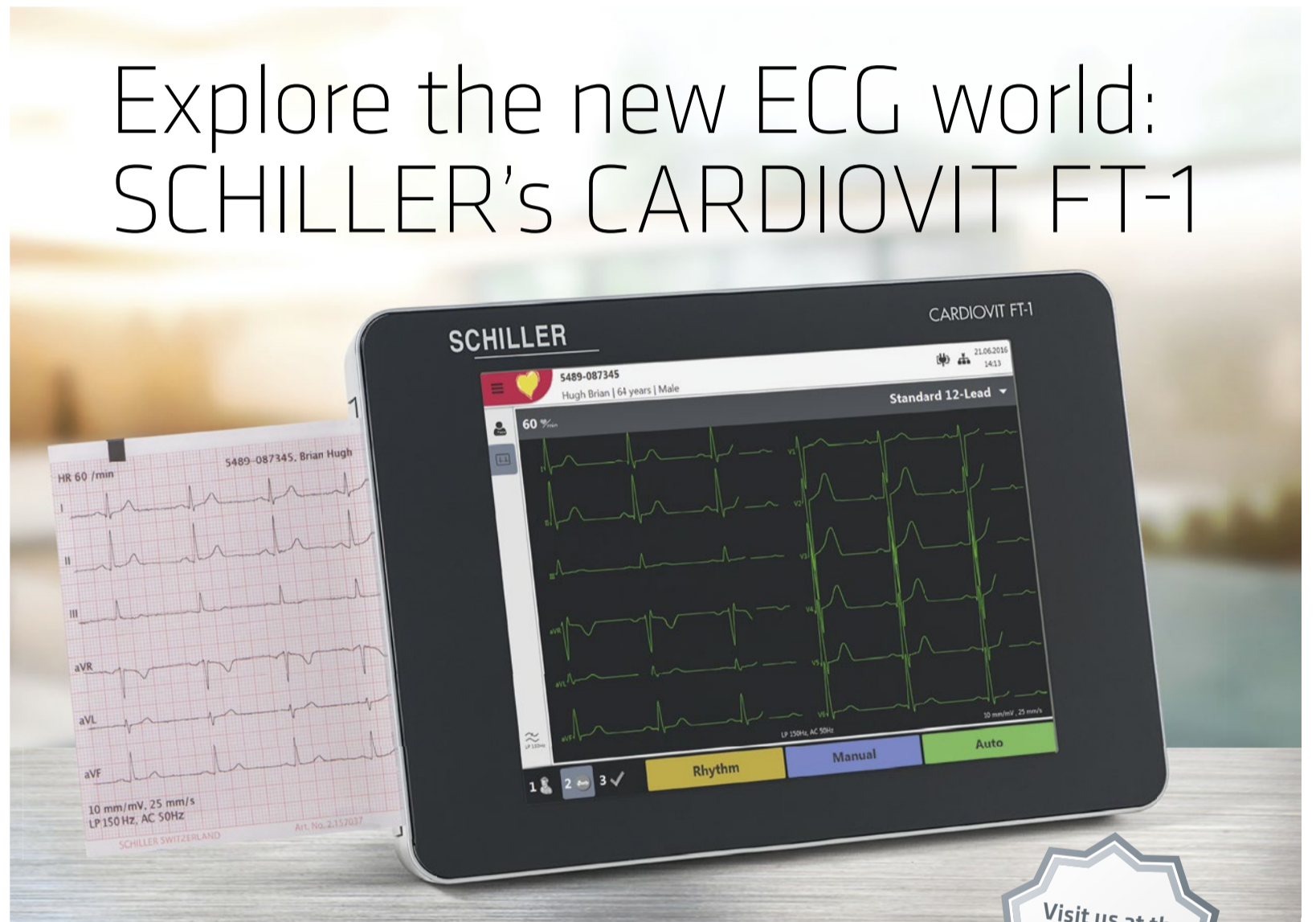
and versatility increase

from page 6

Hospital Zurich, who discussed how earlier management of atrial and ventricular arrhythmias is enabled by detection with ICMs, and Dr Niraj Varma, from the Cleveland Clinic, who spoke about improving outcome of ICD and CRT-D patients by continuous remote monitoring.

'Efficient workflow and robust transmissions are critical to leveraging the benefits of remote monitoring,' Varma said. Biotronik Home Monitoring facilitates this with daily automatic transmissions that preserve the highest order of data integrity, and are yet easy to handle.

'This is a key reason why this system has been associated with improved clinical outcomes in several trials and why the current remote monitoring guidelines are based largely on Home Monitoring data,' Varma explained. ■



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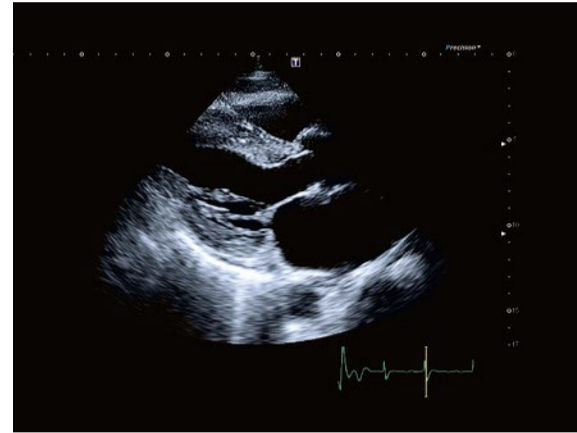
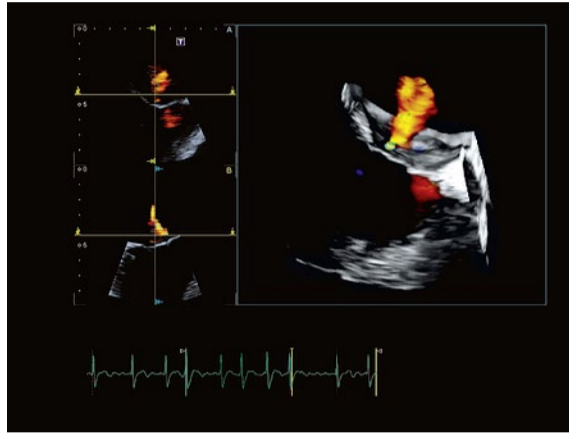
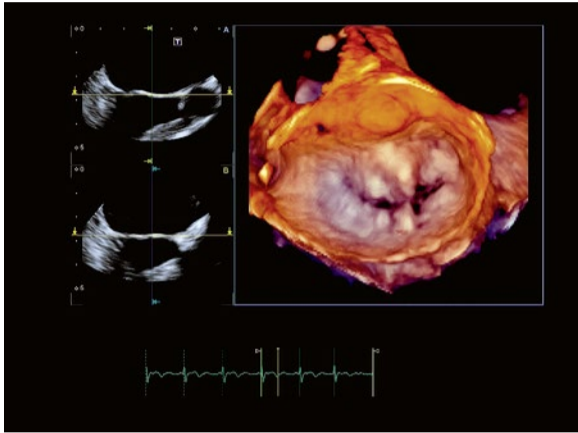


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'This is the future'. Medical scientists endorse a new platform

# Toshiba beams in on cardiology ultrasound



**Live 4-D imaging:** The new ultra wideband transducers have a wide coverage and an extremely good penetration up to 28 centimetres. An area of just one square centimetre can be seen and clearly defined

**Next-generation Aplio i-series premium platform delivers high-frequency probes, advanced applications and ultra-fast processing**

To sharply focus on the specialised requirements in echocardiography, Toshiba engineers built from scratch the Aplio i900CV with a total redesign of hardware and software. The new Aplio i-series is a premium addition to the award-winning Aplio 500 platform, which today is used in more than 31,000 clinical settings worldwide.

'The system works very fast with a reduced requirement for user interaction, which translates into a significant time saving for the echocardiography lab,' according to the head of cardiovascular imaging at the Hospital Clinico San Carlos in Madrid, Spain, Professor Leopoldo Perez d'Isla MD.

The impressive speed of the new architecture and the resulting time savings, 'means that we are improving the cost-effectiveness of the echo-lab, avoiding patient discomfort caused by unnecessary waiting times and increasing opportunities for patient examinations'.

The Aplio i-series jumps ahead to a next generation with an architecture that gives it on-board capabilities for ultra-fast processing of advance applications, and with a new range of high frequency and ultra-wideband transducers.

To maximise the potential of the new architecture, the Aplio i-series matrix transduc-

ers utilise a new lens material that effectively introduces a new technology. Thinner, lighter and with more flexible cables, a wide range of Aplio's i-series transducers feature the Intelligent Dynamic Micro Slicing (iDMS) capability.

New with the Aplio i900CV is a 3-D transoesophageal echocardiography (TEE) transducer that 'is exactly the tool we need,' according to Professor Hans-Joachim Nesser MD. The Head of the Cardiology, Angiology, Medical Intensive Care for the 2nd Internal Department at the Elisabethinen Hospital in Linz, Austria, stated, 'We have long wanted this, and here it is bringing the possibility to view aortic leaflets, or to measure mitral valve parameters where we can not only see the opening, but can even see the stitches where the valve has been repaired.'

Yet, thanks to the new ultra wideband transducers, a TEE exam is not always required. Nesser found that, with the wider coverage and what he called extremely good penetration up to 28 centimetres, 'We can evaluate the aortic valve area with a transthoracic approach. We are able to see distinctly four-chamber views, and have found really fantastic resolution in subcostal views.'

Continuous wave Doppler on the i900CV has a quality not seen before that enables a fast, excellent quality of signal definition that allows an easy diagnosis to determine myocardial performance.

After working with Cardiovascular Imaging Fusion on the i900CV, Nesser concluded, 'This is the future.

In one display using a hybrid format we see calcified segments of coronary arteries derived from CT along with a quantification of the stenosis thanks to 3-D strain imaging, and at the same time a superimposition to the myocardium derived by CT. Using a very nice tool called Activation Imaging, we can add measurements to determine torsion, an important parameter for a variety of diseases, or see areas where there is delayed contraction. We can see rest and stress, related to a specific coronary artery as a superimposition on a CT image, enabling us to make a decision as to intervention.'

Aplio i-series processors are so fast that the system boots up in 15 seconds. Aplio i-series platforms are 30% lighter with a panel streamlined by a reduction of 50% for buttons and controls.

The panel arm supports a 23-inch high-definition display and is so flexible it can fold flat for easier, more convenient handling. And the Aplio i-series platforms come with an optional second console, a detachable wireless tablet that displays real-time images and can control all operations.

The Aplio i-series rolls out in three versions where the Aplio i700 is designed as a multi-service platform across diverse medical specialties, and the Aplio i800 responds to the more exacting requirements of radiology and women's health departments.

Yet it is the advanced features and functionalities of the Aplio i900CV that are specifically designed to target specialised examinations and

interventions in cardiology.

At the heart of an enhanced image quality that was described as 'stunning' by clinicians is the iBeam technology. Electrical dynamic focus with individual matrix element control and multiplexing with ultra-fast processing narrows and sharpens the signal for real-time 3-D beam forming.

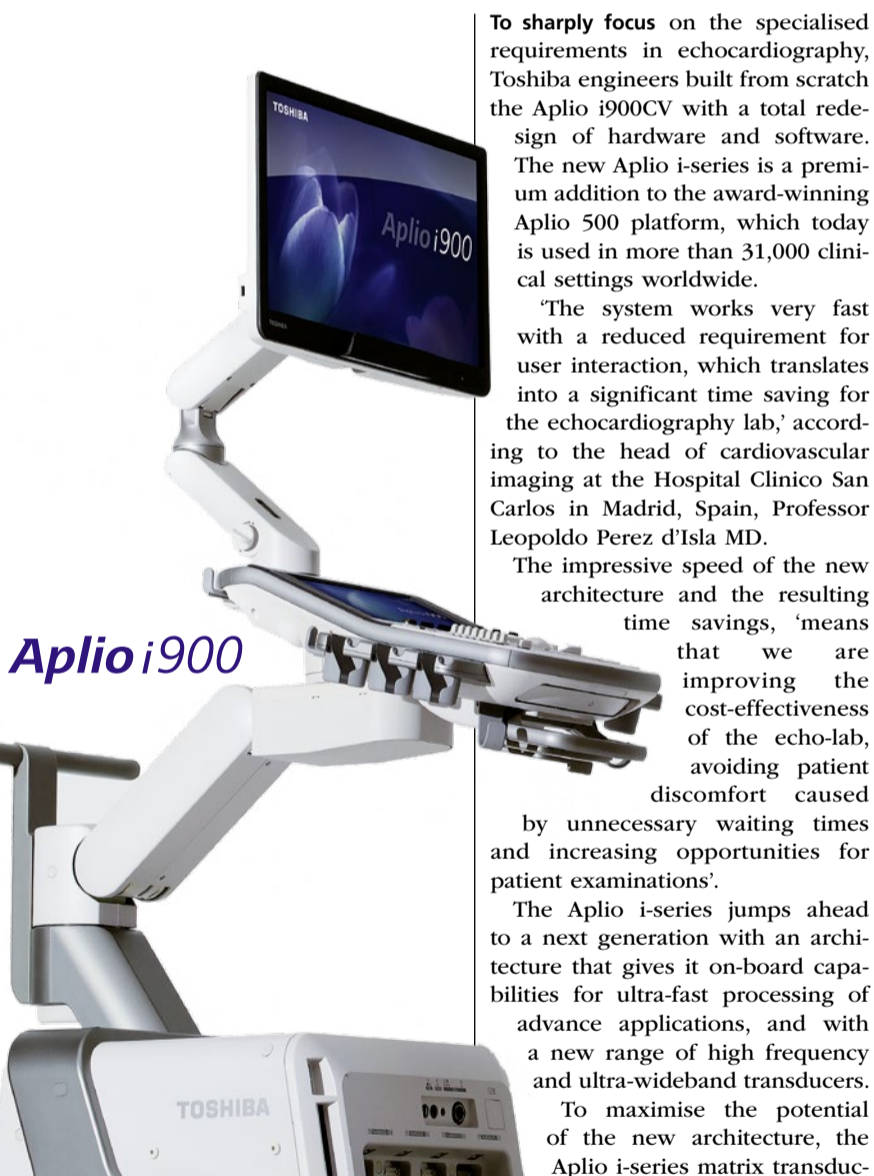
The advanced architecture in the Aplio i-series takes pioneering Toshiba ultrasound functions to a new level.

- **Advanced Superb Micro-Vascular Imaging (SMI)** combined with the new transducers becomes more brilliant with reduced motion artefacts, for never-seen perfusion examination capabilities across all regions of human anatomy.

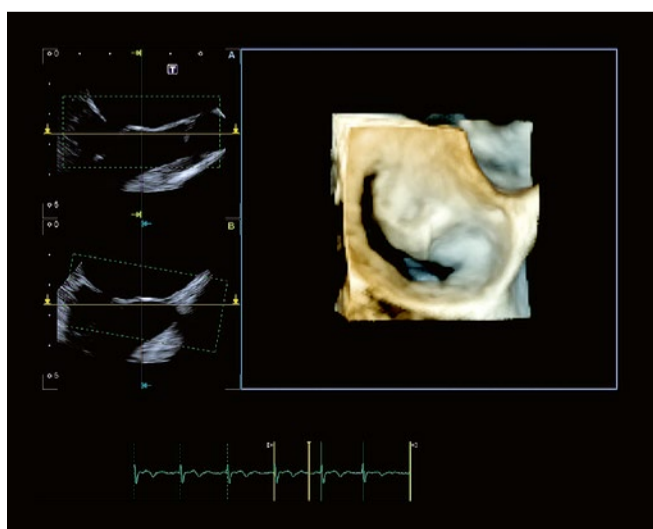
- **Quad Fusion capability** creates impactful viewing for interventional procedures or advanced diagnostics, with a simultaneous combination of CT/MRI images with real-time ultrasound and 3-D ultrasound rendering of a live procedure.

- **Super precise 3-D imaging** is boosted by Aplio i-series iBeam and thin slice acquisition to render near-photo quality images of anatomical structures.

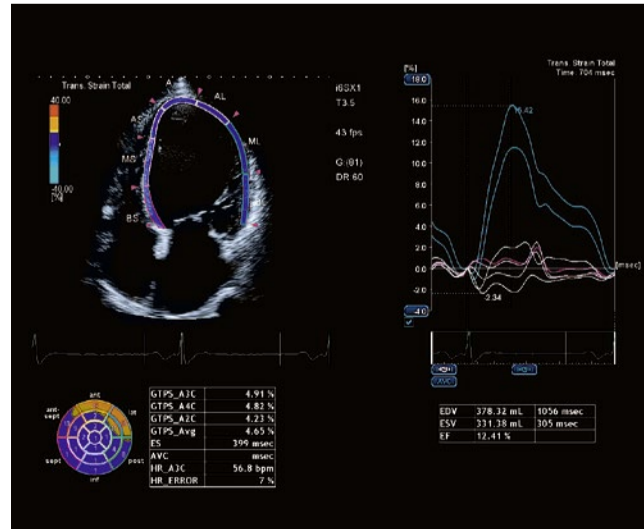
Professor Adrian Lim MD, from Imperial College London said that, beyond the obvious improvements in ergonomics and speed with the Aplio i-series platform, for users of previous models of Toshiba ultrasound systems, 'there is a very familiar workflow such that everything becomes intuitive the moment you step to the console.'



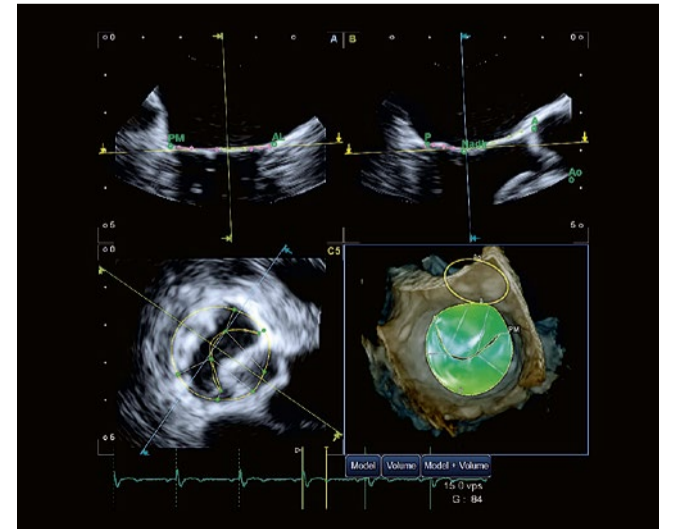
**Aplio i900**



At a simple touch of a button, Aplio demonstrates the mitral valve as seen by the surgeon to facilitate visual assessment of the leaflets for better surgical planning



Aplio's advanced Wall Motion Tracking technology provides immediate visual and quantitative access to global and regional myocardial wall motion dynamics in 2-D and 3-D



The automated MVA tool provides concise anatomic and functional assessment of the mitral valve. The function's quad display offers a clear overview of different scan planes



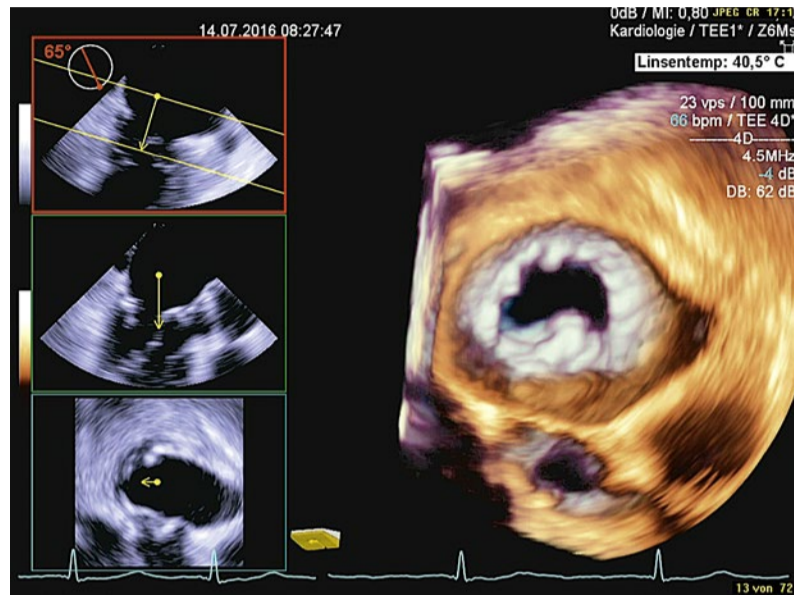
User reports on working with new Siemens equipment

# 3-D transducers prove their mettle in cardiology

One of the first facilities to purchase a complete set of the 3-D TEE transducer, including the equipment, was the Department of Cardiology and Angiology at University Hospital Magdeburg, as Thomas Groscheck, specialist physician for internal medicine at the echocardiography lab explains. Since July 2015 he has worked with the new Siemens transducer – and is enthusiastic.

'In our department we treat all types of cardio-vascular disease, from cardiac insufficiency to hypertension, valve repair and aortic valve replacement,' Thomas Groscheck explains. 'We perform all necessary studies prior to an intervention and do the follow-up for all cardiac patients, particularly those who underwent valve surgery or received a valve replacement.' This is where the 3-D TEE transducer comes in very handy.

'What's so special about this 3-D probe is that it is fast and offers high volume', the specialist explains. This allows live images with a high frame rate, particularly in 3-D, which is very interesting during valve interventions. 'I found the hardware and the software in the equipment to be very fast. Thus you get high temporal and spatial



The 3-D TEE transducer is fast and offers high volume

resolution with regard to valve visualisation in 3-D. This translates into much better quality than our previous transducers delivered.'

## Length of examination

In terms of time spent on examinations the new tool also offers benefits. 'The prep examination for a valve intervention takes ten minutes on average,' according to Mr Groscheck. 'Image acquisition and patient handling pre- and post-exam take about twenty minutes. After

that time all images are available, including the valve models.' Data acquisition is fast and the analysis can be speeded up when all tools for automatic valve assessment are used. The raw data that are generated and which, theoretically, can be read by any machine, are turned into DICOM images, which in turn can be viewed with any DICOM viewer.'

## Handling

Transducer handling has been

improved. With its plastic grip it is lighter than metal models. 'This makes the transducer easy to handle,' the physician reports. 'Nevertheless it takes some to get used to the new probe. The head is a bit more angular, not quite as round as we were used to. The location of the function buttons and the two knobs to control transducer head movement could be improved ergonomically. The control elements are no longer centred, which means the probe has to be held in a certain way in order to use it in an optimum way.' However, these are the only handling issues Thomas Groscheck encountered with the new transducers.

## Temperature advantages

There is one feature Groscheck is particularly enthusiastic about: 'With this transducer, temperature issues are a thing of the past. Finally! Although the device does have a cooling mode with reduced transmission performance, I have never been compelled to use it. Despite the fact that in 3-D mode the transducer heats up to about 40 °C, I always could easily complete longer sequences.' Thus interruptions due to overheating – a common problem in longer examinations with high sound intensity, particularly in 3-D – are no longer required. 'In



Thomas Groscheck is an internal medicine specialist in the echocardiography lab in the Cardiology and Angiology Department, University Hospital Magdeburg. Following his initial training as a nurse he attended medical school at Charité – University Hospital Berlin. He is currently completing his doctorate.

3-D mode, the 3-D TEE transducer works for minutes without any temperature problems. That makes life much easier for patient and physician alike. Obviously, patient safety has been considerably improved with this device,' Groscheck points out.

## Hand in glove

The overall interaction of all elements and components of the new transducer convinced the expert. 'With a bit of training using the transducer is no problem. Transducer, software, and processing programmes for the valve models – they are all well aligned and integrate easily in any daily workflows. Even though the device with all its functions and settings might seem a bit technologically intimidating at first, actually using it is a real pleasure particularly because it works without a hitch and the individual components work hand in glove,' Groscheck sums up. ■

55% of heart recipients now survive for 10 years

## Transplants – a much neglected topic

A small report in the press prompted examination of a much neglected topic. The report read 'Heart Centre at University Hospital no longer carries out transplants', and referred to the University Hospital Frankfurt, one of the 22 Heart Centres that perform these transplantations.

So what happened? Only four transplants were carried out there between 2010 and 2013, and in 2014 and 2015 only two to three were performed per year. Why? The same report also mentioned that around thirty patients per year wait for donor hearts at this hospital. Donor hearts continue to be in short supply, and organ donation is the problem.

There have been no improvements in that situation, not only in Frankfurt, or all of Germany, but also across Europe and globally. The ratio between those who received donor hearts and those waiting for donor hearts is increasingly unfavourable. Figures from Switzerland show an 'average' European example: When 33 people received donor hearts in 2005 not even double that number, i.e. 63, were waiting for donor hearts at the time. Ten years later, in 2015, the number of transplants 'only' increased to 40, whilst the number of patients on the waitlist increased to 134.

In Germany, says Professor F W Mohr, president of the German Society for Thoracic and Cardiovascular Surgery, more than 1,000 patients are currently

waiting for donor hearts. However, only 320 hearts were actually transplanted. 'The average patient has very little chance of receiving a donor heart. The organs donated are only allocated to particularly urgent cases,' Mohr explains. At the beginning of the 1990s still more than 420 heart transplants a year were carried out.

The allocation of donor hearts in eight European countries (Germany, Belgium, Netherlands, Luxembourg, Austria, Slovenia, Hungary and Croatia) is coordinated by Eurotransplant based in Leiden, Netherlands. The allocation is based on medical criteria, with no consideration given to national or any other criteria. Eurotransplant works with a catchment area of 135 million people across Europe. There are similar organisations in Scandinavia, covering about 25 million people, or for Eastern Europe, along with the internationally active Society for Heart and Lung Transplantation based in Addison (Texas, USA).

A look at international figures and developments helps to better understand the situation. As is known, the first ever heart transplantation was carried out by Professor Christiaan Barnard and a 31-strong team in South Africa in 1967. The number of operations increased to 100 transplants (worldwide) in 1980 and to 4003 in 1990, with reported figures of 4203 in 1992, 4364 in 1993, 4429 in 1994 and 4396 in 1995. According

to the Society for Heart and Lung Transplantation, a total of 80,106 heart transplantations were carried out in 300 officially designated centres between 1967 and 2007.

From the mid-1990s the numbers decreased continuously to around 3,000 per year. Significantly better and more effective prophylaxis and major advances in treatment, along with the lack of donor organs, are considered the reasons for this decline.

In January 2016 more than 10,000 patients were waiting for donor hearts across the eight European countries coordinated by Eurotransplant. If it had not been for advances in treatment the number of those waiting for donor hearts would be much higher still, say the specialist medical societies.

However, documenting advantages and disadvantages with statistics does not do justice to the topic of heart transplantations.

The history of heart transplants is also one of particular success. As is known, the first person to receive a donor heart, transplanted by Prof. Christiaan Barnard in 1967, 'only' survived the operation for 18 days. In those days the prospects of a 'longer' life after the operation were also generally not particularly rosy.

However, over the course of the years and decades not only the surgical procedures and the expertise and routines improved but also the direct care and aftercare for patients.



Walter Depner, writer and consultant specialising in the laboratory field

One of the main problems was, and remains, rejection of the donor organ. Not least through the discovery and development of the immune suppressor Cyclosporine has it been possible to achieve major success in this field. This ring-shaped, small protein which consists of 11 amino acids was discovered by the Swiss biologist Hans Peter Frey in 1969 and was publicised in the 1970s. It then led to the development of other, very effective drugs.

It is assumed that the current, five-year survival rate is around seventy-five percent and the ten-year survival rate is still at around fifty-five percent

To conclude, there are three things we can hope for: Firstly, that the number of those requiring donor hearts will continue to fall due to improved medical knowledge and prophylaxis, along with healthier lifestyles in large parts of the population.

Secondly, that the number of organ donors increases rather than decreases, and lastly that the survival rate continues to increase closer towards the 100% mark through more experience, knowledge, routine and capabilities of the surgeons, along with advances in technology and aftercare. ■

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Break-through techniques tap software to reveal disease causes

# Exposing the secrets of the heart

Coronary interventions often rely more on art than science as the decision to treat a patient tends to be based on what clinicians can see, a subjective interpretation of cardiac imaging.

Two new techniques have emerged for cardiovascular diagnostics that are enabling software to help surgeons and cardiologists measure, and thereby better manage cardiac disease. Both rely on powerful computer processing to expose the secrets of the heart.

Bon-Kwon Koo MD, from the Seoul National University Hospital in South Korea, has successfully shown how building on technique recommended in cardiology guidelines, called fractional flow reserve (FFR), a retrospective computational analysis of CT exams can pinpoint the plaque rupture that, up to two years later, would cause a confirmed medical emergency for a patient.

The creator of the FFR technique, Nico Pijls MD, from the Catharina Hospital in Eindhoven, the Netherlands, has since developed a technique for the quantitative assessment of microcirculatory blood flow and resistance, the vital irrigation of heart muscle.

Without FFR, a cardiologist has to subjectively interpret fuzzy angiographic images to decide if the blockage is so severe it needs a stent

to re-open the vessel. Introduced by Pijls 20 years ago, FFR is an invasive technique in which a catheter is pulled across a suspected coronary lesion to objectively measure differences in blood pressure on either side of a blockage and gives the cardiologist evidence to decide whether to place a stent or not.

Koo builds upon this critical measurement, but uses a non-invasive technique. Instead of pushing a catheter into the patient, a super-computer analysis of the patient's CT angiography exam can determine blood pressure measures on either side of suspected lesions.

This technique has been validated in studies sponsored by HeartFlow, based in Redwood City, California, and the company now offers this service to cardiologists.

Going one step further, physicians at 11 heart centres in Europe and Asia initiated a study, led by Koo, to test a hypothesis that going backwards, they could look at CTA exams and identify not only which patients were at risk for a plaque rupture, but specifically identify the plaque that was going to rupture.

For the EMERALD study, sponsored by HeartFlow, Koo added computational fluids dynamics and fluid-structural interaction simulation to the FFR-CT calculations for 226 coronary plaques among the 71 patients enrolled.

Emerald investigators first identified patient cases where the culprit plaque rupture had been documented using angiography, or intravascular imaging such as OCT or IVUS. Then the investigators searched the patient file to find a CT exam that had been performed ahead of the medical emergency. The average among enrolled patients was an exam performed one year earlier.

These CT images were then run through the Emerald algorithms to assess plaque composition, lesion geometry and the haemodynamic forces. Results from the retrospective Emerald study were presented in May this year in Paris, at the interventional cardiology conference, EuroPCR.

'Non-invasive haemodynamic data from CT was a better discriminator of lesions causal of ACS than stenosis severity or adverse plaque characteristics,' Koo concluded.

Moving to a prognostic potential, Koo suggested the combination of all plaque characteristics might fur-

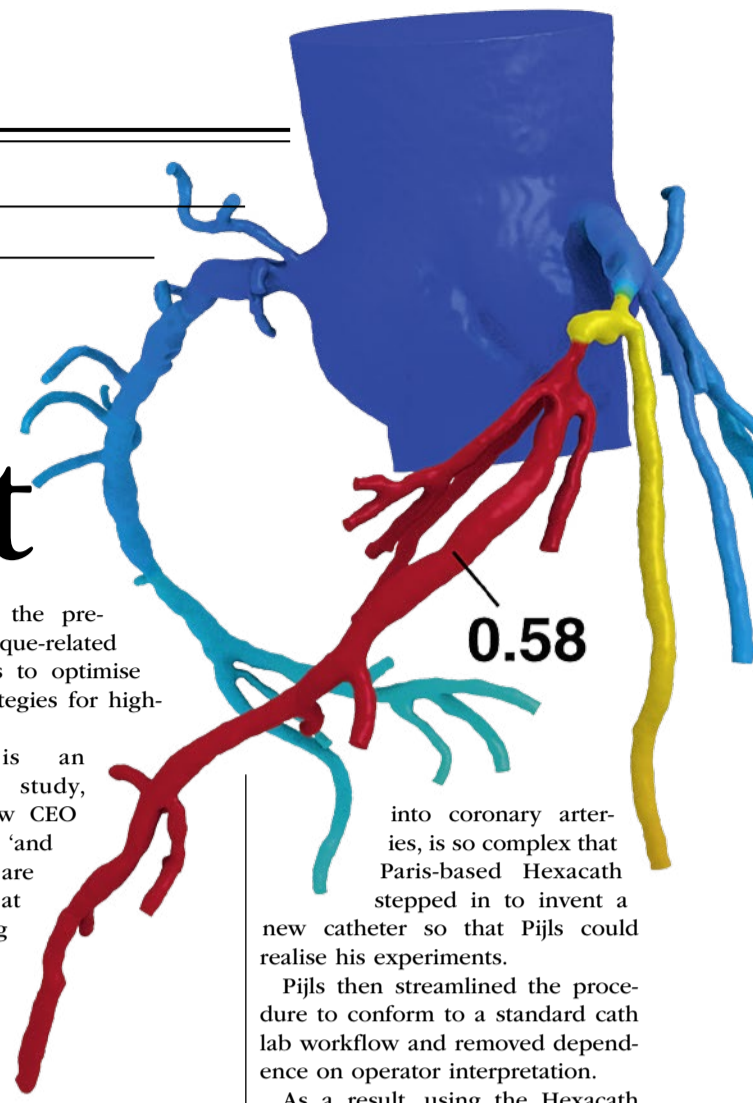
ther improve the prediction of plaque-related clinical events to optimise treatment strategies for high-risk patients.

Emerald is an exploratory study, said HeartFlow CEO John Stevens, 'and it shows we are very good at identifying the plaque at high risk for rupture eight times in 10, which is not just good

but extraordinary. For the moment we still have several hundred more patients cases for validation.'

Dr Pijls also presented his novel approach for measuring microcirculatory in myocardial irrigation at EuroPCR 2016, and when he had finished the panellists applauded in admiration and one of the audience stepped forward to say: 'it blows my mind.'

The calculations for this novel cardiac quantification are so complex it took the software engineering of St. Jude Medical to capture them. The procedure, which required a controlled injection of saline solution



into coronary arteries, is so complex that Paris-based Hexacath stepped in to invent a new catheter so that Pijls could realise his experiments.

Pijls then streamlined the procedure to conform to a standard cath lab workflow and removed dependence on operator interpretation.

As a result, using the Hexacath RayFlow monorail infusion catheter combined with one of St. Jude's pressure wires for FFR, and then standing back to watch the results on the St. Jude monitor, an interventional cardiologist can measure volumetric blood flow directly in selective coronary arteries during cardiac catheterisation and simultaneously, with the same guide wire, calculate the absolute myocardial blood flow, collateral flow, and myocardial resistance.

'We don't know yet what it all means, but at least we have a method to measure it,' Nico Pijls concluded.

Despite unknown valve leaflet durability...

# TAVI is approved for lower risk patients

Younger patients will receive artificial valves shown to degenerate at five years for half of all patients, John Brosky reports

The Medtronic CoreValve Evolut R System received its CE Mark of approval this August to treat aortic stenosis in patients with an intermediate risk for undergoing conventional surgery for a valve replacement. This is a controversial indication for transcatheter aortic valve implantations (TAVI) – one that has been eagerly sought by some clinicians but resisted by others.

director of the structural heart programme at the University Hospital in Bonn, Germany, stated: 'The highly-anticipated intermediate risk indication marks an important milestone for the industry as we look to safely expand TAVI access to younger and less sick patient populations.'

A Medtronic spokesperson told European Hospital that 'A majority of the patients treated with TAVI in

etation with the indication for a vastly larger population of patients at intermediate risk for SAVR is not known, though widely expected to be significant.

Evidence from head-to-head clinical trials has indicated that SAVR and TAVI are fairly evenly matched for efficacy, though with different complication profiles. Traditional surgery poses

a greater risk for

Yet little is known about the durability of TAVI valves that were first introduced in 2002 and did not reach a significant patient population until 2007. Unlike surgical valves,

the delicate valve leaflets for TAVI devices are squeezed, or crimped, to fit into the catheter that snakes through the femoral artery. Once in place, the valve stent holding the leaflets is expanded.

Placing a prosthesis that is expected to last eight years in an 80-year old patient at high risk for surgery has

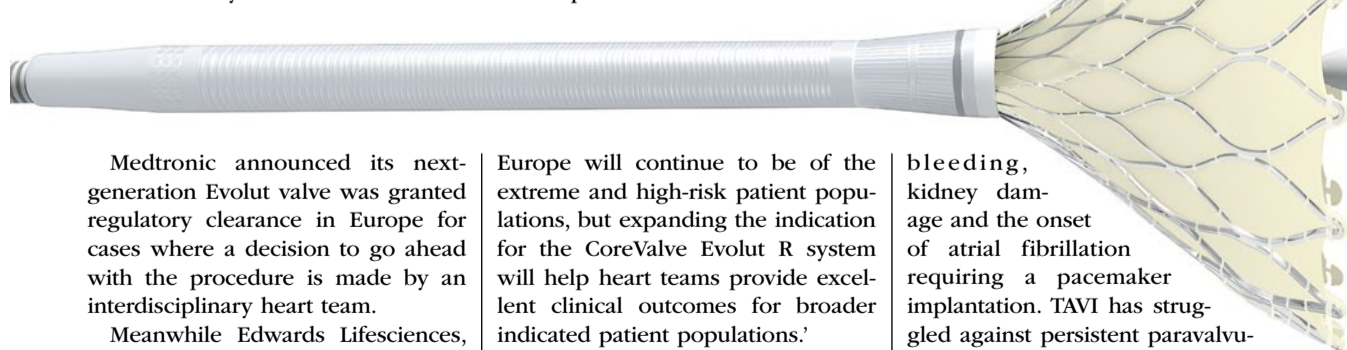
been seen as a benefit for extending the patient's life from an expected one year out to eight years, which is widely accepted as being the expected limit of TAVI valve durability.

The question of placing the shorter-term TAVI device in a 70-year-old patient who could undergo surgery and receive a time-tested SAVR valve is at the heart of the current controversy. The extension of TAVI to lower risk patients was the focus for The Great Debate in May 2016 at EuroPCR, which pitted three leading clinicians on either side of the question.

The debate at EuroPCR quickly centred on valve durability because earlier the same day, at the same congress, results from the first effort to study valves beyond the three- to five-year follow-up in manufacturers' studies was released. Danny Dvir MD from St. Paul's Hospital in Vancouver, Canada, effectively punctured the balloon of TAVI enthusiasm with a report titled 'A First Look at Long-Term Durability of Transcatheter Heart Valves: Assessment of function up to 10 years after implantation'.

Among the 378 patients enrolled, Dvir reported that the median time to degeneration of the implanted valve was five years, and at eight years, some form of valve degeneration affected half of all patients with early TAVI devices.

'Everyone should know there is the phenomenon of valve degeneration, so that when we target younger patients, the lower risk patients who may survive longer, their valve may fail,' he advised.



Medtronic announced its next-generation Evolut valve was granted regulatory clearance in Europe for cases where a decision to go ahead with the procedure is made by an interdisciplinary heart team.

Meanwhile Edwards Lifesciences, the dominant provider of TAVI devices in Europe, reported to investors that it filed for a CE Mark to expand into this same indication with its Sapien 3 TAVI valve in the second quarter of 2016, and that it expects approval in late 2016 or early 2017. In the Medtronic announcement Professor Eberhard Grube MD,

Europe will continue to be of the extreme and high-risk patient populations, but expanding the indication for the CoreValve Evolut R system will help heart teams provide excellent clinical outcomes for broader indicated patient populations.'

TAVI procedures currently hold a 37% share of the market in Europe, against traditional surgical aortic valve repair (SAVR) according to estimates from Wells Fargo Securities. Medtronic devices are used in 31% of those procedures against a 52% share for Edwards Lifesciences. The opportunity to expand TAVI pen-

bleeding, kidney damage and the onset of atrial fibrillation requiring a pacemaker implantation. TAVI has struggled against persistent paravalvular aortic regurgitation and a high pacemaker implantation rate.

Yet, for patients at lower risk for traditional surgery, who tend to be younger, the key concern among clinicians is the durability of the valve leaflets on TAVI devices. SAVR valves have a long history regarding durability that stretches to 25 or 30 years.

