

Today's Highlights

Breakfast Meetings

Meet the Experts over Breakfast #8 - #14
7:00 AM - 8:10 AM

Late Breaking Clinical Trials

Lessons from Five Late-Breaking Clinical Trials.
Main Arena, 09:30 AM - 10:30 AM

5th Left Main and Bifurcation Summit

Co-organized by APSIC & CIT
Coronary Arena, 8:30 AM - 11:30 AM

Carotid Artery Disease

Live Cases and Featured Lectures
Mugunghwa Hall 2, 10:30 AM - 12:30 AM

Structural Heart Disease Symposium

Valvular Heart Disease, PFO and LAA Closure
Live Cases and Featured Lectures
Mugunghwa Hall 2, 2:00 PM - 6:00 PM

Most Distinguished Studies 2010-2011: Meet the Authors and Discuss with the Experts

Art Room, 8:30 AM - 12:30 PM

Imaging Workshop

Art Room, 2:00 PM - 6:00 PM

Moderated Oral Abstract Competition

Abstract Zone, Level B3, 2:00 PM - 6:00 PM

Moderated Complex Case Competition

Case Zone (Ida I), Level B1, 2:00 PM - 6:00 PM
Case Zone (Ida II), Level B1, 2:00 PM - 6:00 PM

Inside

PCI is an Alternative to CABG for Left Main
Coronary Stenosis: PRECOMBAT Trial
[page 1](#)

TCTAP 2011 Late Breaking Clinical Trials
[page 1](#)

FFR Guided and IVUS Supported
Complex Lesion Treatment
[page 3](#)

"Left Main and Bifurcation Summit" in
TCTAP 2011, co-organized by APSIC & CIT
[page 7](#)

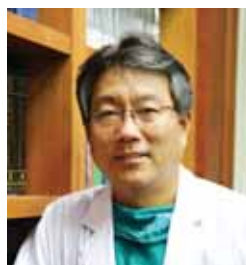
Highlights of ACC-i2 Summit 2011
[page 17](#)

CCT Meeting at Angioplasty Summit-
TCTAP 2011: Complex CTO Interventions
[page 21](#)

Structural Heart Disease Symposium
[page 22](#)

PCI is an Alternative to CABG for Left Main Coronary Stenosis: PRECOMBAT Trial

Coronary Session 3, Coronary Arena, 10:06 AM - 11:30 AM



Dr. Park presented the recent results of PRECOMBAT study and the future direction of percutaneous coronary intervention (PCI) for unprotected left main

coronary artery (LMCA) stenosis. Data from the PRECOMBAT study were recently presented at the American College of Cardiology's 60th annual scientific session in New Orleans and published online ahead of print in the New England Journal of Medicine. The primary objective of the PRECOMBAT trial is to establish the safety and effectiveness of coronary stenting with the sirolimus-eluting balloon-expandable stent (Cypher, Cordis Corporation, Bridgewater, NJ) compared with bypass surgery for the treatment of an unprotected LMCA stenosis. The investigators noted that although coronary artery bypass grafting (CABG) has been considered the treatment of choice, PCI is increasingly used to treat unprotected LMCA stenosis.

The study randomly assigned patients with unprotected LMCA stenosis to undergo CABG (300 patients) or PCI with sirolimus-eluting stents (300 patients). Using a wide margin for noninferiority, they compared the groups with

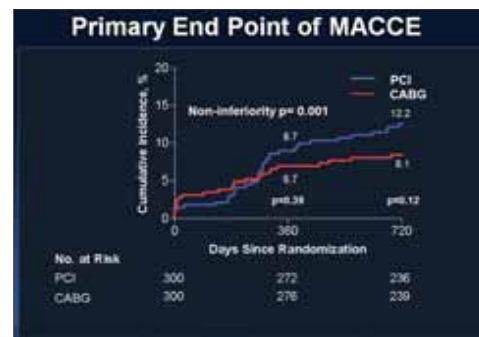
respect to the primary composite endpoint of major adverse cardiac or cerebrovascular events (death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 1 year. Event rates at 2 years were also compared between the two groups.

The study presented that the primary endpoint occurred in 26 patients assigned to PCI compared to 20 patients assigned to CABG (cumulative event rate, 8.7% vs 6.7%; absolute risk difference, two percentage points; 95% confidence interval [CI], -1.6 to 5.6; P=0.01 for noninferiority). By 2 years, the primary endpoint had occurred in 36 patients in the PCI group compared to 24 in the CABG group (cumulative event rate, 12.2% vs 8.1%; hazard ratio (HR) with PCI, 1.5; 95% CI, 0.9-2.52; p=0.12). The composite rate of death, myocardial infarction, or stroke at 2

years occurred in 13 and 14 patients in the two groups, respectively (cumulative event rate, 4.4% and 4.7%, respectively; HR, 0.92; 95% CI, 0.43-1.96; p=0.83). Ischemia-driven target-vessel revascularization occurred in 26 patients in the PCI group compared to 12 patients in the CABG group (cumulative event rate, 9% vs 4.2%; HR, 2.18; 95% CI, 1.1-4.32; p=0.02).

Therefore, Dr. Park concluded that in this randomized trial involving patients with unprotected LMCA stenosis, PCI with sirolimus-eluting stents was shown to be noninferior to CABG with respect to major adverse cardiac or cerebrovascular events. However, the noninferiority margin was wide, and the results cannot be considered straight clinically.

He gotten commented "In spite of higher revascularization after angioplasty, it can be a potential alternative if the two treatments have a similar risk of hard endpoints, such as death, heart attack, or stroke." In addition, he said "when, this study was initiated, there was great enthusiasm about the outcomes of angioplasty, and as a result, off-label use rapidly spread without enough evidence. Therefore, the initiation of a randomized study was urgent." He expected that the randomized international EXCEL study will confirm the safety and effectiveness of drug-eluting stents for unprotected LMCA stenosis, as compared with CABG.



TCTAP 2011 Late Breaking Clinical Trials

Main Arena, 9:30 AM - 10:30 AM

**Zilver PTX randomized
trial of paclitaxel-eluting
stents for**

**femoropopliteal artery
disease: 24-month
update**



Mark W. Burket, MD
At TCT 2010, the one-year follow-up results of the ZILVER PTX trial were present-

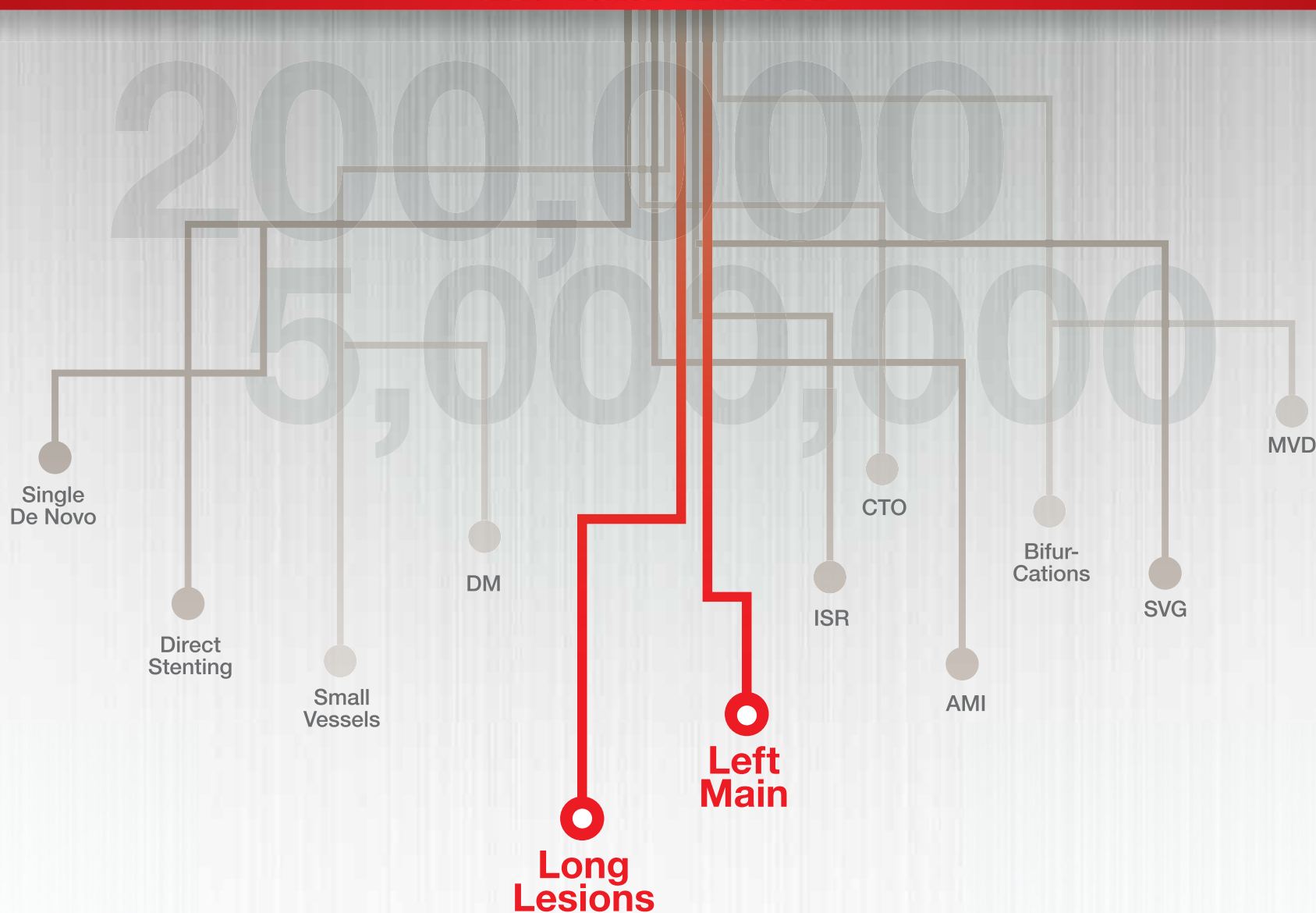
CardioVascular Research Foundation (CVRF)

The CardioVascular Research Foundation (CVRF) is a nonprofit clinical research foundation that contributes to improving the lives of patients with cardiovascular disease by promoting preclinical and clinical researches, educating physicians and teaching patients.

* Please visit CVRF booth at #D1 on the bridge toward Exhibit Hall 2 for our special events during TCTAP2011

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ed, which enrolled 479 patients with moderate to severe symptomatic femoropopliteal artery disease with lesions up to 14 cm. At 12 months, the patency rate was 83.1% with Zilver PTX and 67% with angioplasty plus bare metal stent. Also, the patency rate was 89.9% with Zilver PTX and 73% with the bare metal stent in a head-to-head comparison of provisional stenting, demonstrating that the drug effect was significant. Safety endpoints in the trial were also met. The ZILVER PTX trial will follow patients for up to five years. At the current TCT, it will be interesting to hear whether Zilver PTX has continued to show improved patency at 24 months. About this topic, Dr. Burket will answer all your questions in detail.

Evaluation of LMCA Revascularization by CT Angiography from PRECOMBAT Trial

Joon-Won KANG, MD



Dr. Kang (Asan Medical Center, Seoul, South Korea) will be presenting the data on noninvasive CT angiographic (CTCA) analysis after Left main coronary artery (LM) revascularization compared with the conventional coronary angiography (CCA) from the PRECOMBAT trial. Although CCA is recommended 2 to 6 months after LM stenting due to the unpredictable occurrence of in-stent restenosis (ISR), a follow-up CAG has some risks and complications, especially in case of protrusion of the stent into the ascending aorta. The diagnostic performance of high-resolution MSCT was evaluated to detect ISR after stent-

ing LMCA lesions. In this late-breaking trial, you will be informed of the accuracy and safety of the CTCA by evaluating the LMCA lesions after stenting.

Complete revascularization for multivessel disease: does it improve outcomes?

Young-Hak Kim, MD

Dr. Young-Hak Kim (Asan Medical Center, Seoul, South Korea) will present the impact of angiographic complete revascularization (CR) in patients with multivessel coronary disease (MVD) in the late breaking trial. Traditionally, CR strategy has been regarded as associated with better long-term clinical outcomes after percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery in patients with MVD. Due to technical complexity, low ejection fraction, or safety concerns regarding the implantation of multiple drug-eluting stents (DESs), however, diseased segments have often been incompletely revascularized in patients undergoing PCI. Even with CABG, the strategy of incomplete revascularization (IR) has occasionally been adopted to reduce operation-related complications, particularly when minimally invasive or off-pump surgery is attempted. Dr. Kim, therefore, evaluated the long-term clinical impact of angiographic CR, as compared with IR, in patients receiving PCI with DES or CABG for MVD.

Dynamic Change of Wall Shear Stress after Stenting Bifurcation Lesions: Subgroup Analysis

from DKCRUSH-II Trial

Shaoliang Chen, MD

Wall shear stress (SS) plays an important role in the initiation and proliferation of coronary atherosclerosis, especially for bifurcations. Stenting in the coronary artery will cause many different changes in velocity, flow, cross-sectional area, and especially the wall SS. It will be presented how much wall SS distribution varies with stenting in coronary bifurcation in the subgroup analysis from DKCRUSH-II trial.

Moving Towards Biomimicry- Development of Novel BioMime™ Sirolimus Eluting Coronary Stent System

Upendra Kaul, MD

Are there any perfect drug eluting stents in the world, with a thin strut platform that minimizes vessel wall injury, a drug that ensures noncytotoxic antiproliferative effects and a non-thrombogenic polymeric coating? To date, First-generation DESs were linked with late stent thrombosis as they were created on bulky stent platforms with questionable deliverability and polymer biocompatibility. But the BioMime™ stent has thrown down the gauntlet in claiming to be the ideal one. The BioMime™ sirolimus-eluting stent (SES) has been developed on simple yet fundamentally sound principles. The resultant DES has the ability to be arterially biocompatible, leading to its predictably safe and efficacious profile. During this session, you will hear in detail about this topic.

FFR Guided and IVUS Supported Complex Lesion Treatment

Left Main, Diffuse Tandem, and Bifurcation

Coronary Session 3, Coronary Arena, 8:30 Am - 10:05 AM

Dr. Park said that despite the advance of interventional techniques and adjuvant pharmacologic treatments, percutaneous coronary intervention (PCI) for the complex coronary anatomy including left main coronary artery stenosis, diffuse tandem lesion, or bifurcation has been challenging with less favorable clinical outcomes. And He also underscored that the importance of simultaneous utilization of fractional flow reserve (FFR) and intravascular ultrasound (IVUS) in complex lesion treatment.

Left Main Coronary Artery Stenosis

The conventional coronary angiogram has limitations in assessing lesion morphology and functional severity of coronary stenosis.

Hamilos et al addressed this issue about considerable mismatch between the coronary angiography and FFR in the evaluation for the LMCA stenosis. Although percent diameter stenosis at quantitative coronary angiography correlated significantly with FFR ($r=-0.38$, $p<0.001$), the distribution of percent diameter stenosis and the corresponding FFR value showed a large scatter of data. Among the 213 patients, 62 patients (29.1%) showed the “visual functional mismatch” between angiographic significance and functional significance: 13 patients had a diameter stenosis $>50\%$ while the FFR was >0.80 , and 49 patients had a diameter stenosis $<50\%$ while the FFR was <0.80 (Figure 1). Several studies demonstrated that FFR guided decision making for the treatment of

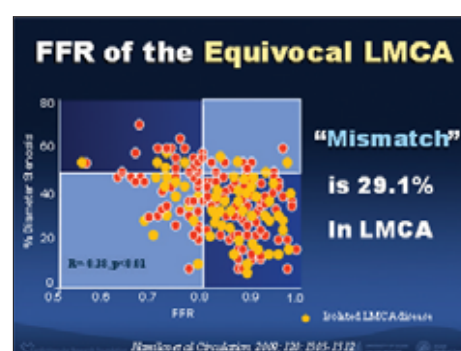


Figure 1

LMCA is associated with favorable prognosis and the intermediate LMCA with $FFR \geq 0.75-0.80$ could be safely deferred (Figure 2). In the meanwhile, IVUS provided useful information to secure the PCI procedure during LMCA intervention. In the MAIN-COMPARE registry, patients with unprotected LMCA

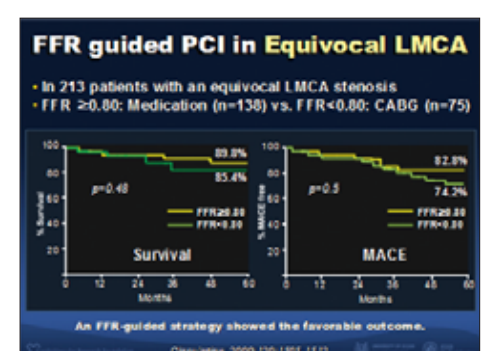


Figure 2

stenosis who underwent PCI under the guidance of IVUS (756 patients) were compared with those who underwent PCI under the guidance of conventional angiography (219 patients). In patients underwent the implantation of drug-eluting stent the use of IVUS guidance reduced the 3-year incidence of

Continued on page 4

from page 3

mortality (4.7% vs. 16.0%, long-rank $p=0.048$). Therefore, IVUS guidance during intervention of LMCA stenosis plays a crucial role in the LMCA intervention regarding stent optimization and safety concern to lower the risk of mortality in drug-eluting stent implantation.

Tandem Lesion Treatment Assisted by Coronary Pressure Measurement

Long coronary artery stenosis still remains considerable challenge to the interventional cardiologist despite of the introduction and widely utilization of drug eluting stent. In the practical point of view, long coronary artery stenosis should be divided into two categories: tandem lesion and diffuse long lesion. Particularly, in tandem lesion, which was defined as the lesion requiring at least two stents and can be divided with normal looking area by angiogram or IVUS examination to land the stent edge, FFR measurement may be helpful in decision making of treatment strategy. To estimate the individual functional significance of stenosis, sound equations were developed and validated in experimental animal study and human study. However, these equations are complex and small inaccuracy in measuring the pressure might induce the large errors in FFR. Also, bal-

loon occlusion was required to obtain the coronary wedge pressure. In addition, from the clinical point of view, it is more practical that relatively more significant functional stenosis was stented first and the remained stenosis was reevaluated by FFR rather than to predict the absolute value of functional significance of individual stenosis using complex equations. Thus, Park et al proposed a novel concept to identify the stenosis with relatively more severe functional significance, "rule of big delta", using sequential pressure measurement in the treatment for the coronary artery tandem stenosis. When tandem lesion was encountered, first above all, FFR of the entire vessel was measured. If $FFR < 0.80$ across the tandem lesion, treat the lesion first which had bigger pressure drop (Δ , pressure) during the pullback of the pressure wire within the tandem lesion, because the pressure drop may surrogate the relative severity of coronary stenosis between two stenotic vessel. Then, recheck FFR after stenting on the lesion with bigger pressure drop to evaluate the hemodynamic significance of remained lesion. If remained stenosis is functionally significant, additional stent is necessary. Otherwise, remained lesion can be deferred. Such a maneuver for the tandem stenosis may help in assessing ischemia pro-

ducing lesions and their functional length. This, in turn, may reduce the stent used and improve clinical outcomes via the reduction of periprocedural myocardial infarction and repeat revascularization. However, subsequent clinical studies to support this concept may be required.

Bifurcation Lesion

The evaluation of side branch and decision whether to dilate the side branch lesions and whether to implant stent at side branch after balloon angioplasty is of importance. However, overlapping of vessel segments as well as radiographic artifacts render bifurcation stenoses particularly difficult to evaluate at angiography. Therefore, the FFR measurement using pressure wire may be helpful to evaluate side branch stenosis. Koo et al. compared FFR with QCA in 97 "jailed" side branch lesions (vessel size > 2.0 mm, percent stenosis $> 50\%$ by visual estimation) after stent implantation. ADDIN EN.CITE ADDIN EN.CITE.DATA There was a negative correlation between the percent stenosis and FFR ($r=-0.41$, $p<0.001$). No lesion with $< 75\%$ stenosis had $FFR < 0.75$. However, among 73 lesions with $\geq 75\%$ stenosis, only 20 lesions (27%) were functionally significant (Figure 3). They also reported the clinical feasibility of FFR-guided side branch PCI strategy for bifurcation lesions. Of the 91 patients, side branch intervention was performed in 26 of



Figure 3

28 patients with $FFR < 0.75$. In this subgroup, FFR increased to > 0.75 despite residual stenosis of $69 \pm 10\%$. At 9 months, functional restenosis was 8% (5 of 65), with no difference in events compared with 110 side branches treated by angiography alone (4.6% vs. 3.7%, $p=0.7$).

Dr. Park concluded that regarding PCI for the complex coronary anatomy, meticulous functional evaluation may lead to identify the simpler functional stenosis than the anatomical stenosis, which can avoid the complex and unnecessary coronary intervention strategy and related complications. Furthermore, IVUS can be used to secure the PCI procedure by preinterventional lesion assessment and postinterventional stent optimization. FFR guided complex PCI, which was supported by IVUS can give us better insight into our understandings of complex anatomical disease and may improve the clinical outcomes of such complex patients.

Non-invasive Imaging for Interventional Cardiologists

Tutorial Arena, Art Room, Level 4, 5:18 PM - 6:15PM

Computed Tomography for Determining Lesion-Specific Ischemia: Role of Computed Fractional Flow Reserve (FFR)

Prior randomized trials have shown that fractional flow reserve or the ratio of maximal blood flow in a stenotic vessel to a normal vessel—is a useful physiologic tool for determining the hemodynamic significance of an anatomic coronary artery disease (CAD) stenosis. This combined anatomic-physiologic approach to CAD assessment allows for enhanced clinical decision-making that improves event-free survival, reduces unnecessary coronary revascularization, and lowers healthcare costs.

At present, no non-invasive test exists that can determine both anatomic coronary artery disease (CAD) severity and whether a stenosis causes ischemia. Traditional

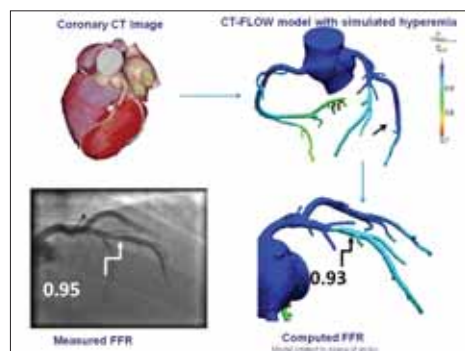


Figure 1

CAD evaluation has relied upon functional stress testing, which can demonstrate myocardial ischemia as a consequence of CAD but does not allow for direct visualization of a coronary artery stenosis. While stress test-guided referral to invasive angiography is efficacious, the inability to directly visualize coronary artery stenoses provokes non-negligible rates of referral to invasive angiography where no significant stenosis is identified. Recently, coronary computed tomographic

angiography (CCTA) has emerged as an alternative to stress testing that evaluates CAD by direct anatomic visualization of stenosis severity, but cannot discriminate whether a stenosis causes ischemia. While prior multicenter data have demonstrated favorable diagnostic performance characteristics of CCTA to detect and exclude obstructive coronary artery stenoses, CCTA stenosis severity demonstrates an unreliable relationship to ischemia, with the majority of high-grade stenoses detected by CCTA not causal of ischemia. Coupled with a tendency towards overestimation of stenosis severity by CCTA, these data have raised concerns that widespread use of CCTA may result in excess referral of patients to invasive angiography, with unnecessary revascularization of non-ischemic coronary stenoses.

In this regard, recent advances in

computational fluid dynamics (CFD) may offer adjunct physiologic data that can be derived from anatomic CCTA data. CFD applied to non-invasive images now allow for ex vivo analysis of blood flow in the cardiovascular system. CFD specifically applied to CCTA images permit prediction of pulsatile flow and pressure fields in coronary arteries, accounting for the complex interaction of the coronary artery vascular bed and the myocardium.

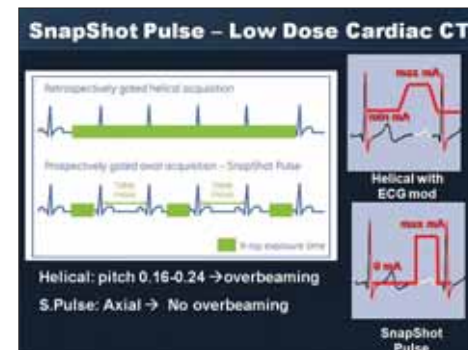


Figure 2

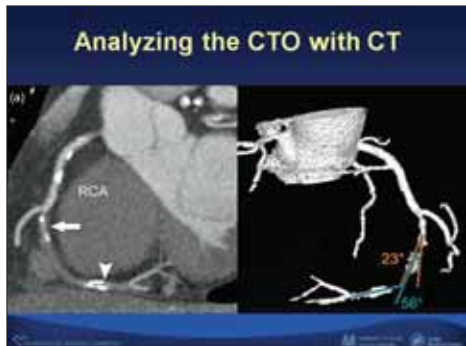


Figure 3

Recently, a novel method of CFD has been developed for calculation of lesion-specific FFR. This computed FFR (cFFR) is a non-invasive technique that uses normally-acquired CCTA images without additional imaging requirements, without modification of CCTA acquisition protocols, and without administration of additional medications.

For patients with suspected CAD undergoing CCTA, the addition of a physiologic measure of lesion-specific ischemia by cFFR may allow for combined anatomic-physiologic assessment of CAD that may improve the identification of patients with high-grade coronary stenoses that cause ischemia. The objective of this lecture is to discuss the performance of cFFR to CCTA stenosis severity for the diagnosis of ischemia, as measured by invasive measured FFR (mFFR), in individuals undergoing invasive coronary angiography (ICA).

Perfusion CT: Present and Future Perspectives

The current management of symptomatic patients with suspected coronary artery disease (CAD) frequently begins with attempts to detect coronary stenosis causing a myocardial perfusion defect by using nuclear isotopic techniques. The identification of such lesions generally leads to invasive coronary angiography for further documentation of vessel stenosis, anatomic characterization, and suitability for catheter-based intervention or surgery if clinically indicated. More recently, the advent of CT angiography suggests that the option of beginning the workup of younger patients with suspected CAD with an anatomic-based study, instead of a test designed to look at myocardial perfusion, makes a lot of sense. Indeed, the possibility of coupling anatomic and functional information in 1 single test tailored to the needs of specific patients could have important implications for the

evaluation of CAD clinically. Initial subclinical studies documenting the possibility of translating these methods to humans indicate that the combination of coronary angiograms with measurements of relative differences in myocardial blood flow during stress are feasible with current 64-slice multidetector computed tomography (MDCT) technology. Previous work using CMR to measure myocardial perfusion suggests that most of the needed information is provided by the stress images. However, differentiation

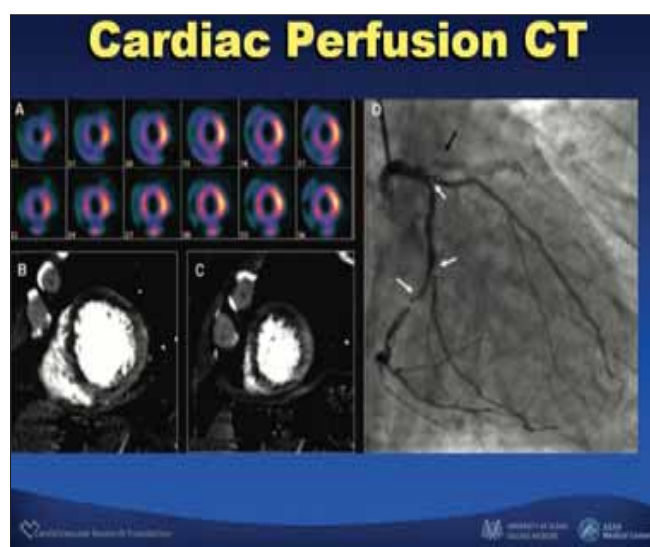


Figure 4

between stress-induced perfusion defects and myocardial scar such as old infarcts or myocardial fibrosis secondary to previous myocardial damage or due to other disease processes hampers the use of stress studies only. Thus, baseline studies at rest are crucial for the full implementation of this technology. In this regard, the main obstacle for its full implementation has been the magnitude of radiation that would be needed for the acquisition of myocardial perfusion information not only during stress, but also at rest using current 64-row MDCT technology with retrospective gating. Recent developments in MDCT technology that would allow for prospective gating during 64-row MDCT, 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 of the patient with chest pain and history of advanced disease, expected to have calcified coronary arteries 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.

Useful Imaging for Structural Heart Intervention: Atrial Septal Defect, Patent Foramen Ovale, and TransAortic Valve Implantation

Recent cutting edge techniques in catheter-based interventions have provided effective alternative treatments to surgery for several structural heart diseases such as atrial or ventricular septal defects. Specific devices have been developed to treat all these clinical conditions. Pre-procedural imaging provides detailed understanding of the operative field prior to the procedure. Integration of imaging modalities during the procedure allows real-time guidance. In the case of conventional cardiothoracic surgery, preoperative imaging findings can be confirmed by direct intra-operative visualization. In contrast, during minimally invasive and transcatheter interventions, procedural decision-making is based increasingly on image guidance. The rapid expansion of these less invasive procedures for a wide range of cardiovascular conditions, including coronary, vascular, structural cardiac, and aortic disease over the past several years, has therefore been paralleled by novel approaches to imaging. Particularly, the advent of transcatheter

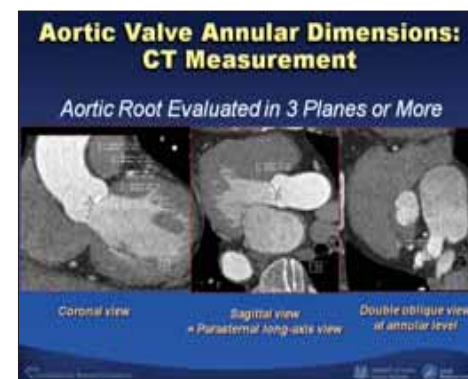


Figure 5

valve implantation/repair techniques constitutes one of the main breakthroughs of the last decades offering an effective alternative to patients with symptomatic valvular heart disease and high mortality operative risk. In addition, the role of novel catheter-based interventions has been explored in several clinical conditions that convey an increased risk of cerebrovascular stroke such as patent foramen ovale or atrial fibrillation. Traditional two-dimensional (2-D) imaging, e.g. standard echocardiography and conventional angiography, relies on acquisition of a limited number of planes/projections, which cannot be changed during the review. In contrast, three-dimensional (3-D) imaging allows fast acquisition of volumetric data sets and subsequent off-line reconstructions along unlimited 2-D planes and 3-D volumes. It is pursued with several imaging modalities including echocardiography, magnetic resonance imaging, and computed tomography. Focused on the emerging experience with computed tomography and rotational angiography, this review discusses the principles and current applications of 3-D cardiovascular imaging for surgical/ interventional guidance. The continuum of applications from preoperative planning to procedural integration is described. To improve the procedural success rate and minimize the frequency of complications, multimodality cardiac imaging plays a central role providing an accurate selection of patients and invaluable assistance during the procedure. Technological advances in the equipments and image post-processing softwares have provided improved accuracy of the image quality and analysis leading to an increasing implementation of these imaging techniques in the clinical practice. The present state-of-the-art article reviews the role of multimodality imaging for planning and guiding interventions in structural heart disease.

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[References] 1. Grundy SM, Cleeman JI, Baird Merz CN, et al. *Circulation*. 2004;110:227-239. 2. Smith SC Jr, Allen J, Blair SN, et al. *J Am Coll Cardiol*. 2006;47:2130-2139. 3. American Diabetes Association. *Diabetes Care*. 2010;33(1):S11-S61. 4. National Kidney Foundation. http://www.kidney.org/professionals/kdoqi/guidelines_cvd. Accessed September 30, 2010. 5. Data on file. Pfizer Inc, New York, NY.

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“Left Main and Bifurcation Summit” in TCTAP 2011, co-organized by APSIC & CIT

Coronary Session 3, Coronary Arena, Mugunghwa Hall 1, Level 1, April 28, 8:30 AM - 12:30 PM

Left Main Summit

Reflections on the Ideal Risk-Stratification Tool: Beyond the SYNTAX Score

The facts about the role of the SYNTAX score according to several data: 1) the SYNTAX score usefully discriminates MACE and MACCE between patients at low risk and those at high risk in patients undergoing left main PCI, 2) in observational registries, the intermediate tertile is frequently poorly calibrated with respect to the outcomes of the high and low tertiles, 3) the SYNTAX score is also a good predictor of hard events but, once again, the intermediate stratum is frequently not well calibrated. So, any prognostic model cannot be fully appreciated without the use of “discrimination” and “calibration”. The discrimination is the probability that the test will assign higher values of risk to patients who will go on to have events compared with those who will not. It is measured with the c-statistic, which ranges from 0.50 to 1.0. The calibration is the ratio of predicted risk to observed risk. It is measured with the Hosmer-Lemeshow test. According to discrimination and cali-

		SYNTAX score		
		< 19	19-27	> 27
EuroSCORE	0-2	L	L	I
	3-6	L	L	I
	> 6	I	I	H

Figure 1

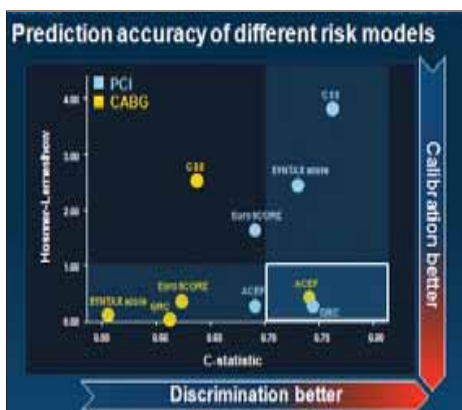


Figure 2

bration power, the EuroScore measured 0.62 & 0.321, the ACEF score 0.74 & 0.426, and the SYNTAX score 0.56 & 0.098. The pitfalls and issues of the SYNTAX score application in clinical practice are: 1) it does not include any subset of lesions (i.e. in-stent restenosis, stenotic bypass grafts, coronary anomalies, muscular bridge and aneurysm), 2) it is time-consuming, 3) there is interobserver and intraobserver variability, 4) it does not account for clinical or procedural variables that are known for impacting the outcomes during and after PCI. Many clinicians think the SYNTAX score to be a useful but incomplete tool and that a clinical Syntax score is needed. Why do we need both clinical and angiographic variables? Because the clinical and angiographic scores symmerized very different information, which showed a low Spearman rank correlation coefficient between SYNTAX score and EuroScore (R2=0.204, p=0.001) So the presenter suggests “The New Risk Stratification named NERS” which includes 17 clinical, 4 procedural and 33 angiographic variables. The NERS shows significant differences in AUC versus SYNTAX score for cardiac death, MI, TVR, ST and MACE (0.85 versus 0.74, p<0.001). The second score named “The Clinical SYNTAX Score (CSS)” is defined as the sum of SYNTAX score and ACEF score. ROC curves for 5-year mortality of 512 multivessel disease patients enrolled in the ARTS II study showed higher correlation than the simple SYNTAX score or the ACEF score. The third score named “The Global Risk Classification (GRC)” defined as a stratification using both the SYNTAX score and EuroScore (Figure 1) showed higher discriminating power than a simple Syntax score. The detailed calibration and discrimination power exhibit different powers according to the different scoring system (Figure 2).



Corrado Tamburino, MD, Ferrarotto Hospital, Universiti of Catania, Italy

Technical approach for Left Main Disease

As one of the pioneers in coronary intervention, Dr. Antonio Colombo reviewed the systematic approach of bifurcation lesions, including distal left main bifurcation lesions. Based on the important randomized trials about the bifurcation lesion stenting, such as the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) study and the BBC (The British Bifurcation Coronary Study: Old, New, and Evolving Strategies), the Provisional T-stent strategy should be the default treatment for most bifurcation lesions; however, there may be subtypes of coronary bifurcation that nonetheless merit a systematic 2-stent strategy (Culotte, Classic Crushing, T-stenting and V-stenting). It means that according to the lesion location, lesion length of side branch, especially, bifurcation lesion type, angulation of the side branch and the operator’s preference, the different stenting techniques will be used for the optimal management strategy. Dr. Antonio Colombo suggested the systematic approach according to the lesion characteristics (Figure 3).



Figure 3



Antonio Colombo, MD, EMO GVM Centro Cuore Columbus, San Raffaele Hospital, Italy

Bifurcation Summit

IVUS-Guided Provisional Stenting: Plaque or Carina Shift

Although drug-eluting stent implantation for unprotected left main (LM) coronary artery stenosis is evolving into a feasible

therapeutic alternative to bypass surgery, stenting lesions at the distal LM bifurcation location remain a challenge and a major determinant of adverse outcomes whether using a one-stent or a two-stent approach. In particular, when using a one-stent cross-over technique, there are two suggested mechanisms of acute luminal loss at the ostium of the left circumflex - carina shift vs. plaque shift. Intravascular ultrasound (IVUS) provides unique insights into the extent and distribution of coronary atherosclerosis pre-intervention and has been used to assess mechanisms and complications of stent implantation. The aims of the current IVUS study are to use pre- and post-stent implantation IVUS imaging of both the left anterior descending (LAD) and the left circumflex (LCX) coronary arteries to assess and predict the geometric changes that are responsible for acute lumen loss at the LCX ostium after implanting a stent from the LAD to the LM (i.e., the single stent cross-over technique) to treat a distal LM bifurcation stenosis. Recently, LM bifurcation lesions with a pre-procedural angiographic diameter stenosis <50% at the LCX ostium were evaluated using pre- and post-stenting IVUS pullbacks from both the LAD and LCX. The major findings were summarized as follows: 1) Although most distal LM bifurcation lesions had only a mild stenosis of the LCX ostium pre-stenting, 78% showed a >10% reduction of MLA within the LCX ostium after cross-over stenting from the LAD to the LM. 2) Carina shift was the primary mechanism of ostial LCX lumen loss; although plaque redistribution was also present, but in less than half of the lesions with a <10% reduction of MLA within the LCX ostium. 3) Narrow carina angle between the LAD and LCX and wide carina angle between the LCX and LM predicted a greater lumen area loss at the LCX carina. Thus, lumen loss of the LCX ostium frequently occurred after cross-over stenting for distal LM bifurcation lesions. Carina shift was the main mechanism of lumen loss within the LCX ostium and was predicted by a narrow distal angle between the LAD and LCX and a wide proximal angle between the LCX

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P H A R M A**

from page 7

and LM. In a minority of patients plaque redistribution may be superimposed on carinal shift to contribute to LCX ostial lumen area loss.

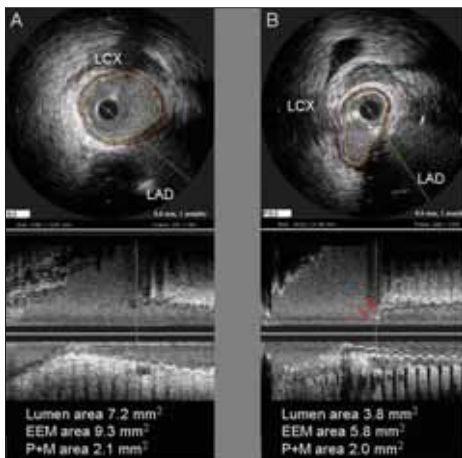


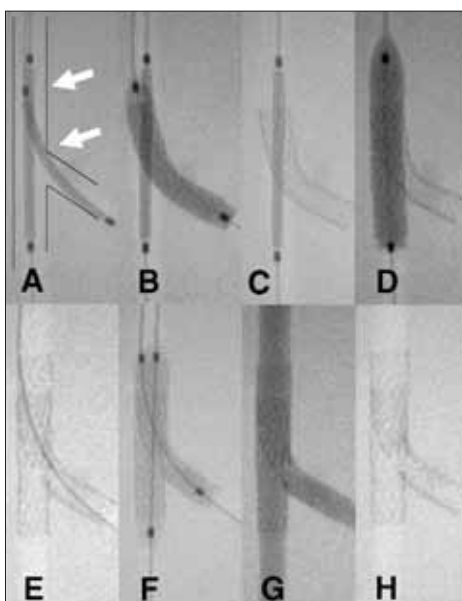
Figure 1



Soo-jin Kang, MD,
Asan Medical
Center

Classic Crush Is Enough!

The Crush technique was introduced in the early years of drug-eluting stent implantation with the aim that this relatively simple technique could optimise the results of bifurcation coronary stenting. Subsequent studies have shown that for the majority of bifurcation lesions a single stent strategy can be used effectively. However, there are lesions in which the bifurcation involves severe disease of a sizeable side branch. When the branch supplies a large mass of myocardium, it is important to ensure a good result in both branches of the bifurcation lesion, and this is likely to require stent implantation to the side branch. The classical crush technique was introduced by Dr. Antonio Colombo as a relatively straightforward strategy of



bifurcation stenting that ensures complete lesion coverage, in particular to scaffold the ostium of the side branch. The technique allows flexibility in that the operator is able to select the most appropriate size of the side branch stent that is needed. Preliminary results were encouraging though further analysis demonstrated the importance of achieving an optimal result. This necessitates high pressure balloon dilatation using appropriately sized balloons, together with mandatory final kissing balloon dilatation. This refinement of the technique will reduce restenosis and the need for repeat revascularization. One of the criticisms of the classical technique of crush stenting is that it may not always be possible to re-wire the side branch through the “crushed” stent struts. This may relate to either technique or to perhaps the lesion anatomy. An important aspect of crush stenting is to perform high pressure non-compliant balloon dilatation in the main vessel to optimise the “crush” and open the stent cells to facilitate re-wiring. Furthermore, re-wiring and passage of a (small) balloon to perform post-dilatation will be much more difficult when the lesion has a very shallow angle between the distal main vessel and side branch. Lesions with a high angle (T-shaped bifurcations) should also be avoided when contemplating any sort of “crush” technique as there is likely to be an area of sub-optimal stent expansion at the ostium of the side branch, which cannot be improved even with high pressure balloon dilatation. In conclusion, the crush technique is a relatively straightforward strategy of bifurcation stenting that ensures complete lesion coverage. When performed optimally, it achieves good long-term results and can be reliably performed successfully if high pressure balloon dilatation is utilised, and if lesions with a very shallow angle are avoided. Classical crush is therefore recommended for lesions with a bifurcation angle between 30-70°. With a correct strategy, the Classical crush technique can be applied quickly and successfully with good long-term results. It is not the technique that is at fault, it is the understanding of how/when it should be applied.

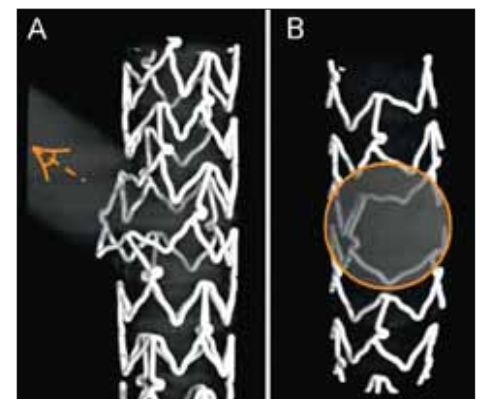


Angela Hoya, MD,
Castle Hill
Hospital, UK

Kissing Balloon Inflation in Single- or Two-Stent Bifurcation Stenting

Kissing balloon inflation (KBI) has been thought to be necessary in the coronary bifurcation intervention in order to achieve the following purposes: 1) to secure the access route to the side branch (SB), 2) to prevent SB narrowing and restenosis, 3) to make a bigger lumen in the proximal main vessel (MV), 4) to assure the stent apposition, and 5) to correct the stent deformation. The efficacy of KBI for the two-stent deployment has been demonstrated in several studies: KBI reduced SB restenosis in crush stenting [1] and culotte stenting, but not in T-stenting. However, there is a growing skepticism for the efficacy of KBI on the major adverse cardiac events (MACE) in the single-stent deployment recently. The Nordic-Baltic III trial, in which the patients with single-stent deployment in the MV were randomized according to the performance of KBI, demonstrated ineffectiveness of KBI in reducing the MACE (2.9% in KBI group vs. 2.9% in non-KBI group). In the Korean Coronary Bifurcation Stenting Registry (COBIS) study, The KBI led to frequent MACE compared to the non-KBI group (8.7% vs. 4.7%) and target lesion revascularization was more frequently performed in the MV. We investigated the configuration of stents which were implanted with cross-over stenting followed by KBI in the bifurcation phantom model. Various configurations of the proximal MV stents were observed because they were dependent on the operator’s decision in terms of the proximal position of the respective balloons and style of overlapping. Even when the proximal ends of both balloons were in the same position, bifurcation angle had an effect on the style of balloon overlapping. In the narrow angled bifurcation, the two balloons were positioned laterally, whereas the stents overlapped longitudinally according to the degree of the bifurcation angle with the style finally changing to an x-shape. Micro-focus computed tomography revealed the oval shape dilation in the proximal MV in the case with long overlapping compared with the case with minimal overlapping with the proximal MV dilated by a short large balloon. In the rheological assessment using the computer simulation, proximal asymmetrical overdilation could generate low-shear stress area in the overdilated area. There was an advantage in the 2-link stent for the complete SB ostial opening by KBI compared to the 3-link stent which had a risk of the strut remained in the SB

ostium, even after KBI. However, in terms of the stent deformation in the proximal MV, the 3-link stent kept its structure, whereas the 2-link stent had widely opened struts which might lead to a deterioration in the efficacy of the drug-eluting stent due to the polymer injury or the decrease in drug concentration in one stent cell. The effect of the jailed strut in the SB ostium on the long-term result has not been clarified. Angiographic assessment of the jailed SB has been revealed to be overestimated and only 30% of the SB which showed more than 75% stenosis in the angiography had less than the value of 0.75 in the flow fractional reserve. In the case with physiologically relevant stenosis in the SB, gentle KBI using small size balloon in the SB has been recommended (balloon / artery ratio 0.8-0.9) to avoid the dissection in the SB ostium. The optical coherence tomography demonstrated the coverage of the jailed strut with tissue, as well as in the other struts which were apposed to the vessel. Since the growth of the tissue on the jailed struts was also demonstrated, further studies are required to assess its effect on coronary flow which may be related to the restenosis and thrombus attachment. In summary, KBI is necessary for the two-stent technique to



complete the stent apposition and get enough luminal area. However, KBI after the single-stent technique does not always assure good long-term results. Asymmetrical overdilation of proximal MV induced by KBI may lead to frequent restenosis due to the dissection in proximal edge and SB ostium, polymer damage, and rheological disadvantage. Optimal KBI can be achieved in the following fashion; minimal overlapping, gentle KBI and usage of a short large balloon for further dilation of the proximal MV.



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Yesterday's Hot lives

IVUS Guided LM Trifurcation Treatment Using Simple Cross-Over Technique

Yesterday, Dr. Seung-Jung Park (Asan Medical Center, Seoul) and Junbo Ge (Zhongshan Hospital, China) treated a distal left main coronary artery (LMCA) disease. This 69-year-old male was admitted with exerting chest pain. His risk factor was hypercholesterolemia. Electrocardiogram was normal and echocardiogram showed normal LV ejection fraction without regional wall motion abnormalities. The left coronary angiography showed tight stenosis of distal LM with true trifurcation lesion (Figure 1). The right coronary angiogram was normal. Dr. Park selected 8Fr JL 3.5 guiding catheter to engage the LMCA and obtained coronary angiogram. At first sight, the stenotic lesion at the distal LM was so tight and true trifurcation lesion. After Dr. Park crossed the 0.014 inch BMW wires into the LAD, RI, and LCX se-



Figure 1



Figure 2

quentially, then he performed intravascular ultrasound (IVUS) evaluation for LAD, RI, and LCX ostium. It showed the significant stenosis at the distal LMCA with diffuse proximal LAD lesion. However, RI, and LCX ostium appeared quiet normal. Dr. Park said "This is a good example of IVUS guided PCI. Angiographically, it is a true trifurcation lesion. However, RI and LCX ostium are completely normal on the IVUS. So, I don't worry about jailing of the RI and LCX ostium when I cross over it." Dr. Park deployed the Promus element stent 3.5X24 mm with post-dilatation using a DuraStar balloon 4.0X15 mm. Final angiogram showed the perfect results without compromising RI and LCX ostium (Figure 2).

Treatment of Two ISR Lesions with Different Ways, Drug Eluting Stent and Drug Eluting Balloon

Yesterday, Dr. Ron Waksman (Washington Hospital Center, USA), a master of ISR treatment, showed live demonstration of the treatment for ISRs using different methods. A 59 year-old gentleman who had a history of PCI at LM to pLAD, Diagonal, LCX, and mRCA complained of chest discomfort. Coronary angiogram (Figure 1, 2) showed the denovo tight stenosis at dLAD and tight ISR at LCX stent os (Xience V 3.0X28) and distal edge of LM to pLAD stent (Xience V 3.5X28). He engaged the XB3.5 guiding catheter into the LCA and gently inserted the 0.014 BMW wire. Predilatation was done at dLAD stenosis and distal edge ISR of LM to LAD stent using Sprinter 2.5(12). Another 0.014 BMW wire was also inserted into LCX and pre-dilatation using Sprinter 2.5(12) was done. At the ostium of LCX, a site of ISR, SeQuent Please 3.0(20), drug-eluting balloon, was inflated over 30sec. Thereafter, Promus Element stent 2.5X12 and 2.75X12 was implanted at distal LAD stenosis and distal edge ISR, respectively. He successfully treated the 2 ISR lesions with different ways, drug eluting balloon and drug eluting stent (Figure 3).

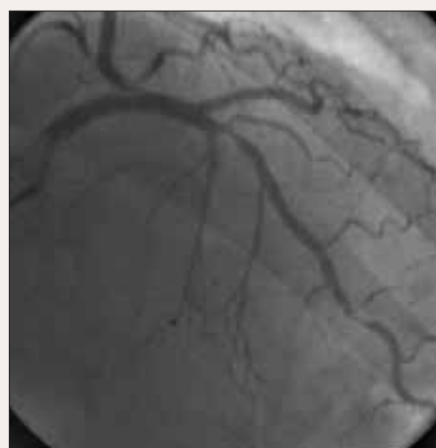


Figure 1

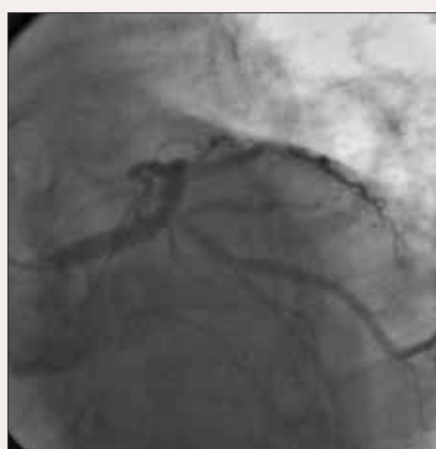


Figure 2

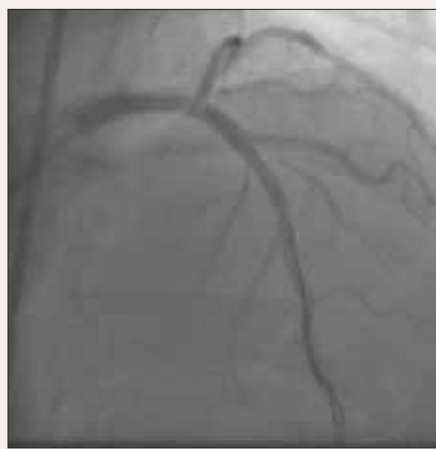


Figure 3

The Case of Treating with Stents for Tight Stenosis of LM Bifurcation Lesion

Dr. Masakiyo Nobuyoshi (Kokura Memorial Hospital, Japan) and Seung-Ho Hur (Keimyung University Dongsan Medical Center, Korea) demonstrated successful treatment for LM bifurcation lesion using simple cross over stent. A 69-year-old man was admitted with effort chest pain for one

month. His risk factor was hypertension and he is ex-smoker. The echocardiography showed akinesia of LV apex and anteroseptum with preserved LV systolic function (EF=54%). The left coronary angiography showed tight stenosis of LM bifurcation with LCX os (Figure 1). The right coronary angiogram showed diffuse long lesion of intermediate severity. Doctor Nobuyoshi punctured the right femoral artery with an 8 Fr sheath. Left coronary ostium was engaged with an 8Fr JL catheter with 4.0 cm curve. A 0.014 inch BMW wire was inserted into the LAD. Wire passage into the LCX was difficult. So, Fielder 0.014 inch wire was inserted at LCX using FINECROSS microcatheter. Predilatation was done using DuraStar 3.5X15 at LAD and Ryujin 2.5X15 mm at LCX. Xience Prime 3.5X23 mm stent was implanted at LM to pLAD using simple cross over stent. Using Dura Star 3.5X15 mm balloon at 28 atm, post adjunctive balloon dilatation was done. Final angiogram showed well expanded stent with TIMI 3 flow (Figure 2).



Figure 1



Figure 2

Vulnerable Plaque: The Challenges Ahead

Is There A Vulnerable Plaque? Pathologist's Navigation Doesn't Lie!

Breakfast Meeting, Tutorial Arena, Level 4, April 28, 7:00 AM

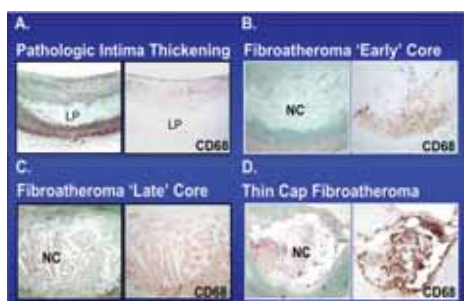


Figure 1

The concept of atherosclerotic lesion progression is a grand sum of wide ranging studies performed in human coronary arteries collected at autopsy. Currently, the most common underlying mechanism of sudden onset of acute coronary syndrome is believed to be rupture of a vulnerable plaque. The newest concept of vulnerable plaque from the worlds-largest autopsy registry data as well as from various diagnostic modalities with their limitations in the assessment of vulnerable plaques will be presented at the Tutorial Arena (Level 4), April 28th, at 7:00 AM by Dr. Renu Virman (CVPPath Institute, Gaithersburg).

The word "vulnerable" plaque was initially coined by Muller to define coronary lesions that morphologically resemble ruptured plaque, and then designated by our laboratory as thin-cap fibroatheroma (TCFA) (Figure 1). The morphology of TCFA shows a relatively large necrotic core with an overlying thin intact fibrous cap infiltrated by macrophages. There is generally a paucity or absence of smooth muscle cells within the fibrous cap. The fibrous cap thickness as a measure of plaque vulnerability is defined to be $\leq 65 \mu\text{m}$ since mean measurement in the thinnest part of remnant cap from a relatively large series of rupture plaques was $23 \pm 19 \mu\text{m}$, with 95% of the caps measuring $< 65 \mu\text{m}$. Despite similarities with rupture, TCFA exhibits a trend towards smaller necrotic cores and overall, less calcification. Cross sectional luminal narrowing is also typically less in TCFA versus rupture where occlusive thrombi have greater underlying stenosis than non-occlusive thrombi. Significant differences in cellular infiltration between TCFA and rupture include fewer cap macrophages and less accumulation of hemosiderin and prior

intraplaque hemorrhage. It has been also established that plaque progression is associated with positive remodeling and that the highest remodeling index is seen in plaque ruptures followed by plaque hemorrhage, TCFA, healed plaque rupture and fibroatheroma. Also, plaque rupture and TCFA are known to occur at proximal locations of the coronary arteries, causing the potential danger of exposing a large area of myocardium to ischemic necrosis in case that the vessel is occluded with a thrombus. Therefore, accurate identification of these vulnerable lesions has become a priority for interventionalists with the idea that treating such lesions by stenting or medication will prevent myocardial loss, thus reducing both morbidity and mortality. Among attempts to identify TCFA, many invasive and non-invasive imaging modalities have been introduced. Intravascular ultrasound (IVUS) allows plaque area and volume measurements albeit with a limited resolution, however it has difficulties to accurately identify "necrotic core" especially in the presence of calcification (figure 2). Another technique, optical coherence tomography (OCT), with a high resolution of 15 to 20 μm has the ability to measure coronary microstructures including fibrous cap

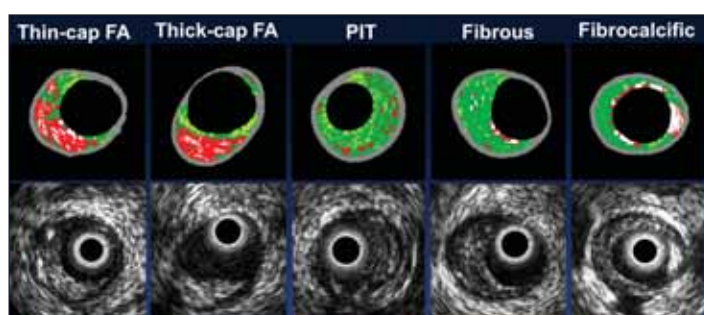


Figure 2

thickness $< 65 \mu\text{m}$ and macrophage infiltration, however it has limited depth of penetration. Near-infrared spectroscopy (NIRS) (Figure 3), which is used to recognize chemical composition of plaque especially necrotic core, appears highly suitable to identify cholesterol ester and free cholesterol, however it has limitation in the assessment of necrotic core depth. Since none of the devices alone are

indeed capable of identifying TCFA with certain accuracy, it is natural that we assume some combination of devices. For this purpose, investigators involved in the development of imaging modalities need to know the histopathology of TCFA in depth. Again, from our experience of the worlds-largest registry of autopsy cases, the most important key for the evaluation of plaque vulnerability is necrotic core size, fibrous cap thickness, and positive remodeling; and if I am allowed to add more, macrophage infiltration of the fibrous cap, hemorrhage in core, and angiogenesis will further help clarify what combination best defines plaque vulnerability.

Looking for Vulnerable Plaque Plaque Profinlings: Insights from the Culprit Plaques

The more specific characteristics of atherosclerotic plaques obtained in the culprit vessel of a patient presenting with acute myocardial infarction (AMI) will be discussed at the Tutorial Arena (Level 4), April 28th, at 7:20 am by Cheol Whan Lee, M.D. (Asan Medical Center). The ADAMTS (a

disintegrin and metalloproteinase with thrombospondin type 1 motifs) proteases are a distinct group of zinc metalloproteases (MMPs) comprising 20 members, ADAMTS-1 to ADAMTS-20, that are structurally related to the ADAM and matrix MMP families of proteinases. ADAMTS proteases are non-membrane-bound enzymes that interact with components of the extracellular matrix (ECM) such as procollagen, hyalactans and cartilage oligomeric matrix protein to cause their degradation. Roles for the proteases in inflammation and atherosclerosis have been suggested by a number of recent studies. The ability of the ADAMTS proteases to degrade versican, the

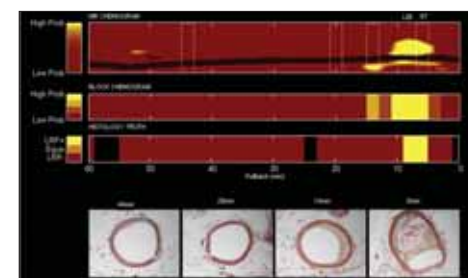


Figure 3

primary proteoglycan in the vasculature, is thought to be central to any hypothesized role for the proteases in atherosclerosis. ADAMTS proteases might contribute to plaque destabilisation by weakening the fibrous cap. Dr. Lee has examined the expression of ADAMTS proteases in coronary atherectomy samples obtained from patients with acute myocardial infarction (AMI) or stable angina. Atherectomy specimens were obtained from 34 patients with AMI (n=23) or stable angina (n=11) who underwent directional coronary atherectomy. The specimens were stained with H&E and analysed immunohistochemically using antibodies specific to ADAMTS-1, -4 and -5 versican cleavage products and markers for endothelial cells, macrophages and smooth muscle cells. Baseline characteristics were similar between the two groups. The proportion of CD31 and CD68 immunopositive areas did not differ between the two groups, but the area immunopositive for smooth muscle α -actin was smaller in the AMI group. The relative area immunopositive for ADAMTS-1 in AMI (1.04% [IQR 0.59-2.09%]) was significantly greater than that in stable angina (0.24% [0.15-0.39%]; $p < 0.001$). In contrast, the proportion of areas immunopositive for ADAMTS-4 or -5 was similar in the two groups. Areas that stained for ADAMTS-1 largely overlapped with those positive for CD68 and versican cleavage products. The areas immunopositive for ADAMTS-1 were significantly correlated with CD68 immunostained areas ($r=0.50$, $p=0.003$). ADAMTS-1, -4 and -5 were present in human coronary atherosclerotic plaques, and ADAMTS-1 was more strongly expressed in AMI plaques than in stable plaques. ADAMTS-1 may play a role in plaque instability.

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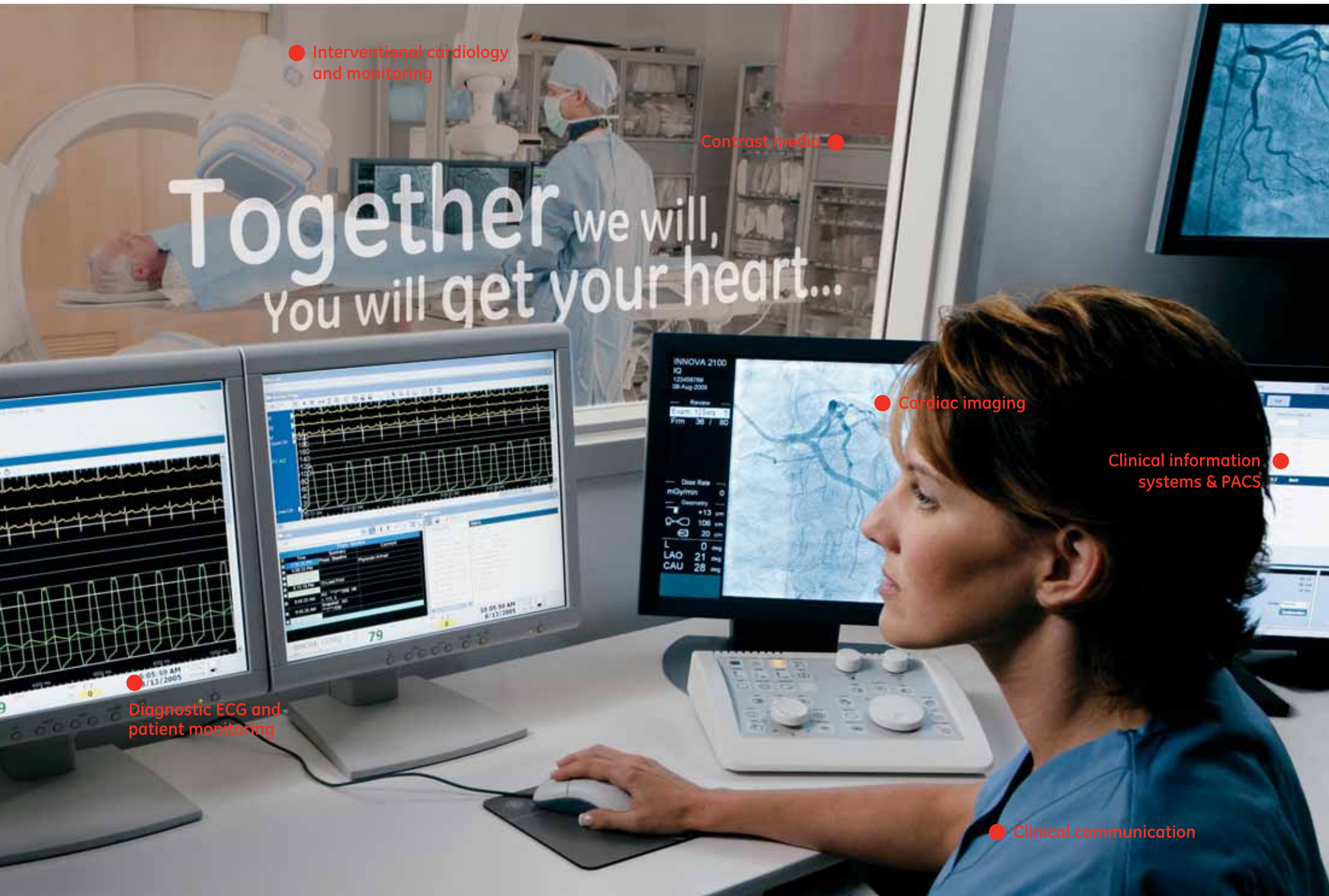
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- iCentral CIC (Clinical Information Center)
- Centricity CV PACS/Centricity Web
- MUSE® Cardiology Information System
- TELEGUARD Cardiac Review & Monitoring Station

Clinical communication

- Data continuity
- Remote monitor view via Mobile Viewers
- Wireless networking
- Handheld solutions
- Centricity Web

Contrast media

- Visipaque



imagination at work

Current and future developments in Interventional and Clinical Cardiology

Tutorial Arena, Art Room, LeVel 4, 8:30 AM - 12:30 PM

The Most Distinguished Studies of 2010-2011

Until now, we have achieved a lot of progress in the treatment of ischemic heart disease using percutaneous coronary intervention (PCI). A lot of problems however, like late and very late stent thrombosis (ST), stent malapposition, in-stent restenosis (ISR) and clopidogrel resistance, still need to be resolved in the future. There is new, important information available from several excellent studies last year and today, we will have time to review those with authors and experts at the meeting in the Tutorial Arena, Thursday April 28th, 9 AM.

Stent Malapposition

The prospective, multicenter Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial has demonstrated the clinical safety of paclitaxel-eluting stent (PES) implantation in patients with ST-segment elevation myocardial infarction (STEMI) within 12 hours of symptom onset in comparison to bare-metal stents (BMS) in 2009. An Intravascular Ultrasound (IVUS) Substudy and Optical Coherence Tomography (OCT) Substudy of HORIZONS-AMI Trial has showed that implantation of PES as compared with BMS significantly reduces neointimal hyperplasia (NIH), but results in a high frequency of late-acquired stent malapposition as a consequence of positive vessel remodeling, and higher rates of uncovered and malapposed stent strut at 13-month follow-up.

We don't know the vascular responses to DES in STEMI exactly. Human pathology studies have demonstrated that DES implantation in a ruptured plaque overlying a necrotic core may impair stent strut endothelialization. These findings suggest that incomplete stent strut coverage may be an important morphometric predictor of ST in STEMI. In some recent OCT studies, sirolimus-eluting stent (SES) implanted in STEMI was identified as an independent predictor of uncovered/malapposed struts, and the number of uncovered struts and the uneven NIH were determinant factors for local thrombus formation. Maehara A. *et al.* evaluated the incidence,

mechanisms, predictors, and clinical impact of acute and late stent malapposition after primary PCI using patients of the HORIZONS-AMI trial. The results were as follows: post-intervention acute stent malapposition (ASM) occurred similarly in both groups. Of these ASM cases, about 40% resolved at follow-up; complete resolution was accompanied by a reduction in external elastic membrane (EEM) area. An ASM area >1.2 mm² best separated persistently from the resolved ASM. At follow-up, a higher frequency of late stent malapposition was detected in PES-treated lesions (46.8%) mainly because of later acquired stent malapposition (30.8%) compared with BMS-treated lesions. Late acquired stent malapposition area correlated to the decrease of peri-stent plaque in the lesions subset without positive remodeling, and only to external membrane change in the group with positive remodeling. Independent predictors of late acquired stent malapposition were plaque/thrombus protrusion and PES use. At the 1-year follow-up, there were no deaths or ST related cases to the presence of stent malapposition. The clinical association between late acquired malapposition in DES and subsequent stent thrombosis remains controversial. Nevertheless, Cook S. *et al.* reported that malapposed struts associated with positive remodeling has been associated with late stent thrombosis. Considering the results of the OCTAMI study by Guagliumi G *et al.* using the zotarolimus-eluting stent (ZES) vs. BMS in patients with STEMI-no difference in strut coverage and similar vessel response to ZES, I am looking forward hearing the author's opinion of second generation DES in stent malapposition.

Bioresorbable Drug-eluting Vascular Scaffolds

After the implantation of DES, a major concern is late and very late ST. Histopathologic studies have shown that the first-generation DES were associated with delayed reendothelialization, localized vascular inflammation, thrombogenic reactions. These concerns made evident that a new approach to coronary stenting was required: an approach that should be free from the long-term safety concerns but

without compromising the beneficial low restenosis rates associated with metallic DES. Fully bioabsorbable scaffolds (BRS) are a novel approach that provides transient vessel support with drug delivery capability, but without the long-term limitations of the metallic DES, such as permanent caging with or without malapposition. Currently the biolimus-A9TM eluting BioMatrixTM stent (Biosensors Interventional Technologies Pte Ltd, Singapore), one of BRS examples, was used in the real world. And its efficacy and safety was reported in some studies including the LEADERS trial and JANICE registry.

The Abbott Vascular everolimus-eluting biorresorbable vascular scaffold (BVS) is the only drug-eluting BRS that is currently undergoing clinical trials (Figure1). The BVS

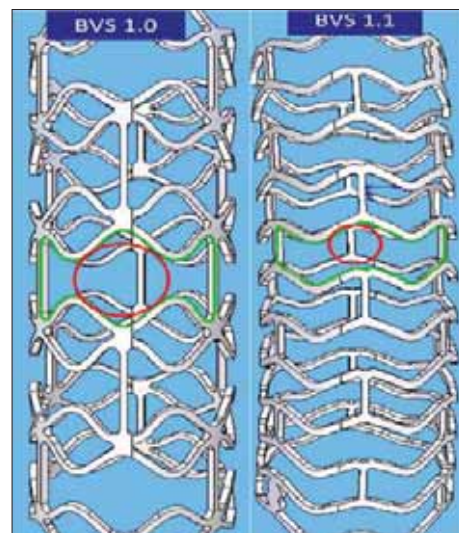


Figure 1. BVS 1.0 has out-of-phase sinusoidal hoops with straight and direct links, whilst BVS 1.1 has in-phase hoops with straight links.

has a backbone of poly-L-lactide (PLLA), which is subsequently coated with a thin layer of a 1:1 mixture of an amorphous matrix of poly-D, L-lactide (PDLLA) and 8.2 ug/mm of the antiproliferative drug everolimus. The PDLLA enables controlled release of everolimus, such that 80% is eluted by 30 days. The first BVS device (Revision 1.0) had a strut thickness of 150 um, a crossing profile of 1.4 mm, and consisted of circumferential out-of-phase zigzag hoops, with struts linked directly together or by thin and straight connections. The safety and feasibility of this BVS implant was assessed in 30 low-risk patients with de novo coronary lesions enrolled in the prospective, open-

label, multicenter FIM ABSORB study. The study demonstrated the clinical safety of the BVS, with only one ischemic driven major adverse event (non-Q wave MI) at 6 months, and no further MACE being reported in the subsequent 42-month follow-up. Angiographic follow-up at 6 months demonstrated a late loss of 0.44 mm. This late loss represented a combination of neointimal hyperplasia, which was comparable to that observed with the metallic EES and a reduction in scaffold area, which occurred as a consequence of a combination of late scaffold shrinkage and nonuniform vessel support. Late scaffold shrinkage, which occurs as a consequence of the loss of radial strength with bioresorption, represents a new phenomenon that has not been observed with nonabsorbable metallic stents. This late scaffold shrinkage leads to important design modifications to the device. The second-generation device, Revision 1.1, has in-phase zigzag hoops linked by bridges, which allow for a more consistent drug application and, as recently confirmed by OCT, has more uniform strut distribution and vessel wall support. The device is currently being assessed in the recently enrolled 101 patient Cohort B ABSORB trial. Forty-five patients underwent angiographic follow-up at 6 months and will have a repeat angiography at 2 years, whilst the remaining 56 patients will undergo invasive imaging at 1 and 3 years. Currently, data from the 6-month follow-up of the first cohort is available and will be presented at this meeting: the late lumen loss amounts to 0.19±0.18 mm with a relative decrease in minimal luminal area of 5.4% on IVUS. The late loss was considerably lower than that seen with the Revision 1.0, and similar to that commonly associated with metallic DES. Furthermore, the late strut shrinkage was almost eliminated: the reduction of scaffold area was only 2.90% with IVUS and -1.9% with OCT. Unlike the first generation of BVS 1.0, the backscattering of the polymeric struts did not decrease over time, which suggests a more delayed loss of mechanical integrity compared with the BVS 1.0. Finally, clinical event rates were low with only one MI and TLR; noteworthy was that there were no ST events according to the protocol or ARC definitions. Long-term follow-up is ongoing.

Second generation DES

The first generation DES has reduced angiographic restenosis and the need for repeat revascularization. But the ongoing risk of restenosis and increased rates of late ST and late-occurring death or MI compared with BMS have pushed the development of the second generation DES (thinner strut thickness and new antiproliferative drugs). There were several studies which documented the efficacy and safety of the second generation DES compared with the first generation DES. The ZEST (comparison of the efficacy and safety of Zotarolimus-eluting stent with Sirolimus-eluting and Paclitaxel-eluting stent for coronary lesions) trial has showed that ZES was noninferior to SES and superior to PES in the composite end point of death, MI, and ischemia-driven target-vessel revascularization at 12 months.

The everolimus-eluting stent (EES), another new DES, compared with PES was evaluated in the SPIRIT trials. The SPIRIT II and SPIRIT III trials showed that there was significantly reduced late lumen loss and noninferior rates of a composite outcome of safety and efficacy with EES as compared with PES. These findings suggested that, if tested in larger populations, EES might achieve superior clinical outcomes compared with the earlier devices. However, given the favorable outcomes with PES, large studies would be required to elicit small differences in low frequency but important clinical end points. Toward this end, two large-scale randomized trials have been performed, the SPIRIT IV and COMPARE trials. Both trials independently showed that EES was superior to PES with regard to their respective primary composite safety and efficacy end points. These results were driven by significant reductions in clinically driven TVR and MI, findings that were in part due to a significant reduction in the rates of ST with EES, as well as to reduced late recurrent ischemia necessitating repeat PCI or CABG. No significant differences were observed in the rates of all-cause or cardiac mortality between the difference stent platforms at

1-year (Table 1).

The differences in efficacy and safety between ZES and EES were evaluated in Resolute All Comers trial. This study was an unrestricted, multicenter, open-label, randomized, controlled, noninferiority trial in patients undergoing PCI in everyday clinical practice. The primary end point was target-lesion failure, defined as a composite of death from cardiac causes, any MI, or clinically indicated TLR within 12 months. There were no significant between-group differences in the primary end point (ZES group; 8.2% vs. EES group; 8.3%), the rate of death from cardiac causes, and myocardial infarction, or revascularization. The rate of ST was 2.3% in ZES group and 1.5% in EES group ($p=0.17$). Angiographically, there were no significant differences in the late lumen loss and the degree of in-stent stenosis. Therefore in the real world including a group of patients for whom the procedure was considered to be predominantly off-label, ZES was as safe and effective as EES.

Stent thrombosis and variability in response to clopidogrel therapy

Intensive investigation continues on the pathobiology of ST because of the associated incidence of death (~20% to 40%), MI (~50% to 70%) and repeat revascularization. Because of the low incidence of ST in clinical trials, real-world registries, ST, particularly occurring late after DES implantation has not yet been adequately characterized. One registry study comprised 611 patients with definite ST (early, 322 patients, late, 105 patients, very late, 184 patients). The main finding of this study was that the baseline characteristics (high rate of hemodialysis, end-stage renal disease -not on hemodialysis-, absence of circumflex target, target of chronic total occlusion, prior PCI, and age 65 years for LST/VLST versus EST, and high rate of hemodialysis, heart failure, insulin-dependent diabetes mellitus, and low body mass index for LST versus VLST), TIMI flow grade (a

significant higher rate of TIMI grade 2/3 flow (36%) at the time of ST in patients with LST than those with EST (13%) and VLST (17%) at the time of ST, and mortality rate after ST, were markedly different according to the timing of ST after SES implantation. These results suggest that the predominant mechanisms might be different between early, late, and very late ST, whereas previously was thought that LST was associated with delayed arterial healing and significant neointimal proliferation. The mechanisms of VLST are currently poorly understood. Delayed arterial healing had also been incriminated as the predominant cause of VLST, but some mechanisms other than delayed arterial healing might be operative in the pathogenesis of VLST-inflammation and positive vessel remodeling. We welcome to hear more up-to-date information in this meeting.

With concerns regarding ST, the other focus is dual antiplatelet therapy (DAPT). Although clopidogrel noncompliance was suspected as a cause of ST, other studies suggested that 68% to 85% of ST observed could not be attributed to clopidogrel compliance alone. So, the relative importance of other factors such as clopidogrel resistance, polymer hypersensitivity, and drug-drug interactions has been emphasized. DAPT-compliant patients, who experience ST, should be considered for evaluation of aspirin and/or clopidogrel resistance with appropriate modification in the oral platelet inhibitor therapy regimen. Roughly one-fourth of patients undergoing stenting may be resistant to the platelet-inhibiting effects of clopidogrel. Resistance to clopidogrel can be related to genetic variation in 1 or more of the cytochrome P450 hepatic enzymes required to convert clopidogrel from prodrug to active metabolite, particularly the reduced-functioning CYP2C19*2 allele. Although risk for ST is greatest in homozygotes (2% to 14% of population), heterozygotes (25% to 30% of population) appear to have a variable but increased risk for ischemic events as well. These results have critical limitations, because they were originated from studies which compared carrier of loss-of-function alleles with noncarrier in the clopidogrel-treated patients, and studies which were not randomized, place-controlled. Pare G. et al. showed that among patients with ACS or atrial fibrillation, the effect of clopidogrel as compared with placebo is consistent, irrespective of CYP2C19 loss-of-function carrier status using the genotype status of patients in CURE and ACTIVE A trials. At this meeting, we will discuss the association between ST, clopidogrel resistance, and genotype with experts.

The treatment of DES in-stent restenosis (ISR)

Despite all the promising technology, research, creativity, effort, and dollars poured into the field of the treatment of DES ISR, its problem has not been eliminated until now. DES ISR has been found to occur over a longer timeline, and its restenosis rate is related to the complexity of the lesion and clinical risk factors. In simple lesions, one can expect a restenosis rate of less than 5% at 1 year. At 5 years, repeat intervention rates are approximately 10%. However, in more complex lesions, restenosis has been documented at 10% at only 2 years, and repeat revascularization rates climbed to 17.2% by 5 years.

The treatment options for DES ISR are: simple balloon dilatation, cutting balloon, scoring balloon, restenting with the same DES, restenting with a new-generation DES, restenting with a DES with a different mechanism of action, redilatation plus brachytherapy, redilatation plus oral sirolimus, redilatation with a drug-eluting balloon, implantation of a fully biodegradable stent, and bypass surgery. Although options are abundant, there are not enough high-quality data to guide our decision unfortunately. In the large, multicenter j-Cypher Registry comparing outcomes after treatment of SES ISR with balloon angioplasty alone-simple or cutting balloon versus implantation of another SES, no difference in mortality or ST was found, but TLR rates were significantly lower in the SES group (23.8% vs. 37.7%, $p=0.001$) at 2-year follow-up. So, authors suggest that repeated implantation of SES for SES-associated restenosis was more effective in preventing recurrent TLR than treatment with balloon angioplasty, without evidence of safety concerns. This observational study has many confounders and other limitations. We will have a chance to listen to the author's/expert's experiences and opinions about the treatment of DES ISR in this session.

Other interesting topics: long-term outcomes after stenting versus bypass surgery for unprotected left main coronary artery disease, elective intra-aortic balloon counterpulsation during high-risk PCI, long-term outcome of open or endovascular repair of abdominal aortic aneurysm, transcatheter aortic valve implantation for aortic stenosis in patients who cannot undergo surgery, will be presented by authors in this session. Although those have already been published, authors and experts in the panel will give up-to-date information of those topics. Let's meet at the Tutorial arena on Thursday morning, April 28th.

Table 1. 1-year clinical outcomes in the SPIRIT IV and COMPARE trials

Outcomes	SPIRIT IV			COMPARE		
	EES (n = 2458)	PES (n = 1229)	p-value	EES (n = 897)	PES (n = 903)	p-value
Death:	1.0%	1.3%	0.61	2.0%	1.7%	0.58
- Cardiac death	0.4%	0.4%	1.00	1.2%	1.1%	0.81
- Noncardiac death	0.6%	0.8%	0.52			
MI:	1.9%	3.1%	0.02	2.8%	5.3%	0.007
- Q-wave	0.1%	0.4%	0.13	0.3%	1.2%	0.03
- Non-Q-wave	1.7%	2.8%	0.05	2.5%	4.3%	0.03
Target vessel MI	1.8%	2.9%	0.04			
Ischemic TLR	2.5%	4.6%	0.001	1.7%	4.8%	<0.001
Ischemic TVR	3.9%	5.9%	0.009	2.1%	5.6%	<0.001
Stent thrombosis (ARC def/prob ¹)	0.3%	1.1%	0.003	0.7%	2.5%	0.002
Major adverse cardiac events (death, MI or ischemic TLR)				6.2%	9.1%	0.02
Target lesion failure (cardiac death, target vessel MI or ischemic TLR)	4.2%	6.9%	<0.001			

¹Definite and probable stent thrombosis referring to ARC definitions
ARC: Academic Research Consortium; EES: Everolimus-eluting stent; MI: Myocardial infarction; PES: Paclitaxel-eluting stent; TLR: Target lesion revascularization; TVR: Target vessel revascularization

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INHIBACE[®] Tab.
(Cilazapril)

Pilgrel[®] tab.
(Clopidogrel bisulfate)

Anpran[®] tab.
(Sarpogrelate HCl)

Brevibloc[®] Inj.
(Esmolol)

Lopid[®]
Capsules
(Gemfibrozil)

COUMADIN[®] Tab.
(Warfarin Sodium)

Moderate Oral Abstract Competition

Abstract Zone, Level B3

“Moderate Oral Abstract Completion” will be held on April 27, 2:00 - 6:00 PM and on April 28, 8:30 - 12:30 AM and 2:00 - 6:00 PM, location Abstract Zone (Ida I). Lots of diligent researchers will show their new results of several major topics- AMI/ACS, Pharmacological Treatment, Imaging, Structural Heart Disease, Complex PCI, DES, and Endovascular Intervention. After four or five presentations on each topic, panelists will select the best oral abstract and hand out an award. This year, 58 abstracts were selected among submitted abstracts from 20 countries. Before the actual presentations, we will introduce some interesting abstracts.

In the “Acute Myocardial Infarction/Acute Coronary Syndrome I” session at 2:00 PM on April 27, Dr. Arunachalam Esakkisppan from India will show that the selective intracoro-

nary administration of nitroprusside prior to PCI is safe and well tolerated, prevents or slows reflow, and improves reperfusion of the infarcted myocardium in AMI.

In the “Acute Myocardial Infarction/Acute Coronary Syndrome I” session at 3:00 PM, Dr. Shi-Wei Yang from Beijing will present the lecture “Mild Decrease of Fasting Plasma Glucose Predicts In-Hospital and 3-Year Mortality in Older Patients with Acute Myocardial Infarction”. This study showed that compared with the euglycemia group, hypo- or hyperglycemia groups were all associated with higher in-hospital and 3-year all-cause mortality. In the “Imaging I” session at 4:00 PM, Dr. Hiroaki Takashima from Japan will present “Comparison of the level of diameter stenosis by quantitative coronary angiography and the value of fractional flow

reserve in each coronary artery.”

On Thursday April 28th, from 8:30 AM, in the “complex PCI” session, Dr. Seung-Woon Rha from Korea will demonstrate the “Long-term Outcomes of Coronary Bifurcation Stenting with First-Generation Drug-Eluting Stents”. In this study, Cypher and Taxus stents were compared for a period up to 36 months. Which patients do you think have higher morbidity or mortality during weekend and weekday presentations of acute coronary syndrome? In the “Acute Myocardial Infarction /Acute coronary Syndrome III” session at 10:00 AM, Dr. Satoshi Mogi from Keio University School of Medicine will present this interesting subject. Dr. Nicolas Dumonteil from France will show that a transfemoral-transcatheter aortic valve implantation (TF-TAVI) has lower 30-day all-cause

mortality than a transapical (TA)-TAVI in the “Structure Heart Disease” session at 11:30 AM. In the “Endovascular Intervention” session at 2:00 PM, Dr. Yusuke Miyashita from Japan will demonstrate the result of retrospective analysis of the renal artery stenting for the salvage of the renal function.

Like these abstracts, there will be presentations of various interesting subjects in the interventional cardiology area. Now, the oral abstract sessions has been extended as one of the most interesting parts of this event, in which all interventional cardiologists from various countries can actively participate. Would you like know the results of above introduced interesting studies? We look forward to your active participation in the “Moderate Oral Abstract Competition” session.

Highlights of ACC i2 Summit 2011

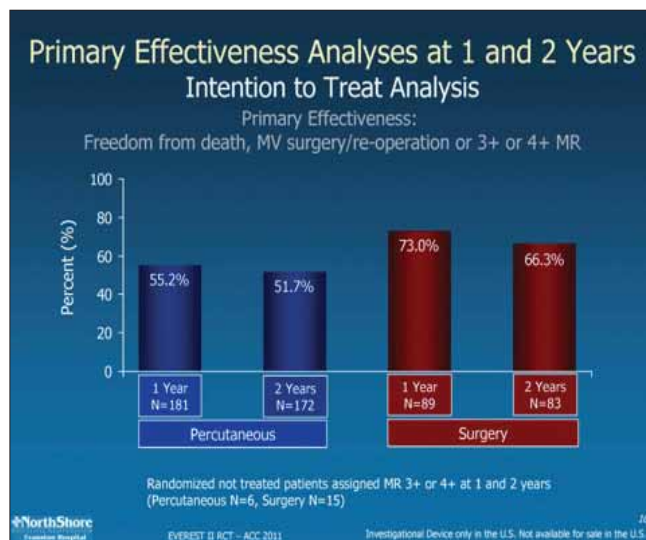
Coronary Session 4, Coronary Arena, Mugunghwa Hall 1, 2:00 PM - 3:00 PM

EVEREST II trial

Dr. Feldman presented the 2-year outcomes from the EVEREST II randomized controlled trial showed that percutaneous mitral valve repair with the MitraClip device is a durable option for patients with moderate to severe mitral regurgitation (MR) through 2 years, but offers less effective MR reduction compared with surgical treatment.

In the EVEREST II trial, 279 patients with moderate-to-severe or severe MR (3+ or 4+) and anatomical criteria suitable for endovascular repair were randomly assigned (2:1) to percutaneous treatment with the MitraClip system (n=184) or surgical repair or replacement (n=95). The primary effectiveness was defined as freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation.

At two years after treatment, data from the EVEREST II trial showed a primary effectiveness rate of 51.7 percent for patients treated with the MitraClip device compared to a primary effectiveness rate of 66.3 % for surgery patients (p=0.04) on an intention-to-treat basis. When percutaneous repair is compared to surgery, percutaneous repair provides increased safety and surgery provides more complete mitral regurgitation reduction. Eighty percent of percutaneous repair patients at one year and 78 percent of patients at two years were free from surgery. Both approaches reduced mitral regurgitation and produced meaningful clinical bene-



fits through two years, with significantly improved left-ventricular volumes and New York Heart Association functional class.

PARTNER trial (Cohort A Study)

Dr. Leon presented the result of PARTNER (Placement of Aortic Transcatheter Valves) trial, the first randomized comparison of a catheter-based method of aortic valve replacement vs. standard surgical therapy, showed that mortality rates were similar at one year between transcatheter aortic valve replacement (TAVR) and valve replacement by open surgery (AVR), although rates of stroke and major bleeding differed significantly.

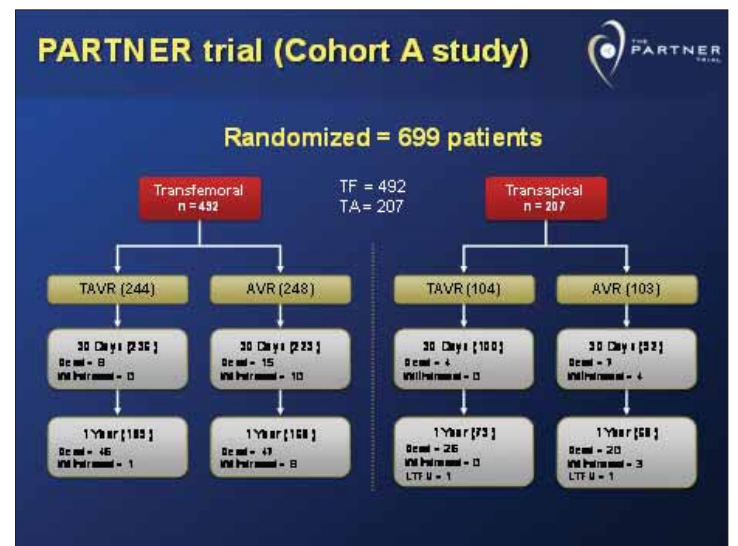
The primary endpoint of the trial was met. In patients with aortic stenosis at high risk for

operation, TAVR was non-inferior to AVR for all-cause mortality at 1 year (24.2% vs. 26.8%, p=0.001 for non-inferiority). The transfemoral TAVR subgroup was also non-inferior to AVR (p=0.002 for non-inferiority). Death at 30 days was lower than expected in both arms of the trial. TAVR mortality (3.4%) was the lowest reported in any series, despite an early generation device and limited previous operator experience. AVR mortality (6.5%) was lower than the expected operative mortality (11.8%).

Both TAVR and AVR were associated with important but different peri-procedural hazards. Major strokes at 30 days (3.8 vs. 2.1%, p=0.20) and one year (5.1% vs. 2.4%, p=0.07) and major vascular complications were more frequent with TAVR (11.0% vs. 3.2%, p<0.001). Major bleeding (9.3% vs. 19.5%, p<0.001) and new onset

atrial fibrillation (8.6% vs. 16.0%, p < 0.001) were more frequent with AVR. TAVR and AVR are both acceptable therapies in these high-risk patients; differing peri-procedural hazards may impact case-based decision-making. Symptom improvement (NYHA class and 6-min walk distance) favored TAVR at 30 days and was similar to AVR at one year. Echo findings showed small hemodynamic benefit with TAVR compared with AVR at 1 year (mean gradient p=0.008, AVA p=0.002) and increased para-valvular regurgitation associated with TAVR (p<0.001).

A multidisciplinary valve team approach benefits patients and is recommended for all future valve centers. TAVR is already the standard-of-care for inoperable patients with







from page 17

severe aortic stenosis. These results indicate that TAVR is an acceptable alternative to AVR in selected high-risk operable patients. Future randomized studies should focus on lower risk patients who are candidates for operation.

Quality of Life after PCI with DES or CABG

SYNTAX was an 1800-patient trial comparing CABG with PCI using the Taxus (Boston Scientific) drug-eluting stent (DES) in patients

with either three-vessel or left-main coronary artery disease. In SYNTAX trial, Cohen et al. evaluated health-related QoL (Quality of Life) using the Seattle Angina Questionnaire (SAQ) at baseline and at 1, 6, and 12 months post-treatment. The primary endpoint of SAQ angina-frequency score remained similar for the 2 treatment groups at 1 month, but over longer follow-up CABG patients showed superior outcomes. They also were more likely to report freedom from angina by 12 months. However, both patient groups showed substantial improvement, defined as

an increase of at least 20 points over baseline SAQ angina-frequency score. Two measures of general health status—the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and the European Quality of Life-5 Dimensions (EQ-5D)—also showed an early advantage for PCI that tapered off by 6 and 12 months.

Additional calculations found a relationship between baseline angina frequency and the benefits of PCI or CABG. Among patients with daily or weekly angina at baseline, CABG provided better relief from angina at 6

months compared with PCI (mean adjusted difference in SAQ score, 4.4 points). Patients with daily or weekly angina also were more likely to be free from angina after CABG than after PCI at 6 months (65.4% vs. 56.9%; $P=0.02$) and 12 months (70.3% vs. 60.0%; $P=0.02$). But patients who reported little or no angina prior to the study showed a different pattern; those with monthly symptoms fared marginally better with CABG and those with no symptoms had slightly better outcomes with PCI (P for interaction=0.03).

Dr. Martin B. Leon has been nominated for the Chien Foundation Lectureship Award of TCTAP2011.



Dr. Martin B. Leon has been nominated for the Chien Foundation Lectureship Award of

TCTAP2011.

Dr. Martin B. Leon was nominated and presented with the Chien Foundation Lectureship Award.

The presentation took place on 27 April 2011. The Chien Foundation Lectureship award was introduced in 2008 and seeks to honor and show appreciation to outstanding teachers and promoters in education and research in interventional cardiology in the Asia-Pacific coun-

tries. Dr. Martin B. Leon was selected based on his significant contributions to the interventional community not only in the US but also internationally. He has received recognition in several prominent teaching universities and hospitals, and is a dynamic and well-known educator and lecturer at many major international conferences.

He has also contributed significantly to the development of interventional cardiology in the

Asia-Pacific countries through his regular visits and also committed participation at the major conferences.

Dr. Leon is also the founder and course director of the world-renowned TCT conference in the US. His unassuming and quiet manners hide a long list of achievements, contributions and long-standing meritorious service to the medical community accomplished over a period of more than two decades.

CardioVascular Research Foundation (CVRF)

For the future of human being's health, we'll get together...

Who we are

The CardioVascular Research Foundation (CVRF) is a non-profit clinical research foundation that seeks to contribute in improving the lives of patients with cardiovascular disease by promoting preclinical and clinical researches, educating physicians and teaching patients.

What we've done

Since its establishment in 2002 and its affiliation with the Asan Medical Center in Seoul, Korea, CVRF has been conducting and supporting a large number of outstanding clinical researches to help conquer cardiovascular disease. The foundation has been also sharing cutting edge knowledge and educating physicians and other professionals by holding international conferences, running educative websites and committing to various physician training programs.

What we will do

The CVRF will do its best to develop innovative technologies and educate professionals and the public related to the cardiovascular field. By achieving these goals, the CVRF is dedicated to increase the survival rate and the quality of life for patients who suffer from cardiovascular disease and its medication.

Save the Dates

IMAGING & PHYSIOLOGY SUMMIT and
CHRONIC TOTAL OCCLUSIONS LIVE 2012
January 6-7, 2012

Call for cases
July 25, 2010 - October 26, 2011

17th ANGIOPLASTY SUMMIT-TCTAP
April 25-27, 2012

Call for Abstracts
August 1, 2011 - November 11, 2011

Call for cases
August 1, 2011 - January 9, 2012

www.cvrf.org



CCT Meeting at Angioplasty Summit-TCTAP 2011 : Complex CTO Interventions

Coronary Session 4, Coronary Arena, April 28, 3:00 PM – 4:00 PM

On Thursday afternoon, at 2:00 PM, the “The imaging modality for CTO procedures” will be lectured by Dr. Eisho KYO of the Kusatsu Heart Center from Japan in the Coronary Arena. Here follow a summary of his lecture. Chronic total occlusions (CTOs) are a subset of lesions presenting a last frontier for percutaneous coronary intervention (PCI). PCI of CTOs is generally well known to be a challenging procedure for the interventional cardiologist. Our enthusiasm for CTO-PCI has facilitated the development of a new CTO guidewires, dedicated microcatheters and several adjunctive techniques, which have contributed to the higher success rate of any complex CTO-PCI. Today we describe invasive and non-invasive imaging techniques that provide detailed anatomical information of the coronary arteries.

MDCT has now been established as the best non-invasive diagnostic imaging modality of the coronary arteries and allows visualization of morphological features at the occluded site. Pre-procedural MDCT examination is performed routinely in patients with CTO in Kusatsu Heart Center. Three dimensional reconstruction of the coronary anatomy provides important information in pre-procedural planning of interventional strategies, such

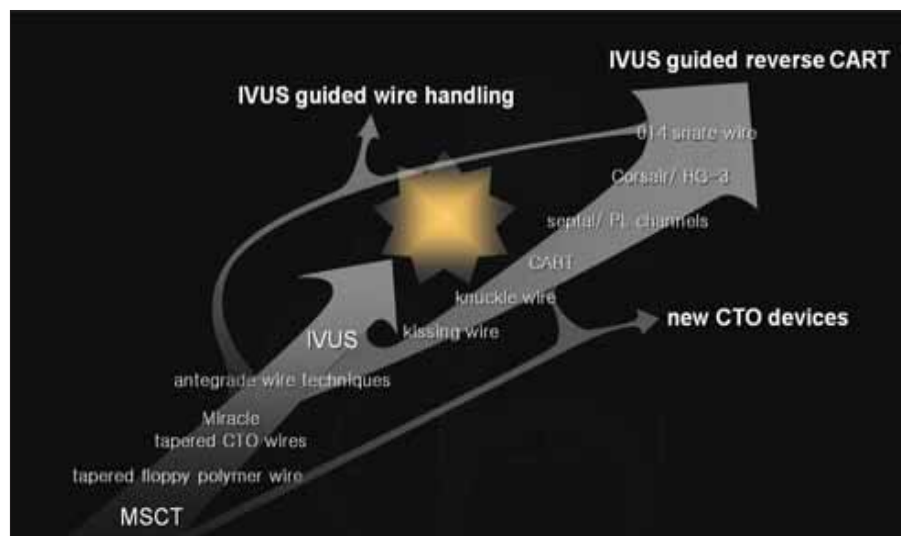
as the best angiographic projection, vessel tortuosity, angle with side branches, bridging collaterals, the caliber of distal vessels and the vessel trajectory at the occluded site. Longitudinal sections and cross-sectional images of the occluded segment can reveal distribution of calcification, shrinkage and stump morphology. Although the presence of severe calcification in the proximal fibrous cap of the CTO makes the antegrade penetration of guidewire more difficult, the use of such images during the procedure can provide a virtual roadmap that can be used to steer the guidewire in the proper direction. A specialized wire can be selected according to the nature of the occluding plaque. IVUS has also been applied to provide real-time interventional guidance as invasive imaging modality. We can clearly identify the entry point into the CTO by placing an IVUS catheter in a side branch of the occluded lumen. Also the true

lumen could be detected by placing the IVUS catheter into a previously created false lumen in antegrade fashion. IVUS guided reverse CART has now been used as a common technique in our retrograde approach by checking vessel size, 2 wires position and plaque morphology between them. We usually use Eagle Eye Gold (Volcano) because tip-transducer distance is only 10mm and the entry profile is low

In the practical viewpoint of the procedure, there have been huge developments for the successful recanalization of chronic total occlusion.

The experts of the CTO intervention from Japan (Dr. Kinzo Ueda & Yasushi Asakura) will provide the latest update of the antegrade and retrograde approach, respectively. From the era of first “just only antegrade approach” to the latest retrograde approach such as

reverse CART using IVUS”, the lecture might cover the whole range of intervention. One of the other challenges of the interventionist is the endovascular CTO lesion in which the occluded segment is sometimes very difficult to recanalize. So Dr. Hiroyoshi Yokoi will also show the optimal approach for this distressed lesion. Co-organized by



Integrated interpretation of MDCT, IVUS and angiograms is the key for success in complex CTO PCI.

CCT, Angioplasty Summit-TCTAP 2011 will prepare a live case demonstration of CTO intervention and selected-case presentations.

Dr. Masakiyo Nobuyoshi Awarded The 1st TCTAP Award ‘Master of the Masters’



Dr. Masakiyo Nobuyoshi, director of Kokura Memorial hospital, was recognized as the 1st recipient of TCTAP Award ‘Master of the Masters’, held on April 27 (Wed) at the Main Arena (Vista hall), the convention center of Sheraton Grand Walkerhill hotel.

This year, organizing committee of ANGIOPLASTY SUMMIT-TCTAP, CardioVascular Research Foundation (CVRF), held a new TCTAP Award ‘Master of the Masters’ during this meeting. This Award seeks to honor and show appreciation to outstanding teachers and dedicators in education in the field of interventional cardiology. This meeting has all benefited from Dr. Nobuyoshi’s outstanding expertise since early days and this may

enable this meeting to much progress over the last years, so they decided him as the 1st Master.

Dr. Nobuyoshi is also recognized as the mentor of Japanese Interventional Cardiologists. Since he performed PTCA for the first time in 1981, he has contributed to the widely accepted use of PTCA through the Japanese Cardiology committee. Furthermore, he has performed PTCA procedures for more than 45,000 patients. Now, he exerts his every effort for educating young physicians as the chairman of the Live Demonstration in KOKURA.

The 2nd TCTAP will hold at next year’s meeting. Who will be the next Master?

Structural Heart Disease Symposium

Endovascular Arena, Mugunghwa Hall 2, Level 1, 2:00 PM – 6:15 PM

The field of structural heart disease (SHD) intervention has grown rapidly over the past several years thanks to innovation of new promising devices and rapidly improving cardiac imaging modalities. Recent advances in catheter-based interventions have offered effective alternative treatments to surgery for several SHD with high mortality operative risk. This includes transcatheter aortic and pulmonary valve implantation, mitral valve repair, and shunt closure procedures. Today, crucial follow-up data of this field will be presented in SHD session.

Valvular Heart Disease, PFO and LAA Closure

For patients with severe aortic valve stenosis, the gold standard treatment has been replacement of the aortic valve via open heart surgery. Cumulative surgical experience and technical improvement have led to excellent results with low morbidity and mortality. However, the outcome may be less favorable for very old patients with medical comorbidities, and most of their cases may be inoperable.

Transcatheter aortic valve implantation (TAVI) has been an emerging alternative for high risk patients with severe aortic stenosis. In Valvular Heart Disease, patent foramen ovale (PFO) and Left Atrial Appendage (LAA) Closure Session, Dr. Samir Kapadia will introduce the results of TAVI in the Cleveland Clinic. There are currently many programs for researching TAVI, and Dr. Antonio Colombo will talk about his combined experience with Core valve and Edwards-Sapien valve, both of which are commonly used for TAVI. Percutaneous mitral valve repair is another recent development in valvular heart disease treatment, and two different approaches have been introduced. The first approach is

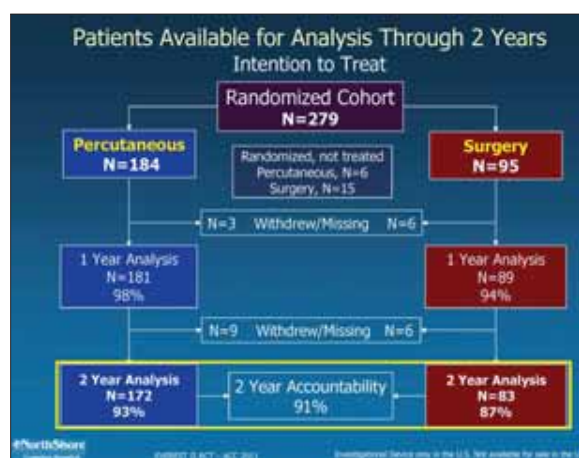


the edge-to-edge technique, which creates a double mitral valve orifice percutaneous mitral valve clipping. A two-year follow up

data of EVEREST II study comparing the percutaneous techniques with surgical treatment reveals that the percutaneous technique is as safe as the surgical one in mitral valve repair. Dr. Corrado Tamburino will introduce the mid-term outcomes following mitral valve repair with the MitraClip system. As the number of patients with right ventricle to pulmonary artery conduit dysfunction after repair of congenital heart disease (CHD) grows, the importance of the percutaneous technique comparable to surgery cannot be underestimated. Over the last 10 years, percutaneous pulmonary valve implantation (PPVI) has become a feasible, safe and effective treatment for both conduit stenosis and regurgitation. Median follow-up data show good freedom from reoperation and recatheterization and demonstrate that PPVI can postpone open-heart surgery, thereby potentially reducing the number of operations. Complications such as stent fractures seen after PPVI have been reported, which require reintervention in some cases (second stent-in-stent PPVI). Dr. James Y. Coe will talk about his experience and mid-term follow-up results of PPVI using Melody valve. In the last AHA meeting (2010), CLOSURE 1 study showed that PFO closure is not effective for patients with stroke of an unknown cause and PFO. Dr. Samir Kapadia will talk about Evidence for PFO Closure in 2011. Also, a state-of-the-art lecture about LAA Closure will be presented by Dr. Horst Sievert.

Special Lecture and Cardiac Imaging during Intervention - CHD session

Dr. Charles E. Mullins, who is a pioneer in congenital cardiac intervention, will give us a special lecture titled "The Remarkable and Rapid Evolution of Congenital Therapeutic Cardiac Catheterization". After a decade of rapid technological development, 3D echo, cardiac CT and cardiac MRI have evolved into a valuable non-invasive imaging technique for cardiac intervention. Some of them may be ready to replace diagnostic catheter angiography. Unlike many vascular interventions using over-the wire system in the well-defined space of vessel, SHD interventions frequently involve navigation in open 3D space, defined by relatively large



cardiac chambers, interaction with moving targets, such as heart valves, and deployment of devices, such as occluders and heart valves, that function quite differently from traditional vascular scaffolds. These differences subsequently impact procedural performance by relying heavily on the operator's knowledge of cardiovascular anatomy and physiology, training with unique navigational devices, incorporation of new procedural skills and familiarity with novel image guidance technologies. Recently, imaging modalities are evolving as rapidly as the interventions being performed in imaging modalities used in both the evaluation and treatment of SHD. Because traditional 2D imaging modalities remain limited in their ability to represent the complex 3D relationships present in SHD, the growing number of SHD, interventions performed worldwide has heightened the need for advanced 3D imaging modalities. Alignment of delivery catheter and devices to the 3D target, a technical aspect that is common to many SHD interventions, is likely facilitated by 3D imaging. Currently, there are two methods of using 3D image data to guide percutaneous interventions. The first is a 3D CTA-or MRA-derived image set obtained pre-procedurally. And the second approach is the real-time (RT) 3D ultrasound imaging. This integration of novel 3D imaging modalities has been utilized in procedures such as aortic coarctation stenting, ventricular septal defect (VSD) closure and atrial septal defect (ASD) closure. To improve the procedural success rate and minimize the frequency of complications, multimodality cardiac imaging plays a central role providing an accurate selection of patients and invaluable assistance during the procedure. Technological advances in the

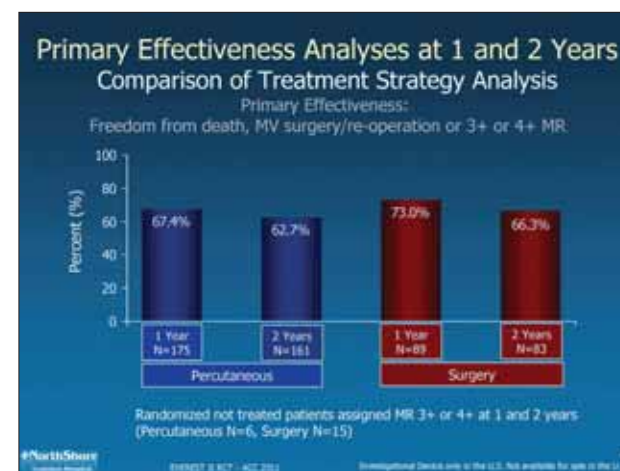
equipments and image post-processing softwares have provided improved accuracy of the image quality and analysis leading to an increasing implementation of these imaging techniques in the clinical practice. Several logistical challenges, including the need to optimize and standardize 3D views and registering device manipulation with presented image data, still require investigation. Solutions

to these issues in the form of advanced image processing, anatomy-based comprehensive analysis, multidimensional fusion and integrated navigation systems could further revolutionize SHD interventions.

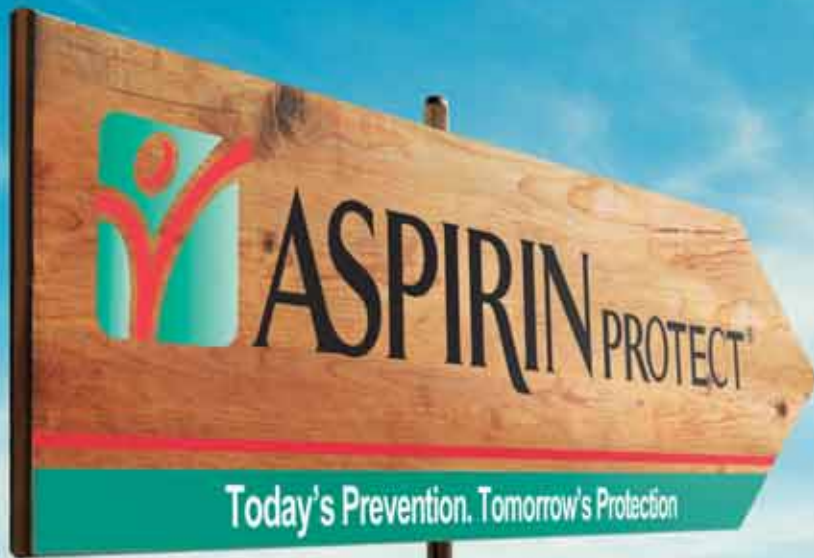
In this session, Dr. Jacques Koolen will talk about Imaging during TAVI, and Dr. Frank Ing will talk about assessing the Pulmonary Arteries: Angiography, CT and MRI. Accurate measurement of the size and location of the ASD is crucial for transcatheter closure of the defect. Dr. Toshio Nakanish will show us Anatomy of ASD and 3D Imaging, followed by Dr. Manabu Taniguchi's lecture on 3D TEE and transcatheter closure of ASD, and Dr. Jin-Young Song's presentation on Cardiac CT. In addition, Dr. R. Krishuna Kumar will talk about 2D and 3D Echo in Planning and Case Selection for VSD Closure.

Evening Satellite Symposium – organized by CVRF and supported by educational grant from AGA Corporation

Eight distinguished lectures on stent implantation and defect closure in congenital heart defects will be presented for two hours in the evening.



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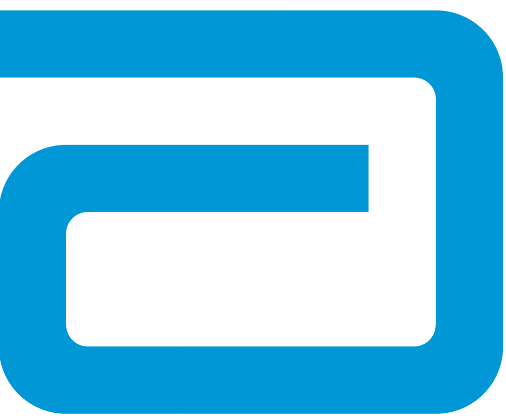


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