DAILY NEWSPAPER

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

April 24

TCTAP 2013

Today's Highlights

Breakfast Meetings
(STEMI, Functional Angioplasty, CTO, In-stent restenosis, Bifurcation, TAVI and PFO with LAA)
7:00 AM – 8:10 AM

Opening and TCTAP Main Session
Main Arena, 8:30 AM – 6:00 PM

TCTAP Award 2013 "Master of the Masters"
Main Arena, 12:25 PM

Imaging and Physiology Summit
Coronary Arena, 2:00 PM – 4:30 PM

DES Summit
Coronary Arena, 4:30 PM – 6:00 PM

Endovascular Symposium, SFA & BTK
Structural Heart & Endovascular Theater,
Grand Ballroom 104, Level 1, 2:00 PM – 6:00 PM

Moderated Oral Abstract Competition
Abstract Zone I, Level 3

Moderated Complex Case Competition
Case Zone I, Level 3

Functional Angioplasty 2013

Update Our Practice for Better Outcomes

Continuous development and advances in techniques and pharmacologic treatment has improved the clinical outcomes of patients receiving percutaneous coronary intervention, during the last decades. Therefore, it is timely to now move the discussion forward on how to optimize PCI results. In this regard, Dr. Seung-Jung Park, director of TCTAP 2013, decided the generalization of functional angioplasty as the most important topic of this year. In fact, considerable number of PCIs was still performed without documentation of objective evidence of ischemia and suboptimal stent results were not frequently undertreated. However, use of FFR and IVUS during PCI procedure is ‹10%, globally. Dr. Seung-Jung Park, therefore, emphasized functional angioplasty and will present fascinating data from the ASAN PCI registry, which showed changes in practice of PCI and outcomes of patients receiving PCI after the routine incorporation of FFR in real practice. His presentation may accelerate the generalization of the concept of functional angioplasty. In addition, many new non-invasive modalities to detect coronary ischemia and new imaging techniques to evaluate the coronary atherosclerosis will be introduced and deeply discussed regarding their clinical utilities. As in other years, many educational live demonstrations will be broadcasted during TCTAP this week.

7th CTO Live 2013

April 23, 10:00 AM - 5:25 PM, CTO Theater

The 18th TCTAP 2013 started with CTO Live 2013 yesterday. The CTO Live 2013 was held successfully with more than five hundred attendees including physicians, technologists, nurses, and medical professionals. CTO Live had new sessions, case reviews and case wrap-up sessions to provoke enthusiasm and provide new knowledge of CTO-PCI. At the case review session, we discussed pre-procedural planning, appropriate technique, and the best device based on the CT angiography, angiography, and patient characteristics for success with operators. After 6 successful live demonstrations, all operators shared their experiences and explained their techniques and tips during the procedure in detail.

Exciting Transformations for TCTAP 2013

Here comes another step forward for the CardioVascular Summit TCTAP. We believe our participants are here with high expectations for learning and experiencing something new, advanced, and innovative in education, which will help have a significant impact on your path. For more than a year, the TCTAP committee has worked very hard to provide the best experience for our participants from more than 60 nations through higher levels of academic content, which can match your needs and expectations, the hospitality of our team, and other various learning opportunities including hands-on workshops and breakout sessions. Each session consists of lectures and case presentations by experts and lively interactive discussions between the panelists and the audience. As the best learning educational hub in Asia Pacific, TCTAP has encouraged physicians to present their scientific findings to a worldwide audience; as a result, 236 cases and 216 abstracts with high educational qualifications are

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Inside

Meeting Information

Registration Desk [Conference Bag & Badge Pick-up]
Location
B3, Registration
Opening Hours
- Tuesday 23, 10:00 AM – 7:00 PM
- Wednesday 24, 6:30 AM – 7:00 PM
- Thursday 25, 6:30 AM – 6:00 PM
- Friday 26, 6:30 AM – 3:00 PM

Scientific Sessions
Opening Hours
- Tuesday 23, 10:00 AM – 5:20 PM
- Wednesday 24, 8:30 AM – 6:00 PM
- Thursday 25, 8:30 AM – 6:00 PM
- Friday 26, 8:30 AM – 3:30 PM

Preview Room for Presenters
Location
2F, Room 208
Opening Hours
- Tuesday 23, 8:00 AM – 6:00 PM
- Wednesday 24, 6:00 AM – 6:00 PM
- Thursday 25, 6:00 AM – 6:00 PM
- Friday 26, 6:00 AM – 3:30 PM

Exhibition
Location
3F, Exhibition Hall
Opening Hours
- Wednesday 24, 10:00 AM – 6:00 PM
- Thursday 25, 8:30 AM – 6:00 PM
- Friday 26, 8:30 AM – 3:00 PM

Information Desk
Locations
- 3F, Main Arena
- 1F, CVRF Booth

Learning Center
Locations
- 3F, Exhibition Hall
- 2F, Room 2-3(Room no.205)

WiFi Zone
Locations
- 2F, Faculty Lounge, Preview Room
- 1F, CVRF Booth

Cyber station
Location
- 1F, CVRF Booth
- 3F, Exhibition Hall

Free Mobile Recharge
Location
- 3F, Exhibition Hall

Lost & Found /Cloak Room
Location
- 3F, Coat Room

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ready to be presented at TCTAP.
The TCTAP committee and all of organizing staff expect active sharing of new and different ideas, information, and experiences during the four days through our new changes in program contents and other elements of this meeting for this year.

ONE.
CardioVascular Summit TCTAP is one of the leading names representing interventional therapy. From Tuesday to Friday, attendees will be surrounded with an interesting, dynamic, and academic environment. The Late Breaking Clinical Trials Session, chaired by Dr. Spencer B. King III, on the second day will focus on the latest groundbreaking outcomes of several notable trials. In addition, at the Main Arena Plenary Sessions under the title of 'Review Year and Future', will introduce an understanding and the latest guidelines on LAA&PFO closure, Transcatheter Aortic Valve Implantation, Functional Angioplasty, DES, etc., as well as address the challenges facing these techniques. Also, there will be more partnership sessions with international societies and centers such as India, China, Indonesia, Malaysia, Australia, France, other European countries, and USA than ever before. The best cardiologists in each country were involved in planning the session and they will share their approach, systems, and best practices with the diverse audience.

TWO.
CardioVascular Summit TCTAP has initiated the 'Master of the Masters' Award in 2011 to recognize and acknowledge meaningful contributions to the field of cardiology medicine and to the growth of TCTAP. Dr. Masakiyo Nobuyoshi, Director of the 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 the New York Presbyterian Hospital/ Columbia University Medical Center, was recognized as the 2nd recipient of this Award in 2012. The third award recipient will be revealed on Wednesday, April 24 in the Main Auditorium. You can also enjoy the sculptures of the three winners in the CVRF booth, located on the 1st floor.

The 1st TCTAP Best Young Scientist Award ceremony will take place in the Main Auditorium on April 26 during the Late Breaking Clinical Trials session. This award is intended to acknowledge, recognize, and encourage mid-level young clinical investigators whose academic clinical research or case study can lead to the development of cardiovascular medicine. For this award, there were 67 young physicians who applied from 14 countries this year. The final recipient will receive a $5,000 scholarship and Certificate of Recognition.

There is an open studio in a round table format in the interview lounge on the 3rd floor of the venue. This interview format is where world-class practitioners get together in one place and share their own perspectives and thoughts on each specific topic.

THREE.
One of the major changes in TCTAP is the location. With expandable space and a variety of facilities, more delegates and partner participants will be able to enjoy this conference than ever before. Coex is a business and cultural hub located in the heart of Seoul's business district. It is a popular entertainment destination in Seoul for both domestic and foreign visitors and is also close to very popular areas such as Myeong-dong, Kwang-hwa-moon, and Insadong. During the day and night, attendees can enjoy both TCTAP and Seoul itself.
Again, CardioVascular Summit TCTAP 2013 will continue to change and grow.

Live Case Transmission Sites

Live case demonstration is the core of the CardioVascular Summit TCTAP 2013. It features different strategies and techniques by world first-class operators for the same type of lesions simultaneously.

International Sites

Columbia University Medical Center, New York, USA
- Main Arena, April 24(Wed.), 8:30 am-9:30 am

Clinique Pasteur, Toulouse, France
- Main Arena, April 25(Thur.), 3:00 pm-4:00 pm

MonashHeart, Monash Medical Centre, Southern Health, Melbourne,Victoria, Australia
- Main Arena, April 24(Wed.), 3:30 pm-4:30 pm

Korean Sites

Asan Medical Center, Seoul
- CTO Theater, April 23(Tues.), 10:50 am-12:10 pm/1:10 pm-2:30 pm/3:00 pm-4:20 pm
- Main Theater, April 24(Wed.), 2:00 pm-3:15 pm/5:00 pm-6:00 pm
  April 25(Thurs.), 8:30 am-9:30 am/10:30 am-11:30 am/ 11:30 am-12:30 pm/2:00 pm-3:00 pm/4:30 pm-5:30 pm
- Structural Heart & Endovascular Theater,
  April 24(Wed.), 3:00 pm-4:00 pm/5:00 pm-6:00 pm
  April 25(Thurs.), 9:30 am-10:30 am/11:30 am-12:30 pm/3:30 pm-4:30 pm

Imaging and Physiology Summit

Paradigm Shift to FFR Guided and IVUS Supported PCI

April 24, 3:30 PM - 6:00 PM, Coronary Arena

This year, the Imaging and Physiology Summit will extensively cover the current concept of anatomic and functional evaluation for coronary atherosclerosis. During the last years, Dr. Seung-Jung Park and his colleagues have led a paradigm shift to functional angioplasty though TCTAP. In this context, in this year, Imaging and Physiology Summit will focus more on the practical approaches and the impact of functional angioplasty on outcome in real world patients.

IVUS and FFR comparison is still an issue. Dr. Ron Waksman (Washington Hospital Center, USA) will present the result of the F1RST trial, which was published recently. In this trial, he enrolled 350 patients at 10 U.S. and European sites who received the IVUS and FFR evaluation simultaneously. The results showed that overall, an MLA ‹3.07 mm (64.0% sensitivity, 64.9% specificity, area under curve [AUC]=0.65) was the best threshold value for identifying FFR ‹0.8. The accuracy improved when reference vessel-specific analyses were performed. An MLA ‹2.4 mm (AUC=0.66) was best for reference vessel diameters ‹3.0 mm, an MLA ‹2.7 mm (AUC=0.71) for reference vessel diameters of 3.0 to 3.5 mm, and an MLA ‹3.6 mm (AUC=0.68) for reference vessel diameters ›3.5 mm. FFR correlated with plaque burden, but not with other plaque morphology. Anatomic measurements by IVUS showed a moderate correlation with the FFR values. These results were quite similar to Dr. Seung-Jung Park and his colleague's previous work. In this study, they demonstrated that optimal cut-off value of IVUS derived MLA corresponding to FFR 0.80 was defined as 2.4 mm^2. In addition, they demonstrated the inaccuracy of IVUS guided decision making in revascularization. They addressed these issues in 201 patients with 236 coronary lesions who underwent pre-interventional IVUS and FFR measurements to determine the best IVUS MLA criteria corresponding to FFR ‹0.80. Multivariate analysis showed that MLA (β=0.020, 95% CI=0.008-0.031, p=0.032), plaque burden (β=-0.002, 95% CI=-0.003~ -0.001, p=0.001), lesion length with a lumen area ‹3 mm^2 of MLA (β=-0.003, 95% CI=-0.005~-0.001, p=0.005), and left anterior descending artery location (β=-0.035, 95% CI=-0.055~-0.016, p=0.001) were independent predictors of FFR ‹0.80. In addition, using ROC analysis, we provided new IVUS MLA criteria showing that the best cut-off value of IVUS MLA for predicting FFR ‹0.80 was 2.4 mm^2, a figure smaller than previously reported.

This year, Dr. Seung-Jung Park will present the predictors for functional severity of the left main coronary artery stenosis. MLA criteria for FFR of 0.80 in isolated LMCA stenosis was defined as 4.5 mm^2, which was smaller than the conventional 6 mm^2. In addition, several factors to predict the functional significance of LMCA disease will be presented (Figure 1, 2). In addition, Dr. Gary Mintz will present clinical utility of IVUS and FFR. IVUS has 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 drug-eluting stent era, IVUS-guided PCI is associated with a lower rate of adverse clinical outcomes in left main or bifurcation stenoses. In the 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. Similar findings were also observed in bifurcation PCI. 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. In addition, Dr. William F. Fearon (Stanford University Medicine Center, USA) will present clinical evidences to show the benefit of FFR guided PCI based on the currently available data. Finally, Dr. Jung-Min Ahn will present the changes in practice and outcomes of PCI after the routine incorporation of FFR (Figure 3).

In this session, many panels will do in-depth discussions for the clinical application of FFR and IVUS in patients with coronary stenosis. Physicians should consider the FFR and IVUS as complementary, not competitively and the simultaneous utilization of two modalities may result in optimal stenting and may indicate the future direction of interventional cardiology.

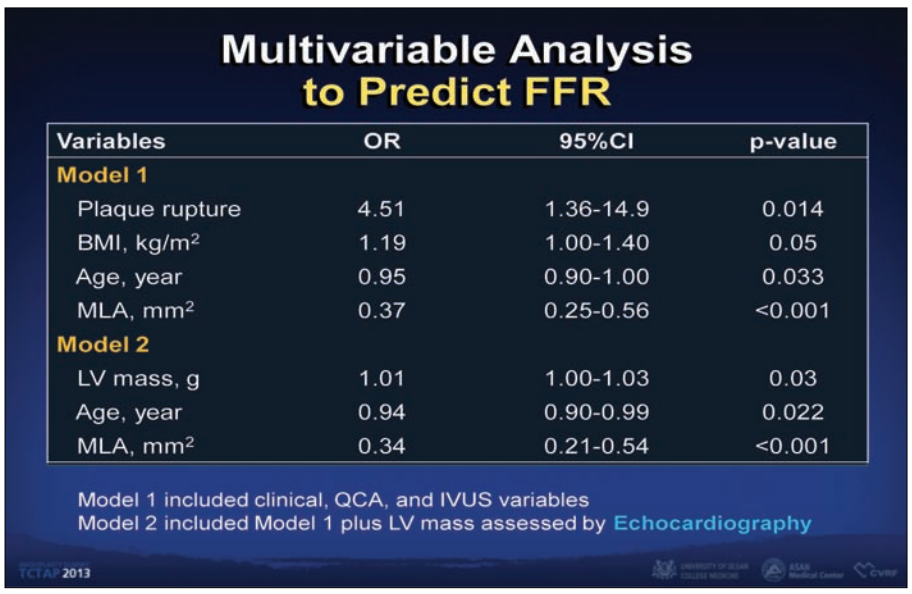

Figure 1. Predictors of FFR 0.80 in isolated LMCA stenosis

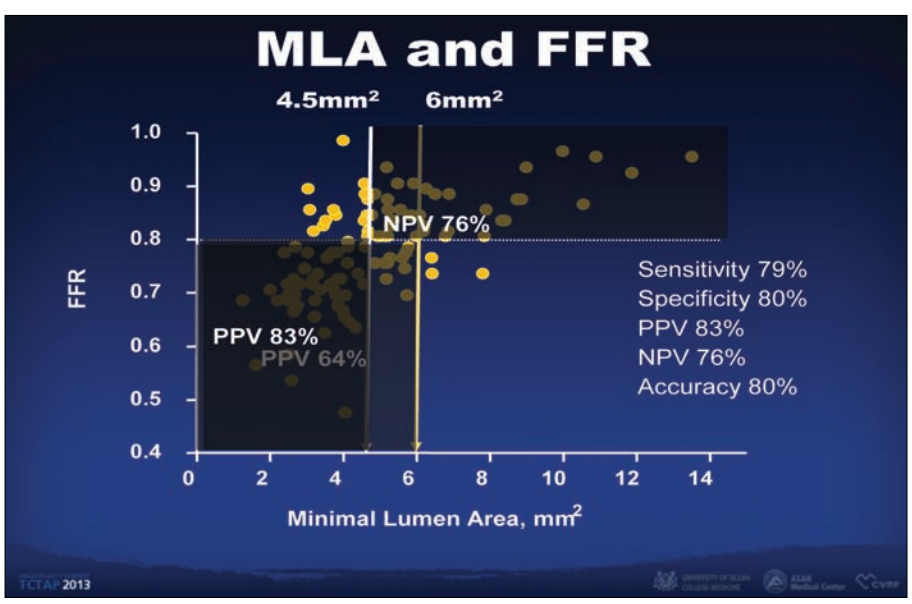

Figure 2. IVUS derived MLA and FFR cut-off value: 4.5 mm^2 is enough

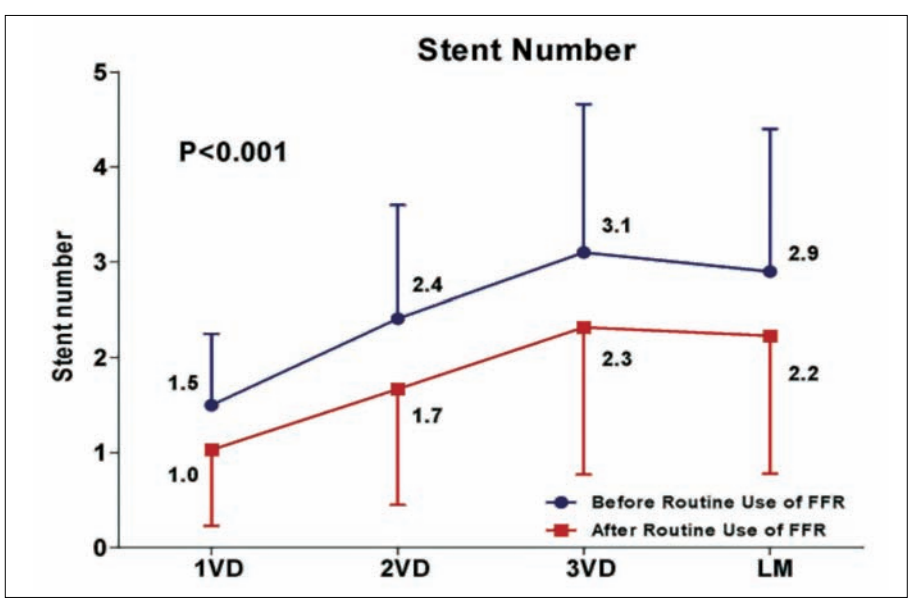

Figure 3. Stent Number was significantly decreased after the routine incorporation of FFR in daily practice

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Beyond the Framingham Risk Score

Cardiovascular disease remains the leading cause of morbidity and mortality throughout the world. A large proportion of patients who develop sudden cardiac death or nonfatal myocardial infarction do not experience prior symptoms; indeed, as many as 50% of myocardial infarctions occur in persons without a known history of symptomatic coronary artery disease (CAD). Therefore, it is important to identify individuals at risk of coronary events before they develop clinical symptoms. To assess the cardiovascular risk in healthy individuals, most clinicians use a combination of traditional risk factors. Of the various risk estimation systems that are available, the Framingham Risk Score (FRS) is the system that is most commonly used to predict 10 year cardiovascular risk. This system is based on history and clinical and laboratory measurements. Although it is used as the gold standard for evaluating screening techniques, it fails to identify many people who are destined to have a coronary event. Therefore, noninvasive imaging tests such as coronary artery calcium (CAC) scoring and coronary computed tomography angiography (CCTA) have been evaluated for their ability to screen for CAD. It has been shown that CAC scoring can predict coronary events better than FRS, with subjects with severe CAC (≥300 or 400) having the greatest risk. CCTA is also considered to be a very accurate diagnostic tool for detecting obstructive CAD. Several recent guidelines have recommended that CAC scoring should only be used to estimate the cardiovascular risk of the intermediate risk population (defined as an FRS-estimated 10 year risk of between 10% and 20%). Several guidelines also consider CCTA for diagnosing CAD in asymptomatic populations, but none of these guidelines actually recommend the use of CCTA for screening. Actually, the Framingham risk estimate is often invoked as a gatekeeper for imaging techniques, such as CAC scoring and CCTA. Recent data from the Multi-Ethnic Study of Atherosclerosis (MESA) suggest that the yield of screening for advanced CAC burden (CAC ≥300) is higher in the low to intermediate risk individuals (FRS of 5.1–20.0%). Additionally, it has been suggested that if subjects classified as low risk in the FRS system are excluded from further screening, about two-thirds of women and a quarter of men with substantial atherosclerosis will be missed. However, the relationships between FRS and CAC and CCTA-detected CAD remain poorly understood.

According to recent studies, the 10 year FRS estimate is of limited usefulness as a screening modality for coronary atherosclerosis in an asymptomatic population because approximately half of individuals with CCTA-detected occult CAD were misclassified into very low and low risk groups on the basis of FRS. Moreover, almost all women, including those with CAD, were classified into these groups and therefore, FRS did not associate independently with the presence of CAD. By contrast, CAC scoring associated significantly with occult CAD in both men and women. The yield of screening for significant CAC scoring and occult CAD was low in the very low risk population, but rose in the low and intermediate risk subjects. Therefore, CAC scoring or CCTA may be useful screening tools for identifying subjects with occult CAD in the low and intermediate risk populations.

Coronary Plaque Imaging by Coronary Computed Tomography Angiography

Coronary CTA has excellent diagnostic accuracy for the detection of coronary plaques against intravascular ultrasound (IVUS) as a reference standard, with an area under the curve for receiver operating characteristic analysis of 0.94 (95% confidence intervals [CI]: 0.92 to 0.96), a sensitivity of 0.90 (95% CI: 0.83 to 0.94), and a specificity of 0.92 (95% CI: 0.90 to 0.93) in a recent meta-analysis (Figure 1, 2). A simple, qualitative plaque characterization scheme has been used for clinical reporting of plaque types on contrast enhanced CCTA. The reproducibility of this qualitative assessment has been shown to be good with both intraobserver and interobserver agreement in excess of 0.88. CCTA showed good reproducibility, mostly for noncalcified lesions and best reproducibility in the left anterior descending artery. For plaque characterization, it has been shown that CCTA-derived attenuation values are different in calcified and noncalcified plaques. Low-density noncal-

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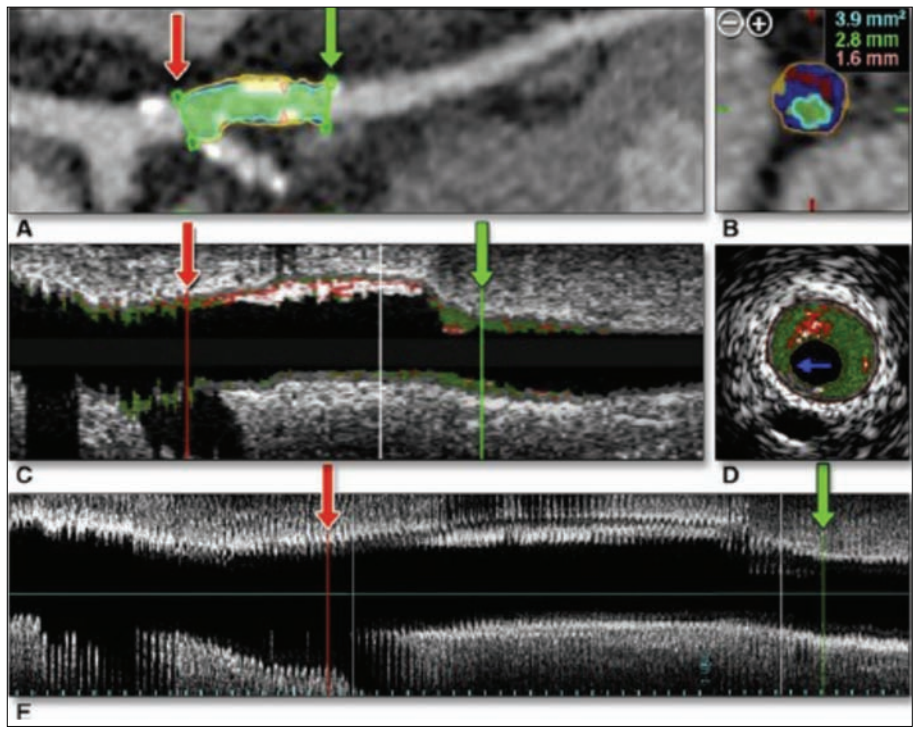

Figure 1. Spatially coregistered coronary CTA and IVUS/VH

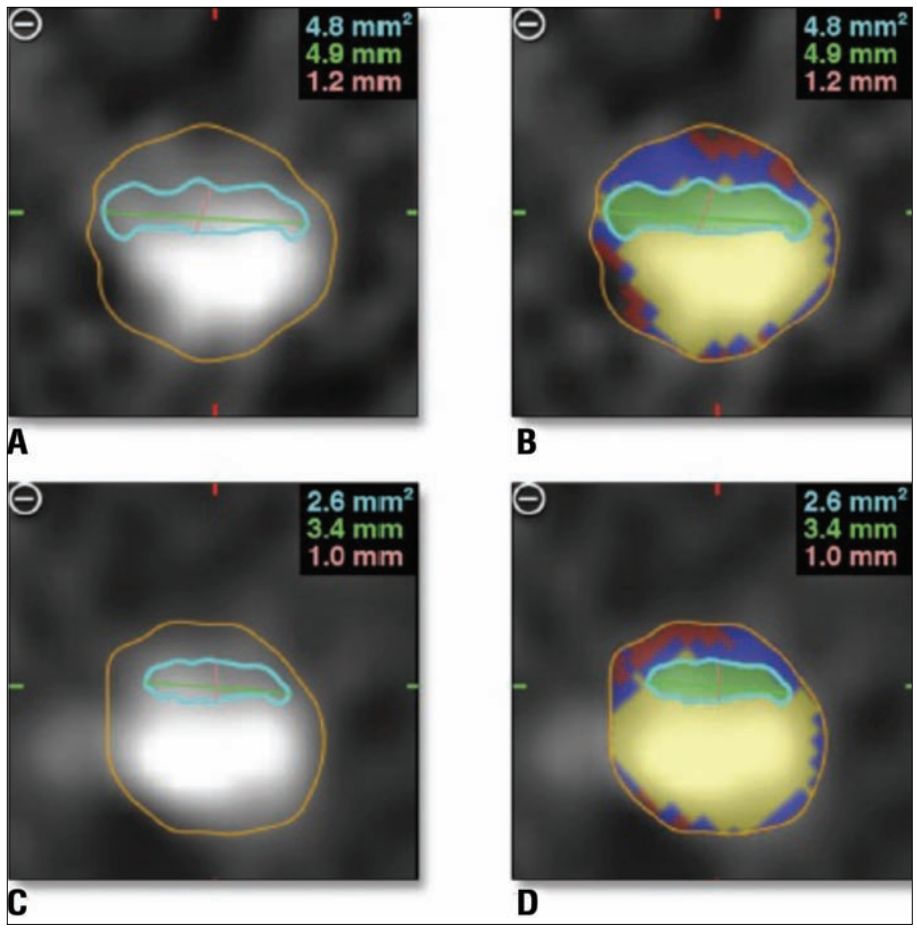

Figure 2. Quantative measurement of coronary plaque progression by coronary CTA, similar to VH

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cified plaques, the presumed lipid rich plaques on CCTA, correlated best with the sum of necrotic core plus fibro-fatty tissue by IVUS/VH (virtual histology). Plaque burden by CTA correlated well with cholesterol deposition by near-infrared spectroscopy (NIRS). Similarly, noncalcified plaques, as well as low and high-density noncalcified plaques, also correlated well with cholesterol on NIRS. For acute coronary syndrome (ACS), several small studies consistently showed that culprit lesions in ACS had a higher proportion of positive remodeling and higher remodeling index. In a large study, retrospective study that culprit lesions of ACS had a higher proportion of positive remodeling (87% vs. 12%; p ‹0.0001), more frequently had components with attenuation values below 30 HU (79% vs. 9%; p ‹0.0001), and typically had "spotty" calcification. They later confirmed in a prospective trial that lesions that would cause ACS during further follow-up had a larger remodeling index, total plaque volume, and low-attenuation plaque volume at baseline. A recent important study showed that CT-derived plaque type had important predictive value, demonstrating that mortality incrementally increased from calcified plaque (1.4%) to partially calcified plaque (3.3%) to noncalcified plaque (9.6%). Accurate detection of coronary atherosclerotic plaques by CT remains difficult, but can be performed with modern equipment after careful patient selection and with sufficient expertise. Attempts at plaque quantification and characterization have been successful, but further refinements regarding reproducibility, accuracy, and ability to predict future events are required. With further improvements in hardware and software, contrast enhanced coronary CCTA may become part of the armamentarium in the quest for the detection of the "vulnerable plaque" and the "vulnerable patient" so that appropriate preventive measures can be instituted in a targeted fashion, at least partially based on the findings of coronary CCTA.

Beyond the Luminology: CT-FFR and Perfusion CT

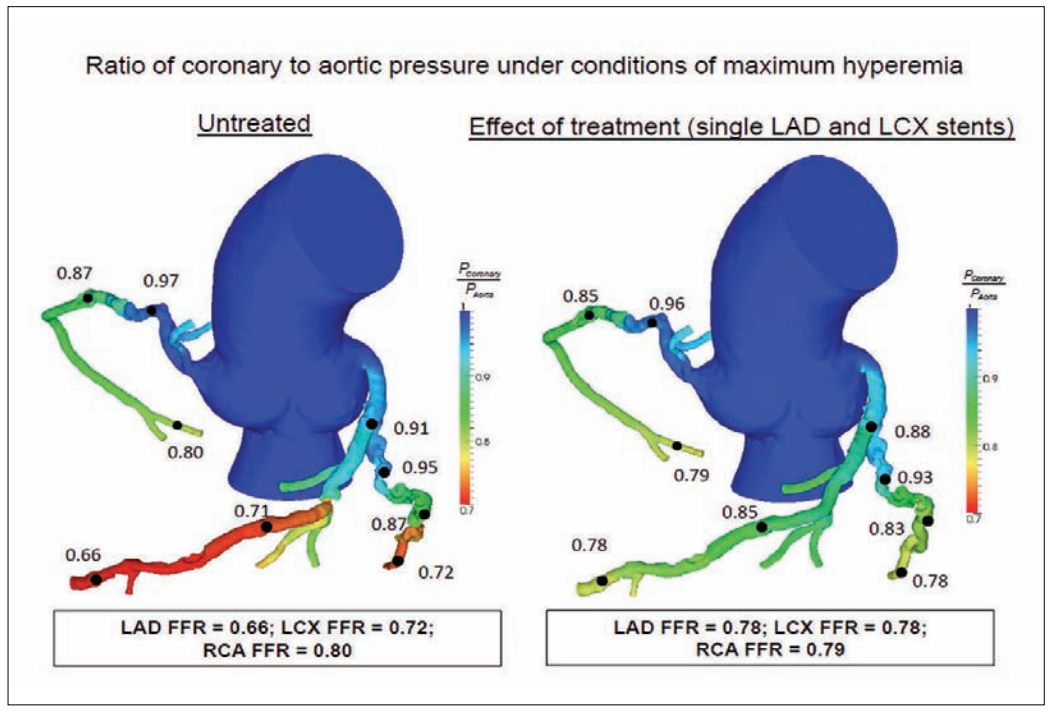

Figure 3. Computed FFR using CCTA in baseline and post-stenting

While CCTA demonstrates good diagnostic performance for detection and exclusion of anatomic coronary artery stenoses, numerous prior studies have revealed an unreliable relationship between detection of obstructive anatomic coronary artery stenoses detected by CCTA and hemodynamically (HD)-significant coronary artery disease (CAD), as detected by reduced myocardial perfusion or coronary blood flow by myocardial perfusion SPECT or fractional flow reserve (FFR), respectively. Measurement of FFR during invasive cardiac catheterization represents the 'gold standard' for assessing of the hemodynamic significance of coronary artery lesions by determining of the integrity of blood flow proximal and distal to the coronary stenoses. HeartFlow, Inc. ('HeartFlow') has developed a non-invasive method to compute FFR (cFFR) from patient-specific CCTA data using computational fluid dynamics under rest and simulated maximal coronary hyperemic conditions (Figure 3). Preliminary results in patients suggest that non-invasive cFFR accurately predicts the hemodynamic significance of coronary lesions when compared to directly-measured FFR during cardiac catheterization. According to the DeFACTO trial, the diagnostic accuracy of cFFR from CCTA was 73% with sensitivity 90%, specificity 54%, positive predictive value 67%, and negative predictive value 84%. Although the study did not achieve its prespecified primary outcome goal for the level of per-patient diagnostic accuracy, use of noninvasive cFFR plus CT among stable patients with suspected or known CAD was associated with improved diagnostic accuracy and discrimination vs. CT alone for the diagnosis of hemodynamically significant CAD. FFR determined at the time of intracoronary FFR was the reference standard. Further confirmatory results, the multicenter, international, prospective study still enrolls patients worldwide.

Recent developments in CT technology that would allow for prospective gating during 64-row CT or for complete myocardial imaging during 1 gantry rotation have created the possibility of reducing radiation exposure enough to enable the performance of combined angiography and myocardial perfusion assessment at rest and during stress. It is feasible to perform both studies with current techniques and a total of 8 to 10 millisieverts. Moreover, if the coronary angiogram provides the complete diagnostic picture, the cardiologist could elect not to perform a perfusion study. Based on current studies of patients with suspected coronary artery disease, we estimate that perfusion imaging would be required in only 25% to 30% of cases, depending on the type of population being studied. Such techniques would be ideal for the assessment patients with chest pain and history of advanced disease, and those who are expected to have calcified coronaries or previously placed coronary stents. It is possible that the addition of perfusion information to the angiographic study would increase the test sensitivity to flow-limiting lesions and facilitate the indication for revascularization procedures even for patients without extensively calcified arteries or coronary stents, based on the combination of anatomic plus functional information. Considering the fast pace of progression of MDCT technology, it is reasonable to speculate that, indeed, the future may be closer than previously anticipated.

No Barrier to Open in CTO

Toshiya Mramatsu (Saiseikai Yokohama-City Eastern Hospital, Japan) made a lecture regarding appropriate techniques for CTO success. He suggested dedicated CTO techniques including single wire technique, double wire technique, IVUS-guide technique, retrograde technique, etc. Appropriate use of them was very important to CTO success, but there has been no clear guideline which techniques are the best for each case. Therefore, application of best techniques in each case is dependent on operator experience and expertise. If CTO lesion had abundant collateral for retrograde approach and no stump to access or failed PCI with antegrade approach, retrograde approach should be considered first. Moreover, the expert lecture session gave excellent knowledge from basics to practice. Dr. Gaku Nakazawa (Tokai University School of Medicine, Japan) made a presentation regarding histopathologic insight of CTO segment. He presented that CTO contained microvasculatures to negotiate with tapered tip wires. Thereby, slow advance of soft tapered tip wire could be able to find the distal true lumen. In addition, Dr. Seung-Whan Lee presented long-term outcomes of the Asan Medical Center CTO registry data of about 400 patients receiving PCI vs. optimal medical treatment. He suggested that optimal medical treatment was as effective as PCI based on the 7-year clinical outcomes of death, MI, and Q-MI. Therefore, the on-going randomized trial of DECISION-CTO (n=1,300) would be a landmark trial to decide treatment strategy in CTO.

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Use in volume-depleted patients(e.g., those treated with diuretics) : Symptomatic hypotension may occur. These conditions should be corrected prior to administration of **COZAAR XQ**

CONTRAINDICATIONS : 1) Patient with known history of sensitivity to active ingredients or dihydropyridines. 2)Pregnancy or possible to be pregnant, nursing mothers (See 7. USE IN PREGNANCY/LACTATION) 3) Severe hepatic impairment 4) Severe aortic valvular stenosis 5) Patient in shock

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| PRODUCT NAME | **COZAAR XQ** Tablet 5/50 mg, **COZAAR XQ** Tablet 5/100 mg. **| INDICATIONS |** 1. Essential hypertensive patients for not adequately controlled with amlodipine or losartan monotherapy. 2. Initial therapy in stage 2 hypertension patients who need combination therapy to achieve their therapeutic blood pressure goals **| Dosage and Administration |** The recommended dose of COZAAR XQ is once daily, administered with water, with or without food. Administrating with regular schedule (i.e. every morning) is recommended. Dosage adjustment with each active ingredient (amlodipine or losartan) is recommended prior to start administrating COZAAR XQ, but initial switching to COZAAR XQ can be considered in case that blood pressure is not controlled by monotherapy of each ingredient as described below/ -5/50 mg : Administer to the patients whose blood pressure is not adequately controlled with amlodipine 5mg or losartan 50 mg monotherapy. -5/100 mg: Administer to the patients whose blood pressure is not adequately controlled with amlodipine 5mg or losartan 100 mg monotherapy. A patient co-administered with amlodipine and losartan, may be switched to COZAAR XQ (fixed dose combination containing same dose of each ingredient) for compliance improvement. **| SPECIAL CAUTIONS |** 1) Volume-depleted patients (e.g., those treated with diuretics) 2) Patients having strictly limited salt diet 3) Patients with moderate to severe renal impairment (i.e. creatinine clearance < 20 ml/min) or patients on dialysis 4) Patients with hyperkalaemia **| ADVERSE REACTIONS |** Adverse reactions evaluated in 3 clinical trials with essential hypertension patients and 1 clinical trial with stage 2 hypertension patients for 8 weeks were common (≥1/100, <1/10): dizziness, headache/uncommon (≥1/1,000, <1/100): Somnolence, Cerebral infarction, Asthenia, Chest discomfort, Chest pain, Early satiety, Oedema peripheral, Pitting oedema, Abdominal discomfort, Dyspepsia, Nausea, Reflux oesophagitis, Pruritus generalized, Urticaria generalized, Palpitation, Flushing, Orthostatic hypotension, Dyspnoea, Cough, Vertigo, Ocular hyperaemia, Pollakiuria. **| USE IN PREGNANCY/LACTATION |** Losartan should not be used in pregnancy, and if pregnancy is detected losartan should be discontinued as soon as possible. COZAAR XQ should not be administered to the nursing mother. **| PEDIATRIC USE |** Since safety and efficacy of COZAAR XQ in children ≤ 18 years of age has not been established, administration of COZAAR XQ is not recommended. **• Updated label was approved as of Mar. 2012. ※ Before prescribing, please consult the full circular for complete and comprehensive information.**

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

FFR at CathLab Today: Getting Closer, But Gaps Remain

Revascularization of coronary artery stenosis should be based on the objective evidence of ischemia. It is common practice for physicians to make decisions on revascularization in the cardiac catheterization laboratory based on the results of angiography, despite the fact that angiographic information does not correlate well with the functional significance of a coronary lesion. Fractional flow reserve (FFR) is a physiologic parameter which can be measured easily during the invasive procedure and can assess the functional significance of coronary stenosis. FFR-guided revascularization strategy is reported to be better than angiography-guided strategy in patients with coronary artery disease in terms of both efficacy and cost. Recently reported FAME I study proved the benefit of FFR-guided drug-eluting stent (DES) implantation over angiography-guided revascularization. Moreover, FAME II study showed that the FFR-guided revascularization reduced the need of urgent revascularization in patients with functionally significant stenosis compared to optimal medical treatment. Therefore, these evidences should translate into a big surge in the use of FFR in real world practice. Dr. Bon-Kwon Koo will present the current status of FFR in Korea. The use of FFR has been rapidly increasing in recent years (Figure 1). In both Korea and Japan, the use of FFR has increased by more than 4 times in 2012 than in 2009. However, there still remain some gaps between ideals and reality. In our institution, the rate of FFR penetration among all patients who underwent coronary angiography has been stable in recent years. It was 6.3%, 8.3%, and 7.5% in year 2009, 2011, and 2012, respectively. Total number of FFR use in China is less than 20% of that in Japan. What can be the causes of this gap? The first and main cause of that gap or the obstacle for the general use of FFR may be the cost of the pressure wire. The pressure wire is still not reimbursed in many countries. Due to reimbursement, the use of FFR has increased dramatically in Japan. As the reimbursement will soon begin in Korea, the use of FFR in daily practice is expected to rapidly increase this year. The cost benefit as well as efficacy of FFR has been proven through several studies; the reimbursement policy will soon change in most countries. The second cause may be the misunderstanding by physicians that FFR can be used only in intermediate stenosis. However, FFR can be used in almost all lesions such as multiple lesions, multi-vessel lesions, left main lesions, and bifurcation lesions. Furthermore, 20% were functionally insignificant even in lesions with severe stenosis in the FAME study. Third, some physicians believe that the use of an additional imaging device such as IVUS or OCT is good enough before deciding on stent implantation. However, several recent studies showed the inaccuracy of anatomic criteria for defining the presence of ischemia causing stenosis. Minor issue may be the handling difficulty of the pressure wire and the burden of hyperemia for FFR measurement. However, this will not be an issue as the profile of the pressure wire is getting better and more convenient ways of hyperemia were developed in recent years.

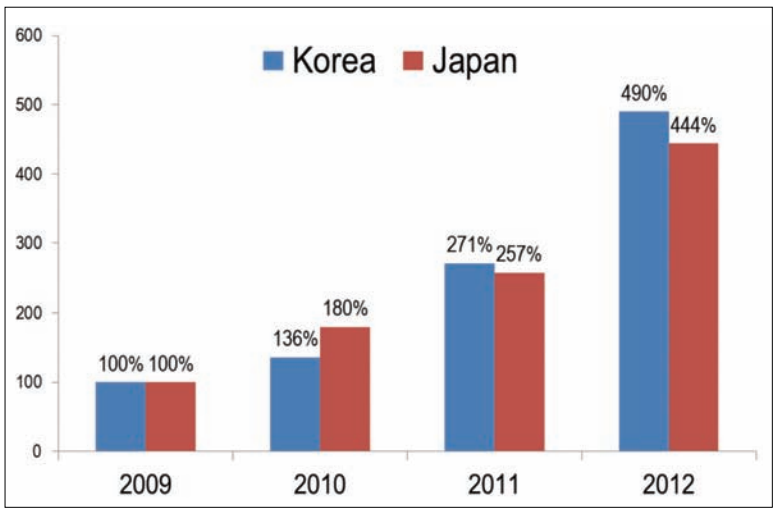

Figure 1. Recent increase in use of FFR compared to year 2009

In conclusion, FFR has enough data supporting its routine use in daily practice to improve outcomes of patients and save cost. The remaining gap between the ideals and real world practice needs should be filled soon.

PFO - To Close, or Not to Close - What is the Evidence?

Dr. Bernhard Meier (Swiss Cardiovascular Center Bern, Switzerland) will present a randomized trial of PFO closure for the prevention of recurrent stoke and valuable commence to PFO closure. The evidence base for PFO closure for prevention of recurrent stoke remains controversial despite a large evidence base. There are four types of evidence: clinical observations and associations, registries, meta-analyses, and randomized trials. The weight of evidence has clearly convinced some that all PFOs should be closed and at the other extreme, left doubt especially in the neurology community that any PFOs should be closed.

It is clear from many observations that thrombus from the venous circulation can enter the PFO tunnel on the right atrial side and cross to the left atrium and then the systemic circulation to cause stroke or systemic embolization. Thrombotic casts from the pelvic or lower extremity venous circulation have been seen both at autopsy and in echo images as they lodge within or travel across the PFO. These observations led to the examination of the frequency of PFO among patients with otherwise unexplained or cryptogenic stroke. While the frequency of PFO is 15-20% in the general population, it is 40-60% among patients with cryptogenic stroke.

Several single center registries have shown that the rate of recurrent stroke in the year after PFO closure is less than the stroke rate in the year preceding closure. The estimated absolute risk reduction is in the range of 3-4%, decreased from 7-8% in the year prior to closure compared with 3-4% for the year after. Meta-analyses of these trials show a relative risk reduction for recurrent stroke or TIA ranging from 39% to 75%. Important criticisms of these registries include the uncertainty of retrospective data collection, non-uniformity of the use of imaging to diagnose stroke, and the inclusion of patients with TIA who may not have real embolic disease.

Three randomized trials have been reported. The Closure-1 trial missed the endpoint by far. It was done with a device that is no longer in use. It included patients with clinically defined (not imaging-confirmed) TIAs, which may not actually be embolic or related to stroke. Recent studies have shown that MRI-negative TIAs are associated with an extremely low risk of subsequent stroke. The majority of the stroke endpoint events during follow-up appeared to have a determinable origin, suggesting that these patients likely had alternative explanations for their index stroke. Nearly half of the stroke endpoint events in the PFO closure arm appeared to be directly related to the device and a quarter of these occurred in the first 30 days after implantation. Device-related complications included new atrial fibrillation (5.7%) and device thrombus (4 cases and 2 cases lead to a subsequent stroke) associated with recurrent events. Also, medical therapy differed between PFO closure and control arm.

The recently reported, randomized RESPECT trial is also negative when the intention to treat principle is considered. The primary endpoint was a composite of recurrence of non-fatal stroke, fatal ischemic stroke, or all-cause mortality within 45 days of randomization, and there were over 2 years of mean follow-up. A higher number of patients dropped out in the control arm (90 vs. just 48 in the device cohort), so the intention to treat analysis was deemed invalid and a number of pre-specified alternative analyses were conducted, which showed a significant advantage for device closure compared to medical therapy. A smaller third randomized trial, the PC trial, had an unclear result due to a relatively small number of patients in the trial, with a 37% relative risk reduction on the composite endpoint compared to medical management (p=0.34) with stroke reduced 80% (p=0.14), but without statistical signifi-

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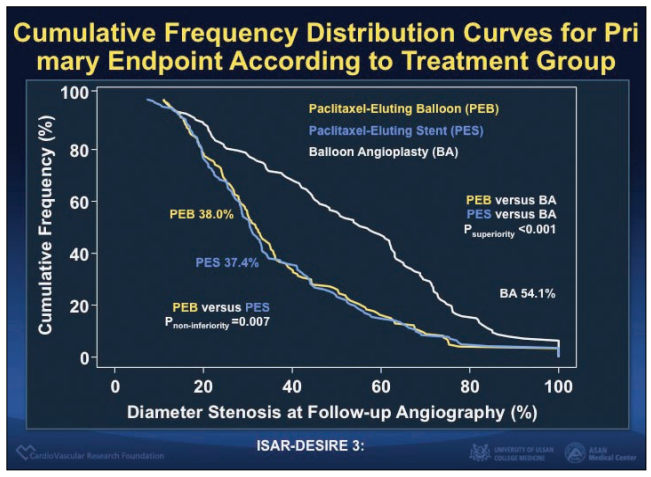
cance.

With this level of evidence, including clinical observations and associations, registries, meta-analyses, and randomized trials, is there any doubt regarding the utility of device closure for PFO after prior cryptogenic stroke? The randomized trials do not paint a consistent picture. The only trial that had a positive result, the RESPECT trial, was negative using an intention to treat analysis, and had only 25 of 980 patients with stroke events during a follow-up period of over seven years. The small number of events limited the potential for the trial to have a more clearly positive result.

What is the essence of the debate given this body of evidence? Predicting the patient who will benefit from PFO closure remains a challenge. Because so many patients have an incidental PFO, recognizing those in whom it is related to stroke has eluded us. Stated another way, how many patients with PFO are we willing to undergo device closure to prevent a stroke? If PFO closure were completely safe this would be less debatable. The population we are treating has a mean age in the mid-40s, and will thus live with a permanent implant for many years. The debate will become less polarized as further evidence is developed. The ongoing randomized REDUCE and CLOSE trials will be helpful and may be the last randomized trials in this field.

ISAR-DESIRE3 DEB, Desirable Option for ISR

In patients presenting with limus-DES restenosis, treatment with a paclitaxel-eluting balloon is noninferior to repeat stenting with a paclitaxel-eluting stent (PES), and both are superior to balloon angioplasty alone, according to results of a multicenter study that will be presented in the BF meeting on Wednesday. For the ISAR-DESIRE 3 (Intracoronary Stenting and angiographic Results: Drug eluting Stents for In-Stent Restenosis: 3 Treatment Approaches) trial, patients were randomized to treatment with a paclitaxel-eluting balloon, paclitaxel-eluting stent, or balloon angioplasty alone. By eight months, the paclitaxel-eluting balloon showed nonin-feriority compared with PES, and both showed superiority over balloon angioplasty alone for the primary endpoint of mean diameter stenosis. At one year, binary restenosis was less common with paclitaxel-eluting balloons and PES than with angioplasty (p <0.001 for both). TLR rates showed a similar pattern, with fewer paclitaxel-eluting balloon and PES patients requiring repeat revascularization than patients treated with angioplasty alone (p <0.001 for both). There was no difference between the paclitaxel-eluting balloon and PES in binary restenosis (p=0.61) or TLR (p=0.09) rates. Also, there were no differences among the treatment groups in rates of death or MI and target lesion thrombosis.



5th Chien Foundation Award

Dr. Shigeru Saito was selected for the 5th Chien Foundation Award for Outstanding Lectureship & Lifetime Achievement in PCI at TCTAP 2013.

The presentation of this honored award took place on April 23 (Tue.) at the CTO Theater, Grand Ballroom 103, Level 1, COEX at 5.20 pm.

Dr. Saito is the Director of Cardiology & Catheterization Laboratories at Shonan Kamakura General Hospital, as well as the Director of Heart Center at Sapporo Higashi Tokushukai Hospital.

He is one of the leading supporters for transradial coronary intervention (TRI) in the world and serves as President of NPO International TRI Network. He is also one of the pioneering physicians who started to use primary stenting in patients with acute myocardial infarction and serves on the editorial boards of Catheterization and Cardiovascular Interventions, Journal of Invasive Cardiology, and the International Journal of Cardiology.

DES Summit: Current and Future

April 24, 4:30 PM - 6:00 PM, Coronary Arena

Drug-eluting stents (DES) consist of a standard metallic stent, a polymer coating, and an anti-restenotic drug (e.g., sirolimus or a derivative of sirolimus or paclitaxel) that is mixed within the polymer and is released over a period as short as days to as long as one year after implantation to reduce the local proliferative healing response. Although, the first generation DES has significantly reduced rates of restenosis compared to bare metal stents (BMS), an increased risk of late stent thrombosis has emerged as a major concern.

The "Current and Future of DES" session will be held with several honorable presenters on April 24 from 4:30 - 6:00 PM.

Today: Pooled Data

First Dr. Gaku Nakazawa (Tokai University School of Medicine, Japan) will make a presentation about "Pathology Insights of DES from Human Specimens" and after, Dr. Alan C. Yeung (Stanford University Medical Center, USA) will make presentations about the efficacy and safety of Promus Element Stent, Endeavor Resolute Stent, and Xience-V Stent, respectively.

Pathologic studies of patients dying from late stent thrombosis demonstrate delayed arterial healing characterized by persistent fibrin deposition and poor endothelialization as the primary substrate. However, recent thorough investigations revealed additional mechanisms of stent thrombosis such as hypersensitivity reaction, excessive fibrin deposit with malapposition, or neoatherosclerosis, which are associated with device specific components and the majority of very late stent thrombosis is likely associated with these abnormal vascular response. Therefore, although the incidence of stent thrombosis following DES implantation is similar in each period, the underlying mechanisms of this complication may vary. Nonetheless, the second or later generation DESs likely show better safety profiles with thinner stent strut, better drug dose, and higher biocompatibility polymer.

The PLATINUM study randomized 1,530 patients to receive the new Promus Element vs. the previous Promus/Xience V with a non-inferiority design in clinical end points. One-year outcomes confirmed the feasibility of transferring the drug and polymer to the new ELEMENT platform by showing similar combined event (target lesion failure) rates: 3.5% for Promus Element and 3.2% for Promus/Xience V (p non-inf.=0.0009 / p sup.=0.72). Two-year outcomes of this study were shown in the recent ACC 2012 meeting; not only did the Promus Element continue to prove to be non-inferior to Promus/Xience V, but also the need for reintervention was considerably lower (higher efficacy) between the first and the second year with the use of the Promus Element as compared to its predecessor Promus/Xience V (0.7 vs. 2.2% respectively, p=0.02). Two-year safety clinical endpoints did not show any significant differences between both DES, but were less with the use of the Promus Element (though this difference was not statistically significant): cardiac death 0.9 vs. 1.6% (p=0.33), acute MI 1.6 vs. 2.2% (p=0.54), and stent thrombosis (ARC definite/probable) 0.5 vs. 0.7% (p=0.99), which removes doubts regarding any possible clinical impact related to the assumed longitudinal deformation of the ELEMENT platform observed only in in-vitro studies and in sporadic case reports.

In 3-year results from RESOLUTE All Comers, a randomized controlled trial comparing the Resolute to the Xience V, the rates of target lesion failure remain equivalent for the two devices: 13.1% for Resolute and 12.4% for Xience V (p=0.614). Additionally, the rates of definite/probable stent thrombosis at three years were low, with no statistically significant difference. Rates of definite/probable very late stent thrombosis were the same for the two devices (0.5% vs. 0.5%, p=1.00). RESOLUTE US enrolled 1,402 patients across 128 U.S.-based clinical trial sites. At one year of follow-up in RESOLUTE US, the results included low rates of target lesion failure (4.7%), clinically-driven target lesion revascularization (2.8%), and definite/probable stent thrombosis (0.1%). These results were achieved despite 34 percent of the patients in the study having diabetes, which typically drives higher event rates.

XIENCE V USA is a prospective, multicenter, single-arm, FDA required condition of approval study designed to examine the performance of Xience V in a real-world all-comer population. The safety and effectiveness of Xience V in real world have been demonstrated previously with low rates of target lesion revascularization, cardiac death, MI, and stent thrombosis at both 1 and 2 years. A total of 5,020 patients (1,871 [37%] standard risk and 3,149 [63%] extended risk) were included in the long term follow-up cohort of the study. All clinical endpoint events were adjudicated independently by the Clinical Events Committee. About 93% of patients remained in the study at 3 years. The overall very late stent thrombosis between 1 and 3 years was 0.23% with 53.1% patients remained on dual antiplatelet therapy (DAPT) at 3 years. Low event rates were sustained through 3 years for the overall population, with higher rates observed in certain high risk subgroups than the standard risk population as expected. Despite that half of the patients were off DAPT at 3 years, the very late stent thrombosis between 1 and 3 years remained low as 0.23%. These results demonstrate continued safety and effectiveness of the Xience V in a highly complex, real-world patient population through 3 years.

Tomorrow: New Technology

An ideal stent would do its job and then disappear. In the future of DES development, bioresorbable polymers and scaffolds are the next frontier. The prospect of a temporary vascular stent, termed 'scaffold' due to it being based on a temporary bioresorbable platform, has always been a goal of the interventional community. Such a device could offer transient radial strength to resist acute vessel recoil, and at a later stage would be fully resorbed, leading to restoration of the vessel's biological properties. Bioresorbable scaffolds have several potential advantages over BMS or DES. These include abolished late stent thrombosis, improved lesion imaging, reduction in revascularization procedures, restoration of vasomotion, freedom from side-branch obstruction, and strut fracture-induced restenosis.

The bioresorbable scaffolds could be either a metallic alloy or a polymer. Iron-based and magnesium-based alloys have been investigated as candidates for bioresorbable scaffolds; however, only magnesium alloys are currently being tested in clinical trials. AMS-1 (Biotronik) largely degraded into inorganic salts by 60 days. The PROGRESS-AMS trial was a single-arm study that, unfortunately, showed a significant rate of restenosis, possibly due to

Summary of biodegradable stents used in clinical studies

Stent	Manufacturer	Material	Coating	Drug	Thickness of struts (mm)	Resorption time (months)
Metallic						
AMS 1.0	Biotronik	Mg	None	None	165	<4
AMS 3.0	Biotronik	Mg	None	Paclitaxel	125	>4
AMS 4.0	Biotronik	Mg	PLLA	Sirolimus	120	>4
Polymeric						
Igaki-Tamai	Kyto Medical	PLLA	None	None	170	24
BVS 1.0	Abbott Vascular	PLLA	PDLLA	Everolimus	150	24
BVS 1.1	Abbott Vascular	PLLA	PDLLA	Everolimus	150	24
DESolve	Elixir	PLLA	None	Myolimus	150	12–24
Ideal BioStent	Xenogenics	SA/AA	Salicylate	Sirolimus	175	0.12
REVA	REVA Medical	PTD-PC	None	None	200	24
ReZolve	REVA Medical	PTD-PC	None	Sirolimus	115–230	4–6
ART 18AZ	ART	PDLLA	None	None	170	3–6
Amaranth	Amaranth	PLLA	None	None	150–200	3–6

	Paclitaxel	Sirolimus	Everolimus			Zotarolimus		Biolimus A9
Name	Taxus Express	Cypher	Xience V/prime	Promus	Promus Element	Endeavor	Resolute	BioMatrix/Nobori
Manufacturer	Boston Scientific	Cordis, J & J	Abbott Vascular	Boston Scientific	Boston Scientific	Medtronic	Medtronic	Biosensors/Terumo
Stent material	Stainless steel	Stainless steel	Cobalt–chrome	Cobalt–chrome	Platinum-chrome	Cobalt–chrome	Cobalt–chrome	316L stainless steel
Strut thickness (μm)	132	140	81	81	81	91	91	112
Polymer	SIBS	PEVA, PMBA	PBMA, PVDF-HFP	PBMA, PVDF-HFP	PBMA, PVDF-HFP	PC	BioLinx	PLA
Polymer thickness (μm)	16	12.6	7.6	7.6	7.6	4.1	4.1	10
Type of polymer	Durable	Durable	Durable	Durable	Durable	Durable	Durable	Biodegrabable
Elution kinetics	10% over 2 wks	>80% within 4 wks	80% within 4 wks	80% within 4 wks	80% within 4 wks	95% within 2 wks	85% within 8 wks	45% within 4 wks

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increased neointimal proliferation and insufficient radial strength. Polymeric bioresorbable scaffolds are frequently made of poly-L-lactic acid (PLLA) and poly-DL-lactic acid (PDLLA), but there are also other polymers available, each with a different chemical composition and bioresorption time. Polymeric scaffolds have less radial strength when compared with stainless steel, necessitating thicker struts leading to potentially reduced conformability. Absorb® bioresorbable vascular scaffold (BVS) is the first drug (everolimus) eluting, fully bioresorbable scaffold, and has achieved a CE mark. It is composed of PLLA and PDLLA, which are completely resorbed in vivo in 12–18 months via a series of overlapping steps, including hydration, depolymerization, and hydrolysis, breaking them into smaller chains, which are further metabolized by phagocytes into soluble monomers (e.g. L-lactate). These monomers are subsequently metabolized into pyruvate, which enters into the Krebs cycle and is eventually converted into carbon dioxide and water. Absorb BVS 1.0 was tested in Absorb cohort A, a multicenter single-arm study, and was found to be safe and had a low MACE at 4-year follow-up. The second generation of this device (BVS 1.1) has enhanced radial strength, mechanical integrity and release kinetics, and was evaluated in Absorb cohort B and is being tested against everolimus DES in Absorb-II RCT.

Fellowship Training Course

April 23, 1:00 PM – 5:00 PM, Coronary Arena

Yesterday afternoon, the "Fellowship Training Course" was held in the Coronary Arena under great interest of hundreds of young cardiologists. The latest knowledge and tips in coronary intervention in left main and bifurcation coronary artery disease were presented by the world's most knowledgeable experts. In addition, several valuable cases were shared to enhance the understanding of the audience. In the left main session, the major concept of functional and anatomical assessment with regards to LM intervention was addressed by Seung-Jung Park, MD, PhD (Asan Medical Center, Korea). He demonstrated the limitation of angiographic prediction of lesion severity and highlighted the functional assessment by measuring FFR value. Furthermore, a systematic review of the comparison of PCI versus CABG, the 5-year results of the SYNTAX trial, issues about in-stent restenosis, and radial approach for LM PCI were presented and discussed. In the bifurcation session, expert's views and the European consensus for a single-stent technique, bifurcation anatomy, application of functional-guided approach, and a new role of drug eluting balloon were covered. This session was especially designed for fellows and young cardiologists just starting their career; all the presentations seek to give the attendant an understanding of the techniques performed on a daily basis. "It is hoped that with this educational program, standardized consensus will have been shared in complex coronary intervention and the learning curve will have been transverse to some extent," said Dr. Seung-Jung Park.

Partnership Sessions with International Societies

April 23, 5:30 PM – 8:00 PM, CTO Theater, Coronary Arena, R 1-2

Now in its 18th year, TCTAP has become a nationally and internationally recognized meeting in cardiology field. There are increased needs of international society and associations to have their own specialized programs enable to share their interests and strengths with TCTAP attendees. Every year TCTAP has tried to find the best opportunity for our partners to keep strong relationship and develop mutually beneficial growth in this field. Therefore, TCTAP 2013 continuously holds a joint session with leading international society, and the objective is to provide an opportunity to present their own interests and study accordingly and to allow members to broaden and deepen their understanding on a wide range of topics.

For this year, the partners attending this session are Chinese Society of Cardiology (CSC), National Intervention Council of India (NIC), Indonesian Society of Interventional Cardiology, and Malaysian Live consisting of focused groups. In the Chinese session, Yong Huo, MD, PhD of Peking University First Hospital and Junbo Ge, MD of Zhongshan Hospital gave featured lectures on STEMI and CTO and presented various interesting cases by Chinese young physicians as well. The sessions organized by NIC, which is in its second year at TCTAP, and by members of Malaysia Live were case based and practical small group sessions. It gave delegates ample opportunity to discuss tricky cases with the specialists and the best cases presented at Malaysia Live meeting. The session titled "How to" consists of 9 case presentations highlighting the most relevant issues in treatment of cardiovascular disease in the daily practice.

Evolving Modality for Infrainguinal Disease

To Stent or Not to Stent

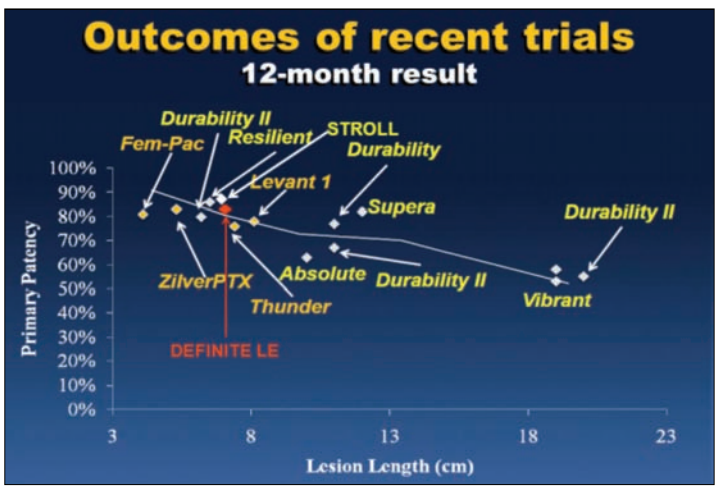
April 24, 2:00 PM – 6:00 PM, Structural Heart & Endovascular Theater, Endovascular Session I & II

During the past years, the contents of this meeting have been growing in their quality and quantity. Most of them have been focusing on interventional cardiology for treating coronary, but there might be a tremendous interest and development in the field of endovascular therapy, which contains whole body arteries, from the carotid artery to below the knee arteries. The CardioVascular Summit-TCTAP 2013 is ready to meet the new era of endovascular therapy in the fields rising interest and prepared by including LIVE case demonstration and a dedicated symposium. We invited world-leading physicians from around the world. Our attendees are eagerly waiting this new cinema theater.

Superficial Femoral Artery

The optimal treatment strategy for iliofemoral occlusive disease remains controversial. The Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial remains the only multi-center, randomized controlled trial (RCT) to have compared bypass surgery with balloon angioplasty first revascularization strategy for treatment due to infrainguinal disease. An intention to treat analysis of the BASIL trial has shown that bypass surgery and balloon angioplasty first strategies lead to similar amputation-free and overall survival out to two years from randomization, although surgery is significantly more morbid and about one-third more expensive in the short term. However, for those patients who survived for more than 2 years after intervention, initial randomization to a bypass surgery first strategy was associated with a significant increase of 7.3 months in restricted mean OS, and a non-significant increase of 5.9 months in restricted mean AFS, during the subsequent follow-up (average 3.1, range 1 to 5.7 years). Hospital costs and health related quality of life measures were not significant between the two groups over the first 3 years. These data suggest that BASIL-like patients who are expected to live more than 2 years should usually be considered for bypass surgery rather than balloon angioplasty. In spite of these results, tremendous endovascular procedures have been performed with the development of techniques and devices.

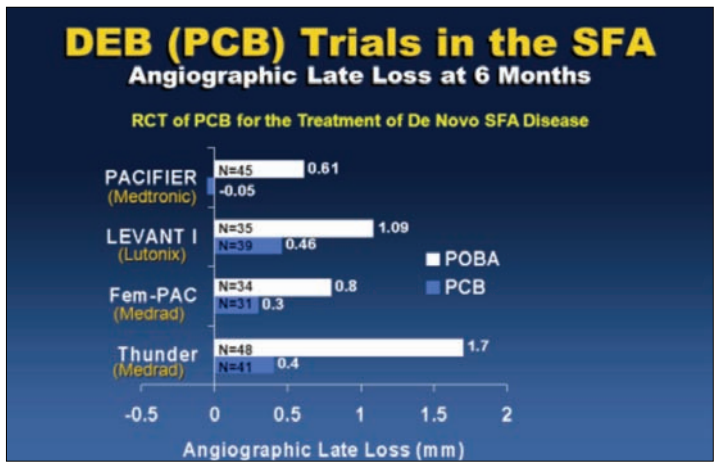
Following a precedent of coronary lesion, the device has been evolved for the bare nitinol stent, drug-eluting stent, and drug-eluting balloon. Unfortunately, different from coronary lesions, we have no confirmative options for the management of superficial femoral artery disease. As for the coronary situation, the drug-coated balloon angioplasty and drug-eluting stent implantation have been evaluated for the default strategy for the inhibition of neointimal hyperplasia. Recently, based on several trials using evolved bare nitinol stent, drug-eluting stent, evolved graft stent, evolved atherectomy device, and drug-eluting balloons, the patency has improved at about more than 80% in 1-year follow-up.



But the lesion length and lesion complexity were not realistic. There might be a big gap between real practice and data results. We must be careful in interpretating trial results.

Recent guidelines from ESC expanded the recommendation level of endovascular therapy in TASC A-C lesions as the first strategy. Even in the TASC D lesion subset, there might be a some residual place for the adoption of endovascular therapy for management.

Nowadays, paclitaxel-coated balloon would be a promising option based on several RCT trials. So, one of the experts in the use and investigation of this field, Massimillano Fusaro's lecture (German Heart Center Munich, Germany) "DEBs for femoropopliteal lesion: Latest trial results" will review the role of DEB in this complex lesion subset. For reference, in a recent meta-analysis about DEB, among total of 381 patients enrolled in 4 randomized trials were included (Pacli-taxel Coated Balloon, n=186 versus UnCoated Balloon, n=195). Median follow-up was 10.3 months. Angioplasty with PCB versus UCB reduces target lesion revascularization (12.2% versus 27.7%; OR, 0.22; 95% CI, 0.13 –0.38; p‹ 0.00001), angiographic restenosis (18.7% versus 45.5%; OR, 0.26; 95% CI, 0.14–0.48; p ‹0.0001), and late lumen loss (range, -0.05 to 0.50 mm versus 0.61–1.7 mm; weighted mean difference, -0.75 mm; 95% CI, -1.06 to -0.45; p ‹0.00001). No mortality difference was observed for PCB versus UCB (2.1% versus 3.2%, OR 0.99, 95% CI, 0.39–2.49; p=0.98).



Many physicians are looking forward to seeing longer and more favorable results from these trials.

In contrast, Dr. Mark W. Burket will present in favor of more traditional stenting. Lastly, after treatment of SFA lesion, we can easily meet restenosis because the patency rate is not good (just 60-70% in 1 year after contemporary nitinol stent implantation). The optimal treatment strategy of restenosis is a really hard situation to solve. Dr. Richard R. Heuser (St. Luke's Medical Center, USA) also will give a lecture "SFA In-Stent Restenosis: What is the optimal treatment strategy?"

Below the Knee

After ilio-femoral lesion coverage, infra-popliteal lesion, which has surprisingly increased, is positioned as very important because of limb salvage. In general, the incidence of 'Critical Limb Ischemia' is still increasing up to 1 in every 100 patients with peripheral artery disease; in case of diabetes, the risk may be increased up to 5 to 10 folds. Usually CLI occurs when the essential supply of nutrients falls below the cut-off level that will sustain tissue viability: ankle systolic pressure ‹50 mmHg in non-diabetics and toe systolic pressure ‹30 mmHg in diabetics. The CLI presented with chronic ischemic rest pain, ischemic ulcer, and ischemic gangrene. Only 50% of patients with CLI will survive with both limbs at 6 to 12 months after diagnosis, but 12 to 18% will die and 30 to 35% will undergo amputation; among them, only 22% will walk again and 30% will stay bed-ridden. For the optimal treatment of BTK intervention, the adoption of endovascular therapy showed promising results, which were not inferior to bypass surgery. Technical success was achieved in 93% (n=427 limbs) with all failures in TASC D lesions. One and 5-year primary patency was 57% and 38% and limb salvage was 84% and 81%, respectively. Infrapopliteal PTA is an effective primary therapy for all but the most severe cases of CLI. In terms of US data, the recently published XCELL (Xpert nitinol stenting for Critically ischEmic Lower Limbs) trial (Rocha-Singh K, Catheter Cardiovasc Interv. 2012) showed a high rate of amputation-free survival

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(78%) at 1 year with infrapopliteal nitinol stenting, but also a high rate of restenosis. In a OLIVE registry, endovascular treatment for infrainguinal vessels in patients with CLI showed 12 months amputation-free survival, the primary endpoint, was 74% and the major adverse limb event-free rate was 88%. Reintervention was required in 34% of patients by 1 year to achieve freedom from ischemic symptoms. Endovascular therapy yields a high rate of limb salvage at 1 year, but need for repeat interventions remains an issue. Still, there is room for debate in reintervention, but we could advocate the endovascular therapy for limb salvage with less invasive strategy in modern era. We have no time to hesitate, just do it!!

To open the occluded artery, many trials must be attempted, but the success rate would not be optimistic. Same situation with coronary chronic total occlusion, the various methods during intervention have been developed. As the coronary situation, the drug-coated balloon angioplasty and drug-eluting stent implantation have been evaluated for the default strategy for the prevention of restenosis and eventually, limb salvage.

Recently, several trials were performed for the investigation of effectiveness of drug-eluting balloon or drug-eluting stent. Some were very promising, but others were very disappointing. Dr. Gian Battista Danzi (Milan Cardiology, Italy) and Dr. Kons-tantinos Katsanos (Guy's and St. Thomas' Hospitals, NHS Foundation Trust, London, UK) will review the whole story of drug-related strategy for BTK lesions. Some trials demonstrated that below knee drug eluting stents have improved primary patency and symptoms compared to bare-metal stents, but have not improved clinical outcomes with regard to limb salvage during a short and mid-term follow-up duration. Among other options, drug-eluting balloon could be considered as improving technology because stenting procedure might not be feasible or optimal in these tough lesion subsets. Optimal balloon angioplasty has shown clinical benefits but sometimes, suboptimal angiographic results. Registries evaluating the use of Drug Eluting Balloons in BTK setting (DEB BTK registry) showed promising results; these results were confirmed by one randomised trial (DEBATE BTK RCT). Similar to our hopes, DEB showed significantly higher patency rate at 12-month follow-up angiogram compared with plain balloon angioplasty (29% versus 72%, p=0.0004). In the DEB BTK registry about all-comers using DEB, 1-year clinical outcomes (TLR=11%, secondary Patency =94%, Limb Salvage 96%) suggest that previous RCT results are reproducible in the “real world” population. Indeed, now might be the time to widely use DEB for BTK artery disease.

Drug-eluting stents (DES) have become the standard therapy for coronary interventions. However, its benefits on peripheral arterial disease, especially in BTK lesion, are not clear. Compared with bare-metal stents, four randomized controlled trials were found. Our analysis demonstrated a clear benefit in patency manifested by a freedom of target lesion revascularization up to four times higher with DES (p=0.001) and an improvement of at least one level on the Rutherford classification up to two times higher at 6 to 12 months (p=0.005). There was a non-significant trend favoring DES in reducing major amputations and death incidence was similar.

Dr. Kazushi Urasawa (Tokeidai Memorial Hospital, Japan) will focus on the techniques for the latest recanalization and tibial CTO lesion. Numerous approaches such as transpedal approach, subintimal angioplasty, and true lumen tracking could be considered for the recanalization of occluded segment of BTK. The lesion is too long and heavily calcified, which is not easy to open. The interventional therapy of critical limb ischemia requires crossing lesions. Often total occlusions that can’t be crossed from above can easily be traversed intraluminally from below. Because there are lots of collaterals which the operator can’t discern where true lumen should be, the distal cap of occlusion may be softer than the proximal cap with “hibernating vessel”. So, the pedal approach (via anterior tibial or posterior tibial artery) would be a viable approach particularly in limb salvage cases.

As one of the practitioners, most expected lectures will be held on scene. Do not hesitate!! Come and see!!!

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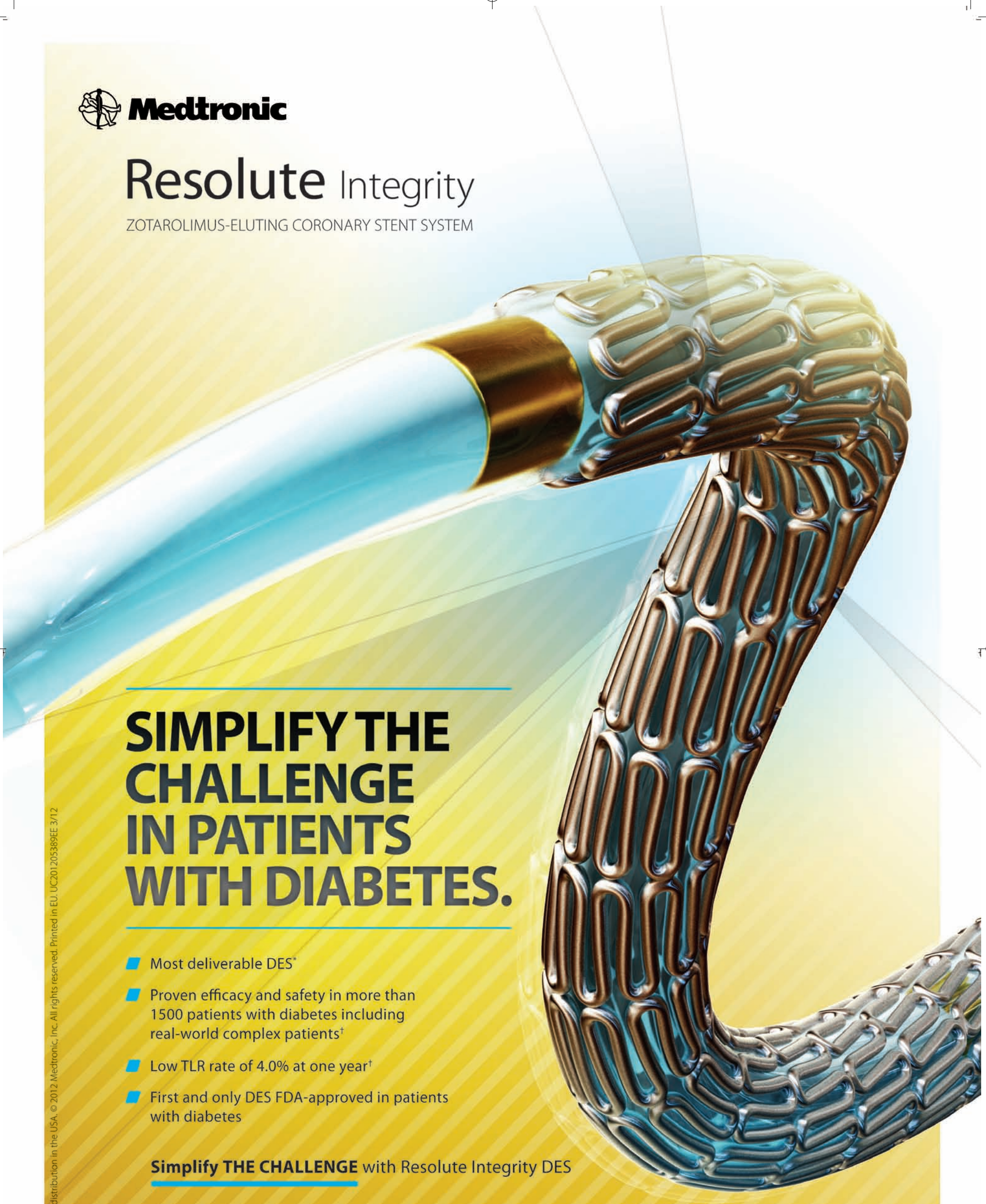

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† Silber S. Pooled post-hoc analysis of Resolute ZES in patients with DM. TCT 2011.

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