# Thursday, April 28, 2016

# TCTAP2016 DALY NEWS **21<sup>st</sup> CARDIOVASCULAR SUMMIT**

# **Today's Highlights**

Late Breaking Clinical Trials & 2016 New Data from AMC

**Coronary & Valve Symposium** 

Endovascular Symposium

New DES & BVS 8:30 AM - 10:30 AM The Latest Update "Presentation

Left Main and Bifurcation

Structural Heart Disease Symposium

Pediatric Structural Heart Disease Symposium 8:30 AM -6:20 PM Room 105, Level 1

TCTAP Best Young Scientist Award 12:22 PM - 12:30 PM The Latest Update "Presentation"

Satellite Symposia Morping Roundtable Forum @7:00 AM Morning Roundtable Forum E Lunchtime Activities @12:45 PM Evening Symposium @6:00 PM

Moderated Abstract & Case Competition 8:30 AM - 6:30 PM

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Left Main and Bifurcation PCI	
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Hot Abstract & Case	

# Left Main and Bifurcation PCI; **Continuously Evolving**

# LM PCI; Anticipating the Results from the EXCEL or NOBLE

Researchers led by

in the BMS era to 51.8%



Yves R. Louvard, MD Institut Hospitalier Jacques Cartier, France

in the late DES era. At the same time, there was an increase in IVUS employed during PCI from 79.9% to 86.6%, respectively. In terms of stent technique, the percentage of devices primarily implanted in left main ostial or shaft lesions declined from 65% to 14.5% across the time periods. In the late DES era, bifurcation lesions were more frequently treated with a single-stent crossover technique than with a 2-stent technique (60.3% vs. 25.1%; P<0.001). Patients undergoing surgery also saw changes, most notably a large and steady increase in off-pump CABG from 14.8% to 66.8% (P<0.001). While the total number of grafts per surgery decreased, use of the left internal mammary artery grew from 86.4% to 96.6% (P<0.001). In the PCI cohort, the incidence of risk-adjusted MACCE (primary endpoint; death, MI, stroke, or repeat revascularization) decreased from 20.18 to 6.77 cases per 100 person-years across the eras (P<0.001 for trend). Risks of death, the composite of death, MI, or stroke, and repeat revascularization also fell (Table 1).

In the CABG cohort, outcomes held steady apart from a reduction in the risk of repeat revascularization (adjusted HR 0.60; 95% CI 0.38-0.95). CABG carried a lower risk of

Table 1. Changes in PCI outcomes for left main disease: 1995-2010

	Adjusted HR	95% CI
MACCE	0.57	0.47-0.70
Death	0.60	0.41-0.87
Death/MI/Stroke	0.65	0.48-0.89
Repeat revascularization	0.54	0.43-0.67

MACCE compared with PCI for the first 2 eras, although the gap narrowed and eventually disappeared by the late DES era; the shift was due to improving PCI outcomes and unchanging CABG outcomes (Figure 1).

In the meantime, 2 RCTs of PCI vs. CABG in this population are underway (EXCEL and NOBLE) and results for both are expected in the fall of 2016. If the results of these trials are positive, they would pave the way for PCI to achieve class I status for the treatment of unprotected left main disease (Figure 2).

### FFR-Guided Bifurcation Treatment: Treat-or-Not Treat and Bifurcation **Techniques**

The bifurcation lesion possesses unique anato -mic and physiologic charac -teristics. The amount of



Figure 1. Trends in outcomes of left main PCI

# EXCEL and NOBLE (TCT 2016)

	SYNTAX	EXCEL	NOBLE				
All-comers	Yes	No	No				
Left main patients	705	1,905	1,200				
SYNTAX score	Any	≤32	Low				
Primary endpoint	MACE	Death/MI/CVA	MACE				
Follow up	1 year	3 year	2 year				
IVUS	Infrequent	Recommended	Recommended				
FFR guidance	Infrequent	Recommended	Recommended				
Stent	PES	EES	BES recommended				
Anglographic FU	At discretion	Not recommended	Not recommended				
reads Heekal Photoscient Adapted from Campos CM, et al. EuroIntervention. 2018;11:V115-0							

Figure 2. EXCEL and NOBLE

Continued on page 5

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Pantera LUX

Statistic Contraction of the second 

BIOTRONIK

# 21<sup>st</sup> CARDIOVASCULAR SUMMIT TCTAP 2016 DAILY NEWS

# **General Information**

# **Shuttle Bus**

Free shuttle bus is provided between COEX and several venue hotels. Visit the CVRF booth for more info -rmation

# **Certificate of Attendance**

Certificate of Attendance for TCTAP 2016 will be distributed along with the badge

- Tuesday, April 26 Thursday, April 28 @ Registration Booth, Level 3
- Friday, April 29 @ Registration Booth, Level 1

# Free Mobile Recharge

- Lounge, Exhibition Hall, Level 3
- Lounge, Grand Ballroom Lobby, Level 1

# Lost and Found / Coat Room

• Tuesday, April 26 - Thursday, April 28 @ Coat Room, Level 3

- Friday, April 29
- @ Registration Booth, Level 1

# **Tour Information**

### Tour information will be provided by COSMOJIN TOUR.

- Tuesday, April 26 Thursday, April 28 @ Main Arena Lobby, Level 3
- Friday, April 29 @ Registration Booth, Grand Ballroom Lobby, Level 1

# Find out who is up for the next rising interventional cardiolo

The 4th TCTAP Best Young Scientist Award Ceremony Thursday, April 28, 12:25 PM The Latest Updated Presentation Theater

# **TCTAP Best Young Scientist Award opens to** ALL young interventional cardiologists!

The award is annually bestowed to one of the young physicians to encourage their academic and clinical work experience with the amount of 5,000 USD. Submission Opens on July 4, 2016

# Apply if you

- Have career within 5 years of the start of their fellowship or training period - Share your own patient care experience with knowledge and understanding
- in the clinical practice in TCTAP
- Introduce new, advanced solutions to complicated issues in TCTAP

Contact: Emilie Cho (emiliecho@summitmd.com)



# Invitation to the ACT Tour at **TCTAP 2016**

We invite you to ACT Tour to experience

**How to register** \* *First Come, First Served Basis* On-site registration: ACT Desk at CVRF Booth (*3F, COEX*)

### **Pick-up place**

# Participants

# Program (For 2 hours)

Presentation and Q&A (*Duration: 20 min*) Cathlab, CCU Tour & the Other Facilies (*Duration: 40 min*) Return to the COEX (Duration: 30 min)

### Time Table

Date	Section	Departure Time
April 27 (Wed.)	Tour 1	4:00 PM
A	Tour 2	10:00 AM
April 28 (Thu.)	Tour 3	4:00 PM





**CVRF** booth Main Arena Lobby, Level 3

# **5 lovely new friends** will be with us this year!

and pose for the camera together! The photo will be printed on-site and if you post this photo on faceboo you will get a special present.

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**Operating Hours** 

Tuesday 26 7:00 AM \_ 7:00 PM Wednesday 27 6:00 AM \_ 7:00 PM Thursday 28 6:00 AM \_ 7:00 PM

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"Let's Meet TCTAP Friends!"

# Program at a Glance : Thursday, April 28, 2016

	Coronary & Valve Theater <i>Level 1</i>	Endovascular Theater <i>Level 1</i>	Presentation Theater <i>Level 1</i>	Room 105 <i>Level 1</i>	Room 203 <i>Level 2</i>	Room 1A <i>Level 3</i>	Exhibition Hall <i>Level 3</i>	Abstract Zone I <i>Level 3</i>	Abstract Zone II <i>Level 3</i>	Case Zone I <i>Level 3</i>	Case Zone II <i>Level 3</i>	Case Zone III <i>Level 3</i>		
07:00		Morning Rou	С Т Т Т											
08:00			7:00AM-8:10AM											
09:00	Live Cases & Lectures TAVR Left Main	Live Cases & Lectures SFA Ilio-Femoral	Focused Workshop DES & BRS 8:30AM-10:30AM	Pediatric Structural	10 <sup>th</sup> Cardiopulmonary	Satellite Meeting 9:00AM-10:00AM		Moderated Abstract	Moderated Abstract	Moderated Complex Case	Moderated Complex Case	Moderated Complex Case		
11:00	Bifurcation 8:30AM-12:30PM	AAA 8:30AM-12:30PM	LBCT & Year-Review Data & Best Young	Heart Disease Symposium 8:30AM-12:30PM	Rehabilitation Workshop (Korean Session) 8:30AM - 12:00PM	e Rehabilitation Workshop (Korean Session)	Heart Disease Symposium 8:30AM-12:30PM (Korean Session			Competition Acute Myocardiac Infarction / Acute Coronary	Competition Complex PCI 8:30AM-12:20PM	Competition Acute Coronary Complex PCI 8:40AM-12:30PM	Competition Complex PCI Imaging & Physiology 8:30AM-12:30PM	Competition Complex PCI Endovascular 8:30AM-12:20PM
12:00	A~ (●) (●)		Scientist Award 10:30AM-12:30PM					8:30AM-12:20PM						
01:00	D Lunchtime Activities 12:45PM-1:45PM				<u>I</u>	Exhibit 9:00AM-6:00PM								
02:00			Focused											
03:00	Live Caes & Lectures Complex PCI TAVR BRS	Live Caes & Lectures Carotid AAA 2:00PM-6:00PM	Workshop Left Main Complex PCI 2:00PM-3:40PM	Pediatric Structural				Moderated Abstract Competition	Moderated Abstract Competition	Moderated Complex Case Competition	Moderated Complex Case Competition	Moderated Complex Case Competition		
04:00 05:00	2:00PM-6:00PM		Structural Heart Disease Symposium	Heart Disease Symposium 2:00PM-6:20PM				DES/BVS 2:00PM-6:00PM	Acute MI & Coronary / Imaging & Physiology 2:00PM-6:00PM	Complex PCI 2:00PM-6:00PM	Imaging & Physiology Complex PCI 2:00PM-6:00PM	Endovascular Complex PCI 2:00PM-6:00PM		
06:00			3:40PM-6:15PM											

% Please refer to TCTAP 2016 Mobile App or Final Program book for the specific program information.

# Live Case Transmission from World-Renowned Medical Centers



# St. Paul Hospital, Vancouver, Canada

8:30 AM - 9:30 AM @ Coronary & Valve Theater, Level 1
Operator(s): John Graydon Webb, Anson Cheung



# Zhongshan Hospital, Fudan University, Shanghai, China

• 2:00 PM - 3:00 PM @ Coronary & Valve Theater, Level 1 • Operator(s): Junbo Ge



# Severance Hospital, Seoul, Korea

- 9:45 AM 10:30 AM @ Coronary & Valve Theater, Level 1
- Operator(s): Myeong-Ki Hong, Byeong-Keuk Kim, Seung-Yul Lee
   IVUS Interpreter: Jung-Sun Kim
- 11:00 AM 12:30 PM @ Endovascular Theater, Level 1
- Operator(s): (Case #7) Donghoon Choi, Chul-Min Ahn, Yongsung Suh (Case #8) Jongyun Won, Sanghoon Shin, Hoyoun Won



# Samsung Medical Center, Seoul, Korea

11:15 AM - 12:00 PM @ Coronary & Valve Theater, Level 1
Operator(s): Hyeon-Cheol Gwon, Joo-Yong Hahn, Taek Kyu Park
IVUS Interpreter: Sang Wook Kim



# Asan Medical Center, Seoul, Korea

- 8:30 AM 10:00 AM @ Endovascular Theater, Level 1
  Operator(s): (Case #5) Mark W. Burket, Seung Hyuk Choi (Case #6) John Robert Laird, Jr., Cheol Woong Yu
- 3:15 PM 4:15 PM @ Coronary & Valve Theater , Level 1
- Operator(s): (Case #4) Seung-Jung Park, Jung-Min Ahn (Case #5) Suk Jung Choo, Hee Jung Kim, Sung Han Yoon
- Echo Interpreter: Ran Heo
- 4:45 PM 6:00 PM @ Coronary & Valve Theater, Level 1
- Operator(s): (Case #6) Seung-Jung Park, Jung-Min Ahn
- (Case #7) Duk-Woo Park, Imad Sheiban
- IVUS Interpreter: Gary S. Mintz
- 5:00 PM 6:00 PM @ Endovascular Theater, Level 1
- Operator(s): (Case #11) Hiroshi Ando, Woo Young Chung (Case #12) Seung-Whan Lee, Jae-Hwan Lee, Young Rak Cho



# Seoul National University Hospital, Seoul, Korea

• 10:30 AM - 11:15 AM @ Coronary & Valve Theater, Level 1 • Operator(s): Hyo-Soo Kim, Han-Mo Yang, Jung-Kyu Han



# Seoul National University Bundang Hospital, Gyeonggi-do, Korea

3:00 PM - 4:00 PM @ Endovascular Theater, Level 1
Operator(s): (Case #9) Oki Kwon, Si-Hyuck Kang, Seungpil Ban (Case #10) Paul Hsien-Li Kao, In-Ho Chae, Donghoon Han



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# WITH CONFIDENCE

# **Yesterday's Hot Live**

A 91 year-old men was admitted for shortness of breathing (NYHA class III). He has a past medical history of hypertension and stomach cancer, and has been recently diagnosed as very severe AS (AVA 0.47 cm<sup>2</sup>). His logistic EuroSCORE and STS score were 10.14% and 5.1%, respectively. A significant stenosis in left main coronary artery was fixed with a DES in a previous staged procedure. Concerning that the left coronary height from annulus was only 7.8 mm, the valve contained heavy calcification, and the annulus perimeter was 72.3 mm, Evolute R 29 mm was selected for TAVR. Without pacing, the device was deployed while giving gentle pressure toward left ventricle to make a precise alignment of the distal end of the device and the annular plane. Final root angiography showed patent coronary arteries, minimal paravavular leakage, and narrow QRS on ECG.





### Continued from page 1



myocardium supplied by the side branch is relatively small and variable. The side branch narrowing is usually accompanied by an eccentric dis -tribution of plaque and negative remodeling; the mechanism of luminal narrowing of

Seoul National University Hospital, Korea

jailed side branch is very heterogenous and the coronary flow patterns through the main vessel and side branch is dynamically changed during the intervention. Therefore, "to treat or not" and "how to treat" had been the major issues in the field of percutaneous coronary intervention (PCI) for bifurcation lesions.

The most important aspect to consider before PCI is the selection of the side branch lesions that cause myocardial ischemia and provide large myocardial territory (at least >10% of ischemic burden). Previous studies have shown that angiographic evaluation is relatively inaccurate and overestimates the functional significance of bifurcation lesions. FFR can be very helpful in the evaluation of the jailed side branch after main vessel stenting. Several studies have consistently shown that the limitations of angiographic % diameter



stenosis in identifying functionally significant jailed side branches can be overcome by FFR interrogation (Figure 3). However, clinical application of FFR in bifurcation lesions requires a comprehensive understanding of coronary physiology and its pitfalls. Finally, it should be kept in mind that the most important thing is the ischemic burden rather than the presence of ischemia itself and the benefit of revascularization over the risk of intervention process. No matter what kind of technology or device is used, unless PCI is targeted for clinically relevant and ischemia causing side branches, PCI will never show better outcomes than that of medical treatment. Therefore, the operators need to ask the following questions to themselves before PCI for each SB. 1) Does this branch has clinical relevance? 2) Does this stenosis cause myocardial ischemia? 3) Can revascularization improve the outcomes of this patient? Don't forget that the patient may suffer a big loss when the operator goes after a small gain.

### **Complex PCI: Left Main and Bifurcation**

» Thursday, April 28, 2:00 PM - 3:40 PM
 » The Latest Update "Presentation Theater", Level 1

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# cardiovascular MD





# **Valve Therapeutics**

### Transcatheter Aortic Valve Im -plantation - Now and the Future: Cardiologist's Perspective



France

Developing TAVI has been a 20-year odyssey of which the starting point took place in the early 1990s with the development of Balloon Aortic Valvuloplasty (BAV) for inoperable patients with severe aortic valve stenosis. The idea of placing

a large-size stent containing a mounted prosthesis within the diseased valve was considered an optimal potential option against the limitation of BAV, the early valve restenosis. In 1994, we confirmed in an autopsy study the efficiency of large size valvular stenting to keep the calcific aortic valve open. Over a 4-year period, the search for a biomedical company interested in the project failed completely. A long list of engineering issues and potential complications was consistently pointed out. The project was even considered 'the most stupid ever heard'!

In 1999, we were able to create and evaluate the first prototypes of balloon expandable transcatheter heart valve in the animal model with a start-up company. Since the first in-human implantation performed by us in Rouen in April 2002, this technique (called TAVI) has been incredibly accepted worldwide. Most of our knowledge is founded on the extensive experience (300,000 patients) acquired with the use of two devices - the balloon expandable Edwards that we developed, and the selfexpanding Medtronic CoreValve, the other device progressing concurrently.

FDA approval was obtained for the Edwards device based on the results of the pivotal "Placement of Aortic Transcatheter Valve (PARTNER) Trial", a randomized US trial published in 2011 and 2012 (for non-surgical patients and high-risk patients, respectively). TAVI was shown to save 25% of lives in nonoperable patients and to compare favourably to surgery in high risk patients. These results have been shown to remain unchanged at 5 years.

The CoreValve US Pivotal Trial has notably shown the superiority of TAVI over surgery on mortality at two years in high risk patients. Expansion of clinical indications and further growth of the procedure can be anticipated. New models of valves have favourably impacted the incidence of the three leading complications (stroke, paravalvular leak [PVL] and vascular complications) particularly in lower risk patients, with significant costeffectiveness. The latest Edwards Sapien 3 valve which requires smaller introducers makes the simpler and safer transfemoral approach available in 90% of the cases, by using a minimalist strategy under local anaesthesia, with very early discharge.

The PARTNER II S3 trial using this new device in more than 1,500 patients has

shown considerable improvement of the complication rate, including PVL which is almost gone and a drop of mortality rate at 1 month to 1.6% and 1.1% in high risk and intermediate risk patients respectively. The new EVOLUT-R Medtronic CoreValve has also demonstrated a significant safety improvement. Other models of TAVI valves are currently under investigation.

The recent PARTNER 2 trial (USA) using the previous generation of Edwards valve, the SAPIEN XT device, demonstrated the non-inferiority of TAVI over surgery in intermediate risk patients. Furthermore, in the USA, the FDA has approved the immediate start of a new randomized trial (PARTNER 3) which aims to compare classical surgery to TAVI (with the SAPIEN 3 valve) in all comers above the age of 65. The results of this trial (non-inferiority of TAVI at one year) might considerably expand the recommendations of TAVI in patients with severe aortic stenosis in the future.

In 2016, TAVI may be recognized as a breakthrough technology with significant and positive socio-medical cultural consequences. TAVI is now entering a new era with remarkable technology enhancements leading to dramatic improvement of outcomes. The impact of TAVI on AS therapy will continue to grow in the next 5 years. TAVI may become the default strategy for the vast majority of AS patients, surgery remaining as an alternative option in suboptimal TAVI indications.

### Management of Young and Lowrisk Patients with Aortic Stenosis: Surgeon's Perspective



University of British

Columbia, Canada

According to the 2006 STS database, the reported perioperative mortality rate with isolated surgical aortic valve replacement (SAVR) in low-risk patients was extremely low: 1.0% for patients younger than 60 years of age and 1.3% for

those between 60 and 70 years of age. The surgical mortality and morbidity is much lower in large cardiac centers. At our center, the 30-day mortality has been <0.1% in patients <60 years of age who underwent isolated SAVR over the past several years. A mortality of >1% will not be acceptable in low-risk and/or young patients.

Considering the above data and the confirmed excellent outcome of SAVR, it is unlikely that TAVI would provide a similar or better outcome than SAVR in this patient population. Furthermore, the TAVI related major complications would be more concerning in the low-risk and/or young patients compared to intermediateand high-risk patients. More importantly, there is no durability data on transcatheter valves in the young patient population. I believe that SAVR should be and will remain the standard treatment for aortic stenosis in low-risk and/or young patients. I want to emphasize that we should be extremely cautious to expand the TAVI indication for low-risk and/or young patients without randomized clinical studies. The long-term effective treatment with SAVR with either mechanical or bioprosthetic valves has been well-established in this population.

One of the arguments to offer TAVI in lowrisk and/or young patients is the feasibility and good short-term outcome of aortic valve-in-valve implants. However, the initial size of implanted surgical valves is a major factor in determining the outcome of subsequent valve-in-valve implants. Recent data has shown that the mid-term outcomes of valve-in-valve implant into small surgical aortic valves (<23 mm) are not acceptable. I don't think TAVI should be offered to the low-risk and/or young patient population, particularly in a situation where a large surgical valve cannot be implanted.

Mechanical valve is still a viable option in young (<50 year old) patients. It has been well-documented that the durability of any bioprosthesis is very poor in the young population and therefore reoperation rate is much higher in patients with bioprostheses compared to those with mechanical valves. Studies have also demonstrated that survival with mechanical valves is superior to survival with bioprostheses in the young population although the rate of anticoagulation related bleeding is higher in patients with mechanical valves. The recent clinical trial on ON-X mechanical valves has demonstrated that anticoagulation with reduced target INR is safe in patients with this mechanical aortic valve, which would reduce bleeding. Considering these factors, I think SAVR with mechanical valves should remain a viable option in very young population

# Valve-in-Valve for Aortic and Mitral Valve

The use of bioprosthetic valve has

increased significantly since the feasibility of transcatheter valve-in-valve (VinV) for the treatment of failed surgical bioprosthetic valves was confirmed in human in 2007. In consideration of reduced durability of surgical bioprosthetic valves in younger patients and the increasing life expectancy of an aging population, this major shift in the use of surgical bioprostheses would result in a significant increase in the incidence surgical valve failure in the future.

The current standard of care for the treatment of failed bioprosthetic valves is redo open-heart surgery. However, redo cardiac surgery is associated with significant morbidity and mortality, particularly in either elderly or high-risk patients. Such patients are often declined, or not referred, for redo aortic or mitral valve replacement. The feasibility and good early outcomes of transcatheter aortic and mitral VinV implantation into failed surgical bioprostheses have been demonstrated by others and us, but the majority of the reported mean duration of follow-up on transcatheter VinV patients was up to 1 year only.

As we are the earliest team in starting the transcatheter aortic and mitral VinV in the world, we now have the longest clinical and echocardiographic follow-up on our transcatheter VinV patients. At our center, a total of 72 patients with aortic (n=42) and mitral (n=31) bioprosthetic valve dysfunction underwent transcatheter VinV implantation with Edwards balloon-expandable transcatheter between April 2007 and December 2013. The median follow-up was 2.52 years with a maximum of 8 years.

The procedure success rate was 98.6%. At 30 days, all-cause mortality was 1.4%, disabling stroke 1.4%, and coronary artery obstruction requiring intervention 1.4%. No patient had greater than mild paravalvular leak. Estimated survival rates were 88.9%, 79.5%, 69.8%, 61.9%, and 40.5% at 1, 2, 3, 4, and 5 years (**Figure 1**), respectively. The small surgical valve size (19 and 21 mm)



Figure 1.

was an independent risk factor for reduced survival in aortic VinV patients. At 2-year follow-up, 82.8% of aortic and 100% of mitral VinV patients were in New York Heart Association functional class I or II. Our date has demonstrated that transcatheter VinV for failed surgical bioprostheses can be performed safely with a high success rate and minimal early mortality and morbidity.

Transcatheter VinV provides encouraging mid-term clinical outcomes in high-risk elderly cohort of patients. Transcatheter VinV is an acceptable alternative therapy for failed aortic or mitral bioprostheses in selected high-risk patients. This study also demonstrated that small surgical valve size (19 and 21 mm) is an independent risk factor for reduced survival in aortic VinV patients. Therefore, it seems reasonable to conclude that surgeons should make every effort to implant surgical aortic bioprostheses of at least 23 to 25 mm, particularly in young patients. At the same time, it is suggested to keep the valve away from the coronary ostia to avoid coronary occlusion with VinV implantation.

Enlargement of aortic annulus and/or aortic root (sinus Valsalva) may be considered to allow future VinV therapy with satisfactory outcomes if necessary to achieve these goals. As an alternative, a more durable mechanical valve may be considered. Since the long-term outcome of the transcatheter VinV implantation remains unknown, a multidisciplinary heart team approach is strongly recommended in patient selection for this transcatheter therapy.

# TAVR in Asia: Data from Asian TAVR Registry



**Sung-Han Yoon, MD** Asan Medical Center, Korea To address the limited data on TAVR in Asian countries, the Asian TAVR Registry has been established. From March 2010 to September 2014, 848 patients from 11 TAVR centers in 5 countries (Hong Kong, Japan, Korea, Singapore and Taiwan) were included. In Asia, TAVR has been utilized for patients with AS estimated as low-, intermediate- and high-risk (mean STS score: 5.2±3.8).

Figure 3.

Overall 30-day, 1- and 2-year mortality rates were 2.5%, 10.8% and 16.7%, respectively. Overall all-cause mortality at 1 year and 2 years were 10.6% and 14.5%, respectively. There were no differences in 1-year mortality (**Figure 2**) and other complications including all-stroke, life-threatening bleeding, AKI (stage 2-3), major vascular complications and safety endpoints between SAPIEN/ XT and CoreValve prosthesis. Despite concerned anatomical features of Asian patients such as small annulus and vascular access, outcomes of TAVR in Asian patients were favorable and comparable to those reported in Western countries.

# Mitral Clip 2016: Indication, Clinical Data and Limitations



Transcatheter-based techniques for the treatment of significant mitral regurgitation (MR) have evolved tremendously in the past decade. Among all catheter-based mitral therapies, the leaflet repair MitraClip system to date has

the largest clinical experience worldwide, having been implanted in over 20,000 patients with established and reproducible safety profile and effective reduction of MR with improvement of symptoms and quality of life in high-risk surgical patients. In the EVEREST II (Endovascular Valve Edge-to-Edge Repair Study) 279 patients were randomized in 2:1 ratio to undergo percutaneous repair with MitraClip (n=184) or conventional MV repair or replacement surgery (n=95).

In the intention-to-treat analysis, the rates of death (6%) were similar for MitraClip and surgery at 1 year. The frequency of 2+ MR was significantly higher after MitraClip, but the proportion of patients with grade 3+ or 4+ MR was not significantly different between the 2 groups at 2 years follow-up (20% percutaneous group vs. 22% surgical group). The combined primary efficacy endpoint of freedom from death, from surgery for mitral valve dysfunction, and from grade 3+ or 4+ MR was 55% in the percutaneous-repair group and 73% in the surgery group (P=0.007). 5-year outcomes of the EVEREST II randomized trial showed persistent LV remodeling with MitraClip after 5 years. Stratified according to MR etiology (degenerative MR or functional MR), there were no differences in freedom from mortality and re-intervention between surgery group and MitraClip group with degenerative MR, as well as with functional MR.

The COAPT (Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for Extremely High-Surgical-Risk Patients) trial is examining the safety and effectiveness of the MitraClip device in high-surgicalrisk patients with MR and heart failure who are randomized to either percutaneous mitral repair or control group with standard medical therapy alone. This trial will not simply test the feasibility of percutaneous repair in patients who are too sick to undergo surgery, but they also represent an important step in understanding whether mitral valve repair offers an advantage at all in patients with failing ventricles.

### **Valve Therapeutics**

- » Thursday, April 28, 3:40 PM 5:20 PM
- » The Latest Update "Presentation Theater", Level 1







Working together with physicians to understand and meet clinical needs for improving patient lives

Booth No: A006

# Satellite Lunch Symposium

April 28 (Thu) | 12:45 - 13:45 | Presentation Theater, Level 1

# New technologies that maximize procedural outcome and long-term benefits

Moderators: *Soo-Teik Lim, Myung-Ho Jeong* Panelists: *Woong-Chol Kang, Soo-Joong Kim* 

<ul> <li>The newest balloon technology for tackling the most challenging CTO cases</li> </ul>	Toshiya Muramatsu
<ul> <li>Can lesion preparation with scoring balloons improve clinical results?</li> </ul>	Jack Wei-Chieh Tan
<ul> <li>EPC Capture Stent: A promising solution amongst the DAPT controversy?</li> </ul>	Roxana Mehran

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# **2016 New Data from Asan Medical Center**

TCTAP2016 DAILYNEWS

This year, four distinguished clinical trials were presented in the session, on the subjects of left main disease, multi-vessel disease, FFR, and CTO. All of these presentations merit attention as the studies dealt with issues of great interest in the field of interventional cardiology.

21st CARDIOVASCULAR SUMMIT

### **Trends in Patient Characteristics, Treatment Strategy, and Outcomes** in Patients with Unprotected Left **Main Coronary Artery Stenosis**



Dr. Pil Hyung Lee began by presenting the results of the multinational, multi-center IRIS-MAIN registry study. He explained that the registry involves consecutive patients with unprotected LMCA disease from

Pil Hyung Lee, MD n Medical Center. Korea

50 academic and community hospitals in Asia. The study used an intended "all-comers" design and the patients were treated with medical therapy, PCI, or CABG. "During the last 2 decades, PCI results have steadily improved, and based on seminal clinical trials that have demonstrated comparable longterm outcomes between CABG and PCI in selected patient subsets, it has achieved recognition as a reasonable alternative to CABG", he said. With this background, the investigators intended to evaluate the changes of patient characteristics, treatment strategies, and associated outcome patterns.

Between January 1995 and December 2013, a total of 5,833 patients with significant LMCA disease were enrolled, of whom 2,351 were referred for CABG, 2,866 underwent PCI, and 616 received medical therapy alone as an initial treatment. Patients were classified according to three historical time periods based on the type of stent used for PCI: wave 1 for 1995-2002; wave 2 for 2003-2006; and wave 3 for 2007-2013. During the 20-year span, deterioration of patient risk profiles and lesion complexities were observed for PCI and CABG. Patient age, prevalence of hypertension, diabetes, hyperlipidemia, and renal insufficiency significantly increased, while left ventricular ejection fraction decreased. Over time, the proportion of patients treated with PCI rather than CABG was observed to substantially increase (25% in wave 1 to 61% in wave 3), whereas the ratio of patients who received medical therapy remained relatively steady. Pharmacotherapy was observed to advance for all three treatment strategies, particularly reflected by the significant increase in the use of antiplatelet agents and statins. Stent techniques were simplified for distal ULMCA lesions with the use of more advanced stent technology. Off-pump CABG was used more frequently over time.

Regarding the clinical outcomes, the adjusted risks for mortality, composite of death, MI or stroke, and MACCE (a composite of death, MI, stroke, or repeat revascularization) continuously decreased by 42%, 40%, and 31% for medical therapy, respectively, and 37%, 35%, and 61% for PCI, respectively, but remained relatively stable for CABG. The adjusted hazard ratios for the long-term risk of MACCE after PCI relative to CABG progressively declined over time: 2.97 (95% confidence interval, 2.12-4.18) in wave 1, 2.14 (1.72-2.65) in wave 2 and 1.50 (1.17-1.92) in wave 3, respectively (Figure 1).

Dr. Lee emphasized that the findings of this large, "all comers" registry study resulted in an identification of a number of important trends in patient characteristics, treatment strategies, and outcomes in patients with unprotected LMCA stenosis over time. He concluded that the changes of our daily

PCI vs. CABG:	Death			PCI vs. CABG: I	Death/MI/Stroke	•	
		HR (95% CI)	Pvalue			HR (95% CI)	P value
WAVE 1		1.26 (0.73-2.18)	0.40	WAVE 1		1.29 (0.81-2.06)	0.28
WAVE 2	-	1.08 (0.82–1.44)	0.58	WAVE 2		1.07 (0.82–1.40)	0.64
WAVE 3	H <b>-</b> 4	0.83 (0.60-1.15)	0.26	WAVE 3	-	0.91 (0.68–1.21)	0.50
0.1	1	10		0.1	1	10	
PCI better		CABG better		PCI better	C/	BG better	
PCI vs. CABG:	Repeat revas	cularization		PCI vs. CABG:	MACCE		
PCI vs. CABG:	Repeat revas	cularization HR (95% CI)	Pvalue	PCI vs. CABG:	MACCE	HR (95% CI)	Pvalue
PCI vs. CABG:	Repeat revas			PCI vs. CABG: WAVE 1	MACCE	HR (95% CI) 2.97 (2.12-4.18)	
	ĺ	HR (95% CI)	<0.001				<0.001
WAVE 1	-	HR (95% CI) 8.00 (4.75–13.49)	<0.001 <0.001	WAVE 1		2.97 (2.12-4.18)	<0.001
WAVE 1 WAVE 2		HR (95% CI) 8.00 (4.75–13.49) 6.57 (4.41–9.80)	<0.001 <0.001	WAVE 1 WAVE 2	)-=-(  -=	2.97 (2.12–4.18) 2.14 (1.72–2.65)	<0.001

Figure 1. Adjusted hazard ratios of outcomes between PCI versus CABG Adjusted hazard ratios are for PCI compared with CABG.



Figure 2. Cumulative incidences of the composite of death, MI, or stroke. From patient-level meta-analysis of BEST, PRECOMBAT, and SYNTAX trial.

practices have moved toward a progressive and appropriate direction to benefit our patients.

### **Coronary Artery Bypass Surgery** Versus Drug-Eluting Stent Im -plantation for Left Main or Multi -vessel Coronary Artery Disease: A **Meta-Analysis of Individual Patient** Data

trials have been published, most of these

trials are not large enough to resolve

uncertainties on the optimal treatment for

these diseases. To provide robust evidence

about the relative merits of CABG and PCI

in the patient population, individual patient

data from BEST, PRECOMBAT, and SYNTAX

The primary outcome was a composite

of all-cause death, MI, or stroke. A total of 3.280 patients were randomized to

CABG (n=1,639) or PCI (n=1,641). During a

median follow-up of 60 months, the rate of

primary outcome was significantly lower

with CABG than with PCI (HR 0.83; 95% CI

0.69-1.00; P=0.046, Figure 2), of which the

difference was mainly driven by reduction

in MI (HR 0.46; 95% CI 0.33-0.64; P<0.001).

The investigators found a significant

interaction between treatment effect

and the type of coronary artery disease,

showing CABG to be superior compared to

PCI in patients with multi-vessel disease,

but not in those with left main disease.

The need for repeat revascularization

was significantly lower in the CABG group



trials were pooled.

Next, Dr. Cheol Whan Lee presented the results of patient-level meta-analysis of 3 randomized clinical trials comparing CABG versus PCI with DES for patients with left main or multivessel coronary artery disease. Although several relevant randomized clinical

compared to the PCI group

Dr. Lee summarized that for patients with left main and multi-vessel disease, CABG reduces long-term rates of the composite of death, MI, or stroke as compared with PCI, the effect particularly pronounced in those with multi-vessel disease.

### Fate of FFR-Guided Deferral Data from IRIS-FFR Registry



Dr. Jung-Min Ahn gave the third presentation regarding the natural history of lesions after measurement of FFR. FFR is proven to safely determine whether a given stenosis requires revascularization or not, and current guidelines recommend

Asan Medical Center.

FFR measurement prior to revascularization unless there is objective evidence of ischemia. However, there have been concerns in applying the results of previous randomized trials in routine clinical practice due to their protocolized characteristics and selective patient enrollment, and also since the dichotomous cut-off value of FFR (0.80) in decision making was validated only in small study compared with non-invasive functional study.

The investigators intended to evaluate natural prognosis of deferred or revascularized coronary stenosis after FFR measurement in routine clinical practice, and to assess the clinical outcome-derived revascularization threshold of FFR in the era of second-generation drug-eluting stent using a large, multi-center IRIS-FFR registry.

Between August 2009 and August 2015, FFR was assessed in 8,633 lesions (5,846 patients), of which 6,468 were deferred and 2,165 were revascularized. The primary end point was the composite of cardiac death, MI, or repeat revascularization (MACE) in relation to a lesion's FFR measurement at baseline, and it was analyzed on per-lesion basis.



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# TCTAP2016 DAILYNEWS

### Continued from page 9

During a median follow-up of 1.9 years, the risk of MACE had significant inverse relationship with FFR (adjusted HR; 1.06 per 0.01 unit decrease in FFR; 95% CI, 1.05-1.08; P<0.001) for deferred lesions, whereas this relationship was not observed in revascularized lesions (adjusted HR, 1.00; 95% CI, 0.99-1.02; P=0.69). For lesions with FFR of ≥0.76, the risk of MACE was not significantly different between deferred and revascularized lesions. Conversely, in lesions with FFR of  $\leq 0.75$ , the risk of MACE was significantly lower in revascularized lesions than in the deferred lesions (for FFR 0.71-0.75. adjusted HR, 0.47; 95% CI. 0.24-0.89; P=0.021, and for FFR ≤0.70, adjusted HR 0.47; 95% CI, 0.26-0.84; P=0.012). They found that the outcome-derived

OF Deferral OF De

Figure 3. Outcome derived revascularization threshold of FFR

 Table 1. Subgroup analysis of clinical outcomes according to the complete revascularization including and excluding chronic total occlusions

# Clinical Outcomes According to the Complete Revascularization (CR)

	CR including CTO	CR excluding CTO	Hazard ratio (95% CI)	P value
Single-vessel disease				
All-cause mortality	27 (8.2)	2 (4,7)	1.57 (0.37-6.60)	0.54
Death or Q-wave MI	31 (9.3)	3 (7.5)	1.20 (0.37-3.93)	0.76
TVR	18 (5.0)	8 (17.9)	0.22 (0.10-0.51)	<0.001
Multivessel disease				
All-cause mortality	22 (9.2)	6 (10.8)	0.82 (0.33–2.01)	0.66
Death or Q-wave MI	.24 (9.9)	6 (10.8)	0.89 (0.37-2.18)	0.80
TVR	6 (2.3)	7 (11.9)	0.18 (0.06-0.53)	0.002
Total	n = 759			
All-cause mortality	49 (8.7)	8 (8.3)	1.00 (0.47–2.11)	1.00
Death or Q-wave MI	55 (9.6)	9 (9.5)	1.00 (0.49-2.02)	0.99
TVR	24 (3.9)	15(14.3)	0.23 (0.12-0.44)	<0.001

revascularization threshold of FFR for MACE was 0.78 based on Cox model (**Figure 3**).

Dr. Ahn concluded that this study confirmed the benefit of revascularization in patients with low FFR and justifies the use of medical treatment in patients with high FFR, in real-world practice.

# Long-Term Clinical Impact of Successful Versus Failed CTO-PCI in Drug-Eluting Stent Era

Lastly, Dr. Seung-Whan Lee presented the result of CTO registry from Asan



Medical Center, which focused on whether a successful CTO-PCI gives survival benefit. There is a long-lasting debate on this subject as the results from previous cohort studies have been inconsistent with regard to the potential survival

Seung-Whan Lee, MD Asan Medical Center, Korea

benefit of a successful CTO-PCI. Since the worldwide rates of CTO-PCI is skyrocketing and the benefit in patient survival has been an important rationale behind performing PCI for CTOs, the investigators evaluated the impact of successful recanalization of native coronary CTOs using contemporary DESs compared with failed CTO-PCI on the long-term clinical outcomes.

From the analysis of 1,173 patients with coronary CTO undergoing PCI (1,004

successful cases), the adjusted risks of all-cause mortality (HR, 1.04; 95% CI, 0.53-2.04, P=0.92) and the composite of death or MI (HR, 1.05; 95% CI, 0.56-1.94, P=0.89) were found to be comparable between patients with successful and failed CTO-PCI, whereas the adjusted risk of TVR (HR, 0.15; 95% CI, 0.10-0.25, P<0.001) and CABG (HR, 0.02; 95% CI, 0.006-0.06, P<0.001) was significantly higher in patients with failed CTO-PCI. Additionally, in patients with multi-vessel disease, for which complete revascularization for non-CTO vessels was per-formed, the long-term survival did not show statistical difference whether or not CTO-PCI succeeded (Table 1).

Dr. Lee concluded that this data at least provides some evidence for the hypothesis that medical therapy alone for CTO may not increase long-term mortality compared with successful CTO-PCI as long as the donor artery for collateral circulation is patent. Importantly, he mentioned that in the future, proper patients are extremely unlikely to be enrolled in observational studies, and the hypothesis should be confirmed through well-designed randomized controlled trials.

### 2016 New Data from Asan Medical Center

» Thursday, April 28, 11:26 AM - 12:22 PM » The Latest Update "Presentation Theater", Level 1

### Yesterday's Highlights

# ACS and Pharmacotherapy -Making the Right Decision

### Multivessel PCI for STEMI: When To Treat the Non-Culprit Stenosis



Multivessel coronary artery disease is found in about 30-50% of patients with STelevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI), and often requires multivessel PCI.

Traditionally, ad-hoc multivessel PCI was not performed at the time of primary PCI in hemodynamically stable patients with STEMI, but it is now recognized as a reasonable therapeutic option in patients with STEMI following release of updated international guidelines. In the session of multivessel PCI for STEMI, Dr. Ellis discussed previous randomized studies and ongoing trials about culpritonly versus ad-hoc multivessel PCI for STEMI patients. Previous guidelines did not recommend ad-hoc multivessel PCI because of safety concerns including increased risks for procedural complications and stent thrombosis. In fact, several observational studies and meta-analyses had showed worse clinical outcomes with multivessel primary PCI.

In recent years, however, 4 clinical trials have been published to support multivessel PCI in STEMI patients: Preventive Angioplasty in Acute Myocardial Infarction (PRAMI), Complete Versus Culprit-Lesion Only Primary PCI (CvLPRIT), Third Danish Study of Optimal Acute Treatment of Patients with ST-segment Elevation Myocardial Infarction (DANAMI 3 PRIMULTI), and Primary Angioplasty in Patients Transferred From General Community Hospitals to Specialized PTCA Units With or Without Emergency Thrombolysis (PRAGUE-13). These trials investigated multivessel PCI at the time of primary PCI or as a staged procedure, demonstrating that the rates of primary endpoint of cardiovascular events were significantly lower in multivessel PCI group compared with culprit-only PCI group. Based on these findings, joint guidelines from the ACCF, the AHA and the SCAI were changed to upgrade PCI in non-infarct arteries from a Class III "harm" to a Class IIb recommendation. However, we have to wait for a more definitive ongoing large COMPLETE trial which is powered to determine whether staged PCI revascularization of non-culprit lesions effectively reduces the incidence of death and myocardial infarction. This 3,900-patient global trial is comparing the effectiveness of complete versus culpritonly revascularization of multivessel disease after primary PCI for STEMI.

Taken together, improvements in adjunctive pharmacology and PCI techniques have

increased the safety of multivessel PCI, which should be considered for patients with tight stenosis in large non-culprit vessels. However, it remains uncertain whether this should be performed simultaneously at the time of primary PCI or in a staged fashion after primary PCI.

# When AF & ACS Collide: Many Regimens, Little Solutions!



One of the most complex problems in coronary intervention is the use of dual antiplatelet therapy (DAPT) after stenting in patients on oral anticoagulation for stroke prevention in atrial fibrillation (AF). Dr. Verheugt discussed these challenging

Freek W.A. Verheugt, MD Onze Lieve Vrouwe Gasthuis (OLVG), Netherlands

issues on the session of when AF and ACS collide. When DAPT is combined with warfarin, bleeding increased two- to threefold in recent studies as well as in a large Danish registry, where especially early bleeding was enhanced. Thus, the search is on to diminish this risk.

There are two randomized studies available in this field. The WOEST trial showed that aspirin can be safely skipped. And in the ISAR-TRIPLE trial 6 weeks of clopidogrel on top of aspirin and warfarin was not inferior to 6 months clopidogrel. The randomized MUSICA-2 study is currently addressing the role of 6 months of triple therapy versus DAPT without warfarin in AF patients with a low stroke risk. Non vitamin-K oral anticoagulants (NOACs) for stroke prevention in AF may be useful in the setting of triple therapy, because they appear safer than warfarin, especially with respect to intracranial hemorrhage.

Specific data on NOACs in combination with antiplatelet agents so far, albeit post hoc and not randomized, come from the RE-LY trial and ARISTOTLE trials with dabigatran and apixaban respectively. Although antiplatelet therapy increased bleeding two- to threefold, the safety advantages of the NOACs over warfarin were maintained. Currently, three prospective trials are running to evaluate the safety and efficacy of a NOAC versus VKA in AF patients undergoing coronary intervention for either stable coronary disease or ACS. In all three there is one arm where aspirin is withheld. Also the prasugrel and ticagrelor are allowed in these studies. Other measures to prevent bleeding may be the liberal use of proton-pump inhibitors and the use of radial access for PCI.

# ACS and Pharmacotherapy - Making the Right Decision

Wednesday, April 27, 4:30 PM - 6:00 PM
 The Latest Update "Presentation Theater", Level 1

# Future Technology in Non-Coronary Interventional Cardiology

# WATCHMAN Device Versus NOAC **Drugs**



12-13

Atrial fibrillation (AF) is the most common arrhythmia and is asso -ciated with a higher risk of embolic stroke. Recent clinical trials have demonstrated a similar or better efficacy and safety of new oral anticoagulants Evanston Hospital, USA (NOAC) compared

to conventional warfarin for patients with AF who are indicated for anticoagulation. However, the discontinuation rate of NOAC and warfarin is relatively high and also there are several clinical contraindications for oral anticoagulation. In such cases, left atrial appendage closure is a good option to prevent systemic embolization or stroke.

According to a meta-analysis, in patients with nonvalvular A-fib, left atrial appendage (LAA) closure decreases the likelihood of hemorrhagic stroke, cardiovascular death, and nonprocedural bleeding at 2 to 3 years of follow-up compared with warfarin therapy. However, closure was linked with more ischemic stroke than warfarin. For the meta-analysis, the researchers looked at 2,406 patients with nonvalvular A-fib who were enrolled in PROTECT AF, PREVAIL, or their respective registries between 2005 and 2014. A total of 1,877 patients were treated with the Watchman device (Boston Scientific) including 1,145 registry patients, and 382 patients from the control arms in both RCTs received warfarin. With regard to the composite efficacy endpoint of stroke, systemic embolism, and cardiovascular death, closure with Watchman met noninferiority criteria vs warfarin among the RCT populations. Event rates per 100 patient-years tended to favor LAA closure, with the exception of ischemic stroke, which was higher in Watchman-treated patients (Figure 1).

Watchman (Boston Scientific) was approved by the US Food and Drug Administration in March 2015 based on the results from the PROTECT AF and PREVAIL trials and their associated registries. A postmarket surveillance study was mandated as a condition of approval, but the real-world data is still limited

# **Balloon Pulmonary Angioplasty** (BPA) for Chronic Thromboembolic Pulmonary Hypertension (CTEP) The prognosis of chro

National Hospital

-nic thromboembolic pulmonary hyper -tension (CTEPH) is reported to be directly correlated with hemodynamic severity. Hence, hemodynamic improvement is essential Hiromi Matsubara, MD for the treatment of Organization Okavama CTFPH

Medical Center, Japan Although pulmonary endarterectomy (PEA) can sufficiently decrease pulmonary arterial pressure, not all patients can undergo PEA due to inaccessibility of the lesions or comorbidities. Medical treatment may be able to improve the patients' condition, however, sufficient improvement of hemodynamics cannot be achieved by medical treatment alone.

In 2012, we reported our initial experience of balloon pulmonary angioplasty (BPA) for the treatment of 68 patients with CTEPH. Although overall outcome of angioplasty was almost comparable to that of PEA, there were remaining problems to be resolved such as the risk of post procedural pulmonary injury and the existence of learning curve in reducing the complication rate.

We have been trying to elucidate the cause of post procedural pulmonary injury and found that most complications were caused by BPA related vascular injury. Some of the vascular injury seems to be related to balloon dilatation itself. Remaining vascular injury seems to be caused by the wire tip and it would be the reason of learning curve. After the refinement of our procedure, vascular injury has been almost eliminated. In the most recent 60 patients, we have never experienced severe pulmonary injury after BPA.

Up to now, we have treated 294 inoperable patients with CTEPH by BPA. There were 7 in-hospital deaths and in-hospital mortality was 2.4%. Improvement of hemodynamics and exercise capacity was obtained in 252 patients who had completed BPA procedures (median 5 procedures). The improvements were maintained at followup after 1.8 years. There were additional 11 deaths during follow up. Currently, 5



First Coast Clinic, USA

> assigned to the Amplatzer PFO Occluder (St. Jude Medical; n=499) compared with guideline-directed medical therapy with one or more antiplatelet medications or warfarin (n=481) in prespecified perprotocol and as-treated analyses, but it

**PFO Closure for Prevention of** 



and efficacy of patent foramen ovale (PFO) closure over medical management for reducing the risk of recurrent cryptogenic stroke. The main RESPECT trial showed superiority of PFO closure in patients

Extended follow-up

results of the RESPECT

trial support the safety

found no significant benefit in the primary intention-to-treat analysis. The new findings provide follow-up of 5.5 years for the PFO occlusion arm and 4.9 years for the medical-therapy arm. In the intentionto-treat population, the relative risk for recurrent cryptogenic stroke was reduced by more than half after PFO closure, according to Kaplan-Meier estimation at the end of follow-up (Figure 2).

Additionally, PFO closure reduced the relative risk of recurrent cryptogenic stroke by 70% when compared with medical therapy (1.5% to 4.3%; P=0.004). One complicating factor of the extended analysis was that 20% of the original patients were no longer aged under 60 years, increasing their susceptibility to noncryptogenic strokes that PFO closure cannot prevent. They concluded that procedure and device safety were bolstered

by no evidence of intra-procedural stroke, device embolization, device thrombosis or erosion during extended follow-up.

### Future Technology in Non-Coronary Interventional Cardiology

» Thursday, April 28, 5:20 PM - 6:15 PM » The Latest Update "Presentation Theater", Level 1

Figure 2. Significant reduction in recurrent cryptogenic stroke

# **Exhibition Event Be the Jack Sparrow** & find TREASURE "Visit Five Exhibition Booths And Get Five Logos" Event Paper The Winners will Put it in Visit 5 Booths **Collect 5 Logos** be given a gift Lucky Draw **EVENT DATE** 10:00AM - 3:00PM Tuesday, 26 / Wednesday, 27 / Thursday, 28 Winner Announcement (3:00PM, During Exhibition Date) 1) Text Message \* Please fill up your PHONE NUMBER on the event paper. 2) Event Screen (Gate A, Exhibition Hall, Level 3) Notification · Event paper provided at the Registration Booth Photo shoot event for winners **Gift Pick up Desk** : Level 3, D2 Hall Lobby, Exhibition Desk (Next to the Registration Booth)

# Left Atrial Appendage Closure vs Warfarin in AF A Patient-Level Meta-Analysis n=2,406



Figure 1. Left atrial appendage closure vs. warfarin in AF

vears survival of the patients with CTEPH treated by BPA is 92%. Therefore, we consider that the safety and efficacy of BPA has been established.

In this presentation, I'd like to talk about the current status of BPA based on our experience in about 300 inoperable patients with CTEPH.

Issam D. Moussa, MD

Cardiovascular

Institute/Jacksonville

# Yesterday's Highlights

# Dr. Barry D. Rutherford Received the 6<sup>th</sup> TCTAP Award 'Master of the Masters'





Dr. Barry D. Rutherford, the Director of Interventional Cardiology Research Program at Saint Luke's Mid America Heart Institute in Kansas City, Missouri, has been awarded the  $6^{th}$  TCTAP Award 'Master of the Masters' held on April 27<sup>th</sup> for his outstanding achievement in the field of interventional cardiology and contribution to the growth of CardioVascular Summit-TCTAP over the years.

TCTAP Award 'Master of the Masters' has been bestowed upon the world-renowned interventional cardiologists who have built undisputed recognition in the field of interventional cardiology and TCTAP since 2011.

Dr. Rutherford, born in Gore, graduated

Otago Medical School Dunedin, New Zealand in 1963. After moving to the U.S., he came to stand out as an educator, extending his teaching career at Mayo Medical School, Mayo Clinic, Rochester, Minnesota. His passion for fostering the young generation has continued on without ceasing and he is currently a Professor of Medicine at University of Missouri in Kansas City, Missouri. He has delivered more than 230 invited lectures across the world so far.

Additionally, he has led the interventional teaching courses at the Mid America Heart Institute in Kansas City with Dr. Geoffrey O. Hartzler and that was the root of current Geoffrey O. Hartzler Interventional Cardiology Symposium. Dr. Spencer B. King who is an old friend of Dr. Rutherford and also the recipient of the 5<sup>th</sup> Master of the Masters Award, described him in the words below. "He has been effective as the leader of one of the most competitive training programs in interventional cardiology. He has exhibited style and grace in training people in interventional cardiology."

Dr. Rutherford surprised the medical society not only with his enthusiasm towards education but also with his performance as an operator. He greatly contributed to the development of techniques for direct balloon angioplasty in acute myocardial infarction and multi-vessel angioplasty. His pioneer spirit came to fruition when he won the TCT 2012 Geoffrey O. Hartzler



Master Clinical Operator Award during the 24<sup>th</sup> annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, which consolidated his power in the field.

Asking a fundamental question to the field of interventional cardiology –*Are we really saving lives in the long term?*-, Dr. Rutherford continues to move forward to enrich interventional cardiology society and leaving an admirable precedent even at this moment.

# TCTAP Award 2016 "Master of the Masters"

» Wednesday, April 27, 9:45 AM – 10:00 AM» Main Arena, Level 3

# TCTAP 2016 Wrap-up Interview: Transcatheter Aortic Valve Replacement

### Moderator: Martin B. Leon

Interviewees: Alain G. Cribier, Eberhard Grube, Susheel Kodali

After the first human report in 2002, transcatheter aortic valve replacement (TAVR) has been incorporated into the treatment strategy for high-risk and inoperable patients with aortic valve stenosis (AS).

The Placement of Aortic Transcatheter Valves (PARTNER) trial showed that mortality at 1 year, 2 years, and 3 years is much the same with TAVR and surgical aortic valve replacement (SAVR) for highrisk patients with aortic stenosis. Recently, the final 5-year results were reported and the reports showed that the final 5-year followup of high risk surgical patients shows equivalent outcomes after TAVR and SAVR. Functional outcomes were also similar and preservation of valve haemodynamics was equivalent in both groups. In CoreValve US trial, TAVR with self-expandable bioprosthesis was associated with improved survival at 1 year when compared to surgery in patients at increased risk for surgery. The two year result of this trial showed that this mortality benefit was sustained at 2 years and significant reduction in major adverse clinical and cerebrovascular events seen at 1 year persisted at 2 years. Based on these results, current American Heart Association / American College of Cardiology guidelines recognize that TAVR is a reasonable alternative approach to SVAR in patients at high surgical risk. Still, SAVR is recommended for patients with low to intermediate surgical risk. Therefore, there are clinical trials comparing TAVR and SVAR in patients with low to moderate risk in progress.

For the treatment of symptomatic severe AS in subjects who are at intermediate risk for aortic valve surgery, PARTNER II trial using balloon expandable bioprosthesis and SURTAVI trial using self-expandable bioprosthesis are in progress. Nordic Aortic Valve Intervention (NOTION) trial compared TAVR and SVAR in lower risk patients, and no significant difference between TAVR and SAVR was found for the composite rate of death from any cause, stroke, or MI after 1

# **PARTNER Trial II** Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients



Figure 1. PARTNER trail II: Transcatheter or surgical aortic-valve replacement in intermediate-risk patients

year. Although TAVR was not superior to SAVR for the primary outcome, the trial showed that TAVR appeared safe and effective in low- and intermediate-risk patients.

The Observational Study of Effectiveness of SAVR-TAVI Procedures for Severe Aortic Stenosis Treatment (OBSERVANT) trial compared clinical outcomes in patients with severe AS and at low to intermediate surgical risk. The results of OBSERVANT trial suggest that SAVR and TAVR have comparable mortality, MACCE, and rates of rehospitalization due to cardiac reasons at 1 year.

With technology advancements, new

generation devices such as SAPIEN 3, Evolut R and Lotus have been introduced. With these new devices, indication of TAVR could be expanded in patients with bicuspid aortic valve or valve in valve. Further study is required to choose the appropriate patients and devices in patients with severe AS and to evaluate the optimal management of TAVR.

### TCTAP 2016 Wrap-up Interview: Transcatheter Aortic Valve Replacement

» Thursday, April 28, 11:00 AM - 11:30 AM

# Is Innovation in Stent Technology Still Possible? Newer DES and BVS

### **Unmet Need for Stent Technology**

14-15

It is becoming increasingly difficult to demonstrate that investigational DES technologies are better than the previous ones, but there is still a universal belief that incremental gains are still achievable with some or remarkable changes of stent platforms. Current metallic stent systems can be meaningfully improved.

However, it is worthwhile to continue focusing on innovations in stent technology. The better stent or scaffold technology should be pursued, but noted the difficulty in proving that newer devices have advantages considering how far adverse event rates have fallen with current-generation DES.

The primary reason for developing newer and better technologies has been due to the concern over the risk of late adverse events occurring 1 year after implantation, such as restenosis and stent thrombosis leading to TLR, particularly in patients with complex lesions or ACS. Compared with the results of DES implantation in all-comers populations, the results in diabetics, patients who require oral anticoagulation, and those with small vessels, multivessel disease, saphenous vein grafts, and renal failure are still suboptimal. Other problems cited with the current systems include deliverability, profile size, polymer hypersensitivity, and also the need for long-term dual antiplatelet therapy.

### **Reducing or Eliminating Polymer; Newer-Generation DES With Abbreviated DAPT Was Better** Than BMS in High Bleeding Risk Patients (HBR)



and extended treatment with antiplatelet therapy may be avoided is by doing away with durable polymer on DES either through gradual degradation after implantation of stents that elute antiproliferative agents

without the use of a polymer (Figure 1).

Theoretically a metallic DES with bioresorbable vs durable polymer would be more biocompatible because there would not be permanent polymer inducing impaired healing or late hypersensitivity. That increase in biocompatibility would lessen the risk of late events and possibly allow for shorter antiplatelet regimens. And, there are several clinical scenarios in which the ability to reduce the potency of antiplatelet therapy or the need for it after stent implantation would be beneficial, especially for patients with high-bleeding risk or patients requiring antiplatelet stopping for active bleeding or urgent surgery.

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Strut and Coating Thickness In Perspective										
	Durable Poly	Durable Polymer Coated Bioabsorbable Polymer Coate					Coated			
	Xience CoCr-EES	Resolute	Biomatrix	Nobori	SYNERGY	BioMime	MiStent	Orsiro		
	Promus PtCr-EES	CoNi-ZES	316L-BES	316L-BES	PtCr-EES	CoCr-SES	CoCr-SES	CoCr-SES		
		$\bigcirc$								
Strut thickness	81µm 0.0032"	89µm 0.0035"	120µm 0.0046"	125µm 0.0047"	74µm 0.0029"	65µm 0.0026"	64µm 0.0025"	61µm 0.0024"		
Polymer	PVDF	BioLINX	PLA	PLA	PLGA	PLLA + PLGA	PLGA	PLLA Probio*		
Distribution / thickness	Conformal 7-8µm / side	Conformal 6µm / side	Abluminal <b>10µ</b> m	Abluminal 20µm	Abluminal 4µm	Conformal 2µ / 2µ	Conformal 5µm / 15µm	Conforma 3.5µm / 7.5µm		

**Contemporary DES Platforms** 

### Figure 1. Contemporary DES platforms

In the past, patients at high bleeding risk have largely been excluded from major trials comparing stent types. As the evidence continues to mount that baremetal stents (BMS) might be the best way for treating patients at high risk for bleeding. BioFreedom represents the latest development in Biosensors' stent technology, featuring an abluminal coating of Biolimus A9™ (BA9™) without the use of a polymer or other carrier (Figure 2). BA9 is a highly lipophilic anti-restenotic drug developed by Biosensors specifically for use with stents. In its First-in-Man ("FIM") study, treatment with BioFreedom demonstrated excellent twelve-month late lumen loss and sustained safety for up to five years, including the absence of definite and/or probable stent thrombosis.

An important clinical trial where BioFreedom is being studied is LEADERS FREE, the world's first prospective, randomised doubleblind clinical trial employing only a onemonth course of dual anti-platelet therapy (DAPT) after the implantation of an active stent. The trial is focused on patients at high risk of bleeding, and has been designed to confirm that BioFreedom is as safe as a bare-metal stent (BMS) in this patient group, while delivering the anti-restenotic benefit of a drug-eluting stent (DES).

\*silicon carbide

The LEADERS FREE trial randomized 2,466 high-risk patients (mean age 75.7 years; 30% women) scheduled to receive PCI to implantation to the BioFreedom DCS (Biosensors International; n=1,239) or the Gazelle BMS (Biosensors International; n=1,227) plus 1 month of DAPT.

In a modified ITT analysis, patients in the DCS arm had a much lower rate of the primary efficacy endpoint (clinicallydriven target lesion revascularization) and safety endpoint (cardiac death, MI, or stent



# **Potential Advantages:**

- ✓ Avoid any possible polymer-related adverse effects
- Rapid drug transfer to vessel wall (98% within one month<sup>2</sup>)
- ✓ Safe to shorten DAPT?



Figure 3. Primary efficacy endpoint and safety endpoint

thrombosis) at 1 year (Figure 3). Additionally, BMS use was associated with higher rates of all secondary efficacy endpoints including any TLR and any revascularization.

Additionally, although researchers only predicted the DCS to prove equally safe as BMS, rates of the primary composite safety endpoint (cardiac death, MI, and definite/ probable stent thrombosis) at 1 year were substantially lower with DCS compared with BMS (9.4% vs. 12.9%; P=0.005 for superiority). Safety was driven by a lower rate of MI in the DCS arm than in BMS (6.1% vs. 8.9%; P=0.01), since stent thrombosis rates were similar in both cohorts (2% vs. 2.2%; P=0.70). Bleeding outcomes, including BARC 3-5 bleeding, were similar in both study groups over 1 year. The LEADERS FREE that target older patients at higher risk are "exactly what we should be doing," he said.

Dr. Philip Urban suggests the use of an algorithm for stent type selection according to the bleeding risk of patients (Figure 4). However, further research is needed to determine whether polymer-free stents are as effective as DES with polymer.



# In Conjunction with Cardiovascular Summit-TCTAP 2016, co-organized by Korea Association of CardioVascular and Pulmonary Rehabilitation (KACVPR)

After the organization of KACVPR (www. kacvpr.com), the annual workshop for specialized cardiopulmonary rehabilitation program has been held during the Cardiovascular Summit-TCTAP meeting. Cardiac rehabilitation is a comprehensive exercise, education, and behavior modification program designed to improve the physical and emotional condition of patients with heart disease. CR is prescribed to control symptoms, improve exercise tolerance, and improve overall quality of life. The primary goal of cardiac rehabilitation is to achieve the patient's optimal physical, psychological, social and vocational functioning through exercise training and lifestyle change. To achieve these goals, a comprehensive understanding of the physiology and practical methods are essential. In the United States (U.S.) and elsewhere around the world, cardiac rehabilitation (CR) is accepted as a component of comprehensive cardiac care. According to

the ACC/AHA evidence classifications, CR usually receives the highest level (Class I and Level of evidence, A). This year, amazing staff from Korea will give lectures on various aspects of CR. In the first session, there will be lectures about the basis of CR. In the second and last session, the lectures will about the latest research and practical approach in CR. We hope to share opinions with many participants who are interested in CR in this workshop.

# 10th Cardiopulmonary Rehabilitation Workshop

» Thursday, April 28, 8:30 AM - 12:00 PM » Room 203, Level 2





www.cvrf.org Program Asan Medical Center Internation Left Main Intensive Course FFR & IVUS Guided PCI **CTO LIVE from the Experts** TAVI LIVE Place\_ **Organizing Directors** atrium (Training Center), 3rd Floor, Seung-Jung Park, MD Cheol Whan Lee, MD East Building, Asan Medical Center, Seoul, Korea **Catheterization Laboratory Activities** 

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



3<sup>rd</sup> generation; Vasodilating β-blocker

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# TCTAP 2016 DAILYNEWS

Continued from page 15

16-17

# Promise of Bio-Resorbable Scaffolds (BRS)



Another way to poten -tially reduce late events is through the use of a fully bioresorbable stent, which performs the drug delivery and support functions of metallic DES within

Aloke V. Finn, MD CVPath Institute, Inc., USA

*cVPath Institute, Inc, USA* the first year and then degrades within 2 years to leave no permanent implant behind. This strategy would solve the problem of a permanent metallic stent left behind, which straightens the vessel, causes compliance mismatch, allows for persistent inflammation, introduces the potential for late strut fractures, and allows for the development of neoatherosclerosis (**Figure 5**). Current BVS achieved successful acute scaffolding of coronary lesions and showed favorable low rates of repeat revascularization and major adverse cardiac events (MACE). Several imaging studies showed beneficial plaque stabilization and sealing. Incomplete endothelialization was observed for DES for several years after implantation. Reactions to a permanent metal implant include reduced neointimal tissue growth and neoatherosclerosis and chronic inflammation risks, all well-known late and very late stent thrombosis. After implantation of BVS, no foreign body remained in the vessel long-term. Thus, late and very late stent thrombosis risks are potentially reduced or eliminated, depending on resorption duration. Due to degradation of stent struts, uncovered stent struts are unlikely to factor in stent thrombosis. Incomplete stent apposition,



Figure 7. ABSORB 1-year meta-analysis



# It is important to fully understand these features when using current BRS

Figure 8. Mechanical and physical properties

as observed with DES after thrombus resolution, is also unlikely (**Figure 6**).



Columbus, San Raffaele

Hospital, Italy

Studies, including ABSORB III, indicate that BRS are noninferior to best-in-class DES in the first year, but a potential advantage for reducing late outcomes—where most interventional cardiologists see the advantage of BRS will not be apparent for several years (**Figure 7**).

However, there are still technical limitations of the current BRS system.

Surrogate endpoints (such as vasomotion, positive remodeling or plaque sealing, etc.) have not so far been enough to convince operators to switch to a device that is more difficult, expensive, and time consuming to implant than a metallic DES. Also, potential obstacles to using BRS include their relatively high profile, limits on deliverability, their thicker struts, and limitations in the ability of radial strength, scaffolding, and expansion (**Figure 8**).

Because BRS are still first generation, there will be greater strides made in this area than in the area of metallic DES with ultrathin struts and bioresorbable polymers. In the future, interventional cardiologists will be using more BRS, although they will have advanced beyond the technologies still in testing today, in addition to a large number of metallic stents that are either polymerfree or contain bioresorbable coatings.

### New DES & BVS

» Thursday, April 28, 8:30 AM - 10:30 AM » The Latest Update "Presentation Theater", Level 1



Problems Encountered with Permanent Polymer Drug-Eluting

Figure 5. Problems encountered with permanent polymer drug-eluting stents



# **Pediatric Structural Heart Disease Symposium**



Damien Kenny, MD

Heart Disease, USA

Congenital & Structural

Rush Center fc

Where Are We with PFO Clo -sure? Long-Term Outcome from Randomized Trials

After a long-time lost at sea, with many false-sightings, we finally may be close to "land" with defining the benefits of transcatheter PFO closure in comparison to medical therapy in preventing recurrent stoke. Islands of hope have come and gone with lessons learned on trial and device design.

However perhaps the most important lesson has been that of the need for patience. After the disappointment of CLOSURE I, it was anticipated that the 980 patients enrolled into RESPECT would provide redemption for a procedure with strong non-randomized evidence to support its preference over long-term medical therapy. Despite the initial data assessment, once the target of 25 primary end-points was reached, suggesting superiority of PFO closure over medical management, the study failed to reach its primary end-point of significant risk reduction of recurrent stroke in the intention-to-treat analysis. However in the extended (10 year) follow-up assessment of the data presented at TCT 2015, those who underwent PFO closure with an Amplatzer PFO occluder (St. Jude Medical) had a 54% relative risk reduction for recurrent cryptogenic stroke vs. those assigned to medical management. Such extended follow-up in older patients was not without consequence. High drop-out rates (>30%) occurred. Also 20% of the cohort aged beyond the original age-cut-off of 60 years, became more susceptible to non-cryptogenic stroke.

However separate evaluation of those under the age of 60 demonstrated a relative risk reduction for all-cause stroke of 52% for the PFO-closure vs control group (P=0.035). In addition, there was a 75% relative risk reduction for cryptogenic stroke for the PFO-closure patients who had atrial septal aneurysm (ASA) or substantial shunts (P=0.007). These data support extensive non-randomized literature: PFO closure has its place in younger patients with cryptogenic stroke particularly with ASA and/or large shunts. Further

randomized trial data are keenly anticipated through the Gore REDUCE trial, evaluating two-year follow-up on 664 patients recruited through 65 international investigational sites, to add weight to the RESPECT data. One can only hope that these data will allow us all to drop anchor on the question of PFO closure and that the data will be interpreted responsibly by implanters if set free in the NEW World of approved PFO closure.

Pediatric Structural Heart Disease Symposium I. PFO & ASD: What's New? » Thursday, April 28, 9:30 AM - 09:42 AM

» Room 105, Level 1

### Percutaneous Pulmonary Valve Replacement: State of the Art

It has been over 15 years since the original description of transcatheter delivery of a valved stent into a 12-yearold boy with significant right-ventricular-to-pulmonaryartery (RV-PA) conduit dysfunction was made. Since then, transcatheter pulmonary valve replacement (tPVR) has evolved into a viable, less invasive alternative to surgical conduit replacement (Figure 1). Although randomized comparisons with surgical implants are lacking, mediumterm outcomes for tPVR are excellent with low morbidity and low valve failure rates particularly following the introduction of pre-stenting of the right ventricular outflow tract (RVOT). More importantly, beneficial effects on right ventricular volumes, left ventricular filling properties, exercise capacity, and electrical remodeling, have been demonstrated. There are ongoing efforts to widen the applicability of this technology, particularly to the significant number of patients with dilated RVOTs, and early experience with a self-expanding valve model has been reported. Challenges exist with this endeavor: namely, customizing a single valve to the wide variability of RVOT morphology





seen throughout the cardiac cycle. Other concerns relating to the cost–effectiveness of tPVR in comparison to surgical valve replacement have been raised, and this issue needs to be addressed before the approach achieves widespread acceptance in developing economies. Ultimately the focus should be directed towards development of a fullyintegrated low-profile system, tissue-engineered for the individual patient thus promoting growth potential and mitigating against valve degeneration, which is vital in the young cohort of congenital heart patients with pulmonary valve dysfunction. Aggressive pursuit of long-term normalization of right ventricular loading conditions must become the driving force in developing this technology.

Pediatric Structural Heart Disease Symposium II. Taped Case & Lecture I – PPVI

» Thursday, April 28, 10:00 AM - 10:12 AM » Room 105, Level 1

# **Endovascular Symposium**

There are still outstanding developments about the technique, devices and scientific evidences about pathophysiolgy about management of peripheral artery disease. So, TCTAP 2016 has prepared awesome lectures about this topic. Come and Feel the heat!! Sweltering heat fills the room, a hot breeze drifts by our face.

# Overcome the Calcified Plaque Using Endo -vascular Therapy



Kazushi Urasawa. MD

okeidai Memoria

Hospital Japan

Kazushi Urasawa, MD, PhD (Cardiovascular Center, Tokeidai Memorial Hospital, Sapporo, Japan) will present about the topic, "Overcome the Calcified Plaque Using Endovascular Therapy". Heavily calcified plaque is one of the major obstacles for endovascular revascularization therapy in patients with peripheral arterial disease. We sometimes experience very difficult situations in which the balloon cannot

cross the lesion because of severe calcification. Two years ago, a CTO crossing device, CROSSER was introduced to the Japanese EVT arena. The Crosser™ Recanalization System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic

total occlusions via atherectomy. The tip of the CROSSER catheter mechanically vibrates against the face of the CTO at 20,000 cycles per second at a stroke depth of approximately 20 microns. This high frequency, low amplitude, longitudinal stroke pulverizes the CTO by mechanical impact, creating a channel through the CTO.

He found that this new device is not only a CTO crossing device but also a very powerful debulking device especially for the severely calcified stenosis and occlusion of peripheral arteries. In order to enhance its debulking capability, we have introduced two unique methods called the CROSSBOW technique and the RAMBO technique. By using these two techniques, we can obtain successful revascularization of severely calcified lesions even in the no-stent zone, such as common femoral artery and popliteal artery without

using stents. In his presentation, he would like to introduce the details, and the Tips and Tricks of CROSSBOW and RAMBO techniques. In addition, great big shot will show their knowledge in theater. We know how much you must look forward to that !!



Figure 1. CROSSER CTO recanalization catheter

Endovascular Symposium Endovascular Session III. Armageddon for Perfection II: Ilio-Femoral Stenosis

» Thursday, April 28, 10:00 AM - 11:00 AM
» Endovascular Theater, Level 1

# Thursday, April 28, 2016

# Turn to Starting Line - Which Stra -tegy for Whom? : CAS vs. CEA vs. **Medical Therapy**



In the carotid station, we are still lindering between safety and efficacy. Even though there is plenty of upcoming evidence, there are concerns about the optimal management in carotid artery stenosis. Robert

Robert Bersin, MD . Swedish Medical Center, USA

Bersin (Medical Director. Endovascular Services, Swedish Medical Center, Seattle, USA) will re-settle the starting point and present 'Turn to Starting Line -Which Strategy for Whom? : CAS vs. CEA vs. Medical Therapy'.

According to the severity of carotid artery, there are higher risk of stroke. As well as stenosis, carotid plaque surface irregularity and plaque charateristics of plaque by Doppler imaging study can also be used to predict the risk of ischemic stroke. If carotid artery narrowing remains asymptomatic (ie, has caused no recent stroke or other neurological symptoms), successful carotid endarterectomy (CEA) reduces stroke incidence for some years. Successful CEA (carotid endarterectomy) for asymptomatic patients younger than 75 years of age reduces the 10-year stroke risk. Half of this reduction is by disabling or fatal strokes. The absolute benefit of revascularization on stroke risk reduction in patients on lipid lowering therapy: 5-years, 3.4% P=0.0005; 10-years, 5.8% P=0.002. Net benefit in future patients will depend on their risks from unoperated carotid lesions (which will be reduced by medication), on future surgical risks (which might differ from those in trials), and on whether life expectancy exceeds 10 years. Currently CREST-2 trial, >70% Asymptomatic Carotid Stenoses with Parallel Randomizations, are actively enrolling subjects and can give some light on our hope. In conclusion, optimal medical management of carotid artery disease includes antiplatelet monotherapy, statins and ACE-1 inhibitors. Symptomatic lesions have a higher incidence of neurologic events over the ensuing 5 years than asymptomatic lesions. Asymptomatic plaques with echolucent cores and/or rapid progression behave like symptomatic lesions and should be treated aggressively. CAS (carotid artery stenting) is superior to endarterectomy in high surgical risk patients (SAPPHIRE), but CAS was found to be inferior to CEA in symptomatic standard risk patients when CAS was performed in Europe (SPACE, EVA-3S and ICSS).

CAS was found to be equivalent to endarterectomy in standard risk patients when CAS was performed by experienced operators in North America (CREST). There is an interaction suggested for age when filter FPDs are used such that the elderly trend to fare better with endarterectomy, and the younger fare better with CAS (SPACE, EVA-3S, ICSS and CREST). Symptomatic status is not a risk predictor of MACE with CAS when proximal protection devices are used. Carotid stenting with the Roadster device may provide an attractive alternative for patients who are not ideal candidates for either CEA or CAS with filter EPDs. Whether revascularization is superior to best medical management in asymptomatic patients is being addressed in the CREST-2 and SPACE-2 trials.

### CAS Should Replace CEA in Pati -ents Eligible for Bypass Surgery with Multilevel Atherosclerosis



Krakow, Poland) will talk about "CAS Should Replace CEA in Patients Eligible for Bypass Surgery with Multilevel Atherosclerosis". Although coronary artery disease

Pitor Odrowaz-Pieniazek

(John Paul II Hospital/

Jagiellonian University,

(defined as a stenosis

of  $\geq$ 50% in one of the

*Pieniazek, MD* John Paul II Hospital/ lagiellonian Elniversity

main coronary artery branches) is found in up to 77% of patients with significant (symptomatic >50% and asymptomatic ≥80%) internal carotid artery (ICA) stenosis, the problem of multivessel coronary artery disease is present in 1.2-7% of patients with severe ICA stenosis. The role of carotid stenosis in the etiology of cardiac surgery associated stroke is unclear, as many authors suggest that the main cause is embolic (material from the aortic plague mobilized during cross-



clamping and cannulation). Extracorporeal circulation, however, has specific features such as: blood pressure drops, low perfusion pressure, the flow is linear apart from pulsatory, and that in combination with severe ICA stenosis can cause hypoperfusion of the brain and ischeamic stroke. Current guidelines recommend carotid revascularization prior to cardiac surgery for neurologically symptomatic patients with 70-99% ICA stenosis. For asymptomatic ICA stenosis, even in severe cases, the role of carotid revascularization is unclear and may be considered only in selected cases. Surgical revascularization techniques, either simultaneous or staged CEA and coronary artery bypass grafting (CABG), have been well known for many years in the treatment of patients with severe carotid and coronary artery disease. These revascularization methods are associated with a high periprocedural event (death, any cerebrovascular accident, myocardial infarction) rate of 11.5% if procedures are simultaneous and 10.2% with staged strategy. In the recent decade, the idea to combine carotid artery stenting (CAS) and CABG has grown. The combined outcome for staged CAS-CABG seems to be a little lower than surgical - 9.4%; some single-center registries have shown an even better outcome for this strategy, the neuroprotection system devices (NPD) were not routinely used. In his experience of 40 cases, who underwent staged CAS and CABG, the periprocedural event rate was even better: 2.5% - one death due to cardiogenic shock, after cardiac surgery, no periprocedural neurological complications were observed. The strategy of simultaneous, hybrid CAS and CABG might be a very promising option. According to the published data, this method is associated with the lowest periprocedural combined event (any/ipsilateral stroke or death) rate of 2.2-4.5%, no MIs were observed. In his experience, since 2010, 51 hybrid CAS+CABG procedures were performed. There were 3 (5.9%) major complications observed - 2 deaths due to multi-organ and heart failure and one myocardial infarction successfully treated with percutaneous coronary intervention, again no serious neurological complications were observed. In our center, which performs > 350 CAS procedures per year, the use of NPD is mandatory. Each CAS procedure is performed according to tailored-CAS strategy: with the selection of the NPD (proximal or distal) and stent (closed, opened-cell or meshstents) to suit the lesion morphology and severity and symptom status of the patient. According to the literature and his single-center experience, CAS performed before cardiac surgery (staged or simultaneous - hybrid) may be a safe and less invasive alternative to surgical strategies for patients with severe, multilevel carotid and coronary atherosclerosis

### Endovascular Symposium Endovascular Session IV. Carotid

» Thursday, April 28, 2:00 PM - 3:00 PM » Endovascular Theater, Level 1





# 21\*\*CARDIOVASCULAR SUMMIT TCTAP2016 DAILYNEWS

Hot Abstract

# Guidewire Assisted Device Placement in Large Atrial Septal Defect with Aortic Rim Deficiency: An Easy and Simple Method

Percutaneous device closure of secundum atrial septal defect (ASD) is the therapy of choice when anatomically appropriate. However, it is sometimes challenging to place a device in large atrial ASD, especially aortic rim deficiency, and several useful equipment or techniques have been developed and reported to securely place a device in such ASD. However, usually these equipment or techniques require additional cost of equipment or femoral vein access.

Yesterday, Dr. Kenji Suda from Kurume University School of Medicine, Japan, introduced a more simple method to place



Kenji Suda, MD Kurume University School of Medicine, Japan a device in such ASD. He presented 3 cases with large secundum ASDs. All ASDs had wide-range aortic rim deficiency and attempts were made to place Amplatzer septal occluders. After placing a long sheath into the left atrium, they intentionally deployed both side discs, then, placed a stiff guidewire, which is used for sizing, into the left upper pulmonary vein through the same long sheath. Keeping a guidewire in position, they pulled back both discs, allowing the discs to align with inter-atrial septum to prevent the discs from prolapsing. They then pulled back the right atrial disc and waist into long sheath with left atrial disc attached on the left side of inter-atrial septum and re-deployed body and right atrial disc to properly place the device (**Figure 1**).

After confirming the secure position of the device, they pulled back the guidewire and finished the procedure. Dr. Kenji Suda said, *"We had failed to place device even with specially made long sheath such as Hausdorf sheath. We could have easily* 







placed devices in all 3 patients with this simple guide wire assistance". He concluded that "Our guide wire assisted device placement does not require additional equipment or placing additional sheath and is an easy and simple method to place a device in large atrial septal defect with aortic rim deficiency".

Pediatric Structural Heart Disease Symposium

>> Thursday, April 28, 4:34 PM - 4:45 PM >> Room 105, Level 1

Hot Case

# Percutaneous Transluminal Angioplasty for Chronic Thromboembolic Pulmonary Hypertension: The First Case in Taiwan



National Ta

Taiwan

University Hospital,

Treatment options of chronic thromboembolic pulmonary hypertension include surgical pulmonary thromboendarterectomy and best medical therapy. Recently, percutaneous pulmonary artery balloon angioplasty has been a less invasive approach that has been showing promise.

Yesterday, Dr. Ching-Way Chen et al. from National Taiwan University Hospital, Taiwan, presented a case of a

patient suffering from chronic thromboembolic pulmonary hypertension. The 51-year-old man had a history of beta thalassemia and splenectomy with baseline hemoglobin of 9.2 g/dL. He developed progressive dyspnea on exertion for one month. Electrocardiography showed sinus tachycardia without ST-T change. Echocardiography showed good LV contractility, enlarged pulmonary trunk and severe pulmonary hypertension with maximal trans-tricuspid pressure gradient (TRPG) of 87.5 mmHg (**Figure 1**). Bilateral pulmonary embolism was confirmed by contrast-enhanced computed tomography.

He received anticoagulation and sildenafil for 6 months. However, symptoms persisted and elevated TRPG was still noted. Thus under the impression of chronic thromboembolic pulmonary hypertension, right heart catheterization revealed pulmonary arterial pressure of 65/23 mmHg and multiple filling defects over bilateral lower lobes with slow blood flow

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(Figure 2). Dr. Ching-Way Chen and his colleagues engaged right pulmonary artery with guiding catheter of Terumo ST 01. Intravascular ultrasound (IVUS) showed mural thrombus and thickening intima (Figure 2) and the vessel size was measured. Percutaneous transluminal angioplasty (PTA) was performed to right lower lung with balloons of Abbott TREK 2.5\*15 mm, Boston Maverick 3\*15 mm and Boston QUANTUM Apex 4.5\*15 mm. Then the left pulmonary artery was engaged with guiding catheter of Boston MP 90. They checked IVUS for vessel size measurement. IVUS showed multiple thrombi. PTA with balloon of Abbott TREK 3.5\*15 mm and Abbott TREK 4.5\*15 mm was performed over infero-posterior branch and basal posterior branch of left pulmonary artery. Final angiography showed

improved distal flow of bilateral pulmonary artery.

Follow-up right heart catheterization showed decreased pulmonary artery pressure. Right pulmonary artery pressure dropped from 65/40/23 mmHg to 33/22/14 mmHg. Dr. Ching-Way Chen said that *"We* here demonstrated a successful case to treat chronic thromboembolic pulmonary hypertension using percutaneous transluminal angioplasty of pulmonary artery. Angiography showed improved pulmonary artery flow and right heart catheterization showed decreased pulmonary artery



Figure 1. Echocardiographic findings of chronic PTE







pressure. Patient's symptoms also improved". He concluded that "Balloon pulmonary artery angioplasty is another promising treatment option to treat patients with chronic thromboembolic pulmonary hypertension".

Moderated Complex Case Competition III

» Wednesday, April 27, 5:10 PM - 5:20 PM » Case Zone III, Level 3

Figure 2. Pulmonary angiogram and IVUS

# Yesterday's Highlights

# **Glorious Best Presenters from Competition Session**

A number of interesting abstracts & cases were submitted from all over the world to TCTAP 2016 this year, and then a few abstracts & cases were selected to be presented in Moderated Oral Competition after being strictly reviewed by the scientific committee. Approximately 100 authors made presentations in Abstract & Case Competition Session and only 15 presenters were selected as the Best Presenters by evaluation. Here is the list of the glorious best presenters.

### **Best Abstract Presenter from Abstract Zone**

- 1-1. Endovascular Intervention: Jong Hyun Choi, MD (Korea)
- 1-2. Endovascular Intervention: Kojiro Miki, MD (Japan)
- 1-3. Other: Wojciech Wojakowski, MD (Poland)
- 2-1. Structural Heart Disease: Wojciech Wojakowski, MD (Poland)
- 2-2. Structural Heart Disease: Hashrul Rashid, MD (Malaysia)
- 2-3. Structural Heart Disease Congenital Heart Disease: Gi-Beom Kim, MD (Korea)

### **Best Case Presenter from Case Zone**

- 1-1. Acute Coronary Syndromes: Liang-Ting Chiang, MD (Taiwan)
- 1-2. Complex PCI: Shih-Wei Meng, MD (Taiwan)
- 1-3. Complex PCI: Wishnu Aditya Widodo, MD (Indonesia)
- 2-1. Complex PCI: **Shingo Hosogi, MD** (Japan)
- 2-2. Complex PCI: Yuzo Akita, MD (Japan)
- 2-3. Complex PCI: Ching-Fen Wu, MD (Taiwan)
- 3-1. Complex PCI: Aaron Wong, MD (Singapore)
- 3-2. Endovascular Intervention: Mu-Yang Hsieh, MD (Taiwan)
- 3-3. Endovascular Intervention: Ching-Way Chen, MD (Taiwan)

# **TCTAP Wrap-up Interview**



TCTAP Wrap-up Interviews are 30-minute moderated interview sessions in an open studio. The purpose of these interviews is to address professional knowledge and experience on selected topics in detail with the world's leading experts in the field of vascular medicine. TCTAP participants are able to watch the interview live during the meeting in designated spots.

### Thursday, April 28

Vulnerable Plaque 8:30 AM - 9:00 AM Moderator: Ik-Kyung Jang Interviewees: Akiko Maehara, Evelyn Regar, Gregg W. Stone

### **Left Main Disease**

9:10 AM - 9:35 AM Moderator: Antonio Colombo Interviewees: Seung-Jung Park, Gregg W. Stone, David Paul Taggart **TAVI** 11:00 AM - 11:30 AM

Moderator: Martin B. Leon Interviewees: Alain G. Cribier, Eberhard Grube, Susheel Kodali

The finished interviews will be broadcast on our websites at www.summit-tctap. com, www.summitmd.com and www. youtube.com/CVRFevents and TCTAP mobile application during and after the meeting.

# www.summit-tctap.com

After meeting you can enjoy not only all the presentation slides presented, but also video clips of Wrap-up Interview, Live demonstration, photos taken and Daily Newspapers distributed during conference via our official website.



# All abstracts and cases presented at TCTAP2016 are published in the online JACC supplement.

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WHEN IT COMES TO **LOWERING LDL-C** FOR PATIENTS WITH HYPERCHOLESTEROLEMIA

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22-23



# The Voices of TCTAP 2016

ASULAR DECEMBENT I am here as an invited faculty for the CTO Live session. I liked the overall conference. One thing I expect for TCTAP conference is increasing the number of CTO live cases. In Japan's case, CTO live session is composed of many more cases over 2 or 3 days. I hope to visit TCTAP 2017, again.

> *Makoto Muto, MD* Director of Saitama Prefectural Cardiology Center, Japan

For me the most interesting topic at this conference would be PCI optimization which is about FFR-OCT. This is my first time at TCTAP conference and I'm most likely to come to the next one.



*Glen Kilpatrick* Marketing Manager of St. Jude Medical, Australia



I'm most interested in CTO. I came last year, so this is my second time at TCTAP conference. I think it's very interesting – new technology, new improvements, and of course, I learn a lot in these sessions. For the next international joint session, it would be nice to have an article appreciating it.

> Ismir Fahri, MD Interventional Cardiologist of RSUD Dr. M. Yunus Benkulu, Indonesia

We liked the updates on the new devices and mitral valve replacement because it's good to know these things to decide which patients are the best candidates and will benefit most from which surgery. It is important we know these things so we can explain to our patients the options that are available.



Maria Delta Canela, MD and Amelita Brillantesm. MD Clinical Cardiologists, Philippines



**Interesting Festival in Korea** 



Beautiful palaces have great value, depicting both the nation's precious tangible and intangible heritage. Combined with state-of-the-art technology and artistic touches, the Royal Culture festival will be held for the first time at the Four Royal Palaces and Jongmyo Shrine. On a beautiful day in May, feel the excitement of spring with an unforgettable experience by joining a program in one of the beautiful palaces.

# Event period : 2016.04.29 - 2016.05.08

# Place : The Four Royal Palaces and Jongmyo Shrine

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- Gyeongbokgung Palace: Gyeongbokgung Station (Seoul Subway Line 3)
- Changdeokgung Palace: Take Bus 100, 102, 104, 90S tour bus or 91S tour bus
- Changgyeonggung Palace: Take Bus 100, 102, 104, 90S tour bus or 91S tour bus
- Deoksugung Palace: City Hall Station (Seoul Subway Line 1 or 2)
- Jongmyo Shrine: Jongno 3 (sam)-ga Station (Seoul Subway Line 1, 3 or 5)
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