

APRIL 24

19<sup>th</sup> CARDIOVASCULAR SUMMIT  
TCTAP 2014

# Daily News

April 22-25, 2014, COEX, SEOUL, KOREA

## Today's Highlights

### Late Breaking Clinical Trials

Main Arena, Level 3, 9:30 AM – 10:55 AM

### TCTAP Best Young Scientist Award

Main Arena, Level 3, 10:55 AM – 11:00 AM

### Left Main & Bifurcation Summit

Coronary Arena, Level 1, 8:30 PM – 11:30 AM

### Highlights from TCT@ACC12

Coronary Arena, Level 1, 11:30 AM – 12:30 PM

### ACS& Pharmacotherapies

Coronary Arena, Level 1, 2:00 PM – 4:00 PM

### TAVI Workshop

Coronary Arena, Level 1, 4:00 PM – 6:00 PM

### Endovascular Symposium

(AAA & Carotid Intervention)  
Endovascular & Structural Heart  
Theater, Level 1, 8:30 AM – 12:30 PM

### Structural Heart Diseases Symposium

(Mitral Valve Treatment, Renal  
Denervation and LAA Closure)  
Endovascular & Structural Heart  
Theater, Level 1, 2:00 PM – 6:30 PM

### Morning Roundtable Forum

(Adjunct Pharmacotherapy in PCI, LM  
PCI, Lower Extremity intervention,  
DES: Why & How? Renal Denervation,  
Left Atrial Appendage Therapies,  
Bifurcation Lesions)  
7:00 AM – 8:10 AM

### Satellite Symposium

Lunchtime Activities 12:45 PM – 1:45 PM  
Evening Symposium 6:00 PM – 8:20 PM

### Moderated Oral Abstracts & Cases Competition

Exhibition Hall, Level 3, 8:30 AM – 6:00 PM

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## Left Main and Bifurcation Summit

Thursday, April 24, 8:30 AM - 11:30 AM, Coronary Arena, Level 1

### Optimal Stenting Techniques for Bifurcation Coronary Lesions: CROSS and PERFECT Trials



Young-Hak Kim, MD, PhD  
Associate Professor  
Asan Medical Center

There is still lack of data about optimal technique of percutaneous coronary intervention (PCI) using drug-eluting stent (DES) for bifurcation coronary lesions. In the session of Left Main and Bifurcation Summit, Dr. Kim will present the recent results of CROSS and PERFECT trials, which were presented in the Late Breaking Trial Session in TCTAP 2014. In the CROSS study, they randomized treatments into the routine (FKB group) and selective (leave-alone group) final kissing balloon (FKB) inflation after main branch (MB) stenting for 306 patients having non-left main bifurcations without side branch (SB) stenosis. In the PERFECT study, the crush (crush group) and single-stent (single-stent group) techniques were randomly compared for 419 patients with non-left main bifurcations with SB stenosis. He will mention that the two trials were conducted during the same period. They prespecified the detailed procedural steps in the protocol to avoid the

bias of each operator's experience during complex stenting. Dr. Kim will say that only 4.5% of FKB in the leave-alone group and 98% in the FKB group indicates the high protocol compliance of investigators. This study enrolled all consecutive patients with bifurcation lesions and separated them into two cohorts of CROSS and PERFECT studies according to the presence of SB stenosis. If heterogenous bifurcations are included in the study, interpretation of the result is not straightforward. It is well known that the lesion complexity of bifurcation lesions greatly influence the results of bifurcation stenting. Another interesting point in this study was to look at the incidence of crossover in the single-stent group. It is not known well how many patients eventually require SB stenting once single-stent implantation is planned in treatment of true bifurcations. In the single-stent PERFECT group, 59 (28.6%) patients received SB stents using crush (25.9%) and provisional T (74.1%) tech-

niques. This finding implies that approximately a third of patients still require two-stent techniques for patients with true bifurcations. At 8-month angiography, in an intention-to-treat principle, the leave-alone group had non-inferior diameter stenosis in SB analysis segment, the primary endpoint of CROSS study, compared with the FKB group ( $34.9 \pm 15.8\%$  vs.  $31.1 \pm 14.5\%$ , noninferiority  $p < 0.001$ ). Instead, as shown in the figure, the restenosis rate in the MB tended to be higher in the FKB group than the leave-alone group. This result confirmed the previous results that a routine FKB does not lead to good angiographic and clinical outcomes. The rate of overall restenosis, the primary endpoint of PERFECT study, was comparable between the crush and single-stent group (8.4% vs. 11.0%,  $p=0.44$ ).

Over 1 year, the composite incidences of death, myocardial infarction, or target lesion revascularization were not statistically different between the FKB and leave-alone groups (14.1% vs. 11.7%,  $p=0.58$ ) and between the crush and single-stent

Continued on page 3

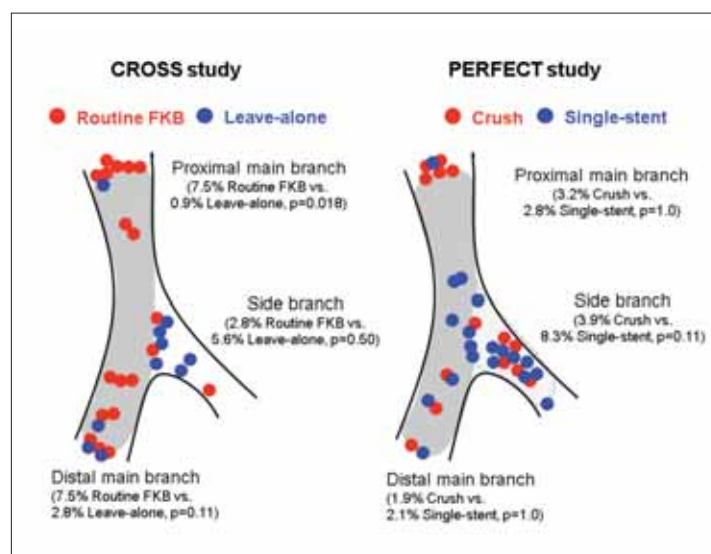


Figure 1.

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By reducing CV mortality with **BRILINTA** vs clopidogrel in the treatment of ACS



\_\_\_\_\_ **lives** could be saved \_\_\_\_\_

PLBR0007MYSG112012

In the PLATO study, BRILINTA plus aspirin significantly reduced the primary composite end point of cardiovascular (CV) death, myocardial infarction (MI), or stroke (absolute risk reduction [ARR] 1.9%, relative risk reduction [RRR] 16%,  $P < 0.001$ ) at 12 months, in an ACS population versus clopidogrel plus aspirin. The difference between treatments was driven by CV death and MI, with no difference in stroke. BRILINTA plus aspirin also significantly reduced CV mortality at 12 months (a secondary endpoint) versus clopidogrel plus aspirin (ARR 1.1%,

BRILINTA™ (ticagrelor) 90 mg film-coated tablets. INDICATIONS: BRILINTA, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute Coronary Syndromes [ACS] (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). DOSAGE & ADMINISTRATION: Treatment should be initiated with a single 180 mg loading dose (two tablets of 90mg) and then continued at 90 mg twice daily. Following an initial dose of ASA, Brilinta should be used with a maintenance dose of ASA 75 – 150 mg daily. Duration of therapy: at least 12 months unless discontinuation is clinically indicated. For oral use. May be taken with or without food. CONTRAINDICATIONS: Hypersensitivity to any component of this product. Active pathological bleeding. History of intracranial haemorrhage. Moderate to severe hepatic impairment. Co-administration of ticagrelor with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, nefazodone, ritonavir, and atazanavir). SPECIAL PRECAUTIONS: Patients with a propensity to bleed (e.g. due to recent trauma, recent surgery, active or recent gastrointestinal bleeding); concomitant administration of medicinal products that may increase the risk of bleeding (e.g. non-steroidal anti-inflammatory drugs (NSAIDs), oral anticoagulants and/or fibrinolytics within 24 hours of BRILINTA dosing). If a patient is to undergo elective surgery and antiplatelet effect is not desired, BRILINTA should be discontinued 5 days prior to surgery. Increased risk of bradycardic events. Pregnancy and lactation. UNDESIRABLE EFFECTS: Hyperuricaemia, dyspnoea, epistaxis, headache, dizziness, vertigo, abdominal pain, constipation, diarrhoea, dyspepsia,



from page 1

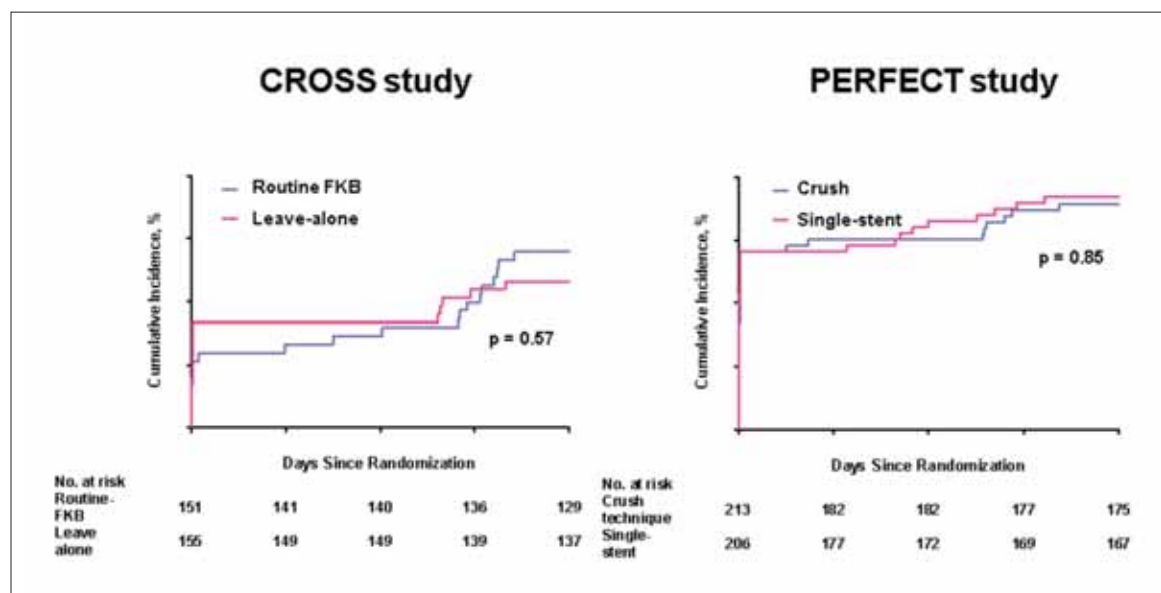


Figure 2.

groups (17.9% vs. 18.5%,  $p=0.84$ ). Therefore, Dr. Kim will conclude that the angiographic and clinical outcomes appear to be excellent after PCI using DES with any stent technique for non-left main bifurcation lesions once the procedure was performed successfully. Therefore, he pointed out that the procedural success is more important than the procedural type for good outcomes.

## Is There a Generation Gap of DES: Results of PRECOMBAT-3 Study

Second generation cobalt-chromium



Jung-Min Ahn, MD  
Assistant Professor  
Asan Medical Center

everolimus-eluting stents showed superior safety and efficacy profiles in various clinical settings compared with first generation sirolimus- or paclitaxel eluting stents and thereby have been established as the standard coronary stents. Recently, third generation, durable-polymer-based drug-eluting stents were developed to satisfy the unmet need for more flexible and highly deliverable devices that can tackle very challenging coronary lesions and vessel anatomies. The platinum chromium everolimus-eluting stent (PtCr-EES) used the durable, biocompatible, inert fluorocopolymer, drug formulation, and dose density identical to cobalt chromium everolimus-eluting stent, but the design and material of their metal scaffold have been changed substantially to provide improved deliverability, vessel conformability, side-branch access, radiopacity, radial strength, and fracture resistance.

However, data so far reported about the clinical outcomes of PtCr-EES implantation for unprotected left main coronary artery stenosis (ULMCA) have been limited. In the session of Left Main and Bifurcation Summit, Dr. Ahn will present the recent results of PRECOMBAT-3 Study. Between August 2010 and July 2013, 300 patients who met the inclusion and exclusion criteria of the PRECOMBAT randomized trial (first randomized trial to compare PCI with sirolimus eluting stent and CABG for the treatment of unprotected left main coronary artery stenosis) were entered into the prospective PRECOMBAT-3 registry study. In brief, the trial included patients with angiographic ULMCA stenosis (>50% stenosis), who did not have ST-segment elevation myocardial infarction, cardiogenic shock, another serious comorbidity, or contraindication to drug-eluting stents. Over 2 year follow-up, major adverse cardiovascular and cerebral events occurred in 13.3% of patients receiving PtCr-EES implantation;

clinical outcomes were similar. Dr. Ahn said that “therefore, PtCr-EES appeared to be safe and effective stent platform in the treatment of UPLMCA stenosis.” However, consistent with previous studies, when compared with CABG, PtCr-EES stent implantation was associated with the higher rate of repeat revascularization, although similar rate of the death, MI, or stroke at 2 year. Despite excellent clinical outcomes of PtCr-EES, it was well known that changes in metal scaffold of PtCr-EES might have

death, myocardial infarction, or stroke in 7.9%; death in 5.4%; myocardial infarction in 1.2%; target vessel revascularization in 6.5%. Definite stent thrombosis occurred in only 1 patient. When compared with patients receiving previous generation drug-eluting stents (from PRECOMBAT 1 and 2 trials), overall

the trade-off of reducing longitudinal stent stability, which would account for the occurrence of longitudinal stent deformation. In this PRECOMBAT-3 study also evaluated the stent deformation using angiographic core lab analysis. Consistent with previous studies, the stent deformation was more frequently observed in patients receiving PtCr-EES stents (4.3%) than patients receiving cobalt-chromium everolimus-eluting stents (1.2%) and sirolimus-eluting stents (0.3%). The excellent radiographic visibility and more importantly, the stent design having 2 connectors (3 connectors in cobalt-chromium everolimus-eluting stents and 6-7 connectors in sirolimus-eluting stents), major architecture to maintain the longitudinal stability of the stent have contributed to the more frequent recognition of stent deformation. However, the PRECOMBAT study did not show the relationship between stent deformation and adverse clinical outcomes. Therefore, Dr. Ahn will point out that the adoption of more flexible stent design was associated with the higher rate of stent deformation. Therefore, operators should be careful to manage the intervention device when they use PtCr-EES stent, although there was no clinical sequela.

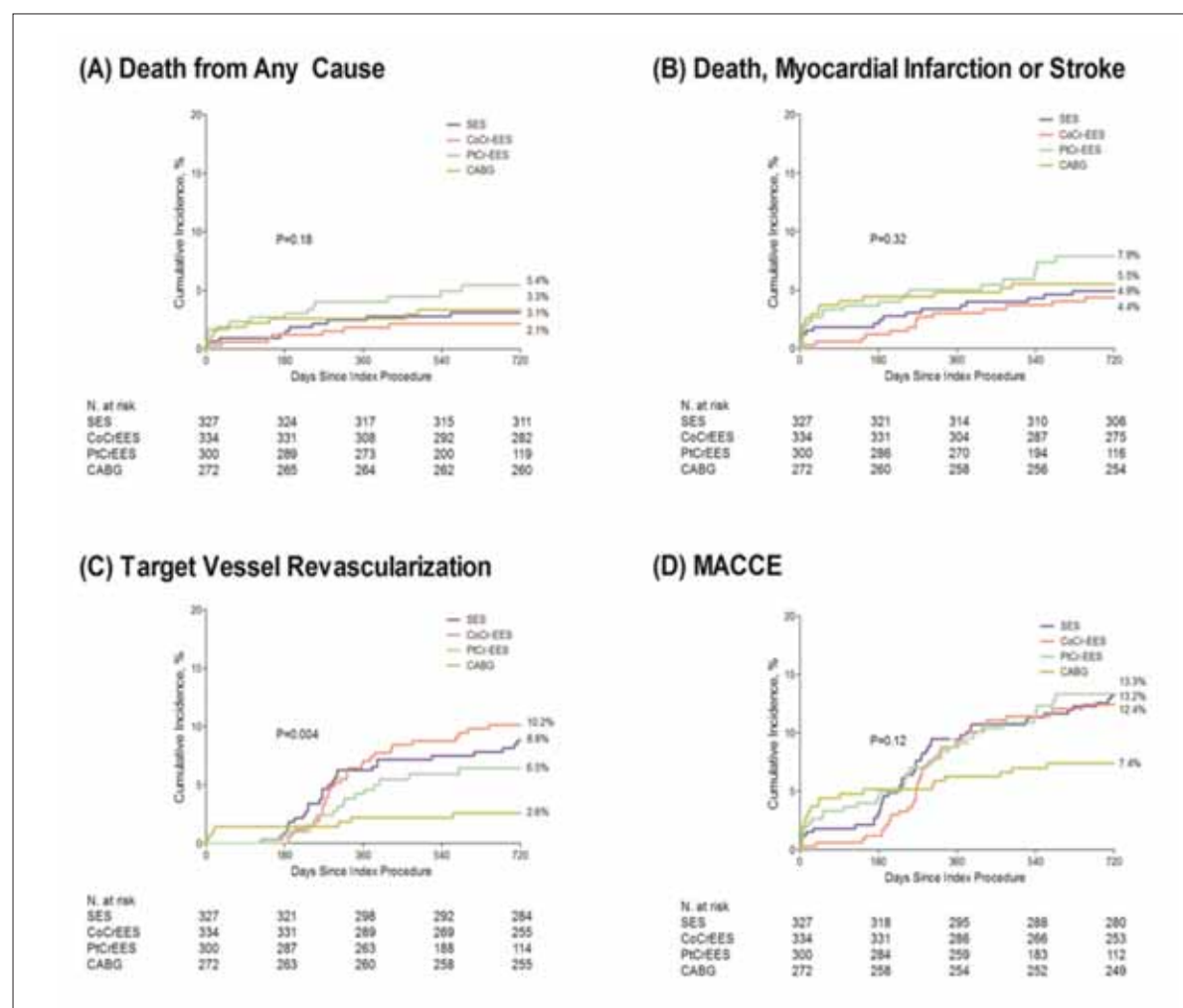


Figure 3.

## Meeting Information

### ◆ Registration / Badge Pick-up

- 3F, Exhibition Hall Lobby  
Thursday 24 6:00 AM - 7:00 PM
- 1F, Grand Ballroom Lobby  
Friday 25 6:00 AM - 12:30 PM

### ◆ Congress Bag Pick-up

- 3F, Exhibition Hall Lobby  
Thursday 24 6:00 AM - 7:00 PM
- 1F, Lobby  
Friday 25 6:00 AM - 12:30 PM

### ◆ Invited Faculty Lounge, 2F

- Thursday 24 6:00 AM - 7:00 PM
- Friday 25 6:00 AM - 12:30 PM

### ◆ Preview Room, 2F (Slide Upload)

- Thursday 24 6:00 AM - 7:00 PM
- Friday 25 6:00 AM - 12:30 PM

### ◆ CVRF Booth, 1F (Organizing Secretariat)

- Thursday 24 6:00 AM - 7:00 PM
- Friday 25 6:00 AM - 12:30 PM

### ◆ Information Desk

- 3F, Main Arena Lobby
- 1F, CVRF Booth

### ◆ Tour Information Desk

- 1F, CVRF Booth

### ◆ Lounge

- 3F, Exhibition Hall, Registration
- 1F, CVRF Booth

### ◆ Exhibition

- Thursday 24 9:00 AM - 6:00 PM

### ◆ Learning Center

- 3F, Exhibition Hall
- 2F, Room 2-5 (Room 209)

### ◆ WiFi Zone

- 3F, Exhibition Hall, Main Arena, Registration Lounge
- 2F, Invited Faculty Lounge, Preview Room
- 1F, CVRF Booth, Coronary Arena, Structural Heart & Endovascular Theater

### ◆ Cyber Station

- 3F, Exhibition Hall
- 1F, CVRF Booth

### ◆ Free Mobile Recharge

- 3F, Exhibition Hall, Registration Lounge
- 1F, CVRF Booth

### ◆ Certificate of Attendance

- 3F, Service Booth  
Thursday 24
- Service Booth  
Friday 25

### ◆ Lost & Found / Cloak Room

- 3F, Coat Room  
Thursday 24 8:00 AM - 6:00 PM

### ◆ Shuttle Bus

- Free shuttle bus is provided between COEX and several venue hotels. Ask at the CVRF booth, 1F or Information desk, 3F for more information.

### ◆ Prayer Room

- 2F, Room 202A  
Thursday 24 8:00 AM - 6:00 PM
- Friday 25 8:00 AM - 12:00 PM



**The 2nd TCTAP**

## Best Young Scientist Award

**April 24, 10:55AM, Main Arena**

Are you curious about the next generation of interventional cardiologist?  
Please come and see the second winner of TCTAP Best Young Scientist and congratulate the rising leader of interventional cardiology field!

**You can be the next TCTAP Best Young Scientist!**

In keeping with its mission to support the young physicians who need to develop and enrich their academic and clinical work experience, TCTAP is presenting TCTAP Best Young Scientist Award annually in the amount of 5,000 USD to the Best Abstract or Case Presenters of TCTAP.

We cordially invite you to

## ACT Tour @ Asan Medical Center

### ► Program

Live Case Demonstration, Presentation and Q&A  
Tour of Cathlab, CCU and Other Facilities

### ► Schedule


Tour 1 : April 24(Thu) at 10 AM  
Tour 2 : April 24(Thu) at 4 PM  
\* Each tour will be limited up to 12 people.

### ► Pick-up Place

ACT Desk at CVRF Booth, 1F Lobby, COEX  
\* Onsite registration is available.

For more information, visit

[www.cvrf.org/act](http://www.cvrf.org/act)



## TCTAP Wrap-up Interview

Moderated interview sessions at the open studio(Main Arena, Lobby) on the selected key topics in the field of vascular medicine with world's leading experts

**Thursday, April 24**


**Invasive Imaging**  
8:45 AM - 9:15 AM  
Moderator : Gary S. Mintz  
Interviewees : Takashi Akasaka, Akiko Maehara, Evelyn Regar

**Antithrombotic Therapies**  
9:30 AM - 10:00 AM  
Moderator : David J. Cohen  
Interviewees : Jean-Philippe Collet, Neal S. Kleiman, Manesh Patel

**LM and Bifurcation**  
3:45 PM - 4:15 PM  
Moderator : David E. Kandzari

Interviewees : Yves R. Louvard, Seung-Jung Park, David Paul Taggart

Interview video clips will be available online after the meeting at [www.summit-tctap.com](http://www.summit-tctap.com), [www.summitmd.com](http://www.summitmd.com) and [www.youtube.com/CVRFevents](http://www.youtube.com/CVRFevents) TCTAP Application



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After meeting, you can enjoy not only all the Presentation Slides presented but also Video Clips of Wrap-up Interview, Live Demonstration and Photos, Daily Newspapers distributed during TCTAP through our website.



Today’s Programs: Thursday, April 24

Plenary Sessions

8:30 AM - 6:00 PM  
Main Arena, Level 3

Live Case Session V-Canada

Transmitted from St. Paul Hospital,  
Vancouver, Canada  
8:30 AM - 9:30 AM

Main Session VI. Late Breaking Clinical Trials  
9:30 AM - 10:55 AM

Main Session VII. TCTAP Best Young Scientist  
Award  
10:55 AM - 11:00 AM

Live Case Session VI  
11:00 AM - 12:00 PM

Main Session VIII  
12:00 PM - 12:15 PM

Live Case Session VII  
2:00 PM - 3:00 PM

Main Session IX  
3:00 PM - 3:30 PM

Live Case Session VIII-France  
Transmitted from Institut Hospitalier Jacques  
Cartier, Paris, France  
3:30 PM - 4:30 PM

Main Session X  
4:30 PM - 4:54 PM

Live Case Session IX  
4:54 PM - 6:00 PM

Coronary Symposium

8:30 AM - 6:00 PM  
Coronary Arena, Level 1

Left Main & Bifurcation Summit I. Bifurcation  
Summit  
8:30 AM - 9:58 AM

Left Main & Bifurcation Summit II. Left Main  
Summit  
9:58 AM - 11:30 AM

Acute Coronary Syndrome & Pharmacotherapies  
I. Adjunct Pharmacotherapies: Evolving  
Issues  
2:00 PM - 3:00 PM

Acute Coronary Syndrome & Pharmacotherapies  
II. STEMI Intervention: Evolving Issues  
3:00 PM - 4:00 PM

TAVI Workshop  
4:00 PM - 6:00 PM

Endovascular Symposium

8:30 AM - 12:30 PM  
Endovascular & Structural Heart Theater, Level 1

Endovascular Session III. Abdominal Aortic  
Aneurysm, or Dissection Intervention  
8:30 AM - 9:30 AM

Live Case Session IV. Carotid Intervention  
9:30 AM - 10:30 AM

Endovascular Session IV. Carotid Intervention  
10:30 AM - 11:30 AM

Live Case Session V. AAA & Carotid Intervention  
11:30 AM - 12:30 PM

Structural Heart Disease  
Symposium

2:00 PM - 6:30 PM  
Endovascular & Structural Heart Theater, Level 1

Structural Heart Disease Session I. Mitral  
Valve Treatment, Renal Denervation, and LAA  
Closure  
2:00 PM - 3:30 PM

Live Case Session I. LAA Closure, Renal  
Denervation and CoA stenting  
3:30 PM - 4:30 PM

Congenital & Structural Heart Disease Session II  
4:30 PM - 6:30 PM

Partnership Session with  
International Society

Highlights from TCT at ACCi2-2014  
11:30 AM - 12:30 PM  
Coronary Arena, Level 1

Morning Roundtable Forum:  
Meet the Experts over Breakfast  
7:00 AM - 8:10 AM

Adjunct Pharmacotherapy in PCI  
Organized by CVRF  
Room 1-1, Level 1

Left Main PCI  
Organized by CVRF  
Room 1-2, Level 1

Lower Extremity Intervention  
Organized by CVRF and Supported by  
Educational Grant from Cook Medical  
Endovascular & Structural Heart Theater, Level 1

Drug-eluting Stent Failure: Why & How?  
Organized by CVRF and Supported by  
Educational Grant from BIOTRONIK  
Coronary Arena, Level 1

Renal Denervation  
Organized by CVRF and Supported by

Educational Grant from Medtronic Co, Ltd.  
Room 1-3, Level 1

Structural Heart Disease: Mitral Valve and  
Left Atrial Appendage Therapies  
Organized by CVRF and Supported by  
Educational Grant from Boston Scientific  
Room 2-1, Level 2

How to Approach the Bifurcation Lesions?  
Organized by CVRF and Supported by  
Educational Grant from Medtronic Japan Co.,  
Ltd.  
\* 8:30 AM - 10:30 AM(\*The official language  
of this session will be Japanese)  
Room 2-1, Level 2

Lunchtime Activities  
12:45 PM - 1:45 PM

Explore a Choice of Treatment in ACS Patient  
Journey: Statin and Anti-platelet  
Organized by CVRF and Supported by  
Educational Grant from Astrazeneca Korea  
Room 1-1, Level 1

New Concepts for Improved Patient Outcomes  
Organized by CVRF and Supported by  
Educational Grant from Biosensors  
Interventional Technologies Pte., Ltd. and DIO  
Corporation  
Room 1-2, Level 1

The Next Revolution in PCI  
Organized by CVRF and Supported by  
Educational Grant from Abbott Vascular  
Endovascular & Structural Heart Theater, Level 1

COMBO Dual Therapy Stent for an Open,  
Stable, Healed Coronary Artery  
Organized by CVRF and Supported by  
Educational Grant from OrbusNeich Medical  
Co., Ltd.  
Coronary Arena, Level 1

The Latest in EVT Intervention - Trends,  
Techniques, and Technologies  
Organized by CVRF and Supported by  
Educational Grant from Terumo Korea  
Corporation  
Room 1-3, Level 1

Strategic Approach for Management of  
Dyslipidemia in Cardiometabolic Patients  
Organized by CVRF and Supported by  
Educational Grant from MSD Korea  
Room 2-1, Level 2

Covidien Luncheon Symposium  
Organized by CVRF and Supported by  
Educational Grant from Covidien  
Room 3-1, Level 3

B.Braun DEB Luncheon Symposium

Organized by CVRF and Supported by  
Educational Grant from B. Braun Korea Co.,  
Ltd.  
Room 3-2, Level 3

Otsuka Pletaal Luncheon Symposium  
Organized by CVRF and Supported by  
Educational Grant from Korea Otsuka  
Pharmaceutical Co., Ltd.  
Room 4-1, Level 4

Evening Symposium  
Lessons Learned and Evolution in Congenital  
Intervention 2014  
Organized by CVRF and Supported by  
Educational Grant from St. Jude Medical  
6:30 PM - 9:00 PM  
Endovascular & Structural Heart Theater, Level 1

Moderated Oral Abstract  
Competition I, II  
8:30 AM - 12:40 PM / 2:00 PM - 6:00 PM  
Abstract Zone I, Abstract Zone II, Exhibition  
Hall, Level 3

Moderated Complex Case  
Competition I, II, III  
8:30 AM - 12:30 PM / 2:00 PM - 6:00 PM  
Case Zone I, Case Zone II, Case Zone III,  
Exhibition Hall, Level 3

Live Case Transmission  
from World-renowned  
Medical Centers

Asan Medical Center, Seoul, Korea  
- April, 24, Main Arena, Level 3 /  
Endovascular & Structural Heart  
Theater, Level 1

St. Paul Hospital, Vancouver, Canada  
- April, 24, 8:30 AM - 9:30 AM, Main  
Arena, Level 3  
- Operator: John Webb MD, David  
Wood MD

Institut Hospitalier Jacques Cartier,  
Paris, France  
- April, 24, 3:30 PM - 4:30 PM, Main  
Arena, Level 3  
- Operator: Marie-Claude Morice MD,  
Thomas Hovasse MD

# New products for improved patient outcomes



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in interventional cardiology devices

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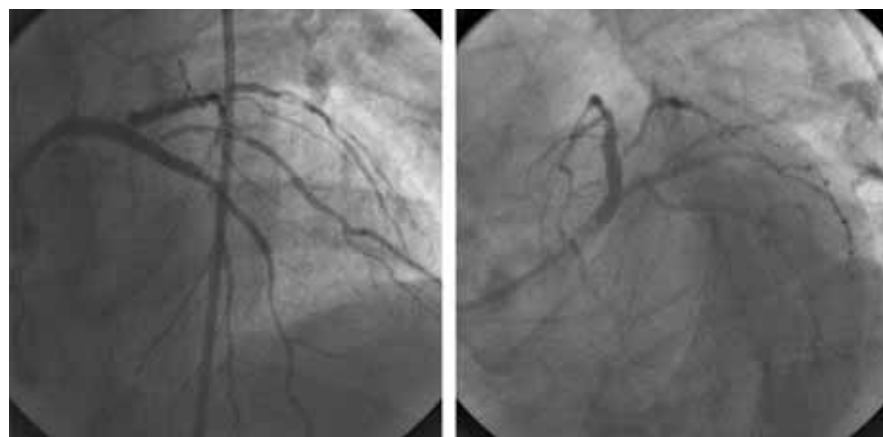
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## Yesterday's Hot Lives

**A** The answer to the questions which was asked in yesterday is **'Crushing technique in LM trifurcation and revascularization of all the lesions except for far LAD depending on angiography.'**

**A** The answer to the questions which was asked in yesterday is **'Crushing technique in LM bifurcation.'**



## Today's Hot Lives

**Q** A 67 year-old female visited an outpatient clinic with effort angina for 4 months. Treadmill test revealed ST depression at stage 3 with chest pain. Echocardiography showed normal LV systolic function without regional wall motional abnormality. Coronary angiogram showed LM with 3VD. Therefore, we first fixed pmRCA lesion with Resolute Integrity.

How would you treat this patient with tight stenosis at distal LM bifurcation (1 stent versus 2 stents)? Which modalities would be helpful to decide a treatment plan for LM PCI?



**Q** A 59 year-old male was referred for abnormal coronary CT angiography findings. One month ago, he underwent regular medical checkups. He did not complain of any symptoms. However, treadmill test was positive at stage 3 with ST depression. Thallium SPECT revealed reversible large sized perfusion defects in LAD and RCA territories. Echocardiography showed ischemic insult at RCA territory with preserved LV systolic function (EF: 57%).

How would you establish a treatment plan for this patient with tight stenosis at distal LM? How would you manage RCA CTO lesion in this patient with LM disease?



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# TAVI Workshop

Thursday, April 24, 4:00 PM - 6:00 PM, Coronary Arena, Level 1

After the first human report in 2002, transcatheter aortic valve implantation (TAVI) has emerged as a less invasive treatment option for patients with degenerative aortic valve stenosis (AS) who are inoperable or high-risk for operation. The Placement of Aortic Transcatheter Valves (PARTNER) trial established the evidence of this less-invasive treatment as standard therapy for these “ignored” patients. Furthermore, recently published US Pivotal trial showed the superiority of TAVI compared to surgical aortic valve replacement in high-risk patients. This procedure first started in France, then it expanded to Europe, United States, and Asia. TAVI has been generalized and already performed in more than 80,000 patients worldwide. In the Asian population, TAVI also showed efficacy in high-risk patients with AS and the clinical outcomes were comparable to Europe and United States.

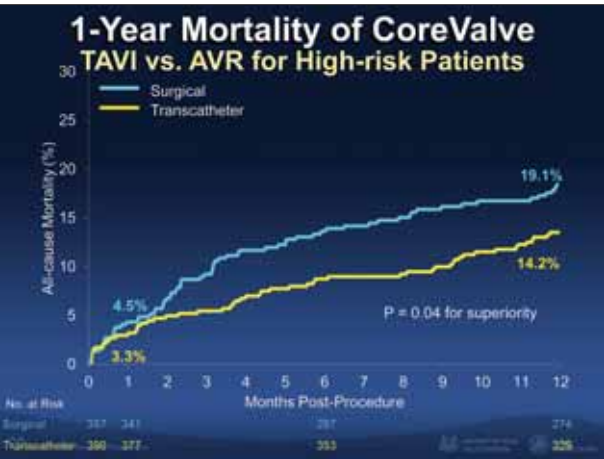


Figure 1.

## Current Outcomes SAPIEN vs. CoreValve

Since its introduction, two devices have been in widespread use throughout the world. The first is the balloon-expandable Edwards Sapien/SAPIEN XT transcatheter heart valve (Edwards Lifesciences Inc., Irvine, California) and the other is the Medtronic CoreValve ReValving System (Medtronic Inc., Minneapolis, Minnesota). In the CHOICE trial, high-risk patients with AS were randomized to receive either balloon-expandable valve or self-expandable valve to assess the comparative performance. The trial showed a greater rate of device success after balloon-expandable valve implantation compared with a self-expandable valve.

## Complications Following TAVI

In the current TAVI population, the overall prognosis is influenced by peri-procedural complications: stroke, major bleeding, major vascular events, and significant aortic regurgitation following TAVI were associated with increased long-term mortality. Conduction disturbance and subsequent need for permanent pacemaker are more frequent with CoreValve implantation. The prediction and management of these complications following TAVI are still matters of concern in daily practice.

## Paravalvular Leak and Permanent Pacemaker

Significant aortic regurgitation, mainly due to paravalvular leak, is caused by prosthesis undersizing, incomplete expansion or malposition of prosthesis (too high or too low implantation). The integration of MDCT assessment of aortic annulus (“virtual basal ring”) is crucial for the selection of valve size and selection of oversized prosthesis reduces the incidence of significant paravalvular leak. Recently, 3D transesophageal echocardiography plays important role in this field. Some studies reported severe calcification of aortic valve is associated with paravalvular leak. The malposition of prosthesis sometimes require re-positioning with using goose-neck catheter in case of too low implantation with CoreValve

or second valve implantation (“valve in series”) to reduce the excessive regurgitation. Need for permanent pacemaker, which is more frequent after CoreValve implantation, is predicted by multiple factors: baseline abnormal conduction such as right bundle branch block, small size of annulus, amount of calcification, and implantation depth of prosthesis. As contribution of new delivery system to optimal implantation of prosthesis and subsequent less need for pacemaker, new generation valves designed to protect the conduction system are awaited.

## Quality of Life After TAVI



PARTNER B demonstrated substantial and sustained survival benefit compared with standard care. However, given the advanced age and multiple comorbidities present in inoperable patients, improved QOL may be an even more important goal of therapy. In PARTNER A, there was no significant survival benefit of TAVI compared with surgical management at 2 years and some complications may even be increased. Therefore, evidence of improved QOL in either the short or long-term is critical to demonstrating the value of TAVI. In the PARTNER trial, the disease-specific status and generic health status were evaluated. Dr. David J. Cohen (Saint-Luke's Mid America Heart Institute, University of Missouri-Kansas City, USA) will present that among inoperable patients with AS, compared with standard care TAVI provides significant improvements in QOL and the impact of TAVI on QOL was maintained at least 1 year. For high-risk surgical candidates, TAVI via the transfemoral approach but not the transapical approach, was associated with short-term advantage compared with surgery.

## Future Directions ~TAVI for Intermediate Risk Patients

CHOICE trial Procedural Outcomes			
	Balloon-expandable Valve N=121	Self-expandable Valve N=120	P Value
Immediate procedural mortality, %	0	0	
Final aortic regurgitation			
Angiography, %			
Moderate	3.3	14.1	< 0.001
Severe	0.8	4.2	
Echocardiography, %			
Moderate	0.8	5.8	< 0.005
Severe	0.8	0	
Device success (primary endpoint)	95.9	77.5	< 0.001

Figure 2.



appropriate for the assessment of risk for TAVI procedure. How about the frailty (dependency in daily living) and anatomical risk (porcelain aorta, previous open heart surgery, chest malformation or radiation damage)? Reflecting these questions, the updated 2014 AHA/ACC guidelines recommend risk assessment combining STS risk estimate, frailty, major organ system dysfunction, and procedure-specific impediments. The next question is how about the clinical outcomes in lower risk patients? On Thursday 5:32 PM at Coronary Arena, Dr. Corrado Tamburino (Ferrarotto Hospital, University of Catania, Italy) will present “TAVI for Intermediate Risk Patients.” The only randomized control trial (PARTNER trial) has been conducted in high-risk population and surgery in low-intermediate risk population has shown excellent results. Lower risk patients (EuroSCORE < 20) showed better clinical outcome but most of these data come from registries. Interestingly, we already observed the trend toward increasing use of TAVI in intermediate risk patients with AS in Europe. There is a paucity of meaningful data, and early indications suggest similar results compared with surgical aortic valve replacement. Although early indications of TAVI in intermediate risk patients demonstrate promising results, ongoing randomized trials (PARTNER 2A and SURTAVI) will determine clinical use of TAVI in moderate risk patients in the future.

## Expanding Indications for TAVI

Furthermore, transcatheter valve-in-valve (VIV) implantation for degenerated bioprosthetic valves can be considered. VIV is clinically effective in the vast majority of patients with failed bioprosthetic valve. The global registry has shown that the VIV procedure had high successful rate (93.1%) with acceptable 30-day mortality (8.4%). TAVI has also been used for the treatment of bicuspid aortic stenosis despite concerns about proper stent expansion, secondary to congenitally abnormal orifice shape. In addition, TAVI has been employed on severe aortic insufficiency, but use is often limited by the relatively large dilated annulus, precluding the use of currently available smaller devices. Finally, the introduction of TAVI over the past 10 years in inoperable and high-risk patients with AS marks a new and exciting era in the treatment of valvular disease. Advances in technology and new devices under investigation should lead to further improvements in outcomes. Before TAVI can expand to lower risk patients with AS or those with varied types of valve disease, evidence in favor of this less invasive treatment has to be provided.



# 4th Master of the Masters Award Given to Dr. Gary S. Mintz

Wednesday, April 23, 9:48 AM - 10:00 AM, Main Arena, Level 3

Dr. Gary S. Mintz, Chief Medical Officer of the Cardiovascular Research Foundation, USA was recognized as the 4th recipient of TCTAP Award 2014 'Master of the Masters', held on Wednesday, April 23 at the Main Arena.

The CardioVascular Summit-TCTAP has initiated the 'Master of the Masters' Award in 2011 to honor and show appreciation to outstanding teachers and dedicators in the field of interventional cardiology as well as to the growth of TCTAP. This year, the organizing committee of TCTAP had agreed unanimously to present this award to Dr. Gary S. Mintz for his excellent expertise in this field and for continued contribution to this meeting as a course co-director from 1996.

Dr. Mintz is a renowned expert in the area of cardiovascular imaging. Since he's joined the Cardiovascular Research Foundation (CRF) in 1991, he has studied over 30,000 patients using intravascular ultrasound and made fundamental observations about the pathology, pathogenesis, mechanisms of coronary atherosclerosis, catheter-based interventions, and restenosis. He is also the author of over 675 articles, 50 book chap-

ters, and 729 abstracts concerning various aspects of clinical cardiology, cardiac ultrasound, hemodynamics, cardiac radiology and coronary arteriography, interventional

cardiology, and intravascular ultrasound.

In addition, Dr. Mintz has always exerted his efforts to educate young interventional cardiologists around the world. For more than

four decades he has contributed significantly in this field as a respectful teacher and compassionate scientist for new generation of interventional cardiologists.



## Register Onsite for Today's ACT Tour at 10am and 4pm Visit CVRF booth on level 1 to join and experience

The ACT Tour, Asan Medical Center Interventional Cardiology Training Program Tour, is one of the special activities run by CVRF (CardioVascular Research Foundation) during TCTAP meeting. ACT Tour at TCTAP was initiated in 2009 and has been successfully held each time with positive responses from participants of this program.

One of the Faculties of the Year members at TCTAP, Dr. Francisco Jose Ayala has joined the ACT Tour in 2012 and 2013, and he shared his experience on ACT Tour with CVRF recently. He is a Professor at the Cardiovascular Department in the University of Chile.

**CVRF** What was your first impression of the Asan Medical Center and its facilities?  
**Dr. Francisco Jose Ayala**

The Asan Medical Center was of my great interest to visit, being the largest health-care complex located in Seoul. The Asan Heart Institute (AHI), with worldwide prominence, is a well-known world leader in heart disease treatment and research, and where you can find the latest technologies and techniques. AHI have been innovators in left main CAD intervention and are proud of its AMC's Cardiology Training Program with more than 120 international physicians attending each year.

AMC is a high-volume and very busy center performing around 2,000 interventions per year with very high success rate and short total stay. With 21 years of experience, AMC averages about 600 surgeries annually, including off-pump and the Da Vinci robotically assisted system at a low cost for CABG compared to the US.

**CVRF** What do you enjoy most about this program?

**Dr. Francisco Jose Ayala**

The AMC Hospital Tour offers the visitor a brief look at the activities at Asan Medical Center. It includes a visit to the East building, Cath Lab facilities, tour of Asan Health Promotion Center, comforts area, and Asan Memorial Hall. I enjoy mostly visiting the cutting edge facilities and sharing our experience with my colleagues worldwide, especially coming from Asian countries.

**CVRF** Lastly, can you leave a word to other colleagues who are interested in this tour program?

**Dr. Francisco Jose Ayala**

I recommend my colleagues to attend this tour, and if possible, to experience the AMC's Cardiology Training Program espe-

**Program (2-hour long): Live Case Demonstration, Presentation and Q&A, Tour of Cath lab, CCU and Other Facilities**

**\* No registration fee**

For more information, visit  
[www.cvrf.org/act](http://www.cvrf.org/act)

cially and CVRF's educational activities. This will certainly be great opportunities for international exchange with other foreign Institutions and great to get training in the field of interventional cardiology or other disciplines of medicine and to learn the cutting edge facilities of AHI located in Asan Medical Center.



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High  $\beta$ 1-Selectivity(Cardioselectivity) <sup>2)</sup>

*Without bronchoconstriction via inhibition of  $\beta$ 2-adrenoceptors*

Vasodilating Properties <sup>3)</sup>

*By stimulating basal endothelial nitrate oxide release*

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

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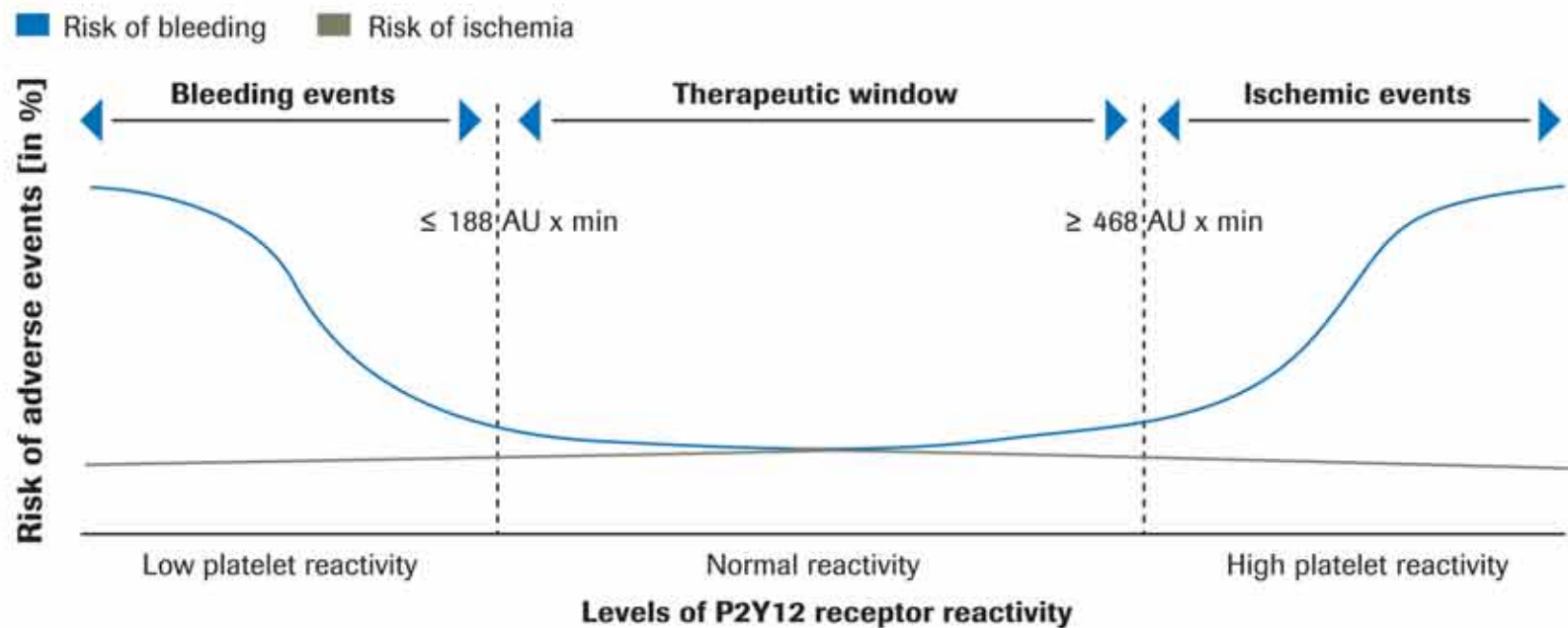




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Sibbing et al. Thromb Haemost. 2011 Aug;106(2):191-202.

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<b>COLtest</b>	Collagen induced aggregation
<b>RISTOtest</b>	vWF and GpIb dependent aggregation (using ristocetin as agonist)
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# Adjunct Pharmacotherapies: Evolving Issues

Thursday, April 24, 2:00 PM - 3:00 PM, Coronary Arena, Level 1

## Is 3-month Enough in the Era of New DES?

Which factors determine required duration of dual antiplatelet therapy (DAPT) regimen? This step must be first to search for solution for this clinical enigma. The degree of vulnerable vessel may follow the level of “disease activity” of ischemic heart disease. Likewise, the degree of vulnerable blood (“thrombogenicity”) including platelet reactivity, inflammation, and hypercoagulability will follow the level of “disease activity.” Therefore, “disease activity” is the integrated whole of “vulnerable vessel” and “vulnerable blood.” Required potency and duration of DAPT will be determined by this disease activity. The result of the large-scale PROTECT (Patient Related Outcomes with Endeavor versus Cypher stenting Trial) trial (n = 8791) provides more information that newer-generation drug-eluting stent (DES) that promote healing of the vessel wall—or at least don't delay it—may not lead to the same risk of late stent thrombosis compared with 1st generation DES. Contrary to the current guidelines for DAPT duration following DES implantation (at least 12 months), mounting evidence has supported that needed duration of DAPT in the era of new DES may be shorter than 12 months. The OPTIMIZE (Optimized Duration of Clopidogrel Therapy Following Treatment With the Endeavor Zotarolimus - Eluting Stent in the Real World Clinical Practice) trial (n = 3,120) reconfirmed that patients who took just 3 months of aspirin plus clopidogrel following PCI with a 2nd generation zotarolimus-eluting stent (Endeavor, Medtronic) faced risks of adverse events sim-

ilar to those of patients who took the recommended 12-month DAPT. One main limitation of the current randomized clinical trials (RCTs) for DAPT duration following DES implantation is the characteristics of enrolled patients. The OPTIMIZE trial just enrolled patients with low risk profile (NSTEMI, 5.4%). However, the clinical data from multiple registries including high-risk patients support the clinical benefit of long-term DAPT usage following PCI. The SWEDEHEART registry is the “real-world” post-AMI large-scale registry. In the recent analysis, clopidogrel coadministered with aspirin for > 3 months compared to 3 months (adjusted HR 0.84; 95% CI 0.75-0.95; p = 0.0042) and > 6 months compared to 6 months (adjusted HR 0.75; 95% CI 0.59-0.95; p = 0.0155) resulted in a significantly lower incidence of death/stroke/reinfarction. Another limitation of the current RCTs for DAPT duration will be the sample size. The PEGASUS TIMI 54 trial is the large-scale RCT (n = 21,000), which is carried out to see if ticagrelor in addition to aspirin therapy decreases frequency of cardiovascular events in high-risk patients who had a MI 1-3 years ago. Another large-scale DAPT study enrolled about 26,000 patients, in which is intended to determine the appropriate DAPT duration (30 vs. 12 months) as well as the safety and effectiveness of DAPT to protect patients from stent thrombosis and major adverse clinical events following the implantation of DES or bare metal stent. In the near future, these trials will add important information on clinical usefulness of longer duration of P2Y12 inhibitor in patients with ischemic heart disease according to the clinical presentation and DAPT regimen.

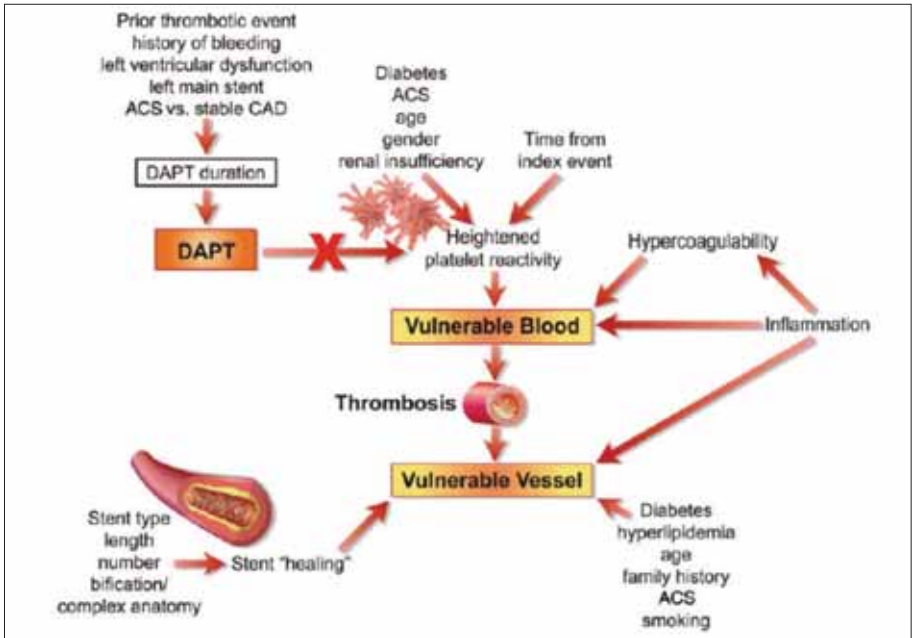


Figure 1.

## All Fired Up: Bivalirudin vs. Heparin During Primary PCI for STEMI

Pretreatment with aspirin plus oral potent P2Y12 inhibitor has been the mainstay in STEMI patients undergoing primary PCI. International guidelines (ACCF/AHA and ESC) recommend selective (“bail-out”) use of glycoprotein IIb/IIIa inhibitors (GPI) and this strategy is increasingly adapted in the routine practice. In addition, the universal use of heparin has been challenged by bivalirudin or fondaparinux. Bivalirudin (Angiomax, manufactured by The Medicines Company) is a specific and reversible direct thrombin inhibitor (DTI), which overcomes many limitations seen with indirect thrombin inhibitors, such as heparin. Bivalirudin is a short, synthetic peptide that is potent, highly specific, and a reversible inhibitor of thrombin. It inhibits both circulating and clot-bound thrombin, while also inhibiting thrombin-mediated platelet activation and aggregation. Bivalirudin has a quick onset of action and a short half-life. There is no risk for heparin-induced thrombocytopenia (HIT) syndrome. These characteristics make bivalirudin an ideal alternative to heparin. Previous two RCTs (HORIZONS AMI and EUROMAX) suggested that major bleeding risk falls with bivalirudin vs. heparin en route to PCI for STEMI. In the EUROMAX (European Ambulance Acute Coronary Syndrome Angiography) trial, the 30-day risk of death or major bleeding fell significantly in STEMI patients treated with bivalirudin compared with heparin-based management (either unfractionated heparin [UFH] or the low-molecular-weight heparin enoxaparin). Both strategies initiated prior to arrival at a hospital for primary PCI and both groups could receive a GPI provisionally. The bivalirudin benefit for that composite endpoint was driven by a significant drop in major bleeding. On the other hand, the relative risk of stent thrombosis with bivalirudin was nearly threefold what was seen in the heparin group and the excess stent thromboses with bivalirudin were driven by events in the acute phase, within 24 hours of PCI.

One recent trial presented at the ACC 2014 took heat like no other: the HEAT-PPCI (How Effective Are Antithrombotic Therapies in Primary PCI) trial. The single-center randomized trial of UFH vs. bivalirudin (Angiomax, the Medicines Company) (with bailout GPI) in STEMI patients surprised attendees on the

Both Drugs with Differential GPI use		
	Bivalirudin	Heparin
	GPI Bailout	GPI Universal
ACUITY	9 %	97 %
ISAR REACT 4	0 %	100 %
HORIZONS	7 %	98 %
EUROMAX	9 %	70 %

Figure 2.

last day of the meeting by showing a significantly lower rate of major clinical events in the heparin group at 28 days and no differences in bleeding complications. The trial recruited 1,829 patients over a 22-month period at a single UK hospital. In the heparin group, patients received a bolus dose of 70 units/kg preprocedure, while bivalirudin was given as a bolus of 0.75 mg/kg, followed by infusion of 1.75 mg/kg/hour during the procedure. Bailout GPI use was similar in the bivalirudin vs. heparin group (13.5% vs. 15.5%). The primary efficacy endpoint had occurred in 8.7% of bivalirudin-treated patients and in 5.7% of heparin-treated patients. Its main factors for endpoint difference were reinfarction and TLR, which were both significantly increased in the bivalirudin group. Definite or probable stent thrombosis was 3.4% in the bivalirudin group and 0.9% in the heparin group (HR 3.91; 95% CI 1.6–9.5; p = 0.001). There were no differences in minor bleeds, as well as major/minor bleeds, between groups. Another BRAVE 4 trial also presented at ACC 2014 appears to support those controversial findings of HEAT-PPCI in STEMI patients undergoing primary PCI, whereas the BRIGHT trial presented in the China Interventional Therapeutics went in the EUROMAX/HORIZONS-AMI direction. The recent clinical trials have raised questions about the bleeding advantage of bivalirudin in the contemporary PCI setting. Although there are no definite explanations for these observations, one explanation, in addition to the discretionary use of GPI, may be the use of more potent P2Y12 receptor inhibitor, which may “cancel out the bleeding benefit” of bivalirudin in modern-day PCI. In the era of potent P2Y12 inhibitor with short-term GPI infusion (< 4 hours) for the high-risk patients, the clinical efficacy and safety between bivalirudin vs. low-molecular-weight heparin vs. UHF should be reevaluated in the large-scale multicenter RCTs with the sophisticated protocol.



# Adjunct Pharmacotherapies: STEMI Intervention

Thursday, April 24, 3:00 PM - 4:00 PM , Coronary Arena, Level 1

## Evolving Issues in STEMI Intervention

Even though patients with acute ST-segment elevation myocardial infarction (STEMI) has been effectively treated with emergency angioplasty, called primary percutaneous coronary intervention (PCI), there has been unresolved several issues of primary PCI. This afternoon, six lecturers will give us valuable talks about multivessel PCI, the efficacy of thrombus aspiration during primary PCI, and the impact of door-to-balloon time on outcomes after primary PCI at the Coronary Arena (Level 1, 3:00 PM - 4:00 PM).

## Should We Do More Revascularization for Patients with Multivessel Disease Undergoing Primary PCI?



David R. Holmes, MD, of Mayo Clinic (USA) will review current guidelines about multivessel PCI during primary PCI in STEMI patients. The guidelines from the American College of Cardiology/American Heart Association and European Society of Cardiology focus on the culprit vessel and discourage treatment of non-infarct-related arteries at the time of primary or rescue PCI in stable STEMI patients. Yet despite unfavorable outcomes reported in retrospective studies and discouragement by guidelines, multivessel PCI is still performed in some STEMI cases. In this session, second speaker Issam D. Moussa, MD, of Cardiac & Vascular Physicians of Dallas (USA) will show the



results of the PRAMI (Preventive Angioplasty in Acute Myocardial Infarction) trial, in which 465 STEMI patients with multivessel disease randomly assigned to PCI in the infarct-related artery with or without immediate treatment of other stenosed vessels. Over a mean follow-up period of 23 months, the combined rate of cardiac death, nonfatal MI, and refractory angina was 9% in patients who received complete revascularization and 23% in those who had infarct-only PCI.

## Manual Thrombus Aspiration in STEMI: Time to Rethink?

Cindy L. Grines, MD, of Detroit Medical Center Cardiovascular Institute (USA) will review current guidelines about thrombus aspiration in primary PCI for STEMI. While in the TAPAS study (Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) all-cause mortality was reduced with thrombus aspiration as compared with conventional PCI alone, a



Swedish registry found that thrombus aspiration plus PCI increased all-cause mortality (HR 1.21). Bernard Chevalier, MD, of Institut Cardiovasculaire Paris-Sud (France) will introduce the randomized TASTE (Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia) trial, which enrolled far more patients (sevenfold) than TAPAS. According to the results of TASTE,

manual thrombus aspiration provides no additional mortality reduction compared with PCI alone in patients with STEMI. A strong trend favored PCI plus thrombus aspiration for reinfarction at 30 days (0.5% vs. 0.9%; HR 0.61 95% CI 0.34-1.07; P = 0.09).

## What is the Next Solution Beyond D2B Time?



Due to multi-disciplinary efforts, door-to-balloon (D2B) time for STEMI patients has been improving steadily. Despite this favorable development, the mortality rate for STEMI patients has not decreased. Mun Kyung Hong, MD, of St. Luke's-Roosevelt Hospital Center (USA) will talk about potential reasons for this discrepancy. One of the most pressing needs and the overwhelming reason for the lack of mortality benefit is the total ischemic time and the unchanging patient behavior with seeking immediate cardiac evaluation with the onset of symptoms. Analysis of CADILLAC and HORIZONS-AMI trials showed that short D2B time is associated with lower mortality only in patients with early presentation and had no statistical impact on those presenting late (>90 minutes) after symptom onset. Although the overall D2B time has improved, this change is not consistent among different operators or regions. Even if a STEMI patient presented early after symptom onset and has STEMI diagnosed promptly, the percentage of patients receiving evidence-based therapy is not the majority. Finally, medication compliance is another possible reason for the unchanging mortality rate. The last speaker, Naoto Inoue, MD, of Sendai Kousei Hospital (Japan) will show his data and introduce some efforts to reduce total ischemic time. Dr. Naoto

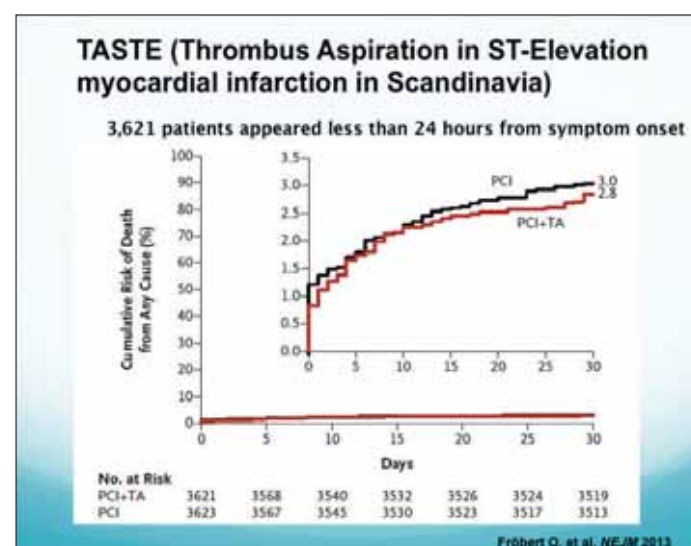


Figure 2.

Inoue investigated detailed time course of reperfusion and its predictor to search for the possibility of reducing total ischemic time in 210 consecutive patients who underwent emergent PCI for both STEMI and non-STEMI. Median D2B time was 50 min. Onset-to-door (OTD) and onset-to-balloon (OTB) median time were 191 min and 254 min respectively. By multivariate analysis the independent predictors of OTD time were non-STEMI, admission of regular hours, and transfer patients.

Both a large meta-analysis and an observational study published in the August 9, 2011 issue of the Journal of the American College of Cardiology supports current STEMI guidelines: in the meta-analysis, staged PCI was associated with lower short- and long-term mortality compared with both culprit PCI and multivessel PCI. Staged PCI advantage reinforced by observational study from STEMI cohort of the HORIZONS-AMI (Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction) trial who underwent PCI for multivessel disease. At 1 year, patients who underwent staged PCI had lower rates of all-cause mortality.

Cooperation with primary physicians and ambulance service and the education for patients are necessary. We hold periodic seminars and clinical paths with primary physician. The training for ambulance service is performed in our lab. Public educational program for citizens and medical lectures in the newspaper or TV are also important. These daily efforts will contribute to the improvement of OTD and OTB time during primary PCI in STEMI patients.

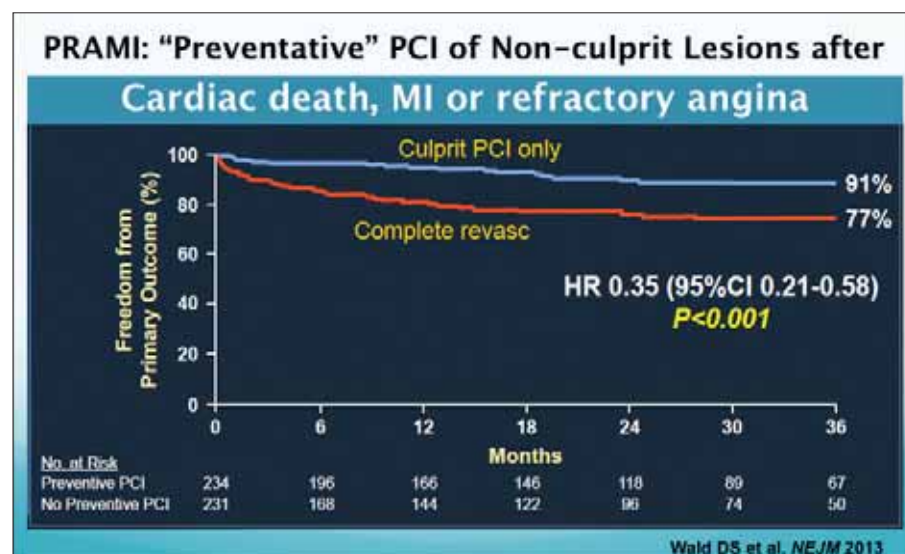


Figure 1.



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## References

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 Investig Drugs.* 2002;11(11):1587-1604.

## VYTORIN Selected Safety 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 ( $\geq 3$  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 ( $\geq 3$  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 abnormalities 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.



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# Highlights of Wrap-up Interview

## Increased FFR, Decreased MACE

Wednesday, April 23, 11:50 AM - 12:20 PM, Main Arena Lobby

**Moderator :** John McB. Hodgson

**Interviewees :** Eric Van Belle, William F. Fearon, Seung-Jung Park

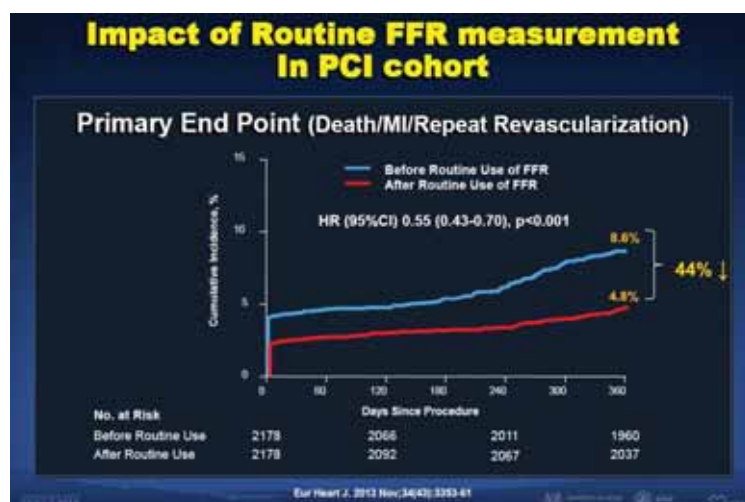
Fractional flow reserve (FFR) is a reliable functional index for epicardial coronary stenosis. It has been previously reported

that deferring lesions of intermediate severity at the angiography with a FFR 0.75-0.80 has good clinical follow-up. According to the 2011 ACCF/AHA/SCAI guidelines, FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD (Class IIa indication, level of evidence: A) Especially in multivessel dis-

ease, FFR-guided PCI led to better clinical outcome compared with angio-guided PCI. Evidences support that physiologic assessment is essential to make a decision on how to treat. So, the penetration rate of FFR is increasing consistently and routine FFR measurement decreased clinical outcomes including death, MI, and repeat revascularization about 40% in PCI cohort ( $p < 0.001$ ). FFR also has benefits in bypass surgery. FFR-guided CABG was better than angiography guided CABG in graft patency rate. However, there was no significant difference between FFR-guided and angio-guided-group in MACE. FAME3 will compare FFR-guided PCI and coronary angiogram-guided CABG in 3VD. New hyperemic stimulants, like Regadenosin, showed same effects compared with adenosine. For maximal hyperemia, we usually use intravenous adenosine, ATP,

dobutamine, Regadenoson, intracoronary Papaverine, adenosine, ATP, Nitroprusside, and nicorandil. HeartFlow has developed a non-invasive method to compute FFR (cFFR) from patient-specific CCTA data using computational fluid dynamics under rest and stimulated 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 catheterization. FFR is very promising. FFR is increasing and it reduce clinical events and cost. We need more functional studies in revascularization.

The finished interviews will be broadcasted on our websites at [www.summit-tctap.com](http://www.summit-tctap.com), [www.summitmd.com](http://www.summitmd.com) and [www.youtube.com/CVRFEvents](http://www.youtube.com/CVRFEvents) after the meeting.



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# Structural Heart Disease Symposium

Thursday, April 24, 2:00 PM - 6:30 PM, Endovascular & Structural Heart Theater, Level 1

## Renal Denervation Therapy (Figure 1)

Recently 2 studies were presented the 2014 ACC meeting, the results remains controversial in this field. In the SYMPPLICITY HTN-3 trial, there showed no benefit of the procedure in terms of systolic blood pressure reduction compared with a sham procedure in 6 months, according to results presented on March 29, 2013 at the American College of Cardiology/i2 Scientific Session and simultaneously published in the New England Journal of Medicine. The results had been anticipated since January of this year, when the main company behind the novel procedure, Medtronic, announced that the trial failed to meet its primary endpoint. Randomized 535 patients with severe resistant hypertension to renal denervation with the Symplicity catheter system (n = 364; Medtronic, Mountain View, CA) or a sham procedure (n = 171) at 88 US centers from October 2011 to May 2013. All patients were prescribed a minimum of 3 antihypertensive medications, including 1 diuretic. At 6 months, there was no difference in the change in office blood pressure (primary endpoint) between the treatment and placebo groups ( $-14.13 \pm 23.93$  mm Hg vs  $-11.74 \pm 25.94$  mm Hg;  $P = 0.26$  for superiority). There was also no difference in the change in ambulatory blood pressure at 6 months ( $-6.75 \pm 15.11$  mm Hg vs  $-4.79 \pm 17.25$  mm Hg;  $P = 0.98$  for superiority). With regard to the primary safety endpoint (composite of death, end-stage renal disease, embolic events resulting in end-organ damage, renovascular complications, or hypertensive crisis at 1 month or new renal-artery stenosis of more than 70% at 6 months), similar rates were observed in the denervation and

placebo groups (1.4% vs 0.6%;  $P = 0.67$ ). Because of the perceived success of the SYMPPLICITY HTN-1 and HTN-2 trials, all of the reasons for the negative results presented in the current study are unclear.

On the heels of the presentation of the negative SYMPPLICITY HTN-3 trial showing no efficacy of renal denervation over placebo, the results of a large registry study show significant reductions in both office and ambulatory blood pressure at 6 months in patients with uncontrolled hypertension. Findings from the Global SYMPPLICITY registry were presented on March 30, 2013 at the American College of Cardiology/i2 Scientific Session. A team led by Michael Böhm, MD, of University tskliniken des Saarlandes (Homburg/Saar, Germany), enrolled 1,000 patients with uncontrolled hypertension who were treated with the Symplicity catheter system (Medtronic, Mountain View, CA) at 231 international sites in 37 countries. At 6 months follow-up, office BP and ambulatory BP were available in 76.6% and 49.1% of patients, respectively. Renal denervation proved safe at 6 months with low rates of cardiovascular death (0.2%), stroke (0.9%), hospitalization for new onset heart failure (0.7%) or A-fib (0.9%), hypertensive crisis/emergency (1.0%), and MI (0.6%). Rates of major adverse events were comparable among the overall population (0.8%), patients in the overall population who met the inclusion criteria for SYMPPLICITY HTN-3 (1.3%), and the treatment arm of the SYMPPLICITY HTN-3 trial (1.4%). Overall, patients experienced significant reductions in office BP at 3 and 6 months. However, when broken into subgroups, those with low baseline BP actually saw an increase over time. The field may need a "reboot," because there has been too much provocative data



to date. Future investigation should occur but in a careful way. Dr. Horst Sievert (Cardio Vascular Center Frankfurt, Germany) will summarize the results of those studies and he will touch on the individual strengths and weaknesses for the study in his session.

## LAA Closure

Based on these theological backgrounds, left appendage (LAA) occlusion devices were introduced as an alternative to anticoagulation in non-valvular atrial fibrillation (AF). The first developed device was the PLAATO device (EV3 Endovascular, Plymouth, MN) in 2001, followed by the Watchman device (Boston Scientific, Plymouth, MN), the Amplatzer cardiac plug (St Jude, Golden Valley, MN), WaveCrest (Coherex Medical, Salt Lake City, UT), and LAMBRETM (Lifetech Scientific Corp., Shenzhen, China). The feasibility and early experience of Watchman device (Figure 2) was reported in 2007. The PROTECT AF trial randomized 707 non-valvular AF patients 2:1 to LAA closure or warfarin with and discontinuation of warfarin after 45 days. In PROTECT AF trial, the efficacy of the Watchman device is non-inferior to warfarin to prevent stroke/thromboembolism

for 2.3 years. For the safety concern during procedure, the implant success rate was significantly improved from PROTECT AF (90.9%) to continued Access Protocol (CAP) trial (94.3%) and PREVAIL trial (95.0%) with considerable decrease of peri-procedural complication. In the recent PREVAIL trial, 407 patients were randomized to either LAA closure with the Watchman device (n=269) or warfarin (n=138). The two primary endpoint (procedure related acute events and events between 7 days and 18 months) was met for prespecified criterion. Although this trial is needed more follow-up duration to confirm the efficacy of Watchman device, the PREVAIL trial demonstrated that the Watchman device had low acute procedure and device-related safety events. Furthermore, in a recent presentation at the Heart Rhythm Society meeting 2013, PROTECT AF trial achieved superiority for the composite endpoint of all stroke, cardiovascular or unexplained death and systemic embolism for 4 year follow-up (2.3% and 3.8% in the WATCHMAN and control groups, respectively ( $RR = 0.60$ , posterior probability of superiority = 96%). The Amplatzer cardiac plug is another clinical available LAA occlusion device. The recent reports demonstrated that LAA closure with Amplatzer cardiac plug was safe and comparable efficacy with warfarin treatment. But, procedure with Amplatzer car-

*Continued on page 17*



Figure 1. Symplicity catheter system

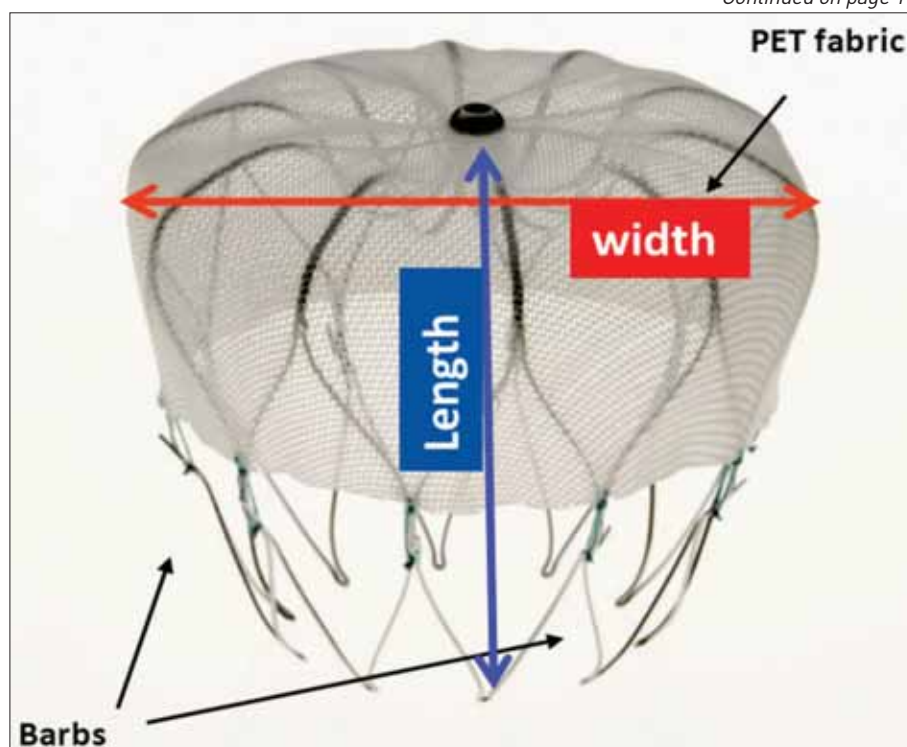


Figure 2. Watchman device



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diac plug also requires a learning curve to minimize peri-procedural complication. Dr. Saibal Kar (Cedars Sinai Medical Center, USA) will present the detailed indication and results of studies in his session.

Transcatheter Pulmonary Valve (TPV) Replacement

In patients with right ventricular outflow tract (RVOT) conduit dysfunction, transcatheter pulmonary valve (TPV) replacement demonstrates high procedural success, excellent short-term function, and low reintervention rates at 1 year, according to results of a post-approval study presented on March 30, 2013 at the American College of Cardiology/i2 Scientific Session. Researchers led by Aimee K. Armstrong, MD of the University of Michigan C.S. Mott Children’s Hospital (Ann Arbor, MI), enrolled 120 patients (mean age 19.9 years, mean weight 59.4 kg) with a stenotic and/or regurgitant conduit from July 2010 to July 2012. Ultimately 99 patients were implanted with the Melody TPV (Medtronic, Minneapolis, MN) for at least 24 hours. At 6 months, 96.7% of the implanted cohort with evaluable data (n = 90) had acceptable hemodynamic function (primary endpoint). Most of the implanted cohort overall (87.9%) also met the primary endpoint (P < 0.01 for both against the performance goal of 75%). At 1 year, hemodynamic function remained high at 94.3% for the implanted cohort with evaluable data and 82.8% for the overall group. RVOT mean gradient fell from 33.3 ± 14.1 mm Hg at baseline to 16.3 ± 7.1 mm Hg at discharge and 15.0 ± 9.9 at 6 months. Most patients (84.8%) had severe or moderate pulmonary regurgitation at baseline, but no evidence of this persisted at dis-

charge or during follow up. There were no instances of catheter reintervention at 1 year and 2 reoperations. Freedom from TPV dysfunction was 96.9% at 1 year, higher than the 93.5 ± 2.4% seen in the IDE trial. The rate of procedural serious adverse events was 13.3% including confined conduit tear, vascular complications, coronary compression, distal pulmonary artery perforation, arrhythmia, fever, paravalvular leak, and pulmonary edema. Within the first year, serious adverse events (8.1%) included endocarditis, sepsis, major stent fracture, pulmonary embolism, and arrhythmia/palpitations.

PFO

The foramen ovale is an essential part of the fetal circulation, allowing right-to-left shunt of oxygenated blood bypassing the non-functional lungs in utero. In approximately 20% of individuals the foramen ovale remains patent after birth. Several conditions, such as cryptogenic stroke or transient ischemic attack, decompression sickness in divers, platypnea-orthodeoxia, high altitude pulmonary edema, and migraine headaches have been found to be associated with a patent foramen ovale (PFO). There is very strong association between cryptogenic stroke and PFO. This association is even stronger in younger patients (<55 years of age). Medical therapy to prevent recurrence of stroke in such patients may be effective. However, the recurrence rate is somewhat high at about 3.8%. Further, the compliance issue with medications has potential implications and also morbidity and mortality from such medications are well known. Therefore, a better option could be closure of the PFO. Surgical closure can be effective, however, surgery has its own complications and also in the two series published had recurrence rates as high as 17%! Over the last almost two decades, device closure has become very popular

with meta analysis of all the studies indicating that device closure was better than medical therapy. However, none of those studies were randomized. To date, there are three randomized trials that were completed and addressed the issue of device closure vs medical therapy. The first such trial is the CLOSURE 1 trial: this trial compared medical therapy vs device closure using the STARFlex device compared to best medical therapy in over 900 patients. This trial failed to achieve its primary endpoints. The second trial was the RESPECT trial where patients were randomized to receive the Amplatzer PFO device vs medical therapy in more than 900 patients. Finally, the PC trial also randomized patients to receive medical therapy vs the Amplatzer device. All three trials failed to meet the primary endpoints. However, the RESPECT trial, if you analyze it as treated, would have been positive. The table below summarizes these three trials, in addition we also show the only remaining randomized trial that is ongoing (REDUCE). The RESPECT trial has not gone to the FDA panel. The major issue is how the FDA will look at the data. If they look at it as per protocol, then the trial is definitely negative. However, if they look as treated, potentially the trial could be positive. So in summary, so far the randomized trials have failed to prove that device closure is superior to medical therapy. The REDUCE trial is ongoing and we hope it will shed more light. Dr. Ziyad M. Hijazi (Rush University

Medical Center, Qatar) will deal with several studies, focusing on the results in his talk.

MitraClip

Dr. Charles Simonton (Abbott Vascular, USA) will present the treatment of mitral regurgitation (MR) using the transcatheter therapy, especially focusing on MitraClip in his talk. According to the Everest II trial, after 5 years, MitraClip therapy safely reduced degenerative MR in patients at prohibitive risk for mitral valve (MV) surgery (figure 2,3). In this group of prohibitive risk of degenerative MR patients, MitraClip therapy provided meaningful clinical improvements in LV volumes, functional class, quality of life, and re-hospitalization.



Figure 3. MitraClip Device

	CLOSURE 1	RESPECT	PC	REDUCE
Subjects	960	980 (event driven endpoint)	414	≈ 664
Randomization	1:1	1:1	1:1	2:1
Entry	Clinical Stroke or TIA	Stroke on MRI	Clinical and Radiologic Stroke/TIA	Stroke or TIA on MRI
Screening event	6 months	9 months	5 years	6 months
Medical Rx	Device Arm: 6mos clopidogrel & 24mos aspirin Control Arm: 24mos aspirin/warfarin or both	Warfarin or aspirin ± dipyridamole	Warfarin or aspirin ± dipyridamole	Both Arms: aspirin or aspirin + dipyrid or clopidogrel
Device	StarFlex NM	Amplatzer	Amplatzer	Helex
Endpoint	Stroke or TIA	Stroke or Death	Stroke/TIA or Death	Stroke/TIA on MR or death

Table 1.

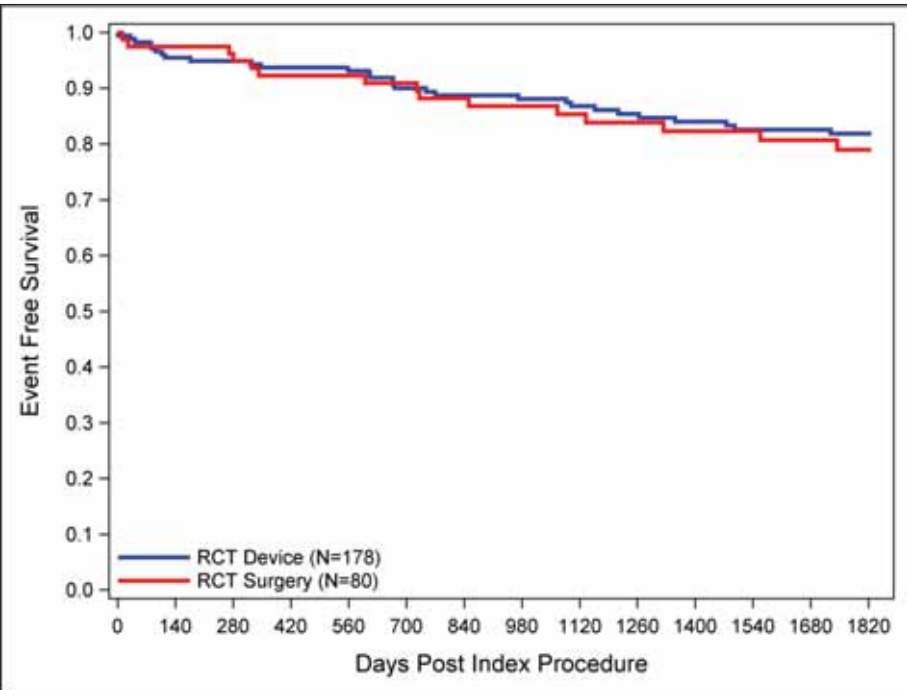


Figure 4. Kaplan-Meier Freedom From Mortality











# Interesting Abstracts & Cases

## From Oral Competition Session on April 23

Wednesday, April 23, 2:00PM-6:00PM, Abstracts & Case Zone, Level 3

### Percutaneous LAAO Can Be Performed Under Conscious Sedation without General Anaesthesia

Percutaneous left atrial appendage occlusion (LAAO) procedure is generally performed with transesophageal echocardiography (TEE) guidance under general anaesthesia (GA). Dr. Ngai-Yin Chan et al. from Princess Margaret Hospital, Hong Kong, China, presented their experience about LAAO procedure under conscious sedation (CS). Whether the complexity of this procedure can be reduced by performing under CS instead of GA has not been studied. The feasibility and safety of performing LAAO procedures in 8 patients (4 men, mean age  $67 \pm 10$ ) under CS with intravenous Midazolam±Fentanyl was studied. TEE was used to guide transseptal puncture and implantation of LAAO devices. All of the eight patients underwent LAAO procedures successfully with CS. The procedural duration and fluoroscopic time were  $98.6 \pm 27.1$  and  $14.4 \pm 5.2$  minutes respectively. The doses of Midazolam and Fentanyl required were  $5.7 \pm 2.0$ mg and  $56.3 \pm 32$ µg respectively. There were no complications arising from the use of CS. Watchman and Amplatzer cardiac plug (ACP) devices were implanted in 5 and 3 patients respectively with a mean size of  $27.6 \pm 5.2$ mm. One patient had minor migration of ACP device on day one of routine TEE surveillance. The device was successfully retrieved percutaneously and the patient was free from any long-term sequelae. With a median follow-up of 15.5 months, warfarin could be successfully stopped in all patients and no throm-

boembolic complications have been observed. Dr. Ngai-Yin Chan said that LAAO procedure can be performed under CS safely, so this approach will significantly reduce the complexity of this increasingly performed procedure.

### Platelet Function Test and Bleeding Risk in Patients with Coronary Artery Disease

Dr. Ho Fai Daniel Fong from Princess Margaret Hospital, Hong Kong, China, showed a case control study that performed to clarify the association between the value of P2Y12 VerifyNow test and clinical result of bleeding events in Asian population. Dr. Ho Fai D. Fong said, "platelet function test, such as VerifyNow, claimed to be able to predict bleeding risk. However, the evidence was limited, especially among the Asian population. This study aimed to evaluate the use of VerifyNow to assess bleeding risk. Subjects with low residual platelet reactivity were hypothesized to have an increased bleeding risk." A total of 120 subjects who were taking a P2Y12 inhibitor and had a VerifyNow test were recruited. The cases were defined as subjects with a PRU value of less than or equal to 95, a threshold for increased bleeding risk as recommended by Western studies. The controls were age matched to the cases. The primary outcome was the increase in bleeding risk associated with a low PRU value at 30 days. The secondary outcome was the increase in bleeding risk associated with a low PRU value at 1 year. The use of the percentage of platelet inhibition was also evaluated as a secondary

outcome.

Bleeding events occurred more frequently in the low PRU group. At 30 days, 31.7% of subjects had a bleeding event while 43.3% of the cases had a bleeding event at 1 year. The majority of these bleeding events were minor bleeding, such as easy bruising. After

adjusting for confounders, there was no statistically significant increase in bleeding risk among those in the low PRU group at 30 days or 1 year. Subjects with a high percentage of platelet inhibition ( $>50\%$ ) was also not associated with a statistically significant increase in bleeding risk. This result suggested that the VerifyNow test was not shown to be useful in assessing the bleeding risk of patients in an Asian population, contrary to the findings from Western literature. Dr. Ho Fai D. Fong concluded that a possible explanation was that the VerifyNow threshold for predicting bleeding might be higher among the Asian population and the definition for low residual platelet reactivity might be different in our locality.

### Successful Treatment of Prolonged Out-of-hospital Cardiac Arrest with Automatic Mechanical Chest Compression Device and Intra-arrest Primary PCI

Dr. Cyril Stechovsky et al. from Motol University Hospital, Czech Republic, presented a series of two case reports of patients with acute STEMI complicated by out-of-hospital cardiac arrest unresponsive to advanced cardiopulmonary resuscitation. Both patients were treated with use of an automated mechanical

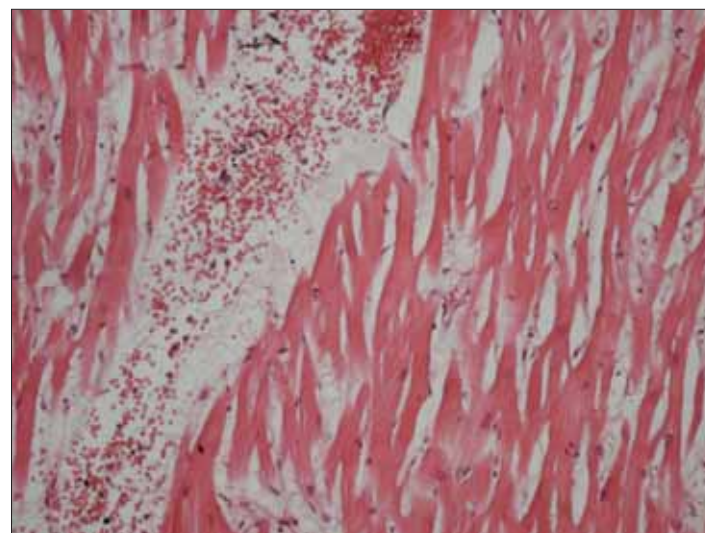


Figure 1. Interstitial edema and hemorrhage

compression-decompression device LUCAS 2 (Medtronic, Minneapolis, MN, USA). Coronary angiography showed occluded proximal left anterior descending artery in the first case and total occlusion of the left main coronary artery in the second case. In both patients a successful intra-arrest primary PCI was performed. LUCAS could be discontinued immediately after the reperfusion. Return of spontaneous circulation (ROSC) was achieved in both cases after 90 minutes of cardiac arrest. The first patient survived to hospital discharge without any neurological impairment. On a 1-year follow-up visit he was in a good condition; echocardiographic examination showed mild spherical remodeling with LVEF of 35%. The second patient died of cardiogenic shock 11 hours after onset of symptoms. An echocardiogram performed after ROSC showed increased echogenicity of both right ventricle and interventricular septum (IVS) and "hypertrophy" of right ventricle (8mm), IVS (14mm) and lateral wall of left ventricle suggesting cardiac contusion. An autopsy revealed a transmural anterolateral myocardial infarction but also massive subepicardial hemorrhage, extreme LV "hypertrophy" with IVS, and lateral wall thickness of 24mm and 22mm respectively, and interstitial edema and hemorrhages on histologic samples (Figure 1) from regions of the myocardium outside

Continued on page 21

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the infarction itself and also from the right ventricle. These lesions were concluded to be a myocardial contusion.

**ACS with Massive Plaque Burden Successfully Treated with the Combination of Excimer Laser Coronary Atherectomy and Filter Device**

Dr. Katsuyuki Hasegawa from Higashi Takarazuka Satoh Hospital, Japan, presented a case of a patient with crescendo chest pain and massive plaque burden in RCA. The 80-year-old man had a history of myocardial infarction and a bare-metal stent was implanted in the middle RCA eight years before. Coronary angiography showed severe stenosis in the proximal RCA and total occlusion of distal RCA with

massive plaque burden. The distal flow of the RCA was provided via collateral channels from the LCA. An Amplatzer left 1.0 guiding catheter was engaged. An XT-R guidewire (Asahi Intecc, Japan) was used to cross the severe stenotic lesion. An IVUS image identified severe stenosis with massive plaque burden. In order to avoid distal embolism, excimer laser coronary atherectomy (Vitasse 1.7mm) was performed before stent implantation (Figure 2). A Filtrap (filter device; Nipro, Japan) was also used to avoid distal embolism throughout the procedure (Figure 2). Filter no-reflow occurred after implanting an everolimus-eluting stent (Xience Xpedition, 3.5x38mm). Thereafter, aspiration of the debris floating in the proximal space to the filter was performed before the retrieval of the filter device. After the

retrieval of the filter device, the RCA was excellently re-canalized without any distal embolism. Dr. Katsuyuki Hasegawa concluded that excimer laser ablation and stent implantation under the distal protection of a filter device was very effective to recanalize occluded RCA with massive plaque burden.

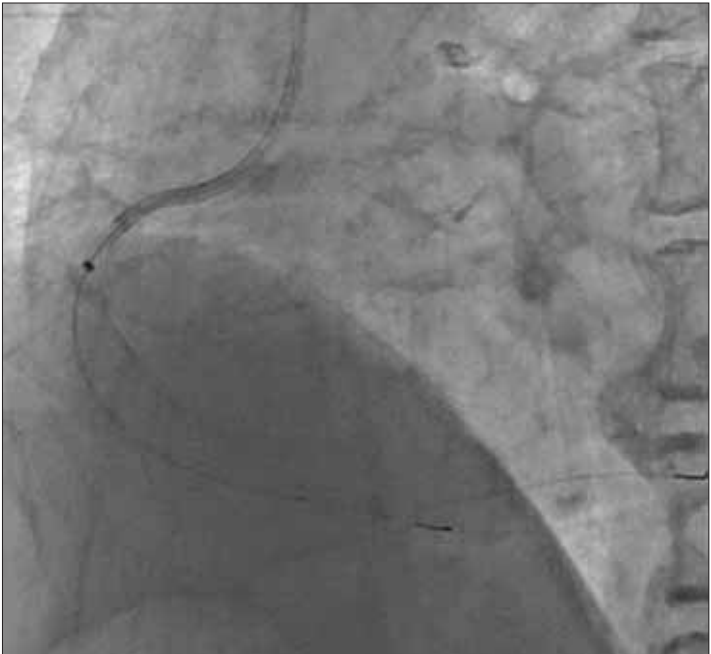


Figure 2. Excimer laser atherectomy with distal filter

**Endovascular Symposium**

**More Interest and More Debate: Carotid Intervention**

Thursday, April 24, 10:30 AM - 11:30 AM, Endovascular & Structural Heart Theater, Level 1

**Proximal protection first option for high risk CAS patients.**  
**A 'Turnover of Power' for Carotid Stenting**



CAS with proximal neuroprotection devices (NPD) in high risk patients in comparison with CAS with distal NPD in low/intermediate risk patients was not statistically significant, according to data to be presented today at the Endovascular Theater by Dr. Piotr Pieniazek from Jagiellonian University, John Paul II Hospital, Krakow, Poland. According to the 'tailored CAS approach,'

applied for 2,005 CAS procedures in his center for the last 12 years, proximal NPD is indicated in 'high risk' lesions ('string-sign,' soft, ulcerated, thrombus containing, symptomatic) and lesions after neck irradiation. The 30-day outcome of CAS with proximal NPD in high risk patients in comparison with CAS with distal NPD in low/intermediate risk patients was not statistically significant and below 2.5% in both groups (Table 1). This data shows that even high-risk CAS can turn into low-risk procedure when proximal NPD is applied. He declared that "proximal NPD can be safely used in high-risk lesions such as thrombus containing lesion or subtotal stenosis coexisting with contralateral occlusion." He will explain that proximal compared to the distal NPD has an inevitable advantage. "Because of proximal flow blockage with proximal NPD usage, when crossing the lesion in the internal

carotid artery the brain circulation is already protected," he said. "Removal of the proximal NPD in the end of CAS procedure is also much easier than when using a filter." He will conclude his lecture, "based on my data, CAS with proximal NPD can have a significantly better outcome than CEA. The routine use of proximal NPD could be of advantage in high risk patients and could make CAS procedure safe and feasible for prior high-risk-'no-option' patient groups. In 2014, when finally CAS has established its role in carotid revascularization, each endovascular specialist should be familiar with the indications and technical aspects of proximal NPD application during CAS."

**Mono Mo.Ma; New Indication for Vertebral Stenting**

Nowadays, he extended the indication for proximal NPD for the high-risk vertebral artery stenting procedures (Figure 1). During this procedure a 'steal syndrome' in vertebral artery is created, which protects the brain and reduces the possible periprocedural complications.

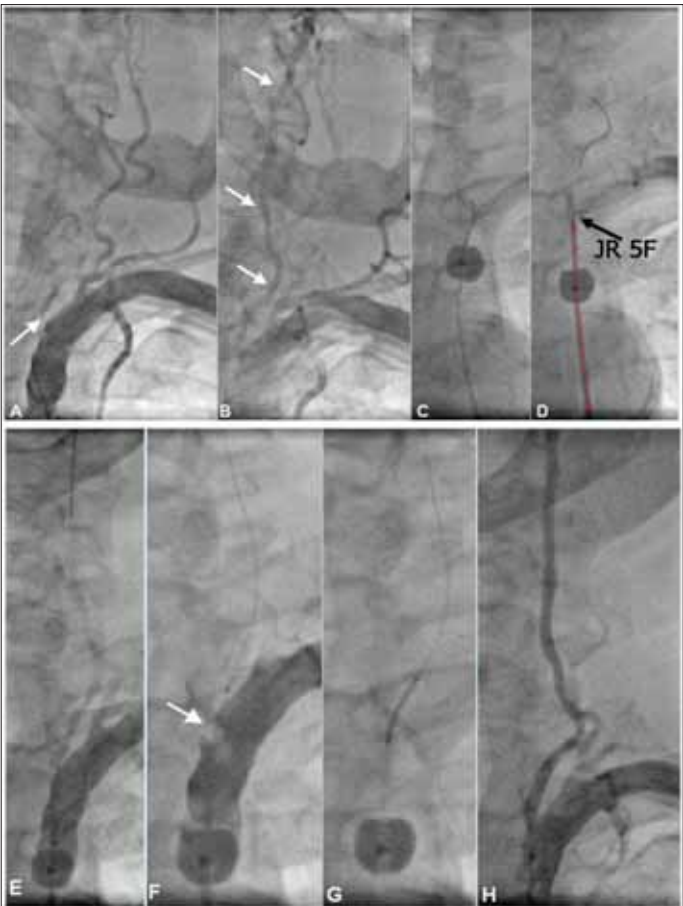


Figure 1. Mono Mo.Ma for vertebral stenting. A 'steal syndrome' occurs and protects the brain.

	Proximal protection (n=747)	Distal protection (n=1,258)	
30-day death	0.80% (6/747)	0.64% (8/1258)	p=0.664
30-day major/disabling stroke	0.40% (3/747)	0.32% (4/1258)	p=0.169
30-day any stroke	1.47% (11/747)	1.75% (22/1258)	p=0.638
30-day death/disabling stroke	1.20% (9/747)	0.95% (12/1258)	p=0.594
30-day death/any stroke	2.27% (17/747)	2.38% (30/1258)	p=0.158

Table 1.

# Features from ACC 2014

Thursday, April 24, 11:30 AM - 12:30 PM, Coronary Arena, Level 1

## Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Disease by Darren Mylotte on Behalf of TAV-in-BAV Group

A total of 143 patients underwent TAV-in-BAV in 12 centers. The Edwards Sapien valve was used for 51 patients, the Medtronic CoreValve was used for 91 patients, and the Lotus valve was used for one patient. In high-risk patients with significant BAV disease, TAV-in-BAV appears to be both safe and effective; short- and intermediate-term clinical outcomes are encouraging though there appears to be a higher incidence of post-implantation aortic regurgitation observed.

## TAVR with the CoreValve Device Superior to Surgery at 1 Year

795 patients with severe aortic stenosis at increased surgical risk were randomized to TAVR with the CoreValve self-expanding nitinol bioprosthesis (n = 394) or surgery (n = 401). Most TAVR-treated patients (82.8%)

underwent iliofemoral procedures. MACCE was lower with TAVR compared with surgery at 1 year (20.4% vs 27.3%; P = 0.03), although there were no differences between the groups in individual rates of major stroke at 30 days (4.9% vs 6.2%; P = 0.46) or 1 year (8.8% vs 12.6%; P = 0.10). Among patients with severe aortic stenosis who are at increased surgical risk, transcatheter aortic valve replacement (TAVR) with a self-expanding bioprosthesis is associated with better survival at 1 year compared with surgery.

## Renal Denervation Fails to Meet Efficacy Endpoints Compared with Placebo Procedure: SIMPLICITY HTN-3

Six-month results of the SYMPLICITY HTN-3 trial show no benefit of the procedure in terms of systolic blood pressure reduction compared with a sham procedure. A total 535 patients with severe resistant hypertension randomized to renal denervation with the Symplicity catheter system (n = 364) or a

sham procedure (n = 171). At 6 months, there was no difference in the change in office blood pressure (primary endpoint) between the treatment and placebo groups ( $-14.13 \pm 23.93$  mm Hg vs  $-11.74 \pm 25.94$  mm Hg; P = 0.26 for superiority). There was also no difference in the change in ambulatory blood pressure at 6 months ( $-6.75 \pm 15.11$  mm Hg vs  $-4.79 \pm 17.25$  mm Hg; P = 0.98 for superiority).

## Global SYMPLICITY Registry Still Shows Positive Results for Renal Denervation

Presentation of the negative SYMPLICITY HTN-3 trial showing no efficacy of renal denervation over placebo, the results of a large registry study show significant reductions in both office and ambulatory blood pressure at 6 months in patients with uncontrolled hypertension. The study included 1,000 patients with uncontrolled hypertension who were treated with the Symplicity catheter. There was a 20.2 mm Hg reduction in office blood pressure at 6 months. Similarly, the office

blood pressure reduction among those patients who were also taking at least 3 anti-hypertensive medications at maximally tolerated doses was 17.3 mm Hg.

## Zotarolimus-eluting Endeavor Sprint Stent in Uncertain DES Candidates (ZEUS study)

The use of zotarolimus-eluting ENDEAVOR stent implantation in patients at low restenosis or at high bleeding or thrombotic risk will decrease the incidence of 12-month major adverse cardiac events (MACE) including overall death, any myocardial infarction (MI) or any target vessel revascularization (TVR). This study showed 24% risk reduction of MACE, 47% risk reduction of TVR, and 65% risk reduction of MI without any difference in bleeding events compared with BMS.


## The NOBORI Biolimus-Eluting versus XIENCE/PROMUS Everolimus-eluting Stent (NEXT trial) from Masahiro Natsuaki

Continued on page 23

# Pantera Lux

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A total of 3,241 patients in multicenter, the BP-BES(Nobori stent) and DP-EES(XIENCE V/PROMUS) stent were compared about TLR at 1 year and death or MI at 3-year. The results of death or MI and TLR between two stents showed no significant differences.

### Incidence and Impact of Stent Thrombosis During Percutaneous Coronary Intervention: Comparison of Cangrelor and Clopidogrel from the CHAMPION PHOENIX Trial by Philippe G  n  reux on Behalf of CHAMPION PHOENIX Investigators.

Authors sought to evaluate the incidence and impact of stent thrombosis (ST) among this large cohort. Angiographic analysis was performed by an independent core laboratory in 10,939 patients. In conclusion, the authors suggested that in the CHAMPION PHOENIX trial, the occurrence of ST was strongly associated with increased mortality and cangrelor use resulted in a significant reduction in ST, with consistent effects on intra-procedural, acute, and sub-acute ARC defined ST.

## Endovascular Symposium

### More Interest and More Debate: AAA

Thursday, April 24, 8:30 AM - 9:30 AM Endovascular & Structural Heart Theater, Level 1

#### Type II Endoleak Should be Treated if Persistent and Greater than 5mm Growth After Implant

The workshop for 'Endovascular Session III' will be held at Endovascular & Structural Heart Theater, Level 1, in the title of 'Endovascular management and its complication related with abdominal aortic aneurysm and dissection.'

Dr. Woong Chol Kang (Gil Hospital, Gachon Univ., Korea), will discuss first in the topic of 'Evolution in AAA Endograft Devices, Technique and Outcomes.' He will do an in-depth review of EVAR from introduction to current restrictions and future perspectives. Dr. Richard R. Heuser (St. Luke's Medical Center, Univ. of Arizona, USA), the third lecturer, will guide the audience on how to manage the endoleak, a common problem related to endovascular AAA treatment. He

will talk about the classification and treatment of endoleak. In his topic, type I endoleak, blood leakage at attachment of site should be treated with PTA, balloon, or stents. Type II endoleak (Figure 1), blood leakage at collaterals, is not benign and should be treated with endovascular embolization using TLA needle cyanoacrylate glue if persistent and greater than 5mm growth after implant should be treated. Type III endoleak, blood leakage due to graft failure, also should be treated with bridging endograft. Type IV endoleak, blood leakage due to porosity of endograft, does not need treatment. Actually, he will highlight up-to-date information related to type II endoleak such as its prognosis, its detection, management, and future perspectives.

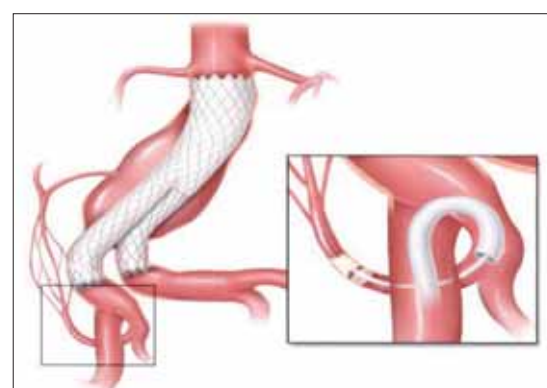


Figure 1. Type II endoleak due to collaterals from distal artery treated by TLA needle cyanoacrylate glue

Dr. John Robert Laird, Jr. (UC Davis Medical Center, UC Davis, USA) will lecture about practical tips for challenging AAA anatomy and endovascular management of complicated type B aortic dissection subsequently. Don't hesitate to join this session if you are interested in Thursday from 8:30 AM to 9:30 AM.

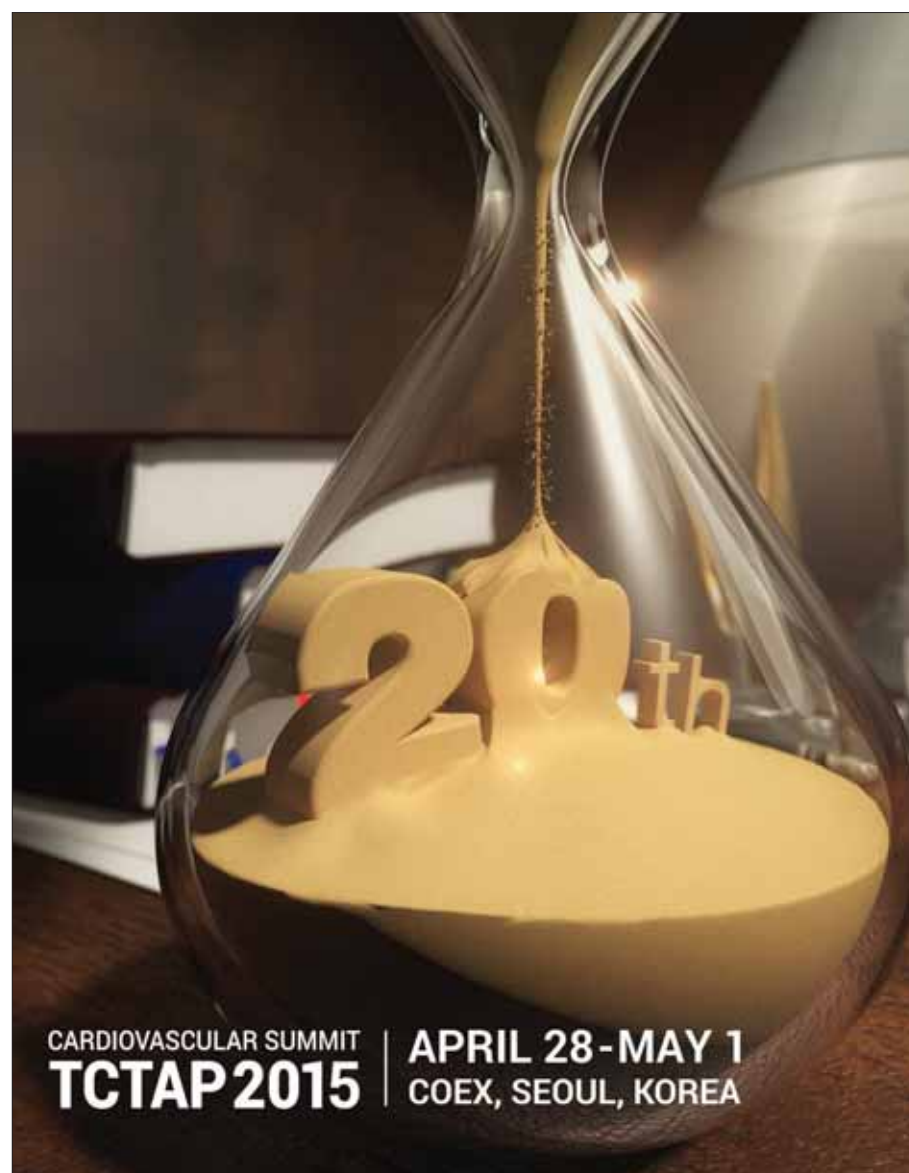
## Must Visit Place in Seoul



### Namsan Hanok Village

**Namsangol Hanok Village** It is a collection of five hanoks (traditional Korean houses) from the Joseon Dynasty (1392-1910), recovered from different parts of the city and relocated to the northern foot of Namsan mountain. The interiors of each of these five houses reflect owners from different walks of life, from the middle class to the yangban (noblemen and aristocrats.)

Please visit Tour Information Desk, Level 1, for more information





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