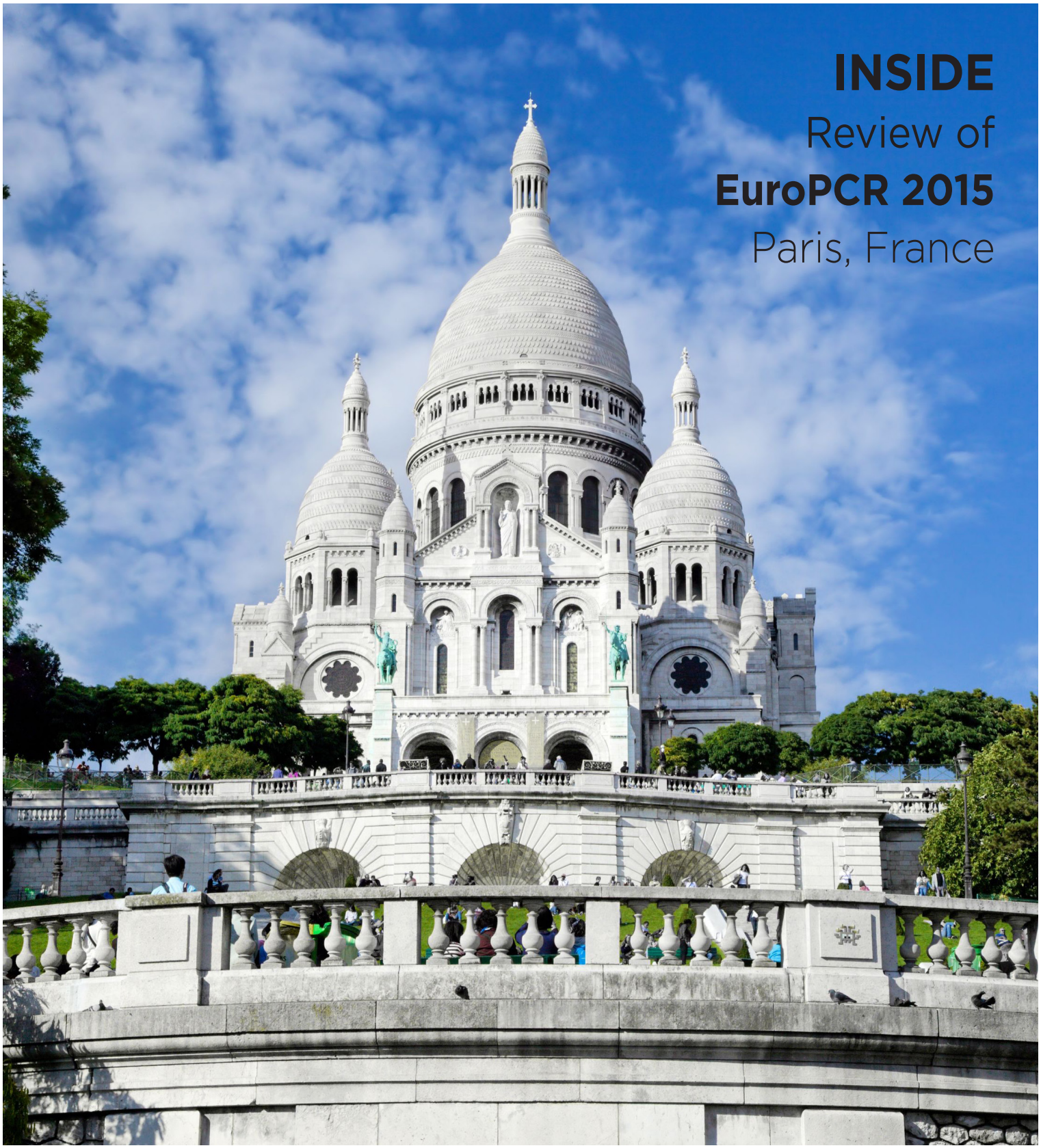
EMJ EUROPEAN MEDICAL JOURNAL

INTERVENTIONAL CARDIOLOGY

ISSN 2053-423X

Vol 3.1 • July 2015 • emjreviews.com



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Review of

EuroPCR 2015

Paris, France

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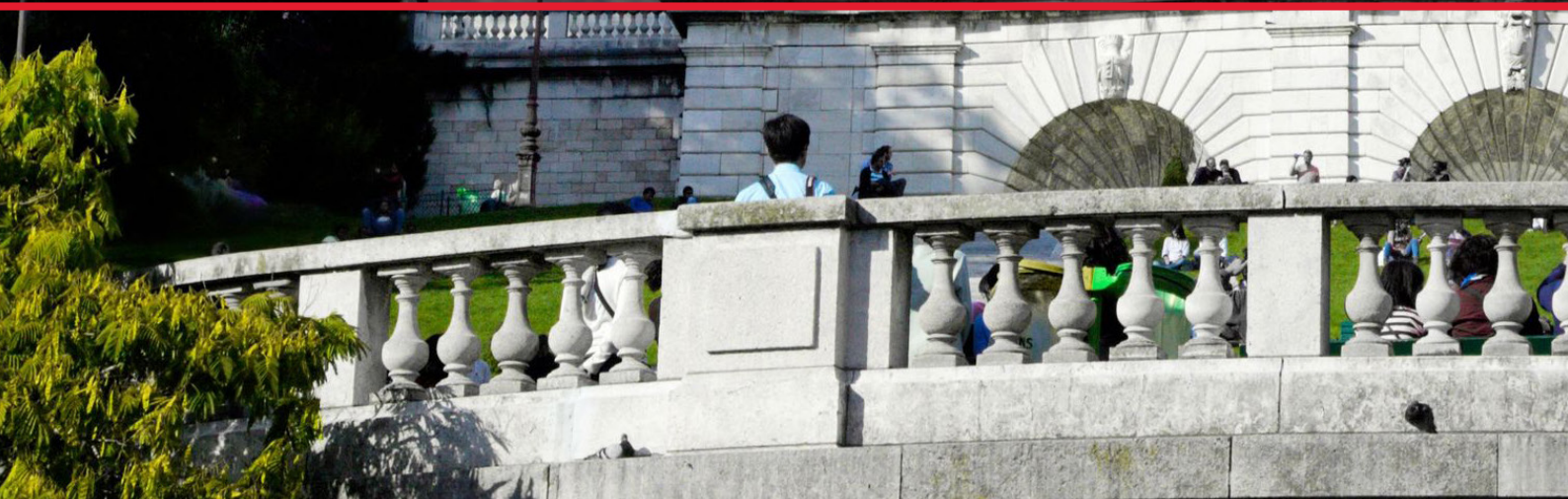
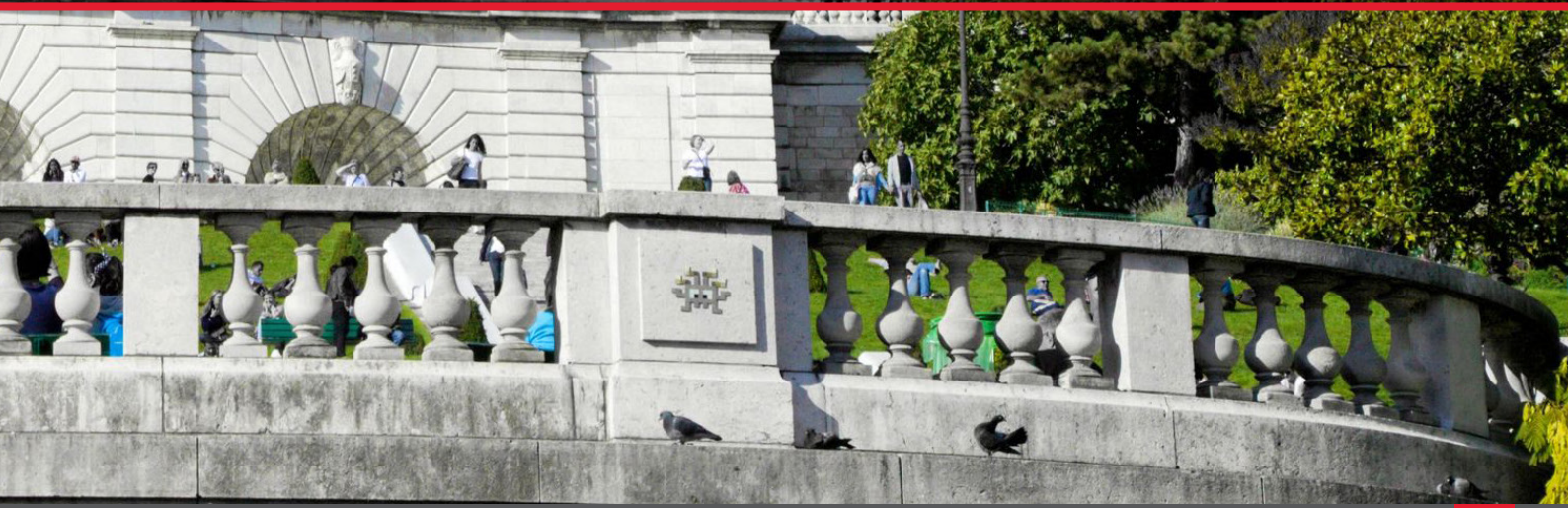


INTERVENTIONAL CARDIOLOGY



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European Medical Journal
EMJ Int. Cardiology Vol 3.1
July 2015

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Welcome

Welcome to this edition of *European Medical Journal Interventional Cardiology,* which we hope will provide you with a thorough analysis of some of the most important topics in this rapidly evolving discipline. Inside, we have dissected the vitals from EuroPCR 2015, held in Paris, France, on 19th-22nd May. This edition provides a timely recap of the congress for those who attended, and ensures that anyone who was not able to experience EuroPCR in person may read about the major research presented during the prestigious event.

A series of important developments and discoveries were presented at EuroPCR, and these have been extensively covered in this issue. To provide just an appetiser of the content, we include reports on the risk of stroke caused by routine thrombectomy, successful trials of new mechanical thrombectomy devices used to treat acute stroke patients, and an update on the use of renal denervation in hypertensive patients failing to respond to multi-drug regimens. In addition, we take a look at the positive initial data from a subset of patients treated with a sirolimus-eluting bioresorbable scaffold, and other research showing that cardiac and renal events are significantly less frequent during angioplasty procedures using an isosmolar contrast medium compared with procedures using low-osmolar contrast media. These reports, along with the many others, provide a flavour of the vital research presented at EuroPCR.

Also featured in this issue are summaries of some of the key presentations given by distinguished names in the field, all of which have been written by the presenters themselves. These summaries include an overview of the balloon elution and late loss optimisation study, which addressed the use of drug-eluting stents and drug-coated balloons for *de novo* small vessel coronary artery disease, while another summary details the limitations of valve-in-valve procedures for the treatment of failed surgical valves. To add to all of this, we have also included full reviews of some of the symposia that took place at the congress, which were presented by some of the most prominent interventional cardiologists in the field.

We hope that our content will not only give our readers a comprehensive overview of EuroPCR 2015, but also provide a snapshot of the current state of interventional cardiology in general. New techniques and technical innovations for the treatment of heart conditions are transforming the lives of many patients worldwide, and it is our hope that the information included in our publication will help contribute to this crucial process.

Spencer Gore

Team Principal, European Medical Journal

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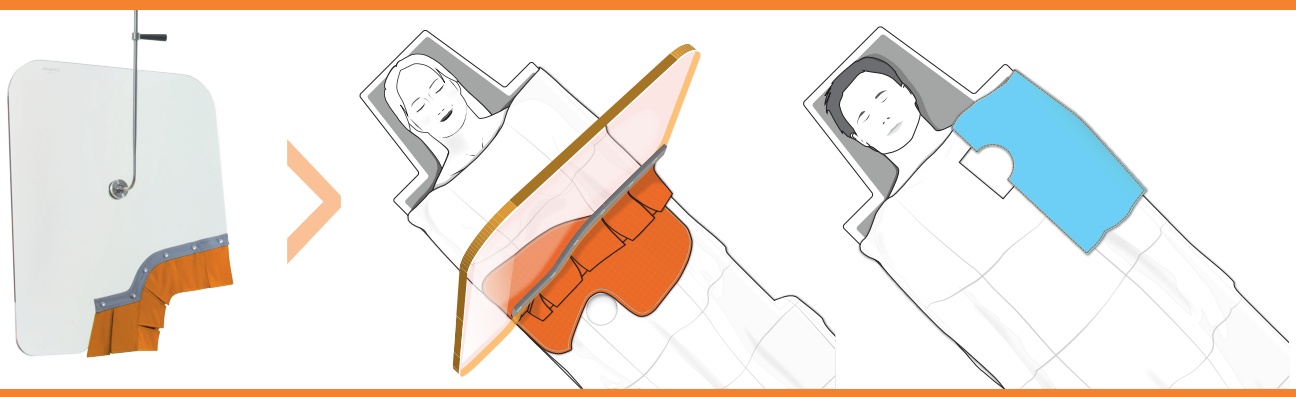

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Foreword

Prof Ran Kornowski

Chairman, Department of Cardiology, Rabin Medical Center;
Professor of Cardiovascular Medicine, Tel Aviv University, Israel

Dear Colleagues,

Heart disease is a leading cause of death in most parts of the world. Interventional cardiology embraces all forms of treatments involved in preventing and curing the morbidity and mortality associated with heart diseases. These are exciting times for the field, and armed with new, improved technologies and effective pharmacological agents, we can now face the challenge of expanded indications among cardiac patients who are in need of medical help. There are numerous emerging developments aimed at achieving therapeutic benefits in myocardial revascularisation, structural-valve interventions, heart failure syndromes, peripheral interventions, and systemic diseases such as diabetes and hypertension.

“Breaking news of particular interest will also be reported in the journal, and this feature is already integrated into social media platforms, providing immediately updated information to readers on their computers or mobile devices. Busy clinicians will thus be able to easily keep themselves informed of the latest developments in the field.”

European Medical Journal is striving to publish high-quality, peer-reviewed articles using an open-access platform of medical publishing, and this edition provides exactly that. All content is freely accessible – a measure that ensures the widest possible dissemination of valuable cardiology knowledge to a global readership. We encourage the submission of current therapeutic and diagnostic developments and novel techniques in all aspects of cardiovascular medicine for future editions.

Furthermore, this edition of *EMJ Interventional Cardiology* reports on the events of EuroPCR 2015 held in Paris from 19th-22nd May 2015, providing a thorough analysis of the vital information that emerged from this congress. Breaking news of particular interest will also be reported in the journal, and this feature is already integrated into social media platforms, providing immediately updated information to readers on their computers or mobile devices. Busy clinicians will thus be able to easily keep themselves informed of the latest developments in the field. We especially look forward to innovations in biodegradable scaffolds, novel valve interventions in all four cardiac positions, sophisticated and guided cardiac imaging technologies, holistic solutions for the failing heart, and additional ground-breaking diagnostic and therapeutic innovations at an early or later stage.

On behalf of the editorial board, I look forward to the advancement of *EMJ Interventional Cardiology* into a productive forum for the propagation of cardiovascular knowledge to readers worldwide.

Best regards,

Ran Kornowski, MD

Ran Kornowski

Chairman, Department of Cardiology, Rabin Medical Center, Beilinson and Hasharon Hospital, Petah Tikva; Professor of Cardiovascular Medicine, The ‘Sackler’ Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.

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- Lieven Annemans et al.

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EUROPCR ANNUAL CONGRESS 2015

PALAIS DES CONGRÈS, PARIS, FRANCE

19TH-22ND MAY

Welcome to the *European Medical Journal* review of EuroPCR 2015

From 19th-22nd May, EuroPCR 2015 hosted the world-leading congress in the fast-developing field of interventional cardiology in Paris, France. With a sensational 19th century cityscape crisscrossed by broad boulevards and the Seine River, Paris is one of the foremost European cities and a global hotspot for art, fashion, and culture. The annual EuroPCR Congress has been a consistent fixture in the city that combines beauty with scientific heritage, not least being the site of the revolutionary work of Pierre and Marie Curie, the latter being the first woman to win a Nobel Prize.

Attracting over 12,000 participants, EuroPCR 2015 once again presented the most important and exciting developments in interventional cardiology, and delivered an experience that will not be soon forgotten. On Wednesday 20th May, the EuroPCR community recognised two outstanding global pioneers of transradial access for coronary catheterisation with the 2015 Ethica Award. The winners Dr Ferdinand Kiemeneij (Netherlands) and Dr Shigeru Saito (Japan) are renowned for their efforts to develop and teach the technique since the early 1990s. Dr Jean Fajadet, who presented the award alongside fellow co-director Dr William Wijns, said: "In addition to providing outstanding clinical

outcomes and reducing bleeding hazards, the use of radial access for diagnosis and intervention is patient-friendly, comfortable, and minimally invasive."

Elsewhere at EuroPCR 2015, Dr Christopher Cook (UK) was given the Best Abstract award, and Dr Lucia Vera Pernasetti (Spain) scooped the award for Best Clinical Case. The recipient of the award for Best Nurses & Technicians Abstract was Mr James Crowhurst (Australia), and the award for Best Nurses & Technicians Clinical Case went to Ms Barbara Copus (Australia).

Throughout the congress a number of hot topics were presented through lectures, posters, and plenary sessions. The most common themes included stenting, thrombectomy, transcatheter aortic valve implantation (TAVI), and angioplasty.

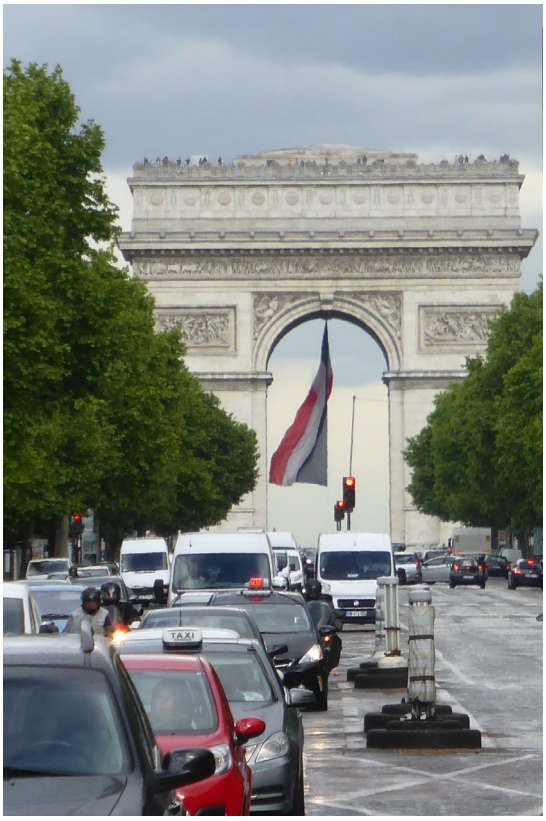
The success of mechanical thrombectomy devices in a series of trials has put pressure on their speedier introduction for the treatment of acute stroke patients. A presentation by Dr Petr Widimsky highlighted that the new technology could drastically decrease the number of individuals who die or are severely disabled by stroke, and, in combination with optimum medical therapy, the boost to neurological function is unprecedented.

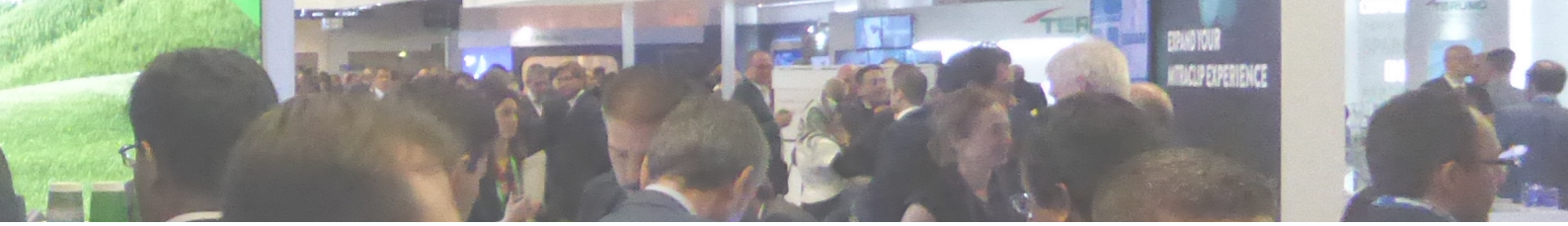
The use of thrombectomy to treat acute myocardial infarction was a fairly common practice until a major study, TOTAL, suggested that this technique may actually increase the risk of stroke. Dr Sanjit Jolly explained the study's findings at EuroPCR 2015, which showed that the rate of stroke within 30 days in thrombectomy-treated patients was significantly higher than in angioplasty-only patients, and discussed the need for future trials to evaluate stroke outcomes alongside efficacy outcomes.

The application of TAVI in lower-risk patients was given a boost by the results of the NOTION trial, which showed that the less invasive procedure is as safe and effective as surgical valve replacement at 2 years. Dr Lars Søndergaard explained how TAVI devices and surgical bioprostheses achieved similar results in patients with relatively low EuroSCOREs, and described how the introduction of computed tomography since the trial's inception has improved the rates of aortic regurgitation seen in patients receiving these devices today. New-generation TAVI devices have also been constructed to decrease aortic regurgitation, thus underlining TAVI as a strong treatment option for the future.

The promise of the technologies displayed at EuroPCR 2015 will surely buoy the interventional cardiology community in its mission to optimise heart surgery and deliver optimum outcomes for patients. We eagerly await the next instalment of EuroPCR in 2016, which will take place once again in the French capital.

"In addition to providing outstanding clinical outcomes and reducing bleeding hazards, the use of radial access for diagnosis and intervention is patient-friendly, comfortable, and minimally invasive."





HIGHLIGHTS

Stent Thrombosis Rates Low with Primary PCI Regardless of Antithrombotic Agent

STENT thrombosis following urgent angioplasty for acute heart attack arose in less than 1% of patients in a large, 'real-world' registry, regardless of whether the antithrombotic treatment used during the procedure was bivalirudin, heparin alone, or a GP IIb/IIIa inhibitor (usually in combination with heparin).

However, patients who experienced stent thrombosis between 2 and 30 days, regardless of therapy course, were more likely to die within 1 year than those who developed stent thrombosis within the first 24 hours of their procedure. "What is new, to my knowledge, is the relationship between stent thrombosis timing and mortality at 1 year," said Dr Per Grimfjard, Vasteras Hospital / Uppsala University, Uppsala, Sweden, who presented the nationwide Swedish Registry data at EuroPCR 2015. "In my opinion, a possible explanation is that a stent thrombosis that happens once the patient has left the hospital is likely to cause a more substantial infarction, the reason being longer delay from symptoms to revascularisation." He added that a more significant myocardial infarction normally results in more heart failure and arrhythmia in the long term.

Recent studies have suggested that bivalirudin, a newer and more expensive antithrombotic, may boost the risk of clots inside newly implanted stents compared with the older drug heparin. However, rates of stent thrombosis have differed substantially between studies. Dr Grimfjard and colleagues chose to review stent thrombosis rates by drug choice in >30,000 patients treated with primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) between January 2007 and July 2014. They found that rates of stent thrombosis were low across all three drug groups analysed (bivalirudin = 0.84%, heparin = 0.94%, and GP IIb/IIIa inhibitor = 0.83%).

The research team is currently registering patients in a 6,000-patient, registry-based, randomised clinical trial called SWEDEHEART-Validate analysing heparin-only versus bivalirudin-plus-optional low-dose heparin in STEMI and non-STEMI patients undergoing PCI.

"A stent thrombosis that happens once the patient has left the hospital is likely to cause a more substantial infarction."

"Hopefully this large randomised trial will bring clarity to the choice of antithrombotic treatment strategy in these patients," said Dr Grimfjard.

Leaflet Thickening in TAVI Clarified by New Data

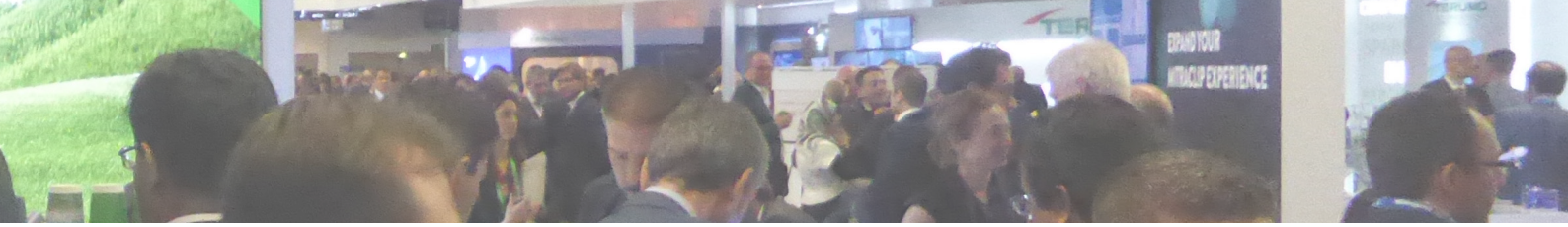
THICKENING of the valve leaflets after transcatheter or surgical implantation of an aortic valve bioprosthesis is relatively rare, not associated with short-term clinical events, and not unique to any one type of valve, according to new data presented at EuroPCR 2015. Experts said that larger and longer-term follow-up studies are required to fully test the validity of these findings.

The number of transcatheter aortic valve implantation (TAVI) operations completed globally easily exceeds 100,000. Imaging studies applied in a USA-based trial of a TAVI device, performed in September 2014, recognised thickening and reduced mobility of the device leaflet after transplantation, triggering concerns that the procedure could have adverse clinical effects for valve recipients. This led to a cessation of the trial.

Researchers presented data from three separate, single-centre studies, offering conclusions from a total of 345 patients treated with a variety of transcatheter or surgical valves. Among the conclusions, computed tomography and echocardiographic imaging at 5 days, 30 days, or at later time points, discovered a spectrum of abnormalities including hypo-attenuated leaflet thickening and impaired leaflet motion in 7-15% of subjects. Abnormalities were not confined to one particular surgical or transcatheter valve. Leaflet irregularities were not associated with clinical events including stroke and valve failure. Most advanced abnormalities resolved with the use of oral anticoagulants, although patient selection and anticoagulant type and dosage have not yet been ratified.

Dr Bernard Prendergast, session co-chair and co-director of PCR London Valves, Director of the Cardiac Structural Intervention Programme, Guys and St Thomas' Trust, London, UK, commented: "TAVI is an established life-saving procedure with a wealth of high-quality clinical evidence demonstrating its safety, durability, and effectiveness. The reassuring data presented today indicate that there is no need for clinicians to adjust their practice in relation to patient selection, performance of the TAVI procedure, or follow-up protocols, including post-procedural imaging and anti-thrombotic therapy."

Over 12,000 participants



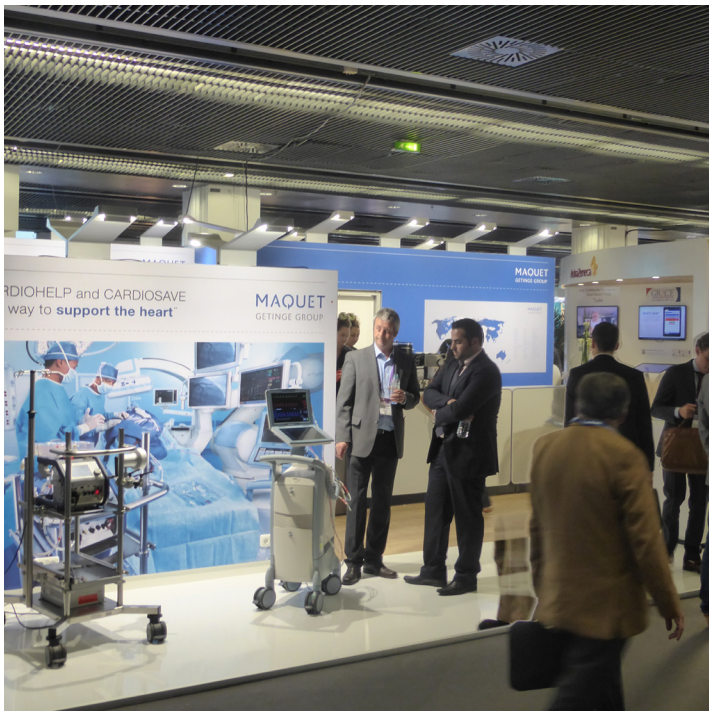
Risk of Stroke Confirmed After Routine Thrombectomy Following Heart Attack

BLOOD clots are commonly removed from arteries in the treatment of acute myocardial infarction (MI) using the technique known as thrombectomy; however, a recent study has shown that this may actually increase the risk of stroke. Data from the TOTAL trial presented at EuroPCR 2015 suggest that stroke risk with thrombectomy during angioplasty is apparent early post-procedure compared with angioplasty alone.

The TOTAL trial compared the use of thrombectomy against percutaneous coronary intervention alone in over 10,000 patients hospitalised for a severe heart attack. Overall, the rates of cardiovascular death, MI, shock, or severe heart failure within 180 days were no different between the two groups. Regarding the safety endpoint, observing stroke within 30 days, TOTAL investigators noticed a significant increase in the rate of strokes in the clot removal group compared with the angioplasty-only group.

Further research revealed that the risk of a composite of stroke or transient ischaemic attack was substantially greater in thrombectomy-treated patients at 30 days than in angioplasty-only patients (0.8% versus 0.4%, p=0.003). Stroke severity was mostly greater in the clot-removal group, and both ischaemic and haemorrhagic strokes were statistically more common in thrombectomy-treated patients. "Given the findings of TOTAL, future device trials to remove thrombus from the coronary artery need to carefully collect and examine stroke outcomes in addition to efficacy outcomes," said Dr Sanjit Jolly, the study's lead author and an interventional cardiologist and Associate Professor, McMaster University, Hamilton, Ontario, Canada.

Prof Jean Marco, PCR Honorary Chairman, noted that the findings, as well as the build-up of extra strokes in both groups between 30 days and 180 days, were likely due to chance. "The risk of stroke is a reality when performing thrombectomy, particularly if the basic rules for the correct use of the procedure are not followed. All tips and tricks for efficiency and safety with this procedure must be clearly explained, disseminated, and implemented if this procedure is to be performed," added Dr Marco.



TAVI Comparable to SAVR in Lower-Risk Patients at 2 Years

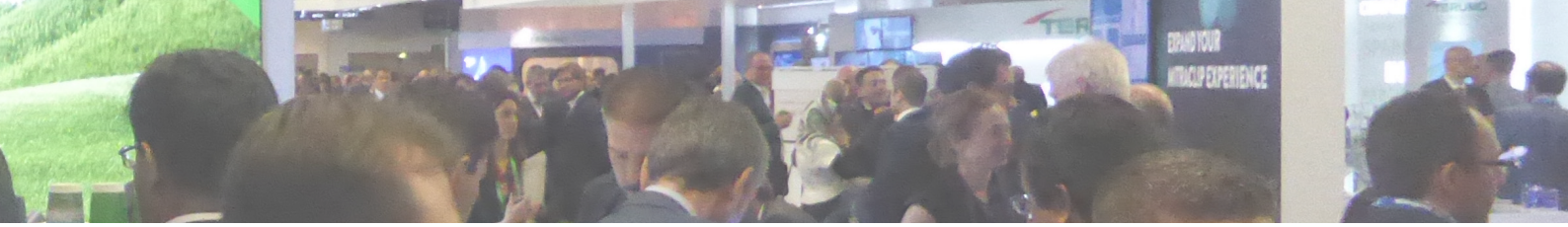
TRANSCATHETER aortic valve implantation (TAVI) is comparable to the 'gold standard' of surgical aortic valve replacement (SAVR) with regard to the incidence of a composite primary endpoint of all-cause death, stroke, or myocardial infarction at postoperative Years 1 and 2 in patients at lower surgical risk, according to data from the Nordic Aortic Valve Intervention (NOTION) trial presented by Dr Lars Søndergaard from the Heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark, at EuroPCR 2015.

"The NOTION study is the first randomised clinical trial to include all-comer patients," said Dr Søndergaard. "Despite the fact that the trial was launched in the early days of TAVI, the 2-year data show that the therapy is as efficient and safe as the well-established SAVR. Although we are still waiting for data on long-term durability of the TAVI prosthesis before routinely offering this new technology to younger patients, the NOTION trial indicates that TAVI can be offered to selected lower-risk patients."

In contrast to the pivotal randomised trials supporting the use of TAVI in patients with severe aortic stenosis, TAVI devices are now increasingly used in patients at lower surgical risk, with approximately half of patients in major European registries displaying EuroSCOREs of <20. NOTION randomised 139 patients to a self-expanding TAVI device and 135 patients to SAVR, with the incidence of the composite primary endpoint being similar between TAVI and SAVR arms at both Year 1 (11.3% versus 15.7%, respectively) and Year 2 (15.8% versus 18.8%, respectively).

In terms of safety, pacemaker implantation was more frequent in the TAVI arm while atrial fibrillation was more common in the SAVR group at Years 1 and 2. The rate of moderate-to-severe aortic regurgitation was significantly higher in the TAVI arm at Year 2 (15% vs 1%; p<0.001), although Dr Søndergaard explained that NOTION was initiated soon after the introduction of TAVI and computed tomography imaging has since been adopted as the gold standard to improve aortic annular sizing.

"Despite the fact that the trial was launched in the early days of TAVI, the 2-year data show that the therapy is as efficient and safe as the well-established SAVR."



Mechanical Thrombectomy Advancements Offer New Hope for Acute Stroke Patients

NEW-GENERATION endovascular devices should be introduced more quickly for the treatment of acute stroke following overwhelmingly successful trials, experts claimed at EuroPCR 2015.

"Sometimes we face something that looks close to a miracle when we are treating a patient with a severe stroke, who is profoundly disabled, and he makes a full recovery before your eyes."

Mechanical thrombectomy devices, known as 'stent-retrievers', use catheters inserted into a blocked cerebral artery to suck out or lyse a clot that is obstructing circulation to part of the brain. Seven clinical trials in the past 6 months have shown that intracranial thrombus retrieval is safe and feasible, and considerably improves neurological function if used alongside the best medical therapy, when compared with best medical therapy alone.

Dr Petr Widimsky, Head of the Cardiocenter and Chair of the Cardiology Department at the Third Faculty of Medicine, Charles University & University Hospital "Royal Vineyards", Prague, Czech Republic, noted that only 10% of patients who suffer a moderate/severe stroke will regain functional independence with conservative treatment. The recent trials indicate that 40-50% of patients recover full or near-full neurological function with this innovative treatment. "And with good patient selection, that may increase to 60%. Sometimes we face something that looks close to a miracle when we are treating a patient with a severe stroke, who is profoundly disabled, and he makes a full recovery before your eyes. It is really dramatic," Dr Widimsky explained.

The risks associated with the procedure lead to an adverse event rate of approximately 5%. These include intracranial bleeding and subsequent strokes in another location, caused by a clot fragment embolising during removal. Radiologists in Europe and neurosurgeons in the USA are currently performing most of these procedures, but these are expected to become more popular with other medical professionals, including angiologists and neurologists, in the near future.

"We are highlighting these new data here at EuroPCR in order to spread the message that this therapy shows great promise. We need to build healthcare systems and train physicians to be able to offer this effective method to as many patients with acute ischaemic stroke as possible," said Dr Widimsky.

New Standards Required for Renal Denervation Research

RESEARCH on the use of renal denervation (RD) in patients with high blood pressure and the inability to control the disease using a multi-drug regimen should not be abandoned until high-quality research is completed in line with agreed-upon standards, according to findings presented at EuroPCR 2015.

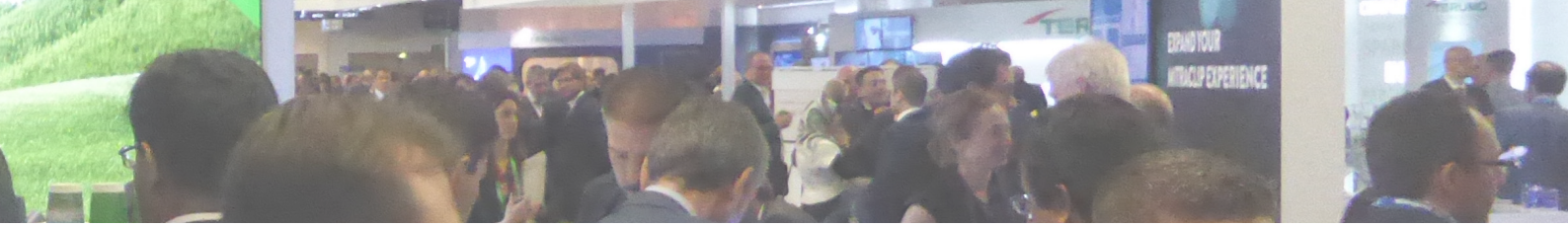
The authors, who were participating in a European Clinical Consensus Conference (CCC), drew their conclusions in the wake of conflicting results from a number of trials that evaluated the safety and efficacy of the procedure. While observational studies and three randomised, controlled trials displayed positive results for RD, other smaller studies and the large, single-blind, randomised, sham-controlled SYMPLICITY HTN-3 trial have failed to show any benefit from the procedure, which has led to some clinicians refusing to endorse it.

However, the authors of the CCC paper examined procedural aspects, patient selection, and clinical trials and noted that there are a number of changes that should be made to the way future trials are carried out in order to ensure greater validity. In general, they believe that research into RD requires standardisation and consistency in order to avoid inconclusive or biased results.

"The open questions around RD touch upon a large number of specialties from interventional cardiologists to hypertension experts and molecular biologists," explained Dr Felix Mahfoud, Saarland University Hospital, Homburg, Germany. "The future of the therapy will depend on closer interactions at all levels, necessitating focussed collaborative high-quality research, smaller projects targeting specific questions, as well as large-scale multidisciplinary research programmes."

In light of the drawbacks of previous trials, the authors concluded that it would be too soon to abandon research into RD, which could potentially deprive many patients of an important treatment option in the future. "Focussed, collaborative high-quality research will be necessary to ensure that future patients are neither denied an effective therapy, nor needlessly put at risk from procedures that bring no benefits," stated Dr Mahfoud.

"Focussed, collaborative high-quality research will be necessary to ensure that future patients are neither denied an effective therapy, nor needlessly put at risk from procedures that bring no benefits."



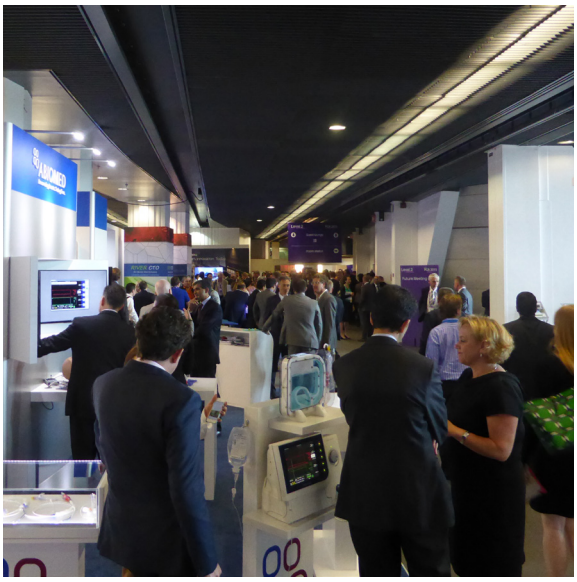
FFR Technology Receives Boost from DEFER and CONTRAST Studies

FRACTIONAL flow reserve (FFR)-guided percutaneous coronary intervention (PCI) and stenting confers clinical benefits that are sustained after 15 years, and the technique can be adapted to an adenosine-free approach that demonstrates greater accuracy than the use of resting indices. These are the main findings from a 15-year follow-up study of patients participating in the DEFER trial and from the primary results of the CONTRAST trial, which were both presented at EuroPCR 2015.

The original and 5-year clinical benefits of PCI and stenting decisions based on the use of PressureWire™ FFR indices were confirmed after 15 years of follow-up in the DEFER trial. The analysis also found that the risk of a myocardial infarction was 6.5-times lower in patients whose treatment was guided by FFR compared with those in the non-FFR-guided group. There were no negative effects from not treating non-significant lesions, and patients receiving a stent for a non-ischaemic stenosis displayed no benefit compared with those who received standard medical therapy. In addition to the reduction in myocardial infarcts, patients in whom revascularisation was deferred displayed very low rates of complications compared with patients in whom lesions were treated without proof of ischaemia.

> "This study confirms the long-term importance of using FFR to guide PCI and improve the outcome of stenting."

"We are pleased to see the sustained benefits of this study over 15 years. We also find it quite important that there were no myocardial infarctions as a result of deferring non-significant lesions, based upon FFR guidance," said original DEFER investigator Dr Nico Pijls, Catharina Hospital, Eindhoven, Netherlands. "This study confirms the long-term importance of using FFR to guide PCI and improve the outcome of stenting."



In the CONTRAST study, researchers compared FFR using adenosine with resting indices (distal coronary pressure to aortic pressure [Pd/Pa] and instantaneous wave-free ratio [iFR]) and adenosine-free FFR using contrast medium (cFFR). The study found that cFFR provided superior accuracy compared with iFR or resting Pd/Pa, which offered similar rates of accuracy to one another, and cFFR did not add additional cost or procedure time.

Fantom™ Scaffold Initial Clinical Results Released

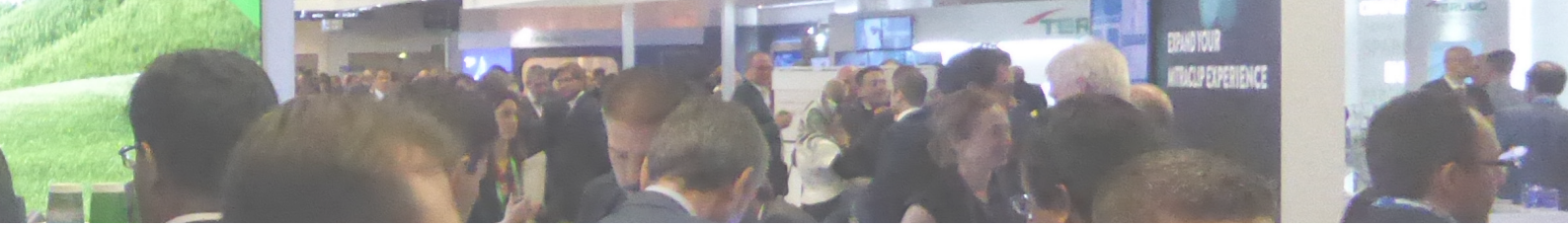
INITIAL clinical data on a subset of patients treated with the Fantom™ sirolimus-eluting bioresorbable scaffold were presented at EuroPCR 2015. and displayed promising results for the treatment of coronary artery disease. The results were reported by Dr Alexandre Abizaid, Director of Invasive Cardiology, Institute Dante Pazzanese of Cardiology, Sao Paolo, Brazil, and co-principal investigator for the Fantom clinical trial programme.

The FANTOM I pilot clinical trial, which registered patients with the Fantom scaffold at two clinical sites in Brazil and Poland, was created to provide early clinical data on the device. Acute performance of the device was demonstrated in these patients, with 100% technical and procedural success and no reported major adverse cardiac events to date, with no incidence of ischaemic target lesion revascularisation, myocardial infarction, or stent thrombosis.

> "In the patients who have completed their 4-month angiographic assessment we have observed that the scaffold is performing well and the treated vessels remain widely patent."

"We are pleased with the early clinical results we are seeing with the Fantom scaffold," said Mr Jeff Anderson, Senior Vice President of Clinical and Regulatory Affairs, REVA Medical, Inc., San Diego, California, USA. "In the patients who have completed their 4-month angiographic assessment we have observed that the scaffold is performing well and the treated vessels remain widely patent."

Patients are currently being enrolled in the FANTOM II trial, which aims to supply the required data for a European CE regulatory mark for the Fantom device. Initial data from the FANTOM II trial, together with continued follow-up data from patients registered in the pilot clinical trial will be presented at



the Transcatheter Cardiovascular Therapeutics (TCT) Conference, to be held in October in San Francisco, USA.

Unlike metal stents, bioresorbable scaffolds are temporary, and will disappear from the body over a period of time once they have restored blood flow and supported the artery through the healing process. This reabsorption allows the return of natural movement and function of the artery, which cannot happen with permanent metal stents.

World's First Hybrid Drug-Eluting Stent (Orsiro) Shows Promise

ONE-YEAR results from the SORT OUT VII trial, presented at EuroPCR 2015, have proved Orsiro's non-inferiority to the bioabsorbable polymer umirolimus-eluting Nobori stent in an all-comers population.

The substantially lower rate of definite stent thrombosis, a potentially dangerous adverse event (AE) following coronary intervention, in patients in the Orsiro arm was also encouraging; just 0.4% of Orsiro patients versus 1.2% of patients in the Nobori arm.

Launched in 2011, the Orsiro drug-eluting stent (DES) is a hybrid solution that combines passive and active elements; proBIO passive coating envelops the stent and minimises interaction between the metal stent and the surrounding tissue. In a Hot Line session at EuroPCR, SORT OUT VII principal investigator Dr Lisette Okkels Jensen, Odense University Hospital, Odense, Denmark, explained the design and endpoints of the investigator-initiated randomised, multi-centre, two-arm, non-inferiority trial. SORT OUT VII compares the ultra-thin strut sirolimus-eluting Orsiro with the umirolimus-eluting Nobori DES in the treatment of coronary artery lesions.

"Several factors, including significantly thinner struts and more controlled drug release, distinguish Orsiro from other bioabsorbable polymer DESs."

A total of 1,261 patients underwent treatment with Orsiro, while 1,264 patients were treated with Nobori. At 1 year, the primary endpoint target lesion failure, defined as a combination of cardiac death, myocardial infarction, or target lesion revascularisation within 1 year, occurred in 3.8% of the Orsiro group versus 4.6% of those in the Nobori treatment arm (p value for non-inferiority <0.0001).

Physicians discussed possible explanations for Orsiro's enhanced safety profile and low stent thrombosis rate. Orsiro's unique ultra-thin strut stent design enables greater flexibility than thicker strut creations, potentially leading to improved apposition of the vessel wall and quicker endothelialisation after percutaneous coronary intervention.

"Several factors, including significantly thinner struts and more controlled drug release, distinguish Orsiro from other bioabsorbable polymer DESs," commented Dr Jensen. "These refinements could explain the trend towards lower rates of AEs for Orsiro, exemplified by the considerably reduced risk of definite stent thrombosis seen in SORT OUT VII."

Visipaque™ Reduces Risk of Renal and Cardiac Events During Angioplasty

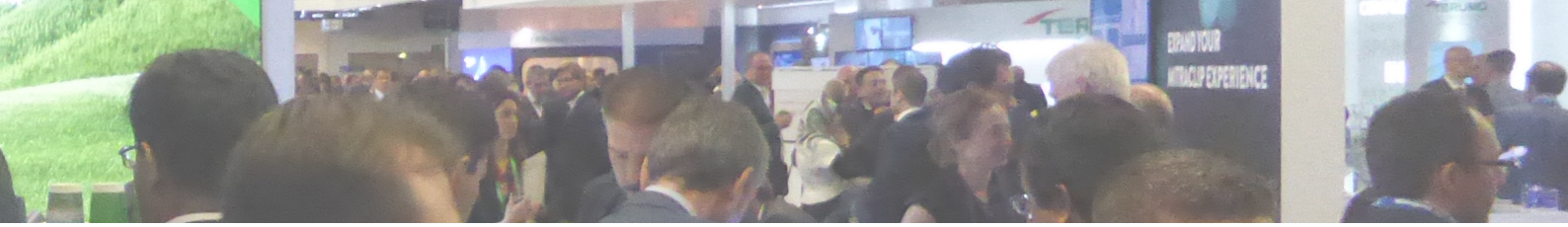
CARDIAC and renal events are significantly less frequent during angioplasty procedures using isosmolar contrast medium (IOCM) agent Visipaque™ (iodixanol) compared with procedures using low-osmolar contrast media (LOCM), according to research presented at EuroPCR 2015.

"The results of this study are highly encouraging and support the use of isosmolar contrast media in high-risk percutaneous coronary intervention."

The study, funded by GE Healthcare, retrospectively analysed data from the Premier hospital database in the USA, which describes 334,001 angioplasty procedures that took place between January 2008 and September 2013. The researchers found that 10.5% fewer major adverse renal and cardiac events (MARCE) occurred when Visipaque was used compared with LOCM ($p<0.01$). The difference was even greater between those hospitals that solely used either IOCM or LOCM, with 26.7% fewer MARCE taking place in the IOCM group compared with the LOCM group. In addition, 2.7% and 0.6% fewer renal failure and kidney injury events, respectively, were observed with the use of IOCM compared with LOCM.

"The results of this study are highly encouraging and support the use of isosmolar contrast media in high-risk percutaneous coronary intervention. These data suggest that prior studies with signal of reduced risk of contrast-induced acute kidney injury with Visipaque do indeed translate into a reduction in clinically meaningful MARCE," said Dr Peter McCullough, Vice Chief of Medicine, Baylor University Center, Dallas, Texas, USA.

Practitioners from 120+ countries



These findings are likely to be of great benefit to patients undergoing angioplasty procedures, especially those who are more vulnerable. Indeed, the data showed that angioplasty procedures that used Visipaque tended to be performed in older (66.8 versus 63.8 years; p<0.01) and sicker patients based on the Charlson Comorbidity Index (4.0 versus 3.4; p<0.01). Compared with LOCM, IOCM was also used in more emergency procedures and in more patients who were classified as 'major' or 'extreme' according to the 3M™ APR-DRG indices of mortality and severity of illness.

Sapien 3 Valve Demonstrates Outstanding 30-Day Outcomes in Intermediate-Risk Patients

MORTALITY and stroke rates are cut drastically by transfemoral treatment with the SAPIEN 3 transcatheter aortic valve in intermediate-risk patients, according to 30-day outcomes announced by EDWARDS Lifesciences Corporation. These independently examined data are consistent with the results recently reported in a similar study of 1,000 patients treated at 51 centres in the USA. The study was presented at EuroPCR 2015 by Dr Alec Vahanian, Chair of the Cardiology Department, Bichat University Hospital, Paris, France.

In the multi-centre study of 101 intermediate-risk patients, all-cause mortality was 1%. The frequency of other important complications was also low: the disabling stroke rate was 2%, the major vascular complication rate was 2%, and the permanent pacemaker rate was 4%. The researchers also observed that the SAPIEN 3 valve had outstanding haemodynamic performance with very low incidence of substantial paravalvular regurgitation, with only 2.3% of patients experiencing moderate paravalvular leaks; there were no reports of severe leaks.

"Intermediate-risk patients treated with the Edwards SAPIEN 3 valve had remarkably low mortality at 30 days. There were very low rates of all other major complications, notably major vascular complications and new permanent pacemaker implantation," said Dr Vahanian. "These results are meaningful since this study in multiple countries repeated the results in the large US study."

The SAPIEN 3 Trial is a prospective, multi-centre, non-randomised study. This investigation was designed to document the 30-day outcomes of intermediate-risk patients treated through the transfemoral approach with the SAPIEN 3 valve at 13 centres in Europe and Canada. The SAPIEN 3 Trial is designed to analyse patients annually for 5 years.

> "Intermediate-risk patients treated with the Edwards SAPIEN 3 valve had remarkably low mortality at 30 days."

The SAPIEN 3 valve was approved in Europe in January 2014 for the treatment of high-risk and non-operable patients with severe aortic stenosis. However, it has not been approved for the treatment of intermediate-risk patients in any country. The valve is an

investigational tool and is not yet available in the USA; it is currently being analysed in the USA in the Partner II Trial.

Long-Term Safety and Efficacy of BioMatrix™ DES Family Confirmed

BIOMATRIX™ drug-eluting stents (DESs) are safe and efficacious across a 3-year period in a 'real-world' patient population, according to the final long-term findings of the e-BioMatrix registry presented at EuroPCR 2015.

Initiated in March 2008, e-BioMatrix is a large, prospective, multi-centre, single-arm, observational registry aimed at assessing the reproducibility of the safety and efficacy profile of the BioMatrix DES family. The stents had already achieved positive results in LEADERS, an all-comers randomised trial in real-world patients, and the registry was designed to confirm this across a wider range of centres over the long term. The registry included patients treated with either BioMatrix or BioMatrix Flex™ DESs, which both integrate a highly lipophilic anti-restenotic drug designed specifically for use with stents, Biolimus A9™ (BA9™).

The objective of e-BioMatrix was to evaluate the BA9-eluting stents in routine clinical practice across a wide range of centres, focussing on stent thrombosis and bleeding. A total of 5,470 patients were registered at 57 centres, and 4,903 patients (89.6%) were followed up across a 3-year period. The primary endpoint for the registry was the incidence of major adverse cardiac events (MACE) at 12 months; secondary endpoints included the incidence of MACE and stent thrombosis at 3 years.

The MACE rate was 9% at 3 years (cardiac death: 2.1%; nonfatal myocardial infarction: 3.2%; clinically indicated target vessel revascularisation: 5.6%). The incidences of definite or probable stent thrombosis and major bleeding were 0.9% and 2.5%, respectively. Dual antiplatelet therapy (DAPT) was administered to all patients for at least 6 months, with a recommendation for up to 12 months. Acetylsalicylic acid was administered indefinitely.

"The very low rate of definite and probable stent thrombosis confirm that this sequela, while still associated with very significant morbidity and mortality, is no longer a frequent problem," said principal investigator Dr Philip Urban, Interventional Cardiologist, Hôpital de la Tour, Geneva, Switzerland. "Shorter DAPT courses could be expected to be associated with a decreased incidence of major bleeding."

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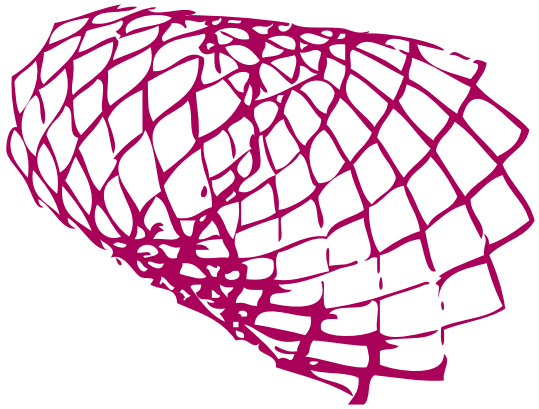
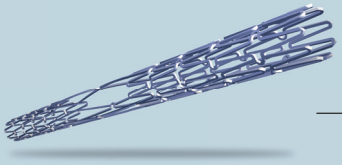
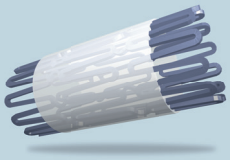


AndraTec

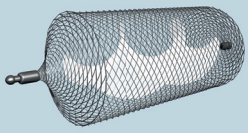
Advanced Interventional Technologies



PillaR
Bifurcation-Reconstruction-Device

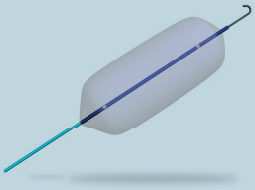


Optimus-CVS
Balloon Expandable Covered Stent



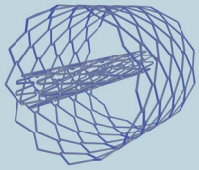
PillOW
AAA-Occluding Device

Exeter
Advanced Retrieval Technology

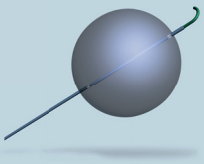


AltoSa-XL
Balloon Dilatation Catheter

AltoSa-Premier
Maximum Pressure XL-PTA Balloon



Optimus™
Largest Balloon Expandable Stent



AltoSa-SFT
Balloon Dilatation Catheter

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Rainer Wessely

Center for Chest and Cardiovascular Medicine, Cologne; Professor of Medicine, University of Technology, Munich, and Fresenius University of Applied Sciences, Cologne, Germany.

Q: What inspired you to focus your work and research on interventional cardiology?

A: I guess it was the relative simplicity of treatment that is highly effective without the obligation of general anaesthesia, along with the possibility of the quick recovery of the patient. This has fascinated me for more than a decade, since I began my training in interventional cardiology and angiology.

Q: Since your career began, how much has the field developed in terms of providing new treatments for patients with heart conditions?

A: No doubt, we have seen tremendous progress in interventional cardiology. The introduction of drug-eluting stents has clearly advanced the field a lot. Another example of a new treatment redefining the field is transcatheter aortic valve replacement, which now seems to have evolved as a treatment option for intermediate-risk patients. In terms of peripheral artery disease, significant advances to conquer chronic total occlusions and below-the-knee interventions have led to new frontiers for patients with peripheral arterial disease.

Q: In a recent paper that you co-authored, you found that the use of the STENTYS Self-Apposing® stent in the setting of primary percutaneous intervention was feasible and associated with acceptable cardiovascular (CV) event rates, which improved when post-dilation was performed. How much of an impact has this research had so far, and how much do you think stent therapy has developed in recent years?

A: Self-apposing technology has evolved as a standard in peripheral interventional procedures, in particular for the treatment of carotid lesions or lesions of the superficial femoral artery. The concept of self-apposing stents in the CV bed is intriguing, in particular in ST-segment elevation myocardial infarction (STEMI) and tailored lesions. If the technology is improved and made cost-effective, it will certainly be an essential tool for interventional cardiology.

Q: Have you noticed any changes in the type and prevalence of heart conditions in recent years?

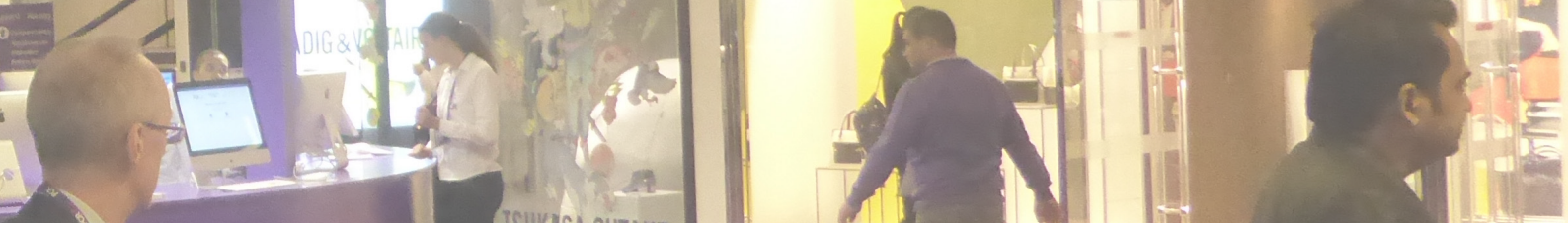
A: Due to improvements in drug therapy, as well as in general prevention measures, STEMIs are decreasing, at least in Western Europe. However, due to the ageing population and the availability of sensitive markers, non-STEMIs are still prevalent. The major problem that we face in cardiology these days is heart failure, which is still in need of groundbreaking solutions. Translational CV solutions will probably provide novel strategies, maybe combined with interventional procedures, in the not-too-distant future.

Q: Do you feel that more should be done to inform the public about how to maintain a healthy heart?

A: I honestly think that we have been somewhat successful in raising awareness of how a healthy heart can be maintained. The vast majority of people know about the negative impact of smoking, obesity, and unhealthy food. However, we still need to enlighten people about the possible symptoms of heart disease, especially regarding myocardial infarction, heart failure, and arrhythmias such as atrial fibrillation, that may eventually lead to stroke. Another major field is teaching younger people about a healthy lifestyle, including nutrition, as well as physical activity, and the avoidance of negative stress.

Q: Do you think that there are any lessons that other countries could learn from the way that healthcare is administered in Germany?

A: The major achievement of the German health system is that we have had full health insurance coverage for the entire population for more than 125 years. However, as with any other country in the world, we face significant challenges to cover growing healthcare costs. However, insurance for



everybody in the country, for undoubtedly our most important asset: physical and mental health, is the foundation of a robust and successful health system.

Q: How important are events such as EuroPCR for enabling interventional cardiologists to keep up to date with the latest research?

A: These events are part of the never-ending cycle of training and education that is critical for every physician, in particular in the fields of general and interventional cardiology and angiology. However, it is also important to regularly read original, peer-reviewed contributions and meta-analyses published in the leading journals of the field, in order to secure a pluralistic insight into state-of-the-art, evidence-based medicine.

Q: As a prominent member of many international cardiology societies, have you found that we are moving towards a more integrated approach across the world in this area of medicine?

A: Definitely, over the years we have developed platforms to share our knowledge globally. Nowadays, we see people from all over the world attending meetings and congresses that have been firmly established on all continents. The internet also provides further access to scientific databases and journals, making it feasible to access the most recent scientific and clinical advancements in medicine even from remote areas.

Q: What has been the single greatest achievement of your career to date?

A: My greatest achievement is maintaining a continuous dedication to my profession in order to help patients. That sounds banal, but it is the absolute truth. I am very grateful to have the opportunity to work as an interventional specialist.

Q: What is the biggest challenge facing interventional cardiologists today in your view, and what can be done to overcome it?

A: Shifting the focus away from medical challenges, interventional CV medicine has to be cost-effective given the ever-growing numbers of patients that we must treat in the future. Evidence-based medicine and independent economic analysis must be part of the armamentarium in order to ensure that we will be able to treat all of our patients appropriately in the coming decades.

Lorenz Räber

Attending Physician in Interventional Cardiology, Swiss Cardiovascular Centre, The University Hospital of Bern, Bern, Switzerland.

Q: Why did you decide to focus your work and research on the field of interventional cardiology?

A: As a medical student, I did quantitative coronary analysis (QCA) on a computer placed in one of the cath labs at Bern University Hospital. Needless to say that, during the many hours of QCA, I could follow some of the procedures performed by Bernie Meier and Stephan Windecker, and witnessed many discussions among their peers. There is no question that this left a lasting impression.

"Cardiovascular-related morbidity and mortality remains high in Europe."

Q: Much of the research that you undertake focusses on coronary stents, antiplatelet agents, and invasive imaging of coronary atherosclerosis. How far has our knowledge and understanding of these areas developed since you first began your research?

A: Substantial progress has been achieved in this area since I started. Firstly, the superior safety of newer generation drug-eluting stents (DESs) over early-generation DESs was established and bare metal stents disappeared from the cath lab. We had the privilege to contribute to this evidence with several large, randomised trials and the Bern—Rotterdam Registry. Secondly, the ABSORB bioresorbable vascular scaffold (BVS) received CE approval based, at least in part, on the

excellent research conducted by Prof Serruys and Dr Onuma in Rotterdam. Thirdly, the introduction of ticagrelor and prasugrel changed the field of antiplatelet therapy after a lonely career for clopidogrel for more than a decade. Finally, optical coherence tomography became available for clinical use and is slowly replacing intravascular ultrasound.

Q: In a very recent paper published in the *European Heart Journal,* your research group investigated the association between neoatherosclerosis (NA) and native atherosclerosis disease progression. You found that patients with evidence of NA 5 years after DES implantation show a significant increase in native coronary artery disease progression. What are the implications of this interesting finding?

A: This study is the result of a long-term follow-up of the SIRTAX study population, including serial angiographic follow-up and optical coherence tomography investigations at 5 years. I started working on this patient cohort as a student and could perform the 10-year follow-up this year, probably a result of not changing institutions too many times! But back to the question: the mechanistically plausible results suggest a close association between the formation of atherosclerosis in the DES-related neointimal tissue (NA) and native coronary artery disease progression. Therapeutic strategies known to attenuate atherosclerosis progression, such as high-dose statin therapy, may also be effective in suppressing the development or progression of NA.

Q: How far has the entire field of interventional cardiology moved forward since your career began?

A: The progress during the last years is unsurpassed by any other medical discipline with the exception of oncology. The most evident progress is the continuing shift from open heart surgery to percutaneous interventions, a change that will further dominate the field for the next decades.

Q: What is likely to be the 'next big thing' in interventional cardiology in your opinion?

A: Device-related: this will be the expansion of transcatheter aortic valve implantation (TAVI) to low-risk patients and new concepts in mitral-valve interventions. Furthermore, new iterations of fully bioabsorbable scaffolds will be developed for the treatment of coronary artery disease, with the aim being to achieve superiority over metallic DESs over the long term. Drug-related: PSCK9 inhibition has received approval and will change primary and secondary prevention, and hopefully anti-inflammatory drugs (e.g. interleukin antagonists) are able to prove their efficacy to target atherosclerosis.

Q: What are the major improvements that you have witnessed while working in the cardiology departments of hospitals?

A: The introduction of TAVI and the subsequent optimisation of the technique with regard to ease of use and improvement of clinical outcomes, such as the decrease in the rate of strokes, abolishment of paravalvular leakage, and falling rates of pacemaker implantation.

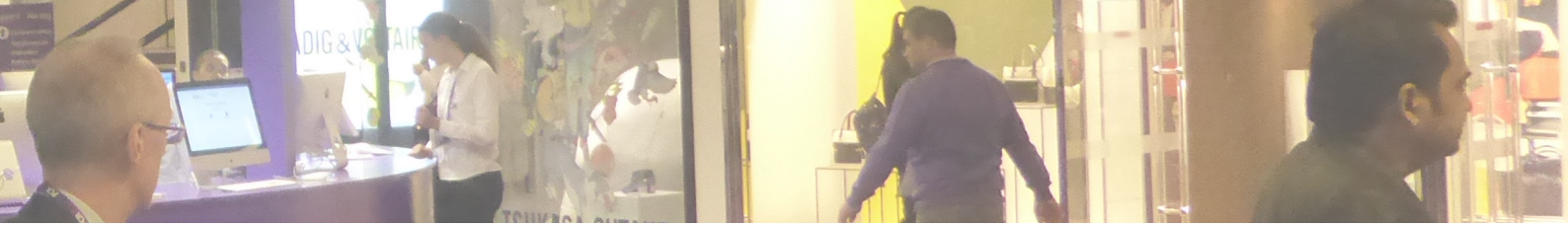
Q: Have there been any changes in the prevalence and type of heart conditions since you first began working in cardiology departments? Do you think Europe has a particular problem with heart disease?

A: Cardiovascular-related morbidity and mortality remains high in Europe. What has changed is the complexity of patients accepted for interventional treatments and therefore the awareness of the entire spectrum of coronary and valvular heart disease present. The threshold for conservative treatment has increased substantially as technical equipment and expertise have improved.

Q: Do you think that governments in Europe could do more to prevent heart disease?

A: There is always more that can be done in terms of prevention while the incidence of heart attacks is not decreasing substantially. Prevention has received increasing attention at a political level in Central and Northern Europe, but much more could be done in Eastern Europe.

Q: How important is the annual EuroPCR congress in enabling interventional cardiologists to develop relationships and embark upon research projects together across national borders?



A: EuroPCR is the largest interventional congress worldwide and naturally offers a unique opportunity for networking and extension of collaborations.

Q: Are there any particular areas of interest that you will be looking out for during this year's congress in Paris?

A: I will look for new techniques in chronic total occlusion interventions as there are substantial advancements in this field. Secondly, registry data on ABSORB BVS are of great interest to me. Regarding structural heart disease, we have approximately four new devices available that focus on retrievability and accurate positioning, thus data regarding these technologies are another hot topic. Mitral-valve interventions are the 'new kid on the block' and also demand attention. There are four first-in-man devices worth focussing on.

Q: What advice do you have for young medical students who are thinking of embarking on a career in interventional cardiology?

A: There is a high degree of certainty that this area will become a true passion of theirs, with all the advantages and disadvantages of that — so be careful!

Pierfrancesco Agostoni

Interventional Cardiologist, Department of Cardiology, University Medical Center Utrecht, Utrecht, Netherlands.

Q: What was it that particularly drew you to the field of interventional cardiology?

A: During my medical university training I was attracted to surgical specialties, but I found that surgeons were too focussed on the purely technical aspects of their operations, with less focus on the pre and postoperative care of the patient and even less on long-term follow-up. On the other hand, medical disciplines were very much focussed on the 'global care' of the patient (medications, lifestyle, and follow-up), although the doctors could not solve the problems as they could not operate. In interventional cardiology I found the possibility to join both worlds of medicine, and that is what I find very attractive: interventional cardiologists are surgeons with a medical mind (or doctors with a surgical mind).

Q: How did your time in the military as a medical officer impact on your career? How did it differ from your current position?

A: My experience in the Italian army was the first 'real' job in which I had some responsibilities and where I needed to make decisions on my own; it was good training for my future jobs. My position there was as a medical officer and therefore I was seen as a 'tout court' physician and not as a cardiologist.

Q: What changes have you witnessed in interventional cardiology since your career began? How do you think the field has evolved in that time?

A: I am not so old, although I have been in the field more than 15 years. A lot of changes have occurred in this period: technical changes (better stents in terms of profile and trackability, drug-eluting and bioabsorbable stents, drug-eluting balloons), devices for structural heart disease (transcatheter aortic valve implantation [TAVI], MitraClip), closure of auricola, patent foramen ovale closure, devices for congenital heart disease, devices to treat hypertension and heart failure, and changes in the mindset of those performing the procedures (increasingly complex cases are considered operable due to technical innovations). The combination of technical evolution and mental advancement has led to a discipline that is fully mature and conscious of its possibilities.

Q: What do you think will be the biggest challenges faced by interventional cardiologists over the next 5 years, and what can be done to overcome them?

A: I think the biggest challenge is collaboration with other disciplines: cardiac surgeons, vascular surgeons, interventional radiologists, interventional

neuroradiologists, radiologists, neurologists, etc. Good collaboration between different specialties will lead to even better care and treatment of increasingly complex cases.

Q: How does the prevalence and treatment of heart conditions differ between the Netherlands and Italy? Have you noticed any disparity since you relocated? What do you think can be learnt from these countries in the handling of heart conditions, and how do you feel they measure up to the rest of Europe and the world?

A: I think that the overall quality of care in the Netherlands is high because all the institutions offer a level of care that is at least satisfactory; of course, there are also several centres that are world-leading in their field. In Italy there is greater disparity between institutions: there are centres that are top-notch and there are others that are suboptimal. Moreover, in my personal view, the professional satisfaction of medical specialists in the Dutch system is higher than those in the Italian system. These two reasons led me to choose the Netherlands as the country where I want to continue with my profession. In my view, both Italy and the Netherlands, due to their social systems, offer medical care to all citizens and this is very nice from an ethical perspective. This leads these two countries (together with all other European countries and Canada) to score very highly in terms of their healthcare system. In general, the care of patients is high in both countries and the overall differences are small and more related to single centres.

Q: What can governing bodies and other influencers do to promote better cardiovascular health in the general population?

A: Primary prevention should probably be the major focus of the future: lifestyle changes, starting with the right medications before major problems can occur, etc. We are currently focussing on the very sick (consider current TAVI patients, for example: a population of patients >80 years old and with many comorbidities) in whom we invest a lot of resources for a very small gain (a few years extra). Primary prevention focussed on the 'healthy' population would have a major impact in terms of health gain.

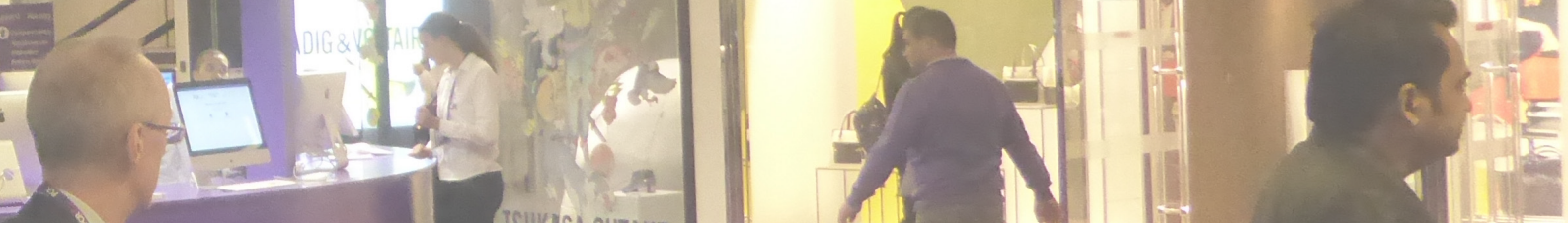
Q: How much have coronary angioplasty procedures developed over the years? What new advances in technology have there been and how have they influenced practice?

A: Angioplasty is still developing; almost every month a new device appears with the potential to change one or more aspects of the procedure, although only a few of these devices make it through to practice. However, it is extremely interesting and stimulating to be part of this 'selection process', and I am lucky in that I could take part in several of these processes. In any case, the current materials that we have are really, really good overall, and allow us to do procedures that we could have only dreamt of 10 years ago. A major example would be the case of chronic total occlusions (CTOs). In this field, expert CTO operators can currently guarantee to re-open 90% of unselected CTO lesions. My personal success rate in unselected CTO is currently around 85%, but I hope to reach 90% (or maybe even surpass it) with some more experience and knowledge.

Q: What do medical congresses such as EuroPCR have to offer the field, and what do you feel their focus should be?

A: Congresses are crucial for the dissemination of medical best practice. EuroPCR is the top European congress in interventional cardiology, and its function is to lead the way for interventionalists in their routine practice. The focus of congresses should be education and networking. Sometimes at such big congresses, however, it is a bit easy to lose this focus as too many topics are discussed together. In my practice, I prefer to follow specific courses if I need to learn something new. I simply spend 1-2 days completely dedicated to a (new) technique and then I have the confidence that I can manage the technique better; this is more difficult at big congresses. However, the networking possibilities offered by large congresses such as EuroPCR are definitely noteworthy.

"Primary prevention should probably be the major focus of the future."



"Angioplasty is still developing; almost every month a new device appears with the potential to change one or more aspects of the procedure..."

Q: Tell us a little bit about your current work – what do you hope to achieve personally in the next year?

A: I am in a phase where I am moving from my current position at an academic hospital into a new position at a non-academic hospital. Therefore it is fairly difficult for me to answer this question properly now. However, I know my dreams and I know what I would like to achieve in the upcoming years. I am extremely interested in complex cases ('no option' or 'hopeless' patients) who may have been under clinical management in other hospitals for years, without possibilities for further interventions. My 'dream' would be to become a national referent for this kind of patient, so that when my colleagues do not know what to do with them anymore they can refer them to me for a possible second option and to find new or complex potential solutions for their problems. This type of focus would allow me to practise and improve my skills in the catheterisation laboratory and to remain cutting-edge with scientific and technological advancements in the field.

Q: What has been your proudest achievement in medicine to date?

A: My proudest achievement is to hear from severely symptomatic patients that could not be treated in other hospitals (because of a lack of options in those centres) that after my treatment they have had a major improvement in their symptoms. This is something that happens relatively often, although it is also combined with the disappointment of hearing from other patients that my treatment did not help them at all. This disappointment is the motivation to continue searching for new treatment modalities and new techniques.

Leszek Bryniarski

Institute of Cardiology, Jagiellonian University Medical College, Kraków, Poland.

Q: How did you come to specialise in interventional cardiology? What drew you to this particular specialty?

A: It was by accident. My dream was to become a surgeon, but it required courage to opt for a specialisation where, in an academic hospital such as in Kraków, you become an independent operator after your 40s and you do not know from the beginning if you will be good at what you are choosing to do. During the late 1980s, when I started my specialisation, cardiology was different from what it is now, although some breakthroughs had started to appear. It was the beginning of invasive cardiology, the first angioplasties were performed by Grüntzig, the beginning of novel intensive care, and the beginning of novel echocardiography. I thought that it was a field that would expand swiftly and was worth dedicating myself to. I was able to get a job in a cardiology clinic and I started to create a haemodynamic team there.

Q: What have been the most important professional changes that you have experienced since your career began, and how have they impacted upon your practice?

A: Performing angioplasties as a first operator at the beginning of the 1990s. These were different times: there were no stents and severe dissection ended with a coronary artery bypass graft. Performing the first balloon inflation was an extreme experience. Compared with later challenges, even left main angioplasty, they were more difficult. Now we have stents and left ventricle assisting devices. Back then we knew that if something went wrong then the patient

would end up in the operating theatre. Dealing with that psychological barrier helped me with my future work.

Q: Given the obvious benefits, it is surely a priority to continue the development of more minimally invasive techniques and reduce the need for open-heart surgery. Do you foresee a future where all heart conditions can be treated through non-invasive means?

A: I am sure that because invasive cardiology is entering areas occupied by cardiac surgeons, this will force progress in cardiac surgery. That is why we have more and more micro-invasive cardiac surgeries.

Q: What impact does the lifestyle of the average Polish citizen have on their cardiovascular (CV) health, and how does it compare with that of the rest of Europe and the rest of the world?

A: Unfortunately, we have much to do in that field. The percentage of people not having any physical exercise puts us in one of the worst positions in Europe. On the other hand, more and more people, especially the young ones, use their free time for physical activities; they are also more aware when it comes to their diet. Initiatives from the Polish Cardiac Society and interventional cardiologists in the area of primary and secondary prevention are also very important.

Q: Is there any disparity in the quality of CV treatment between Poland and the rest of Europe? If so, what can be learnt from the Polish experience?

A: We are leading in Europe when it comes to invasive myocardial infarction (MI) treatment. There are more than 150 cath labs working 24/7 in Poland – this means that there is nowhere in Poland where a patient with MI is more than 60 minutes away from a cath lab. Development of this system was started in Lesser Poland at the beginning of this century. Before that, only a few cath labs were working 24/7. We created (initially using facilitated angioplasty) a network of cath labs that created a revolution in acute MI treatment. It has also led several other countries to follow our example.

Q: What can be done by physicians, governing bodies, and other influencers to promote the improvement of CV health?

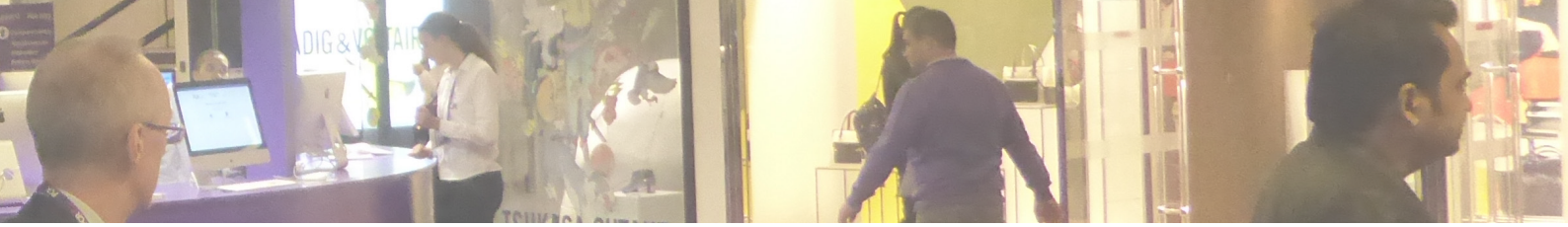
A: So far, the CV health medical societies have achieved quite a lot. People live longer and in better health than 10 years ago, although there is still much to do. In my opinion, we should continue to promote a healthy lifestyle, especially among young healthy individuals. Help from governing bodies seems to be mandatory in order to prepare education programmes. Youngsters nowadays spend more time in front of laptops and do not realise that sitting can be as dangerous as an inappropriate diet or smoking. The earlier they are taught about a healthy lifestyle (e.g. at primary school) then the healthier our society will become.

Q: How important are international congresses, such as this year's EuroPCR in Paris, to the field?

A: International congresses give practitioners an opportunity to solidify and expand their knowledge. It is an opportunity to share experiences, give or receive advice on dealing with clinical problems, and simply to learn something new. During congresses such as EuroPCR, we can see how people all over the world cope with the same problems that we have during our daily practice, which promotes the type of constant development that is mandatory for good clinical practice.

Q: Congresses often have a strong focus on providing a platform for younger, less-experienced medical practitioners to present their work, perhaps for the first time. What advice would you give to the young physicians and researchers presenting at this year's EuroPCR?

A: EuroPCR gives younger medical practitioners the opportunity to present challenging cases or results of trials. It is extremely important for them to go beyond the comfort zone of the department and cath lab in which they are working daily. I am happy to see more and more fellows join EuroPCR every year, so we can share our experience with them. My piece of advice would be to keep doing it because this is the process of constant development.



Q: What has been the single biggest challenge of your career and how did you overcome it?

A: It was entering European and worldwide cardiology, and showing that Polish cardiology has a major contribution to both scientific and practical progress in interventional cardiology.

Q: Finally, do you have any overall comments on the field of interventional cardiology and the advancements that are being made across healthcare settings?

A: Personally, I am engaged with the topic of chronic total occlusions (CTO). For a few years I have been a member of the EuroCTO club and I think that knowledge regarding qualification for percutaneous coronary intervention (PCI) in CTO, and the role of these procedures, is still insufficient, although we are trying to work on that. We are simultaneously trying to convince our government that PCI in CTO should have better financing because these procedures are much more expensive and take longer to perform than angioplasty of a single vessel. These two procedures currently have the same financing in Poland.

"So far, the CV health medical societies have achieved quite a lot."

Alexandre Avran

Director, Department of Interventional Cardiology, Clinique Générale de Marignane and Hôpital Privé Clairval, Marseille, France.

Q: At which point during your medical studies did you decide to specialise in the field of interventional cardiology?

A: It was during my second year after specialising in cardiology; I initially performed echocardiography and then moved on to cardiac pacing before choosing interventional cardiology.

Q: Is this an area of medicine that has grown significantly since you first began your career? How far has treatment in interventional cardiology advanced, and what sort of impact would you say this has had for patients with heart conditions?

A: This area of medicine has really grown since I first began. The greatest changes have been: the use of stenting, which has evolved into the use of drug-eluting stents and bioresorbable vascular scaffold (BVS) stents; the development of anti-aggregant treatment; our ability to treat chronic total occlusion lesions; and the continual improvement of all of our surgical devices and tools. The impact that all this has had on patients is very important because we can now solve most cardiac problems and achieve excellent results in most patients.

Q: Have you witnessed any changes in the prevalence and types of heart conditions during your time as a cardiologist?

A: There have been changes in the management of acute coronary syndrome and myocardial infarction. Prevalences have also changed: most of the coronary lesions we used to see were in patients who were smokers, but now it is diabetic patients in which these are most common.

Q: Would you say that heart disease is an increasing problem in France and the rest of Europe?

A: Yes, heart disease is an increasing problem in both France and the rest of Europe. This is because we are detecting more cases than before and because diabetes, dyslipidaemia, and hypertension are all increasing, similar to the USA.

Q: What more could governments and healthcare providers do to try and reduce the prevalence of heart problems in citizens?

A: We need to better educate the population regarding the risk factors for heart disease. Governments have achieved a lot in terms of reducing smoking but have not achieved so much for dyslipidaemia or hypertension.

Q: Are you generally happy with the way that healthcare is administered in France? Are there any lessons that other systems around the world could learn from French practices/procedures?

A: Yes, I am generally happy with the way that healthcare is administered here in France: patients can choose whether they want to be treated in a public or private system, and there is the same coverage and care. I am not sure if there are many lessons to learn from the French system because it is similar to the rest of Europe.

Q: What do you think is going to be 'the next big thing' in interventional cardiology?

A: The use of BVS stents.

Q: How important is the annual EuroPCR congress for the improvement of patient care?

A: EuroPCR is the largest annual interventional cardiology congress in France and is therefore very important for the improvement of patient care. There are a lot of other French congresses that are also important for this improvement and which can be more interactive than EuroPCR due to their smaller size.

Q: Are there any particular aspects of this year's meeting that you are looking forward to/found very interesting?

A: I specialise in performing procedures for chronic total obstruction and so I was very happy to find some sessions dedicated to this topic.

Q: How important is the role of publications such as EMJ in terms of spreading the latest news and developments to cardiologists around the world?

A: The role of publications is very important to us: we cannot know about everything as soon as it happens and so the role of journals such as EMJ is to serve as our link to the latest news from the field.

Q: What advice do you have for young medical students who are thinking of specialising in interventional cardiology?

A: I can only offer some advice: they need to be fascinated by the field of interventional cardiology. It is a very difficult specialisation with a lot of emergency and night calls; it is helpful to learn from a good mentor.

Giuseppe Biondi Zoccai

Assistant Professor, Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Rome, Italy.

Q: Did your experience serving as a medical officer in the Italian Army and as Chief Medical Officer in the Task Force Falco of NATO have a significant impact on your career in medicine?

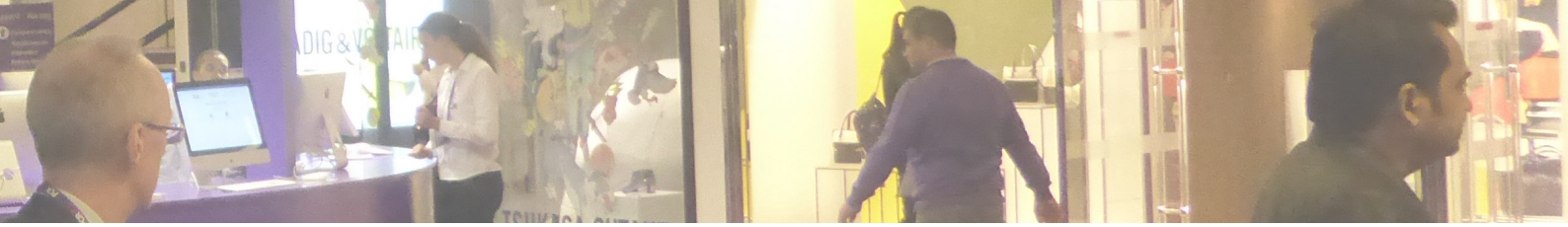
A: My service time has been very influential on my professional and personal life, as the challenges we faced were very important in shaping my approach to working with people and facing problems. Luckily, clinical medicine and clinical research are much less confrontational and hierarchical than a parachute regiment.

Q: What in particular made you decide to focus your work and research on interventional cardiology?

A: I like interventional cardiology as it means taking care of the patient from inception; before the development of cardiac disease (e.g. when performing primary percutaneous coronary intervention for acute myocardial infarction), to rehabilitating them from the acute event. In addition, I enjoy the fact that a single interventional procedure recapitulates most of the skills required for clinical cardiology, from interpersonal to resuscitation skills.

Q: How much has the procedure of intracoronary stenting improved since you first began researching this area?

A: There have been many improvements in the way the procedure is carried out. In general, we now routinely use radial access, and we have very safe and effective stents. Most importantly, we now



have a clear understanding of what is beneficial and what is not important or not safe for patients.

Q: How has our understanding of the impact of inflammation in heart disease developed since you first began researching it?

A: In truth, I am no longer focussing very intensely on cardiovascular (CV) inflammation as a research topic. I do, however, assist many bright clinician-investigators who are leaders and pioneers in this field, such as Antonio Abbate and Luigi M. Biasucci. Accordingly, I can attest that inflammation remains key in CV disease, and we are now entering a new era in which disease-modifying agents such as monoclonal antibodies and recombinant proteins (e.g. anakinra) may prove to be very useful in carefully selected patients.

Q: Have you seen any changes in the type and prevalence of heart conditions seen in daily practice both in Italy and across the world in recent years?

A: As far as my practice is concerned, I have not seen substantial changes in the type of patients or conditions that we treat. It is true that patients are getting older, but they are in relatively better shape than they have been in the past. In addition, we now study patients early during their disease course, and thus can impact more forcefully on their condition and improve their long-term morbidity and mortality outlook.

Q: What more can be done to educate people about how to avoid heart conditions, in your opinion?

A: I think that we need to be more direct, use social media, and provide direct or indirect incentives to avoid risk factors and increase the uptake of healthy habits, for example creating more cycling routes in cities or discouraging smoking in most urban areas.

Q: What do you think are the biggest challenges facing interventional cardiologists today?

A: The biggest challenges are budget restraints and the great success of drugs and devices, which have simplified procedures and treatments thus making the field a little bit banal.

Q: What has the impact of METCARDIO been on meta-analysis and evidence-based cardiology training since you founded the international collaboration back in 2003?

A: I have always treasured METCARDIO, but it is true that it has not thrived substantially over the years. Yet this is not a setback for the field as the Cochrane Collaboration has grown exponentially, and METCARDIO needs to remain a quasi-personal project capable of informally supporting young researchers interested in evidence synthesis, without any challenge to larger entities or institutions.

Q: What advice would you give to medical students thinking of focussing their interests on interventional cardiology?

A: They must figure out what they like and what they do not like early on (they can always change their mind later, but it is easier to understand that you do not like something if you have first tested it thoroughly by pretending you liked it in the first place). Then, they must focus on two parallel but independent tracks of expertise. For instance, a good combination is acute cardiac care and coronary intervention, another is structural heart disease and transoesophageal echocardiogram, and so forth. In my opinion the world will be dominated in the future by people who can bridge the gap between different disciplines, rather than people who are experts in one but cannot communicate with others.

Q: What do you think has been the single greatest accomplishment of your career to date?

A: My greatest accomplishment has been the training and mentoring of several very authoritative young colleagues, in Rome and elsewhere, who have proved themselves to be truly competent and enthusiastic clinician-investigators, including Luca Testa, now working in Milan, Fabrizio D'Ascenzo, now working in Turin, and Michael Lipinski, now working in Washington, D.C.

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TREATMENT OF SECONDARY MITRAL REGURGITATION VIA PERCUTANEOUS ANNULOPLASTY

This symposium took place on 21st May 2015 (13:35-14:35), as part of EuroPCR 2015; the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

Chairperson

Michael Haude[1]

Speakers

Christian Spaulding,[2] Stephan Fichtlscherer,[3] Christoph Hammerstingl[4]

1. Medical Clinic I, Neuss City Clinic, Lukas Krankenhaus GmbH, Neuss, Germany
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4. Heart Center, University of Bonn, Bonn, Germany

Disclosure: Michael Haude has acted as consultant for Biotronik, Cardiac Dimensions, and OrbusNeich. He has received honoraria from Abbott Vascular, AstraZeneca, Biotronik, Daiichi Sankyo and Eli Lilly, Direct Flow Medical, Medtronic, and Volcano. He has received an institutional grant/research support from Abbott Vascular, Biotronik, and Cardiac Dimensions. Christian Spaulding has acted as consultant for Abiomed, GE Healthcare, Medtronic, and Zoll. He has received honoraria from AstraZeneca, Bayer Healthcare Pharmaceuticals, Biosense Webster, Johnson & Johnson and Cordis, Johnson & Johnson, Biosensors International, Lilly, The Medicines Company, and Servier. Stephan Fichtlscherer has acted as consultant for ACIST Medical Systems, Edwards Lifesciences, Siemens, Volcano, and Cardiac Dimensions. He has received honoraria from Cardiac Dimensions. Christoph Hammerstingl has received honoraria from AstraZeneca, Bayer Healthcare Pharmaceuticals, Cardiac Dimensions, Medtronic Academia, and Mitralign. He has received an institutional grant/research support from Abbott Vascular.
Acknowledgements: Writing assistance was provided by Dr Jill Powell, apothecom scopemedical Ltd.
Support: The publication of this article was funded by Cardiac Dimensions. The views and opinions expressed are those of the authors and not necessarily of Cardiac Dimensions.
Citation: EMJ Int Cardiol. 2015;3[1]:39-45.

MEETING SUMMARY

Functional mitral regurgitation (FMR) is a common occurrence in patients with heart failure (HF). FMR is associated with as much as a 2-fold increase in mortality, as well as in HF hospitalisations. Over the past 15 years, efforts to address FMR have focussed on the development of transcatheter devices that replicate the effect of annuloplasty; however, besides open heart surgery, optimal medical treatment remains the standard of care (SoC) for these patients. To date, the only CE-marked option available for clinical use as a transcatheter annuloplasty device is the CARILLON® Contour System® from Cardiac Dimensions. The efficacy demonstrated in clinical trials, implantation technique, and comprehensive patient treatment was discussed during the symposium at EuroPCR and is presented in detail in this article.

Overview of the CARILLON Mitral Contour Device and Clinical Data

Professor Christian Spaulding

FMR occurs in HF patients as a result of dilation of the heart's mitral annulus, which can be caused by either ventricular or atrial dilation. The mitral valve (MV) leaflets no longer seal adequately and the valve allows blood to regurgitate. This can lead to a dramatic reduction in cardiac output and exacerbates HF symptoms.

The current SoC is medical therapy, which has been shown to improve patient survival but not patient quality of life (QoL). Few patients with FMR are indicated for MV surgery, and of these 84% are often not referred or are denied treatment. This is therefore a huge clinical problem and an unmet need. To address this, a number of interesting devices have been developed; this presentation will describe the CARILLON device.

Implantation is a rapid procedure that can be completed in less than 40 minutes, with or without general anaesthesia. The implantation technique has a short learning curve in comparison with other devices. In 10-15% of cases the device may have an impact on blood flow in the coronary circumflex artery (Cx), which is assessed by coronary angiogram (CA) during implantation. In such cases, the CARILLON device can be removed and, if feasible, a second device placed in a different position (Figure 1).

The CARILLON system comprises a handle assembly, a 9 Fr delivery catheter, and the permanently implanted device. Additionally a marker catheter is used. The marker catheter contains marker bands spaced at 1 cm intervals in order to measure vein length and diameter for implant size selection. The implants consist of distal and proximal anchors (nitinol and titanium) joined with a ribbon connector (nitinol). The distal anchor is secured in the great cardiac vein by expanding the anchor in the vein and locking it in place with the delivery catheter. The pressure applied on the vein wall by the expanded and locked anchor enables secure positioning. Manual tension is applied to the delivery system, which pulls the proximal anchor towards the coronary sinus ostium, plicates the periannular tissue of the MV, which improves leaflet coaptation, and thus reduces regurgitant flow. The proximal anchor is deployed and locked in the coronary sinus by retracting the delivery catheter and advancing an inner locking sheath.

Three prospective, controlled, multicentre trials have assessed the safety and efficacy of the CARILLON device: AMADEUS,[1] TITAN,[2] and TITAN II.[3] All studies included patients with dilated ischaemic or non-ischaemic cardiomyopathy; moderate-to-severe FMR 2+ to 4+, with an ejection fraction of <40%; and who were New York Heart Association (NYHA) Class II-IV with a 6-minute walk distance (6MWD) test result of 150-450 m.

Click here to access the CARILLON device animation

Figure 1: Animation demonstrating implantation of the CARILLON device.

Patients needed to be stable on HF medication and there were no anatomical exclusions — the study enrolled all comers.

The primary endpoint was the same for each study: the 30-day rate of major adverse events (MAEs), with the following secondary endpoints: haemodynamic changes (up to 1 year), FMR quantification, left ventricle dimensions, functional changes (up to 2 years), 6MWD, NYHA class, and QoL (up to 1 year) as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ).

The TITAN study compared patients implanted with the CARILLON device with those who did not receive the device, due to a reduction of blood flow in the Cx necessitating removal of the device[2] or due to a <1 Grade acute reduction in mitral regurgitation (MR), as required by the study protocol. In comparison, TITAN II was a single-arm study of patients who received the device.[3] Baseline demographic results for the TITAN (n=53) and TITAN II (n=30) studies showed an average age of approximately 62 years for TITAN and 70.5 years for TITAN II. Most of the patients were NYHA Class III (>90% in each study) with MR Grade >3 (84.5% for TITAN; 64% for TITAN II).[2,3]

Safety results from both studies demonstrated no MAEs after 30 days that could be attributable to the device. There was one death (1.9%) in the TITAN study, due to nephropathy and renal failure occurring several days after the procedure, and one death (2.8%) in the TITAN II study due to a non-cardiac cause; neither event was attributed to the device. No patients showed the following MAEs: myocardial infarction, cardiac perforation, device embolisation, surgery, or percutaneous coronary intervention related to the device.

Echocardiography results from the TITAN study showed a significant reduction in MR for implanted patients (Figure 2a). This change occurred over time and continued to improve up to a year after implantation of the device. Left ventricle reverse modelling occurred in patients with the implant versus those without (Figure 2b).

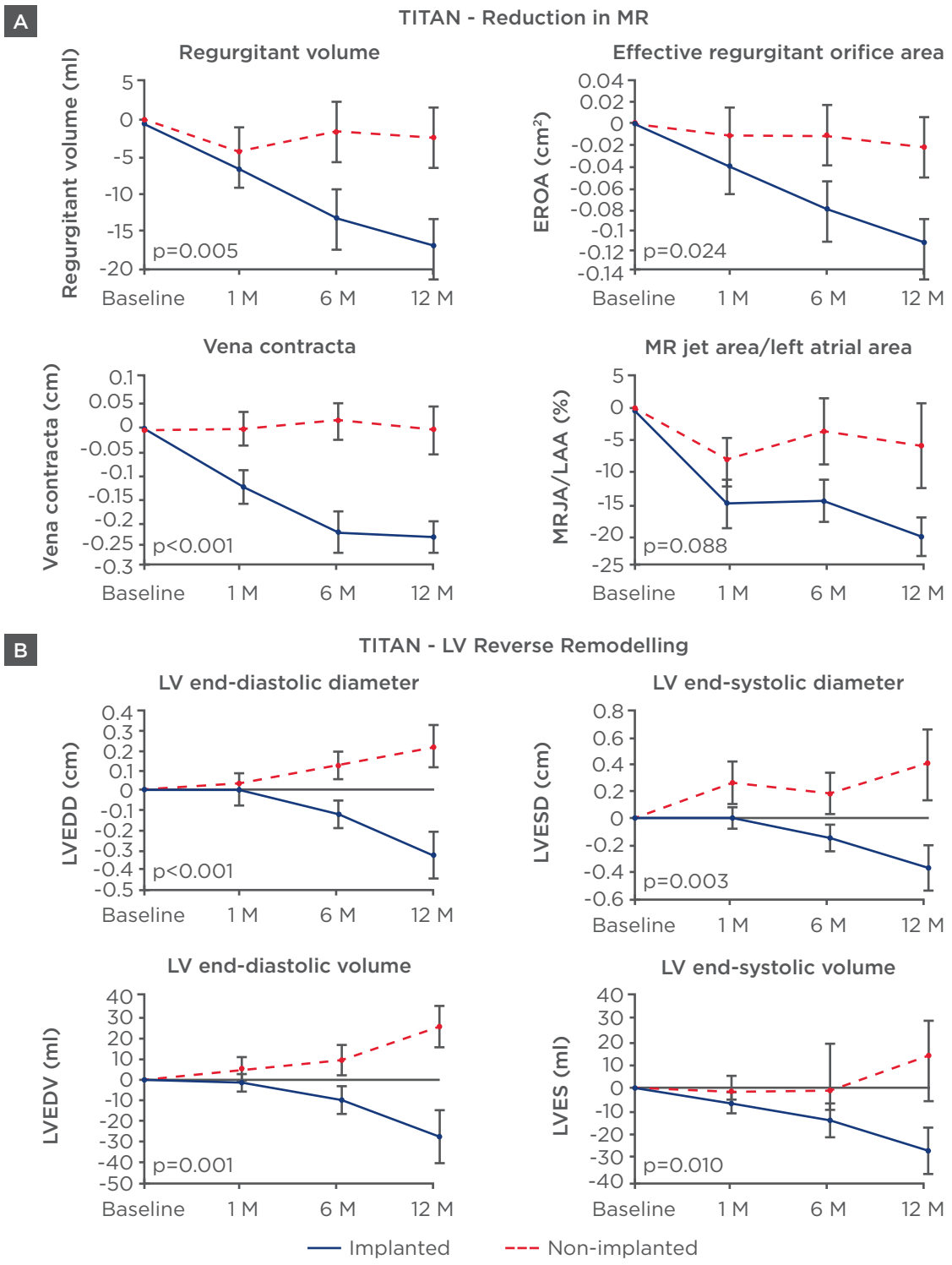

Figure 2: Results from the TITAN study.[2]

Echocardiographic changes in functional mitral regurgitation (MR) severity and left ventricular dimensions between implanted (n=36) and non-implanted (n=17) patients. Statistical significance was calculated by comparing the difference between the two groups from baseline to 12 months. A) Reduction in MR severity as assessed by changes in regurgitant volume, effective regurgitant orifice area, vena contracta, and MR jet area/left atrial area. B) Left ventricle (LV) reverse remodelling assessed during both systole and diastole.

EROA: effective regurgitation orifice area; MRJA/LAA: mitral regurgitation jet area/left atrial area. LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; LVEDV: left ventricular end-diastolic volume; LVESV: left ventricular end-systolic volume.

Reproduced with permission from Siminiak T et al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. Eur J Heart Fail. 2012;14(8):931-8.

Patients without the device experienced additional left ventricular dilatation. In addition, patients with the device experienced improvements in their 6MWD test results and in NYHA class, resulting in a full class reduction.

After three successful trials involving a total of more than 100 patients, the manufacturer has initiated a double-blind, multicentre study (REDUCE FMR; NCT02325830) in Australia and Europe to further assess the benefits of the CARILLON device in this patient population. This study compares patients implanted with the CARILLON device versus patients receiving medical treatment as per current HF guidelines. Patients initially randomised to the control group of this study may be offered the CARILLON device once they have completed the protocol-defined follow-up period. The inclusion criteria are the same as for the TITAN/TITAN II studies; 120 patients will be randomised 3:1 to the device plus an optimal medical regimen of heart failure therapy (optimal medical management [OMM]) versus remaining on OMM alone. The study includes a 1-year follow-up period, with the primary endpoint assessing the change in regurgitant volume at 12 months. In addition to REDUCE FMR, a three-centre pilot study of 30 patients is under way in which patients will receive either the CARILLON device or the MitraClip.[4]

In conclusion, results from the TITAN studies demonstrate that effective and safe reduction of FMR with the CARILLON device is feasible. REDUCE FMR is a double-blind, randomised study that will compare the CARILLON device plus OMM with OMM alone.

Discussion and audience interaction

The following questions were taken from the audience and addressed by the panel:

Is the CARILLON device indicated for patients with severe FMR or is it just used for those with moderate/moderate-to-severe FMR? Can the device be used in patients with MR resulting from prolapse or a torn leaflet, or is this technique reserved for patients with HF? The delegate asking the question also asked whether regurgitation is assessed during the procedure.

Prof Spaulding answered that the trials included patients with FMR Grade 2. Prof Haude added that use of the CARILLON device is indicated for patients with FMR and that it should not be used in patients with primary leaflet diseases or significant MV prolapse. He added that the MitraClip procedure aims to reduce regurgitation during the procedural surgery; however, MR reduction occurs over time with the CARILLON device.

Do you use the CARILLON device for severe MR?

Prof Haude answered that the device has been used for all grades of MR and, in his experience, patients with MR Grade 2+ benefit the most from the device. Very sick NYHA Class IV patients with severe MR often do not respond to treatment irrespective of the intervention. Prof Spaulding added that patients obtain greater benefit when the device is placed earlier in the course of their treatment, and he recommends not waiting until a patient has revisited the intensive care unit for the fourth, fifth, or sixth time.

Is there a way to monitor the effects of the CARILLON device during the implantation procedure? Can you see any changes immediately after implanting?

Implanters will often measure the vena contracta while the MV is plicated during the procedure in order to assess the acute impact of the CARILLON device. As previously noted, there is probably a reverse remodelling process that continues to improve the results over a 6-12 month period.

Practical Application of Percutaneous Annuloplasty: Case Review

Professor Stephan Fichtlscherer

The CARILLON device is available in different length anchor sizes in order to align with patient anatomical assessments prior to implantation (Figure 3).

A patient case was described in real time using a video to show details of the implantation procedure (Figure 4).

A CA precedes implantation of the device in order to determine the relationship between the Cx, the right coronary artery (RCA), and the great coronary sinus. A marker catheter is first inserted in order to determine the size of the proximal and distal anchors required for each individual patient and the length of the vein.

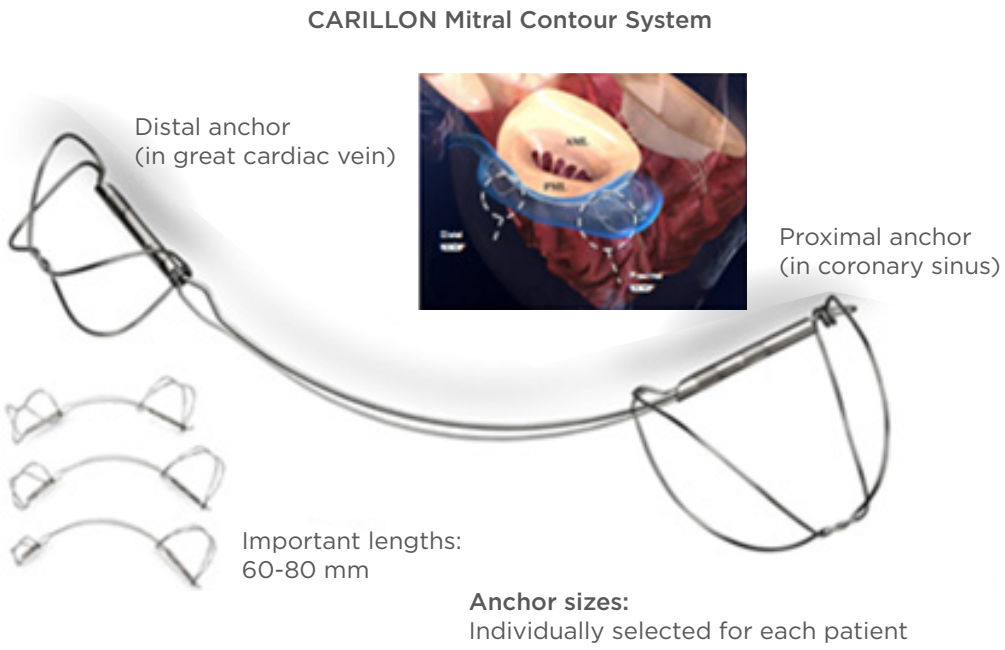

Figure 3: The CARILLON Mitral Contour System.

While the procedure can be performed without anaesthesia, Prof Fichtlscherer stated that in his hospital the procedure is performed with anaesthesia and intubation so that a transoesophageal echocardiogram (TOE) can be performed during implantation. Under TOE, the anchoring system is tensioned in order to reshape the mitral annulus. Successful implantation is determined using echocardiographic assessment, and the device decouples if satisfactory blood flow is confirmed in the Cx. In addition, the RCA is checked for any occlusion or damage.

Prof Fichtlscherer concluded his presentation by stating that he finds the CARILLON device to be effective, with 80% of patients demonstrating an improvement of one NYHA class, and patients demonstrating a 50% reduction in MR overall. He added that the device has an excellent safety profile together with a short learning curve. Lastly, he noted that the CARILLON device is a flexible technology allowing subsequent adjunctive therapy to be implanted, such as the MitraClip, valves, or cardiac resynchronisation therapy (CRT) leads.

Discussion and audience interaction

Although the CARILLON device does not occlude the coronary sinus, allowing future insertion of a CRT probe, what should be done for patients who already have a CRT probe in the coronary sinus?

Prof Fichtlscherer replied that he would not implant a CARILLON device in such patients, as removal of the CRT leads is possible but not recommended to ensure patient safety. He added that some centres have in fact removed a CRT lead in order to allow for implantation of a CARILLON device; however, this is not indicated at this time.

Is constriction of the Cx during the procedure mechanical or physiological, and how often can the constriction be alleviated by the use of nitroglycerin?

Prof Fichtlscherer replied that, from his experience, this is seen in around 10% of patients and acknowledged that this is a very important point. He added that sometimes pulling on the device impacts the Cx, which results in vasoconstriction of the vessel, and he recommended administering nitroglycerin or verapamil followed by a wait of up to 10 minutes to allow the constriction to subside. He added that a small percentage of these patients would not respond to the medication, and that the device would need to be recaptured and a second device placed in a different position.

CARILLON as a Part of the Heart Failure Treatment Plan

Doctor Christoph Hammerstingl

FMR affects 20-60% of patients with a reduced left ventricular ejection fraction (LVEF), depending

on the definition of FMR.[5] Guidelines state that patients with an effective regurgitation orifice area (EROA) ≥20 mm^2 have FMR of sufficient severity to impact their prognosis and should receive treatment.[6] This is in contrast to primary or degenerative MR in which the cut-off is ≥40 mm^2.

Indeed, it has even been reported that FMR Grade 2+ has an impact on prognosis.[7] In addition, the discrepancy between EROA calculated using the proximal isovelocity surface area (PISA) method and the EROA determined by direct measurement suggests that FMR is often underestimated using PISA-calculated EROA, and that more patients should receive treatment at an earlier stage in their disease. Implantation of the CARILLON device was described as previously presented. It was emphasised that substantial improvements in MR following implantation could take months.[2,3]

Correct timing of implantation should be taken into consideration, as HF is a progressive condition. In patients for whom interventional therapy for MV regurgitation is being considered, guidelines state that improvements should be sought initially via CRT (in select patients) and by optimising medical therapy for a period of 6 months. However, clinical data have shown that improvement in FMR is seen only in approximately half of CRT patients, and they typically have a worse prognosis if they are aged over 75 years, are high-risk with NYHA Class III-IV, or have severely reduced LVEF (≤25%) or chronic renal failure.[8,9] Therefore, applying a stepwise approach and allowing evaluation time between treatments may not be appropriate in such a frail patient population.

Prof Hammerstingl concluded that his approach is to first assess the severity of HF together with the pathophysiology of the underlying heart disease, and to determine the FMR severity. If the coronary status does not indicate that the patient requires a coronary artery bypass graft and medical therapy has been optimised as far as possible, then in the highest-risk patients who are still highly symptomatic with severely depressed LVEF a multimodal treatment plan should be undertaken in which the CARILLON device is implanted first, then the CRT is implanted where necessary with a short waiting time.

Click here to access case study video

Figure 4: Video of patient case showing real-time implantation of the CARILLON device.

Discussion and audience interaction

When a patient is equally suitable for the MitraClip or the CARILLON device, which should they receive first?

Prof Hammerstingl replied that this is unclear at present and that both devices should be discussed with the patient in order for them to reach an informed choice. Prof Haude replied that his recommendation would be the CARILLON device due to its ease of use, high safety profile, and efficacy. Prof Fichtlscherer commented that some patients, particularly those with a large left atrium (LA), small ventricles, or greatly dilated annuli, would benefit from receiving the CARILLON device first. Prof Hammerstingl agreed that anatomical issues should be taken into consideration and if the LA is really large then difficulties will arise in using the MitraClip, and these patients represent better candidates for the CARILLON system. Prof Spaulding added that in the EVEREST II study[10] there were very few patients with FMR who were actually included, so perhaps there are insufficient data regarding MitraClip use in patients with FMR. He mentioned that ongoing studies are assessing the MitraClip in patients with FMR.

Summary

Professor Michael Haude

In conclusion, the CARILLON Mitral Contour System is the only CE-marked option currently designed for transcatheter mitral annuloplasty in patients with FMR. The procedure is simple, effective, and easy to learn. Clinical data demonstrate promising efficacy outcomes and the CARILLON device allows for future adjunctive therapies. Further research will refine patient selection for receipt of the CARILLON device and determine the ideal time for implantation. Clinical and commercial experience to date is more than 350 implanted CARILLON devices.

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COMPLEX RETROGRADE CTO PCI WITH DOUBLE RENDEZVOUS TECHNIQUE AND ROTATIONAL ATHERECTOMY

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Case Report

A 56-year-old hypercholesterolaemic male who was a previous smoker with a family history of heart disease was admitted to a local hospital with new onset of effort angina. Coronary angiography showed critical stenosis of the medium and distal left anterior descending artery (LAD) and proximal left circumflex artery (LCx), with a chronic total occlusion (CTO) at distal LCx. The collateral flow distal to the CTO was supplied by the LAD through an extremely tortuous epicardial channel. The patient was successfully treated via percutaneous coronary intervention (PCI) and placement of one drug-eluting stent (DES) at medium LAD and proximal LCx. During the same hospitalisation, an attempt at antegrade LCx recanalisation was made but was unsuccessful. As a result of persistent effort angina despite optimal medical therapy, the patient was referred to our centre for a new attempt at LCx CTO recanalisation. The J-CTO score of the lesion (Figure 1A) was 4 because of the blunt stump, the presence of calcification, the occlusion length, and the previous failed attempt. This was suggestive of a very complex CTO PCI with a low success rate (below 80%).[1]

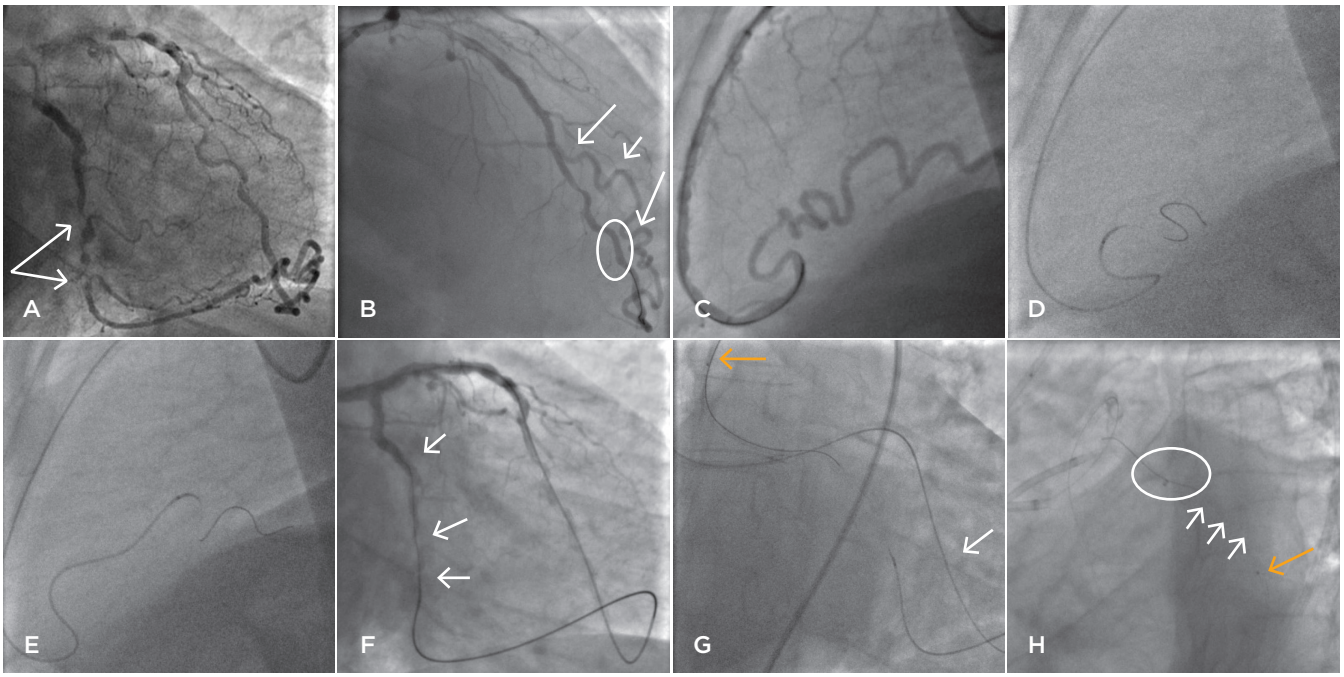

Figure 1:
A) Chronic total occlusion of the distal left circumflex artery.
B) Distal left anterior descending artery stenting before epicardial channel navigation.
C-E) Successful epicardial collateral channel crossing with Sion guide and Corsair 150 cm microcatheter.
F) Fielder XT-A retrograde crossing of the occlusion.
G) Retrograde wire in 6 Fr guiding catheter from radial artery but unsuccessful Corsair retrograde crossing despite wire-anchoring balloon (yellow arrow).
H) Unsuccessful Finecross (yellow arrow) retrograde crossing of chronic total occlusion despite Guideliner use.

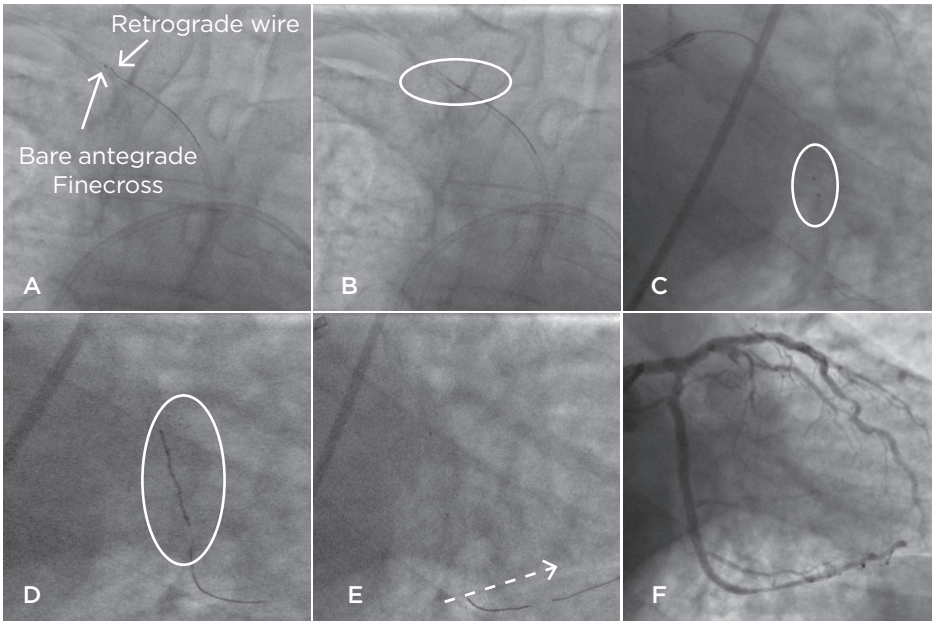

Figure 2:
A-B) First rendezvous technique.
C) Second rendezvous technique: antegrade and retrograde Finecross aligned at proximal and distal cap of the occlusion.
D) Second rendezvous technique: antegrade RotaWire successfully entering the retrograde Finecross.
E) Second rendezvous technique: RotaWire advancement.
F) Final result.

Dual arterial access with 8 Fr right femoral and 6 Fr right radial artery was obtained. First, an antegrade approach with an 8 Fr extra backup (EBU) 4 guiding catheter 90 cm was considered. Attempts with Fielder XT-A, Gaia 2®, and then Conquest Pro guidewires inside microcatheters (both Finecross® and Corsair®) were made but antegrade wiring failed. A retrograde approach via the ipsilateral epicardial channel from the distal LAD was then selected. Before collateral channel crossing, focal stenosis of distal LAD was treated with implantation of one DES (Figure 1B). A Sion™ wire inserted in a Corsair 150 cm microcatheter successfully navigated the tortuous collateral up to the distal part of the occlusion (Figure 1C-E). Crossing of the CTO was achieved with a Fielder XT-A (Figure 1F) retrograde wire that successfully entered a second 6 Fr EBU 4 guiding catheter inserted from the right radial artery using the 'ping-pong' technique.

At this point it was impossible to advance the retrograde microcatheter (both Corsair and Finecross) through the LCx CTO, despite retrograde wire trapping and Guideliner™ use, due to the severely calcified lesion (Figure 1G-H). Therefore, it was impossible to externalise the retrograde wire. We then opted for the rendezvous technique: a Finecross 130 cm microcatheter was advanced bare into the antegrade 6 Fr guiding catheter and inserted over the retrograde wire (Figure 2A-B). The antegrade Finecross was carried up to the proximal part of calcified stenosis but it could not cross the lesion. A second rendezvous was then performed by advancing an antegrade RotaWire™ Floppy into the retrograde Finecross 150 cm that was very close to the antegrade microcatheter (Figure 2C-E). Subsequently, rotational atherectomy with 1.25 and 1.5 mm burr was performed, followed by medium-to-distal LCx PCI with implantation of three DESs and a good final result (Figure 2F). At 5 months follow-up the patient was asymptomatic with negative maximal exercise test.

Discussion

Recanalisation of CTO represents the final frontier in interventional cardiology. The retrograde

approach has definitely improved the chance to succeed in CTO revascularisation.[2] In experienced hands, this technique has a high success rate with a low complication risk.[3-7] In the present case, the retrograde wire successfully crossed the CTO but the calcified lesion prevented microcatheter progression, without any possibility to externalise the retrograde wire. The use of the rendezvous technique (also known as the 'tip-in' method) helped us to solve this challenge; this technique was originally described by Kim et al.[8] In our case, the first rendezvous was done with an antegrade microcatheter inserted over the retrograde wire, but it could not cross the lesion and had no chance of exchanging the retrograde wire with an antegrade one. With the second rendezvous, and after positioning the antegrade microcatheter in front of the retrograde one and with both aligned, we succeeded in entering RotaWire into the retrograde Finecross. We eventually managed to position an antegrade wire through the severely calcified CTO. We chose a RotaWire Floppy for the second rendezvous because we realised the need for rotational atherectomy to treat this severely calcified lesion.

Conclusion

Retrograde CTO recanalisation techniques have evolved, resulting in high success rates and acceptable safety compared with the early days. At the same time, the number of patients and the complexity of CTO lesions treated with this method (previously labelled as 'unrevascularisable') have increased. Severely calcified lesions are the most complex type of CTO, both in antegrade and retrograde approaches. Familiarity with appropriate techniques and dedicated materials is essential for successful recanalisation and can help to overcome unexpected obstacles. To our knowledge, this is the first case of retrograde CTO PCI to be successfully achieved with the use of double rendezvous technique and rotational atherectomy.

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STEMI IN MULTI-VESSEL CORONARY DISEASE: TO PRAMI OR NOT TO PRAMI?

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Significant multi-vessel (MV) coronary artery disease (CAD) is present in up to 40% of patients presenting with ST-segment elevation myocardial infarction (STEMI)[1] and has been associated with increased mortality in these subjects.[2] Current guidelines recommend treatment of the infarct-related artery (IRA) only in the absence of cardiogenic shock, thereby either leaving bystander disease untreated (culprit-only revascularisation) or addressing these lesions during a later elective procedure (staged revascularisation) if ischaemia is documented.[3] However, these recommendations derive from a series of retrospective observational registries[4] and subgroup analyses of randomised clinical trials (RCTs)[5] suggesting worse clinical outcomes with in-hospital complete revascularisation. Recent RCTs have demonstrated

that index admission preventive percutaneous coronary intervention (PCI) in non-IRA coronary arteries improves clinical outcomes at 126 or 237 months in subjects presenting with STEMI and significant MV disease.

We present the case of a 57-year-old male with no significant cardiovascular risk factors who was admitted to our centre following an acute onset of chest pain and evidence of inferior ST-segment elevation on an electrocardiogram. He was haemodynamically stable, and bedside transthoracic echocardiogram demonstrated moderate left ventricular dysfunction (LVD) with severe infero-lateral hypokinesis. Urgent coronary angiography via the right radial approach showed minor atheroma of the left main stem (LMS); severe proximal left anterior descending (LAD) artery disease with a focal stenosis in the mid vessel, and a further significant lesion in a tortuous distal segment; proximal occlusion of left circumflex (LCx) artery, which was the culprit lesion; and chronic total occlusion (CTO) of the dominant right coronary artery (RCA) in the mid vessel with reasonable collaterals from the LAD septal system.

We therefore proceeded to intervene on the occluded LCx artery: a Balance Middle Weight (BMW) wire was passed to the lateral obtuse marginal branch, following which we attempted thrombus extraction. However, due to the heavily calcified and tortuous vessel, this would not pass. The LCx was treated with intracoronary abciximab and predilated with 2.5 and 3 mm balloons, with restoration of Thrombolysis in Myocardial Infarction (TIMI) Grade 3 flow. At this stage, it became clear that the LCx was severely diseased from the mid-course to the ostium with notable size mismatch and involvement of the LMS.

Different treatment strategies could have been adopted at this point, including:

i) Discontinuation of primary PCI (PPCI) and referral to the cardiothoracic team for consideration of emergency coronary artery bypass surgery;
ii) PPCI to mid-LCx segment only;
iii) PPCI of LCx from mid-segment to the ostium with or without LMS PCI;
iv) PPCI from mid-LCx to the LMS and bystander LAD revascularisation.

In view of the general reluctance of the surgical team to operate on acute cases with LVD, and in view of the encouraging results of recently published studies,[6,7] we decided to proceed to complete revascularisation of the left coronary system: after exchanging for an extra support wire and with microcatheter support, we delivered a 3.5 × 26 mm drug-eluting stent (DES) to the stenosed segment. We then prepared the proximal LAD with a BMW wire and 2.5 and 3 mm balloons. The proximal circumflex was then stented back into the left main with a 3 × 30 mm DES, which was optimised with a 4.5 mm non-compliant (NC) balloon. The LAD was rewired with a Pilot 50, predilated with 1.5 and 2 mm balloons, and stented with a 3 × 26 mm DES in the mid-segment and a 4 × 26 mm DES proximally. Following re-wiring of the LCx with a Pilot 50, we performed kissing inflations to the left main bifurcation with 4 mm NC balloons in both limbs, and finally optimised the LMS with a 5 mm short NC balloon: this led to excellent angiographic results with TIMI-3 flow in both the LCx and LAD. The patient tolerated the procedure without complications and following standard post-STEMI care in a coronary care unit, was successfully discharged on long-term dual antiplatelets. The patient's bystander RCA CTO disease will be addressed at a later stage with non-invasive functional tests.

In summary, we have presented a challenging case of STEMI with severe bystander CAD disease, in which IRA-only revascularisation was considered not appropriate and complete revascularisation of the left coronary system led to excellent angiographic and clinical results. Large RCTs are required in order to definitively establish whether index admission preventive PCI improves clinical outcomes in patients presenting with STEMI.

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EXTENSIVE THROMBOSIS DURING A COMPLEX BIFURCATION PERCUTANEOUS CORONARY INTERVENTION: WHAT WENT WRONG?

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Introduction

Percutaneous coronary intervention (PCI) of complex true coronary bifurcation lesions is challenging, with higher rates of acute complications, lower success rates, and higher restenosis and target lesion revascularisation (TLR) rates. Diabetes mellitus (DM) is associated with greater atherosclerotic burden, higher incidence of bifurcation lesions, and unfavourable outcomes after PCI. The use of one-stent or two-stent strategies in patients with DM is still debatable.

Case Report

Here we present the case of a 57-year-old man with a past medical history of DM and hypertension who was complaining of chest pain on exertion with positive treadmill stress test. The patient showed good left ventricle systolic function (ejection fraction: 62%) on echocardiography. Coronary angiography revealed a triple vessel disease with proximal left anterior descending (LAD)/first diagonal (Dg) true bifurcation lesion (medina 1-1-1), multiple stenosis of a small left circumflex (LCx), and severe distal disease of a normal right coronary artery (RCA). Taking into consideration the large diameter and territory of distribution of the side branch (SB), we decided to perform PCI of the LAD–Dg bifurcation lesion with a two-stent technique as intention-to-treat. We proceeded with a 7 Fr femoral access using an extra back-up 3.5 guiding catheter. Both the SB and main branch (MB) were wired and pre-dilated. We then performed a classical T-stenting using a drug-eluting stent in the SB concomitantly with low-pressure balloon inflation in the MB.

The initial angiographic result was quite good, with normal flow in both the MB and SB and no evidence of SB dissection. When preparing to stent the MB, the patient experienced heavy chest pain with ST elevation on electrocardiogram. Angiographic control revealed SB thrombosis. Balloon inflation in the SB with abciximab intracoronary bolus infusion was performed, which permitted SB flow recovery but with slow flow in the LAD. Balloon inflation in the LAD resulted in LCx and Dg thrombosis, ventricular fibrillation, and then cardiac arrest. The patient was resuscitated and then a left main–LAD stenting was performed. Angiographic control revealed LCx occlusion with slow flow in the LAD and Dg. Unfortunately, the procedure resulted in an unrecoverable cardiac arrest.

Conclusion

Data from randomised trials show no clear advantage for routine double stenting over the provisional strategy with regard to restenosis and TLR. The provisional approach should be the default in most bifurcation lesions. When a two-stent strategy is decided upon, adequate coverage

of SB ostium is of paramount interest. T-stenting and modified T-stenting are less labourious bifurcation techniques, but are associated with incomplete SB ostium coverage in almost all cases. SB occlusion in our case was likely to be the consequence of ostial dissection secondary to incomplete SB ostium coverage. When using a two-stent strategy, we have to take into consideration the angulation of the SB relative to the main vessel and also keep in mind that T-stenting is best suited to right-angle bifurcation. When the bifurcation angle is sharp, other bifurcation techniques such as crush, mini-crush, or culotte must be used.

FIRST-IN-MAN EVALUATION OF THE NOVEL BALLOON DELIVERY SYSTEM FOR THE SELF-APPOSING CORONARY ARTERY STENT: IMPROVING PRECISE STENT DELIVERY

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The Self-Apposing® stent (STENTYS SA, Paris, France), a next-generation self-expanding coronary artery stent with a nitinol platform, has proven to be useful in cases in which exact stent sizing is challenging, particularly in patients presenting with an ST-segment elevation myocardial infarction (STEMI). To optimise precise stent positioning and deployment, a novel balloon delivery system, Xposition, for the STENTYS Self-Apposing sirolimus-eluting stent has been developed. The findings of the first clinical experience, as evaluated in the first-in-man SETUP trial, were presented at EuroPCR 2015.

The SETUP study was a prospective, single-arm, first-in-man study performed in two Dutch centres (Academic Medical Center, Amsterdam, and Albert Schweitzer Hospital, Dordrecht) to evaluate the feasibility of the use of the novel STENTYS Xposition S in *de novo* coronary lesions. The study enrolled 25 patients with stable and unstable coronary artery disease. There was a technical success rate of 100%, which was defined as the ability to cross and deploy the stent at the intended site. Angiographic success, defined as residual stenosis <30% and post-percutaneous coronary intervention (PCI) thrombolysis in myocardial infarction Grade 3 flow on visual estimation was found in all cases (100%). There was no longitudinal geographic miss as assessed by quantitative coronary angiography, which was defined as the entire length of the stenotic segment not completely covered by the stent. Optical coherence tomography (OCT) was performed directly after stent placement and after final post-dilatations. Percentage of malapposed stent struts was significantly lower after post-dilatation than directly after stent placement (0.6% versus 2.4%; p=0.013). Mean stent area increased significantly from 9.7 mm^2 after stent placement to 10.5 mm^2 after post-dilatation (p<0.001). These OCT findings suggest that post-dilatation can optimise stent expansion and apposition of this device. This first-in-man study demonstrated that the use of the novel STENTYS Xposition S is feasible, with a high technical success rate.[1]

The problems of stent mis-sizing (resulting in axial geographic miss) and mis-positioning (resulting in longitudinal geographic miss) during PCI are underappreciated and found in >60% of cases.[2] It has been described that geographic miss causes endothelial flow disturbances, which increase the intramural wall stress and the wall shear stress. This results in unfavourable endothelial healing with more pronounced intimal hyperplasia formation.[3,4] The self-apposing properties of the nitinol platform reduce stent strut malapposition rates, and therefore the risk of axial mismatch. A previous randomised trial comparing the Self-Apposing stent with a balloon-expandable stent in STEMI patients demonstrated a significantly lower rate of stent strut malapposition in the

self-apposing group 3 days after primary PCI, as assessed by OCT.[5] Given this background, the Self-Apposing stent may be preferred in specific coronary anatomic subsets or for complex lesion characteristics in which stent sizing is challenging and the risk of axial mismatch is considerable. Lesions with a high thrombus load in STEMI patients, tapered target vessels with a large difference in proximal and distal diameters, and target vessels involving coronary aneurysms or bifurcation lesions are examples in which this device could be favourable. In the present study, we observed low malapposition rates directly after stent placement, which improved further after post-dilatation in real-world lesion complexities, including ostial lesions, highly calcified lesions, and lesions with high thrombus burden, using the Self-Apposing stent. In these complex cases, precise positioning may be challenging using the conventional delivery system for the Self-Apposing device, whereby the stent is deployed by retracting a delivery sheath. With the Xposition S, the novel balloon-based delivery system, we noticed significant improvement over the previous delivery system in terms of ease of use, stent crossing, and delivery. We believe that Xposition S could advance the treatment of patients with complex artery anatomy.

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BRIEF OVERVIEW OF THE BALLOON ELUTION AND LATE LOSS OPTIMIZATION (BELLO) STUDY – ABSTRACT PRESENTATION AT EUROPCR 2015

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The optimal treatment of *de novo* small vessel coronary artery disease (CAD) is currently unclear. Possible treatment options include the implantation of drug-eluting stents (DESs) or treatment with the use of drug-coated balloons (DCBs). DESs are, however, limited by the requirement for a prolonged duration of dual antiplatelet therapy (DAPT) and are also associated with high restenosis rates, whilst the long-term efficacy of DCBs has not been previously investigated.

The Balloon Elution and Late Loss Optimization (BELLO) study was an investigator-initiated, prospective, multi-centre, single-blinded, active-treatment controlled clinical trial that randomised 182 patients undergoing percutaneous coronary intervention to either paclitaxel DES (Taxus Liberte, Boston Scientific, Quincy, Massachusetts, USA) implantation (n=92) or use of a paclitaxel DCB (IN.PACY Falcon, Medtronic, Santa Rosa, California, USA) (n=90). We have previously reported that DCBs are associated with less angiographic late loss and similar rates of restenosis and revascularisation compared with DESs at 1-year follow-up. The purpose of this presentation was to report the final pre-defined, protocol-mandated, 3-year clinical follow-up results of this study population.

A total of 166 patients completed the 3-year follow-up (83 patients in each group) and 7 patients died: 2 patients in the DCB group (1 sudden cardiac death, 1 following coronary artery bypass graft surgery) and 5 patients in the DES group (3 cancer, 1 respiratory failure, 1 following stroke). Nine patients (4.9%) were lost to follow-up. The principal finding presented was

that there was a statistically significant difference between groups with regard to the occurrence of the first major adverse cardiovascular event composite (comprising of all-cause death, myocardial infarction, and target vessel revascularisation): 13 events (DCB group) versus 28 events (DES group) (p=0.015). There were no reported instances of target stent (or vessel) thrombosis in either group. Whilst the study was not powered for this endpoint, we can conclude from these data that the use of DCBs is not inferior to paclitaxel-eluting stents for small vessel disease and, additionally, raises the interesting hypothesis that the treatment of small vessels with DCBs may be associated with an outcome benefit.

The group discussion led by the chairperson of the session focussed upon the impact of these findings in routine clinical practice. There was a general consensus that this approach was particularly attractive in patients who presented with vessels too small to allow optimal DES implantation, and also in patients at high risk of bleeding complications who would not require prolonged DAPT following treatment with a DCB.

The discussion then turned to future directions of DCB treatment. An important point raised was that this study utilised a first-generation paclitaxel DES, which has now been completely superseded by newer-generation stents that use limus compounds as the anti-proliferative drug of choice, in association with thinner struts. Consequently, they are associated with reduced rates of in-stent restenosis and late stent thrombosis. An important question that remains unanswered is whether the results presented in the BELLO study would be equally applicable to these more contemporary stents. Similarly, by virtue of its pharmacology, paclitaxel is the only anti-proliferative drug currently available with DCBs. However, with advances in nanotechnology and balloon technology, limus DCBs may soon be available, which may further improve the efficacy of DCB treatment.

With regard to the best current practice for the interventional cardiologist, the group concluded that, with the benefit of the long-term follow-up data from the BELLO study presented at EuroPCR 2015, the use of DCBs can be considered a safe and efficacious treatment of *de novo* CAD in small vessels.

LOOKS COMPLEX? KEEP IT SIMPLE: A ONE-STENT STRATEGY IN CORONARY BIFURCATIONS

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In the specific scenario of percutaneous coronary intervention (PCI) for coronary artery bifurcations, it should be clear that the use of one stent is better than any other endovascular option. Therefore, the default approach to a bifurcation lesion should be one of maximising efforts to manage the lesion with a single stent implanted into the branch considered to be the most vital according to several obvious considerations. In expert hands, this approach is possible in more than 90% of cases, even when approaching angiographically challenging lesions.

Implanting two stents instead of one is required when the final result of the one-stent strategy causes a situation that is likely to evolve into significant myocardial damage. This is the case in a patient suffering chest pain at the end of the procedure because of low flow, and with ischaemic electrocardiogram changes due to a residual obstacle to the normal flow within one of the branches of the bifurcation. Deliberately implanting two stents precludes the option of trying with a single one, but the T-stenting technique and the reverse mini-crush are possible approaches that allow trying a provisional first, and which provide the option of implanting a second stent only in cases of real need.

Conversely, most interventionalists have a 'hair trigger' with regard to the implantation of multiple stents. This is often perceived as an indicator of skills and experience, is obviously more rewarding from an aesthetic point of view, and generally

supports the feeling of having done a better job. However, these are only emotion-based perceptions that contradict what evidence-based medicine has demonstrated many times in a totally replicable manner in every available experience, i.e. that the implantation of two stents is burdened by more thrombosis and restenosis, and that, in the case of the left main bifurcation, this translates into a significantly higher mortality. On this specific point, one should always consider that the most important bifurcation is the left main, and therefore operators should apply the best of their experience and understanding in order to be able to do a safe and effective left main PCI using one stent only. To achieve such a level of proficiency, which is largely based on the capability of 'predicting' the final result, operators should develop their own experience in secondary bifurcations before progressing to the unprotected left main. In fact, one should bear in mind that, in an elective patient at low surgical risk, a mammary artery graft may be much better than two stents in the left main, and this should be considered and discussed with the patient before planning an elective (multiple stent), unprotected left main intervention.

When discussing this topic at the congress, some important messages that the experts stressed were:

- Plan the strategy (aiming for a single stent) before starting
- Use intravascular ultrasound (IVUS) if angiography is not absolutely clear in showing the anatomy of the lesion(s)
- Prepare the lesion adequately in order to be able to place the stent(s) properly
- Also use IVUS after the procedure in order to verify good stent expansion and the absence of residual stenosis, malapposed struts, or any other angiographically 'invisible' source of possible complications
- Perform a suitable proximal optimisation treatment and a final kissing
- Maintain the patient on long-term dual antiplatelet therapy for at least 12 months

Bioresorbable scaffolds and drug-eluting balloons may, theoretically, add to the long-term efficacy of treating bifurcation lesions by avoiding permanent obstacles to the circulation at the bifurcation level, but so far this remains wishful thinking; further research is needed in this specific field, but, until new data are available, single stenting of the main branch should be the way to treat bifurcations displaying important prognostic characteristics such as, first and foremost, the unprotected left main trunk.

DELAYED CORONARY OBSTRUCTION AFTER AORTIC VALVE-IN-VALVE

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Treatment of failed surgical valves with transcatheter aortic valve implantation, valve-in-valve (ViV), is a less invasive approach for patients with failed tissue surgical valves. These patients are commonly old and have numerous comorbidities, and therefore a less invasive approach is appealing in this clinical scenario.

One of the limitations of ViV procedures is an elevated risk for coronary obstruction (CO). This complication was described in approximately 2% of patients in the global ViV registry (VIVID), and is commonly related to the type of surgical valve that is failing and its mechanism of failure. CO is a serious procedural complication and is associated with a high mortality rate. Importantly, over recent years a number of pre-procedural and technical aspects have been described to possibly identify those patients at increased risk, prior to performing aortic ViV procedures. In order to improve clinical outcomes in such high-risk patients a modified ViV procedure, redo surgical valve replacement, or medical treatment only may be considered. A disturbing phenomenon is delayed CO. In these rare cases the flow towards the heart muscle is normal (or near normal) at the end of a ViV procedure. Nevertheless, an obstruction to flow occurs later on.

In the case presented during EuroPCR 2015, an 80-year-old high-risk male was treated with a

ViV procedure. The patient had congestive heart failure secondary to severe regurgitation and moderate stenosis of a surgical valve (Perimount #25, Edwards Lifesciences) implanted in 2001. Screening for the ViV procedure by angiography and computed tomography scan revealed that the patient was at risk for CO of both the left and right coronary arteries. The ViV procedure used a 26 mm SAPIEN XT device and indeed resulted in obstruction of the left coronary vasculature, which was treated well by coronary stenting. The flow towards the right coronary artery was preserved. The patient came to evaluation again 1 year after the ViV procedure complaining of chest discomfort. Coronary angiography revealed an occlusion of the right coronary artery by the valve implanted a year before and severe narrowing of the stent implanted in the proximal left coronary system. The patient was referred for surgical removal of the implanted valve that resulted in this complication and re-implantation of a surgical biological valve.

This case reveals an important limitation of ViV procedures, which is delayed CO. We have noticed that ostial stenting during the ViV procedure may not prevent late occlusion. In addition, delayed obstruction of an unstented vessel can occur as well. It seems that patients at risk of coronary occlusion by ViV procedures would be better treated by redo surgical procedure and not by a ViV procedure.

TAVI IN INTERMEDIATE-RISK PATIENTS — WHAT SHOULD WE BE DOING NOW?

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Transcatheter aortic valve implantation (TAVI) has gained widespread acceptance in the treatment of elderly and high-risk patients with aortic stenosis (AS) by means of a minimally invasive approach. Transfemoral, transapical, or transaortic access routes are most commonly utilised in the placement of a prosthetic valve, self or balloon-expandable, at the patient's native calcified aortic leaflets and annulus. Overall outcomes of TAVI procedures have improved over the past years. Despite optimism based on perfect outcomes in selected clinical trials and improvements in overall results, all-comers registry data still show substantial complications in up to 5% of patients.[1] Thus, based on current evidence, there is a clear indication for TAVI therapy in elderly and higher-risk patients.

As we enter the second decade of TAVI technology, we will see further improvements in valves and delivery systems, including smaller profiles, safer and more precise positioning and implantation, improved solutions against paravalvular leakage, and some retrievability options, amongst others. These developments, together with the overall improvement of current TAVI outcomes, will lead to further expansion of clinical use.

Decisions regarding when to perform TAVI are taken, and should be taken, by the interdisciplinary heart team: decisions are based on patient-specific factors and comorbidities; direct patient assessment by the heart team; specific imaging such as computed tomography (CT) to evaluate annular diameter, cusp calcification, and access routes, amongst others; and an overall patient evaluation based on scores. Despite the fact that there is no perfect scoring system to evaluate the risk before TAVI, the Society of Thoracic Surgeons (STS) score may have the best predictability at present and is being used frequently. In addition, the logistic Euroscore I is an easy tool, which overestimates the immediate risk, but may instead be a suitable parameter for 1-year outcomes. At present, German clinical practice reveals mean STS scores of around 5% in patients receiving TAVI on an all-comers basis.[1] Thus, on average, intermediate-risk patients are being treated by means of TAVI already, when evaluating this on the score values only.

Intermediate risk can be classified as an STS score between 4-8%, which is substantiated by the current analysis of Thourani et al.[2] on 141,905 patients from the STS database who received aortic valve surgery. In addition to this,

the judgement of the heart team is warranted. In order to further broaden the evidence for using TAVI in intermediate-risk patients, randomised clinical trials for this patient group comparing TAVI against conventional surgical therapy are warranted. In fact, the PARTNER 2 and SURTAVI trials involving intermediate-risk patients are under way. Patient inclusion, however, is quite selective in these series and thus may not reflect routine clinical practice. To close this gap, an investigator-initiated clinical trial (DEDICATE) is underway in Germany, planning for an all-comers patient inclusion and heart team decision based on an STS score between 3-6%. We must await the outcomes of these trials before drawing further conclusions on future standards for intermediate and lower-risk patients.

In addition to this, trials in younger and lower-risk patients need to adjust their primary endpoints. For the elderly and high-risk populations, a primary endpoint of 1-year survival has usually been defined in the past decade of TAVI treatment. In intermediate-risk patients, short-term survival will not be so much of an issue and other patient-related factors may become more important. Therefore, a primary 5-year endpoint should be chosen for younger and intermediate-risk patients.

In current clinical practice we see improved outcomes for TAVI, as well as for conventional surgery, based on technically well-developed valves and respective low-profile application systems, together with increasing examiner experiences. In addition, specific imaging and thus analysis of the patients is performed, usually by CT, which contributes a great deal to the improved outcomes of TAVI. For younger patients, however, we must define individual success factors for the respective procedures: younger patients quite frequently experience heavy and excentric calcifications, bicuspid aortic valves, or other concomitant pathologies, which then require minimally invasive but conventional surgical approaches. Thus, further specific evaluations and individual patient analysis by the heart teams is warranted to obtain perfect outcomes in the treatment of AS.

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EVALUATION OF THE MITRALIGN® PERCUTANEOUS ANNULOPLASTY SYSTEM FOR THE TREATMENT OF FUNCTIONAL MITRAL REGURGITATION: 6-MONTH RESULTS

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Background

An estimated 4 million people in Europe and 4 million people in the United States have significant mitral valve (MV) insufficiency, also known as mitral regurgitation (MR), with an annual incidence of 250,000.[1] Approximately 50,000 of these patients undergo surgery each year.[2] If left untreated, MR is associated with chronic volume overload, which leads to heart muscle dysfunction, development of congestive heart failure (CHF), and thus increased morbidity and mortality. The presence of MR has been proven to increase the risk of mortality in patients with CHF, which is a disease affecting more than 25 million people worldwide. As MR worsens so does CHF and, hence, the risk of mortality. Compared with CHF patients with no MR, mild MR increases the risk of mortality at 5 years by 18% and moderate-to-severe MR increases this risk by 53%.[3] Treatment for MR is performed in order to improve a patient's prognosis.

Figure 1: Pledget implant pair.

Table 1: Patient characteristics in the Mitralign® Percutaneous Annuloplasty System study.

Characteristic (n=51)	
Age (mean ± SD)	68.5±11.2
Male	72.5
Idiopathic cardiomyopathy	45.1
NYHA III/IV	49.1
Atrial fibrillation/flutter	31.4
Diabetes	25.6
Previous myocardial infarction	43.1
Chronic renal disease	25.5
Prior CABG	19.6
Hypertension	78.4
Ejection fraction (mean ± SD)	32.7±8.5
Cardiac Medication	
ACE Inhibitor/Angiotensin II Blocker	94.1
Beta Blocker	96.1
Diuretics	98.0

Values are percentages unless otherwise indicated. NYHA: New York Heart Association functional classification; CABG: coronary artery bypass graft; ACE: angiotensin-converting enzyme.

MV repair is considered superior to MV replacement because of lower operative mortality, improved late survival, a reduced risk of endocarditis, and fewer thromboembolic complications.[1,4-8] There is also a growing body of evidence that supports early MV repair instead of valve replacement for significant functional MR (FMR). Early benefits of repair include shorter hospital stays, reduced need for anticoagulant therapy, and lower in-hospital mortality and complication rates.

Materials and Methods

It has been proposed that two goals of treatment in patients with FMR should be to slow or reverse left ventricular (LV) remodelling, and to improve the patient's symptoms or functional class.[9] The Mitralign® Percutaneous Annuloplasty System (MPAS) for treating FMR is a novel device for percutaneous MV repair. The mechanism of treatment for the MPAS is to deliver pledgets to the posterior mitral annulus and subsequently plicate the annulus in order to reduce annular circumference (Figure 1). The MPAS study is a prospective, single-arm, multi-centre, first-in-human study using the MPAS and enrolled FMR patients, including those considered high-risk for surgery; patient characteristics are presented in Table 1.

The primary safety endpoint of the study was all major adverse events (MAEs) within 30 days post index procedure. An MAE was defined as the occurrence of any of the following: MV-related cardiac surgery/intervention, myocardial infarction, cardiac tamponade, stroke, or device/procedure-related death. The primary performance endpoint of the study was defined as freedom from MV-related cardiac surgery/intervention, freedom from device and/or procedure-related death within 6 months, and freedom from an increase in ventricular diameter at 6 months.

Results

At 30 days, freedom from all-cause mortality and freedom from all MAEs was 92.2% and 80.4%, respectively. At 6 months, freedom from all-cause mortality, freedom from valve surgery/intervention, and freedom from increase in ventricular diameter was 88%, 80%, and 97%, respectively. At 6 months, the annular dimensions of the MVs were significantly reduced in the A-P and S-L directions by −0.35±0.4 cm ($p<0.01$) and −0.32±0.3 cm ($p<0.01$), respectively. There were also significant reductions in the LV end-diastolic diameter and end-diastolic volumes: −0.31±0.5 cm ($p<0.01$) and −26.8±38 ml ($p<0.01$), respectively. Improvement in patient symptoms, as measured by the 6-minute walk test (6MWT), showed a significant improvement from baseline to 6 months in all patients (~48.0 m; $p=0.03$).

Discussion and Conclusion

In FMR patients in whom the MPAS device was used, the MPAS device significantly reduced annular dimensions in both the A-P and S-L directions and also significantly decreased LV diameter and volume at 6 months. Moreover, there was a significant improvement in the functional symptoms of the patients at 6 months as demonstrated by the results from the 6MWT. According to the goals of FMR treatments described above, the MPAS device has been shown to positively affect the slowing or reversing of LV remodelling, in this case significantly reversing the remodelling, as well as improving the patient's symptoms. This study with the Mitralign system has shown that percutaneous tissue plication is a well-tolerated and effective treatment modality for patients with FMR.

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