DAILY NEWSPAPER

APRIL 23~26, 2013, SEOUL, KOREA
THE CONVENTION CENTER, COEX
18th

April 25

TCTAP 2013

Today's Highlights

Breakfast Meetings
(Antithrombotic Therapies, LM, Carotid Innovation, Multivessel, OCT, BTK, Renal Denervation, DES and Diabetes)
7:00 AM – 8:10 AM

Late Breaking Clinical Trials (5 topics)
Main Arena, 9:30 AM – 10:25 AM

TCTAP Best Young Scientist Award
Main Arena, 10:25 AM

Left Main & Bifurcation Summit
Coronary Arena, 8:30 AM – 11:30 AM

ACS Digest 2013 – The Challenges and the Future
Coronary Arena, 2:00 PM – 4:00 PM

TAVI Workshop
Coronary Arena, 4:00 PM – 6:00 PM

Endovascular Session III: AAA to Carotid Artery Stenosis
Grand Ballroom 104, Level 1,
8:30 AM – 12:30 PM

Structured Heart Disease Symposium
Grand Ballroom 104, Level 1,
2:00 PM – 6:30 PM

Moderated Oral Abstract Competition
Abstract Zone I, Level 3

Moderated Complex Case Competition
Case Zone I, Level 3

Late Breaking Clinical Trials

April 25, 9:30 AM – 10:25 AM, Main Arena, Level 3

Highlights from the "Late Breaking Clinical Trials" meeting will be held 9:30 AM – 10:25 AM at the Main Arena, Level 3. Brand new data from this year will be presented for the first time. These sessions provide notable exposure and recognition for studies likely to significantly affect clinical practice. Evaluation of the presentation in the Late Breaking Clinical Trial sessions will be based on the impact and novelty of the research. Late Breaking Clinical Trials at TCTAP 2013 covers information on the latest scientific breakthroughs on five featured topics including drug-eluting stents, acute coronary syndrome, diabetes mellitus, transcatheter aortic valve implantation, and functional angioplasty.

- **Comparison of Platinum Chromium Versus Cobalt Chromium Everolimus-eluting Stent in Real World Practice:** Outcomes from the Multicenter Prospective IRIS-DES Registry by Jung-Min Ahn, MD (Asan Medical Center, Seoul, Korea)

- **Are Elderly Patients with Acute Coronary Syndromes Undertreated?** Data from Euro Heart Survey on ACS III Registry by Wojciech Wojakowski, MD (Medical University of SIlesia, Poland)

- **Randomized Comparison of Zotarolimus-eluting Stent Versus Sirolimus-eluting Stent Implantation for De Novo Coronary Artery Disease in Patients with Diabetes Mellitus (ESSENCE-DIABETES II):** Results from the ESSENCE-DIABETES II Trial by Gyung-Min Park, MD (Asan Medical Center, Seoul, Korea)

- **Transfemoral Aortic Valve Implantation in Patients with an Annulus of Intermediate-sized Who Are Treatable with Either the Edwards Valve or the CoreValve** by Yusuke Watanabe, MD (Institut Hospitalier Jacques Cartier, France)

- **Trend in Outcomes of Percutaneous Coronary Intervention with the Integrated Use of Fractional Flow Reserve and Intravascular Ultrasound** by Seung-Jung Park, MD (Asan Medical Center, Seoul, Korea)

Integrated Approach Using IVUS and FFR for LM and Non-LM Bifurcation Stenosis

Left Main and Bifurcation Summit

April 25, 8:30 AM - 11:30 AM, Coronary Arena

Dr. David Paul Taggart (University of Oxford, United Kingdom) will highlight the principle of treatment for complex left main (LM) disease for appropriate revascularization using PCI or CABG. The creation of Heart Team serves the purpose of a balanced multidisciplinary decision process. Informing patients about treatment choices also allows reflecting of the advantages and disadvantages associated with either therapy. According to the review by Dr. Kanzari for patients with LM disease, PCI is now an attractive alternative to CABG for patients with low SYNTAX score, which is utilized to show angiographic complexity of patients and predict outcomes of PCI. When the score was ≥33 in patients with LM disease, the incidence of major adverse cardiac or cerebrovascular events (MACCE) was significantly higher after PCI using drug-eluting stent (DES) than CABG. At 5 years after enrollment, the MACCE rates were 30.4% vs. 31.5% in the low (≤22) SYNTAX score group (p= 0.74), 32.7% vs. 32.3% in the intermediate (23-32) score group (p=0.88), and 46.5% vs. 29.7% in the high (≥33) score group (p=0.003) between PCI and CABG patients. Therefore, current guidelines from ACCF/AHA/SCAI and ESC/EACTS state that PCI for

Inside

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from page 1

LM stenosis is a class IIa or IIb indication for those patients with LM lesions with non-extensive coronary disease (SYNTAX score ≤32) at a low stenting risk or those at a high surgical risk. The PRECOMBAT trial randomized 600 patients with LM patients to either CABG or PCI with DES in a non-inferiority study design in Korea. In this trial, PCI was not inferior to CABG in 1-year MACCE rate (absolute difference, 2%; upper margin of 95% CI, 5.6%; hazard ratio, 1.56; p for noninferiority=0.011). At 2 years, the MACCE rate (12.2% vs. 8.1%; hazard ratio, 1.50; 95% CI, 0.90-2.52; log-rank p=0.12) and the composite rate of death, myocardial infarction, or stroke (4.4% vs. 4.7%; hazard ratio, 0.92; 95% CI, 0.43-1.96; log-rank p=0.83) remained comparable between the PCI and CABG groups.

For optimal procedure of PCI, Dr. Park (ASAN Medical Center, Seoul, Korea) will propose the integrated approach using IVUS and FFR for LM and non-LM disease. FFR is a well-known pressure derived index to identify the ischemia-producing stenoses, calculated by the mean distal coronary pressure divided by the mean aortic pressure. For LM disease, although identification of LM stenosis is not clearly demonstrated using angiography alone, an angiographic stenosis diameter of 50% is still considered a cut-off value for significant LMCA stenosis. In spite of potential limitations of FFR in determining significant LM stenosis, Dr. Park will suggest the practical benefit of FFR in the intermediate LM stenosis. Because recent IVUS analysis demonstrated the diffuse nature of atherosclerosis involving both the parent LM segment and both flow dividers of left anterior descending artery (LAD) and left circumflex artery (LCX), distal LM bifurcation could not be treated separately and is considered as a "single disease unit" if FFR values in the distal segment are lower than 0.8 (Figure 1). IVUS has also played a key role in contemporary stent-based PCI in accurately assessing coronary anatomy, assisting in the selection of treatment strategy, and in defining optimal stenting outcomes. In DES era, IVUS-guided PCI is associated with a lower rate of adverse clinical outcomes in left main or bifurcation stenoses. In MAIN-COMPARE registry, the risk of 3-year mortality was about 60% lower when IVUS rather than angiography guidance was employed in a propensity matched population. Using the IVUS database from the Asan Medical Center, Dr. Park will recommend the optimal IVUS area after stenting to prevent in-stent restenosis was 5.0 mm^2 for the LCX ostium, 6.3 mm^2 for the LAD ostium, 7.2 mm^2 for the polygon of confluence, and 8.2 mm^2 for the proximal LM above the polygon of confluence (Figure 2). Dr. Morice and Dr. Colombo will demonstrate how to do optimal PCI for complex LM diseases. The debates on the optimal revascularization strategy between PCI and CABG will be further clarified in the ongoing EXCEL trial to be demonstrated by Dr. Kandzari.

For non-LM bifurcation stenosis, anatomical evaluation using IVUS and functional evaluation using FFR will also be highlighted by Dr. Nam (Keimyung University Dongsan Medical Center, Korea) and Dr. Kang (ASAN Medical Center, Seoul, Korea). The IVUS-guided PCI, compared with angiography-guided PCI, may allow optimal stent deployment, including a larger acute lumen gain, adequate stent apposition, and full lesion coverage. Earlier identification by IVUS of procedure-related complications, such as stent edge dissection, and subsequent treatment thereof, may be another contributing factor. Regarding the appropriate bifurcation stenting technique for complex bifurcation lesions, Dr. Lefèvre and Dr. Chieffo (San Raffaele Hospital, Italy) will summarize various techniques according to the bifurcation lesion morphology. When the side branch is not severely diseased, simple stenting technique is mostly preferred in practice. However, when the operator decides to use two-stent technique, any bifurcation technique, such as T-stenting, Culotte technique, Crush technique, or modified Crush technique can be used by the operator's preference. The most important factor, which is a modifiable prognostic, is how to perform optimal stenting successfully. For instance, Dr. Hikichi will demonstrate the strengths and weaknesses of different stenting techniques based on the Bench test. Dr. Erglis (Pauls Stradins Clinical University Hospital, Latvia) and Dr. Kim (ASAN Medical Center, Seoul, Korea) will present comparable results of various stenting techniques and determinants of good long-term prognosis.

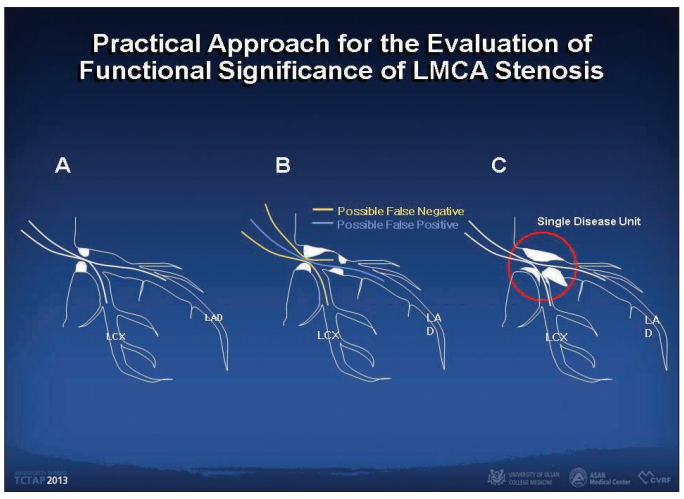

Figure 1.

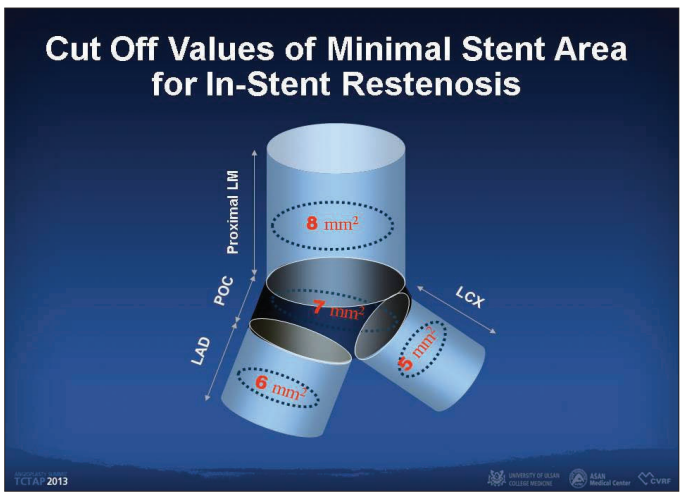

Figure 2.

Nearby Attractions

Pulmuone Kimchi Museum

Location: B2 of COEX Mall at Samseong-dong (Directions: Samseong Station Exit 6 (Line 2) connects to the COEX Mall. Walk through the mall towards the aquarium and movie theater and take the escalator next to the ASEM Pharmacy to B2 level)
Hours: 10:00 – 18:00 (Last time to enter at 17:30) Closed Mondays and holidays
Admission: Adults ₩3,000, Young adults (ages 8-19) ₩2,000, Children under 7 ₩1,000

The Pulmuone Kimchi Museum was opened in 1986. It is dedicated to the culture, history, and making of the traditional Korean food: kimchi. Visitors can take a 20-30 minute tour through the museum and learn everything about kimchi through paintings, books, writings, and ancient traditional utensils that were used to prepare the dish. Regional variations can also be learned. There are tasting rooms and a shop to buy quality kimchi. Come learn why kimchi is one of Korea's most treasured foods.

COEX Aquarium

Location: Inside COEX Mall at Samseong-dong (Directions: Samseong Station Exit 6 (Line 2) connects to the COEX Mall)
Hours: 10:00 – 20:00
Admission: Adult ₩17,500, Youth ₩14,500, Children ₩11,000

The COEX Aquarium houses more than 600 different species. Visitors will get a chance to meet underwater creatures from around the globe. The Ocean Kingdom exhibit hall features a 2,000 ton tank filled with sharks, turtles, and a wide variety of fish. There is even an exhibit dedicated to seals. This is a place that can be enjoyed by all members of the family.

The 1st TCTAP Best Young Scientist Award

April 25, 10:25 am, Main Arena

The First Winner of
TCTAP Best Young Scientist Award will be finally revealed.
Please join the Award Ceremony to see the rising leader
of interventional cardiology field!

Challenge to be the next leader!

To support academic activities for young physician leaders, this award bestows every year on one winner from the Best Abstract and Case presenters of TCTAP. The winner will be invited to attend TCTAP as a faculty member and will be given a scholarship of total amount of 5,000 USD with the award ceremony in the main arena.

Current Status of Transcatheter Aortic Valve Implantation

April 24, 10:15 AM – 10:45 AM, Main Arena, Auditorium, Level 1

Edward Sapien Valve

CoreValve

In the 18th CardioVascular Summit TCTAP 2013, the program about the controversies and highlights about transcatheter aortic valve implantation (TAVI) in severe aortic stenosis was discussed in hot topics. On Wednesday morning at 10:15 AM in the Main Arena, Dr. Alain G. Cribier (Hospital Charles Nicolle, France) presented "TAVI Is Preferred in All High-risk AS Patients" and Dr. Alan C. Yeung refuted with "Surgical aortic valve replacement (sAVR) remains the Procedure-of-Choice for Most AS Patients."

At the Breakfast Meeting on Wednesday at 7:00 AM - 8:10 AM there was a "Transcatheter Aortic Valve Implantation" session covering comparison between Edwards Sapien and Medtronic CoreValve to the prevention and management of complications: periprocedural aortic regurgitation and AV block.

SAVR has long been the mainstay of therapy for severe aortic stenosis. However, TAVI is now generally accepted as the new standard of care for patients with symptomatic aortic stenosis who are not candidates for open surgery. Arguably, TAVI may also be a preferred alternative to SAVR in carefully selected high-risk, but still operable patients in whom morbidity and mortality may be reduced. Although TAVI outcomes continue to improve, concerns remain with respect to vascular injury, stroke, paravalvular regurgitation, and valve durability. However, it seems likely that with ongoing refinement of transcatheter valve systems, techniques, and patient selection, TAVI is becoming an increasingly appealing option for a much broader range of patients. Randomized trials and ongoing surveillance will play an important role as we enter a new era of rigorous clinical evaluation for minimally invasive therapies for structural heart disease.

CoreValve is Enough! vs. Edward Sapien is Better!

The CoreValve ReValving System (Medtronic Inc., Minneapolis, Minnesota) utilizes a self-expanding nitinol (a nickel-titanium alloy that is malleable at low temperature, but relatively rigid at body temperature) frame. The leaflets and annular seal are constructed of porcine pericardium. This transcatheter heart valve (THV) is compressed within its Accutrak delivery catheter (Medtronic) and introduced through an 18-F sheath into the common femoral or subclavian artery.

The current state-of-the-art Edwards Sapien XT THV (Edwards Lifesciences Inc., Irvine, California) utilizes a balloon expandable cobalt chromium alloy tubular frame within which there are sewn leaflets constructed from bovine pericardium. The inflow of the frame is covered with fabric to provide an annular seal.

These 2 valve systems share more similarities than differences. Both devices utilize similar low-profile delivery systems, are compatible with fully percutaneous access, and can be implanted in a conventional cardiac catheterization laboratory with fluoroscopic guidance alone under local anesthesia.

Only limited nonrandomized comparisons are available. Deployment of the CoreValve device may be more intuitive and does not require rapid pacing, while deployment of the Sapien device may be more targeted. The CoreValve device can, up to a point, be repositioned or removed. However, this process may not be benign. Coronary obstruction may rarely occur with both THVs, but may be more frequent with the Sapien type valves. Atrioventricular block requiring pacemaker implantation is more common with CoreValve. Currently, the Sapien THV is supported by the randomized PARTNER studies. However there is extensive experience with the CoreValve device and similar rigorous evaluation is underway. Regardless of current differences, both THV systems continue to evolve and iterative improvements can be anticipated.

Dr. Eberhard Grube (HELIOS Heart Center, Sieaburg, Germany) introduced "Superiority of Medtronic CoreValve" in the breakfast meeting on Wednesday and also Dr. John Webb gave us valuable comments about the "Supremacy of Edwards Sapien."

Conduction Disturbance: Can We Prevent AV Block After CoreValve Implantation?

The atrioventricular conduction system passes superficially through the interventricular septum immediately below the aortic valve. Injury during valve implantation may result in partial or complete heart block.

Risk factors include advanced age, right bundle branch block, atrioventricular delay, prosthesis oversizing, and ventricular positioning. In the PARTNER randomized studies, new pacemakers were no more frequent 1 year following SAPIEN valve implantation than with medical management (4.5% vs. 7.8%, p=0.27) or with SAVR (5.7% vs. 5.0%, p=0.68). However, CoreValve implantation is more frequently associated in early and late atrioventricular block, presumably due to greater extension into the left ventricular outflow tract with compression of the septal conduction tissues. The requirement for new pacemakers was 3-fold higher following CoreValve, as compared with Sapien implantation in both the United Kingdom and French national registries. For this reason, routine prophylactic temporary pacing leads are routinely used with more prolonged electrocardiographic monitoring.

Dr. Won-Jang Kim (Asan Medical Center, Seoul, Korea) presented the concept of perivalvular index as a predictor of AV block after CoreValve implantation.

Periprocedural Aortic Regurgitation: How to Prevent and Manage?

Significant transvalvular regurgitation is rare after TAVI. However, paravalvular regurgitation due to incomplete annular sealing is common. Paravalvular leaks may occur due to prosthesis undersizing or incomplete expansion or due to implantation of a prosthesis too high or too low such that the sealing cuff is not apposed to annular tissue. Core lab echocardiographic evaluation in the PARTNER trials documented greater than or equal to moderate paravalvular aortic regurgitation after TAVI in 11.8% of the inoperable patients and 12.2% of operable patients. However, net aortic regurgitation (both valvular and paravalvular combined) was actually reduced after TAVI. Severe paravalvular regurgitation may result in severe hemodynamic consequences, although improved implantation techniques and more accurate annulus sizing have made such severe leaks increasingly less common. Most leaks are, in fact, mild to moderate, well tolerated, not associated with hemolysis, and do not worsen with time. Nevertheless, it is clear that moderate and even mild leaks are associated with a less favorable late survival than no leak. Whether this association represents cause and effect is unknown. When paravalvular regurgitation is excessive redilation, repositioning or implantation of a second overlapping transcatheter valve can often reduce or correct the problem. However, these interventions may be associated with a poorly understood increased risk of embolic stroke and should not be taken too lightly.

PARTNER Analyses Provide Valuable Insights into TAVI

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Recently, some experts provided an in-depth look at the data from the PARTNER trial on gender differences and quality of life. In PARTNER, there appears to be differences in the clinical outcomes of TAVI in women compared with men, consistent with prior observational studies. Some of this may be correlated with baseline differences. Among inoperable patients in PARTNER cohort B, there were similar mortality benefits of TAVI over standard therapy in both women (30.9% vs. 48.4%) and men (30.5% vs. 51.2%; p=0.8 for intractical significance (28.2% vs. 37.3%; p=0.07). Independent predictors of outcomes may actually differ based upon whether a woman or man is treated with TAVI.

For inoperable patients, TAVI provided substantial and sustained QOL improvements across a broad range of disease specific and generic domains. The QOL benefit in these patients is comparable to an approximate 10-year reduction in age. The question remains, however, on how to prospectively identify patients who will not benefit from TAVI. For high-risk surgical candidates, the impact of TAVI on QOL differed according to access site. The transfemoral approach was associated with substantial early QOL benefits compared with AVR, with similar results at later time points in the PARTNER trial. The transapical approach was associated with no benefit of TAVI over AVR at any time point.

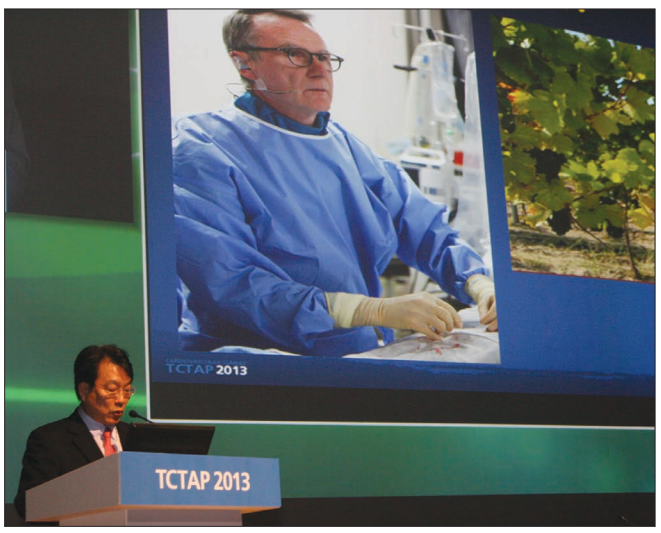
Future Directions and Expanding Candidacy for TAVI

Although the growth rate of TAVI appears to have slowed based on registry data from 2012, there is potential for expanding its application to low-risk elderly patients. According to the 2012 European joint guideline, TAVI is recommended only "in hospitals with cardiac surgery on site and with a heart team available to assess individual patient risk." Dr. Alain Cribier said that prior to expanding the TAVI indications, several components need to be addressed including: improved valves and delivery systems, randomized controlled trials in specific patient subsets, and further investigation of valve and platform durability. In addition, Dr. Cribier stated that cost-effectiveness remains an important issue in expanding the indication for TAVI. Within a few years, with FDA approval, TAVI might result in an explosion, both in the United States and worldwide in non-operable and high-risk patients.

In the next decade, expansion of indications to other subsets of patients, such as elderly intermediate or low-risk patients, can be anticipated.

Dr. Antonio Colombo for The 3rd TCTAP Master of the Masters Award

April 24, 12:15 PM – 12:30 PM, Main Arena, Auditorium, Level 3



Dr. Antonio Colombo, Director of the Cardiac Catheterization Laboratory at Columbus Hospital and San Raffaele Hospital, both in Milan, Italy was recognized as the 3rd recipient of TCTAP Award, 'Master of the Masters.' The Award ceremony was held on Wednesday, April 24 at the Main Arena in Coex Convention & Exhibition Center.

CardioVascular Summit TCTAP initiated 'Master of the Masters' Award in 2011 to recognize and acknowledge meaningful contribution in the field of cardiology medicine. Dr. Masakiyo Nobuyoshi, Director of Kokura Memorial Hospital was honored as the 1st recipient in 2011, and Dr. Martin B. Leon, Director of the Center for Interventional Vascular Therapy at New York Presbyterian Hospital/Columbia University Medical Center was recognized as the 2nd recipient of this award in 2012. This year, the organizing committee of CardioVascular Summit TCTAP agreed unanimously to present this award to Dr. Antonio Colombo for his excellent expertise in the field of interventional cardiology and for significant and continued contribution to this meeting as the course co-director.

Dr. Antonio Colombo is well known for many great innovations in interventional cardiology. He is a leading exponent in the use of drug-eluting stents, as well as one of the first leaders to use intravascular ultrasound (IVUS) for stent deployment in 1994 and to understand the importance of good stent expansion to avoid stent thrombosis. His revolutionary and creative ideas have always been a unique gift which allowed him to be a world-leading interventional cardiologist. "He has the unique capacity for being a brilliant technical interventional cardiologist, a very rigorous and thoughtful academician, but also has unusual creative spirit which allows him to challenge convention and come up with new ways to treat patients with complex disease," said Dr. Martin B. Leon in the congratulatory message to him. Dr. Colombo is also acclaimed around the globe for his humanity. Dr. David Holmes pointed out three impressive memories of Dr. Colombo related to his creativity, zestful life, and humanity. "I can remember meeting at a cocktail party where we talked about the fact that we were concerned that new people growing up in the field were concentrating on becoming technicians, rather than well-rounded cardiologists, and people who had very reasoned and careful and thoughtful and humane appro-ach to our patients that we are taking care of," he said.

Dr. Colombo shared his professional knowledge, vast experience, and even passion of life with colleagues from every part of the world including his team and patients in his daily life. His great contributions to this field of cardiovascular medicine will be continued for the best medical treatments to improve patient safety and outcomes.

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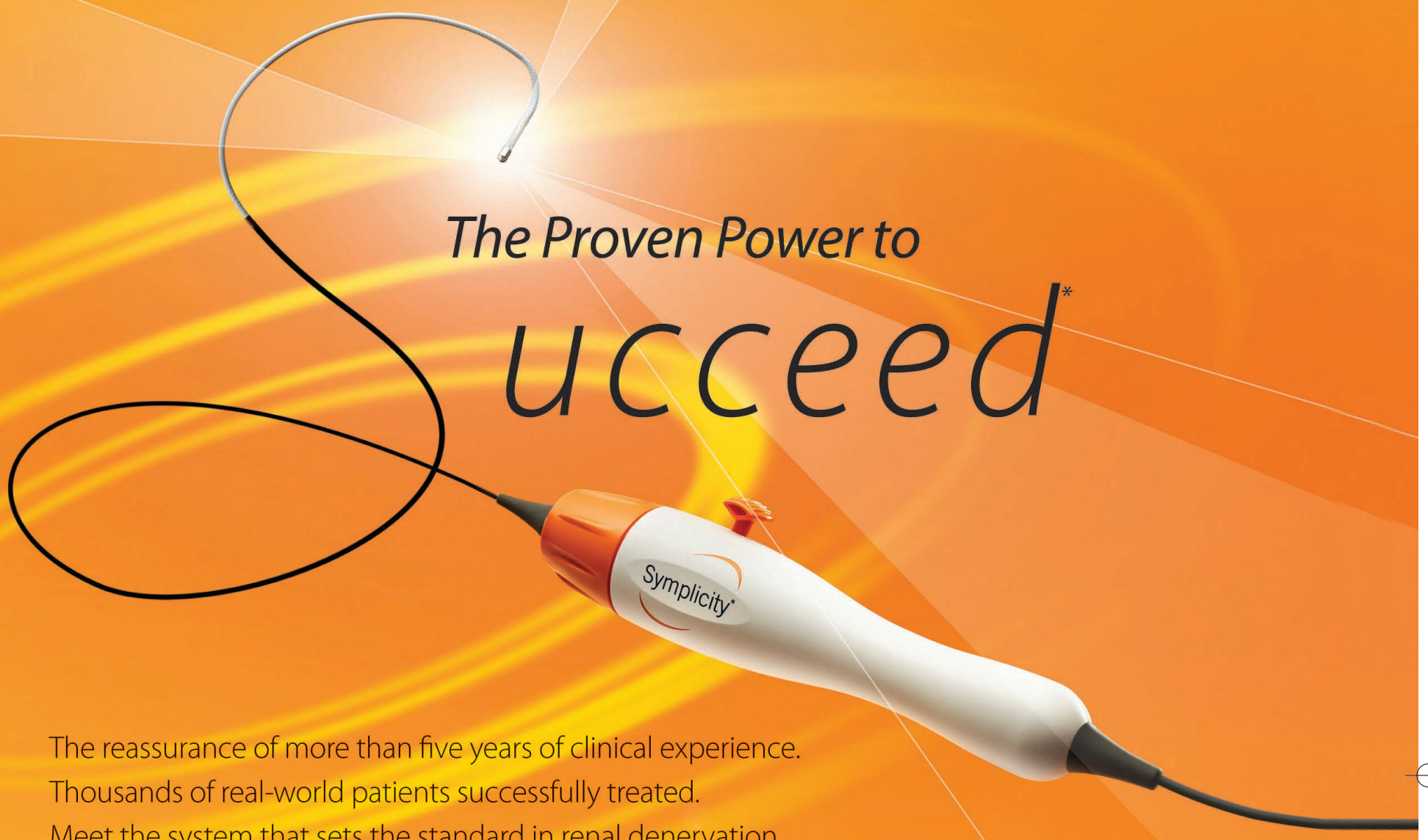

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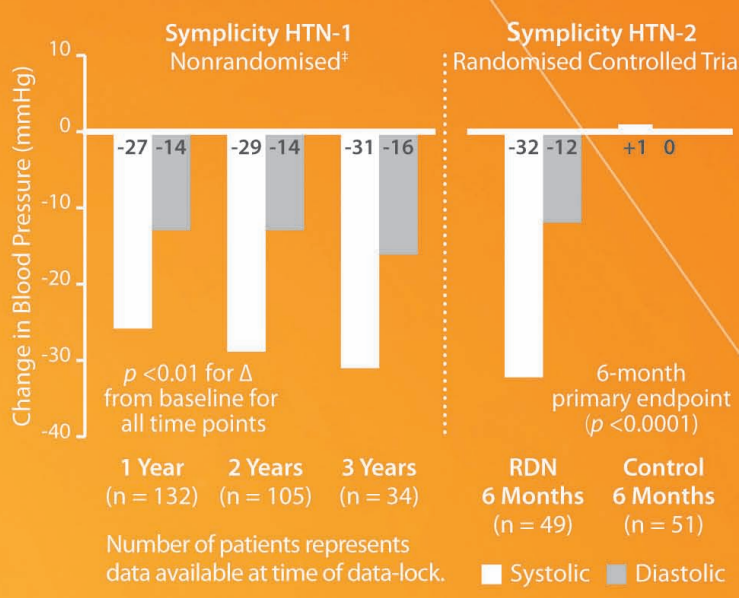

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* Based on published data from a randomised, controlled study and long-term data beyond two years.
† Symplicity HTN-2 Investigators. *The Lancet*. 2010.
‡ Symplicity HTN-1 Investigators. *Hypertension*. 2011. Expanded results presented at the Transcatheter Cardiovascular Therapeutics (TCT) Conference, 2012.

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Reference 1) Drugs. 2010;70(1):41-56 / 2) Br J Pharmacol. 2001;133(8):1330-8 / 3) Circulation 2001;104(5):511-4

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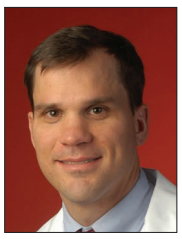
Nebivolol

Welcome All Early Birds to the Breakfast Meeting!

7:00 AM – 8:10 AM, Structural Heart & Endovascular Theater, Coronary Arena, Room 1-1, 1-2, 1-3, Level 1
7:00 AM – 8:10 AM, Room 2-1, Level 2
7:00 AM – 8:10 AM, Room 3-1, Level 3



Early in the morning yesterday, there were many great lectures and discussions from many experts in the "Breakfast Meeting." In this meeting, there were sessions of "STEMI intervention", "Functional Angioplasty", "CTO intervention", In-Stent Restenosis", "Bifurcation Coronary Intervention", "Transcatheter Aortic Valve Implantation", and "Stroke Prevention Therapies: PFO, LAA." Among these sessions, Dr. William F. Fearon (Stanford University Medical Center, USA) lectured with a subject of "FAME2 & CORAGE trials: Going Functional, It's Solution!" in the "Functional Angioplasty" session. The content is as the following: "Percutaneous coronary intervention (PCI) improves survival in patients with acute coronary syndromes (ACS). In contrast, in patients with stable coronary artery disease, PCI as an initial management strategy has not been associated with a relevant benefit over optimal medical treatment (OMT). The potential benefit from PCI depends on identifying and reversing significant myocardial ischemia, while performing PCI on non-ischemic stenoses is not beneficial and likely harmful. Careful selection of ischemia-inducing stenoses, seems therefore essential in optimizing the results of revascularization in patients with stable coronary artery disease. Pressure-derived fractional flow reserve (FFR) is a coronary wire-based index which assesses the potential of an angiographically visible coronary stenosis to induce reversible myocardial ischemia. FFR is more accurate than non-invasive testing or coronary angiography and can be obtained readily in the catheterization laboratory. An FFR ›0.80 is associated with the absence of inducible ischemia, while stenoses with an FFR ≤0.80 are mostly associated with myocardial ischemia. FFR-guided PCI is supported by robust clinical outcome data. The goal of this talk will be to outline how functional angioplasty with FFR-guidance improves outcomes in patients with stable coronary disease, and to describe why the results of FAME 2 differ from those of COURAGE, which compared angiography-guided angioplasty with medical therapy in stable coronary disease patients."

The other lecture was done by Dr. Alain G. Cribier (Hospital Charles Nicolle, France) in the "Transcatheter Aortic Valve Implantation" Session. He lectured about "Valve Technology Is Still Evolving!" The summary of this lecture is following: "The development of transcatheter aortic valve implantation (TAVI) by our group has been a 20-year odyssey. In 1993, post-mortem studies validated the concept of intravalvular stenting in calcific aortic stenosis. The first prototypes of balloon-expandable valves were tested in an animal model in 2000. The first-in-man implantation was performed in Rouen in 2002, rapidly followed by two prospective series in compassionate cases in our centre. TAVI took flight in 2004 in the hands of Edwards Lifesciences, with major improvements in devices and approaches. At the same time, the self-expanding CoreValve was launched. Thousands of high-surgical-risk patients were enrolled in feasibility studies, leading to the Conformité Européenne (CE) mark being granted in 2007 for the two devices. A number of postmarketing registries have shown dramatic improvements in procedural and midterm results and decreased complication rates, with more experience and improved technology. The results of the randomized PARTNER study in the USA recently confirmed the important place of TAVI in non-operable and high-surgical-risk patients. To date, more than 50,000 patients have benefitted from TAVI worldwide (2,300 patients in 33 centres in France in 2011) and the number is consistently increasing. An optimal multidisciplinary collaboration and formally trained experienced physicians are the keys to success. An extension of indications to lower-risk patients might be expected in the coming years but should be cautiously investigated. Ten years after the first-in-man case, TAVI is here to stay and the future is promising."

Also today (April 25, Thursday), early in the morning, the breakfast meeting with more contents will be held from 7:00 AM to 8:10 AM for the cardiac interventionist who wants to be an early bird. In these meetings, several hot topics in the interventional fields will be dealt with. Many experts related to each field are going to take part as moderators and panelists. They will do case presentations, topic presentations and hot discussions with their subjects. The topics are the following: in the room 1-1 (level 1), the "Antithrombotic Therapies" session supported by AstraZeneca Korea will be opened. In this session, there will be discussion about the subjects of "Platelet function test-Buckling the Belief" and "Blood Thinner for ACS-Rethinking the Data." In the room 1-2 (level 1), The "Main Coronary Intervention" session supported Abbott Vascular will be held. In this session, the subject of "Technical tips" and "PCI vs. CABG" are to be discussed. In the Structural heart & Endovascular Theater on same level, there will be discussion about "Carotid Innovation: No Debris!" with support of Medtronic Co. In the Coronary Arena on the same level, there will be "Revascularization in Multivessel Disease" session. The "BTK Intervention: My Best Brilliant Techniques for Saving Foot" session will be held in the room 2-1 (Level 2). In the room 3-1 (Level 3), The "Renal Denervation" session supported by Medtronic Co will open with the subject of "Time to Generalize" and "Early vs. New Device." In the room 3-2 on the same level, "Drug-Eluting Stent" session will be held with support of Boston Scientific. And, in the room 4-1 (Level 4), the "PCI strategy for Diabetes Patients" session will be held with support of Medtronic Japan Co.

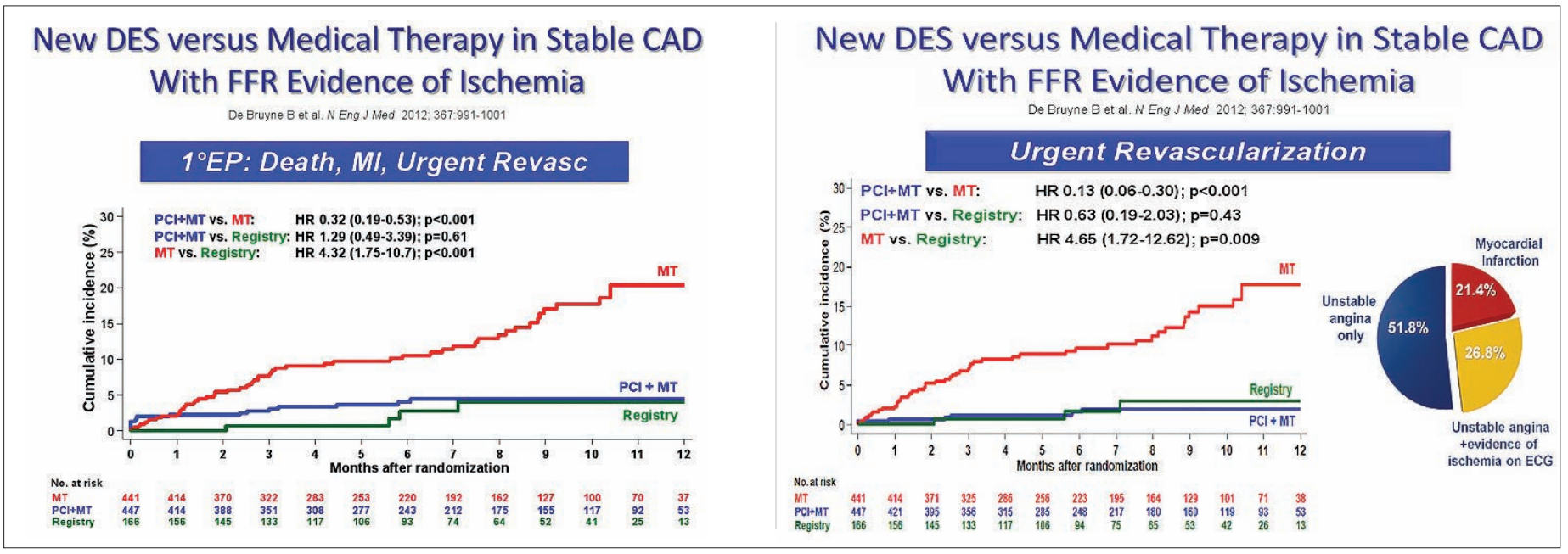


Figure 1. FAME 2 study showed the FFR guided PCI in stable angina reduced the need for urgent revascularization

REFERENCE: 1. IMS Data, MAT January 2012 (value)

Yesterday's Hot lives

Distal LM Bifurcation Lesion Containing Plaque Ruptures

Yesterday, Dr. Seung-Jung Park treated a LM bifurcation lesion. A 61-year-old woman was admitted for staged PCI at LM bifurcation lesion. One month ago, she visited the ER presenting resting chest pain. At that time, her ECG showed ST depression at inferolateral leads and cardiac enzymes were elevated. She was diagnosed as NSTEMI. Her coronary angiogram showed LM bifurcation lesion with severe three vessel disease. Although she was recommended for CABG, she refused open heart surgery. Therefore, we first fixed a proximal RCA lesion with a Resolute Integrity stent (3.5 x 22 mm). Her coronary risk factors were hypertension, diabetes, and hyperlipidemia. The left coronary angiogram showed severe LM bifurcation lesion with plaque ruptures and significant stenosis at distal LCX (Figure 1).

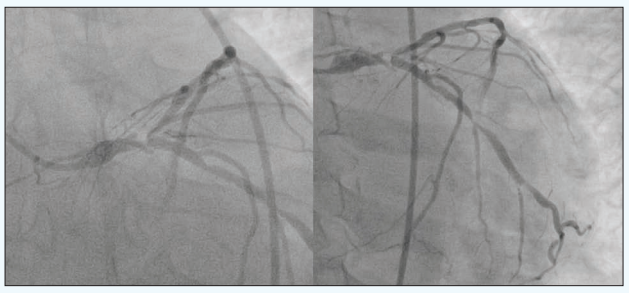


Figure 1. Pre-PCI

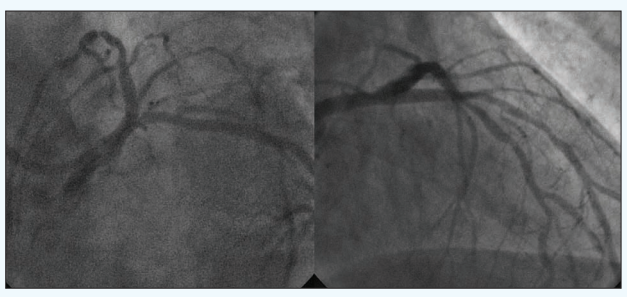


Figure 2. Post-PCI

Eight Fr and five Fr sheaths were inserted into the right and left femoral arteries, respectively. A 0.014 inch Fielder FC wire with a Finecross® 130 cm microcatheter was introduced into the LCX and was exchanged into a 0.014 inch BMW wire. A 0.014 inch Shinobi wire with a Finecross® 130 cm microcatheter was also placed into the LAD. After predilatation with a Maverick 2.0 x 20 mm balloon at LM to LAD, we observed slow flow. Therefore, an IABP in the descending aorta through the left femoral artery and started with 2:1 pumping and injected glycoprotein IIb/IIIa inhibitor (Abciximab) in a bolus dose. After stabilization, they performed intravascular ultrasound (IVUS) evaluations at the LM to LAD and LCX, respectively. Because LCX ostium was relatively preserved at IVUS examination, Dr. Park first deployed a Resolute Integrity stent (3.5 x 30 mm) at the LM to the LAD. After rewiring to the LCX with a 0.014 inch Choice PT wire and balloon dilation with a Mini Trek (1.5 x 12 mm) at LCX ostium, they reevaluated the LCX with an IVUS. And then, a Resolute Integrity stent (3.0 x 26 mm) was deployed at proximal to distal LCX. Additional balloon dilatations were performed at proximal to distal LCX using Maverick (2.5 x 20 mm) and Empira NC (3.0 X 20 mm) balloons, sequentially. After dilatation with an Empira NC (3.5 X 20 mm) at the LM to LAD, final kissing balloon dilatation was performed with an Empira NC (3.5 X 20 mm) at the LM to LAD and a Maverick (3.0 X 20 mm). And then, after an IVUS evaluation, additional balloon dilatation was per-formed at proximal to distal LCX using an Empira NC (3.0 x 20 mm) balloon. After that, Dr. Park check-ed the FFR values of LAD and LCX using a pressure wire. The FFR values of LAD and LCX were 0.94 and 0.80, respectively. Final angiogram showed that the procedure was successful (Figure 2).

Transcatheter Aortic Valve Implantation with the Edwards Valve

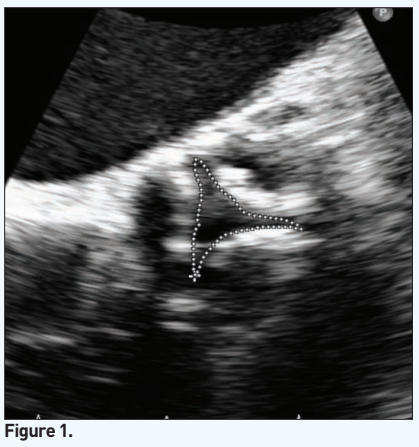


Figure 1.

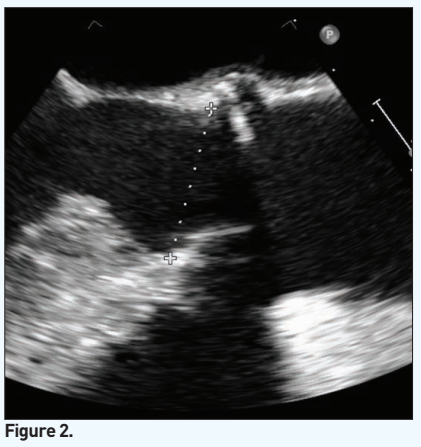


Figure 2.

Yesterday, Dr. Alain G. Cribier and Dr. Young-Hak Kim demonstrated successful treatment with the Edwards valve for severe AV stenosis. An 82 year-old male was admitted with dyspnea on exertion (NYHA class III) for about six months. He had a past medical history of hypertension, angina, and COPD. His logistic EuroSCORE was 19.2%. Transthoracic echocardiography showed severe degenerative AV tight stenosis and concentric LVH with normal LV systolic function (EF=58%). AV area by continuity equation was 0.5 cm^2. TransAV maximal velocity was 5.6 m/s. Mean and peak pressure gradient were 84 and 126 mmHg. Transesophageal echocardiography showed the opening limitation of AV because of calcification and degenerative change (Figure 1). His AV was tricuspid and annulus size by TEE was 24 mm (Figure 2). Annulus size by CT was 23.5 - 25.4 mm and perimeter was 82 mm. Distance from annulus to LM and RCA ostium was 17 mm, respectively. The right peripheral artery by CT angiography was enough to assess. Therefore, we chose the right approach.

The aortic annulus size measured by TEE and CT was about 24 mm. Therefore, a 26 mm Edwards SAPIEN valve was selected for implantation. Under sedation, 6 Fr sheath and temporary pacemaker were inserted through the left femoral vein, and 7 Fr sheath and 6 Fr pigtail catheter were inserted through the left femoral artery. After right peripheral angiogram with pigtail catheter, they checked the proper puncture site of the right femoral artery. A 7 Fr sheath was inserted through the right femoral artery, and then three 8 Fr Proglide devices were placed into the right femoral artery. The right femoral artery was dilated using an 18 Fr dilator, and then 18 Fr Edwards sheath was inserted sequentially. An AL 1 diagnostic catheter with a 0.035 inch Lunderquist wire was used to cross the aortic valve. After crossing AV, predilatation of the stenotic AV was undertaken with a 23 mm x 40 mm Edwards transfemoral balloon under rapid ventricular pacing and aortic root angiography (Figure 3). Under fluoroscopy control, a 26-mm Edwards SAPIEN prosthesis crimped on the delivery catheter (RetroFlex 3 Delivery System) was placed at the best position of the aortic annulus and then it was successfully deployed by inflating the balloon under rapid ventricular pacing and aortic root angiography (Figure 4). Final fluoroscopy showed a well-positioned Edwards Valve. After intervention, the puncture site was sutured by three prepared Proglides.

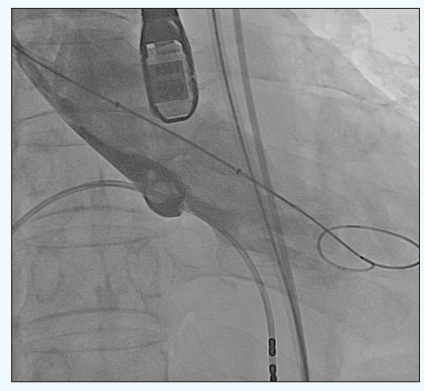


Figure 3.

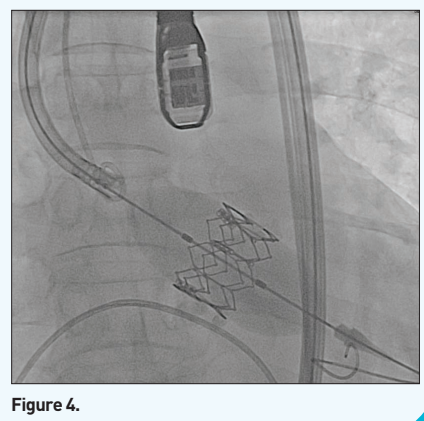


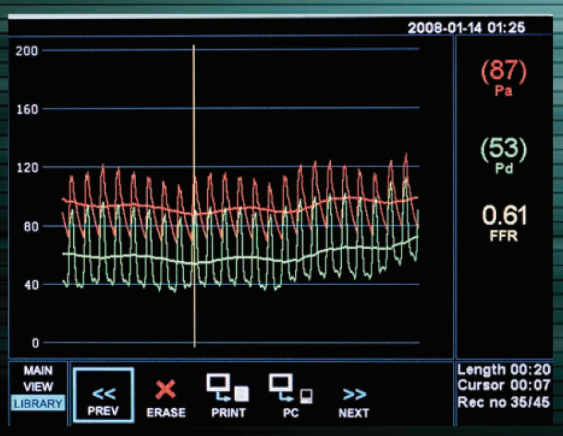
Figure 4.

CLEAR ADVANTAGE

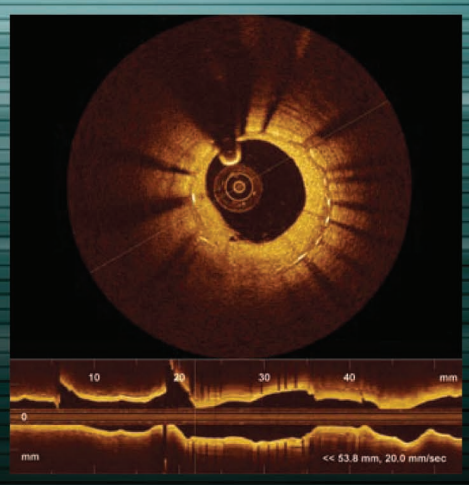
FFR + OCT – ONLY FROM ST. JUDE MEDICAL

PressureWire™ Certus™
FFR Measurement System

PressureWire™ Aeris™
Wireless FFR Measurement System



C7-XR™ OCT
Intravascular Imaging System



Complex coronary lesions require quick decisions using smarter, faster diagnostic strategies. From the company that brought you the ability to identify the culprit lesion with FFR, now comes the ability to redefine lesion assessment with the clarity of OCT. Two original technologies from one trusted source — and a powerful new standard in PCI optimization.

IDENTIFY functionally significant lesions with FFR in multi-vessel disease patients.[1]

OPTIMIZE interventions with enhanced visualization with OCT for stent optimization and follow-up.

VERIFY restored blood flow confirming full, functional revascularization.[1]

Pioneering advancement of intravascular lesion assessment. SJMprofessional.com

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MORE CONTROL. LESS RISK.

1. Tonino P, et al. Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention. NEJM. 2009;360:213-224.

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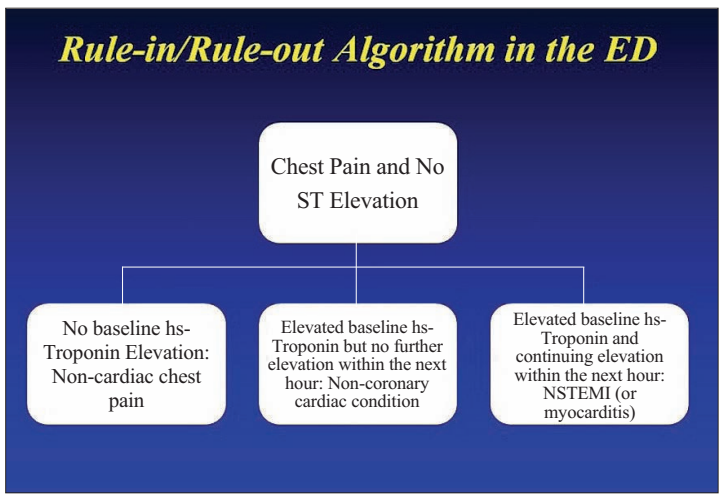
Product referenced is approved for CE Mark.

Acute Coronary Syndrome: Evolving Issues

April 25, 2:00 PM - 3:00 PM, Coronary Arena

Acute Chest Pain in the Emergency Room

Acute myocardial infarction (AMI) represents the most urgent form of acute coronary syndrome and requires immediate diagnosis and treatment for improved outcomes. For patients presenting with ST-segment elevation MI (STEMI), the diagnosis is rather apparent from the combination of clinical symptoms and EKG changes. However, for those with non-STEMI, the diagnosis may not be simple, especially when the EKG is not diagnostic and /or the symptoms are atypical. For these patients, it is paramount to make the correct diagnosis with the aid of cardiac biomarkers. Novel hs-troponin could facilitate the prompt and correct diagnosis of non-STEMI and prevent unwarranted discharge or delay of treatment for patients at high risk for ischemic complications. An advantage of hs-troponin includes the ability to detect extremely minute amounts of cardiac troponin levels and thus, enables both early diagnosis of myocardial injury and identification of small myocardial infarction. Recent studies with hs-troponin in patients presenting with chest pain suggest that the optimal protocol should use both the baseline value and the absolute changes one hour later. Patients with elevated baseline value and an increase in absolute value in the subsequent hour should be classified as AMI and treated accordingly. This protocol can rule out those without a true AMI (low baseline value and no increase) and distinguish those with non-coronary condition, such as Takotsubo or myocarditis. Thus, the following protocol can be used in the emergency room to rule-in and rule-out AMI based on the hs-troponin values within one hour of presentation.



In addition, screening low to intermediate-risk acute chest pain patients in the emergency department with coronary computed tomographic angiography is safe and may reduce time spent in the hospital and overall cost compared with conventional testing methods. However, CTA-evaluated patients are more likely to undergo invasive angiography and revascularization, according to a recent meta-analysis of randomized trials.

IABP Shock II Questions IABP

The findings of the IABP-SHOCK II trial have important implications for clinical cardiology. Surprisingly, the addition of IABP insertion to the treatment regimen did not significantly reduce 30-day mortality, the primary endpoint (39.7%), compared with the control group (41.3%). In this study, the IABP was inserted after percutaneous coronary intervention (PCI); therefore, whether IABP use before PCI is beneficial remains unclear.

Thrombus Management in STEMI

Many approaches exist to try to improve myocardial salvage and reduce infarct size in patients with evolving heart attack. Two of those approaches revolve around trying to prevent distal embolization of thrombus and soft atheromatus debris from the infarct artery: thrombus aspiration and intracoronary abciximab.

Thrombus aspiration has been the only technique that has improved mortality in AMI in the last 10 years. But, thrombectomy does not appear to reduce thrombus burden in patients with STEMI undergoing primary PCI, according to results from a multicenter randomized trial- 'TROFI' published online February 8, 2013, ahead of print in the European Heart Journal. For the TROFI trial, Patrick W. Serruys, MD, PhD, of Erasmus Medical Center (Rotterdam, The Netherlands) and colleagues randomized 141 STEMI patients at 5 European centers to primary PCI with (n=71) or without (n=70) thrombectomy between November 2010 and October 2011. Thrombectomy was performed using the Eliminate device (Terumo Clinical Supply, Gifu, Japan), and all patients received a Nobori biolimus-A9-eluting stent with biodegradable polymer (Terumo). High-resolution optical frequency domain imaging (OFDI) was used to measure flow area. After treatment, minimal lumen diameter and reference vessel diameter were larger in the thrombectomy group compared with the non-thrombectomy group. However, the minimum flow area (primary endpoint) and stent area were similar between the groups. In terms of clinical outcomes, there were no differences between groups for cardiac death, re-infarction in the territory of the infarction-related vessel, clinically driven TVR, TVF, all-cause death, stroke, definite stent thrombosis, or non-target vessel revascularization. However, in order to optimize techniques and narrow down patient populations that may derive the greatest benefit from thrombectomy, adequately powered randomized trials are needed.

Next, intracoronary abciximab with a potent antiplatelet agent is hypothesized to work by leading to a much, much higher concentration of abciximab right at the site of the thrombus than if it is given by the normal intravenous route. The concentration can be 1,000x as high in the coronary artery as intravenously, and that can directly cause disaggregation of platelets. Since the early thrombus is very platelet-rich, intracoronary abciximab may lead to less macroscopic or large embolic debris. In the latest INFUSE-AMI trial, the results clearly demonstrate that in high-risk patients presenting early in the course of a large evolving AMI undergoing primary PCI with bivalirudin anticoagulation, bolus intracoronary abciximab delivered to the infarct lesion site results in a significant reduction in infarct size at 30 days. A randomized trial powered for clinical and safety endpoints is warranted to determine the role of local abciximab delivery in STEMI.

Adjunct Pharmacotherapy: Beyond the Clot

April 25, 3:00 PM - 4:00 PM, Coronary Arena

Revisiting Anticoagulant in ACS

Traditional anticoagulants in clinical use for the prevention or treatment of thromboembolic disease are heparin and its analogues and warfarin. However, they have two major limitations: a narrow therapeutic window of adequate anticoagulation without bleeding, and a highly variable dose-response relation among individuals that requires monitoring by laboratory testing.

These limitations have provided the impetus for the development of other antithrombotic agents. The major examples of these newer anticoagulants are the factor Xa inhibitors and the direct thrombin inhibitors; some of these newer agents are orally active. The direct thrombin inhibitors, in contrast to heparin, can inactivate fibrin-bound thrombin.

In some patients with ACS, chronic oral anticoagulation are required to lower the

Continued on page 14

from page 13

risk of systemic thromboembolism, such as those with atrial fibrillation, left ventricular systolic dysfunction or thrombus, or prosthetic heart valves. The issue of whether chronic anticoagulant therapy reduces the risk of recurrent cardiovascular events, such as myocardial infarction (MI) or cardiac death, after ACS has been evaluated in clinical trials. As there are no studies comparing warfarin plus DAPT to DAPT alone or to warfarin plus a single antiplatelet agent, the applicability to current practice of the studies presented below is limited. Efficacy and safety outcomes have been evaluated in ACS patients treated with warfarin alone, aspirin alone, and therapy with both. The available evidence suggests that combined therapy may reduce the risk of ischemic events compared to aspirin alone when the Inter-national Normalized Ratio (INR) is strictly maintained between 2.0 and 3.0. As combined therapy also increases the risk of bleeding compared to monotherapy, the benefit with warfarin is partially offset.

Dabigatran is a direct thrombin inhibitor that has been approved for use for the prevention and treatment of venous and arterial thromboembolic disorders. But, dabigatran has not been evaluated for efficacy in the setting of ACS. The lower of the two doses of the new oral anticoagulant rivaroxaban tested in the ATLAS ACS 2 TIMI 51 trial has shown promising results, with a reduction in overall and cardiovascular mortality vs placebo, despite an increased risk of bleeding and intracranial hemorrhage (ICH). The ATLAS 2 results may come as a surprise to many after the APPRAISE-2 trial when another factor Xa inhibitor, apixaban, had to be stopped early because of increased bleeding rate. Rivaroxaban, particularly at the 2.5 mg twice daily dose, appears to improve outcomes in patients with recent ACS when added to dual antiplatelet therapy. It should be kept in mind that the level of anticoagulation achieved with either the 2.5 or 5 mg twice daily dose is less than that seen with the 15 or 20 mg once daily dose, as is used in patients with atrial fibrillation.

Reshaping the Guidelines

As we know, stent restenosis and stent thrombosis are potential complications of coronary artery stenting; their incidence is highest in the first year after PCI. Stent restenosis, which occurs more frequently with bare metal stents (BMS) than drug-eluting stents (DES), may occasionally present as an acute myocardial infarction. In all patients who receive DES, the combination of aspirin and a second antiplatelet agent, referred to as dual antiplatelet therapy (DAPT), is used for at least 12 months according to the present guidelines. There are ongoing studies testing the hypothesis that a shorter duration is equally efficacious. The REAL-LATE and ZEST-LATE trials showed promising results. DAPT is typically the combination of aspirin plus clopidogrel, prasugrel, or ticagrelor, all of which are referred to as platelet P2Y12 receptor blockers. There are three limitations to the use of clopidogrel: delayed onset of action, large individual variability in platelet response, and irreversibility of its inhibitory effect on platelets. Clopidogrel has been evaluated in patients with stable coronary artery disease, while prasugrel and ticagrelor have been studied in patients with acute coronary syndromes.

Evidence from TRITON-TIMI 38 (prasugrel) and PLATO (ticagrelor) provides strong support for the general idea that agents with higher levels of platelet inhibition have lower cardiovascular event rates but higher rates of bleeding compared to clopidogrel. In patients not undergoing an invasive approach, the relative efficacy and safety of ticagrelor compared to clopidogrel and prasugrel or compared to clopidogrel alone were analyzed in the PLATO and TRILOGY trials respectively; in the former, ticagrelor was superior to clopidogrel, while in the latter, prasugrel was not shown to be superior to clopidogrel.

Goodbye to ASA

Patients on oral anticoagulant therapy who are undergoing stenting should be treated with clopidogrel but not aspirin, according to results from an open-label multicenter randomized trial 'WOEST' published online February 13, 2013 in the Lancet. Oral anticoagulants are obligatory in most patients with AF and those with mechanical heart valves. The study showed a large reduction in overall bleeding using the Thrombolysis in Myocardial Infarction (TIMI) criteria in patients receiving dual therapy with oral anticoagulants and clopidogrel compared with those receiving triple therapy including aspirin. Efficacy did not seem to be compromised. If anything, there appeared to be lower rates of ischemic events and a significant reduction in all-cause mortality.

2013 TCTAP Wrap-up Interview

FFR and IVUS

Fractional flow reserve (FFR) is a reliable functional index for epicardial coronary stenosis. It has been previously reported that deferring lesions of intermediate severity at angiography with a FFR 0.75-0.80 has a good clinical follow-up. Especially in multivessel disease, FFR-guided PCI led to better clinical outcome compared with angio-guided PCI. Evidences support that physiologic assessment is essential to make a decision on how to treat. Recent studies validated the optimal MLA threshold predicting FFR. Although the MLA cut-offs are ranged from 2.0-3.0 mm, they suggested that there is no MLA cut-off showing accuracy higher than 70%. Even in subgroup-specific MLA cut-off (according to vessel size, lesion segment, LAD or non-LAD), their predictabilities were disappointing. Because MLA is only one of the multiple determinants of FFR, it cannot predict FFR accurately. Thus, the decision for treatment should be based on the functional lesion assessment.

With regard to stent optimization, IVUS criteria have been well established and used during PCI. IVUS is useful to optimize stent area and to select the appropriate landing zone, which may contribute to the better clinical outcome of PCI. Thus, FFR and IVUS are complementary to making a decision during PCI.

OCT

Intracoronary OCT is an emerging imaging technology for evaluating the cross-sectional and 3-dimensional (3D) microstructure of blood vessels at a resolution of approximately 10 μm. Because its resolution is higher than IVUS, OCT may be capable of characterizing the superficial structure of the vessel wall in greater detail. The current consensus standards may be broadly used as a standard reference regarding the OCT imaging modality, intended for researchers and clinicians who use OCT and analyze OCT data. OCT is useful to evaluate vulnerable plaque morphology and is related to the immediate post-stenting outcomes such as no reflow and periprocedural myocardial infarction. Moreover, OCT clearly demonstrates the precise mechanism of stent failure. In-stent neoatherosclerosis is an important mechanism of restenosis and stent thrombosis in the late phase. Recent studies reported that TCFA, rupture, and thrombi were frequently seen in lesions with in-stent restenosis or very late stent thrombosis. With a better resolution, OCT is more reliable to detect neointimal vulnerability.

OCT is useful in risk stratification of coronary lesions. It is also used to optimize stent procedure. Excellent resolution of OCT makes it possible to detect small dissection, malapposition, and thrombi. Published IVUS data suggested that optimally large area and small plaque burden at the stent landing zone should be achieved to avoid restenosis or stent thrombosis. However, because of the poor penetration depth of OCT, it is hard to know the vessel size and plaque burden.

Although OCT gives us much information, we need more studies providing the criteria for PCI optimization and the impact of the OCT findings on the clinical outcomes.

Structural Heart Disease

April 25, 2:00 PM – 4:30 PM, Structural Heart & Endovascular Theater, Structural Heart Disease Session I

In recent years, there have been tremendous advances in both the understanding of structural heart disease and the interventional therapeutic modalities aimed to treat them.

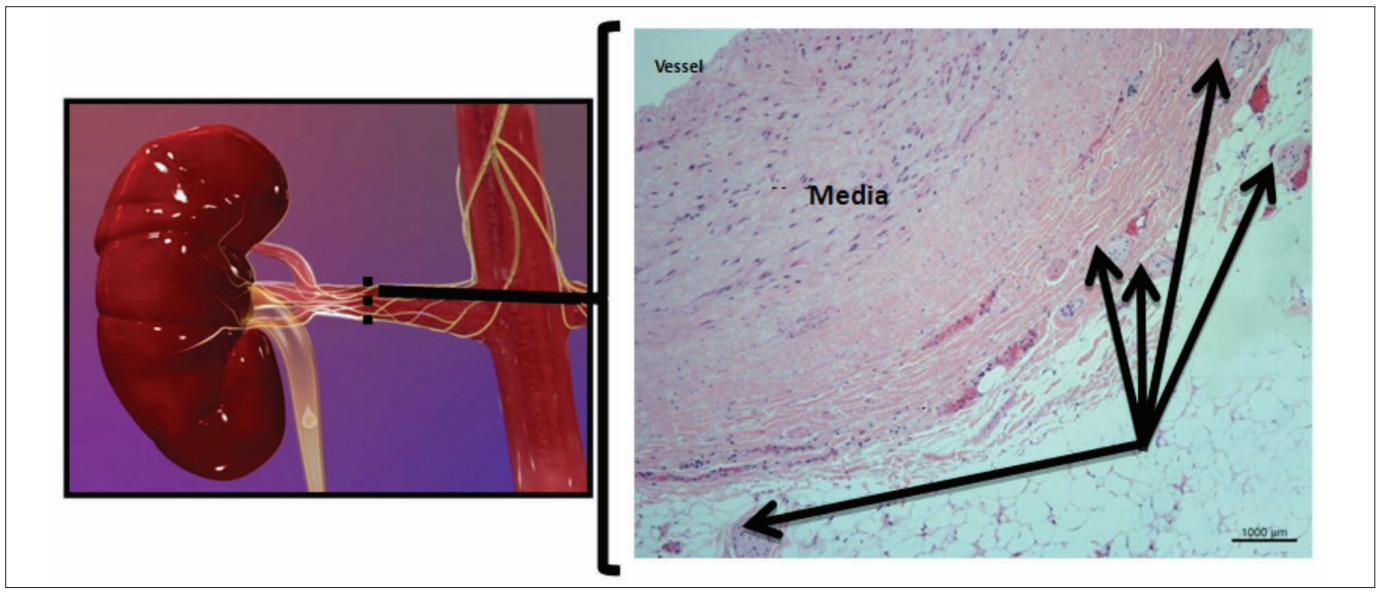


Figure 2. Post-sympathetic ganglion arise from T10-L2 and follow the renal artery to the kidney, primarily lie within the adventia

LAA Closure

Saibar Kar, MD (Cedars Sinai Medical Center, USA)

In patients with non-valvular atrial fibrillation (AF), embolic stroke is associated with left atrial thrombi. The left atrial appendage (LAA) is the site of thrombus formation and the source of embolism in more than 90% of cases based on autopsy studies and echocardiography. Occlusion of the LAA may prevent thromboembolism by removing the site of thrombus formation. Different devices for percutaneous closure of the LAA were subsequently evaluated. The first was the PLAATO device (EV3 Endovascular, Plymouth, MN) in 2001, followed by the Watchman device (Boston Scientific, Plymouth, MN), and the Amplatzer cardiac plug (St Jude, Golden Valley, MN).

The PLAATO device (Figure 1-A) was the first LAA occlusion device. Although this device is no longer in use for LAA closure, the data from its clinical use still provide valuable information. In 210 patients receiving the PLAATO device, there was an estimated 61% reduction in the calculated stroke risk. The PROTECT AF trial randomized 707 patients 1:2 to warfarin or LAA closure with **the Watchman device (Figure 1-B)** and discontinuation of warfarin after 90 days. In PROTECT AF trial, the Watchman device is non-inferior to warfarin for stroke/thromboembolic protection in patients with non-valvular AF during 2.3 years. Continued Access Protocol (CAP) trial also demonstrated continued safety improvement with experience. In the recently presented PREVAIL trial, 407 patients were randomized to either LAA closure with the Watchman device (n=269) or warfarin (n=138). The device was implanted more successfully in the PREVAIL trial (95.1%) than in 2 prior Watchman studies: PROTECT AF (90.9%) and CAP registry (94.3%; P=0.04). The first primary endpoint, acute occurrence of death, ischemic stroke, systemic embolism, and procedure or device related complications requiring major cardiovascular or endovascular intervention, was met for prespecified criterion with only 6 total events (2.2%) in the device group (95% upper confidence limit <2.67%). Compared with the PROTECT AF and the CAP registry, the PREVAIL showed decreased composite vascular complications (p=0.004) and perforations requiring surgical repair (p=0.027). There was also a decrease in procedural stroke rates (p=0.007) and little difference in the outcomes of new versus experienced operators. Although LAA closure did not meet success criterion in the second primary outcome (composite of stroke, systemic embolism, and cardiovascular/unexplained death at 18 months), the Watchman showed a benefit with regard to the third primary endpoint (ischemic stroke or systemic embolism occurring after 7 days and up to 18 months). The PREVAIL trial showed the possibility that the Watchman device could be an alternative to oral anticoagulation therapy for thromboembolic prevention in patients with non-valvular AF. **The Amplatzer cardiac plug (Figure 1-C)** is the latest device to come from the Amplatzer family of devices and has been specifically designed for LAA closure. The initial European and Asia-Pacific experiences showed that LAA closure with Amplatzer cardiac plug was safe and feasible with encouraging 1-yr clinical outcomes. These findings suggest that LAA occlusion could be used as an alternative for patients who cannot use oral anticoagulants such as warfarin.

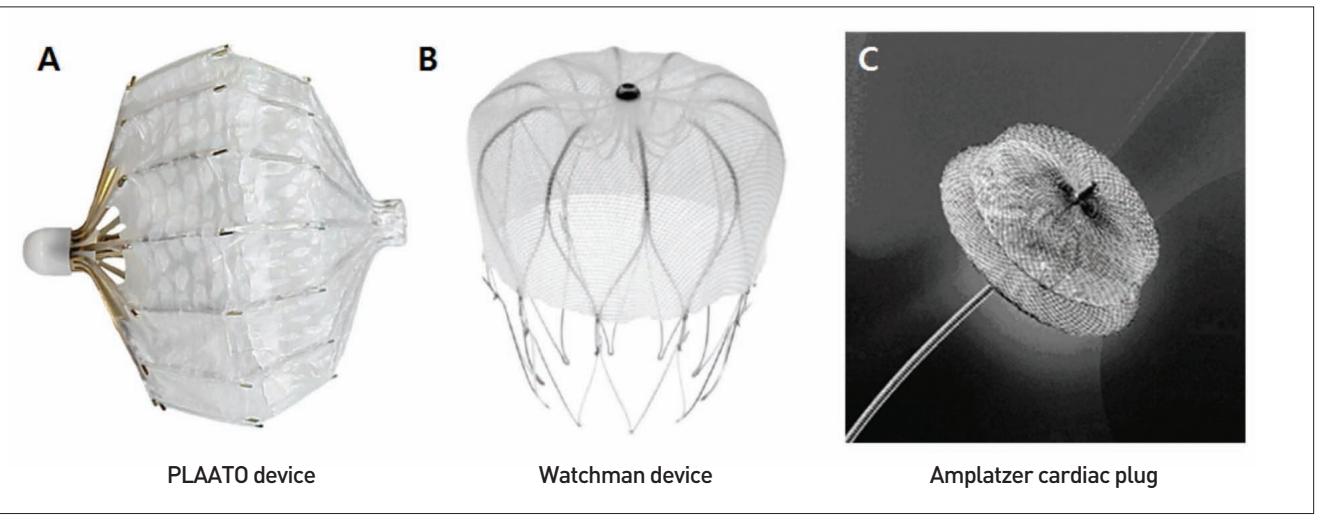


Figure 1.

Renal Denervation

Horst Sievert, MD (Cardiovascular Center Frankfurt, Germany)

Hypertension affects approximately 25% of the global adult population and its prevalence and consequent health cost is predicted to rise to 1.5 billion hypertensive patients in 2025. Appropriate antihypertensive treatment blood pressure (BP) goals are not achieved in a large proportion of patients, the so-called resistant hypertensive patients, which is defined as persistence of BP levels above the goal in spite of the concurrent use of three antihypertensive agents in adequate doses from different classes including a diuretic. Several hypertension centers reported it ranges from 5 to 30%. In patients with resistant hypertension, transcatheter renal deneravation (TRD) by delivery of radiofrequency energy is emerging as a new approach to achieve sustained BP reduction. The sympathetic innervation of the kidneys is achieved through a dense network of postganglionic neurons that innervate the kidney (Figure 2). In the past

Continued on page 17

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century, surgical splanchnicectomy that led to renal denervation improved survival of hypertensive patients when compared to conservative management available at that time, but this invasive surgical technique faded quite suddenly with the dawn of effective antihypertensive drug therapy. TRD is a percutaneous procedure, minimally invasive, characterized by short recovery times, and absence of significant systematic side effects.

Evidence on the clinical effectiveness of this procedure in hypertensive patients comes from the Symplicity clinical trial program consisting of a group of studies focusing on the effects of TRD in the treatment of resistant hypertension. In the Symplicity Hypertension (HTN)-1 study, which enrolled 45 patients with resistant hypertension treated by TRD, showed that TRD causes substantial and sustained BP reduction without serious adverse events. The Symplicity HTN-2 study is multicenter, prospective, randomized clinical trial, that included patients with resistant hypertension and office SBP at least 160 mmHg (or 150 mmHg for patients with type 2 diabetes). A total of 106 patients (TRD=52) were randomized and 49 of 52 patients underwent TRD. At 6 months, office SBP/DBP values in the TRD group decreased by 32/12 mmHg (baseline 178/96 mmHg, p ‹0.0001), whereas no changes in the control group occurred. Differences in office SBP/DBP between the two groups at 6 months were 33/11 mmHg (p ‹0.0001). At 6 months, 41 (84%) of 49 patients who underwent TRD had a reduction in SBP of 10 mm Hg or more, compared with 18 (35%) of 51 controls (p ‹0.0001). There were no major complications after TRD. In 2011, recruitment for the Symplicity HTN-3 trial started in the USA with a protocol that is more stringent than Symplicity HTN-2 and involves more frequent ABPM. If the results of the Symplicity HTN-3 trial are as gratifying as that of Symplicity HTN-2, a true alternative to medications will exist for resistant hypertension.

PFO Closure

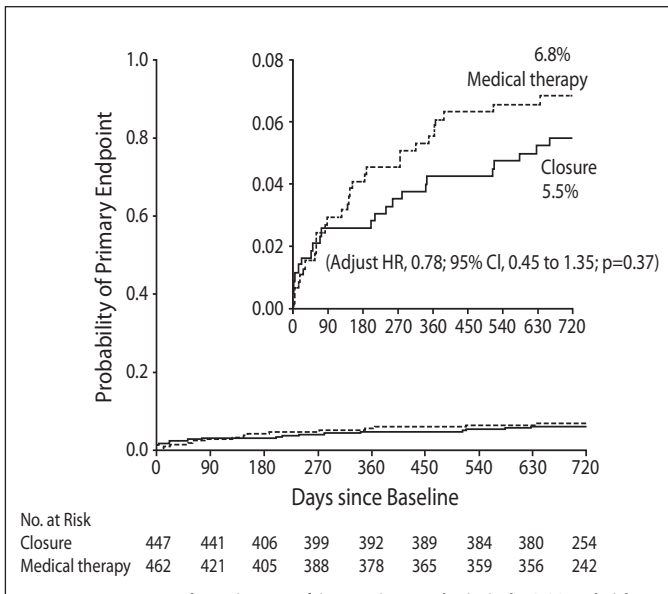
About thirty percent of the population has a residual embryologic defect known as a patent foramen ovale (PFO). PFO is clinically linked to paradoxical embolism, migraine, and decompression sickness. Since the first report by Bridges et al. in 1992, many studies have reported on the safety and efficacy of percutaneous PFO closure. Despite the intuitive attractiveness of PFO closure, controversy exists regarding the overall benefit of this therapy. Several large randomized trials comparing medical therapy in the form of aspirin or warfarin and percutaneous device closure for the prevention of recurrent cryptogenic stroke were already conducted or in progress.

Recently, three randomized trials (CLOSURE I, RESPECT, and PC trials) compared the effectiveness in prevention of stroke for device closure over medical treatment. The CLOSURE I (closure or medical therapy for cryptogenic stroke with PFO) was conducted in 909 cryptogenic stroke or transient ischemic attack (TIA) patients and closure with a device didn't offer a greater benefit than medical treatment alone for the prevention of recurrent stroke or TIA during 2 years (closure vs. medication; 2.9% vs. 3.1% and 3.1% vs. 4.1%, p=NS in stroke and TIA respectively). The RESPECT (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment) enrolled 980 patients over eight years. All patients were diagnosed with a cryptogenic stroke and PFO, with 49% of patients having large strokes as their qualifying stroke event. Patients in the study were relatively young at an average age of 46 years. In the intention-to-treat analysis, there was a non-significant 46.6% reduction in the risk of stroke (p=0.157). In the per-protocol and as-treated analyses, the 63.4% and 72.7% relative reduction in risk was statistically significant (p=0.032 and p=0.007, respectively). The Percutaneous Closure or PFO versus medical treatment in patients with cryptogenic embolism (PC) trial included 414 patients randomized to PFO closure or medical therapy. Patients were included in the study if they were younger than 60 years of age and had a clinically or neuroradiologically verified ischemic stroke or transient ischemic attack with a documented intracranial ischemic lesion. There was a nonsignificant 37% relative reduction in the primary end point of death from any cause, nonfatal stroke, transient ischemic attack, and peripheral embolism (p=0.34). Although there was an 80% reduction in the risk of stroke, this reduction did not reach statistical significance (p=0.14). Another trial, the REDUCE study sponsored by Gore Medical, is currently ongoing. Through these trials, we will get answers about which patients might benefit from PFO closure.

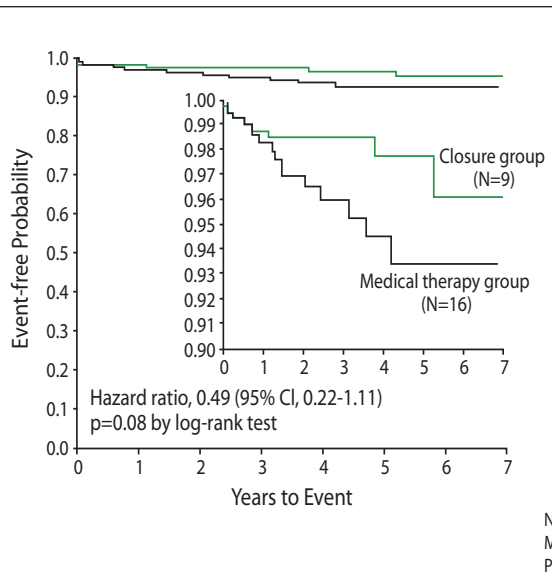
Mitral Clip

The mitral apparatus is a complex structure consisting of the mitral valve leaflets, the annulus, chordae, papillary muscles, and ventricle. A defect at any level may result in regurgitation of blood from the left ventricle to left atrium. Severe mitral regurgitation (MR) is associated with increased mortality regardless of symptoms.

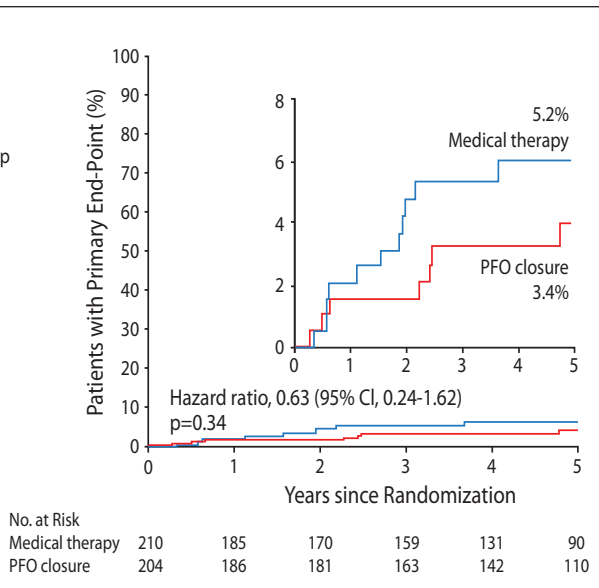
Endovascular edge-to-edge repair method mimics a surgical technique developed by Alfieri and colleagues in the 1990s. Through a trans-septal approach, the device (MitraClip, Abbott Vascular) grasps and approximates the leaflets to decrease the severity of MR. The Endovascular Valve Edge-to-Edge Repair Study (EVEREST) II trial randomized 279 patients with moderately severe or severe (grade 3+ or grade 4+) MR in a 2:1 ratio to undergo either percutaneous or surgical repair of the mitral valve. Although the primary composite end point of freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ MR at 12 months was significantly better in the surgery group, the MitraClip procedure was associated with superior safety and similar improvements in clinical outcomes. This trial also showed the possibility that the MitraClip would be an option for older patients, patients with functional rather than degenerative MR, and those with left ventricular dysfunction. Recently, a cohort of 372 high-surgical-risk patients, including 78 from the EVEREST II population and 294 from REALISM, showed significant improvements in symptoms, hospitalization, and heart-chamber volumes a year after receiving the device. The Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk Patients (COAPT) study in the US in patients with severe heart failure at high risk of surgery and the Randomized Study of the MitraClip Device in Heart Failure Patients with Clinically Significant Functional Mitral Regurgitation (RESHAPE-HF) trial in Europe in patients with severe heart failure at lower surgical risk are currently underway and should provide us with useful information about the potential for percutaneous mitral repair.



Kaplan-Meier curve of time to primary end point in the CLOSURE I trial. NEJM 012;366:991-9.



Primary end-point events in the intention-to-treat cohorts in the RESPECT trial. NEJM 2013;368:1092-100.



Kaplan-Meier cumulative estimates of the rate of the primary End-Point in the PC Trial. NEJM 2013;368:1083-91.

Figure 3.

CardioVascular Research Foundation (CVRF)

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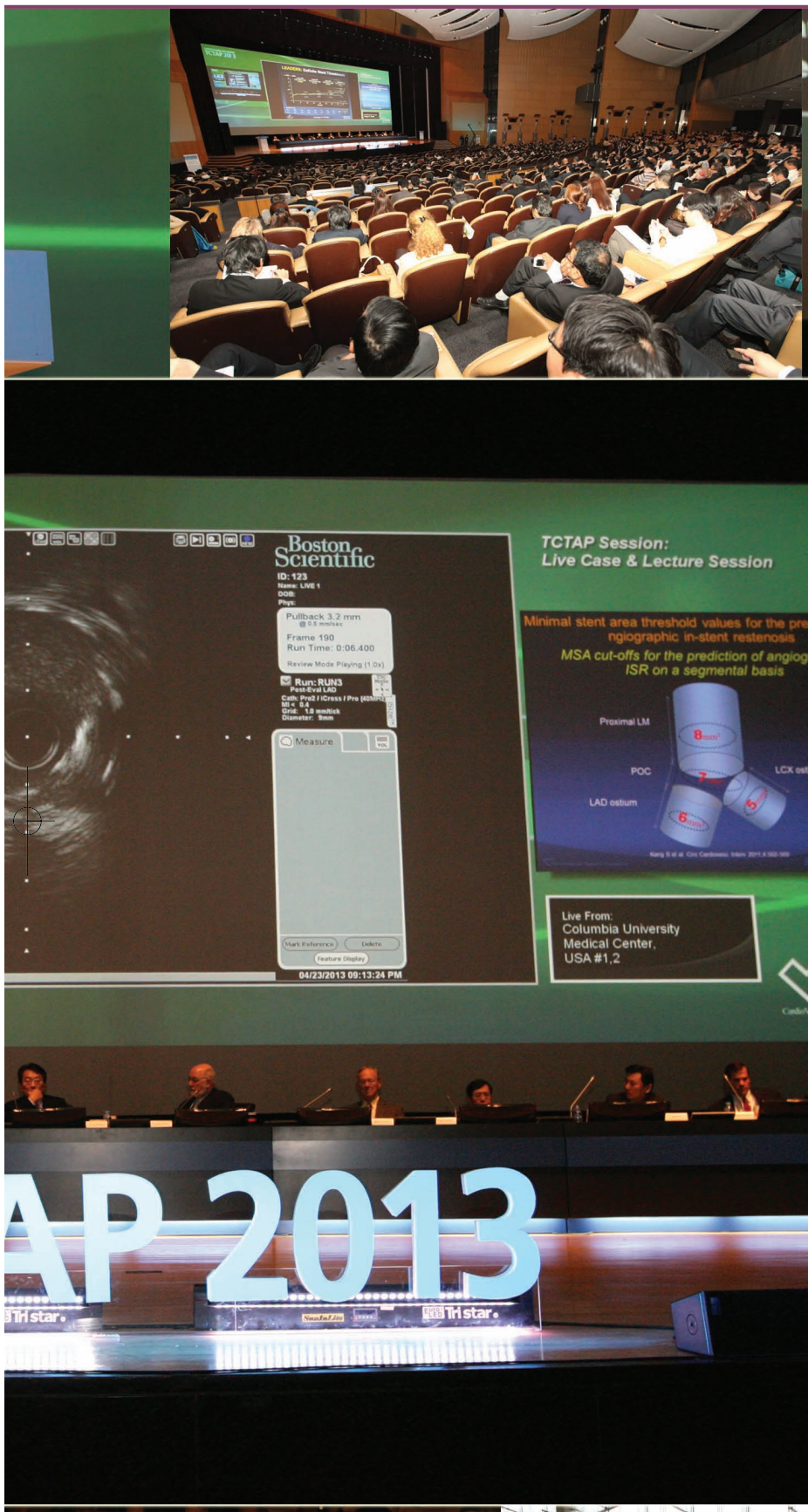

Interesting Oral Abstracts

From Oral Abstract Competition

April 24, Abstract Zone, Level 3

Comparison of Instant Thrombolysis Plus Early PCI and Primary PCI in STEMI, View of CMR Early After Reperfusion Therapy

Dr. Heng Ge et al. from Renji Hospital, Shanghai, China presented their data about a comparison of instant thrombolysis plus early PCI and primary PCI (PPCI) in STEMI patients, view of CMR early after reperfusion therapy. CMR scan were performed on a 3.0-T Philips Achieva scanner 2 to 8 days after reperfusion. Left ventricular functional assay was done and myocardial edema and hemorrhage were detected and necrosis size and microvascular obstruction (MVO) were determined. Twenty patients in thrombolysis group (n=22) received subsequent stent implantation. One patient took only balloon angioplasty and 1 patient didn't take further PCI therapy. All patients in PPCI group (n=20) received stent. Final TIMI flow was grade 3 after PCI was achieved in 82% of patients in thrombolysis group and 88% in PPCI group (p=0.32). Time from symptom onset to CMR scan was similar (3.4 ±1.7 and 3.6±1.4 days in thrombolysis and PPCI group, respectively, p=0.78). CMR results were statistically equal between thrombolysis and PPCI group: LVEF were 49.09 ±10.63% and 50.12 ± 10.97% (p=0.77); Necrosis percentage of left ventricle were 21.82 ±13.32% and 27.0±15.47% (p=0.263); Rate of intramyocardial hemorrhage was 36.4% and 29.4% (p=0.65). Rate of MVO was 68.2% and 58.8% (p=0.55). Of 6 patients with failing thrombolysis (TIMI flow grades 0 or 1 in infarction-related artery in angiography), LVEF, necrosis percentage, and rate of hemorrhage or MVO were all numerically worse than those with successful thrombosis (TIMI flow grade ≥2 in initial angiography), LVEF was 45.16±10.76% vs. 50.56 ± 10.54%, p=0.3; necrosis percentage was 29.33 ±11.71% vs.19.01 ±13.10%, p=0.11; hemorrhage 83.3% vs. 18.8, p=0.021; MVO 83.3% vs. 62.5, p=0.67. They concluded that according to the current CMR data, strategy of instant thrombolysis plus early PCI may have comparable efficacy as PPCI in STEMI patients. However, thrombolysis failure may be related to worse outcomes even with a successful rescue PCI.

The Effect of BMI on In-hospital Mortality for Acute STEMI

Dr. Deuk-Young Nah et al. (Dongguk University College of Medicine, Gyeongju Hospital, Gyeongju, Korea) showed multicenter Korean registry data evaluating the in-hospital mortality in patients with AMI related to body mass index (BMI); a total of 5,207 patients with acute STEMI in Korean AMI registry between January 2008 and November 2011. They categorized the patients according to BMI degree: lean (‹18.5 kg/m^2, n=179), normal (18.5-22.9 kg/m^2, n=1,813), overweight (23-24.9 kg/m^2, n=1,837) and obese (›25 kg/m^2, n=1,828). Overweight and obese patients were younger and lean patients were older and there more women (76/179=42.5%). In lean, normal weight, overweight, and obesity, in-hospital mortality was 9.5%, 5.6%, 3.5% and 3.1%, respectively (p=0.001). BMI by binary multiple logistic regression analysis adjust with age, sex, and Killip class was not significantly associated with in-hospital mortality. It is suggested that BMI itself at admission had no impact on in-hospital mortality in patients with acute STEMI. Dr. Nah concluded that the inverse relationship between obesity and in-hospital mortality has not been demonstrated ("obesity paradox") in this study.

The Incidence Rate of TLR after the Third Time DES Implantation to Treat DES ISR is Very High

Dr. Masatsugu Nakano et al from Saiseikai Yokohama City Eastern Hospital, Yokohama, Japan presented their single center experience about the incidence rate of binary restenosis or TLR after the third time DES implantation to treat DES re-restenosis. Of 49 patients who underwent the third time PCI for DES re-restenosis, subjects were classified into two groups: those with the third DES implantation, D group (30 patients with 27 DES re-restenosis), and those with the balloon angioplasty, B group (19 patients with 19 DES re-restenosis), for a comparative study. In average 1.9±1.1 years follow-up, the D group had low incidence rate of binary restenosis (D: 53.4% vs. B: 75.0%; p=0.342) or TLR (D: 36.7% vs. B: 52.6%; p=0.271) than B group. But that was not statistically significant. They concluded that although the third DES implantation for DES re-restenosis tends to have low TLR rate after procedure than balloon angioplasty, the incidence rate of TLR is very high.

A Novel Polymer-free SES Coated with Anti-CD34 Antibody Shows Less Neointima Formation and Early Recovery of Endothelial Function

Dr. Tao Zhang et al. from Chinese PLA General Hospital, Beijing, China showed their short term outcome about a novel combo stent (CS), polymer-free sirolimus-eluting stent (SES) coated with anti-CD34 antibody in a porcine model. They compared a combo stent (CS), with a permanent-polymer SES (SES), a polymer-free SES (PFSES) and a bare-metal stent (BMS) at 14 days and 28 days in a porcine model with optical coherence tomography (OCT) and histological analysis. He presented their 14 days OCT data; there was a reduction in neointimal proliferation by CS and PFSES compared with SES and BMS (neointimal thickness: BMS, 0.44 ±0.12 mm; SES, 0.42±0.03 mm; PFSES, 0.14 ±0.11 mm; CS, 0.11 ±0.06 mm; p‹0.005; BMS/SES › CS/PFSES). At 28 days, both CS and PFSES were associated with reduced neointimal proliferation, whereas SES exhibited increased neointima (neointimal thickness: BMS, 0.62±0.11 mm; SES, 0.63±0.08 mm; PFSES, 0.18 ±0.06 mm; CS, 0.21 ±0.06; p‹0.005; BMS/SES › CS/PFSES). On the histological evaluation at 14 days and 28 days, combo stent showed decreased fibrin and inflammation, compared with SES and PFSES. In addition, the combo SES is associated with increased endothelium-dependent relaxation, protected vascular endothelial function. It is suggested that the use of combo stents may have a potential short-term benefit over traditional polymeric-coated drug-eluting stents.

Clinical Outcomes of DEB in Treatment of Coronary ISR Compared to POBA and DES

Dr. Soon Yong Suh et al. from Gachon University Gil Hospital, Incheon, Korea presented their retrospective data about the efficacy and safety of a paclitaxel drug eluting balloon (DEB) in treatment of ISR vs. POBA and DES. Among 179 patients, 190 ISR lesions, 67 patients treated with POBA and 54 patients with DES and 58 patients were treated with the DEB. Mean clinical follow up was 16.3±11.2 months. During the follow up, overall, total major adverse cardiac events were 20 (11.2%). There were 6 cardiac deaths (3.3%), one myocardial infaction (0.6%), and 13 target lesion revascularization (7.3%) and 3 stent thrombosis (1.7%). But there was no significant difference between 3 groups (POBA: n=10, 14.9%; DES: n=4, 7.1%; DEB: n=6, 10.7%). They concluded that treatment of coronary ISR with DEB is feasible and showed relatively low MACE compared to POBA and DES in small and short-term of this study and large and long term, prospective trial will be needed.

Unended Debate: Stent vs. Surgery

April 25, 8:30 AM – 12:30 PM, Structural Heart & Endovascular Theater, Endovascular Session III & IV

Carotid Artery Stenosis

Which strategy between carotid endarterectomy and carotid artery stenting will be superior or which patient subset will be beneficial by selecting one strategy? There are still endless questions and controversies. There have been so many trials to compare the two strategies but we don't have any confirmative answers because all trials have different patient characteristics such as symptom status and surgical risk and the trials used different procedure devices such as embolic protection device and different type of stent. And lastly, the experience also might work the in-consistent answers. We clearly know that the role of carotid stenting must be considered as a great option for patient management.

For the advanced step, we will focus this year on the interventional skills and devices for the improvement of patient's outcome such as proximal protection device. The reason why crossing the lesion to provide distal protection is important during carotid artery stenting is because it results in a higher rate of cerebral microembolization compared with a proximal protection device. Especially in patients with high-risk, lipid-rich plaques undergoing carotid artery stenting, a proximal occlusion device provided better protection against microembolization than a distal protection filter. The proximal endovascular occlusion device uses balloons to occlude the external carotid artery and common carotid artery in order to stop blood flow in the target internal carotid artery. According to the randomized trial, "better brain protection" with the proximal endovascular occlusion device would be beneficial. But, it is not easy to extrapolate to all distal protection devices as the results might differ with different systems and the clinical effects of microembolization are not established yet.

Mortality: Endovascular vs. Open Repair	HR	95% CI	*P* Value
At 2 Years	0.63	0.40-0.98	0.04
At 3 Years	0.72	0.51-1.00	0.05
At 8 Years[a]	0.97	0.77-1.22	0.81

[a] Kaplan-Meier estimate.

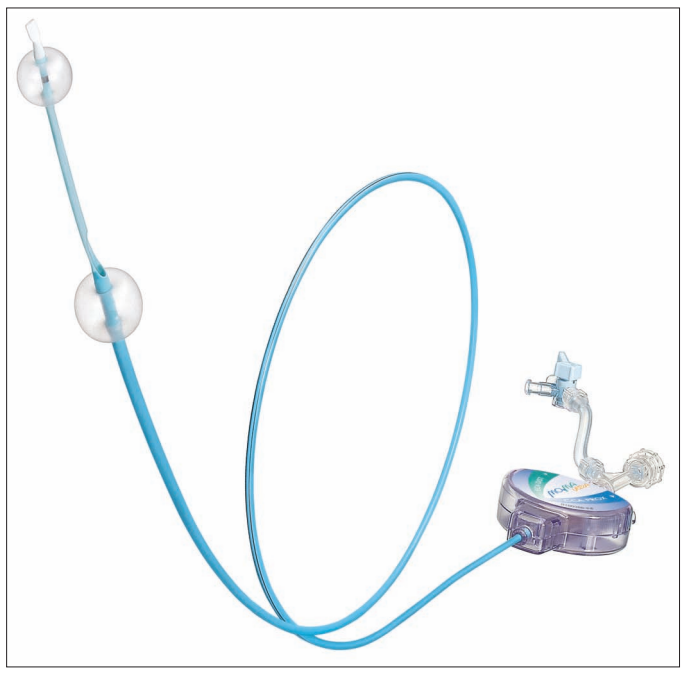

Figure 1. The Mo. Ma device

The Mo. Ma device protects the brain from embolization by two highlight-compliant atraumatic balloons blocking antegrade blood flow from the common carotid artery and retrograde blood flow from the external carotid artery. The Mo. Ma catheter is a tool thought to protect the brain while treating internal carotid stenosis with PTA/stenting with at least similar results in stroke prevention as surgical carotid endoarterectomy, but with the added advantage of low invasivity. The idea was born 11 years ago, but it took years to be perfected and submitted for FDA approval with the Armour study. This was realized one month ago and Mo. Ma is recognized as the best protective device for carotid PTA/ stenting available today with a complication rate of 2.3%. All of the other embolic protection systems to date have been distal protection devices. The problem with those devices is that during the passage of embolic protection devices through the stenosis of the blockage, there's a possibility of embolization. There's a period in which the brain is not really protected during the procedure, whereas with the proximal protection with the aortic-type clamping procedure, balloon inflation in the common carotid artery and in the external carotid artery, there's protection throughout each step of the angioplasty and stenting procedure. Theoretically, it is a better and safer way to treat real difficult carotid lesions. We are looking forward to "New Game Changer in Carotid Stenting", which will be presented by Dr. Richard R. Heuser (St. Luke's Medical Center, USA).

The chronic total occlusion of the carotid artery could be considered as one of the most difficult and challenging lesion subset to recanalize for interventionists. According to the development of devices, techniques, and knowledge, many physicians have some interest in this tough corner. So, "Recanalization of Carotid CTOs: Indication and Methods for a Controversial Procedure" by Dr. Paul Hsien-Li Kao (National Taiwan University Hospital, Taiwan) can clearly show the road to the goal with a safer approach.

In addition, we can adjust our knowledge after meeting with several hot issues such as "The fate of Asymptomatic Carotid Artery Stenosis: Is Really Risky? Must Be Recanalized?" by Dr. Seung-Whan Lee (Asan Medical Center, Seoul, Korea).

Abdominal Aortic Aneurysm

An aortic aneurysm is a weak area in the aorta, the main blood vessel that carries blood from the heart to the rest of the body. As blood flows through the aorta, the weak area bulges like a balloon and can burst if the balloon gets too big. In the past 30 years, the occurrence of abdominal aortic aneurysms (AAA) has increased threefold. Abdominal aortic aneurysm (AAA) is a vascular disorder fraught with contradictions. It is mostly benign, causing no limitation in daily activity. Yet the first occasion of symptoms, aneurysm rupture, is often lethal. For the proper management of AAA, endovascular repair is a minimally invasive treatment and has gained popularity over the last decade. In comparison to the conventional open surgical repair, endovascular AAA repair (EVAR) is associated with a lower morbidity and mortality rate. Recently, the long term results of OVER trial, which included 881 patients total with asymptomatic state randomized to EVAR (n=444) or open (n=437), was published. Authors suggested that endovascular repair and open repair resulted in similar long-term survival. The perioperative survival advantage with endovascular repair was sustained for several years, but rupture after repair remained a concern. Endovascular repair led to increased long-term survival among younger patients, but not among older patients for whom a greater benefit from the endovascular approach had been expected.

In a retrospective cohort study, researchers further explored the comparison by identifying 4,529 Medicare beneficiaries (mean age 76) who underwent isolated open or endovascular repair (703 and 3,826, respectively) of intact AAA from 2003 through 2007. Early survival advantage for endovascular repair persisted long-term (2.6 years) and in multivariable analysis. In the long term, endovascular repair of abdominal aortic aneurysm

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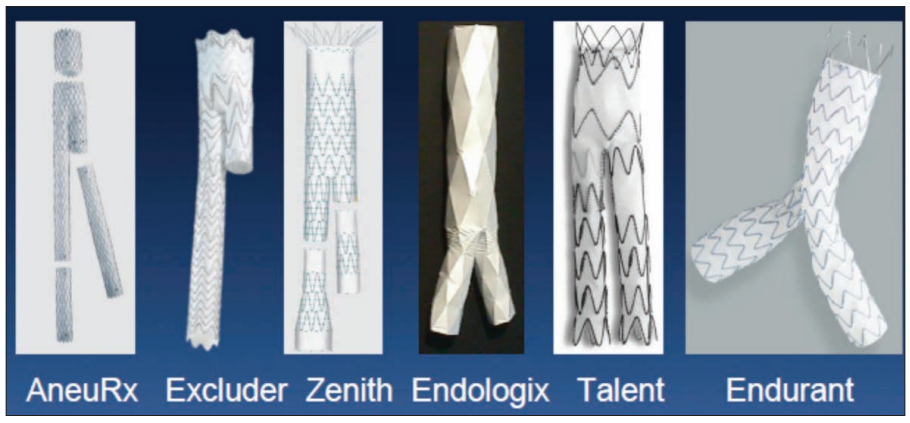

appears to perform as well as or better than open repair among patients with similar baseline characteristics, although a retrospective cohort study can never adjust for all factors. These results in older patients suggest that selection of a procedure should be based more on anatomic features (i.e., whether the patient satisfies anatomic criteria for endovascular graft placement) than on demographic or clinical features.

We can use several current generation EVAR devices with lower profile. Which have evolved dramatically from the old generation? The proportion of EVAR is getting larger; up to 70-80% of all AAAs. We are waiting for the next-generation of AAA EVAR grafts because of current limitations such as limited graft size, angulation, access vessel morphology, deployment accuracy, etc. There are evolving tools which will be used in the near future.

Even after several randomized trials, surgeons still love to perform the surgery because the priority must be open repair. After first endovascular repair of AAA in 1990, experiences have increased in many interventionists. According to the accumulating experiences, data also has been accumulating for the current evidence of recommendation. Still, surgery must be adopted as the default strategy. We can clearly hear the surgeon's view from Dr. Tae Won Kwon (Asan medical center, Seoul, Korea). According to the current trend, many interventional cardiologists want to hear hopeful news about the EVAR's role in the management of AAA. So, Dr. Young-Guk Ko (Severance Hospital, Korea) will present the real dream of EVAR, the opposite position of surgeons. Ongoing evidences from several clinical trials and development of devices and techniques of EVAR, we can clearly feel the "Big Gap between Practice and Evidence."

When patients undergo EVAR of AAA, there will be increased rates of graft related complications and reinterventions. We can anticipate several complaints after EVAR treatment such as back pain, fever, endoleak, etc. Common post-implant syndrome consists of back pain and fever in up to 50% of cases, but blood culture and antibiotics is not necessary because majority of them were usually benign. Patients who have had EVAR undergo lifelong surveillance to evaluate the presence of aneurysm expansion and endoleaks. Detection of endoleaks is essential as endoleaks are associated with aneurysm expansion and even rupture. Due to the concern of endoleak, we can classify the type according to the main mechanism of endoleak. There are five different types of endoleaks, which are classified based by the source of vessels that causes the inflow into the aneurysm sac. Type I endoleaks are leaks at the proximal or distal attachment sites. Type II endoleaks are caused by retrograde flow through collateral vessels into the aneurysm sac. Type III endoleaks are holes, defects, or separations in the stent-graft material. Type IV endoleaks represent porous graft walls. Type V endoleaks have been described as being due to endotension with an enlarging aneurysm sac without a visible endoleak. We must correct the major problem which can make an endoleak using the several methods and devices. In conclusion, endoleaks and late complications can occur, but can usually be managed effectively non-surgically. Dr. Richard R. Heuser will give a lecture for this titled "Unwelcome complication of EVAR?" After hearing this dedicated AAA session, we all hope we are "getting more advanced interventionist."

Features from ACC 2013

April 25, 11:30 AM – 12:30 PM, Coronary Arena, Level 1, Coronary Session IV

CHAMPION-PHOENIX

Cangrelor Cuts Complications of PCI vs. Clopidogrel

A randomized trial of over 11,000 patients found that intravenous cangrelor reduced the risk of periprocedural complications at all kinds of PCI compared with taking a pill of clopidogrel. It was a battle between two ADP-receptor blockers as well as between IV and oral antiplatelet therapy at coronary interventions. Cangrelor's benefit of a 22% drop in a composite efficacy end point was driven by reductions in MI and stent thrombosis and was not associated with an increase in bleeding complications. There were cautions, however. When bleeding complications were defined using other accepted criteria, some kinds of bleeding were more common with cangrelor.

STREAM Trial

First Success for Fibrinolysis Before Transport to PCI

In this trial, fibrinolysis with tenecteplase and contemporary antithrombotic therapy given before transport to a PCI-capable hospital coupled with timely coronary angiography is as effective as primary PCI in STEMI patients presenting symptom onset within three hours who cannot undergo primary PCI within one hour of first medical contact. There was a significant increase in intracranial hemorrhage (ICH) in the fibrinolysis group, which led to the dose of tenecteplase being halved in people aged 75 years and older fairly early on in the course of the trial. After which, the intracranial hemorrhage rate in the fibrinolysis group was reduced to 0.5%, which was not significantly different from the PCI group.

PARTNER A Trial

Equal Outcomes, High Mortality for Both TAVI and SAVR Arms

In the three-year results comparing transcatheter aortic-valve implantation (TAVI) with open surgical aortic-valve replacement (SAVR) in high-risk patients with severe aortic stenosis, the rates of both stroke and all-cause mortality were similar between both groups of patients. However, more than two out of five patients did not survive. In the three-year outcomes, all-cause mortality was 44.2% for TAVI and 44.8% for surgical AVR and stroke rates were 8.2% in the TAVI group and 9.3% in the surgical AVR group. Paravalvular regurgitation remained significantly different between the two groups and even patients with mild regurgitation showing higher mortality at three years.

PREVAIL Study

Watchman Device Meets Safety End Point

Preliminary data from the PREVAIL study of the Watchman device for the prevention of stroke and systemic embolism in patients with nonvalvular AF appear to give some reassurance on safety issues raised previously. The device had a 95.1% implant success rate, up from the 91% rate in PROTEC. The main safety end point including acute occurrence of death, ischemic stroke, systemic embolism, and procedure related complications requiring major cardiovascular or endovascular intervention occurred in 6 out of 269 patients (2.2%) who received the device. But the trial has been surrounded by so much controversy, with reports of end points being changed, attempts not to present all the data, and finally an embargo break by the sponsor, lead the ACC to cancel the presentation completely.

TERISA Study

A Unique Benefit of Ranolazine in Diabetic Angina?

The first prospective international randomized controlled study of 949 patients focusing specifically on angina in patients with type 2 diabetes has shown that ranolazine is an effective treatment in this patient population. Ranolazine, a selective inhibitor of the late sodium current, reduced episodes of stable angina in diabetes patients already receiving one or two antianginal drugs and led to less use of sublingual nitroglycerin. The benefits appeared more prominent in patients with higher rather than lower HbA1c levels.


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