



EACTS ANNUAL MEETING 2010 HIGHLIGHTS Page 10

Is the transfemoral approach the preferred approach for aortic valve implantation? Page 16

### In this issue...

#### **EACTS President**



Alfieri and discovers his early career influences and thoughts for the future. 2

#### **Editor-in-Chief**

We meet Professor Friedhelm Beyersdorf to discuss his new roles within the

Association's two journals

#### STMC

Dr J Rafael Sádaba outlines the need to establish Europeanwide training standards for cardiac trainees.

PARTNER trial

6

#### Martin Leon

reviews the results from the first cohort of patients

from this landmark RCT.

#### ART

David Taggart discusses the one-year outcomes of a randomized trial comparing bilateral vs. single internal mammary CABG. 26

## **EACTS introduces member's newsletter**

Pelcome to the first issue of EACTS News, a new publication aiming to keep EACTS members informed with all the latest news and views from the Association. The newsletter will be published three times a year (April, July and December) and I encourage you to send in your feedback, which we hope will be a forum for stimulating debate. We will feature your views in the "Members Letters' section.

In this first issue we have an exclusive interview with new EACTS President, Ottavio Alfieri, who discusses his career and aims during his term in office. We also have two articles from Professor David Taggart who outlines the clinical implications of two trials, ART and SYNTAX. We also hear from Dr Rafael Sabada who outlines the important work of the Surgical Training and Manpower Committee, and Dr Leslie Hamilton expresses his views on 'Training, Education and Accreditation'.

For those members who did not attend the 24th Annual meeting in Geneva, we have a special report, featuring the Presidential Address,

award winners and other highlights. In addition, we have a short report from the recent EACTS Leadership Course.

This edition also includes a report from the PARTNER Trial and features an interview with the trial's Principal Investigator, Dr Martin Leon, as well as additional comments from Professor John Pepper and Mr Neil Moat.

It is hoped the newsletter will also encourage further discussions concerning topical issues in cardio-thoracic surgery. With this in mind, 'The Big Question' section will feature two specialists debating a contemporary issue. This edition also includes a look ahead to the Second Robotic Course in Cardio-Thoracic Surgery with Dr Franca Melfi.

I would like to take this opportunity to thank all the contributors of the newsletter for their efforts, as well as our partners from industry for their support in this exciting new venture. Please send your comments to: communications@e-dendrite.com *A Pieter Kappetein MD PhD Secretary General* 



Pieter Kappetein

#### **Three-year SYNTAX results** Support for new ESC/EACTS guidelines on myocardial revascularisation

#### David Taggart

Raising standards through education and training

Professor of Cardiovascular Surgery University of Oxford, UK

The new joint European Society of Cardiology (ESC) and European Association for Cardiothoracic Surgery (EACTS) guidelines on myocardial revascularization

myocardial revascularization were presented at the European Society of Cardiology annual meeting in Stockholm at the end of August 2010 and subsequently published<sup>1</sup>. These guidelines are unique for several reasons: (i) in contrast to previous guidelines.

produced independently by cardiologists and cardiac surgeons, the new ESC/EACTS guidelines emphasize the

"For the first time there is an individual section on the process of decision making"

need for a multi-disciplinary/heart team collaboration in the management of the whole spectrum of coronary artery disease. This collaborative approach was highlighted in the membership of the writing committee, which was cochaired by a cardiologist and a surgeon and included 25 members comprising nine non-interventional cardiologists, eight interventional cardiologists and eight cardiac surgeons.

(ii) the guidelines acknowledge that while meta-analyses of randomized trials constitute the hierarchically strongest form of evidence based medicine, *Continued on page 8* 

TH



David Taggart

ANNUAL MEETING 1–5 October 2011 Lisbon, Portugal



In the first issue of EACTS News, we are delighted to feature an interview with Association's new President, Professor Ottavio Alfieri. Professor Alfieri has had a long and distinguished career as a cardio-thoracic surgeon. In this unique interview, he discusses his early career and influences, the edge-to-edge technique for percutaneous correction of mitral regurgitation, the need for EACTS to strengthen its links with professional organizations of other disciplines and his fascination with the Italian Renaissance.

#### Why did you decide to pursue a career in medicine?

I was attracted to the medical profession from an early age, mainly inspired by the devotion of my father, an obstetrician-gynaecologist, to his work and patients. Later on I became more and more aware that it was the only profession offering the combination of human interaction, the opportunity to help people and the chance to express personal talent, acquiring and creating useful knowledge

#### Why did you enter cardiac surgery?

As with many things in life, it was by chance. As an undergraduate in the late 1960s, I won a scholarship and spent three months at Buffalo University in Buffalo, NY, US. During that period, at Buffalo Children's Hospital, I had the opportunity to witness the extraordinary achievements of paediatric cardiac surgery at that time. Dr S Subramanian, the Chief of Cardiac Surgery at Buffalo, was successfully correcting complex congenital heart defects in neonates and small children using deep hypothermia and circulatory arrest. This experience as medical student had a great impact on me and I decided then and there that I would become a cardiac surgeon.

#### Who have been your greatest influences and why?

After graduation I went back to Buffalo for a clinical fellowship with Dr Subramanian and spent one year with him. Needless to say, Dr. Subramanian had a great influence on me. In a short period of time he was able to transfer not only knowledge and experience but also passion and enthusiasm. My training in cardiac surgery in Italy was under Professor Lucio Parenzan, a renowned pioneer of this discipline in my country. He was for me an important mentor who encouraged me in many projects and pushed me to complete my specialist training overseas. So I had the extraordinary opportunity to spend a year as a research fellow in Birmingham, Alabama, USA, with Dr John Kirklin, a true giant in the history of cardiac surgery. Dr Kirklin as a surgeon, teacher, investigator and human being, has been deeply inspiring my entire professional life.

Finally, I would like to mention my experience at the St Antonius Hospital, in Nieuwegein, the Netherlands, where I enjoyed working with highly skilled surgeons and expert cardiologists in a friendly and supportive atmosphere. In the Netherlands I became acquainted with an effective organisational system and the "heart team



Ottavio Alfieri (centre) with Pascal Vouhé (left) and Peter Kappetein

concept", which necessitated strict cooperation between surgeons and cardiologists in making decisions about patient management. The multidisciplinary approach to patient care was an extremely valuable lesson I learned in Nieuwegein.

#### What current areas of research are you involved in?

Early in my career, congenital heart diseases were the main topic of my clinical investigations. Later on my interest moved to coronary artery disease, valve disease, heart failure, and arrhythmias. Recently, the mitral valve has become the main focus for my research group.

Many years ago I introduced an original technique to correct mitral regurgitation. This was the edge to edge technique, consisting of approximating the free edge of the mitral leaflets at the site of the regurgitant jet. This technique allowed us to correct a large series of complex mitral regurgitation in a simple manner, and we have been able to document excellent long-term results in different subsets of organic mitral regurgitation. In tandem with clinical investigation, our research team has been studying the haemodynamic features and stress forces of a double orifice mitral valve using three-dimensional computational models in close cooperation with bioengineers. The edge to edge technique, due to its simplicity, is nowadays the only effective method to correct mitral regurgitation percutaneously. As a matter of fact, the so called Alfieri stitch can be reproduced with a clip inserted percutaneously

through the femoral vein and then through the atrial septum to reach the mitral valve. In our Institution the role of the percutaneous clip procedure in the treatment of patients with mitral regurgitation is currently been investigated.

Our research team is devising original solutions for reconstructive mitral and tricuspid valve surgery. New prosthetic rings have been designed and are under evaluation, along with other new devices, which are being evaluated in the lab and in clinical settings under rigorous regulatory conditions.

Original techniques have also been developed for the treatment of atrial fibrillation.

#### As President of the EACTS, what do you hope to achieve over the next 12 months?

The EACTS has been always acting as a dynamic, lively and energetic professional organization, with the ability to promptly respond to the requirements of the members, to the changes of our discipline and to the evolution of treatment modalities. Particularly in the last years major changes took place in the internal organization of the EACTS, with a very positive impact on the quality of the Annual Meeting and of the educational products in general. My intention is to act in full continuity with the past and to promote the development of our profession based on the concept of patientcentered care in the context of a multidisciplinary environment.

Bearing this in mind, it is important to

**Tel** +44 (0) 1491 411 288 Fax +44 (0) 1491 411 399 strengthen the links with the professional organizations of other disciplines and to provide an appropriate new education for cardiothoracic surgeons. Patient-centered care also means skilful adoption of new modalities of treatment. Innovations and new technologies have to be evaluated rigorously and with total neutrality, using scientific methods. The task of a professional association is to provide an independent judgement and regulate the introduction of new therapies

A relevant goal of the EACTS should be to promote more services for the members and to offer educational products in line with the evolving profile of our profession. In the global world scenario, the EACTS is growing fast and therefore we have to look to wider horizons and not to stop at the borders of Europe. We have to be aware that many countries around the world look to Europe for education and training in cardiothoracic surgery.

#### What are the biggest challenges facing cardiothoracic surgery over the next decade?

Conventional surgical procedures are expected to decrease consistently over the next decade. On the contrary, minimally invasive and percutaneous methods will be more commonly used to treat structural heart diseases and other thoracic disorders

Hybrid procedures will be more often adopted as a convenient option, particularly for patients with complex pathologies and comorbidities

In ten years, the patient population submitted to cardiothoracic surgery will be much older, with more comorbidities and a higher prevalence of heart failure and atrial fibrillation. Considering the features of the patient population and the wide spectrum of therapeutic options offered by the rapidly evolving technology, the treatment will be tailored to the individual patient, for an appropriate solution of a specific problem.

A multidisciplinary interaction will be mandatory in such a scenario.

The decision-making process will be more complex in the future, particularly in relation to the cost-benefit ratio and the sustainability of the care.

The rapid advancements in basic science should be taken in consideration by cardiothoracic surgeons, since many patients are expected to benefit, for instance, from cell or gene therapy. The challenges facing cardiothoracic surgery over the next decade require a new system of education, since the model of classical training is definitely obsolete

Importantly, individual attitudes and personal talents should be recognized and enhanced. Education must be tailored to create unique and special professional profiles.

#### Away from your professional life, how do you relax?

My main interest and preferred way of relaxing outside work is a 'cultural hobby': to learn more about the Italian Renaissance. This period lasting from the 13th century until 1600 was characterised by great changes and achievements in literature, poetry, sculpture, painting, architecture, philosophy, science and music. I am fascinated by this extraordinary historical period and by the numerous incredible personalities of that era.

**Editor in Chief** Pieter Kappetein Managing Editor

**Owen Haskins** owen.haskins@e-dendrite.com Dendrite Clinical Systems

Design and layout Peter Williams williams\_peter@mac.com Publisher

**Head Office** The Hub Station Road Henley-on-Thames, RG9 1AY, United Kingdom Website www.e-dendrite.com

Copyright 2010 ©: Dendrite Clinical Systems and the European Association for Cardio-Thoracic Surgery. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, transmitted in any form or by any other means, electronic, mechanical, photocopying, recording or otherwise without prior permission in writing of the editor.

#### N E W



Enhanced Ease of Use and Procedural Control

s. Millin

### E D W A R D S **NovaFlex** Transfemoral Delivery System

1910

Precise Placement and Controlled Navigation

## Treat your patients with greater ease

### The new, improved transapical system that enables precise transcatheter valve placement

The Ascendra2 delivery system offers new design features that improve the transapical (TA) delivery of the advanced Edwards SAPIEN XT<sup>®</sup> transcatheter heart valve including:

- Enhanced procedural control with a reduced sheath profile for easier access and closure
- Easy to use with a new handle design for single-handed valve delivery and improved hemostatic control
- Direct access for accurate, short-distance valve placement



# Introducing the Editor-in-Chief Friedhelm Beyersdorf

Cardio-Thoracic Surgery in September 2010, Professor Friedhelm Beyersdorf (Department of Cardiovascular Surgery, Albert-Ludwigs University Freiburg, Germany) was appointed as Editor-in-Chief of two leading journals; the European Journal of Cardio-Thoracic Surgery (EJCTS) and the Interactive CardioVascular and Thoracic Surgery (ICVTS). EACTS News was delighted to speak with Professor Beversdorf to discuss the differences between the two journals, what advice he would offer to potential authors and how peer-reviewed journals may change in the future.

rofessor Beyersdorf brings with him considerable experience having served on the editorial boards of numerous prestigious journals including The Journal of Thoracic and Cardiovascular Surgery, Circulation, The Thoracic and Cardiovascular Surgeon and Perfusion, as well as being a member of the editorial boards of both the EJCTS and ICVTS (specialising on coronary disease). He began by outlining his roles and responsibilities and the significant differences between the two iournals: "I am responsible for all the scientific aspects of the journals and ultimately, after consultation with reviewers, decide the final content of the journal. However, as the content of the journals differ considerably it is important to correctly judge the type of papers to include.

#### **EJCTS and ICVTS**

The EJCTS was first published in 1987 and is one of the top three peer-reviewed cardio-thoracic journals in the world. The journal provides a medium for high-quality original scientific reports documenting clinical and experimental advances in surgery of the heart, the great vessels and the chest. In contrast, the ICVTS was first published in 2000 and is conceived as 'virtual conference' relying on both modern media and open discussion.

"The European journal is the prestigious, scientific-driven journal, whereas the Interactive journal is more experimental and we publish data that is new, innovative and provocative. The papers included in the Interactive journal are not always evidence-based papers and therefore come into different categories such as institution reports," he explained. "In order to encourage discussion between readers, after editing, all accepted reports are posted immediately on-line. An electronic, moderated discussion is then opened for 28 days. After closure of the discussion period, the reports pre-published on-line, as well as the moderated discussions, are published in the ICVTS archival version and in the traditional paper format."

Each year there are approximately 3,000 papers submitted to the journals and these papers are subjected to rigorous checks by the editorial staff to see whether the paper meets submission process criteria (correct references, authors etc). "This is important, as we want to guarantee all

manuscripts in the journal have the same uniform style and format. This ensures all papers are easily understood and referenced," he stressed. "In the next process, the paper is transferred to the Associate Editor of that subject who will distribute the paper to two reviewers. So three specialists will have seen the paper and a decision is then made whether to publish the paper, reject the paper outright or send the paper back for further revisions."

#### Advice for authors

Given that the majority of papers are referred back to the authors for further revision, does he have any advice for authors, particularly first time authors who may be thinking about submitting an article to the journals? "The subject must be innovative and

topical such as how to solve a clinically relevant problem. The paper should be written in the usual style (in-

troduction, discussion etc), and importantly include a hypothesis which is then tested by the study conducted by the author," Beyersdorf noted. "I would strongly advise that the authors have a bio-statistician as a co-author so they can assess whether the data will stand up under rigorous examination."

He also advised that the paper should be written in such a way that even if the reader is not 100% famil-

iar with the subject they can understand why the study was undertaken, what the results are and why the author has arrived at such a conclusion. Finally, he recommended that all authors should visit the websites of both journals where they will find advice on how to submit a paper, the

#### "For cardiovascular surgery, the EJCTS is in the top three cardiovascular journals when considering the highest impact."

style, format and content etc.

With some 3,000 papers submitted each year, the journals continue to feature every aspect of cardiovascular and thoracic surgery from case reports, follow-up papers and institutional reports, to randomised clinical trials and meta-analysis. "In

addition, we also have special issues dedicated to congenital, transplantation, thoracic surgery and so on, so that over the year in the four is-



Despite the large number of papers submitted to the journals, Beyersdorf maintains that the quality of the papers continues to improve.

> "There is no doubt the quality of the papers submitted to the EJCTS has improved as witnessed by the editorial staff, the readers and the

impact factor. The impact factor is an important scientific measurement that is used to gauge the quality of the papers and reflects the average number of citations to articles published." And it is for this reason he believes that the EJCTS in particular still manages to attract the most outstanding papers, as authors will submit their paper to the journal with the highest impact factor: "For cardiothoracic surgery, the EJCTS is



learn more about the Interactive CardioVascular and Thoracic Surgery, advice on how to rite and submit a paper or access articles please visit: bttp://icvts.ctspetiourpak.org/



Friedhelm Beyersdorf

in the top three cardiovascular journals when considering the highest impact factor."

#### The future

The Internet and the ability of anyone to publish anything has created a debate as to whether medical papers should be reviewed at all, with some claiming that the reader should be the one to decide whether they accept or reject the author's conclusions. Beyersdorf believes that this is an ongoing, very heterogeneous discussion. "On the one hand some believe that a peer-reviewed journals should no longer be published because everything can be published on the Internet and readers can then decide if it is worthwhile or not. This places the entire responsibility of what is being published on the author. So if it is wrong, it's wrong, if it is plagiarised the author will face the consequences. On the other hand, the peer-reviewed process has the advantage of having been reviewed by three expert reviewers for those who cannot distinguish between a correct and incorrect statement or conclusion, so the reader is comfortable to some extent that the paper's conclusions are not totally unfounded.

So what does he think the future holds? "Technology will play an important role. We are in the process of increasing the inter-activeness of the journal to a greater extent, for example we are thinking about having an 'app' for the journal so subscribers can read it on their iPhone. In fact, one advance is that we can accept and publish short video clips online demonstrating new and adapted techniques, and in the future we hope to have more webbased materials such as interviews with the authors. Ultimately, this is all about educating and making sure surgeons, internists and family physicians are aware of the different options available."

MITRAL VALVE REPLACEMENT THE MECHANICS OF DURABILITY





MECHANICAL PROSTHETIC MITRAL HEART VALVE



Over a 20-year period, mechanical valves show superior survival characteristics' compared to tissue valves. For mitral valve replacement choose mechanical valves with over 20 years clinical experience and over 40 years manufacturing expertise. SORIN GROUP. The choice of cardiac surgeons worldwide.



### **Issues in cardio-thoracic education and training**

The Surgical Training and Manpower Committee (STMC) was established to represent the views and interests of European cardio-thoracic residents, identify issues in training and facilitate education. EACTS News, spoke with Chair of the Committee, Dr J Rafael Sádaba, to discuss the committee's roles and responsibilities. European-wide training standards and the benefits to trainees/residents of becoming a member of the Association.

ccording to Rafael, the STMC is unique within EACTS as it does not belong to a particular domain (adult cardiac, thoracic, congenital or vascular), but relates to all of them. It exists mainly to represent the views and opinions of trainees and identifies issues on training and education, as well as finding common ground to develop standards in surgical training. The committee also promotes communication channels with other organisations, as well as supporting the academic activities within EACTS.

"The STMC is also unique in that It has both residents and surgeons as members. One of the resident members sits in Council as EACTS trainees representative, and importantly, since last year, the representative has voting rights in Council," he said. "Previously, they could just express the views and opinions of trainees/residents and I think this is a significant change that acknowledges their importance."

#### Database

Another important programme the Committee is undertaking is to establish a database on training units in Europe. At present there is a lack of knowledge on the number of training units in Europe, even at national level this information is sometimes not available. There is no data on the number of trainees, facilities, number of cases etc. To have this type of information is important at two levels.

First it gives an idea on the current status of cardiothoracic surgery in Europe and helps to compare how things are done in different countries

Second, it provides trainees with information on different training programmes, so they can decide on where to go for fellowships or other type of educational activity.

"One of the important aspects of the database is that we intend it to be updated regularly. So one of our aims to assign a contact person in each centre so they can update the database on changes to their centre's training programme, the number of trainees and so on. This year the Committee has appointed two new members who will be responsible for

constructing the database," said Rafael. "We hope to collect some preliminary information by next year's meeting in Lisbon. In the past we have depended on the national associations with very little success, this time the success of the enterprise will depend on the collaboration from members

#### **European Working Time Directive**

A recent survey undertaken by the Committee and published in the Interactive CardioVascular and Thoracic Surgery (Sabada et al: 2010;11:243-246) highlighted serious concerns among residents/trainees regarding the European Working Time Directive (EWTD), with most claiming that the Directive has had a negative impact. In particular, they point to insufficient time allocated to allow trainees to become competent surgeons as a result of the duty hours restrictions. According to Rafael, the apprenticeship model that has been utilised for decades is out-dated and is no longer fit for purpose under the current conditions: "As a result of the EWTD, we must optimize the time residents spend in hospitals and we have to shift the balance towards training from provision of service. Training should be competencebased and properly structured, which is not the case in the majority of European countries."

The outcomes were quite clear that cardio-thoracic surgical training in Europe is disorganized. There are unequal surgical requirements, unequal syllabuses, unequal methods of assessing progress, unequal lengths of training programmes, unequal methods of accreditation and unequal application of the EWTD.

Therefore, there needs to be significant changes in the structure of training. As an organisation, EACTS has no executive powers and can only voice its concerns and make recommendations. Nevertheless, Rafael claims that EACTS is in an ideal situation to look at the system from a European-wide perspective and provide learning management courses, workshops and advice on training and education, as well as facilitating exchange programmes.



#### **Established standards** of training

"We would like to see at the national level established standards of training that would be applicable across national borders. This would include technical proficiency, quality assurance and targets of knowledge. It is also important that the 'trainers' also have established standards and we need to have educational programmes on training for 'trainers'," he added.

The overall assessment of medical education in Europe is 'very poor', claims Rafael, as there is no Directorate of the European Union responsible for medical training. As a result he mentioned that a 'Bologna type reform', for post-graduate medical education could address some of these issues of medical training and assessment.

#### **Best Trainer award**

One innovation EACTS is planning to develop is a European-wide 'Best Trainer' award. To achieve this trainees/residents will be asked to

nominate trainers who they believe are exceptional. The trainer will then undergo a process of evaluation including inter-

views with the trainer, trainees/residents, peers, nurses and other people in the hospital. It is hoped this will help communicate what makes a good trainer and what is incorporated into a good training programme.

In summary, the STMC would like to see

- the harmonisation of educational programmes, which should be able to deliver minimal standards of knowledge and technical ability;
- regular and independent assessment to ensure the quality of the training, and an 'exit exam' at the end of training; and
- compulsory courses for the trainers so they can learn how to train to established levels to ensure universal standards across Europe.

"The structure of surgical training in the US is more advanced than what we have in Europe. Nevertheless, there are countries in the European union that have excellent training programmes with comprehensive curriculums that could be adopted throughout the whole European Union," he added. "It is our iob in the Committee to communicate to our members, trainers and trainees that these excellent programmes exist."

" I believe that every surgeon is by nature a scientist and therefore research should be encouraged from the earliest years of training."

Young Investigator Awards

Of course, this is not to say that the quality of surgical trainees is poor. Indeed, judging by the outstanding papers presented at this year's Annual Meeting in Geneva, the quality has never been of such a high standard. The papers were so good that Rafael said the panel of five members may have to be expanded in order to process the number of manuscripts. "It is clear there is high-quality research being conducted by cardio-thoracic residents in Europe and their efforts should be praised," said Rafael. "It is getting more difficult each year to decide the winners of the awards because the standards are so high. I believe that every surgeon is by nature a scientist and therefore research should be encouraged from the earliest years of training."

#### **EACTS** membership

As well as encouraging residents/ trainees to join EACTS, he also encourages participation from medical students who would benefit greatly from the advantages membership brings. "We would like to invite medical students to join EACTS so they will have access to our educational activities and exchange programmes between countries, as well as have a pro-

gramme specifically for medical students at the Annual Meeting," revealed Rafael. "As a member of EACTS it gives you the opportunity to be part of the largest scientific society of cardio-

thoracic surgeons in the world. Also, it opens up opportunities for education and training, as well as access to a large network of cardiothoracic specialists with whom members can share their knowledge and experiences.

#### **STMC** database

If you are interested in the STMC database, please contact a member of the Committee via the EACTS website: www.eacts.org

#### Young Investigator Awards

If you are interested in submitting a paper for the Young Investigator Awards at the EACTS S Annual Meeting in 2011 (Lisbon, Portugal), please visit the EACTS website: www.eacts.org

f you would like to comment on training standards for ca diothoracic trainees/residents, *EACTS News* would be de-ighted to publish your opinions. Please send your comments to: **communications@e-dendrite.com**.

Introducing the Trifecta™ Valve from St. Jude Medical

## We're not saying we're the best tissue heart valve ...



Product references warpresed by D. Nork. Not analyzed warren (Hir (CL, Demonstrated)), how million and an international constraints. Change of part 18. - Lab Mechaning Constraints in protect and an ing in part estably. Lemma depaysion and (\*\* exception a regimental of access record indeprese constraints) and former on St. and Mechanic record of its analysis. Theory of St. Des Willick, the rest spaces waveland both total the little little management and an independent accession and wave of St. Des Willick, the and its solution total with both total the little little management conservation accession and wave of St. Des Willick, the and its solution total total total total total total total total total accession and total accessed.

### Training, education and accreditation

Leslie Hamilton Freeman Hospital Newcastle upon Tyne, UK

y objective in writing is to stimulate debate. We must be concerned when we consider the myriad systems of training we currently have within Europe. The CCT (Certificate of Completion of Training) means different things in different countries and yet being 'European' means equal recognition of qualifications. There must be a possibility of agreeing the basic principles. And I mean the process, not whether it should be cardiac, thoracic, vascular or some combination

Theoretically post-graduate training comes under the auspices of UEMS (European Union of Medical Specialists). Your EACTS Council has tried to generate some activity through this body but to no avail. EACTS should take the lead.

First, we need to define the innate abilities needed to be a good trainee – general aptitude, the ability to assimilate complex information and of course technical dexterity. Then we need to establish a method of measuring these so that we can have a selection process, which is fair and transparent – interviews, presentations and technical skills stations? What place publications, research and references? Do we limit the number of trainees selected? We surely have a moral duty to have some relationship between the number of trainees and future manpower needs.

Training is the process of learning skills. So we need a curriculum to define what skills are needed to be an independent surgeon. How long should training be? – as long as it takes to acquire these skills. Is there a need for general surgical training and if so, how much? (some programmes in the US are now taking trainees directly into cardiothoracic surgery). As part of the training process, trainees must provide some service in caring for patients - in the ward and in the intensive care unit. This contribution will be in different ways at different stages of their training. The system should not depend solely on their contribution other non-medical staff (nurse practitioners / surgeon's assistants) can acquire the skills to care for patients so that the surgical trainee can be freed to train.

Mention of the European Working Time Directive is always guaranteed to spark debate. Yet I am amazed at the lack of understanding

of the details of these regulations when I talk to both trainers and trainees. The misconception that hours are limited to a maximum of 48 per week is widespread – up to 78 is within the regulations. The emphasis of the EWTD is how many hours can be worked without rest/sleep (13 is the maximum) I have read papers suggesting that when I was training I had >30,000 hours available - a large proportion of these were resident in the intensive care unit (learning a job which is now rightly done by Intensivists) and then the following day in theatre after no sleep. Sleep deprived brains do not facilitate learning and the acquisition of skills.

We need to consider how the trainee will learn (education) and be clear about how we will assess their progress. We should use tools/systems which are objective and not base judgements solely on our subjective feelings. Importantly, we must be open about how we will decide if they are not making progress and so be taken off the training programme. Often forgotten is how we select trainers (not every surgeon is a good teacher) and how we assess them in their role. Trainers should be selected and rewarded

Finally, we need to give formal recognition (accreditation) to the fact that the trainee has acquired the necessary skills. This will require an assessment process with different components - to test the different aspects of a trained surgeon. A written examination to assess factual knowledge? An interview to probe their ability to apply knowledge to patient care and to assess their understanding of the evi-



Leslie Hamilton

dence base for practice? Observation of the interaction of the trainee with patients? (a 'clinical" examination?). Possibly the most difficult but arguably the most important guestion is how do we assess their technical skills? Is confirmation from (several) trainers that they have "good hands" sufficient?

A sobering question to finish – who carries the responsibility if the subsequent results of the clinical practice of the trainee are poor?

This is an important debate, which we as the specialty Association have a responsibility to lead.

### **Three-year SYNTAX results**

Continued from page 1 trial patients may not always be typical of those encountered in routine clinical practice<sup>2</sup>

For the first time there is an individual section on the process of decision making and patient information which recommends a multi-disciplinary/heart team approach when recommending intervention by stents or surgery. Likewise the guidelines recommend that there should be less use of 'ad hoc' stenting (ie the decision to proceed with stenting immediately after diagnostic angiography), and especially in the setting of multi-vessel disease, as this reduces the opportunity to fully discuss and allow time for consideration of all treatment options.

Although there are concerns that

the multi-disciplinary/heart team approach may be cumbersome, and particularly in hospitals without onsite cardiac surgery facilities, in reality most treatment recommendations can be made by following local protocols based on the guideline recommendations and do not require individual discussion of every patient. However, more complex clinical situations will still require multidisciplinary dialogue: for example there may be situations where surgery is the more suitable intervention but contraindicated by severe co-morbidities while, on the other hand. contraindications to the use of dual anti-platelet medication for drug eluting stents might favour surgery

While randomized trials<sup>3</sup> and large

historians for CARC means RCI is stable matients with lasis

propensity matched registries<sup>2</sup> confirm that CABG offers a survival benefit and marked freedom from re-intervention in severe coronary artery disease, CABG and stents have a similar survival over the short to medium term, in patients with lower tercile SYNTAX scores. However, at three years, mortality was 5.7% for CABG and 9.5% for stents (p=0.02) in all 1095 SYNTAX patients with three vessel disease, and with the same frequency of stroke at 2.9% and 2.6% respectively (p=0.64)<sup>4</sup>. This probably reflects the fact that while stents may directly treat proximal stenotic lesion(s), bypass grafts to the mid coronary vessel may offer additional prophylaxis against the development of new proximal disease<sup>2</sup>.

In contrast, the respective mortalities were 8.4% and 7.3% (p=0.64) for all 705 patients with left main stenosis<sup>5</sup>; crucially the mortality was significantly lower for stents than CABG in patients with SYNTAX scores <33 while the reverse was observed in those with SYNTAX scores >32. Unlike three vessel disease, for all severities of left main stenosis stroke was higher with CABG whereas freedom from repeat revascularization for CABG was only seen in the highest tercile SYNTAX scores.

Taking all the SYNTAX patients together (including the 35% who went immediately to surgery because of severity of disease and were not randomized) this means that 80% of all patients with three vessel disease and two thirds with left main stem stenosis already have a significant survival advantage with CABG at three yearsentirely consistent with reports from several propensity matched registries<sup>2</sup>. A further important consideration is the remarkable safety of contemporary surgery; for example in all 78,000 patients undergoing elective CABG in the UK in 2004-08 the hospital mortality was 1.1%<sup>6</sup> a figure similar to that in the 3102 patients in the Arterial Revascularization Trial<sup>7</sup> while the mortality for elective stenting is even less at around 0.5%.

The collaborative evidence based approach of the new ESC/EACTS guidelines promotes a more transparent and robust approach to ensure

the best intervention, real patient choice and genuine informed consent. This approach serves the best interests not only of patients but also doctors by allowing them to robustly defend their rationale for particular interventions. We should work intensively in close collaboration with our cardiology colleagues to promote and implement the new guidelines in daily practice.

#### References

- 1. Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Associa-tion for Cardio-Thoracic Surgery (EACTS). Eur Heart J 2010: 20:2501-55.
- 2. Taggart DP. Thomas B. Ferguson Lecture. Coronary artery bypass grafting is still the best treatment for multivessel and left main disease, but patients need to know. Ann Thorac Surg 2006;82:1966-75.
- Serruys PW, Morice MC, Kappetein AP, et al; SYN-TAX Investigators. Percutaneous coronary interven tion versus coronary-artery bypass grafting for severe coronary artery disease. N Engl J Med 2009; 360:961-72
- Mohr FW. SYNTAX 3VD: Three-year outcomes л from a prospective randomized trial of Paclitaxeleluting stents compared to bypass graft surgery in patients with triple vessel coronary artery disease TCT 2010 Washington.
- Serruys PW. SYNTAX Left Main: Three-year out-5 comes from a prospective randomized trial of Paclitaxel-eluting stents compared to bypass graft surgery in patients with left main coronary artery disease. TCT 2010 Washington.
- Bridgewater B, Kinsman R. Sixth national Adult Cardiac Surgical Database Report. Demonstrating Quality. 2008 Dendrite Clinical Systems, Henleyon-Thames, Oxfordshire, UK 2009.
- Taggart DP, Altman DG, Gray AM, et al; on behalf of the ART Investigators. Randomized trial to compare bilateral vs. single internal mammary coronary artery bypass grafting: 1-year results of the Arterial Revascularisation Trial (ART). Eur Heart J 2010; 20:2470-2481.

suitable for both procedures and low predicted surgical mortality							
Subset of CAD by anatomy	Favours CABG	Favours PCI					
IVD or 2VD – non-proximal LAD	llb C	IC					
1VD or 2VD – proximal LAD	IA	lla B					
3VD simple lesions, full functional revascularisation achievable with PCI, SYNTAX score ≤22	IA	lla B					
3VD complex lesions, incomplete revascularisation achievable with PCI, SYNTAX score >22	IA	IIIA					
eft main (isolated or 1VD, ostium/shaft)	IA	lla B					
eft main (isolated or 1VD, distal bifurcation)	IA	llb B					
eft main + 2VD or 3VD, SYNTAX score ≤32.	IA	llb B					
_eft main + 2VD or 3VD, SYNTAX score ≥33	IA	IIIB					

In the most severe patterns of CAD, CABG appears to offer a survival advantage as well as a marked reduction in the need for repeat



Members views

oers views would like to comment on any of the aspects ning training and education, express your opi ing the outcomes from the SYNTAX trial or dis ESC/EACTS guidelines, EACTS News would b

Introducing the Trifecta" Valve from St. Jude Medical

### We'll let the data speak for itself.



For more information on Trifecta – a pericardial, supra-annular stented tissue heart valve created exclusively for the aortic position – contact your local St. Jude Medical sales representative.



(). (R. and Statical, Trivela Well Late-Person Yes, Report of the events index application y 2018.

Product orderation is approved for CE Modil, Not address for two in the U.S. For the depicted may on the assistable in all our man. Charactery your Standard increase done to product and entry in each careful.

General derivation wind, <sup>10</sup> minutes a regulated to severy which haders at several random will be a Norman in the activity of Norman in the several and both controls. Unit 2016, an regulated and units of the several independent derivation of Several Theorem 2016 and the several random several terms of Several Several and the several random several terms of Several Several Several Theorem 2016.

COURSE outer Broking to Altriation recorded

### EACTS ANNUAL MEETING 2010 HIGHLIGHTS

### **Record attendance at** GET **EACTS Annual Meeting 2010**

The 24th EACTS Annual meeting was held in Geneva, Switzerland, 11–15 September 2010. More than 4,000 delegates attended the meeting from the entire spectrum of the cardio-thoracic field. A breakdown of attendees can be seen in the figure below.

The organizers of the EACTS Annual Meeting would like to thank all delegates and industry sponsors for their continued support, and look forward to seeing you in Lisbon for 25th Annual Meeting 1–5 October. Breakdown of physicians attending

Allied Health Professional 98 2% Resident/Nurse/Student 357 9%

Techno-College participants 2003–2010





### 'The surgeon and the musician'

EACTS President, Pascal Vouhé, began his Presidential Address by stating that it was the climax of his career and paid tribute to his colleagues, patients, his wife Dominique and his three children. He also paid tribute to Professor Marko Turina, whom he thanked for his advice, support, his Presidential nominations and all he has done for the Association.

ntitled, 'The surgeon and the musician' the Presidential Address discussed the association between surgery and music. He cited examples from history of great musicians who were also talented and practiced physicians, such as René-Théophile-Hyacinthe Laénnec, a poet and a flute player, who invented the stethoscope and is consider to be the father of chest medicine.

Vouhé then explained in detail, several studies which have shown an association between music and improved outcomes for patients including reducing patients' stress levels and reducing the requirement for analgesics. In addition, he also cited a study in which surgical staff reported an increase in efficiency and performance, excellent hand-to-eye

greater communication when listening to music. Furthermore, there are studies which have shown surgeons who are asked to perform mathematical and laparoscopic procedures, performed the procedure with greater speed and accuracy if they were listening to music (Mozart), compared to surgeons who performed the procedures in silence.

He stated that MRIs have shown musicians have 'special brains' with

#### "Without music, surgery (life) may be a mistake."

large left planum temple (the area responsible for acoustics and linguistics). Musicians have great accuracy in



coordination and reaction times, and very good spatial visualization. Vouhé said that research has shown musi-

> cians who excel began playing music before they were ten vears old and aided by years of deliberate practice (over 10,000 practice hours).

He said that surgeons too have special brains, as a surgeon who excels has great concentration levels, has great anticipation and improvisation



The aim of music is to arouse the emotions and provide at state of satisfaction, restoring harmony, explained Vouhé, and the goal of surgery is not that different, as surgeons hope to restore normal physiological function and also the patient's harmony. Vouhé added that music is the most powerful of the arts, as it is a universal language that



Members 1,059 27%

teaches us how to listen and can express every human emotion. He concluded his Address by paraphrasing Friedrick Nietzsche: "Without music, surgery (life) may be a mistake.

Following his Address, Vouhé welcomed onto the stage his good friend and world-renowned cellist, Professor Roland Pidoux, who captivated the audience with his recital of Johann Sebastian Bach's Suite No.3 for Cello Solo

MITRAL VALVE REPLACEMENT THE MECHANICS OF DURABILITY





MECHANICAL PROSTHETIC MITRAL HEART VALVES



Over a 20-year period, mechanical valves show superior survival characteristics' compared to tissue valves. For mitral valve replacement choose mechanical valves with over 20 years clinical experience and over 40 years manufacturing expertise. SORIN GROUP. The choice of cardiac surgeons worldwide.



### EACTS ANNUAL MEETING 2010 HIGHLIGHTS

### **EACTS Techno College** Innovation Award 2010

EACTS News is pleased to report the 2010 EACTS Techno College Innovation Award was won by Georg Nollert (Siemens) for the syngo Aortic ValveGuide, which supports image-guided transcatheter aortic valve implantations (TAVI).

ccording to Nollert, an increasing number of operating rooms are being equipped with high-end angiographic C-arms. These so-called "hybrid ORs" (figure 1) enable advanced imaging in 2D and planning, finding the best projection, CT-like 3D imaging ("syngo DynaCT").

"Technological advances have resulted in enormous growth of TAVIs. Until recently TAVI procedures had only been supported by 2D imaging (fluoroscopy), which has limitations in and evaluating the result", he added.



The automated process based on syngo DynaCT 3D images supports planning, execution, and evaluation of TAVIs to make them quicker. safer and easier, claims Nollert. All the necessary steps can be done in one single procedure in the hybrid OR based on 2D and 3D imaging with the angiographic C-arm. Leaving the sterile area to use a workstation, or even a transfer to radiology for a CT scan is no longer necessary

#### Automated processes for safe and easy valve implantations

At the beginning of the procedure 3D images are acquired with the Carm rotating around the patient for five seconds. These images are sent to the workstation and automatically reconstructed and segmented in less than 30 seconds. The software automatically detects the relevant landmarks and marks them in colour – the coronary ostia and a "perpendicularity ring". This ring is 1cm below the hinge points of the aortic cusps. The image can then be rotated to achieve an optimal perpendicular projection with the C-arm. This is in-



Figure 1: Hybrid operating room at Rikshospitalet Oslo, equipped with Siemens' Artis zeego angiographic C-arm

into a line. With the push of a button, the C-arm moves into that exact position. The software also allows for the necessary measurements of the anatomy, e.g. maximum diameter of sinuses.

During imaging, the 3D syngo DynaCT images can be overlaid onto live fluoroscopy for further device guidance. They automatically adapt to movements of the table, C-arm or zoom. It is also possible to change the image to a 'contour view', which displays only the contours of the aorta as well as the anatomic landmarks. This way the visibility of the live fluoro image is higher than when

overlaving the full 3D volume

#### Benefitting the surgeon and the patient

According to Nollert, the new solution makes TAVIs more efficient because the imaging greatly facilitates the positioning of the valve. "It can help save dose and contrast media in comparison to conventional CT and consequently will be safer for the user and the patient. And most importantly, it saves time and manual work by doing most of the steps fully automatically and much quicker than with existing conventional solutions," he concluded.

#### Georg Nollert with the 2010 EACTS Techno College Innovation Award dicated by the ring degenerating

### Hans Borst Award 2010: **TEVAR vs. open surgical repair**

Which is the more cost effective intervention for descending thoracic aortic pathologies?

Pradeep Naravan Bristol Heart Institute, Bristol, UK

he management of descending thoracic aortic pathologies is a challenging prospect. Historically, the therapeutic options for the treatment of descending thoracic aortic pathology ranged from a very conservative medical management to an extremely invasive open surgical repair. Following reports of successful stentgrafting of thoracic aorta; thoracic endovascular repair of aorta [TEVAR] has emerged as another option for management of thoracic aortic pathologies.

In the last decade there has been a dramatic rise in the incidence of TEVAR as a therapeutic option for management of descending thoracic aortic pathologies. Compared to TEVAR, historically, open surgical repair was associated with higher mortality and signifi-



Pradeep Narayan accepts the Hans Borst Award from Pascal Vouhé and Peter Kappetein

cant post-operative morbidity. TEVAR is also associated with significantly shorter length of

stay in the intensive care unit, significantly reduced overall hospital stay and require fewer unit stay coupled with lesser

blood transfusions. A shorter hospital and intensive care

utilisation of other resources inherent with open surgical repair, like transfusion of blood products, may intuitively be translated into cheaper hospitalisation costs thereby reducing the financial burden on the institution and the health care system.

We therefore carried out a retrospective study over a period of 13 years to examine the hypothesis that compared to operative repair; TEVAR may be a less expensive option for management of descending thoracic aortic pathologies. A consecutive series of 85 patients undergoing intervention on the descending thoracic aorta were included in the study.

In our study, compared to operative repair, TEVAR was associated with a better short term outcome but similar mid term outcome. While staff costs, costs of consumables. transfusion, intensive care and hospital stay were all significantly higher in patients undergoing operative repair, this was offset by the high costs of stents leading to signifi-

cantly higher procedural costs in the TEVAR group. Also, the incidence of re-interventions was higher in the TEVAR

group. As a result, in our study TEVAR did not prove to be cost effective compared to operative repair of descending thoracic aortic pathologies in the short term. Any survival advantage in the early period is lost at follow up.

Our findings mirror the data available from interventions on abdominal aorta. The United Kingdom EVAR Trial Investigators reported that during an eight year follow up period endovascular repair was found to be associated with a greater risk of graft related complications and higher risk of re intervention and was found to cost more than the operative repair group. Also one has to bear in mind that the results and durability data of stent grafts beyond ten years is largely unknown and hence patients undergoing TEVAR will need monitoring for long periods of time with computed tomography scan or magnetic resonance imaging. Thus, a higher risk of re-interventions and longer term surveillance issue for possible stent graft deterioration will eventually prove TEVAR to be a much more expensive option compared to operative repair.

#### WE WROTE THE BOOK ON IAB CATHETERS NOW WE'VE REWRITTEN THE CHART THE NEW MEGA 8FR. 50CC IAB



#### TIME FOR A NEW FRAME OF REFERENCE WHEN SELECTING THE RIGHT IAB FOR COUNTERPULSATION THERAPY

Introducing the MEGA 8Fr. 50cc IAB: The world's first 50cc IAB catheter on a true 8Fr. shaft – introduced by MAQUET, a proven leader in cardiovascular technology.

New height and sizing guidelines for patients 162cm (5'4") and taller, the benefits of a 50cc IAB are now available for smaller patients. The MEGA spans the IAB clinical reference sizing chart. An ideal replacement for traditional 50cc IABs, the MEGA also offers advantages for physicians using 40cc catheters. In fact, it delivers 25% more blood volume displacement than 40cc IABs while offering improved unloading and augmentation."

#### TO LEARN MORE VISIT

http://ca.maquet.com/theraples\_solutions/resources/case\_ studies/

Be sure to download the CATH LAB DIGEST Case Study.



#### CARDIOVASCULAR

MORE HEMODYNAMIC SUPPORT

### MEGA 8Fr. 50cc when compared to the 40cc IAB catheter showed:

- On average 58% more systolic unloading
- On average 15% increased augmentation area\*
- Reduction in aortic end diastolic pressure

#### Download the CATH LAB DIGEST study:

http://ca.maquet.com/products/ballcons/mega/ case\_studies

Datascope Corp. 15 Law Drive Fairlield, NJ 07004, USA Phone: +1 973 244 6100 http://ca.maquet.com www.maquet.com

'Date on Ille





"Data on file.

10 MAQUET Registered Tedemark of MAQUET Groot & Co. KG - 2018 Copyright MAQUET Cardiovascular LLC or its attillates. All rights reserved.

A Caution: U.S. Federal Law restricts this device to safe by or on the order of a physician. Refer to Instructions for Use for current indications, warnings, contraindications, and precautions.



24th EACTS ANNUAL MEETING 11-15 SEPTEMBER 2010 This year's meeting in Geneva was attended by a record number of delegates. Here are some of the memorable highlights...





### EACTS ANNUAL MEETING 2010 HIGHLIGHTS

### **C** Walton Lillehei Young Investigators Award 2010: New concept for transcatheter replacement of the tricuspid valve

Kenji lino and Georg Lutter University of Schleswig-Holstein, Kiel. Germanv

ranscatheter valve surgeries have already been conducted in selected patients with aortic and pulmonary disease and have gained increasing acceptance in highrisk patients. This has prompted investigation of the feasibility of transcatheter implantation of atrioventricular valved stents. Indeed. Boudjemline et al. reported that placement of a valved stent into the tricuspid position is feasible in 2005, while von Segesser et al. described transcatheter mitral valved stent implantation at the same time. When considering the use of such devices in patients with tricuspid regurgitation (TR), the gap between the native annulus and the stent present an obstacle, especially because the tricuspid annulus is not exactly circular and because it must be dilated to various degrees in patients with severe TR. Preservation of the tricuspid valve apparatus can be difficult due to the interference of the radial force of the stent and its positioning and rare repositioning. Dr Kenji lino, a young cardiac surgeon from Kanazawa University, Japan was able to design a novel self-expanding valve stent with super-absorbent polymer (SAP) for minimally invasive replacement of the tricus-



Kenji Lino accepts the C Walton Lillehei Young Investigators Award

pid valve under the mentorship of Prof Dr Georg Lutter, a cardiac surgeon from University of Schleswig-Holstein, Kiel, Germany who pioneered several transcatheter aortic, pulmonary and mitral valve procedures. After deployment, SAP absorbed aqueous fluids from the bloodstream. This results in gel formation and distension, which promotes sealing and reduces paravalvular leakage.

Lino and Lutter conducted acute animal ex-

periments in Kiel, Germany and were able to successfully deploy the novel tricuspid valved stent with SAP across normal tricuspid valves in pigs using transesophageal guidance. The deployments were performed through a transventricular approach via of a small lower ministernotomy incision. Six of seven pigs exhibited normal haemodynamics immediately after tricuspid valve stent implantation and maintained stability for the entire period of



Georg Lutter

monitoring. Accurate positioning of the valve stent was documented in six of seven pigs SAP expanded and filled the gap between the stent and the native annulus in all animals Mild paravalvular leakage was found in two of six animals. However, the observed leakage decreased to trace levels six hours after implantation. These encouraging acute experimental results lead to a series of successful survival experiments which are currently underway.

### Young Investigators Award 2010: Cardiac Mild hypothermia during cardiac ischaemia: A simple and powerful approach to prolong ischaemic tolerance

Mathieu Stadelmann, Thierry Carrel, Hendrik Tevaearai

and Sarah Longnus, Berne University Hospital and University of Berne, Switzerland

he lack of donor hearts is a major obstacle in cardiac transplantation and is expected to worsen as the number of potential candidates continues to grow. Non-heartbeating donors (NHBDs) represent a currently untapped source of hearts that could significantly increase the availability of donor organs. However, unlike those from brain-dead donors, hearts from NHBDs are subjected to an inevitable period of warm ischaemia between cardiac arrest and preservation. These hearts are generally considered nonsuitable for transplantation, given that cardiac ischaemic tolerance is believed to be close to zero. Therefore, prolonging cardiac ischaemic tolerance would provide a



greater window of time for cardiac preservation, which could effectively increase the availability of donor hearts by covery upon reperfusion. To do enabling widespread adoption of NHBDs for heart transplantation

We investigated the hypothesis that mild hypothermia

(32°C) during cardiac, global, no-flow ischaemia preserves functional and metabolic reso, we established a model of ischaemia-reperfusion in isolated rat hearts to simulate the period of warm ischaemia prior to heart preservation in

the setting of cardiac transplant from NHBDs. Hearts were subjected to 30-minutes, working-mode, aerobic perfusion, then global, noflow ischaemia and 60-minutes reperfusion. Ischaemia was either normothermic (37°C) for 20 or 30 minutes,



or mildly hypothermic (32°C) for 40 minutes.

Among hearts exposed to normothermic ischaemia, contractile function recovered al-Mathieu Stadelmann (left) most completely after 20 minutes, whereas no recovery was detectable after 30 minutes. With mildly hypothermic ischaemia, contractile function also recovered almost completely, despite a two-fold longer period of ischaemia (40 minutes). Therefore, simply slightly reducing temperature during ischaemia effectively

**Isolated Heart Preparation** 

improves functional recovery upon reperfusion. Mild hypothermic ischaemia likely acts through increasing coronary perfusion, decreasing anaerobic/aerobic metabolic mismatch and reducing necrosis. The identification of complementary parameters may help in development of strategies to maximize cardiac ischaemia-reperfusion tolerance, thereby contributing to the development of protocols for transplantation of hearts from NHBDs

### Raising standards through education and training



## 24th EACTS Annual Meeting **Presentations**

Are now available to view online

Highlights from this year's sessions include:Techno CollegePost Graduate CoursesPresidential AddressSpecial Topic SessionsAdvanced Technique SessionsState Courses

To view the presentations, please visit: www.webges.com/cslide/library/eacts

### EACTS ANNUAL MEETING 2010 HIGHLIGHTS

### Young Investigators Award 2010: Thoracic Novel approach for detection of isolated tumor cells in the PV

#### Drs Soichiro Funaki and Noriyoshi Sawabata

Osaka University Graduate School of Medicine, Osaka, Japan he presence of isolated tumor cells (ITCs) in the pulmonary vein

(PV) of a lung resected for lung cancer has been reported to be a prognostic factor. Previous investigations noted correlations between prognosis and the presence or amount of ITCs, though few studies have investigated the clinical implications of the morphological characteristics of those cells. We assessed the clinical implications of ITCs in the PV using a novel approach of enrichment that maintained their morphological characteristics.

Ninety-four consecutive patients with primary non-small cell lung cancer (NSCLC) without preoperative chemo- and/or radiation therapy (p-stage I in 75, II in 13, III or IV in six) were studied. Blood samples were drawn from the PV draining the lung just after pulmonary resection, then ITCs were enriched using a CD45 negative selection method and density-gradient centrifugation, followed by Papanicolaou staining using 1ml of PV blood and immunohistochemical staining for cytokeratin in cases with an additional available blood sample. The ITCs were classified based on patterns of cluster formation into four types (Figure 1); no tumor cells (N), singular tumor cells (S), clustered cells (<0.2mm) (CS), and bulky clustered cells (>0.2mm) (BCS). We evaluated the correlations between ITC morphology and clinical results.

ITCs were detected in 68 of 94 patients (72.3%). BCS type was observed in two, CS in 33, and S in 33 cases, with N type found in 26. Over a median follow-up period of 13 months (six-22 months), cancer recurrence occurred in 16 cases (17.0%), 14 in the CS/BCS group, one in S, and one in N. Log-rank analysis revealed that the disease-free survival rate was exclusively worse in patients with clustered ITCs as compared to the other two groups (p<0.01) (Figure 2).

The present method was useful to detect and enrich ITCs from the PV, and showed the clinical relevance of their morphology in lung cancer cases. The presence of ITC clusters may be a prognostic biomarker for patients with resected NSCLC



Soichiro Funaki (left) accepts the award

Norivoshi Sawabata



Figure 1

### Young Investigators Award 2010: Congenital Prognostic significance and correlations of neurohumoral factors in early and late postoperative period after Fontan procedure

#### Jacek Kolcz,

Polish–American Children's Hospital, Krakow, Poland

he fate of patients with single ventricle defects after the staged construction of Fontan circulation with recent modifications is unknown but like many predetermined courses can be predicted in some respects. In the natural history of diseased cardiovascular system complex interactions between local, humoral, and neural factors lead to abnormalities in the circulatory control. These adaptive responses are aimed at maintaining adequate vital organ perfusion but can lead to unfavourable and undesirable changes both in the heart and the vascular system. Fontan patients have an impaired regulation of cardiac autonomic system and activation of many neurohormonal factors as well as the rennin-angiotensin-aldosterone system. These changes may contribute to numerous early and late postoperative complications e.g. dysregulation of fluid homeostasis, effusions, detrimental remodeling protein-losing enteropathy and limited exercise capacity. They can also serve

as important indices for risk stratifica-

tion prediction of unfavourable events and adjustment of treatment. This research work focused on neurohumoral activity and its clinical associations in early and late postoperative period after fenestrated, lateral intraatrial total cavopulmonary connection (TCPC) stratified by single ventricle morphology. Between 2007 and 2010, we prospectively studied 28 early postoperative and 48 late post-

350 300 E<14 days 280 +14 Cim's 200 150 100 50 0 -80 -100 RNP5 RAP 1 BNPT

> Figure 1. Relationship between prolonged length of stay and proBNP plasma concentration (BNP - brain natriuretic factor).

operative TCPC patients. Plasma concentrations of vasopressin, endothelin-1, proBNP, proANP were measured. Forty-eight patients underwent exercise tests 15 years after TCPC on average. We reviewed hemodynamic and clinical data to determine neurohumoral activation and clinical status early and late after TCPC depending on ventricular morphology. Within the group of patients hospitalized longer than 14 days, regardless of ventricular

morphology, plasma concentration of proBNP in the 7th postoperative day was significantly higher compared to patients hospitalized shorter than two weeks (p=0.04, Figure 1).

There was a significant effect of preoperative ventricular end-diastolic pressure VEDP (p=0.008) and vasopressin concentration (p=0.02) on the appearance of postoperative prolonged pleural effusions regardless of ventricular morphology. A significant correlation



Figure 2. Comparison of ROC curves for preoperative VEDP, preoperative vasopressin concentration and combined predictor (a product of preoperative vasopressin concentration & VEDP) for postoperative effusions.

between a combined predictor (a product of preoperative vasopressin concentration & VEDP), time of effusions (r=0.59, p=0.006) and length of hospitalization (r=0.61, p=0.04) was noted. The cut-off point with 89% specificity and 95% sensitivity was determined (Figure.2.). There was a significant correlation of endotheline-1 (r=0.84;p=0.008) and proBNP (r=0.88; p=0.02) concentrations with respiratory equivalent of carbon dioxide at peak exercise (VE/VCO2peak) related to older age at TCPC.

#### Conclusions

Prevalence of postoperative pleural effusions and length of hospitalization can be predicted using a combined prognostic factor, i.e. the product of preoperative vasopressin concentration and VEDP. Prolonged hospital stay may be anticipated by preoperative proBNP plasma concentration. Exercise performance is related to the age at TCPC. Endotheline-1 and proBNP can be useful for the identification of highrisk Fontan patients and adjustment of treatment in late follow-up.





### EACTS 2011 Ethicon Cardiovascular Simulation Award

EACTS, in partnership with Ethicon, is proud to announce the first EACTS Ethicon Cardiovascular Simulation Award

The Contest is to create a Simulator which replicates for training purposes Coronary Anastomoses. Development Criteria of the Simulator:

Low Fidelity

**Cost Effective** 

Reusable

Portable/Flat Pack assembly

The projects will be submitted under the form of a transportable self-construction package. It will have a graphical description of its building process and a textual description of the materials used.

The award will be presented during the 25<sup>th</sup> EACTS annual meeting.

An educational grant of **3000** € will be given to the winning team/person and the award simulator will be manufactured and used throughout Europe for training.

Contest opened to all residents and trainees.

Deadline for Submission: 1<sup>st</sup> of September 2011 For questions or submission, e-mail info@eacts.co.uk For more information, visit www.eacts.org/content/residents

### **EACTS First Postgraduate Leadership Course**

ntense, outstanding and enlightening are just three of the many adjectives used by cardiovascular and thoracic surgeon attendees to describe the EACTS First Postgraduate Leadership Course held in Ascot, UK from November 8th to 12th.

The course opened with an enlightening speech by Sir Bruce Keogh, Medical Director of the UK National Health Service, who challenged participants with a clear vision for the new patient-led approach that health care providers will face in the future. This was a comprehensive vision of what the understanding of delivering better health care services should be.

Immediately after, F Charles Brunicardi, Chair of the Michael Ev De-Bakey Department of Surgery at Baylor College of Medicine, enthralled EACTS surgeons with an outstanding talk about the role of modern leadership in healthcare.

Over the next 35 hours of an intense learning experience, William Murray, Eva Archer Smith, Adrian Lee, Marko Turina, Ottavio Alfieri, Paul Sergeant and many other keynote and exceptional speakers brought to the table the most relevant leadership issues both from the perspective of their expertise in the field and their personal experience, as well-known performers in leader-



ship roles within EACTS and other prestigious European universities and hospitals.

Thanks should also be given to Edwards Lifesciences, Medtronic and

St Jude Medical for providing some solid speakers that kindly addressed the audience and added an extra and priceless value to the course. In summary, a remarkable experience that in the future should not be missed!

I look forward to seeing you in Ascot next year for the second edition of the Leadership Course. Jose Luis Pomar Chair: Acquired Cardiac Domain and Course Organiser

### The European Registry of Aortic Disease (EuRADa) coming up soon

Ernst Weigang University Medical Center Mainz, Mainz, Germany

More of the set of the

medical treatment and long-term therapy are. The main goal of clinicians is to reduce the morbidity and mortality rate of these diseases.

Current studies do not adequately define the best treatment options for aortic diseases. The decision as to which treatment is best is highly individual and depends on the underlying aortic pathology, extent of aortic disease, and each patient's anatomy and co-morbidities. Further studies are necessary to ensure that individual decisions regarding the best medical care are based on a high level of evidence.

The aim of the European Registry of Aortic Disease (EuRADa) is, by collecting standardised data on patients with aortic diseases, to enhance our knowledge about these diseases via intensive data analysis. With this knowledge we hope to improve treatment in the future and identify key parameters affecting patient survival rates. EuRADa is designed to collect specific information about patient clinical status, diagnostics, treatment options, complications, cause of death, and follow-up data. The mid- and long-term aim of EuRADa is to continuously improve therapy by analysing and interpreting these data.

The key aspect is the database itself for collecting anonymous patient data. EuRADa collects parameters addressing all aortic diseases and all potential treatment options (conservative/pharmaceutical, interventional/endovascular, and open surgical). Each set of data is closed by the user when all the data have been included and the data has been validated. Those data can no longer be changed and are then included in the analysis. Thus, in-

> complete data sets cannot be subject analysis. Followp data, which nust also be valiated, can be inluded at regular ntervals. Postoprative follow-up lata will be colected at 30 days, six months, one /ear and then once annually for up to ten years. EuRaDa is a

EuRaDa is a long-term project. After a test phase of Eu-RADa, the centres will be connected to



Ernst Weigang

the registry step by step. Achieving a high level of evidence in the treatment of patients with aortic disease is this register's primary goal. To successfully translate into action the evidence-based knowledge gained through EuRaDa, it is important that as many European centres and other medical societies treating aortic diseases as possible participate in this ambitious project.

EuRADa is being developed under the leadership of Ernst Weigang (Department for Cardiothoracic and Vascular Surgery of the University Medical Center, Mainz), and is supported by the Vascular Domain of the EACTS and the EACTS Council.

1994					
talaka - Jammar	Summary				
il Lanati 5 keart: 8 keart: 9 keartika 9 keartika	And had had a lot of the Theorem Salation of Jakows J Salation of Jakows J Tradeof 9 Indiana Salation J Salation Salation J Salation Salation J	Last added Data 1995; H.S. M. M. M. 2005; H.S. M. 2005; 2005; H.S. M. 2005; 20	2 Jacks Recaller 1 price das 5 pairs das 6 pairs das	Litta Ganes Servit State Genn State Genn State Genn State Genn State Genn State Genn	A THE A
	Extend now had too to common to too     Type one enter too too balance produce     Autor conterns the support     Autor conterns the support     Support a too content to     Support a too content of the content on too     Type of the support     Type of the support	ar. Sanati. Gal Salad (Sa Sali) sa Isan			

### Raising standards through education and training





## ANNUAL MEETING

### 1–5 October 2011 Lisbon, Portugal

### Abstract deadline: 1 April 2011

For information please contact: EACTS Executive Secretariat 3 Park Street, Windsor Berkshire SL4 1LU, UK Telephone: +44 (0) 1753 832166 Fax: +44 (0)1753 620407 Email: info@eacts.org Website: www.eacts.org Francesco Maisano Cardiochirurgia, Ospedale San Raffaele, Milan, Italy

### Is a transfemoral app transapical approach for a

the blo

ranscatheter aortic valve implantation (TAVI) is the natural evolution of surgical aortic valve replacement: the prosthesis is delivered via a vessel, and it is implanted sutureless, compressing rather than excising the native valve, using image guidance<sup>1</sup>. The clinical adoption of TAVI is beyond expectations as it has rapidly become a valuable alternative to surgery and

medical therapy in highrisk patients. The initial reports were surrounded by scepticism: first Andersen suggested feasibility of the transfemoral approach (TF-TAVI) in the animal model<sup>2</sup>, and then Alain Cribier applied the concept in clinical practice<sup>3</sup>. TF-TAVI has the poten-

tial to disruptively change the speciality of cardiothoracic surgery as we have learned and practised it in the last 50 years. Why should aortic valve surgery not follow the track of oesophagoscopy, bronchoscopy, electrophysiology, aortic endografting and other examples of minimally invasive evolutions of surgery?

#### The value of TF-TAVI

The least invasive access for transcatheter implantation of an aortic valve is the TF-TAVI: it is usually carried out under local anaesthesia, with a totally percutaneous approach. Small size catheters, rapid pacing and steerable delivery catheters for balloon expandable valves and advanced delivery systems for the self expanding valves have improved implant precision, although vascular complications are still a frequent adverse event following TF-TAVI. In the future adjunctive devices such as dedicated sheaths, closure devices and embolic protection devices will further enhance the TF-TAVI outcomes. Recently, publication of the results of cohort B of the PARTNER trial, showed that TF-TAVI applied to inoperable patients with critical aortic stenosis reduces repeat hospitalization and more impressively one year all-cause mortality by approximately

50%, as compared to either medical therapy or balloon valvuloplasty<sup>4</sup> Considering that these data were collected in a first generation era (more complex devices delivered utilizing larger bore sheaths by operators still near the beginning of their learning curve), the results show that the safety and efficacy profile of the TF-TAVI approach in very high-risk patients are unequivocal.

"Surgeons should adopt TF-TAVI as part of their armamentarium to offer an unbiased choice of the approach that best fits to the individual anatomical and clinical characteristics."

> The results of the PARTNER trial confirm findings from several registries<sup>5-7</sup>: early and long term mortality risk in the TF-TAVI cohorts are promising, although survival data are strongly affected by patient selection. Vascular complications and stroke remain the most challenging adverse events in all series, although their rate will be reduced by new generation devices.

#### TA-TAVI: The option for the patients not suitable for the TF approach

The transapical approach (TA-TAVI) provides direct approach to the aortic valve, with no constraints in the

### YES

size of the delivery system<sup>8</sup>. The latter feature is becoming less important as the most recent TF-TAVI delivery systems are miniaturized enough to be applicable in the large majority of patients although it un-

derlines the versatility of the approach (to implant larger devices. to treat the mitral valve, aortic endografts, etc). Direct approach offers excellent control during the deployment of the valve and reduces aortic manipulation. However, in the SOURCE

registry (the largest study including TF-TAVI and TA-TAVI), the risk of stroke is not reduced by the TA approach<sup>5</sup>. Also the procedural success rate is not different in TF vs. TA-TAVI: TA-TAVI patients have a higher rate of SAPIEN-in-SAPIEN implants for valve malposition, conversion to open surgery, and valve embolization (Table 1). It must be noted that the SOURCE registry was not designed to compare the TF vs. the TA approach and that outcomes may be strongly influenced by selection bias and learning curve. However, data from the self-expanding CoreValve experience suggest that when the subclavian access has

outcomes were not different, despite of a similar selection bias compared to the SOURCE TA-TAVI patients (transfemoral first policy)9 The Canadian registry is the only dataset showing comparable results of the two approaches: of note, patient characteristics of the TF-TAVI and TA-TAVI in the Canadian registry are less different and suggest a more fair distribution of high risk patients in the two arms<sup>7</sup>. No registry supports TA-TAVI superiority compared to TF-TAVI. In addition. TA-TAVI is associated with a number of unanswered issues: How we can predict apical intraoperative or delayed bleeding? What is the role of the apical scar? Is the apical approach repeatable<sup>10</sup>? It is obvious that in centers where the TA-TAVI approach comes first, the TA-TAVI results are better that those reported in the SOURCE data. This is most probably as the result of the patient selection, however, this strategy is operator-centered rather than patient-centred.

been used instead of the TF-TAVI,

#### Choosing the optimal access

In the absence of specifically designed comparative trials, access choice should be based on a multidisciplinary team approach. Indeed, the operator should adapt the approach to the patient rather than the patient adapt to the approach, according to feasibility, efficacy and safety. Even assuming equal efficacy

Table 1: Thirty days outcomes in the SOURCE registry (non matched data)

Transfemora	al (n=463), n (%)	Transapical (n=575), n (%)	Total (n=1038), n (%)
Death	29 (6.3)	59 (10.3)	88 (8.5)
Short-term procedural success*	434 (95.2)	522/563 (92.7)	956 (93.8)
SAPIEN-in-SAPIEN valve	3 (0.6)	19/575 (3.3)	22 (2.1)
Conversion to open AVR	8 (1.7)	20/575 (3.5)	28 (2.7)
AR>grade 2+	7 (1.5)	13 (2.3)	20 (1.9)
Valve embolization	0 (0)	3 (0.5)	3 (0.3)
Coronary obstruction	3 (0.7)	3 (0.5)	6 (0.6)
Transfusion	46 (9.9)	51 (8.9)	97 (9.3)
Stroke	11 (2.4)	16 (2.6)	27 (2.5)
Renal failure requiring dialysis	6 (1.3)	41 (7.1)	47 (4.3)
Permanent pacemaker	31 (6.7)	42 (7.3)	73 (7.0)
Vascular complications	106 (22.9)	27 (4.7)	133 (12.8)

Adapted from M. Thomas et al, Circulation. 2010;122:62-69.

and safety, one should choose the least invasive approach: the one that does not require general anaesthesia, chest tubes, thoracotomy. With the current delivery systems, the precision of TF-TAVI implant is equal to the TA-TAVI, and the risk of vascular complications is mitigated. This is why TF-TAVI comes first in my practice, although alternative approaches (TA-TAVI, subclavian, and the direct aortic approach) are key to increasing safety and efficacy in selected patients and offering the possibility of TAVI to a wider range of patients. Surgeons should adopt TF-TAVI as part of their armamentarium to offer an unbiased choice of the approach that best fits to the individual anatomical and clinical characteristics.

- References
  1. Mack MJ. Minimally invasive and robotic surgery.
  JAMA 2001 Feb 7;285(5):568-72. 2. Andersen HR, Knudsen LL, Hasenkam JM. Transluminal implantation of artificial heart valves. De scription of a new expandable aortic valve and initial results with implantation by catheter tech ique in closed chest pigs. Eur Heart J 1992
- nique in closed chest pigs. Eur Heart J 1992 May; 13(5):704-8. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for cal-cific aortic stenosis: first human case description. Circulation 2002 Dec 10;106(24):3006-8
- Leon MB. Smith CR. Mack M. Miller DC. Moses Leon MB, Smith CK, Mack M, Miller DC, Moses M, Svensson LG, et al. Transcatheter a outric-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010 Oct 21;363(17):1597-607. Thomas M, Schymik G, Walther T, Himbert D, Johann J, Chymik G, Walther T, Himbert D,
- Lefevre T, Treede H, et al. Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) Registry: A European registry of tran scatheter aortic valve implantation using the Ed ards SAPIEN valve. Circulation 2010 Jul
- wards SAPIEN valve. Circulation 2010 Jul 6;122(1):62-9. Piazza N, Grube E, Gerckens U, den Heijer P, Linke A, Luha O, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalv-ing system: results from the multicentre, expanded evolution excited 1. uage following CE mark are ing system: results from the multicentre, expandio evaluation registry 1-year following CE mark ap-proval. EuroIntervention 2008 Aug;4(2):242-9. Rodes-Cabau J, Webb JG, Cheung A, Ye J, Du-mont E, Feindel CM, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very bind or mohibitive surgical risk: acute and late high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience J Am Coll Cardiol 2010 Mar 16;55(11):1080-90.
- J Am Coll Cardiol 2010 Mar 16;55(11):1080-90. Walther T, Simon P, Dewey T, Wimmer-Greinecker G, Falk V, Kasimir MT, et al. Transapical minimally invasive aortic valve implantation: multicenter ex-perience. Circulation 2007 Sep 11;116(11 Suppl):240-5. Petronio AS, De Carlo M, Bedogni F, Marzocchi A, Klugmann S, Maisano F, et al. Safety and efficacy of the subclavian approach for transcratheter aortic 8.
- of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalvi ystem. Circ Cardiovasc Interv 2010 Aug;3(4):359
- 00. 10. Payne DM, Rodes-Cabau J, Doyle D, Dumont E. Redo transapical aortic valve implantation: Feasibil-ity of a repeat approach through the left ventricu-lar apex. J Thorac Cardiovasc Surg 2010 Oct 4.

Department of Cardiac Surgery, Heart Center, University of Leipzig, Germany Droach preferred to a aortic valve implantation?

question

o defend the transapical (TA) against the transfemoral (TF) approach for transcatheter aortic valve implantation (TAVI) is perhaps more difficult than contrawise. This is because:

- It means to argue against an increasing number of (referring) interventional cardiologists since most of TF procedures will not be performed by surgical hands and
- 2. To defend the obviously more invasive procedure requiring general anaesthesia and minithoracotomy. Undoubtedly the transfemoral approach became more and more attractive and less invasive, which can be explained by smaller transfemoral delivery systems (18F) and the availability of percutaneous femoral artery closure systems, but this can not be a rational for a transfemoral first strategy.

#### TA approach is not inferior

Until today there are significant site biases in the use of TA- vs. TF-TAVI procedures which cannot be explained on a rational clinical need basis. Published intra- and interstudy comparisons of TAVI registry data using all previous device generations frequently indicate improved clinical outcomes in TF vs. TA patients. Data from the recently published SOURCE trial for example demonstrated lower 30-day mortality rates in TF (6.3%) than in TA (10.3%) procedures. However, these differences can be easily explained by intrinsic differences in the key risk factors and higher comorbidity profiles of the TA patients and by an associated strong selection bias. The lack of a true intrinsic difference in the application approach is also supported by data from the Canadian multi-centre TAVI registry that showed comparable early and mid-term results in TA and TF patients in a balanced

casemix. In centres with a TA-first strategy clinical results had even a lower 30-day mortality rate than in TF procedures (Leipzig experience). Procedure-related adverse events like high-grad atrio-ventricular conductance blocks and paravalvular leakages vary exclusively between the different valve concepts, but not between the delivery routes. Thus, it can be summarized that there were absolutely no reliable scientific data to support the TF over the TA approach.

However, even if results are comparable in many situations, patients and referring medical doctors give mostly preference to a less invasive strategy. We have to accept that probably about 60% of all TAVI candidates can be treated by either approach. It is foreseeable that in the near future these patients will be provided predominantly by TF approach, especially when even smaller delivery sheaths and more flexible transfemoral catheter systems will be available. Thus, CV surgeons have to adapt for these new technologies and like cardiologists have to be trained in these procedures.

### NO

shorter interval between balloon valvuloplasty and TAVI deployment. Moreover, at present time the TA approach is the only option to treat patients with a 29mm balloonexpandable prosthesis. Due to several rationales the transapical approach seems also to be ideal for TAVI-in-surgical-valve procedures. There are also patient-related factors which might favour selection of the TA approach in a given patient. These specific risk factors can be identified by looking to the differences in baseline characteristics between TF and TA patients. Accordingly, primary TA-TAVI candidates are patients, who are more likely to have peripheral vascular disease, aortic arch pathologies, carotid artery disease, porcelain aorta, concomitant coronary artery disease, mitral valve disease, previous cardiac surgery or severe spine deformities and thus can be summarized as true non-surgical candidates. In these pa-

"We and our cardiology partners should aim to overcome personal and financial interests and to find a team decision for the best approach in every particular patient."

But when does it favour the TA approach? There are several potential technical advantages like an easier antegrade crossing of the aortic valve, more precise valve positioning and better coaxial valve alignment by a short distance between the access point and the aortic valve, the use of larger valve sizes and a tients stroke rate of the TF approach is 6.7% as data from the Cohort B data of the PARTNER trial indicate and thus is at least 2.5-fold higher than rates that are known for the TA approach.

There are also other scenarios when to prefer a TA strategy. TAVI through an anterior minithoracotomy might be in the future combined with an aortic coronary artery bypass surgery or the application of left atrial appendage closure devices to treat concomitant coronary artery diseases or to reduce the lifetime risk of cardiac embolization in patients presenting persistent atrial fibrillation, respectively.

Ardawan Julian Rastan

Finally, advocating the transapical approach does not only include highlighting the advantages of the transapical approach, but also addressing the limitations of the transfemoral approach. One major limitation of the TF approach is the high vascular complication rate by accessing the femoral artery. Even if TF-TAVI can be made through an 18 French sheath, major vascular complications remains significant and are associated with a significantly higher rate of 30-day mortality rate (93.5 vs. 82.2, p<0.01) as shown in the combined cohort 1 and 2 of the SOURCE registry.

### Limitation of the opponents approach

Approximately 20% of all TAVI candidates might favourably be treated by transfemoral approach. Considerations for a TF approach include patient risk factors like O2-dependence, COPD, extreme frailty or chest wall deformity/radiation, but also anatomic aspects like a small hypercontractile left ventricle, severe LV dysfunction or an unfavourable LV apex anatomy. Other potential disadvantages of the TA approach are a steeper learning curve, more frequent hypotension and the risk to entrap the mitral valve apparatus during implantation. Compared to the TF approach, the impact of adverse events during TA-TAVI implantation (apical bleeding, cardiopulmonary bypass use, resuscitation or conversion to sternotomy) on survival is much greater

than for TF procedures.

TF-TAVI offers the potential to perform the procedure under local anaesthesia. However, it is not well proven that this is more comfortable and safer for the patients, but it might be beneficial in severely impaired lung function. Beyond this, it is obvious that local anaesthesia means to abandon periprocedural transoesophageal echocardiography as an important imaging modality to control periprocedural success.

#### Conclusion

Clinical data less than the lower invasiveness today favour TF approach. However, based on experiences CV surgeons have from percutaneous coronary interventions it is not useful to give the indication and performance of TF procedures exclusively to interventional cardiologists. This potentially bears the risk of an uncontrolled wild TF-TAVI application, limited follow-up interests and increasing costs. Thus, we and our cardiology partners should aim to overcome personal and financial interests and to find a team decision for the best approach in every particular patient. Better understanding of TA and TF procedure outcomes has already resulted in differential patient profiling favouring one or the other approach under many circumstances. TA and TF are thus complimentary and not competitive procedures and the decision for the one or the other approach should be an individualized case-based team process in the best interest of our patients

TA approach is of course more invasive today, but offers several benefits compared to the TF route. TA will, however, never be as 'less invasive' than TF. This limitation can be eliminated only when percutaneous transapical application systems will be available in the future.



**Members views** Which approach do you favour and which approach do you believe results in the best outcomes? *EACTS News* would be delighted to publish your views.

Please send your comments to: communications@e-dendrite.com. We will publish as many of your comments as possib

### **PARTNER** trial **Clinical significance** and implications

The Placement of AoRtic TraNscathetER valves (PARTNER) trial is the first randomized, controlled, clinical trial to compare transcatheter aortic valve implantation (TAVI) against standard therapy or surgery. The results from the first cohort (comparing TAVI with standard therapy in high-risk patients with severe aortic stenosis) were recently presented at the 22nd Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in October and published in the New England Journal of Medicine (2010; 363:1667-1668). EACTS News spoke with the trial's co-Principal Investigator Dr Martin B Leon (Center for Interventional Vascular Therapy, New York-Presbyterian Hospital/Columbia University Medical Center), who outlined the clinical significance of the results and the important implications the trial could pose for treating valvular heart disease.

#### Trial design

The trial has been divided into two cohorts (Cohort A and Cohort B) Uniquely, all patients were assessed by a surgeon and interventionalist using the assistance of the Society of Thoracic Surgeons (STS) risk score and best clinical judgment. The inclusion criteria included patients with severe calcified aortic stenosis defined as an echo-derived valve area of <0.8 cm<sup>2</sup> (EOA index <0.5cm<sup>2</sup>) and a mean gradient of >40mmHg or jet velocity >4.0m/s; NYHA functional class II or greater; and a risk of death or serious irreversible morbidity as assessed by a cardiologist and two surgeons that must exceed 50% in the 'inoperable' cohort.

Cohort A included 700 patients and is designed to compare patient outcomes after treatment with either the Edwards SAPIEN transcatheter valve or traditional open-heart surgery. Patients in this cohort were deemed high-risk candidates for surgery and were randomized to receive either transcatheter valve replacement or surgical valve replacement.

Cohort B has recruited 358 patients with aortic stenosis who were not considered to be suitable candidates for surgery. Patients were then randomized to receive standard therapy (a combination of watchful waiting, medications, and balloon aortic valvuloplasty) or TAVI of a balloonexpandable bovine pericardial valve. Of 179 patients in the TAVI group, 173 underwent the procedure. Of 179 in the standard-care group, 84% underwent balloon valvuloplasty, 10% eventually underwent aortic valve replacement, and 2% underwent TAVI at a non-participating institution. The primary end point was the rate of death from allcause at one year.

#### Outcomes

At one-year, the rate of death from any all-cause (Kaplan–Meier analysis) was 30.7% in the TAVI group, compared with 50.7% in the standard therapy group (hazard ratio with TAVI, 0.55; 95% confidence interval [CI], 0.40 to 0.74; p<0.001). The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% in the TAVI group, compared with 71.6% in the standard therapy group (hazard ratio, 0.46; 95% CI, 0.35 to 0.59; p<0.001). Among survivors at one year, the rate of cardiac symptoms

(New York Heart Association class III or IV) was lower among patients who had undergone TAVI, compared with patients who had received standard therapy (25.2% vs. 58.0%, p<0.001).

"The outcomes from this cohort of patients from the PARTNER trial show that the difference between the two groups in all cause mortality (Kaplan-Meier analysis) was 20% at one-year. So it was a highly statistical significant study showing that

even in these 'sickest of the sick' patients that are not candidates for surgery. TAVI results in such a substantial reduction in all-cause mortality," said Leon. "Based on the reduction in mortality during the first year of the study, balloon-expandable TAVI should be the new standard of care in patients who are not suitable candidates for surgery, when you consider that you only need to treat five patients to save one life in this study."

#### Stroke rate

However, the positive all-cause mortality data were tempered by a higher incidence of major strokes (5.0% vs.



1.1%, p=0.06) and major vascular complications (16.2% vs. 1.1%, p<0.001), at 30 days in the TAVI group vs. standard therapy group.

"If we look at both arms of the PARTNER trial, those who were inoperable and those who could have surgery, we are still operating on the upper decile of patients with aortic valve stenosis, so these patients are not patients we see every day. At 30-days there is a significant difference in major strokes rates. InterestMartin Leon

ingly, between 30-days and a year there were no further changes, with an additional 2.8% of patients in both groups suffering strokes. This suggests this is an elderly strokeprone patient population," commented Leon.

"The stroke issue is somewhat confusing. For the major strokes that occurred in the TAVI group, some occurred early, some many days later and some were haemorrhagic and not ischaemic. The etiology of the strokes is not entirely clear, although many were clearly procedure-related, occurring in the first several days after TAVI." He added that the stroke rate could be a multi-factorial issue with many patients in atrial fibrillation and also receiving a variety of anti-platelet and anti-thrombotic medications

Nevertheless, although Leon believes that the stroke rate is a concern but even if strokes are added to all-cause mortality in a composite analysis there is still an absolute reduction of 18.5% in a year in favour of those in the TAVI group.

In regard to vascular complications, he suggested that these could be explained by the use of first generation devices (22-24 Fr sheaths) in elderly patients (small stenosed vessels) and hoped that with improved techniques and new-generation devices the rate of vascular complications will be reduced in the future. "In older patients with vascular disease, it is difficult utilize the larger device used in the PART-NER trial. The next-generation devices, such as the Sapien XT will reduce both the vascular and bleeding complications as they make it easier to navigate the peripheral vasculature and make the trauma of approaching and crossing the valve less, and may reduce some of the embolic complications that may have contributed to the strokes," he added.

Encouragingly, in the year after TAVI, there were no reported instances of deterioration in the functioning of the bioprosthetic valve. However, Leon cautioned that bio-



PARTNER Trial design diagram (AVR = Aortic valve replacement)



Edwards Sapien XT transcatheter heart valve



Edwards Sapien transcatheter heart valve prosthetic valve durability must be

compared to surgical valve and therefore examined out to ten and 15 years.

#### Heart team

PARTNER utilized a 'heart team' approach with an interventionalist and a surgeon agreeing that a patient was not eligible for surgery for that patient to be enrolled (a full 66% of patients were screened but never included in the trial as a result). According to Leon, this approach was a very important aspect of the study and helps to explain the 'pretty good' procedural results in this study considering how sick the patients were.

"We continue to believe that this is a very important aspect of the study. It was based on the SYNTAX model and built on so that at every site there had to be a co-Principal Investigator that was a surgeon and

an interventionalist and the executive committee consisted of four surgeons and four interventionalists. Everything was carefully shared and discussed, and every procedure had to be

attended by both a surgeon and an interventionalist," he commented. "So we think the patient screening, procedures, complication management and post-operation therapy is greatly benefitted by having this coordinated 'heart team' approach. I think such an approach is going to be good for cardiovascular medicine, as it could lead to changes in how

2

ę

Hards on training to 7951 and 2005

<u>\_\_\_\_</u>

we train young people and how we take care of patients."

Although he acknowledges the importance of these results, Leon is under no illusion that more results are needed to confirm the role of TAVI in additional patient groups. "In these patients. I believe that TAVI should become the standard of care. However, this is a vast minority of patients and I do not believe you can extrapolate these data to include other patients groups who could undergo surgery and determine that TAVI is somehow superior. That question can only be answer by future randomised clinical trials", he concluded. "At the American College of Cardiology meeting in 2011, we hope to present some results from the surgical cohort and these outcomes will guide us further as to where TAVI fits in the overall treatment strategy. This study

John Pepper

perts, Professor John Pepper and Mr . Neil Moat (both from Royal Brompton & Harefield NHS Foundation Trust, London, UK), and asked what impact they believed the results

"The patients included in the PARTNER trial were from a very high risk population group and to that extent the results were very encourag-

ing," commented Moat. "However the outcomes at one-year were still poor in the TAVI group and we really need to see the longer



sent a paradigm shift in treatment, but in management," said Pepper. "I think it is impressive that the number needed to treat in this trial to show that TAVI was better than standard treatment was only five. It is also interesting that 64% (114 patients) in the control group had a balloon valvuloplasty, which was ineffective, something that we already knew. There was a small 'cross-over' of 6.7% to conventional AVR where the mortality was high at 33% for

dure that is associated with specific peri-procedural risks (eg. manipulation of the ascending aorta and arch with the catheter).

The 'heart team' approach was also endorsed by Moat who added that the approach was the way that decisions should be made on individual patients (see ESC/EACTS guidelines on revascularisation), and represents a return to the principles of good medical practice.

The next-generation Edwards Sapien XT transcatheter heart valve will be utilised in the PARTNER II study and Pepper believes that this will lead to changes: "I think it is most likely that new technology will improve results, but I also believe it is likely that patient selection will also change." Moat agreed with Pepper that the improvements in technology, implantation techniques and patient selection will improve the short term outcomes

As for the results from cohort A (comparing TAVI with conventional surgery), Moat believes the outcomes could have a greater bearing on clinical practice than the results from cohort B: "They will be very interesting and informative. I suspect that they will have greater relevance given that they will address a larger potential patient population."

"We wait to see the results of TAVI versus conventional aortic valve replacement, promised in the Spring of next year. Patients and primary care physicians may well prefer TAVI," added Pepper.

Neil Moat wait' policy. The results do not repre-

but in management" AVR and 80% for AVR and root reterm survival (out to three or five years) in this cohort, placement although the numbers as well as cost effectiveness data beized trials to compare treatments and were low." provides us with the observations and fore we can say this is the gold stan-In regard to the higher incidence data that prove invaluable in our dedard even in this very high risk of major strokes and major vascular cision-making process, and ultimately events, neither Moat nor Pepper cohort.' "The PARTNER trial shows that for improving the outcomes for all our were surprised stressing that this patients judged as 'inoperable' by was understandable and predictable patients. FACTS News also discussed the experienced aortic valve surgeons, in this group of patients given the PARTNER results with two TAVI ex-TAVI is better than a 'watch and fact that they underwent a proce-The PARTNER trial is funded by EACTS Daily News EACTS Daily Ne BEACTS Daily Ne BEACTS Daily New BEACTS Daily News EACTS Techno Colle Monday's highligh The surgion and the matician Welcome to the 24th E Annual Meeting in Con Innovation Award 20 All four issues of the 

EACTS Daily News newspaper are now available online. To download your

free pdf copy, please visit: www.e-dendrite.com/ publishing/ conference-news

EACTS News 25



#### **Clinical comment: David Taggart** assesses the Arterial **Revascularisation Trial (ART)**

#### David Taggart

Professor of Cardiovascular Surgery University of Oxford, UK, and Principal Investigator of the Arterial Revascularisation Trial (ART).

he one-year outcome of the Arterial Revascularisation Trial (ART) was presented at the European Society of Cardiology in Stockholm and simultaneously published as a fast track article in the European Heart Journal (Taggart DP et al; on behalf of the ART Investigators. Randomized trial to

compare bilateral vs. single internal mammary coronary artery bypass grafting: One-year results of the Arterial Revascularisation Trial (ART). Eur Heart J 2010:20:2470-2481).

The Trial is a trial of 3,102 patients (making it one of the largest trials ever conducted in cardiac surgery) randomised to bilateral or single internal mammary artery (IMA) grafts. In 1986 the Cleveland Clinic established that there was a survival benefit in patients receiving at least one IMA and in 2001 our own group published a systematic review in the

Lancet suggesting there was an additional survival benefit with two IMA. Nevertheless the use of bilateral IMA grafts is uncommon being used in only around than 10% of patients in Europe and fewer than 5% in the US.

We therefore undertook a trial funded for ten-year follow-up by the Medical Research Council and the British Heart Foundation in the United Kingdom to randomise over 3,102 patients in 28 different centres in seven countries (Austria, Australia, Brazil, India, Italy, Poland, United Kingdom) with 68 participatina suraeons.

The one-year outcomes showed a very low 30 day mortality of 1.2% and a one year mortality of 2.4% in both groups demonstrating the safety of contemporary CABG. There were no differences in the incidence of death, myocardial infarction, stroke or need for repeat revasculari-

sation. There was however a small increase in the risk of sternal wound reconstruction from 0.6% in the single IMA group to 1.9% in the bilateral IMA group. This translates into a number needed to harm of more than 70 patients to result in an extra sternal wound reconstruction. However we hope to identify, by multivariable regression, the factors which predispose to sternal wound reconstruction and therefore to avoid bilateral IMA in those patients.

Once again all the contributors to the ART Trial should be congratulated for their fantastic efforts in demonstrating the safety of contemporary CABG with one or two IMA. As the ART Trial is funded for ten-year follow-up we should be able to establish whether there is a survival benefit with bilateral IMA and reduction in the need for repeat interventions at one year which were all under 2%



### **EACTS Robotic Course in Cardio-Thoracic Surgery**

**Members views** If you would like to comment on any of the aspects concerning training and education, or express your opinion regarding the outcomes from the ART Stuc EACTS News would be delighted to publish your vie

Franca Melfi University of Pisa, Italy

#### February 23-26, 2011

he advanced engineering technology on minimally-invasive surgery, makes it possible to overcome some technical difficulties which can occur during a

'conventional' minimally invasive surgery. Robotic-assisted surgery represents an extraordinary technological advance for a broad range of procedures traditionally requiring open surgery. By enabling surgeons to perform complex operations through small incisions, the robotic surgical system (Surgical Intuitive, Inc., Mountain View, CA) can be considered the most recent and advanced stage of this process thanks to its 3D vision and seven degrees of freedom (7DOF) of its instrumentation, to replicate the human wrist. The surgeon's hand movements are scaled and filtered to eliminate hand tremor then translated into micro-movements of the proprietary instruments. The camera used in the system provides a true stereoscopic pic-

ture (3D) transmitted to a surgeon's console. These improved ergonomic conditions and instrument mobility at distal articulations seem beneficial in thoracic procedures

In cardiothoracic surgery there is not yet a standardized technique the surgeon can precisely follow, and even very experienced surgeons may have very limited robotic experience. To perform robotic surgery in a safe and straightforward manner, it is neces-



sary to standardize procedures and establish operative schemes. EACTS plays an important role by promoting the educational opportunities for the training surgeons in the field of high-technology

On February 23-26, 2011, the 2nd EACTS Robotic Course on Cardio-Thoracic Surgery will be held in Strasbourg (France). The course will cover important clinical aspects relating to the use of robotics in variety of cardiac and thoracic procedures. Surgeon faculty will demonstrate operating room configuration, system preparation, port placement, as well as pre-, intra- operative techniques using the robotic surgical system. Cadavers and large animal models will be employed.

#### **Target Audience and Objectives**

Surgeons who have access to the da Vinci system and are interested in learning robotic cardio- thoracic surgery, are highly recommended to join this course. By the end of the training programme participants should be able to:

- List the basic features and potential benefits of the robotic surgical system
- Understand the application of various instruments
- Demonstrate the techniques of cardio-thoracic suturing and knot tying using robotics
- Articulate patient selection, patient positioning, surgical techniques, indications and contraindications
- Apply the principles in order to be a safe and efficient robotic surgeon

A highly-qualified international panel of ex-



perts will take part to this course. Their presence will give precious information in terms of indications and technical surgical sequences in order to avoid an inappropriate use of this new technique. What we expected for the attendees to this Course is:

- Improvement in surgical performance.
- Reductions in operative times with increasing number of procedures while obtaining results that conform to specific standards.

We are all aware of that there will be in the future a great need for highly skilled surgeons in this field. We believe that this course will give a great opportunity to train surgeons in the field of high-technology applied to surgery, which is in line with the mission of the EACTS 'to promote and foster education and research in the field of cardiothoracic surgery.

#### EACTS is meeting the National Societies

During the past few years the EACTS always organized a meeting with representatives from the national societies during the EACTS Annual Meeting. However, the possibility to discuss issues in depth was limited due to time constraints during the meeting. Therefore, the EACTS has convened a meeting with the Presidents of the National Societies on

and would like to discuss the following issues:

- Organization of post-graduate education
- Harmonization of cardio-thoracic training programs in Europe
- Functioning and representation for the UEMS
- European Board of Thoracic and Cardiovascular Surgeons
- European Databases

The National Societies have been personally invited by the Secretary General. If you do not have received an invitation please contact Rianne Kalkman: RianneK@eacts.co.uk

#### 8 April 2011, Paris, France

Franca Melfi

#### **EACTS Events in 2011**

23–26 February **EACTS Academy: Cardio-Thoracic Robotic** Surgery Level II Strasbourg, France

#### 11-12 March 2011

**Right Ventricular Outflow** Tract Management from Neonates to Adults: An **Interdisciplinary View** Palma de Majorca, Spain

#### 16–18 March **EACTS Academy:** Open and endovascular aortic therapy Windsor, UK

#### 1-5 October 2011 25th EACTS Annual Meeting

Lisbon, Portugal

#### For information contact: **EACTS Executive Secretariat** 3 Park Street, Windsor, Berkshire SL4 1LU, UK Phone: +44 1753 832166 Fax: +44 1753 620407 Email: info@eacts.co.uk Web: www.eacts.org

### **Key International Events in 2011**

If you would like to list your events here please

communications@e-dendrite.com

2–5 April

#### January 31–February 02

**Society of Thoracic** Surgeons 47th Annual Meeting San Diego, US Contact The Society of Thoracic Surgeons, 633 N. Saint Clair Street, Suite 2320, Chicago, IL 60611 Phone: (+1) 312 202 5800

(+1)312 202 5801

email the details to:

Email: sts@sts.org

### 60th American College of

Cardiology Annual **Scientific Session & Expo** (ACC.11) New Orleans, US Contact Conference Secretariat – ACC Email: resource@acc.org

#### American Association for **Thoracic Surgery (AATS)** 91st Annual Meeting 2011 Philadelphia, US Contact: Meeting Organiser: American Association for Thoracic Surgery (AATS) Phone: (+) 978 927 8330 (+) 978 524 8890 Fax:

#### 17-20 May

7-11 May

**EuroPCR** Paris, France Fax: +33 5 34 45 26 46 Email: europcr@europaorganisation.comm

#### 27-31 August

**European Society of Cardiology Congress 2011** Paris, France

Contact: Congress Secretariat Phone: (+33) 4 9294 7600 (+33) 4 9294 8629 Fax:

#### 7-11 November

Transcatheter Cardiovascular

#### Therapeutics (TCT 2011) San Francisco, US

Contact Cardiovascular Research Foundation Phone: 646-434-4500 Email: info@crf.org

#### 10-16 November

American Heart **Association Scientific** Sessions (AHA 2011) Orlando, FL Contact Conference Secretariat -AHA Email: scientificconferences@ heart.org

### Competition crossword Fax back to +44 (0) 8700 560 633

Compiled by Sam Nashef, Papworth Hospital, UK. Entries must be received by 13 January 2011. The winner will be the first correct answer randomly selected by the Editor.

#### Your name

Fax.

#### Cryptic clues

Across

- 1/6/29/30 Moving to granary by frying peas, carrots and cabbage when familiar (8,6,6,8)
- Satire is cute, but oddly uncompromising (6)
- 10 Drop in and work on board for seafood (8)
- See 26 Down 11
- 12/24 From California city, random 26down attack (10.10)
- I forgot to mention maltreated song (5) 13
- Nonconformist to defeat the devil? Sounds like it (7) 15
- 19 See 26 Down
- 21 Poet after Bob and before Thomas (5)
- 24 See 12
- Greeting said to be lofty (4) 26
- Earl of Beaconsfield shows princess round the coun-27 trv (8)
- 28 Script is essential to merit a license (6) 29 See 1

#### Down

- Much emotion expressed when tour bus breaks 2 down at junction (8)
- 3 In the red shabby gown worn by compiler (5)
- 4 Fall of Man-U playing in Paris: you come in (6)
- Agreed veto? The opposite! (3,4) 5
- 6 Salad: scary item at heart of menu (1,2,5)
- 7 Like bathroom, but led it astray (5)
- 8 You've already seen this agent dine (6)
- 14 Field is clear, but avoid extremes (3)
- Compiler extremely chilly indeed (3) 16
- 17 Elegant Kenneth's birds (8)
- Swelling with pride leader follows group (8) 18
- 20 Fixing North in trouble (7)
- Some spent it yearning for independent existence (6) 22
- 23 Perhaps gain an indication for 1, 6ac, 29, 30 (6)
- Large vessel in the sea, or tanker (5) 25
- 26/11/19 Listen to yours once, taking a breather with overcoat used in 1,6ac,29,30 (5-4,7)

#### Your email

In a cryptic crossword, the clue is in two parts. One part gives the definition of the answer, another part gives a different way of reaching the same answer. The parts of the clue are run together to further mislead the solver. For example, for the clue, "Planet's broken heart (5)" the answer would be 'Earth' ('Planet' = the definition, and "broken heart" implies an anagram is needed of "heart" = 'earth'. Try the cryptic clues first, but if these are too difficult, the non-cryptic ones will help as both sets of clues have the same answers. Please use BLOCK CAPITALS and BLACK INK and complete your personal details.



#### Non-cryptic clues

Across 1/6/29/30 Operation (8,6,6,8)

- 9 Stern (6)
- 10 Seafood (8)
- See 26 Down 11
- 12/24 Heart attack (10,10)
- 13 Religious song (5)
- Nonconformist (7) 15
- See 26 Down 19
- 21 Folk singer (5)
- 24 See 12
- 26 Elevated (4) 27 British prime minister in 1868 and 1874 (8)
- 28 Script (6)
- 29 See 1
- Down
- Explosion (8) 2 In debt (5)
- 3 4 Fall (6)
- 5
- Positive ballot result (3,4) 6 Alternative to set menu
- (1, 2, 5)7 Like bathroom wall (5)
- 8 Redo (6)
- 14 Field (3)
- Verv cold (3)
- 16 17
- Poultry (8)
- Swelling (8) 18 20 Fixing (7)
- 22 Body (6)
- 23
- A possible indication for 1, 6ac, 29, 30 (6)
- Large vessel (5) 25

26/11/19 Kit which may be used in 1,6ac,29,30 (5-4,7)





### Treat your patients with more options

#### Expanding options for your patients with the Edwards SAPIEN XT" valve

The Edwards SAPIEN XT<sup>\*</sup> valve offers the proven design benefits of the world's most widely implanted surgical tissue valves. Now, Heart Teams can deliver a transcatheter aortic valve featuring:

- Advanced leafliet design and manufacturing based on Edwards Lifesciences' clinically proven valves.
- Optimized frame height for proper placement and non-interference with surrounding anatomy
- . High radial strength for proper hemodynamics and valve durability
- Three size options (23 mm, 26 mm, and, coming scon, 29 mm)

