

Daily News

THE CONVENTION CENTER, SHERATON GRANDE WALKERHILL HOTEL, SEOUL, KOREA

Thursday, April 26, 2012

Today's Highlights

Morning Roundtable Forum: Debates and Learning

- 7:00 AM – 8:10 AM

Late Breaking Clinical Trials

Main Arena, 9:30 AM – 10:30 AM

Left Main & Bifurcation Summit: "Paradigm Shift"

Coronary Arena, 8:30 AM – 11:30

ACS Today – Unsettled Issues

Coronary Arena, 2:00 PM – 3:00 PM

AAA to Carotid Artery Stenosis

Live Cases and Featured Lectures

Mugunghwa Hall 2, 8:30 AM – 12:30 PM

Structured Heart Disease Symposium

Mitral Valve Treatment, Renal Denervation,

LAA Closure and PFO Closure

Mugunghwa Hall 2, 2:00 PM – 6:00 PM

The State of the Art Lecture; Wrap-Up and Brand-New Knowledge with Expert

Art Room, 8:30 AM – 12:30 PM

Imaging & Physiology Workshop

Art Room, 12:30 PM – 6:00 PM

Moderated Oral Abstract Competition I

Abstract Zone, Level B2

Moderated Complex Case Competition

Case Zone, Level B3

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To download the **TCTAP2012 APP**

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TCTAP 2012 Late Breaking Clinical Trials

Main Session 3, Main Arena, Level B2, 9:30 AM - 10:30 AM

VARC Outcomes Following TAVI with Both Edwards SAPIENT™ and Medtronic CoreValve ReValving System® Devices: 30-Days and One-Year Results from the Milan Registry



Alaide Chieffo, MD

The aim of this study was to assess clinical outcomes following transcatheter aortic valve implantation (TAVI) according to the Valve

Academic Research Consortium (VARC) definitions in our single center experience.

In total, 400 consecutive patients with severe symptomatic aortic stenosis underwent TAVI in the San Raffaele Scientific Institute, Milan, Italy from Nov. 2007 to Feb. 2012 utilizing either Edwards SAPIENT™/SAPIEN XT™ or Medtronic CoreValve ReValving System® devices, since they were commercially available in Europe. The overall mean age was 79.4 ± 7.4 years, logistic EuroSCORE 24.0 ± 17.0% and STS score was 8.7 ± 8.4%. In the majority of cases (n=333; 83.3%), the transfemoral access site was used. Thirty-day mortality was 4.7%, myocardial infarction 1.3% and stroke 1.0%. Life-threatening bleeding occurred in

22.7% and 13.5% had a major vascular complication. The median clinical follow-up length was 363.0 (IQR 185.5-530.0) days. At one-year, all-cause mortality was 13.5% and cardiovascular mortality 7.9%.

A further sub-analysis was performed in the transfemoral population in those patients undergoing new generation SAPIEN XT™ implantation (n=141) vs. CoreValve® (n=92). No difference between SAPIEN XT™ and CoreValve® was observed at 30-days in all-cause mortality (respectively 3.1% vs. 6.7%; p=0.2) or in the freedom from the combined safety endpoint (75.4% vs. 72.2%; p=0.597). However, there was a significantly higher device success amongst the SAPIEN XT™ group (97.1% vs. 89.1%; p=0.012), mostly as a consequence of the lower need for a second valve (1.4% vs. 7.6%; p=0.018). Furthermore, there were significantly less conduction disturbances/arrhythmia (17.3% vs. 34.8%; p=0.002) as well as pacemaker implantation (5.1% vs. 31.5%; p<0.001).

In this single center experience, TAVI appeared relatively safe and effective in patients with severe symptomatic aortic stenosis considered high-risk for surgical aortic valve replacement, with a low mortality rate at 30-days and one-year follow-up and acceptable outcomes

according to VARC definitions. With SAPIEN XT™ there was a lower incidence of arrhythmia and pacemaker implantation and higher device success.

Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy: Long-term Effects of Varying Alcohol Dosing



Josef Veselka, MD

The idea of inducing a septal infarction by catheter techniques was suggested by the observation that myocardial function of selected areas of the left ventricle can be suppressed by balloon occlusion of the supplying artery during angioplasty. The outflow pressure gradient in hypertrophic obstructive cardiomyopathy (HOCM) decreased significantly when the first septal artery was temporarily occluded by an angioplasty balloon catheter. This concept was also supported by observations that the outflow pressure gradient decreased after anterior myocardial infarction in HOCM patients.

Sigwart published his experience with alcohol injection into the septal branch ("non-surgical myocardial reduction") of three patients with HOCM in 1995. Since then, several modifications of the original technique have

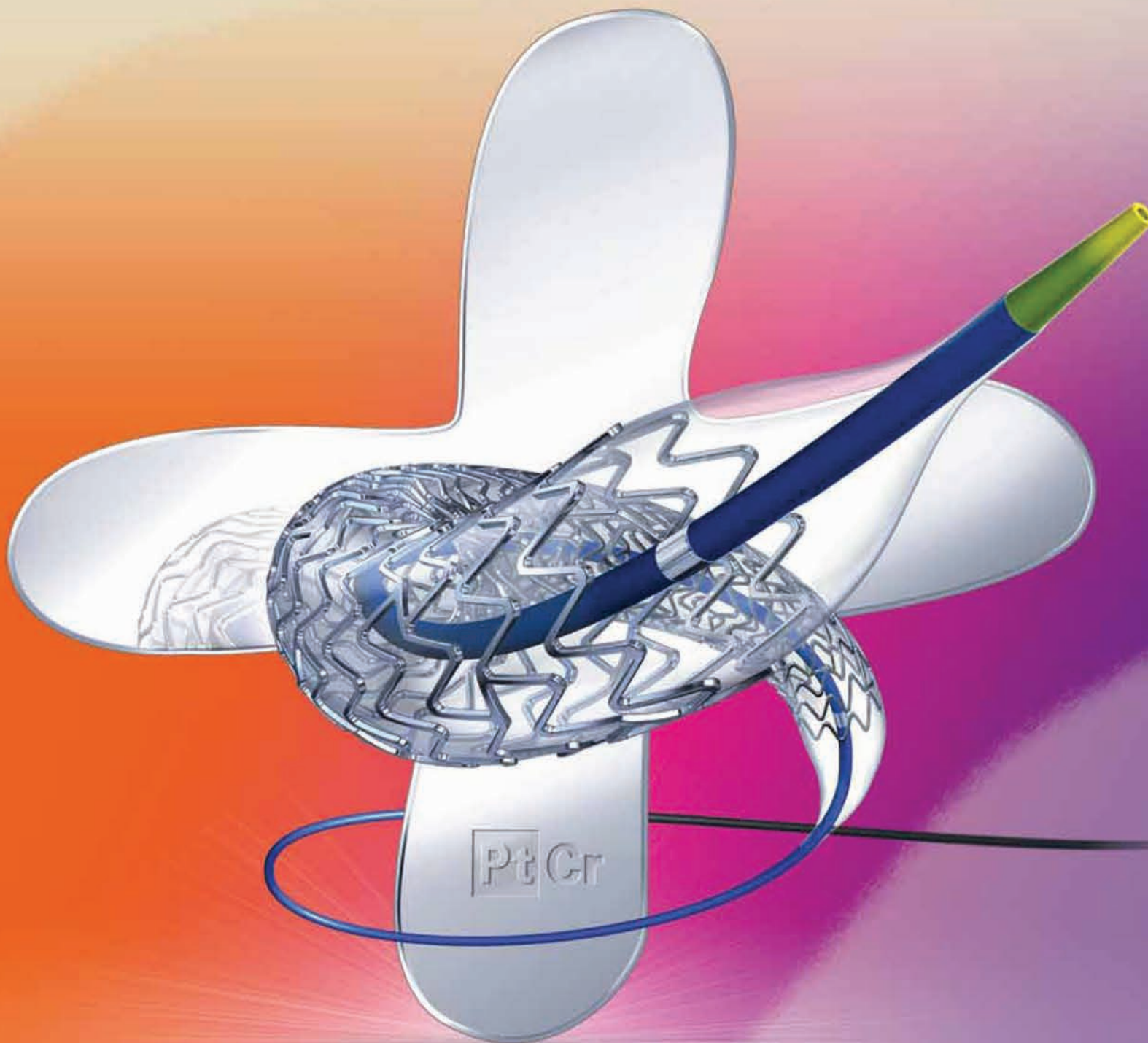
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VARC 30-Days Outcomes According to Valve Type (Transfemoral Only)

	All N=233	SAPIEN XT™ N=141	CoreValve® N=92	P value
Death; n (%)	10 (4.6)	4 (3.1)	6 (6.7)	.207
Cardiovascular Death; n (%)	8 (3.7)	3 (2.3)	5 (5.6)	.204
Stroke; n (%)	2 (1.0)	1 (0.8)	1 (1.2)	.758
Myocardial Infarction; n (%)	3 (1.3)	1 (0.7)	2 (2.2)	.343
Major Vascular Complication; n (%)	26 (11.2)	17 (12.1)	9 (9.8)	.577
Life-Threatening Bleeding; n (%)	33 (14.4)	16 (11.7)	17 (18.5)	.151
Acute Kidney Injury Stage 3; n (%)	15 (6.6)	11 (8.0)	4 (4.4)	.285
Device Success; n (%)	218 (94.0)	136 (97.1)	65 (72.2)	.012

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.



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Data on file at Boston Scientific.
PROMUS Element Plus stent illustration not indicative of clinical performance.

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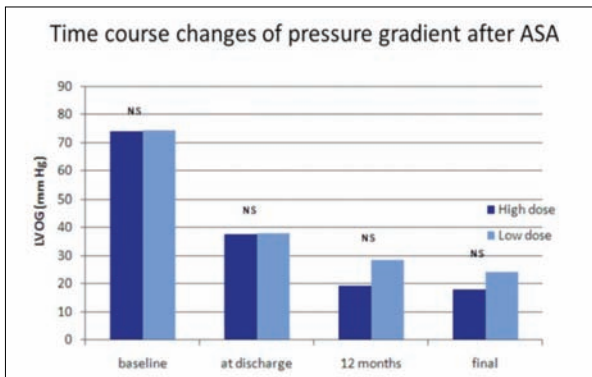
from page 1

been described.

Several years ago, the post-procedural course of hemodynamic changes is not related to the use of small (1-2 ml) or high (>2 ml) alcohol doses, and at 6-months follow-up, both groups of patients were not significantly different with regards to symptoms or electrocardiographic and echocardiographic findings. The main limitation of these studies is the fact that the long-term outcomes of the study population are unknown and the low number of included patients. To address these limitations, we decided to increase the size of the study population and to determine the long-term (60-138 months) clinical and echocardiographic outcomes of patients treated with low (1-2 ml) or high (>2 ml) doses of alcohol for obstructive HCM.

Seventy-six patients were randomized into two arms in a 1:1 ratio and subsequently were treated by alcohol septal ablation (ASA) with low (1-2 ml) or high (> 2 ml) doses of alcohol. For both groups, the final volume of alcohol injected into each individual patient was at the discretion of the first operator. Thirty-seven patients were enrolled in the low-dose group and 39 patients in the high-dose group. Both groups of patients matched in all baseline clinical and echocardiographic data. Clinical and echocardiographic examinations were performed at baseline, 1 year after the procedure and at the end of follow-up (at least 60 months after ASA)

There was no difference in the length of follow-up (median 85 vs 84 months; range 60-138 vs 60-134 months; NS). Overall, 7 patients (9%) died during the follow-up period. During the first post-procedural year, 1 patient died from



each group. Both patients died of cancer. Two patients from the low-dose group and 3 patients from the high-dose group died during the subsequent follow-up period (NS). There were no significant differences between the groups and all main changes occurred in the first post-procedural year. Time course of pressure gradient is summarized in the Figure below.

This study demonstrates that ASA treatment for HOCM is safe and effective in the long-term. No differences were found between patients treated with low or high doses of alcohol with respect to the long-term efficacy and safety of ASA.

Long Term Clinical Outcomes in Patients Treated with the Resolute Zotarolimus-eluting Stent

Ian Meredith, MD



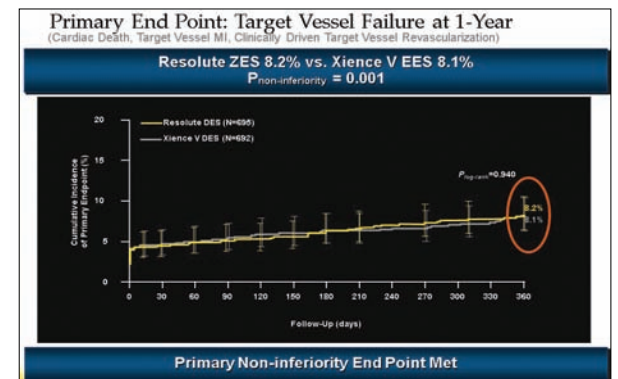
Dr. Meredith will be presenting the data on long term clinical outcomes of the Resolute zotarolimus-eluting stent (R-ZES), which is a new generation drug-eluting stent comprised of a cobalt-alloy bare metal stent and durable polymer. The RESOLUTE Clinical program is a set of 5 trials (1 randomized and 4 single arm) evaluating the R-ZES in 5,130 patients, prospectively designed with similar procedures including: data collection forms and procedures, adverse event definitions and adjudication procedures, statistical programming algorithms, and data sets. Patient-level data were pooled to compare long-term safety and efficacy of the R-ZES with another contemporary drug-eluting stent.

They used propensity scoring, calculated from 32 covariates, to adjust for differences in baseline characteristics for comparisons between the R-ZES and the everolimus-eluting stent (EES) arm of the RESOLUTE All Comers trial. Additional analysis was performed to also adjust for duration of antiplatelet therapy.

The following studies (N, longest follow-up) contributed to patients being treated with the R-ZES: the RESOLUTE first-in-human study (N = 139, 5 years); the randomised RESOLUTE All Comers, non-inferiority trial, comparing R-ZES (N = 1140) with the XIENCE V EES (N=1152, 2 years). With 2-year follow-up completed for 3628/5130 (70.7%) patients from 3 of the 5 studies, the cumulative incidence of target lesion failure was R-ZES: 9.4% vs EES, 10.7%, p=0.40, cardiac death: 2.4% vs 2.2%, p= 0.70, target-vessel myocardial infarction: 3.4% vs 4.5%, p=0.51; ischemia-driven target lesion revascularization: 4.8% vs 5.2%, p=0.98 and ARC definite and probable stent thrombosis: 0.96% vs 0.98%, p=0.32.

In addition, the adjusted risk for adverse events was comparable between the R-ZES and the EES for the subset of patients who have completed the 2-year follow-up. You will get further information in this presentation.

% (n)	1 Year n = 130 pts 131 lesions	2 Year n = 130 pts 131 lesions	3 Year n = 129 pts 130 lesions	4 Year n = 129 pts 130 lesions	5 Year n = 127 pts 128 lesions
Death (all)	2.3 (3)	3.1 (4)	4.7 (6)	6.2 (8)	7.1 (9)
Cardiac	0.8 (1)	0.8 (1)	0.8 (1)	0.8 (1)	1.6 (2)
MI (all)	5.4 (7)	5.4 (7)	5.4 (7)	5.4 (7)	6.3 (8)
Q Wave	0	0	0	0	0
Non Q wave	5.4 (7)	5.4 (7)	5.4 (7)	5.4 (7)	6.3 (8)
Cardiac Death + MI	6.2 (8)	6.2 (8)	6.2 (8)	6.2 (8)	7.1 (9)
ST Def/Prob	0	0	0	0	0
Early (0 - 30d)	0	0	0	0	0
LST (>30d - 1yr)	0	0	0	0	0
VLST (>1 yr)	-	0	0	0	0
TLR	0.8 (1)	1.5 (2)	1.6 (2)	2.3 (3)	3.1 (4)
TVR (non-TL)	0	0	0.8 (1)	1.6 (2)	2.4 (3)
TVR	0.8 (1)	1.5 (2)	2.3 (3)	3.9 (5)	5.5 (7)
MACE	8.5 (11)	10.0 (13)	11.6 (15)	14.0 (18)	16.5 (21)
TVF	6.9 (9)	7.7 (10)	8.5 (11)	10.1 (13)	13.4 (17)



4th Chien Foundation Lectureship at TCTAP 2012 will be awarded to Professor Koh Tian Hai

The presentation of this prestigious award will take place on April 26 (Thu.) at the Coronary Arena, Mugunghwa Hall 1, Level 1, Sheraton Grande Walkerhill Hotel at 11:25 am.

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.

This year's awardee is Professor Koh Tian Hai. Professor Koh is the Medical Director of the National Heart Centre in Singapore, and is a prominent and active member of the cardiology circle, not just in Singapore but also in the international circuit.

Professor Koh Tian Hai
Medical Director
National Heart Centre Singapore

TCTAP BEST YOUNG SCIENTIST AWARD

TCTAP has generated this new academic award, TCTAP Best Young Scientist Award to be granted to young cardiologists.

Qualifications and Procedures

This award will be bestowed to two (2) winners after the conference, each from cases and abstracts selected by scientific committee as described in these qualifications and procedures.

- Eligible candidates must be selected by a panel of experts as the best case or abstract of the session.
- The selected best case or abstract presenters must provide a Curriculum Vitae (CV) and letters of recommendation after the conference to the secretariat of ANGIOPLASTY SUMMIT-TCTAP.
- Award notification will be notified to the winners along with official faculty invitation to TCTAP2013.

Benefits

The winners will be

- Invited to attend TCTAP2013 as a faculty
- Given a scholarship of 5,000USD
- Invited to the conference ceremony in the Main Arena during TCTAP2013

FFR Guided and IVUS Supported Functional Angioplasty in Left Main Coronary Artery Disease

In this TCTAP 2012 meeting, Seung-Jung Park, MD from Asan Medical Center, Seoul, Korea summarized the concept of optimal treatment of left main coronary artery disease: **FFR guided and IVUS Supported Functional Angioplasty in Left Main Coronary Artery Disease.**

Significant narrowing of the left main coronary artery puts a patient at high risk, since it can jeopardize the entire myocardium of the left ventricle, and it has the worst prognosis of any form of coronary artery disease. Therefore, for several decades, based on clinical trials for comparing coronary-artery bypass grafting (CABG) with medical therapy, bypass surgery has been regarded as the treatment of choice for patients with unprotected left main coronary artery (LMCA) disease. However, recently, marked advancements in techniques of percutaneous coronary intervention (PCI) and adjuvant pharmacologic therapy make a new evaluation of the optimal revascularization therapy for LMCA disease. In fact, several clinical trials and large off-label experiences demonstrated that stenting yields mortality and morbidity rates that compare favorably with CABG, which allows PCI to receive a class IIb indication for the treatment of LMCA stenosis in the current guideline update. Therefore, SJ Park said “now is the time to discuss how to optimize the PCI results moving away from the long-standing debate about the feasibility and safety of LMCA stenting.”

First, identification of a significant stenosis in LMCA is of critical prognostic importance. Traditionally, angiographic diameter stenosis of 50% has been considered as a cut-off for significant LMCA stenosis. The conventional coronary angiogram,

however, has limitations in assessing lesion morphology and the true luminal size of the LMCA. Recently, SJ Park presented that **reverse mismatch** (insignificant angiographic stenosis but reduced FFR) was more frequent in LMCA as compared with non-LM epicardial artery, mainly due to the large myocardial burden (Figure 1). Therefore, FFR measurement should be performed for the LMCA evaluation, particularly when significant LMCA stenosis is clinically suspected.

Several studies demonstrated that the FFR guided decision of making the treatment of LMCA associated with favorable prognosis and the intermediate LMCA with $FFR \geq 0.75$ - 0.80 could be safely deferred. In an evaluation of 213 patients with intermediate LMCA stenosis, the 138 patients with $FFR \geq 0.80$ were treated medically, whereas the 75 patients with $FFR < 0.80$ underwent coronary artery bypass grafting. Their 5-year survival rates were 89.8% and 85.4%, respectively ($P=0.48$). In a trial of 54 patients with angiographically intermediate LMCA, those with $FFR \geq 0.75$ ($n=24$) received medical treatment, whereas those with $FFR < 0.75$ ($n=30$) underwent surgical revascularization. The survival rates at 3 years were 100% and 97%, respectively, and the event-free survival rates were 76% and 83%, respectively. In a study of 142 patients with LMCA stenosis, those with $FFR \geq 0.80$ ($n=82$) were treated medically, whereas those with $FFR < 0.75$ ($n=60$) underwent coronary revascularization (6 underwent PCI and 54 underwent bypass surgery). During a follow-up of 14 ± 11 months, the rates of cardiac death or MI were 6% and 7%, respectively ($p=0.70$). In a study of 51 patients with suspected LMCA stenosis, surgical

revascularization was performed if FFR was < 0.75 along the left main stem, whereas medical treatment was administered if FFR was > 0.80 or if PCI was required elsewhere in the coronary tree; if FFR was ≥ 0.75 but ≤ 0.80 , treatment depended on additional individual criteria. Estimated survival after 4 years of follow-up was 81% among patients in the surgical treatment group and 100% among patients in the medical treatment group. An investigation of 55 patients with ambiguous LMCA stenosis, 14 with $FFR < 0.75$ and 41 with $FFR \geq 0.75$, found that the 38 month survival rates were 100% in both groups. However, FFR measurements in patients with LMCA stenosis should be interpreted with caution because isolated LMCA stenosis is very rare with most associated with disease in the left anterior descending artery and/or left circumflex artery, both of which tend to increase FFR measured across the LMCA stenosis. Therefore, the functional significance of LMCA stenosis should be reassessed following the correction of distal coronary artery stenosis. In addition, because of the potential for the guiding catheter to obstruct blood flow across the LMCA stenosis, FFR measurements should be performed with the guiding catheter disengaged from the coronary ostium and with hyperemia induced by intravenous adenosine.

IVUS can complement the limitation of FFR measurement in LMCA disease because of the high positive predictive value of IVUS minimal lumen area in LMCA stenosis. We evaluated the correlation of the FFR and IVUS MLA and found that the best predicted an $FFR < 0.80$ was IVUS measured MLA $< 4.5 \text{ mm}^2$ (83% sensitivity, 83% specificity, 83% accuracy, $AUC=0.89$, 95% $CI=0.759 - 0.960$, $p<0.001$). Of interest is that positive predictive value of IVUS measured $MLA < 4.5 \text{ mm}^2$ is acceptably high by 83%, in contrast with the non-LMCA stenosis. In the meantime, SJ Park evaluated the optimal IVUS-MSA criteria to prevent ISR in

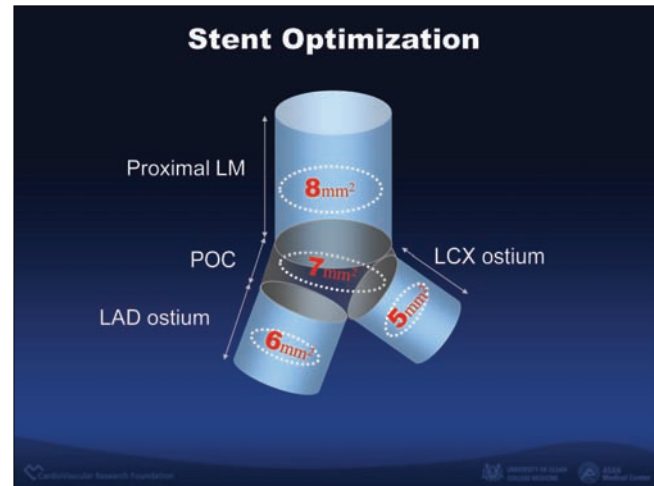


Figure 2. Optimal Stent Area in LMCA Stenting

403 patients undergoing sirolimus-eluting stent implantation for LMCA disease. The best IVUS-MSA criteria that predicted angiographic ISR on a segmental basis were 5.0 mm^2 for the LCX ostium, 6.3 mm^2 for the LAD ostium, 7.2 mm^2 for the POC, and 8.2 mm^2 for the proximal LMCA above the POC (Figure 2). SJ Park also published the importance of IVUS surveillance in LMCA stenosis. In the MAIN-COMPARE registry, patients with unprotected LMCA 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). The 3-year outcomes between 2 groups showed that a tendency of lower risk of 3-year mortality with IVUS guidance in the overall population; particularly, in patients who underwent the implantation of drug-eluting stent, the use of IVUS guidance reduced the 3-year incidence of mortality (4.7% vs. 16.0%, long-rank $p=0.048$).

SJ Park concluded that FFR guided complex PCI, which was supported by IVUS, can help us better to understand complex anatomical disease and may improve the clinical outcomes of complex LMCA disease.

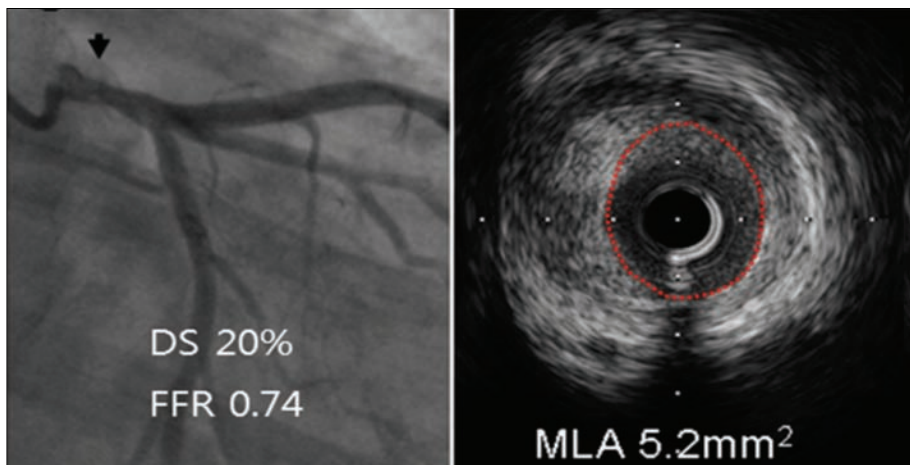
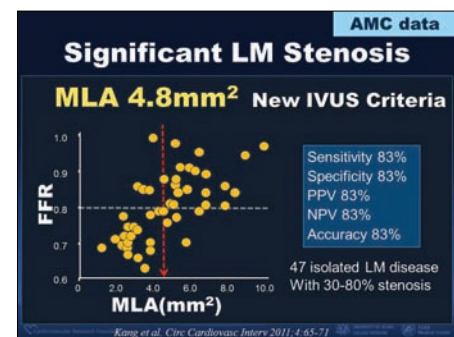


Figure 1. Example of “Reverse-Mismatch”



TCTAP Session & Featured Lectures

Main Arena, Vista Hall, Level B2, 10:10 AM, 11:09 AM

The Use, Abuse and Value of Platelet Reactivity Testing During Complex PCI

Sorin Brener, MD

It has been well known that platelet inhibition varies substantially in patients treated with clopidogrel and high residual platelet activity is associated with a higher rate of ischemic events than lower platelet reactivity. Up-to-date knowledge about platelet function test and its implications in clinical practice will be presented at the Main Arena, Vista Hall (Level B2), April 25, at 10:10 am by Sorin Brener. Numerous tools for platelet function test have been developed in recent years. Through the test we realized that there are significant variations in the response to antiplatelet agents, most of them to clopidogrel. Several studies have shown that the platelet function assessed by the VerifyNow Analysis is clearly related to post-PCI ischemic risk (Brar SS, et al. JACC 2011;58:1945). To date, GRAVITAS and TRIGGER-PCI studies have been completed and those outcomes will be shown in this session.

Genetic mutations play a big role in the variations. The newer generation antiplatelet agents including prasugrel, ticagrelor and cangrelor could get over the variations in response to clopidogrel. Furthermore, those new agents are known to be more potent than clopidogrel. In general, the more the platelet function is suppressed, the better the clinical outcomes are. However, bleeding risk increases when the platelet function is suppressed even below a certain threshold. In that point, the platelet function test may be useful in clinical practice.

The general consensus on this issue was the following platelet function testing may be considered in patients at high risk for poor clinical outcomes. In clopidogrel-treated patients with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered. The routine clinical use of platelet function testing to screen clopidogrel-treated patients undergoing PCI is not recommended. Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel. When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by

genetic testing, treatment with an alternate P2Y12 inhibitor (e.g., prasugrel or ticagrelor) might be considered. The routine clinical use of genetic testing to screen clopidogrel-treated patients undergoing PCI is not recommended.

Complications after TAVR: Frequency and Clinical Importance

Martin B. Leon, MD

Nov. 2, 2011, The FDA approval of the first transcatheter aortic valve for replacing a native valve damaged by severe aortic stenosis marks an exciting time in the field of interventional cardiology. However, it is important to step back and examine potential complications of this relatively new technique. These issues will be discussed at the Main Arena, Vista Hall (Level B2), April 25, at 11:09 am by Martin B. Leon.



With regards to transcatheter aortic valve replacement (TAVR), recent growth has been phenomenal. Estimates from Europe, for example, indicate that the number of TAVR procedures performed there in 2001 will exceed 17,500. Leon (New York-Presbyterian Hospital, Columbia University Medical Center) and colleagues initiated the Valve Academic Research Consortium, also known as VARC, to identify the most relevant clinical endpoints and endpoint definitions in response to a tidal wave of uncontrolled TAVR clinical research. Several groups reviewed the literature and completed a study-level meta-analysis of more than 3,500 patients from 17 studies. Most patients were older (mean age, 81 years) and female.

Stroke definition and ascertainment are highly variable in surgical aortic valve replacement (AVR) and TAVR literature. Stroke frequency is increased after TAVR - about two to three times compared with AVR - and the difference is an early peaking hazard, and appears largely due to ischemic embolic events. Transcranial doppler studies suggest that native valve manipulation may be an important contributor to early stroke. Cerebral embolic protection and increased pharmacotherapy are currently under investigation. Although there is much to learn about stroke and TAVR, it is not an unmanageable complication.

Vascular complications after TAVR, including hematoma dissection and perforation are frequent and have been associated with increased mortality. Vessel-sheath size ratio, calcification and center experience appear to be important predictors. Meticulous CTA screening, site/operator experience, reduced caliber devices and dedicated access site closure systems will improve future outcomes.

Paravalvular leak after TAVR occurs frequently in up to 80% of patients. However, definitions and grading of paravalvular severity remain inconsistent and problematic. Causes and predictors of paravalvular leak are multifactorial, and may include optimal valve sizing, calcification and valve position. Operator experience and post-dilatation have been associated with reduced paravalvular leak. Significant paravalvular leak has been a predictor of subsequent mortality, although observation is limited. New TAVR designs may reduce paravalvular leak in the future.

The need for permanent pacemakers after TAVR is an important complication that requires more intense and prolonged in-patient monitoring and exposes patients to lifelong hazards. The threshold for needing a permanent pacemaker after TAVR is extremely variable and better guidelines are required. In the future, improved implantation techniques and modified TAVR systems will reduce the rates of permanent pacemakers after TAVR to levels similar to surgical AVR.

Short and mid-term TAVR system durability appears encouraging, with infrequent endocarditis, maintained hemodynamic performance and no other signs of structural valve deterioration. However, several caveats exist, including a lack of long-term data and unknown imponderables such as late effects on coronary arteries and the mitral valve.

'Master of the Masters'

Dr. Martin B. Leon, director of Center for Interventional Vascular Therapy, Columbia University Medical Center / New York-Presbyterian Hospital, was recognized as the 2nd recipient of TCTAP Award 'Master of the Masters', held on April 25 (Wed) at the Main Arena (Vista hall), the convention center of Sheraton Grand Walkerhill hotel.

CardioVascular Research Foundation (CVRF), organizing committee of ANGIOPLASTY SUMMIT-TCTAP has held an award 'Master of the Masters' during TCTAP since 2011 and Dr. Masakiyo Nobuyoshi, director of Kokura Memorial Hospital, was honored as the 1st recipient of this award last year. TCTAP Award 'Master of the Masters' is bestowed to honor and show appreciation to outstanding teachers and dedicators in the field of interventional cardiology. Especially TCTAP has been benefited from Dr. Leon's outstanding expertise and value enabling this meeting more special. Therefore, the organizing committee has generously agreed to nominate him to this award.

Dr. Leon is the founder of Cardiovascular Research Foundation (CRF) and course director of the world-renowned TCT conference in the US. He has contributed significantly to the interventional cardiology not only in US, but also internationally through this conference. Furthermore, he has exerted further efforts to develop the intervention field in Asia-Pacific through the collaboration between CRF and ANGIOPLASTY SUMMIT-TCTAP. 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.

The 3rd TCTAP Award will be held at the next year's meeting. Who will be the next master?





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1. G. Stone SPIRIT IV 2-year, P. Smits COMPARE 2-year, L. Okkels Jensen SORT-OUT IV 9-month stent thrombosis rates from TCT 2010. RESOLUTE AC 1-year stent thrombosis rate from Serruys, P. W., et al. (2010) NEJM 363(2): 136-14, and S. Windecker LESSON 1 3-year stent thrombosis rate from ESC 2010.

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See The Lancet publication on-line ¹



See presentation on-line ²

* Based on LEADERS results on MACE, definite VLST and cardiac events associated with definite stent thrombosis out to 4 years.

1. Stefanini GG et al., Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4-year follow-up of a randomised non-inferiority trial. The Lancet. 2011; 378(9807): 1940-8.

2. Ischinger T et al., Long-term Clinical Results from the All-comers LEADERS Trial: 4-year follow-up data, oral abstract presentation, TCT 2011.

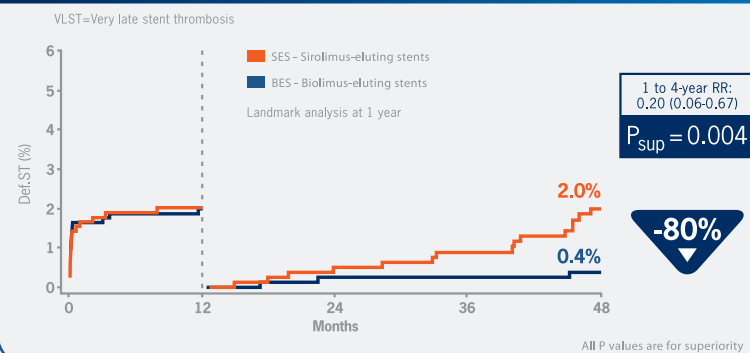
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BioMatrix Flex™ - cutting the MACE rate out to 4 years



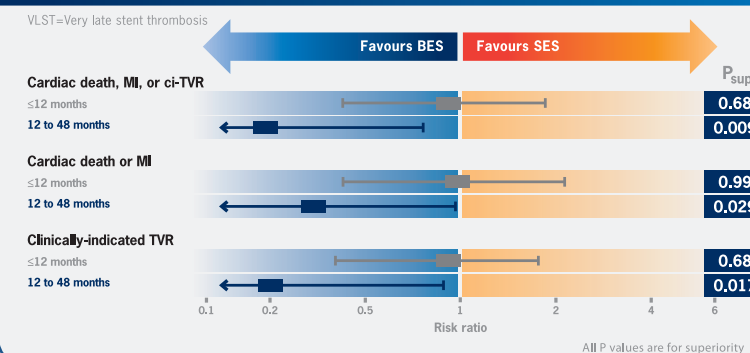
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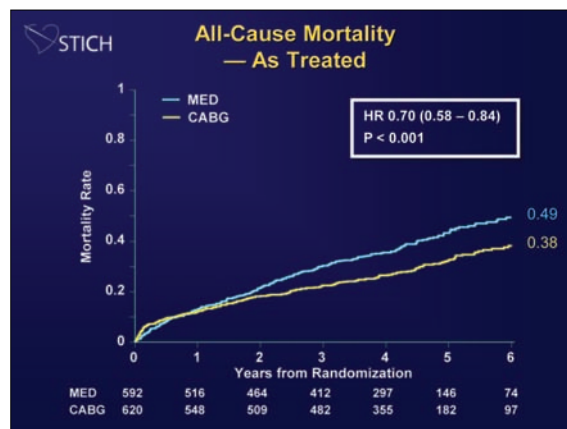


Breakfast Meeting: STICH or Not STICH

Tutorial Arena, Level 4, 7:00 AM – 8:10 AM

STICH (the Surgical Treatment of Ischemic Heart Failure) trial is the largest randomized, controlled study ever to compare CABG plus the best possible medical therapy to aggressive medical therapy alone in patients with coronary artery disease and heart failure.

In the main STICH study, for which 1,212 patients with ischemic LV dysfunction and an EF of 35% or less were enrolled, no significant all-cause mortality differences were observed by intention-to-treat analysis between patients undergoing coronary artery bypass grafting (CABG), compared with optimal medical therapy. In the CABG group, however, the prespecified secondary endpoint of cardiovascular death—that is, the mortality outcome more likely to be influenced by CABG—was reduced by 19% with borderline statistical significance ($P=0.05$) whereas the composite endpoint of cardiac death and hospitalization for cardiac cause was significantly reduced by 26%. Interestingly, a significant 30% all-cause mortality reduction was observed in the CABG group in the as-treated analysis, which took into account the substantial crossover rate (17%) of patients assigned to medical therapy who underwent CABG, pointing to the possibility that such crossover may have diluted the benefit of CABG in the primary intention-to treat analysis. Therefore, as acknowledged by the authors, the results of the STICH study do not definitively deny the advantage of CABG in LV dysfunction but rather provide, from secondary



analysis, provisional evidence in favor of revascularization in ischemic LV dysfunction.

A viability STICH substudy evaluated whether imaging could be used to identify which patients are likely to benefit from bypass surgery. Researchers recruited a total of 601 patients to have one of two types of imaging tests: a nuclear perfusion scan or dobutamine echocardiography. The results of that study showed that survival of patients with viability was significantly longer than that of patients without viability, but patients with viable myocardium undergoing CABG did not show survival benefit compared with those treated with optimized medical therapy. The study results thus disputed the conclusion of the previous metaanalysis and questioned the recommendations of guidelines for viability-guided treatment in patients with ischemic LV dysfunction.

Breakfast Meeting: Antiplatelet Therapy

Wednesday, April 25, Tutorial Arena, Level 4, 7:00 AM – 8:10 AM

Antiplatelet therapy is a first-line medical treatment for patients with any clinical manifestation of coronary disease. As percutaneous coronary interventions (PCI) increase in number and complexity, more patients must be treated with antiplatelet therapy for cardiovascular diseases in which arterial thrombosis plays a major role, including double or even triple antiplatelet regimens after stent implantation. Nevertheless, a significant number of patients continue to experience recurrent complications despite being properly treated, due to some reasons: pharmacokinetics and interactions of drugs, genetic background and increased thrombus formation. New antiplatelet agents such as prasugrel or ticagrelor have been developed for patients at high risk of thrombosis. Prasugrel is an ADP-P2Y₁₂ receptor inhibitor that has a faster and more consistent inhibitory effect of platelet aggregation. In the TRITON-TIMI 38 trial, prasugrel therapy was associated with less major adverse cardiac event occurrence than clopidogrel therapy in high-risk ACS patients undergoing PCI. The effect of prasugrel therapy on the occurrence of stent thrombosis was dramatic (about 50% reduction). There was also a significant increase in major non-CABG bleeding risk (32%), which persisted over the duration of treatment. Ticagrelor is a direct-acting P2Y₁₂ receptor blocker with some pharmacokinetic advantages over prasugrel and

clopidogrel (mainly because is not a pro-drug and does not need hepatic transformation into an active metabolite and its reversible platelet inhibition). The PLATO study showed the superior clinical efficacy of ticagrelor. So their benefits in terms of mortality and major cardiovascular events have been demonstrated, but some concerns remain regarding the possible increase in bleeding. In addition, both high on-treatment platelet reactivity (HPR) and the cytochrome (CY) P2C19 reduced function genotype are associated with a significant increase in ischemic risk in PCI patients treated with clopidogrel, and this is not surprising given the central role of the ADP-P2Y₁₂ interaction in the genesis of coronary thrombosis. The recent 2011 American and European guidelines have given a class IIb recommendation for platelet function testing or genotyping if the results of testing may alter management. Several studies have been published that question the value of platelet function and genetic testing. Whether platelet function testing combined with genetic test-guided treatment might be a successful management strategy in high-risk ACS patients is being investigated in ongoing randomized trials. Until the results of these large-scale trials of personalized antiplatelet therapy are available, the routine use of platelet function assays or genotype testing in the care of patients with cardiovascular disease remains unproven.

Satellite Symposia

MEET THE EXPERTS OVER BREAKFAST

Current Issues in the Cardiovascular & Endovascular Interventional Field: Focus Reviews and Case Presentation with Discussion in a Small Group Environment

**Wednesday 25 - Friday 27
7:00 AM - 8:10 AM**



Yesterday's Hot lives

Transcatheter Aortic Valve Implantation with the CoreValve

Yesterday, Dr. Seung-Jung Park and Eberhard Grube demonstrated successful treatment with the CoreValve for severe AV stenosis. An 83 year-old female was admitted with dyspnea on exertion (NYHA class II) for about three months. She has a past medical history of diabetes, hypertension, and claudication. Her logistic EuroSCORE was 26.35%. Her coronary angiogram was normal. Transthoracic echocardiography showed very severe degenerative AV stenosis and severe concentric LVH with normal LV systolic function (EF=66%). AV area by continuity equation was 0.64 cm². Transaortic valve maximal velocity was 5.4 m/s. Mean and peak pressure gradient were

63 and 115 mmHg. Transesophageal echocardiography showed the opening limitation of AV because of heavy calcification and thickening (Figure 1). Her AV was tricuspid and annulus size by TEE was 21 mm (Figure 2). Annulus size by CT was 20-21 mm and perimeter was 81 mm (Figure 3). Distance from annulus to LM and RCA ostium was 14.7 and 15.2 mm, respectively. The right lowest diameter was 7.6mm and there was no problem in vessel size and calcification. Therefore, we chose the right approach.

Although the annulus size by TEE and CT was 21 mm, perimeter was 81 mm. After discussion, we selected the larger sized CoreValve (29 mm). 6 Fr sheath and a temporary pacemaker were inserted through left femoral vein and 7 Fr sheath and 6 Fr pig-tail catheter were inserted through left femoral artery. After right peripheral angiogram with pig-tail catheter, we checked the proper puncture site of right femoral artery. 7 Fr

sheath was inserted through right femoral artery and then three 8 Fr Proglide devices were placed into the right femoral artery. After removal of the sheath, 18 Fr Ultimom sheath was placed. Then an AL 1 diagnostic catheter with a stiff wire was used to cross the aortic valve. After crossing AV, the stiff wire was replaced by a super-stiff wire and then the 18 Fr CoreValve delivery catheter system (AccuTrak) was advanced gently into the vessel. The CoreValve crossed over AV using the super-stiff wire and deployment was done. After the CoreValve im-

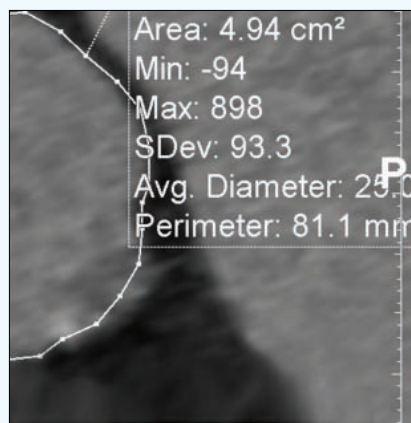


Figure 3

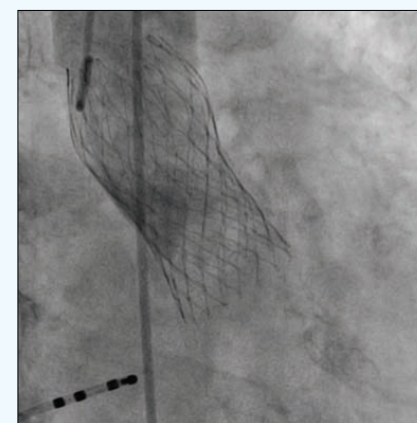


Figure 4

plantation, adjunctive balloon dilatation was done using a Tyshak II 25x40 mm. Final fluoroscopy showed a well-positioned CoreValve (Figure 4).

After the intervention, the puncture site was sutured by three prepared Proglides.

Left Main Ostial Lesion Treatment Using Simple Cross-Over Technique

Yesterday, Dr. Gregg W. Stone and Duk-Woo Park treated left main ostial lesion. A 76 year-old female was admitted with effort chest pain for about six months. Her coronary risk factor was hypertension. The physical examination was normal. The ECG and cardiac enzymes were unremarkable. Cardiac stress perfusion CT showed severe stenosis of LM ostium and decreased perfusion at LAD territory. Thallium test and treadmill test were not done. The left coronary angiogram showed discrete tight stenosis at left main ostium (Figure 1). An 8 Fr sheath was inserted through right femoral artery and the left coronary ostium was engaged with an 8Fr JL 4.0 catheter with side hole. Two 0.014 inch BMW wires were inserted into the LAD and LCX, respectively and then they performed intravascular ultrasound evaluation from LM to LAD. Without predilatation, they deployed a Xience-Prime stent 3.5x28 mm at the LM ostium. Thereafter, post-stenting adjunctive balloon dilatation was done using Dura Star 4.0x15 mm and Quantum 4.5x12 mm sequentially. Final angiogram showed a well-expanded and well-positioned stent (Figure 2).



Figure 1



Figure 2

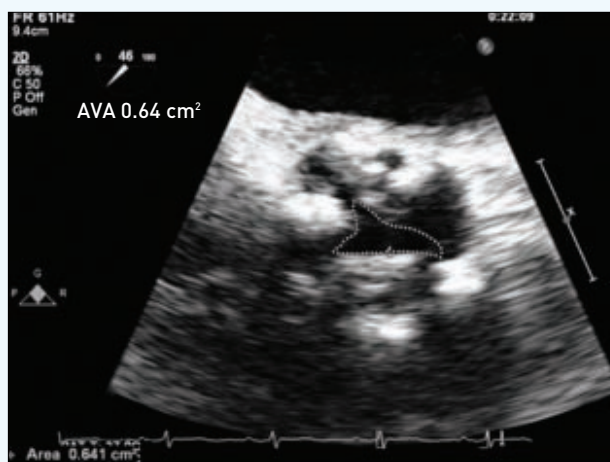


Figure 1



Figure 2

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Product Information

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[Indications and Usage] VYTORIN is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipidemia. VYTORIN is indicated for the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable. **[Dosage and Administration]** The patient should be placed on a standard cholesterol-lowering diet before receiving VYTORIN and should continue on this diet during treatment with VYTORIN. VYTORIN should be taken as a single daily dose in the evening, with or without food. The recommended usual starting dose is 10/20 mg/day. Initiation of therapy with 10/10 mg/day may be considered for patients requiring less aggressive LDL-C reductions. **[Contraindications]** Hypersensitivity to any component of this medication, active liver disease or unexplained persistent elevations in serum transaminases, pregnancy and lactation, patients with hereditary problems of galactose intolerance, Lapp lactase deficiency or of glucose-galactose malabsorption.

[Warnings] Myopathy and rhabdomyolysis are known adverse reactions to HMG-CoA reductase inhibitors and other lipid-lowering drugs. Simvastatin, like other inhibitors of HMG-CoA reductase, occasionally causes myopathy manifested as muscle pain, tenderness or weakness with creatine kinase above 10 X ULN. Myopathy sometimes takes the form of rhabdomyolysis with or without acute renal failure secondary to myoglobinuria, and rare fatalities have occurred. The risk of myopathy is increased by high levels of HMG-CoA reductase inhibitory activity in plasma. In three placebo-controlled, 12-week trials, the incidence of consecutive elevations (≥ 3 X ULN) in serum transaminases was 1.7% overall for patients treated with VYTORIN and appeared to be dose-related with an incidence of 2.6% for patients treated with VYTORIN 10/80. In controlled long-term (48-week) extensions, which included both newly-treated and previously-treated patients, the incidence of consecutive elevations (≥ 3 X ULN) in serum transaminases was 1.8% overall and 3.6% for patients treated with VYTORIN 10/80. These elevations in transaminases were generally asymptomatic, not associated with cholestasis, and returned to baseline after discontinuation of therapy or with continued treatment. It is recommended that liver function tests be performed before the initiation of treatment with VYTORIN, and thereafter when clinically indicated. Patients titrated to the 10/80-mg dose should receive an additional test prior to titration, 3 months after titration to the 10/80-mg dose, and periodically thereafter (e.g., semiannually) for the first year of treatment. Patients who develop increased transaminase levels should be monitored with a second liver function evaluation to confirm the finding and be followed thereafter with frequent liver function tests until the abnormality(ies) return to normal. Should an increase in AST or ALT of 3 X ULN or greater persist, withdrawal of therapy with VYTORIN is recommended. VYTORIN should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease. Active liver diseases or unexplained persistent transaminase elevations are contraindications to the use of VYTORIN. **[Adverse Reactions]** VYTORIN has been evaluated for safety in more than 3800 patients in clinical trials. VYTORIN was generally well tolerated. Clinical AE reported in $\geq 2\%$ of patients treated with VYTORIN and at an incidence greater than placebo regardless of causality assessment from three similarly designed, placebo-controlled trials were headache, influenza, upper respiratory tract infection, myalgia, pain in extremity. [Pregnancy/Nursing mother]Should not take VYTORIN. [Pediatric/Geriatric Use]There are insufficient data in pediatric patients. The safety of VYTORIN was similar between geriatric and younger patients. Greater sensitivity of some older individuals cannot be ruled out. [2011. 12.15]

※ **Before prescribing, see full prescribing information for VYTORIN.**

Reference | 1. Shepherd J. The role of the exogenous pathway in hypercholesterolaemia. *Eur Heart J Suppl.* 2001;3(suppl E):E2-E5.
2. Bays H. Ezetimibe. *Expert Opin Investing Drugs.* 2002;11(11):1587-1604



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Left Main & Bifurcation Summit: "Paradigm Shift"

Coronary Session 2, Coronary Arena, Level 1, 8:30 AM - 11:18 AM

Left Main Summit

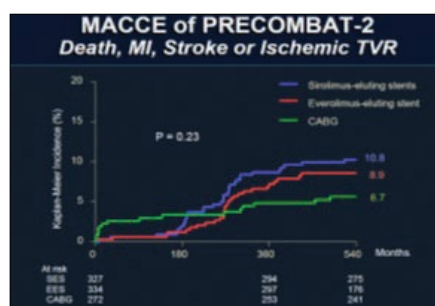
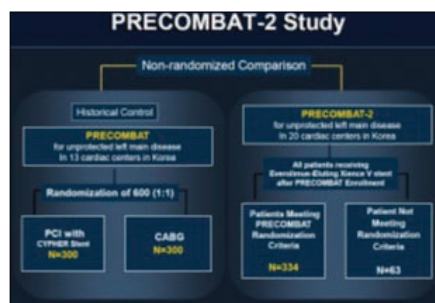
4-year Outcomes of SYNTAX Left Main

Dr. Patrick W. Serruys will be lecturing about "4-year Outcomes of SYNTAX Left Main", which was previously presented at TCT 2011 (San Francisco) in this Left Main Summit session. In the left main subset of SYNTAX trial, a total of 673 randomized patients (CABG=324 vs PCI=349) were followed for 4 years. At 4 years, major adverse cardiac and cerebrovascular events [MACCE: death, stroke, myocardial infarction (MI), and repeat revascularization] were analyzed. The result showed higher repeat revascularization rate in PCI group (PCI: 23.5% vs. CABG: 14.6%, $P=0.003$). However, rates of the composite safety endpoint (death/stroke/MI 17.1.0 vs. 17.7%, $P=0.79$) and stroke alone (1.5 vs. 4.3%, $P=0.03$) were not significantly different between treatment groups. In the low score (0-22) and intermediate score (23-32) group by SYNTAX Score, there were no significant differences about all endpoints (death/ stroke/MI/revascularization) between the two groups. But, when the SYNTAX Score was high (≥ 33), the rate of repeat revascularization was higher in PCI group (31.3% vs 11.8%, $P < 0.001$). In conclusions, at 4 years, revascularization with PCI has comparable safety and efficacy outcomes to CABG and PCI is therefore a reasonable treatment alternative in this patient population, in particular, when the SYNTAX Score is low (< 22) or intermediate(22-32) for patients with left main disease.

Outcomes of Left Main PCI with New Generation DES: PRECOMBAT-2 Study Using Everolimus-Eluting Stent

Dr. Young-Hak Kim of Asan Medical Center, Republic of Korea will present the outcomes of PRECOMBAT-2 study. Recent registries and randomized studies have shown that PCI is safe and effective in patients with unprotect-

ed left main coronary artery stenosis. In particular, the SYNTAX left main study and PRECOMBAT trials showed that PCI with sirolimus-eluting stents or paclitaxel-eluting stents was noninferior to CABG in terms of 1-year incidence of major adverse cardiac or cerebrovascular events. These results have led to recently updated recommendations that PCI may be considered an alternative to surgery in patients who are not at high risk. Nonetheless, PCI for left main stenosis, particularly with bifurcation involvement, remains technically challenging and is related to higher rates of stent thrombosis and repeat revascularization. As compared with first generation DES, the reduced strut thickness (81 μ m) and thinner polymer coating (7.6 μ m), in conjunction with improved biocompatibility of the polymer, everolimus-eluting stents may favorably affect neointimal hyperplasia. The PRECOMBAT-2 trial evaluated the safety and efficacy of PCI using everolimus-eluting Xience V stents (Abbott Corp.) for patients with left main stenosis. The outcomes were presented by Dr. Park SJ. They assessed 334 consecutive patients who received everolimus-eluting stents for left main stenosis between 2009 and 2010. The 18-month incidence rates of major adverse cardiac or cerebrovascular events, including death, myocardial infarction, stroke or ischemia-driven target vessel revascularization, were compared with those of PRECOMBAT randomized study comparing patients who received sirolimus-eluting stents ($N=327$) or coronary artery bypass grafts ($N=272$). Everolimus-eluting stents (8.9%) showed a comparable incidence of major adverse cardiac or cerebrovascular events as sirolimus-eluting stents (10.8%; adjusted hazard ratio of everolimus-eluting stents, 0.84; 95% confidence interval, 0.51-1.40; $p=0.51$) and CABG (6.7%, HR, 1.40; 95% CI, 0.78-2.54; $p=0.26$). The composite incidence of death, MI or stroke also did not differ among patients receiving EES (3.3%), SES (3.7%; HR, 0.63; 95% CI, 0.27-1.47; $p=0.29$), and CABG (4.8%; HR, 0.67; 95% CI, 0.29-1.54; $p=0.34$). However, the incidence of



ischemia-driven TVR in the EES group (6.5%) was higher than in the CABG group (2.6%, HR, 2.77; 95% CI, 1.17-6.58; $p=0.02$), but comparable to SES (8.2%, HR, 1.14; 95% CI, 0.64-2.06; $p=0.65$). Angiographic restenosis rates were similar in the SES and EES groups (13.8% vs. 9.2%, $p=0.16$). Dr. Park said that "this study has a limitation because of non-randomized study design. However, the outcomes of everolimus-eluting stents, as compared with the first-generation DES or CABG, indicate the safety and efficacy of new-generation DES for left main stenosis. In particular, the numerically low incidence of repeat revascularization warrants further studies to prove the efficacy of new-generation DES."

Bifurcation Summit

Dr. Bon-Kwon Koo (Seoul National University Hospital, Seoul, Korea) will present with a subject of "Why FFR and Why Not FFR in Bifurcation Lesions?" in the Bifurcation summit at 10:06. WHY FFR? Angiographic evaluation alone is sometimes inaccurate and does not reflect the functional severity of lesions, especially in ostial lesions. Fractional flow reserve (FFR) is an easily obtainable lesion-specific parameter for the physiologic evalua-

tion of epicardial coronary artery stenosis, which takes into account the interaction between the anatomic stenosis and the area of perfusion supplied by a specific coronary artery. From recent studies, it was found that 1) FFR-guided provisional side branch intervention strategy is feasible and effective, 2) angiographic evaluation overestimates the functional severity of jailed side branch lesions in every step of the provisional strategy for bifurcation lesions and 3) functional status of jailed side branch lesions after drug-eluting stent implantation does not change significantly during follow-up. These results indicate that FFR measurements in bifurcation lesions can be helpful in decision making for revascularization and can prevent unnecessary complex coronary interventions and related complications in patients with bifurcation lesions. WHY NOT FFR? FFR is not needed in all bifurcation lesions and should be carefully used in complex bifurcation lesions. The following should be fully understood before the application of FFR to the complex bifurcation lesions: 1) As the amount of ischemia is clinically more relevant than the presence of ischemia, FFR should be measured in large side branches 2) When FFR is measured for side branch lesions, the influence of proximal and distal lesions should always be considered 3) It is difficult to predict the functional significance of jailed side branch lesion based on anatomic and physiologic parameters assessed before the intervention. 4) The risk and benefit of FFR measurement should be carefully evaluated in cases of highly angulated, diffused, multiple or calcified lesions and the pressure wire should not be jailed by a stent. 5) FFR does not need to be measured in side branches with $<$ TIMI3 flow or severe dissection. 6) As the lesions included in most of previous studies were relatively short ostial side branch lesions, the results of previous studies cannot be applied as they are in diffuse or multiple side branch lesions. 7) In cases of side branch stenting, high side branch FFR does not always guarantee excellent results.

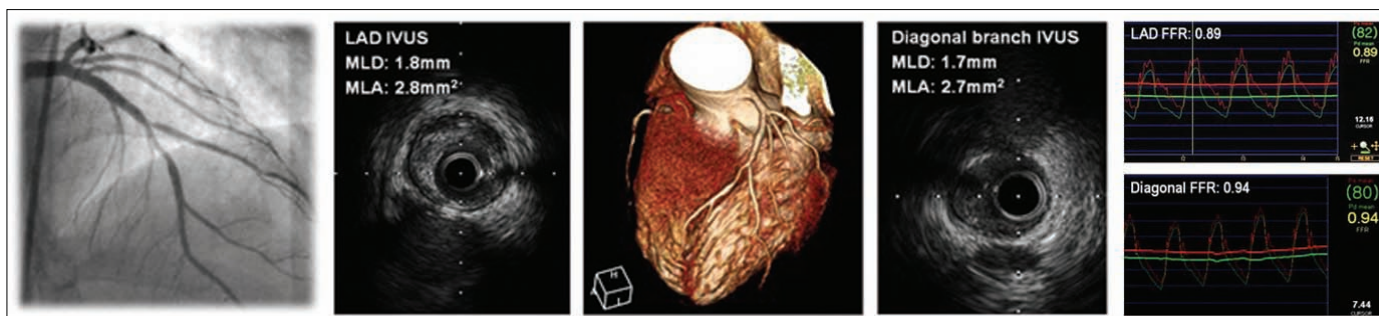


Figure. A case example which shows the discrepancy between the results of anatomical evaluations and fractional flow reserve. LAD; left anterior descending coronary artery, IVUS; intravascular ultrasound, MLD; minimum lumen diameter, MLA; minimum lumen area, FFR; fractional flow reserve

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The State of the Art Lecture; Wrap-Up and Brand-New Knowledge with Expert

Periprocedural Antithrombotic Therapy During PCI- Lessons from ISAR-REACT 1, 2, 3, 4, Trials

Thursday, April 26, Art Room, Level 4, 8:30 AM

Adnan Kastrati, MD (Deutsches Herzzentrum, Technische Universität, Munich, Germany) will give a lecture about periprocedural antithrombotic therapy during PCI with the results of the ISAR-REACT trial. He focused on the results of ISAR-REACT 4, which was recently published in the New England Journal of Medicine. The direct thrombin inhibitor bivalirudin protects patients with NSTEMI from severe adverse events as well as a combination of abciximab and unfractionated heparin following PCI while reducing major bleeding. The data suggests that bivalirudin might be the preferred drug for patients undergoing PCI for an acute MI, with or without ST-segment elevation. They studied 1,721 patients with NSTEMI who had been pre-treated with 600 mg of clopidogrel prior to PCI. Patients were randomized to 70 U/kg bolus of heparin

plus abciximab in a 0.25 mg/kg bolus followed by an infusion of 0.125 µg/kg/min for 12 hours (n=861) or bivalirudin in a bolus of 0.75 mg/kg followed by an infusion of 1.75 mg/kg/hr (n=860) for the duration of PCI. The primary endpoint of severe adverse events (death, any recurrent MI, urgent TVR, or major bleeding) was identical for both groups at 30 days at 10.9% in the abciximab group and 11.0% in the bivalirudin group (RR 0.99; 95% CI 0.74-1.32; P=0.94) (Figure 1). The cumulative incidence of death, any MI, and urgent TVR was also identical at 12.8% with abciximab and 13.4% with bivalirudin (RR 0.96; 95% CI 0.74-1.25; P=0.76). The individual component endpoints of death (1.4% with abciximab and 1.6% with bivalirudin), MI (12.0% vs. 11.4%), and any urgent TVR (0.8% vs. 1.3%), were all equivalent

between arms. Major bleeding, meanwhile, was more frequent with abciximab (4.7% vs. 2.6%; RR 1.84; 95% CI 1.10-3.07; P=0.02) (Figure 2). They defined major bleeding as intracranial, intraocular, or retroperitoneal, Hb decrease >40g/L plus either overt bleeding or need for transfusion of 2 or more units, which was a very rigorous definition of serious bleeding. This results support the findings of HORIZONS-AMI, a prospective, open-label, randomized, multicenter trial that compared the direct thrombin inhibitor to heparin plus abciximab in 3,602 patients undergoing primary PCI. Abciximab and unfractionated heparin, as compared with bivalirudin, failed to reduce the rate of the primary endpoint and increased the risk of bleeding among patients with NSTEMI undergoing PCI.

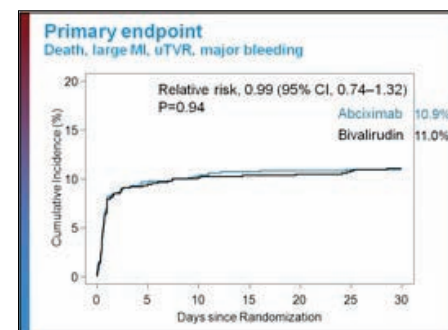


Figure 1.

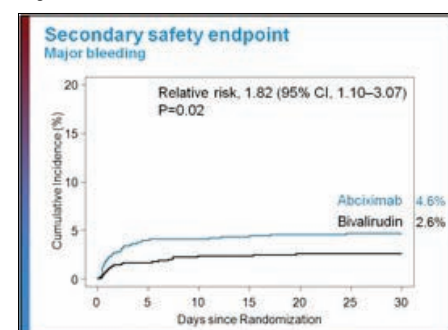


Figure 2.

Imaging & Physiology Workshop

In-Stent Neointerthrosclerosis: A Final Common Pathway of Late Stent Failure

Thursday, April 26, Art Room, Level 4, 3:36 PM

Soo-jin Kang, MD (Asan Medical Center, Seoul, Korea) will talk about 'Neointerthrosclerosis' as a mechanism of late stent failure including late stent restenosis and very late stent thrombosis. In-stent restenosis (ISR) is generally considered to be a stable process, however, recent studies have reported that one third of patients with ISR are presented with acute coronary syndromes. Furthermore, there is emerging histological and angiographic evidence of late de novo in-stent neointerthrosclerosis. They performed optical coherence tomography and grayscale and virtual histology intravascular

ultrasound in 50 patients (30 stable, 20 unstable angina) with 50 DES in-stent restenosis lesions and intimal hyperplasia >50% of stent area over 32.2 months. OCT findings indicating in-stent neointerthrosclerosis (Figure 1) were frequently identified in patients with DES-ISR, especially late DES-ISR, including TCFA-containing intima in 52%, intimal rupture in 58%, and thrombi in 58%. Irrespective of clinical presentations of DES-ISR (unstable or stable angina), 90% of the lesions had lipid-containing neointima (Figure 2). Even in stable angina patients, one third showed TCFA-containing intima and

half had in-stent intimal rupture. Neointimal fibrous cap thickness decreased over time, with a follow-up duration >20 months being the best cut-off value to predict the presence of TCFA-containing intima. All of these findings suggest either atherosclerotic neointimal degenerative changes over time or neointerthrosclerosis superimposed on a stable neointimal platform, consistent with our recent data using VH-IVUS analysis. Furthermore, VH subgroup analysis in the current study supported OCT findings in that the presence of VH-defined TCFA-containing neointima and high content of NC was relat-

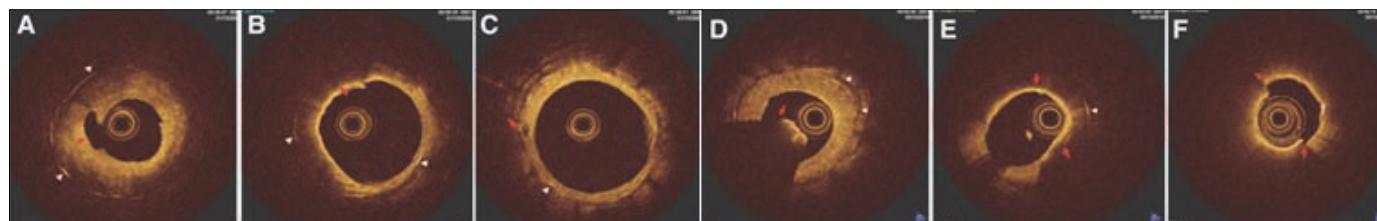


Figure 1. Optical coherence tomography findings of neointima inside DES

A, Intimal rupture (red arrow); B, TCFA-containing neointima surrounded by signal-poor lipidic area (red arrow); C, fibrotic neointima with microvessels (red arrow); D, Intraluminal red thrombus with fast attenuation (red arrow); E, TCFA-containing neointima (red arrow) with lipidic tissue; F, intimal rupture (red arrow) surrounded by TCFA-containing neointima.

In-Stent Neointerthrosclerosis OCT Analysis in 50 DES-ISR Lesions with %IH>50%				
	Total N=50	Stable N=30	Unstable N=20	P
Follow-up (months)	32 (9-52)	14 (8-51)	41 (16-56)	0.178
Lipid neointima	45 (90%)	25 (83%)	20 (100%)	0.067
Fibrous cap thickness, µm	60 (50-162)	100 (60-205)	55 (42-105)	0.006
Incidence of thrombi	29 (58%)	13 (43%)	16 (80%)	0.010
Incidence of red thrombi	7 (14%)	1 (3%)	6 (30%)	0.012
Incidence of rupture	29 (58%)	14 (47%)	15 (75%)	0.044
Incidence of TCFA	26 (52%)	11 (37%)	15 (75%)	0.008
Neovascularization	30 (60%)	15 (50%)	15 (75%)	0.069

Figure 2. OCT findings according to clinical presentation in the DES-ISR lesion

ed to the longer follow-up duration. This study demonstrates in-stent TCFA-containing neointima, neointimal rupture, and thrombi in DES failure patients presenting with ISR (whether stable or unstable). These findings suggest that in-stent neointerthrosclerosis assessed by OCT and VH-IVUS may be an important mechanism of DES failure, especially late after implantation.

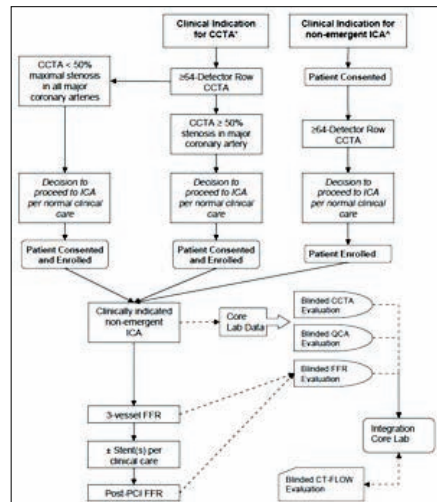
The State of the Art Lecture: Non-Invasive Imaging

Thursday, April 26, Art Room, Level 4, 5:00 PM – 6:00 PM

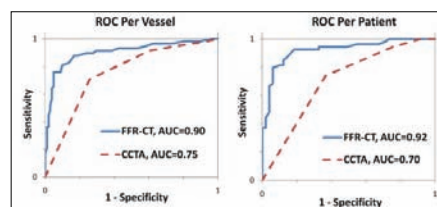
Computed FFR: What Is the Final Goal?

Recently, coronary CT angiography (CCTA) of 64-detector rows or greater has emerged as a novel non-invasive imaging modality that is capable of providing high-resolution non-invasive images of coronary artery lesions. While CCTA demonstrates good diagnostic performance for detection and exclusion of anatomic coronary artery stenoses, numerous prior studies have revealed an unreliable relationship between detection of obstructive anatomic coronary artery stenoses detected by CCTA and hemodynamically (HD)-significant coronary artery disease (CAD), as detected by reduced myocardial perfusion or coronary blood flow by myocardial perfusion SPECT or fractional flow reserve (FFR), respectively. Similarly, a non-negligible minority of individuals have been identified to possess HD-significant CAD; specifically CCTA anatomic assessment demonstrated angiographically mild (<50%) maximal per-patient stenosis. These findings emphasize the need for additional measures beyond anatomic stenosis severity for the detection and exclusion of HD-significant CAD. Measurement of FFR during invasive cardiac catheterization represents the “gold standard” for assessment of the hemodynamic significance of coronary artery lesions by determination of the integrity of blood flow proximal and distal to coronary stenoses. FFR evaluation of anatomic coronary stenosis reveals a similarly unreliable relationship of anatomic coronary artery stenosis severity by quantitative coronary angiography (QCA) of coronary artery blood flow. These findings have important clinical implications, as FFR-guided coronary revascularization in contrast to anatomic angiographic-guided coronary revascularization improves long-term clinical outcomes of patients with CAD. At present, there are no non-invasive cardiac tests capable of simultaneous determination of both anatomic coronary artery stenosis severity and the hemodynamic significance of the observed coronary artery stenosis. HeartFlow, Inc. (“HeartFlow”) has developed a non-invasive method to compute FFR (cFFR) from patient-specific CCTA data using computational fluid dynamics under rest and simulated maximal coronary hyperemic conditions. Preliminary results in patients suggest that non-invasive cFFR

accurately predicts the hemodynamic significance of coronary lesions when compared to directly-measured FFR during cardiac catheterization (Figure).



Dr. James K. Min (President of Society of Cardiac Computed Tomography) will present the first randomized controlled trial “Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography (DeFACTO)” in the Tutorial Arena (Figure).



Perfusion CT: Can It Replace the MRI?

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

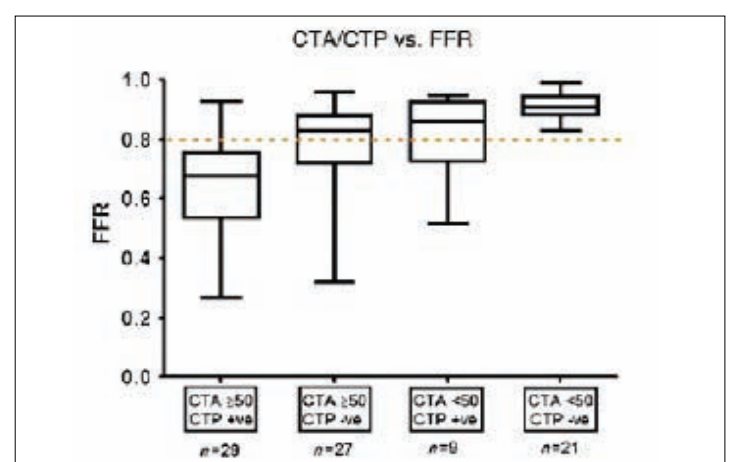
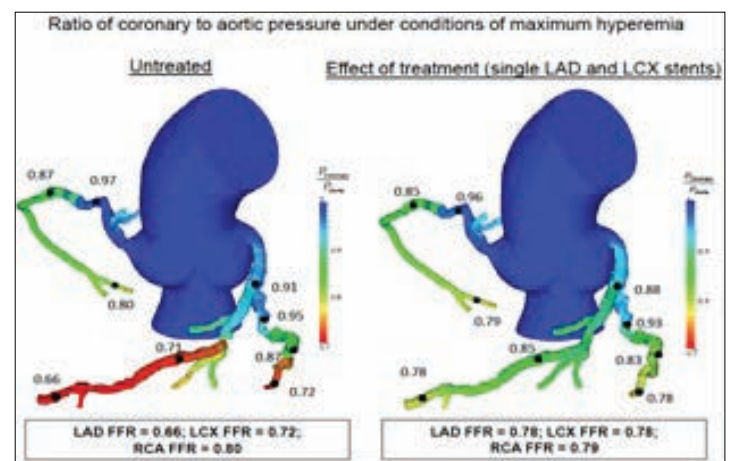
CAD clinically.

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 between stress-induced perfusion defects and myocardial scars 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

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 coronaries or previously placed coronary stents. It is possible that the addition of perfusion information to the angiographic study would increase the test sensitivity to flow-limiting lesions and facilitate the indication for revascularization procedures even for patients without extensively calcified arteries or coronary stents, based on the combination of anatomic plus functional information.

Considering the fast pace of progression of MDCT technology, it is reasonable to speculate that, indeed, the future may be closer than previously anticipated. Dr. Gudrun Feuchtner (Professor, Innsbruck Medical University) will cover the recent development of perfusion CT technology and clinical trials in the Tutorial Arena.



April 23-26, 2013, Seoul, Korea

The Convention Center, Sheraton Grand Walkerhill Hotel

18TH

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Moderate Oral Abstract Competition

Abstract Zone, Level B2, 2:00 PM - 6:00 PM

“Moderate Oral Abstract Competition” will be held on April 25th (Wednesday), 2:00 - 6:00 PM and on April 26, 8:30 - 12:30 AM and 2:00 - 6:00 PM, at the Abstract Zone I & II (Level B2). 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, sixty abstracts were selected among abstracts submitted from about 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 25, Dr. Brian Noronha from UK will show the result that the risk of GI bleeding is substantially lower in Fondaparinux treated patients as compared to Enoxaparin in NSTEMI patients. In the “Acute Myocardial Infarction/Acute Coronary Syndrome II” session at 3:00 PM, Dr. Soon Jun Hong from Korea will present about “Cardiovascular Event Rates during the Four-Year Follow-Up Were Lower in ST-Elevation Myocardial Infarction Patients with Early Increases in Mobilization of Oct 4-high Nanog-high Stem Cells into the Peripheral Circulation”. This study

showed that mRNA levels of pluripotent embryonic stem markers such as Oct 4 and Nanog were significantly higher in AMI patients without MACE during the 4-year follow-up. On April 26th (Thursday), in the “Imaging I” session at 8:30 AM, Dr. Kunihiro Shimamura from Japan will present “Difference of Ruptured Plaque Morphologies between Non ST Elevation Acute Coronary Syndrome and Asymptomatic Patient; as Optical Coherence Tomography Study.” This study demonstrates that the morphological feature of plaque rupture and the intracoronary thrombus could relate with the clinical presentation in patients with coronary artery disease. In the “Imaging III” session, Dr. Tomohisa Tada from Germany will demonstrate the “Differential Vascular Healing Patterns with Rapid Absorption Biodegradable Polymer Sirolimus-Eluting Stents versus Durable Polymer Everolimus-Eluting Stents”. This study shows that rapid absorption biodegradable polymer sirolimus-eluting stents as compared to durable polymer everolimus-eluting stents were associated with enhanced vascular healing at 4 months. In the “Complex PCI II” session from 3:00 PM, Dr. Hideyuki Takimura from Japan will present “Impact of The Novel Metal-Catheter (CORSAIR®) on Retrograde Recanalizations via Transseptal Pathways for

Chronic Total Occlusion”. In the “Structural Heart Disease I” session in Abstract Zone II at 10:30 AM, Dr. Guang-yi Wang from China will show the outcomes of long-term follow up of percutaneous transcatheter closure of secundum atrial Septal Defects and the results of “CoreValve Experience of severe AS in Taiwan” will be presented by Ying-Hsien Chen from Taiwan in the “Structural Heart Disease II” at 11:30 AM. Their initial experiences shows that TAVI with CoreValve is feasible in Chinese population with high technical success and acceptable short-term outcome. In the “Endovascular Intervention” session at 2:00 PM in Abstract Zone II, Dr. Hsiu-Yu Fang from Taiwan will demonstrate the result of the safety and feasibility of sheathless transradial carotid artery stenting (compared with Transbrachial Carotid Artery Stenting). Like the above abstracts, there will be presentations on various interesting subjects in the interventional cardiology area. Now, the oral abstract sessions has been 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.

What’s Going On in Chronic Total Occlusion during ANGIOPLASTY SUMMIT TCTAP 2012?

Thursday, April 26, Coronary Arena, Mugunghwa Hall 1, Level 1, 3:00 PM - 5:00 PM

- 1. Breakfast meeting, “Techniques for CTO intervention – Stay Calm, Be Confident”, Thursday, AM 7:00 - 8:00 in the Coronary Arena**
- 2. CTO Forum in Collaboration with Japanese CTO club and CCT (Complex Cardiovascular Therapeutics), Thursday, PM 3:00 in the Coronary Arena**
- 3. Amazing CTO intervention LIVE transmission from Toyohashi Heart Center, Japan, Thursday, 1) 3:00 PM in the Main Arena (Vista Hall, Level B2), 2) 4:00 PM in the Coronary Arena (Mugunghwa Hall 1, Level 1)**

The special lectures and live case demonstrations with world renowned experts in the field of CTO will provide participants with the latest information on techniques and devices for their daily interventional practice.

- Learn the advanced techniques and device selection for chronic total occlusions to optimize procedural success.
- Update on the state-of-the-art techniques, technology and new devices.
- Review the clinical indications and evidence for chronic total occlusion intervention.

First, during the breakfast meeting we will meet the experts of CTO intervention from all over the world including Asia, America and Europe. During the CTO intervention, the interventionist might meet hurdles and difficulties for the opening of totally occluded segment. There have been tremendous developments in devices and techniques for the CTO intervention, but we



still have some hesitations for the opening of CTO lesion because of the lack of confidence and other numerous reasons. Dr. Barry D. Rutherford (Saint Luke's Hospital, USA) will present the case for the aggressive approach to patients with CTO lesions. Dr. Nicolaus J. Reifart will review the changes in strategy and outcomes in Europe. Two very skilled experts in CTO intervention from Japan, Dr. Yasushi Asakura (Toyohashi Heart Center) and Dr. Toshiya

Muramatsu (Saiseikai Eastern Hospital), will provide the optimal solution for management of problems and complications during the intervention. Both have performed numerous cases of CTO lesions in Japan and other nations as an invited operator. Many audience members can expect a nice response from the difficulties of the success and learn from them as an indirect experience. Same with the last several years, this ANGIOPLASTY SUMMIT TCTAP-2012 will also hold the CTO forum, which was made by collaborating with the Japanese CTO club and the CCT. This meeting will cover pathology with imaging to intervention via antegrade and retrograde. Dr. Satoru Sumitsuji (Nozaki Tokushukai Hospital, Nagoya Tokushukai General Hospital) will present the fundamental wire

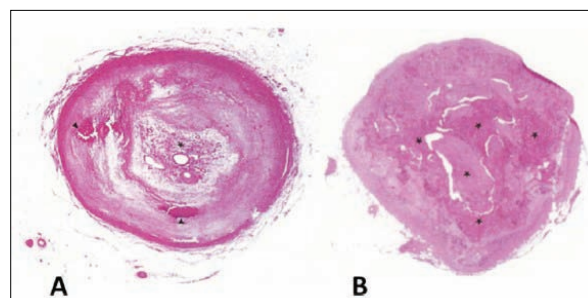


Figure 1.

Figure 2: A diagram illustrating the process of retrograde recanalization for CTO. It shows a wire being inserted from the distal side of the occlusion, crossing the lesion, and then used to guide a catheter for dilation.

Figure 2.

CardioVascular Research Foundation (CVRF)

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Providing the result of an unbiased interpretation about pharmaceutical or mechanical intervention in coronary artery disease and cardiac transplant studies

- Quantitative Coronary Angiographic (QCA) Core Laboratory
- Intravascular Ultrasound (IVUS) Core Laboratory
- OCT/VH-IVUS Imaging Center

Conference

ANGIOPLASTY SUMMIT-TCTAP

- Focusing on Evidence-based Medicine in Interventional Cardiovascular Medicine
- Live Cases, Late Breaking Clinical Trials, Scientific Symposia, Practical Workshops, Case Reviews, Abstracts, Exhibitions, and much more
- Presentations on Innovative Devices and Future Therapies

IMAGING & PHYSIOLOGY SUMMIT

- Live Case Demonstrations related to Imaging & Physiology
- Expanded Basic Image Interpretation Workshop for IVUS & VH-IVUS, OCT, and FFR
- Clinical State-of-the Art Lectures
- Challenging Case Competitions with the Experts

CHRONIC TOTAL OCCLUSION LIVE

- Invited Operators from Japan
- Live Case Demonstrations: Advanced Operator's Techniques & Novel Devices
- Case Presentations & Reviews: Interactive Discussions with Experts and Q&A
- Special Lectures: Technical Tips & Tricks to Optimize Procedural Success

TRANSCATHETER AORTIC VALVE IMPLANTATION SUMMIT

- Live Cases Demonstrations: TAVI from "A to Z" by Pioneers in this Emerging Technology Field
- Special Lectures on All about TAVI and Good Practice of Team Work
- Case Based Learning by Experts' Real Case Presentation

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ACT Program (Asan Medical Center Interventional Cardiology Training Program)

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- Exclusive Training program for Small Group (Max. 12 attendees)
- Interact & Discuss with Operators during the Procedure
- Learn from Evidence-Based Medicine
- Special Lectures from Experts on Left Main, CTO, DES, Clinical Data Management
- Hands-on Experience as a Second Operator

Fundraising

"Leading to Greatness for the Better Human Life"

Fundraising and donations will be used to improve survival rate and quality of life for patients with heart disease.

Contact Information :

Tel. 82-2-3010-7254

E-mail. cvrfund@summitmd.com



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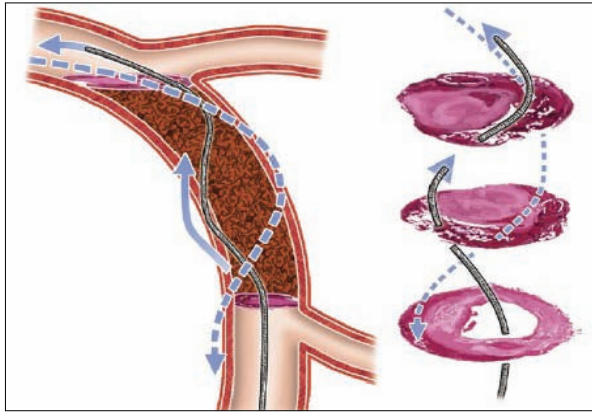


Figure 3.

technique and current standard strategy of percutaneous intervention for CTO with histopathological insights. In this review, CTO histopathology and wire techniques are discussed on the basis of the fundamental concepts of antegrade and retrograde approaches. Compared with the

rather shorter duration of CTO lesion, longer-term occlusion has much calcium deposition without microchannels, but shorter chronic total occlusion that has organized thrombus with microchannels in original lumen area with some calcification (arrowhead) in dense fibrous tissue. (Figure 1) The wire manipulation is more difficult with longer-term occlusion in spect of histopathological characteristics. During the antegrade approach, once the wire migrated into the subintimal space, the wire easily advances into the subintimal space; yet it is difficult to cross to the distal true lumen because of lower resistance to advance into subintimal space coupled with increased resistance to traversing the plaque (Figure 2). During the retrograde approach, antegrade subintimal tracking (dotted line) and retrograde subintimal tracking (solid line), even though the angiogram shows that the 2 wires are separated (antegrade and retrograde), both wires can be positioned in the same subintimal space. After the retrograde wire comes into the same lumen with the antegrade wire, crossing into the

proximal true lumen with the retrograde wire is highly promising. (Figure 3)

Dr. Eisho Kyo (Kusatsu Heart Center, Japan) will show some imaging data concerning the CTO lesion including the 64-multislice computed tomography (MSCT). Calcification was identified as the one of the strongest predictor that not only influenced technical success, but also procedural success. The very skillful two Japanese interventionists (Dr. Yasushi Asakura and Masahiko Ochiai) will introduce the diverse techniques, emerging devices, selection of wires and manipulation, selection of collateral channels and prediction of procedural success or failure during the antegrade and retrograde approach. After acquisition of knowledge and skill, we will meet real CTO intervention honorable interventionists from the Toyohashi Heart Center, Japan. Dr. Osamu Katoh and Dr. Etsuo Tsuchikane will carry out the impressive procedure from the selection of wire to the technique of passing the lesion.

New DES

Coronary Arena, Mugunghwa Hall 1, Level 1, Coronary Session 5, 5:00 – 6:00 PM

The appearance and development of the drug eluting stent (DES) have changed the landscape of interventional cardiology. However, we want more effective, more durable and safer stents. The “New DES” session will be held with several honorable presenters on April 26, 5:00 - 6:00 PM.

Second-generation DES

The PLATINUM (A Prospective, Randomized Investigation of a Novel Platinum Chromium Everolimus-Eluting Coronary Stent) was a fairly large randomized clinical trial of 2 DES, the Promus everolimus-eluting stent vs the Promus Element stent. They use the same drug and same polymer, and same elution kinetics, but there is a different stent platform with the Element stent having a platinum-enriched and perhaps more visible stent and some other property advantages that have been promoted. These DES trials have shown very low rates at 1 year of TLF. To be fair, it seems like these data that we have seen from Promus Element, Resolute, and even some of the Xience V data are still supportive of using these stents in clinical practice. Dr. Gregg W. Stone will present the lecture “Lessons from the pooled data using Xience Everolimus-eluting stent”. The “Results of Resolutes series of studies” will be reviewed by Dr. Martin B. Leon in succession. The RESOLUTE (A Randomized Comparison of a Zotarolimus-Eluting Stent with an Everolimus-Eluting Stent for Percutaneous Coronary Intervention) all-comers 2-year trial data has demonstrated a

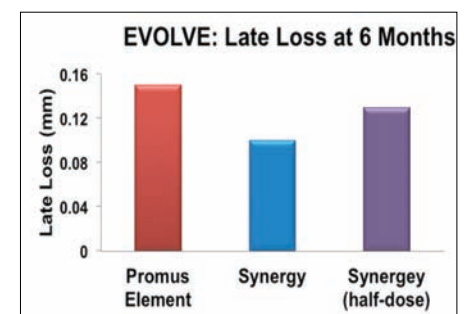
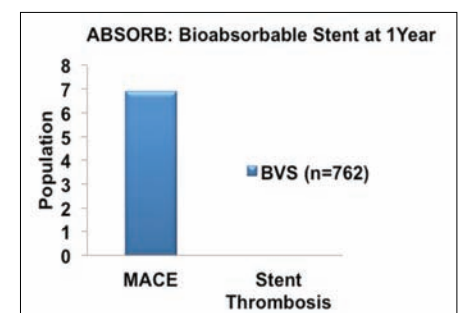
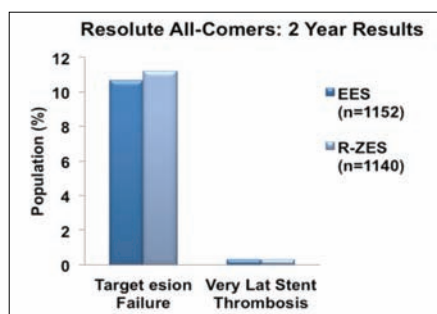
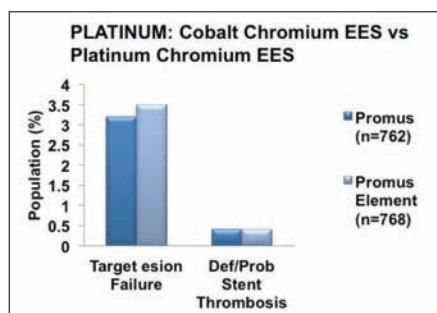
stable outcome for the Resolute stent showing that the stent thrombosis rate between 1 and 2 years was fairly level between the Resolute and the Xience™ stent (Abbott Laboratories; Abbott Park, Illinois). The US RESOLUTE trial also showed a stent thrombosis rate of 0.1% at 1 year, and altogether a target lesion failure (TLF) rate of 4.7%.The TWENTE study was very much like the Resolute All Comers trial. It has strengths and weaknesses compared with the Resolute All Comers trial. It's largely a single-center study, but they did have an independent clinical event adjudication and an independent core lab. It was a very meticulously done study, 1,300 patients were randomized to either the Xience V® or the Resolute® stent. It was truly all comers; 85% of the people coming through the

doors of the cath lab went into the trial, so there was a very high rate of accrument. What was interesting was that the target lesion failure, which is the primary endpoint, was absolutely superimposable for those two.

Bioabsorbable Stents

The 4-year results of the LEADERS trial showed a statistically significant separation in late stent thrombosis with the biolimus A9 drug on a polylactic acid polymer. The EVOLVE trial used the Synergy™ stent and they looked at Synergy and Synergy half-dose against the Promus Element™ stent. This is PLGA (copoly lactic acid/glycolic acid), adluminally directed, 3- to 5-micron thickness polymer releasing everolimus in the same dose as the everolimus in the Promus, Xience V® and the Platinum Element stent. Synergy had incredibly low late losses that were consistent and non-inferior to the Promus Element stent. The Promus Element stent in this trial had a late loss of 0.15 mm ± 0.34 mm. We saw 0.1 mm ± 0.26 mm in the full-dose arm and 0.13 mm ± 0.25 mm in the half-dose arm and there were no differences in clinical events. So the EVOLVE trial suggested that you could actually deliver the same amount of drug and get the same surrogate response in terms of late loss without having the polymer there for a long time. PLGA of 3-5 microns thick is gone in 4 months. Another interesting trial was the NEXT. NEXT used a new stent that has a well on the external

surface of the stent and it has no polymer at all. It just has an excipient to release sirolimus. This trial showed late loss of 0.14 mm +/- about 0.26 mm for all of the patients and it showed that same sort of late loss even in the diabetic patients. There were at least 40 diabetic patients in the small study. The ABSORB data in about a hundred patients with a bioresorbable stent showed recovery of endothelial function at 1 year for these patients. These patients are obviously highly scrutinized because of the promise around this bioresorbable stent. The outcomes with TLF rates of 3.0%-4.0% are the best outcomes which are observed with DES today. It is a combination of technique or the adjunctive pharmacology, but it is going to be a real challenge for new stents with bioresorbable



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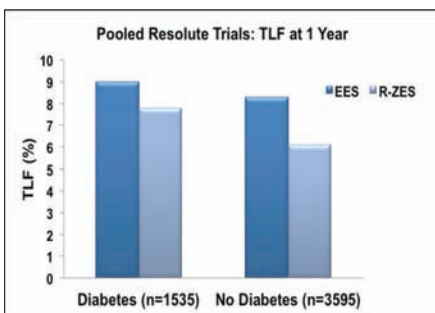
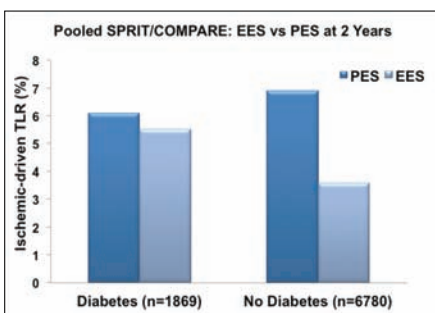
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polymers or bioresorbable stents to demonstrate even noninferiority. A noninferiority trial with a TLF rate of 2.5% is going to require 9000 patients. In the “New DES” session, Dr. Stephen G. Ellis will review the data about these interesting stents under the title of “Bioabsorbable stents status in the United States”.

DES in Diabetes

Patients with diabetes are especially prone to restenosis after stenting, making drug-eluting stents (DES) preferable to bare metal stents (BMS) in this patient population. Whether next-generation DES will improve outcomes compared with first-generation DES is an area of ongoing research and controversy. There are some data showing that the second-generation stents are better than the first-generation stents, but it's not that clear cut. We have some conflicting data. For example, the SIRTAX-LATE trial showed that the Cypher stent is better than the Taxus in diabetics; this was first-generation versus first-generation. On the other hand, we have this huge meta-analysis of the SPIRIT trial (Clinical Trial of the Xience V Everolimus Eluting Coronary Stent System) and the comparison of the Everolimus-eluting Xience-V Stent with the Paclitaxel-Eluting Taxus Liberté Stent (COMPARE) trial showing no difference between the Xience V and Taxus stent in patients with diabetes; the data is

somewhat confusing. The SORT-OUT IV showed a trend that the Xience V stent is superior to the Cypher stent in diabetic patients, but it's a subgroup analysis, again. To solve the controversial data, we need a randomized trial that specifically addresses diabetes. In India, a new prospective randomized trial has been launched, which is called the TUXEDO trial (Taxus Element vs Xience V in a Diabetic Population). The trial has diabetes as an inclusion criterion and they have a primary clinical endpoint (cardiac death, MI and TVR at 12 months). You can check on the progress of the TUXEDO from Dr. Upendra Kaul, principle investigator of the trial at the



“New DES” session.

Is there any evidence to show that there's any difference in how the new-generation stents behave in diabetes? The data on the diabetic subgroup (1500 patients) of the pooled resolute trials showed that there is no difference, at least between 2 second-generation DES (the Xience V and the Resolute stent) in diabetic patients.

Drug Eluting Balloons

The drug eluting balloons (DEB) are another innovation in interventional cardiology. The rationale of using DEB is based on the concept that with highly lipophilic drugs, even short contact times between the balloon and the vessel wall are sufficient for effective drug delivery. Using a paclitaxel-eluting balloon, 3 RCTs have targeted in-stent restenosis (ISR) following BMS implantation: PACCOATH-I, II and PEP-CAD-II. Recently, Long-term follow-up data from the 108 patients in the PACCOATH-I and II showed that the benefit of treating ISR with a paclitaxel-coated balloon is sustained over the long-term (5-years). 4 DEBs have provided clinical data for ISR after BMS and DES: DIOR-II, In.Pact Falcon, Pantera Lux and SeQuent Please. All these 4 DEBs seem to have a

single digit number of TLR rates within the first 9 to 12 months after PCI of BMS-ISR. However, the TLR rates after PCI of DES-ISR seem to be generally higher. The current guidelines recommend DEB only for ISR of BMS. However, many interventional cardiologists expect something beyond the guidelines. The THUNDER trial with drug-eluting balloons in the femoropopliteal arteries showed improved short-term



patency rates compared with plain balloon angioplasty. Dr. Juan F. Granada will present the “Re-Emergence of Local Drug Delivery: Challenge and Opportunities” in the last lecture of this session. He will review several trials and show the clinical role of the DEB in coronary and peripheral therapy. It is expected that he will demonstrate the evolving technology and possibilities of the DEB.

DEBs	Study	Time of TLR	TLR BMS-ISR	TLR DES-ISR
DIOR-II	VALENTINES-I	9 months	5.1% (of 157 pats)	10.8% (of 83 pats)
In.Pact Falcon	Registry	6 months	4.3% (of 26 pats)	—
Pantera Lux	PEPPER	12 months	2.4% (of 41 pats)	17.1% (of 35 pats)
	DELUX	6 months	2.0% (of 277 pats)	6.6% (of 248 pats)
SeQuent Please	PEPCAD-II	12 months	6.3% (of 66 pats)	4.3% (of 25 pats)
	SES-ISR	6 months	—	—
	WWR	9 months	3.8% (of 730 pats)	9.6% (of 457 pats)

Structural Heart Disease Symposium

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

Mitral Valve Treatment



Future therapies of percutaneous treatment for mitral regurgitation and the evolving role of the MitraClip system (Abbott Vascular) were presented in the symposium as first action. The MitraClip system is the first device that is “truly nonsurgical” and the one that is farthest along in terms of testing and clinical application, Chuck Simonton, MD, said. It recapitulates the surgical procedure by fixing the two free mitral edges together to create a double orifice. Surgery has provided proof of principle that this strategy yields durable results. Thus far, about 2,000 patients worldwide have been treated with the MitraClip in both registries and randomized trials. A registry analysis from

the EVEREST II study cohort showed that percutaneous repair of mitral regurgitation (MR) in high-risk patients reduced MR and improved clinical symptoms. However, outside experts cautioned that due to a number of limitations in the study, the results, though positive, should only be viewed as providing impetus for a more definitive trial. EVEREST II randomized 279 patients with moderate to severe MR and anatomical criteria suitable for endovascular repair to percutaneous treatment with the MitraClip (n=184) or surgery (n=95) in 2:1 ratio. The results revealed that the primary efficacy endpoints of freedom from death, valve reoperation, and 3 or 4 grade MR favored surgery. However, MitraClip therapy was safe and resulted in improvements in quality of life according to the New York Heart Association's functional classification, showing it was as

good as or better than surgery. Maurice Buchbinder, MD thinks that the data we've got available is very encouraging and there is more optimistic data expected to be presented within the next 12 months. There is some clinical experience with other mitral technologies, such as coronary sinus annuloplasty devices, Dr. Buchbinder said. They have been slow to come into clinical use because of technical issues of delivering a device to the coronary sinus as well as concerns about mechanical integrity. Recently, however, encouraging data have emerged from the TITAN trial showing a reduction in mitral regurgitation severity and improvements in left ventricular function and exercise capacity out to 1 year with the Carillon Mitral Contour

System (Cardiac Dimensions). The main limitation of this approach is that the sinus crosses the circumflex in a significant proportion of patients. Also on the horizon are a number of novel approaches. For example, one device anchors a balloon-like catheter in the left ventricular apex, filling the space of the regurgitant orifice. This has the attraction of being



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procedurally simple. Also in preclinical development are replacement technologies. However, these devices face formidable challenges, including large size and difficulty anchoring them in the mitral orifice.

“The steps we have taken in mitral valve therapy are really giant steps because it is a new field,” moderator, David E. Kandzari, MD, concluded.

Renal Denervation

Catheter-based renal denervation by radiofrequency ablation results in substantial and sustained blood pressure reduction without serious adverse events in patients with refractory hypertension. A first-in-man trial was reported at the annual American College of Cardiology meeting in March 2009; a randomized trial was presented at the American Heart Association Scientific Sessions 2010 and published simultaneously in the *Lancet*. Horst Sievert, MD, emphasized its efficacy and safety in patients with resistant, very-difficult to control hypertension, and suggested this treatment would become part of more general care for severe hypertension. Renal denervation not only reduces resis-

tant hypertension but also decreases left ventricular mass and improves diastolic function in patients with hypertensive heart disease, according to a new analysis stemming from the Symplicity HTN-2 trial. Renal denervation’s positive effect on LV hypertrophy is “a big plus” for renal denervation David E. Kandzari, MD said, pointing to the results of the LIFE trial comparing a beta blocker with an angiotensin receptor blocker in patients with hypertension and LV hypertrophy. Renal denervation may be especially useful for patients with diastolic heart failure, because the patients have a big, thick heart that doesn’t relax normally in diastole, although contractile function is okay. Dr. Kandzari also cautioned that renal denervation requires further validation, even though the results we have seen so far are positive.

ASD Closure



Ostium secundum atrial septal defect (ASD) is one of the most common congenital heart diseases (CHDs) and accounts for the majority of CHD in

adults. During the last decade, there has been a remarkable change in the treatment strategy of ASD, shifting the therapeutic gold standard from surgery to transcatheter closure, along with refinements and evolution of device technology. The reports on the outcome of transcatheter ASD closure have shown an excellent efficacy as well as a low complication rate. However, the procedural details and/or outcomes of this “usually straight forward” procedure may be influenced by several factors including morphologic characteristics of the defect, comorbid disease, as well as individual factors including age and the weight of the patient. Since the risk-benefit relationship in both the very young and the elderly subsets of the patients has not been clearly defined yet, closure of an ASD with a device may be subtracted from the treatment option in these patient groups.

Jae Young Choi, MD presented the issue relating age and device closure of ASD. He reviewed current evidences relevant to age issue in the treatment of ASD and presented data from his own institute. In the registry cohort, 754 patients were treated by transcatheter technique using Amplatzer septal occluder (ASO) and 223

patients treated by surgery. Among the transcatheter closure group, 79 were small children or infants weighing 10kg or less, 48 were elderly patients aged 60 years or more, and the remaining 627 were aged in between. Comparing the 3 subgroups in terms of safety and efficacy of the procedure, none of the subgroups appeared to have significant difference, except for the more frequent switching of treatment modality to surgery in smaller subgroup and more frequent incidence of pulmonary hypertension and atrial arrhythmia in the elderly subgroup.

Dr. Choi suggested further modification in design for smaller ASO is warranted toward appropriate waist-diameter to rim-width ratio to facilitate suitability of device closure in smaller patients with less room for a larger device. He also said “elderly patients with comorbidity such as pulmonary hypertension, atrial arrhythmia, myocardial dysfunction or ischemic heart disease needs meticulously planned strategy, taking into account all treatment options for an optimal treatment outcome”. He concluded that transcatheter closure of ASD is a viable option in the wide age spectrum with comparable safety and efficacy to standard age group.

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