28th CARDIOVASCULAR SUMMIT
TCTAP 2023 Daily News

May 6 (Sat) - 9 (Tue), 2023

Seung-Jung Park, MD

Asan Medical Center,
Korea (Republic of)

Welcome

“Inside TCTAP 2023: TCTAP as a Bridge Providing Opportunities to Move Beyond the Horizon”

Extending sincere appreciation to the attendees who have joined our meeting virtually for the past three years, we are heartily welcoming everyone back to the offline meeting of TCTAP 2023. We are looking forward to expanding tremendous networking opportunities as being one of the best platforms for educational exchanges in the field of interventional cardiology.

TCTAP 2023 aims to bring together leading interventional cardiologists worldwide to share expertise and their provoking thoughts on recent research and issues. Through the following highlights of four-day meeting, we hope to provide abundant experience to participants with sufficient time to acquire knowledge.

Live Case Demonstrations from World-leading Centers

Live Case Demonstrations will be broadcasted from nine world-renowned international medical centers. The sessions showcases how the disease is being treated by the operators in real-time and enable audiences to grasp global perspectives of the prevailing issues.

Late-breaking Research from Asan Medical Center & Spotlights on Major Clinical Trials in Asia-Pacific with Expert’s Opinion

In the Late-breaking Clinical Trials session, leading cardiologists from Asan Medical Center and international medical centers in Asia-Pacific share the new data from recent clinical research. The presentations and subsequent debates will be of great educational value.

TCTAP Hot Topics

The Hot Topics program highlights the most up-to-the-minute topics of interventional cardiology in demand. The two-day sessions spotlight on debates for gathering multifaceted perspectives from experts with topics including MedTech Innovation, Antithrombotics, Transcatheter Aortic Valve Replacement, Surgical Aortic Valve Replacement, Left Main, Multi-Vessel, Bifurcation Percutaneous Coronary Intervention (PCI), Mitral & Tricuspid Valve Therapy, Vulnerable Plaque, Imaging & Physiology, Complex PCI, Endovascular Aortic Repair, Thoracic Endovascular Aortic Repair, and Peripheral.

TCTAP Workshops

This one-day course will present lectures and cases by world-renowned experts to address recent issues, share tips & tricks on the latest procedures and develop ideas for the change in concept.

TCTAP Award Ceremonies: the 13th Master of the Masters Award & the 10th Best Young Scientist Award

Sending congratulations once again to our previous masters, Dr. Gregg W. Stone in 2020, Dr. Renu Virmani in 2021, and Dr. Alan C. Yeung in 2022, we proudly present the on-site award ceremony of the 13th Master of the Masters Award. This year’s award will be a promising opportunity to meet the masters face-to-face and enjoy the special lecture.

Moreover, do not miss out on the 10th Best Young Scientist Award as well, to acknowledge mid-level young clinical investigators who will become future leaders of cardiovascular medicine.

Partnership Sessions with International Societies and Meetings

Twelve international societies will be with TCTAP this year to share the excitement. The three-day collaborations seek to provide informative programs with the world’s most comprehensive interventional cardiology societies in connection with TCTAP.

28th TCTAP 2023 Daily News

Program at a glance: Saturday, May 6, 2023

	Valve & Endovascular Theater	Presentation Theater 1	Presentation Theater 2	Abstract Zone	Case Zone	Art Hall
07:00						
07:30						
08:00						
08:30						
09:00						
09:30						
10:00						
10:30	**Workshop** LM & MV & Bifurcation & CTO					
11:00						
11:30		**Partnership session** PCR Tokyo Valve				
12:00						
12:30						
13:00	**Lunchtime Activities**					
13:30	**Workshop** Valve Intervention	**Partnership session** SCAI	**Moderated Abstract Competition**	**Moderated Abstract Competition**	**Moderated Complex Case Competition**	**Partnership session** CIAT
14:00						
14:30		**Partnership session** European Bifurcation Club				
15:00						
15:30	**Workshop** Imaging & Physiology	**Partnership session** TTT				
16:00						
16:30		**Partnership session** HKSTENT				
17:00	**Workshop** Complex PCI					
17:30						
18:00						
18:30						
19:00						
19:30						
20:00						

Partnership Session with International Societies and Meetings

Saturday, May 6

@ Presentation Theater 1, Vista 3, B2

PCR Tokyo Valve @ TCTAP 2023
11:30 AM - 12:30 PM

SCAI @ TCTAP 2023
1:30 PM - 2:30 PM

European Bifurcation Club @ TCTAP 2023
2:30 PM - 3:30 PM

TTT @ TCTAP 2023
3:30 PM - 4:30 PM

HKSTENT @ TCTAP 2023
4:30 PM - 5:30 PM

@ Art Hall, Level 4

CIAT @ TCTAP 2023
1:30 PM - 2:30 PM

Sunday, May 7

@ Main Arena, Walker Hall, Level 1

TCT @ TCTAP 2023
10:50 AM - 12:20 PM

@ Presentation Theater 1, Vista 3, B2

CCT @ TCTAP 2023
1:30 PM - 2:30 PM

Singapore LIVE @ TCTAP 2023
2:30 PM - 3:30 PM

@ Art Hall, Level 4

ISIC @ TCTAP 2023
1:30 PM - 2:30 PM

ICSM @ TCTAP 2023
2:30 PM - 3:30 PM

Monday, May 8

@ Valve & Endovascular Theater, Vista 1, B2

Live Case #10: TAVR and TEER
Collaborated with China Valve
9:50 AM - 11:10 AM

Sunday, May 7, 2023

	Main Arena	Valve & Endovascular Theater	Presentation Theater 1	Presentation Theater 2	Abstract Zone	Case Zone	Art Hall
07:00							
07:30		**Meet the Experts over Breakfast**					**Meet the Experts over Breakfast**
08:00							
08:30	**Live Case** LM						
09:00							
09:30	**Opening & Keynote Lectures**						
10:00							
10:30	**Master of Masters Award**						
11:00							
11:30	**Partnership session** TCT @ TCTAP						
12:00							
12:30							
13:00	**Lunchtime Activities**						**Lunchtime Activities**
13:30	**Live Case** TAVR	**Hot Topic** MedTech Innovation	**Partnership session** CCT	**Moderated Abstract Competition**	**Moderated Abstract Competition**	**Moderated Complex Case Competition**	**Partnership session** ISIC
14:00							
14:30			**Partnership session** Singapore LIVE				**Partnership session** ICSM
15:00		**Hot Topic** Antithrombotics					
15:30	**Live Case** Complex PCI		**Hot Topic** LM & MVD (Concept Changes)				
16:00							
16:30		**Hot Topic** TAVR vs. SAVR	**Hot Topic** LM & MVD (Practice Changes)				
17:00							
17:30		**Hot Topic** New TAVR					
18:00							
18:30							
19:00							
19:30							
20:00							

Monday, May 8, 2023

	Coronary Theater	Valve & Endovascular Theater	Presentation Theater 1	Presentation Theater 2	Abstract Zone	Case Zone	Art Hall
07:00							
07:30	Meet the Experts over Breakfast						
08:00							
08:30	Live Case LM	Live Case TEVAR/EVAR	All About New Data from AMC	Best Clinical Trials from Abstracts	Moderated Abstract Competition	Moderated Complex Case Competition	
09:00				Best Young Scientist Award			
09:30			Late-Breaking Clinical Trials 2023				
10:00	Live Case CTO	Live Case TAVR and TEER		Moderated Abstract Competition			
10:30							
11:00			Future Perspective on Ongoing Trials from AMC				
11:30	Hot Topic Bifurcation	Hot Topic Mitral & Tricuspid		Satellite Symposium			
12:00							
12:30	Lunchtime Activities						Lunchtime Activities
13:00							
13:30	Live Case LM & Bifurcation	Live Case Peripheral	Hot Topic Imaging & Physiology	Moderated Abstract Competition	Moderated Abstract Competition	Moderated Complex Case Competition	
14:00							
14:30							
15:00	Live Case Complex PCI	Live Case TAVR	Hot Topic Complex PCI				
15:30							
16:00							
16:30	Live Case RayFlow	Live Case TEER	Hot Topic EVAR, TEVAR, Peripheral				
17:00							
17:30							
18:00							
18:30	Gala Evening *Invitation only						
19:00							
19:30							
20:00							

Tuesday, May 9, 2023

	Coronary Theater	Valve & Endovascular Theater	Presentation Theater 1	Presentation Theater 2
07:00				
07:30	Meet the Experts over Breakfast			
08:00				
08:30	Live Case CTO	Live Case Tricuspid	Challenging Complex Case Competition	Challenging Complex Case Competition
09:00				
09:30		Live Case TAVR		
10:00	Live Case CTO			
10:30				
11:00	CTO Technique 2023			
11:30				
12:00	Live Case LM			
12:30				
13:00	Lunchtime Activities		Lunchtime Activities	
13:30		26th KCTA Symposium *Korean session		
14:00				
14:30				
15:00				
15:30				
16:00				
16:30		CE Program for Radiologist *Korean session		
17:00				
17:30				
18:00				
18:30				
19:00				
19:30				
20:00				

Hot Debates on TCTAP2023

TCTAP Workshops

Evolution of Valve Intervention (TAVR, Mitral, Tricuspid)

Saturday, May 6, 1:30 PM - 3:10 PM
Valve & Endovascular Theater, Vista 1, B2

TAVR for Younger Patients (Sixties)

- 1:54 PM Interventionist's Perspective (Tullio Palmerini)
- 2:02 PM Surgeon's Perspective (Tsuyoshi Kaneko)

Live Case

Live Case & Lecture #5: CTO

Monday, May 8, 9:50 AM - 11:30 AM
Coronary Theater, Walker Hall, Level 1

Debate I : Proximal LAD CTO with Nice Collaterals

- 10:46 AM To Treat (Dimitrios Karmpaliotis)
- 10:54 AM Not to Treat (Jung-Min Ahn)

Debate II : Antegrade vs. Retrograde

- 11:02 AM Antegrade Wire-Based Approach Works! (Maoto Habara)
- 11:10 AM Early Switch to Retrograde Approach is Needed! (Hsien-Li Kao)

Hot Topics

Left Main & Multi-Vessel (Concept Changes After ISCHEMIA)

Sunday, May 7, 3:30 PM - 4:20 PM
Presentation Theater 1, Vista 3, B2

Great Debate on MVD 2023

- 3:54 PM Medical Therapy is Enough (Sripal Bangalore)
- 4:02 PM Surgery is Still Standard (David Paul Taggart)

Game of Thrones, TAVR vs. SAVR

Sunday, May 7, 4:10 PM - 5 :30 PM
Valve & Endovascular Theater, Vista 1, B2

Game of Thrones 2023, TAVR vs. SAVR

- 5:05 PM TAVR is Better (Eberhard Grube)
- 5:13 PM SAVR is Better (Vinayak Bapat)

General Information

Shuttle Bus

Free shuttle bus will be provided between Grand Walkerhill Hotel and subway stations (Gangbyeon-Line 2, Gwangnaroo-Line 5). Visit the **CVRF Booth** and hotel concierge for more information.

Certificate of Attendance

Certificate of Attendance for TCTAP 2023 will be distributed along with your badge. Please check the back of your badge.

Lounge / E-Science Station

- Lounge: CVRF Booth, Vista Lobby, B2
  Exhibition 1, Grand Hall, B1
- E-Science Station: Vista Lobby, B2F

Registration / Coat and Luggage

- Opening Hours
  May 6, 9:00 AM - 6:00 PM
  May 7, 6:30 AM - 6:00 PM
  May 8, 6:30 AM - 6:00 PM
  May 9, 6:30 AM - 1:00 PM
- Location: Grand Hall Lobby, B1F

Information Desk

If you have any problems or queries, please visit the information desk.

- CVRF Booth, Vista Lobby, B2
- Registration Booth, Grand Lobby, B1

Donghoon Choi, MD

Yonsei University College of Medicine, Korea (Republic of)

“TCTAP has become a meaningful, globally recognized platform of active academic exchange”

Hello, I am Donghoon Choi, serving as the 14th President of the Korean Society of Interventional Cardiology.

I am very glad that TCTAP 2023 is finally back offline for the first time in three years after the COVID-19 pandemic.

Congratulations on the successful opening of TCTAP 2023.

As we will be meeting face-to-face, the programs will provide attendees with the opportunity to review and learn the latest clinical research, and it is my honor to be joining as a faculty member.

Through the years, TCTAP has remained a place for academic activities, providing learning opportunities via live broadcasting, and now has expanded into an international academic conference to promote education and reinforce clinical research activities.

Above all, I believe TCTAP has become a meaningful, globally recognized platform of active academic exchange through well-designed education programs by the world-renowned Korean and international faculties.

I hope that the prestige and history of TCTAP will continue to develop in the future. Lastly, I would like to thank everyone who worked hard for this conference.

Sincerely,
Donghoon Choi,
the President of the Korean Society of Interventional Cardiology

Live Case Transmission from World-Renowned Medical Centers

Sunday, May 7

Asan Medical Center, Korea
- 8:10 AM - 9:30 AM @ Main Arena, Walker Hall, Level 1 / LM PCI
- 1:30 PM - 2:50 PM @ Main Arena, Walker Hall, Level 1 / TAVR
- 3:10 PM - 4:30 PM @ Main Arena, Walker Hall, Level 1 / Complex PCI

Monday, May 8

Asan Medical Center, Korea
- 8:10 AM - 9:30 AM @ Coronary Theater, Walker Hall, Level 1 / LM PCI

Severance Hospital, Korea
- 9:50 AM - 10:30 AM @ Coronary Theater, Walker Hall, Level 1 / CTO

Asan Medical Center, Korea
- 1:30 PM - 2:50 PM @ Coronary Theater, Walker Hall, Level 1 / LM & Bifurcation PCI

Fuwai Hospital, China
- 2:50 PM - 4:10 PM @ Coronary Theater, Walker Hall, Level 1 / Complex PCI

Cardiovascular Center Onze Lieve Vrouwziekenhuis, Belgium
- 4:55 PM - 5:15 PM @ Main Arena, Walker Hall, Level 1 / Live Case Video: Absolute Flow Measurements in the Cathlab

Seoul National University Bundang Hospital, Korea
- 8:10 AM - 9:30 AM @ Valve & Endovascular Theater, Vista 1, B2 / TEVAR/EVAR

The Second Affiliated Hospital of Zhejiang University, China
- 9:50 AM - 10:50 AM @ Valve & Endovascular Theater, Vista 1, B2 / TAVR and TEER

Seoul National University Bundang Hospital, Korea
- 1:30 PM - 2:50 PM @ Valve & Endovascular Theater, Vista 1, B2 / Peripheral Intervention

Seoul National University Hospital, Korea
- 3:10 PM - 4:30 PM @ Valve & Endovascular Theater, Vista 1, B2 / Complex TAVR and Complex PCI

Asan Medical Center, Korea
- 4:30 PM - 5:20 PM @ Valve & Endovascular Theater, Vista 1, B2 / TEER

Tuesday, May 9

Minneapolis Heart Institute, USA
- 8:10 AM - 9:30 AM @ Coronary Theater, Walker Hall, Level 1 / CTO

St. Paul's Hospital, University of British Columbia, Canada
- 8:10 AM - 9:30 AM @ Valve & Endovascular Theater, Vista 1, B2 / Tricuspid

Mie Heart Center, Japan
- 9:30 AM - 10:50 AM @ Coronary Theater, Walker Hall, Level 1 / CTO

Severance Hospital, Korea
- 9:40 AM - 10:20 AM @ Valve & Endovascular Theater, Vista 1, B2 / TAVR

Asan Medical Center, Korea
- 11:30 AM - 12:30 PM @ Coronary Theater, Walker Hall, Level 1 / Final Live from AMC: LM PCI

Opening of TCTAP 2023 & Key Note Lectures

Opening of TCTAP 2023 & Key Note Lectures

Nico Pijls, MD
Catharina Hospital, Netherlands

30 Years History of FFR: From the Concept to Current Status - Legend's Perspective

In the early days of coronary intervention, some pioneers in coronary intervention recognized the value of coronary artery pressure measurement. However, reliable techniques and devices to measure coronary pressure did not accurately exist at that time. With the development of the true pressure wire and hyperemic method, fractional flow reserve (FFR) was introduced in the 1990s. FFR is a fraction of mean distal coronary pressure (Pd) to mean aortic pressure (Pa) at maximal coronary hyperemia.

Today, FFR is used widely in clinical practice. Furthermore, many non-hyperemic methods to measure coronary pressure also have been developed to avoid the inconvenience that occurs during hyperemic stimulation. However, there are clear distinctions between FFR and non-hyperemic indices. FFR is linearly related to maximum achievable blood flow and this linearity is only present under maximum hyperemic circumstances. Clinically, leaving out hyperemia can miss significant stenosis, especially in younger patients with proximal lesions in large coronary arteries.

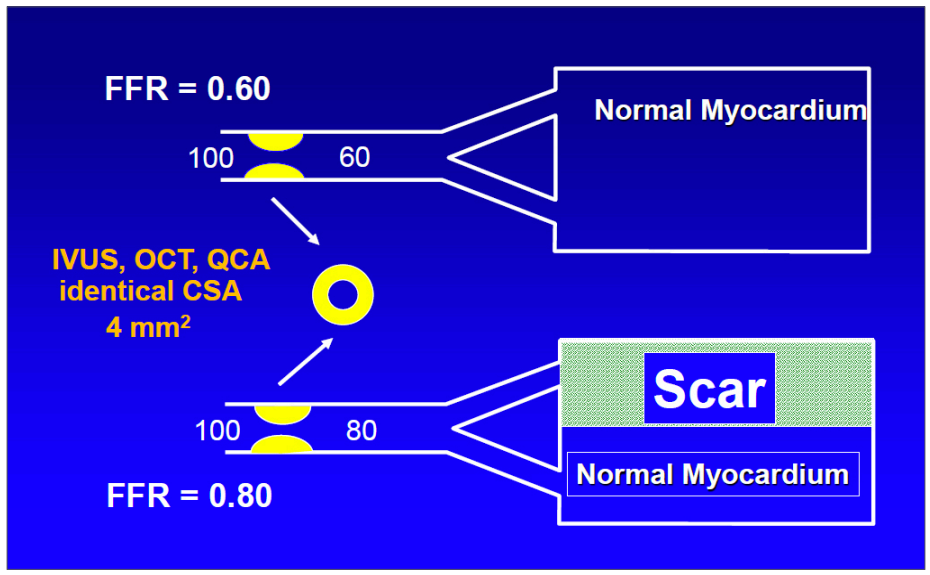


Figure 1. FFR calculated by ratio of mean Pd to mean Pa

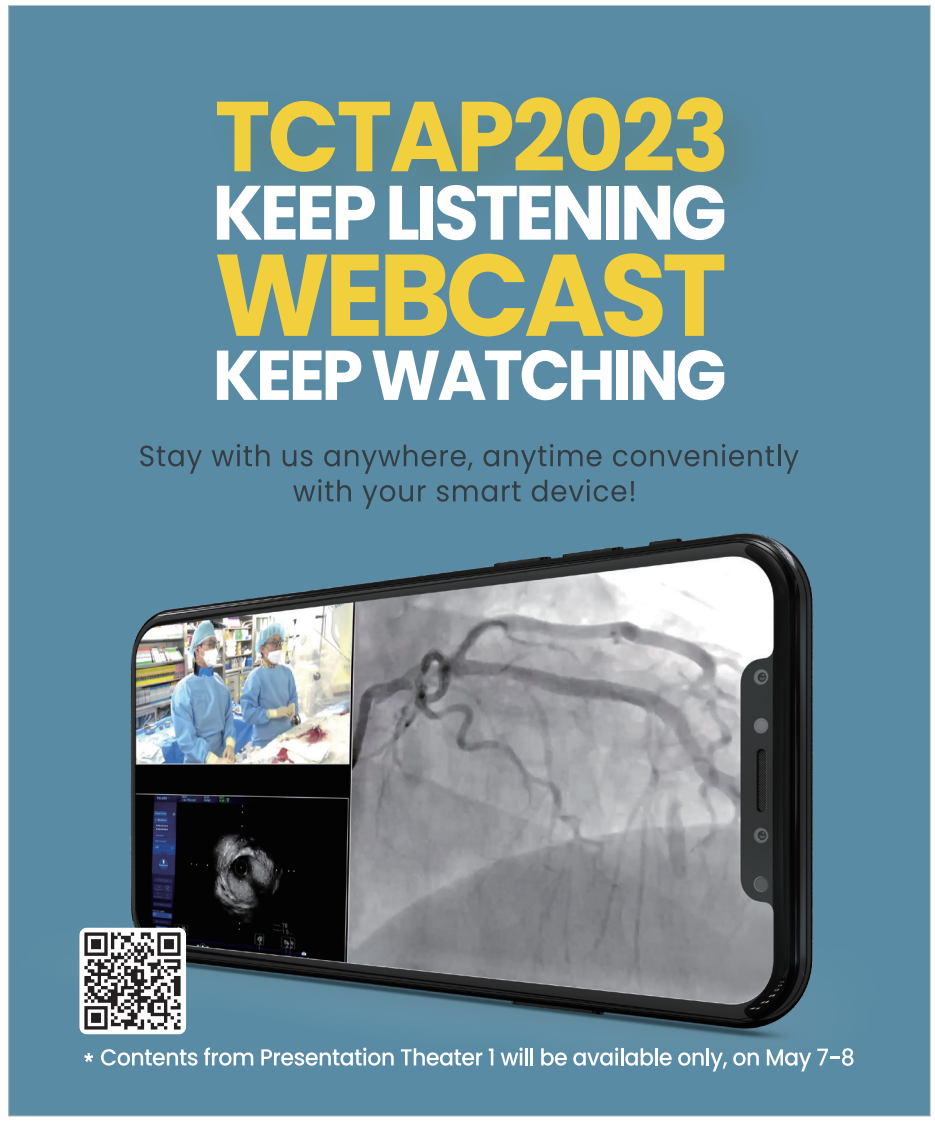
FFR has a sound scientific basis and experimental validation, is accurate, reproducible with an unequivocal normal value and a clear-cut-off with a narrow gray zone, and easy to perform. FFR is the link amid stenosis severity, maximal blood flow, perfusion territory, and myocardial ischemia. FFR can assess the severity of many complex lesions and functional improvement after percutaneous coronary intervention (PCI) (**Figure 1**).

Numerous clinical trials have investigated the role of FFR-guided PCI in comparison with angiography alone, medical treatment, or coronary artery bypass grafting (CABG). For instance, the FAME trial showed lower stent use and lower major adverse cardiac events (MACE) in the FFR-guided PCI group compared to the angio-guided PCI group. The FAME-2 trial showed better clinical outcomes in the FFR-guided PCI group than in the medical therapy group. The FAME-3 trial demonstrated that FFR-guided PCI using current-generation drug-eluting stents (DES) did not meet the criteria for noninferiority compared with CABG among patients with angiographic three-vessel disease.

In conclusion, anatomy alone is insufficient to understand the physiologic significance of coronary artery disease. FFR provides superior insight into coronary pathophysiology and greatly improves the correct diagnosis of coronary artery disease. There is incontrovertible evidence for improved outcomes of coronary disease and revascularization by the systematic use of FFR.

Opening of TCTAP 2023 & Key Note Lectures

›› Sunday, May 07, 9:30 AM - 10:16 AM
›› Main Arena, Walker Hall, Level 1



Clinical Science

Late-Breaking Clinical Trials 2023 in Asia-Pacific

Jung-Min Ahn, MD
Asan Medical Center,
Korea (Republic of)

10-Year Extended Follow-up of BEST Trial

Clinical trials in the era of drug-eluting stents (DES) have shown that percutaneous coronary intervention (PCI) including SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) and FREEDOM (Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease) has a higher risk of repeat revascularization, spontaneous myocardial infarction, and mortality in multivessel coronary artery disease (MVCAD) patients. Previous trials using first-generation DES and little use of intracoronary imaging have limited applicability in contemporary practice. However, the new-generation DES have a lower incidence of cardiac events and mortality than first-generation stents, and intracoronary imaging can optimize the PCI results.

The BEST (Randomized Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients With Multivessel Coronary Artery Disease) trial, which randomly assigned MVCAD

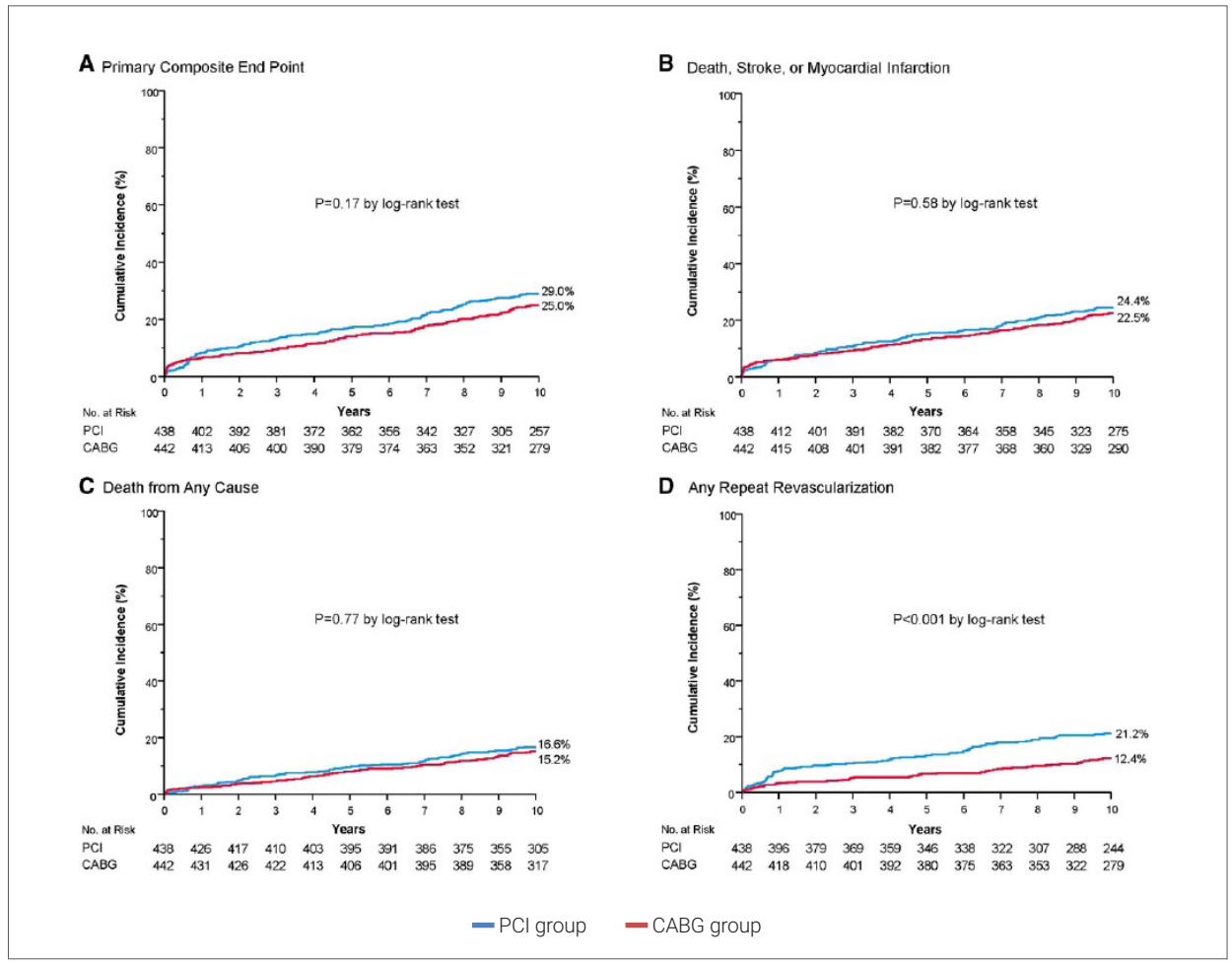


Figure 1. Kaplan-Meier curves for the primary endpoint and the major secondary endpoints

TCTAP Wrap-up Interviews

Here, the most debated issues will be discussed in an interactive way. TCTAP 2023 Wrap-up Interviews are 20-minute moderated interview sessions in an open studio.

The purpose of these interviews is to address professional knowledge and experience on selected topics in details with world's leading experts in the field of cardiovascular medicine. Distinguished experts will provide various aspects of the selected topics and exchange lessons learned through open discussions.

Saturday, May 6

Physiology
4:50 PM - 5:10 PM
- Moderators: Jung-Min Ahn, Nils Johnson
- Interviewees: William F. Fearon, Bon-Kwon Koo, Nico Pijls

CHIP
6:00 PM - 6:20 PM
- Moderators: David Hildick-Smith, Duk-Woo Park
- Interviewees: Sunao Nakamura, Ziad A. Ali, George D. Dangas

Sunday, May 7

Concept Changes After ISCHEMIA Study (LM, MVD, Bifurcation PCI)
4:30 PM - 4:50 PM
- Moderators: Sripal Bangalore, Seung-Jung Park
- Interviewees: Adrian P. Banning, David Paul Taggart, Antonio Colombo

Antithrombotics
5:00 PM - 5:20 PM
- Moderators: Kyung Woo Park, Michael S. Lee
- Interviewees: Joo-Yong Hahn, Tullio Palmerini, Takeshi Kimura

TAVR
5:40 PM - 6:00 PM
- Moderators: Samir R. Kapadia, Duk-Woo Park
- Interviewees: Alain G. Cribier, Eberhard Grube, Vinayak Bapat

Monday, May 8

CTO
11:50 AM - 12:10 PM
- Moderators: Jung-Min Ahn, Dimitrios Karmpaliotis
- Interviewees: Gerald Werner, Hsien-Li Kao, Kambis Mashayekhi

Mitral, Tricuspid Valve Therapy
12:40 PM - 1:00 PM
- Moderators: James Flaherty, Do-Yoon Kang
- Interviewees: Vinayak Bapat, Shih-Hsien Sung, Samir R. Kapadia

Imaging
3:00 PM - 3:20 PM
- Moderators: Jung-Min Ahn, Akiko Maehara
- Interviewees: Gary S. Mintz, Ik-Kyung Jang, Takashi Akasaka

EVAR, TEAVR, Peripheral
5:30 PM - 5:50 PM
- Moderators: Young-Guk Ko, Lawrence A. Garcia
- Interviewees: John Robert Laird, Jr., In-Ho Chae, Aloke V. Finn

patients to undergo either PCI with everolimus-eluting stents or coronary artery bypass grafting (CABG), demonstrated that CABG significantly reduced the composite rate of death, myocardial infarction (MI), or target vessel revascularization. Nevertheless, there was no significant difference in mortality between the two groups. The present study aims to evaluate longer-term outcomes between the two treatments in MVCAD patients who were followed up for up to 13.7 years.

The BEST trial was a prospective, open-label, randomized trial comparing PCI with everolimus-eluting stents and CABG in MVCAD patients and was conducted at 27 international heart centers. The primary endpoint was the incidence of major adverse cardiac events (MACE), such as death from any cause, MI, or target vessel revascularization. The major secondary endpoints are a safety composite of death, MI or stroke, and a composite of death, MI, stroke, or any repeat revascularization.

A total of 880 MVCAD patients were randomized, with 438 receiving PCI with everolimus-eluting stents and 442 undergoing CABG. The median length of follow-up after randomization was 11.8 years (interquartile range, 10.6-12.5 years; the maximum follow-up, 13.7 years) without significant difference between groups. The mean age of the patients was 64.5±9.4 years; 41% had diabetes; and 77% had 3-vessel coronary artery disease. The baseline demographics and clinical, angiographic characteristics of the patients were well-matched between the two groups. The SYNTAX score was 24.4±7.8 and complete revascularization was achieved in 50.9% and 71.5% of the patients in the PCI group and the CABG group, respectively.

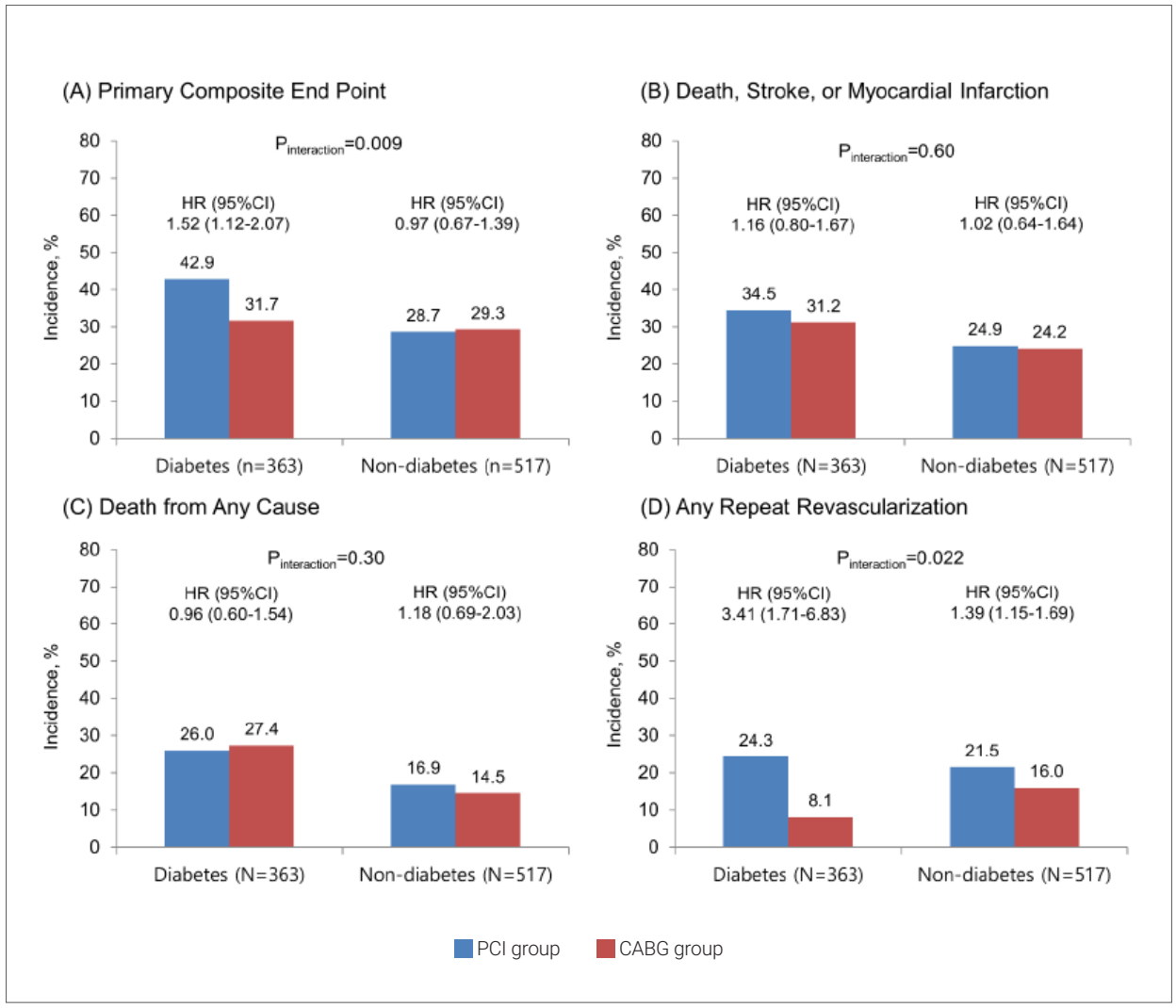


Figure 3. Outcomes according to the type of revascularization and diabetes

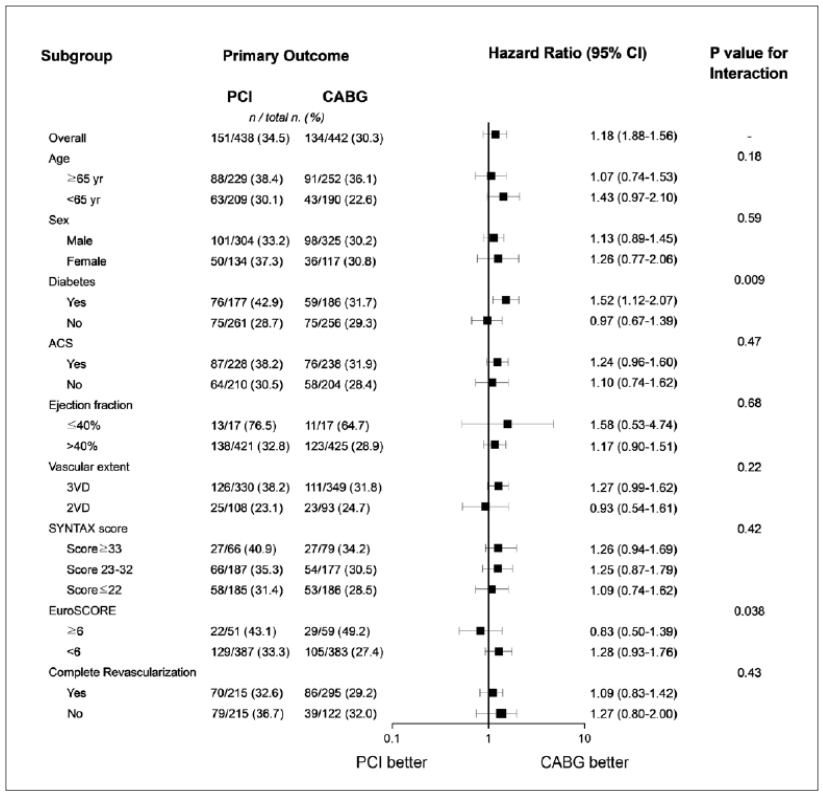


Figure 2. Subgroup analyses of the primary endpoint

The primary endpoint occurred in 151 patients (34.5%) in the PCI group and 134 patients (30.3%) in the CABG group (hazard ratio [HR], 1.18; 95% confidence interval [CI], 0.88-1.56; *P*=0.26) (**Figure 1A**). There was no significant between-group difference in the secondary safety composite endpoint of death, stroke, or MI (28.8% and 27.1%; HR, 1.07; 95% CI, 0.75-1.53; *P*=0.70) and death from any cause (20.5% and 19.9%; HR, 1.04; 95% CI, 0.65-1.67; *P*=0.86) (**Figure 1B** and **1C**). However, the incidence of spontaneous MI (7.1% and 3.8%; HR, 1.86; 95% CI, 1.06-3.27; *P*=0.03) and repeat revascularization (22.6% and 12.7%; HR, 1.92; 95% CI, 1.58-2.32; *P*<0.001) was higher after PCI than after CABG (**Figure 1D**).

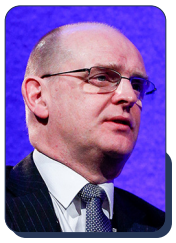
Pre-specified subgroup analyses are presented (**Figure 2**), and a significant interaction between the treatment assignment and diabetes status was expected (*P*=0.009). Among patients with diabetes, PCI significantly increased the risk of the primary endpoint (42.9% and 31.7%; HR, 1.52; 95% CI, 1.12-2.07; *P*=0.007) compared with CABG. In contrast, the primary endpoint did not differ significantly between the two groups in patients without diabetes (28.7% and 29.3%; HR, 0.97; 95% CI, 0.67-1.39; *P*=0.79). Overall mortality was also similar between groups in patients with diabetes (26.0% and 27.4%; HR, 0.96; 95% CI, 0.60-1.54; *P*=0.87) (**Figure 3**).

This study is expected to provide valuable insights into the comparative long-term outcomes of PCI with everolimus-eluting stents and CABG in MVCAD patients.

Clinical Science
Late-Breaking Clinical Trials 2023 in Asia-Pacific
›› Monday, May 08, 9:30 AM - 10:50 AM
›› Presentation Theater 1, Vista 3, B2

Meet the Experts over Breakfast

Acute Coronary Syndrome



Adrian P. Banning, MD

Oxford University Hospitals NHS Foundation Trust, UK

How Can We Improve Reperfusion Therapy in AMI

Revascularization and adjunctive strategies: beyond the ESC guidelines

With all the remarkable advancements in percutaneous coronary intervention (PCI) and adjunctive pharmacotherapy, the mortality following acute myocardial infarction (MI) has declined over the past decades. The management of MI is one of the most impressive successes of evidence-based medicine, effectively decreasing the incidence of cardiovascular mortality from >40% in the early 1950s to <10% today. However, we have reached a plateau in the improvement of clinical outcomes following MI.

Microvascular obstruction (MVO) is a common complication following primary PCI in patients with MI, and it can have significant negative effects on patient outcomes (**Figure 1**). MVO occurs when there is impaired blood flow through the microvessels in the infarct zone, leading to reduced myocardial salvage and increased infarct size, even in patients with successful reperfusion. This is important because the size of the infarct is a predictor of adverse events, such as heart failure and death. An elevated index of microcirculatory resistance (IMR) reflects microvascular function, and when measured after primary PCI, it can predict an adverse clinical outcome (**Figure 2**). Based on previous report, improved perfusion of the myocardium measured by IMR during primary PCI is not universal. Approximately one-third of patients presenting with ST-elevation myocardial infarction (STEMI) still have limited improvement or have worsened perfusion despite stenting. Therefore, the aim of MI treatment would be not only to achieve successful reperfusion of the occluded artery with primary PCI but also to ensure adequate microvascular perfusion in the infarct zone. In addition to standard therapy for MI, different therapeutic interventions have been investigated for improving microvascular perfusion. These interventions include vasodilators, glycoprotein IIb/IIIa inhibitors, and mechanical thrombectomy devices. Besides these, several therapeutic interventions are considered to minimize ischemia-reperfusion injury. Dr. Banning will introduce several novel and exciting therapies that could improve outcomes in primary PCI. These include relatively novel strategies, such as myocardial cooling, left ventricular unloading, supersaturated oxygen (SSO_2), and pressure-controlled intermittent coronary sinus occlusion (PICSO). In this presentation, the PISCO therapy is more focused. The PICSO therapy is designed to reduce reperfusion injury by intermittently occluding the coronary sinus, which drains blood from the heart, and delivering pressure-controlled pulses of saline into the coronary venous system. This creates a retrograde flow that helps to flush out any debris and microthrombi that may have accumulated during the blockage, improving microcirculatory flow and tissue perfusion. Several studies have suggested that PICSO therapy can improve myocardial perfusion and reduce infarct size, which could lead to better clinical outcomes for patients with MI. Trials on these novel strategies are ongoing.

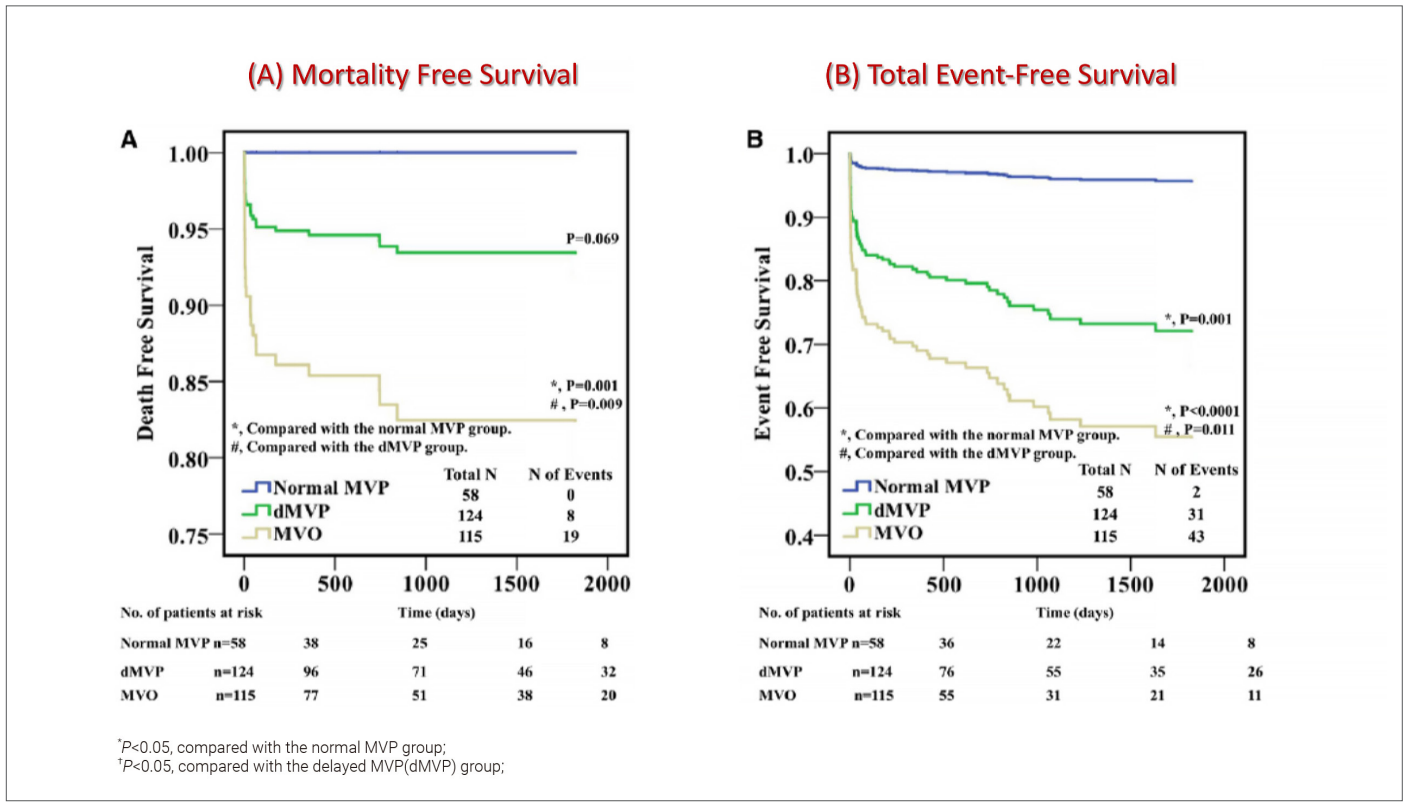


Figure 1. Free survival depending on the existence of MVO

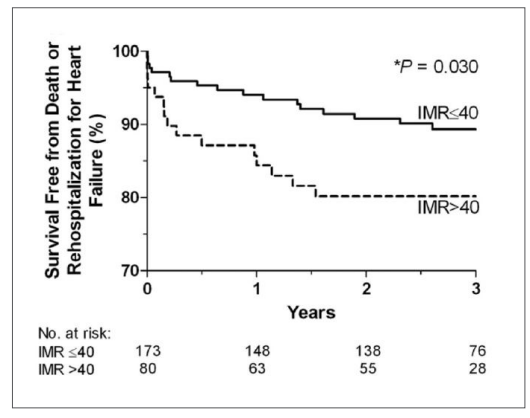


Figure 2. The percent of survival free depending on IMR

Late-Breaking Research from Asan Medical Center & Spotlight on Major Clinical Trials in Asia-Pacific with Expert's Opinion

May 8 @ Presentation Theater 1, Vista 3, B2

All About New Data from AMC
8:10 AM - 9:20 AM

- TP- TAVR Registry
- Racial Differences of Prosthesis-Patient Mismatch After TAVR
- Prognostic Impact of Mildly Impaired Renal Function After Multivessel Revascularization
- Effect of OMT on Long-Term (10-Yr) Outcomes After Myocardial Revascularization
- Key Analysis from POST-PCI
- Early Percutaneous Mitral Commissurotomy or Conventional Management for Asymptomatic Mitral Stenosis
- ADAPT-TAVR Cardiac CT Substudy

Late-Breaking Clinical Trials 2023 in Asia-Pacific
9:30 AM - 10:50 AM

- HOST-EXAM and HOST-EXAM Extended study
- FFR vs. IVUS to Guided-PCI (FLAVOUR Trial)
- RENOVATE-COMPLEX-PCI
- RACING Trial
- POST-PCI Trial
- BEST Trial
- ADAPT-TAVR Trial

Future Perspective on Ongoing Trials from AMC
11:00 AM - 12:20 PM

- OCTIVUS Trial
- TAILRORED-CHIP Trial
- EPIC-CAD Trial
- DEFINE-DM Trial
- PREVENT Trial
- ASSURE-DES Trial
- RENOVATE Trial
- FATE-MAIN Trial

Meet the Experts over Breakfast
Acute Coronary Syndrome

›› Sunday, May 07, 7:00 AM - 8:00 AM
›› Art Hall, Level 4

TCTAP Workshops

LM & Multi-Vessel Diseases and Bifurcation & CTO After ISCHEMIA Study

David Joel Cohen, MD

Cardiovascular Research Foundation, USA

Left Main Revascularization Consensus and Gaps in 2023

For decades, coronary artery bypass grafting (CABG) has been the standard choice of revascularization for significant left main coronary artery (LMCA) disease. However, with remarkable advancements in device technology and adjunctive pharmacology, percutaneous coronary intervention (PCI) offers a more expeditious approach with rapid recovery and is a safe and effective alternative in appropriately selected patients with LMCA disease. Several landmark randomized clinical trials (RCTs) have shown that PCI with drug-eluting stents for LMCA disease is a safe option with similar long-term survival rates to CABG surgery, especially in those with low and intermediate anatomic risk.

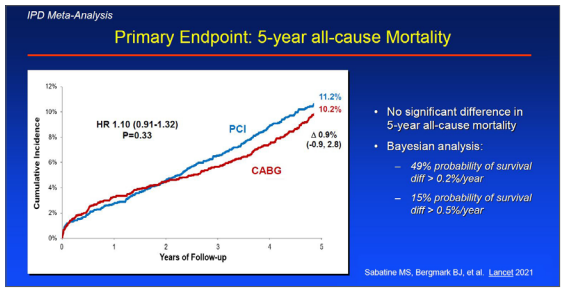


Figure 1. 5-year all-cause death between PCI and CABG in meta-analysis

Should CABG be preferred for most patients?

The most recent individual patient-level meta-analysis incorporating long-term follow-up results from key RCTs (SYNTAX, PRECOMBAT, NOBLE, and EXCEL trials) showed no statistical difference in 5-year all-cause death between PCI and CABG, although a Bayesian approach suggested a difference probably exists favoring CABG (**Figure 1**). Spontaneous myocardial infarction and repeat revascularization were more common with PCI than with CABG. Overall, there was no difference in the risk of stroke between PCI and CABG, but the risk was lower with PCI in the first year after randomization. A Heart Team approach to communicate expected outcome differences might be useful to assist patients in reaching a treatment decision.

Role of mechanical circulatory support

If the Heart Team decides to proceed with PCI as a revascularization method, several technical aspects of the PCI strategy should be considered to optimize PCI outcomes. Left main PCI should be performed as much as possible by experienced operators in catheterization laboratories with intracoronary imaging, invasive coronary physiology, and mechanical circulatory support (MCS). MCS use remained low but increased from 0.2% to 0.6% of high-risk elective PCIs between 2007 and 2017, and unprotected left main PCI was the main high-risk feature associated with prophylactic MCS use. Patients with normal left ventricular function rarely require planned MCS. When the left main anatomy is complex (distal bifurcation lesion, severe calcification requiring atheroablation) and cardiac reserve is limited (ejection fraction <30%, pulmonary capillary wedge pressure >30 mmHg), MCS should be considered for unprotected left main PCI.

1-stent vs. 2-stent strategies

An up-front 2-stent strategy for bifurcation lesions has been deemed inferior to provisional stenting; nevertheless, the optimal stent strategy for LMCA bifurcation lesions remains unknown. The DKCRUSH-V trial demonstrated that PCI for true distal LMCA bifurcation lesions using a planned double-kissing crush 2-stent strategy resulted in a lower rate of target lesion failure at 1 year than the provisional stenting strategy. In contrast, the EBC-MAIN trial demonstrated that the stepwise layered provisional approach was associated with numerically fewer major adverse cardiac events than planned dual stenting. Currently, the initial single-stent crossover and provisional side branch approach is recommended for LMCA bifurcation lesions. However, the choice of strategy should be based on angiographic features, such as vessel size, side branch involvement, lesion length, as well as operator expertise. A more detailed evaluation of the anatomic severity can be obtained by intracoronary imaging, which is essential for pre-interventional lesion assessment and post-interventional stent optimization.

TCTAP Workshops
LM & Multi-Vessel Diseases and Bifurcation & CTO After ISCHEMIA Study
›› Saturday, May 6, 10:30 AM - 12:30 PM
›› Valve & Endovascular Theater, Vista 1, B2

TCTAP 2023 TRAINING CENTER OPEN!

SATURDAY, MAY 6

Session	Place	Time
Basic Understanding and Hands-on of Interventional Devices for Technical Assistants	Training Center 1	2:00 PM ~ 3:00 PM

SUNDAY, MAY 7

Session	Place	Time
J.S.A : Jetstream and Ranger for RARRT	Training Center 1	2:00 PM ~ 3:00 PM
Key Principles to achieve lifetime management : ViV	Training Center 1	3:30 PM ~ 4:30 PM
Asahi Intecc ETOSS & Sion assembly	Training Center 2	3:30 PM ~ 5:30 PM

MONDAY, MAY 8

Session	Place	Time
Experience the Difference with New Perclose ProStyle for TAVI Procedures	Training Center 1	2:00 PM ~ 3:00 PM
School of Rock: Conquer the Calcium	Training Center 2	2:30 PM ~ 3:30 PM
Key Principles to achieve Minimalistic TAVI	Training Center 1	3:30 PM ~ 4:30 PM

ONSITE REGISTRATION

Location — At Company Booth for Each Session

Running Hour
May 6(Sat), 2023. 2:00 PM ~ 3:00 PM
May 7(Sun), 2023. 2:00 PM ~ 5:30 PM
May 8(Mon), 2023. 2:00 PM ~ 4:30 PM

THE OPENING OF TCTAP 2023

COME AND JOIN

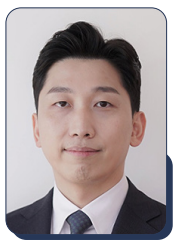
9:30 AM, May 7 (Sunday)

Main Arena, Walker Hall, Level 1
@ GRAND WALKERHILL SEOUL

The organizing committee is offering attendees the most cordial of welcomes to the TCTAP 2023. Join the special opening ceremony and find out what we have prepared for this year!

Clinical Science

Future Perspective on Ongoing Trials from AMC



Do-Yoon Kang, MD
Asan Medical Center,
Korea (Republic of)

OCTIVUS Trial

The clinical value of intracoronary imaging for percutaneous coronary intervention (PCI) guidance is widely acknowledged. Although optical coherence tomography (OCT) and intravascular ultrasound (IVUS) are the most commonly used intravascular imaging methods for guiding and optimizing PCI in daily clinical practice, there are limited data on head-to-head comparison between OCT-guided and IVUS-guided PCI concerning clinical endpoints. Prior studies (ILUMIEN-3, OPINION, etc.) which compared the two imaging modalities might have been hampered by the use of surrogate imaging endpoints, limited patient numbers, and strict inclusion criteria including relatively simple lesions. Future clinical trials should focus on a large, unselected patient population that is more representative of routine clinical practice.

The OCTIVUS trial is an investigator-initiated, multicenter, open-label, pragmatic randomized controlled trial comparing the efficacy and safety of OCT-guided versus IVUS-guided PCI strategies in an all-comers population with minimal exclusion criteria (**Figure 1**). Due to the lack of stringent exclusion criteria, a large proportion of patients with acute coronary syndrome, multivessel disease, or complex lesions, such as left main, bifurcation, long, or restenotic lesions, the patients who represented those undergoing PCI in contemporary clinical practice, could be enrolled in this trial. PCI optimization criteria are predefined using a common algorithm for online OCT or IVUS. The primary endpoint was target-vessel failure (cardiac death, target-vessel myocardial infarction, or ischemia-driven target-vessel revascularization) at 1 year, which was tested for both noninferiority and superiority.

From April 2018 through January 2022, a total of 2,000 patients were enrolled. This year, the primary results will be available. It is anticipated to provide valuable clinical evidence regarding the comparative efficacy and safety of OCT-guided versus IVUS-guided PCI strategies in a broad population of patients undergoing PCI.

Seung-Jung Park, MD
Asan Medical Center,
Korea (Republic of)

PREVENT Trial

Acute coronary syndrome is commonly caused by the rupture of vulnerable plaque, which often has a mild angiographic appearance. Although systemic pharmacologic management is considered a standard therapy for stabilizing vulnerable plaque, the role of the local treatment to prevent plaque rupture has not yet been determined and has only been tested in small trials. The PREVENT trial is designed to compare the effectiveness of preventive percutaneous coronary intervention (PCI) plus optimal medical therapy (OMT) to OMT alone in patients with functionally insignificant, high-risk vulnerable plaques.

The PREVENT trial is a multinational, multicenter, prospective, open-label, active-treatment-controlled randomized clinical trial (**Figure 2**). Patients with at least one angiographically significant stenosis (diameter stenosis >50%) without functional significance (fractional flow reserve [FFR] >0.80) and vulnerable plaque characteristics in intracoronary imaging are eligible for enrollment. Target lesions should have at least two of four intracoronary imaging criteria for vulnerable plaque; (1) minimal lumen area (MLA) <4.0 mm^2; (2) plaque burden >70%; (3) maximal lipid core burden index (LCBI) in a 4 mm segment >315 by near-infrared spectroscopy (NIRS); and (4) thin cap fibroatheroma (TCFA) as determined by optical coherent tomography (OCT) or virtual histology (VH).

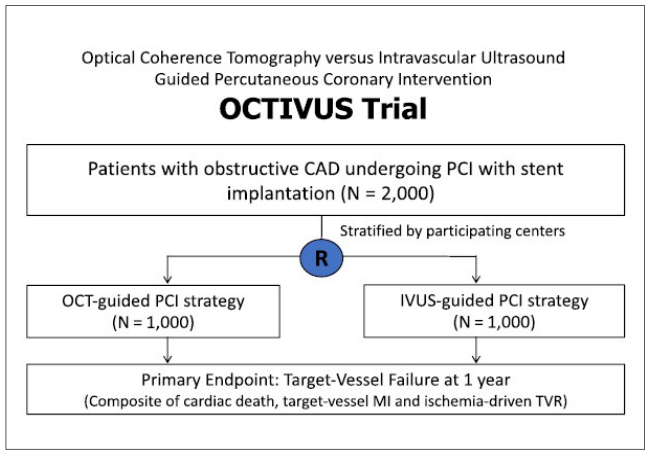


Figure 1. The study design of the OCTIVUS trial

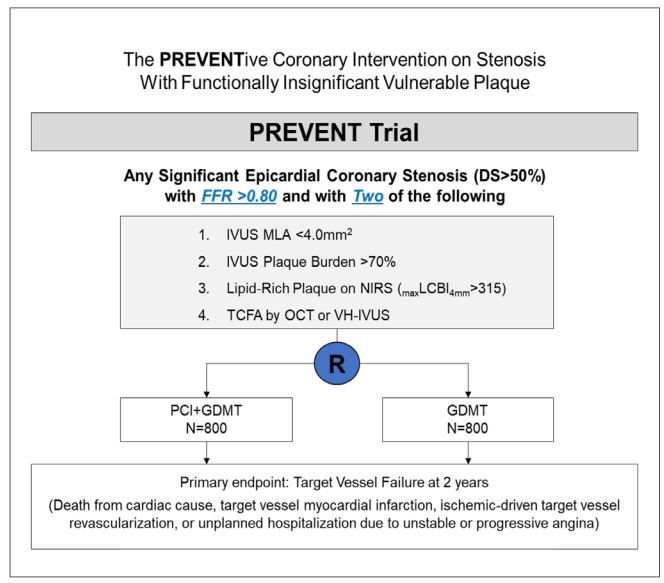


Figure 2. The study design of the PREVENT trial

Enrolled patients were randomly assigned in a 1:1 ratio to either a preventive PCI on vulnerable plaque using bioabsorbable vascular scaffolds or metallic everolimus-eluting stents plus OMT or OMT alone. The primary endpoint is a target-vessel failure, defined as a composite of death from cardiac causes, target-vessel myocardial infarction, ischemic-driven target-vessel revascularization, and hospitalization for unstable or progressive angina at 2 years.

Enrollment of a total of 1,608 patients has been completed. Follow-up of the last enrolled patient will be completed in September 2023 and primary results will be available by early 2024. The PREVENT trial is the first, a large-scale randomized trial with adequate power for clinical outcomes to evaluate the effect of preventive PCI on non-flow-limiting vulnerable plaque with high-risk features. The results of this trial will provide compelling evidence to determine whether preventive PCI of focal vulnerable plaques on top of OMT improves patient outcomes compared to OMT alone.

Clinical Science
Future Perspective on Ongoing Trials from AMC
›› Monday, May 08, 11:00 AM - 12:20 PM
›› Presentation Theater 1, Vista 3, B2

Meet the Experts over Breakfast

All Bifurcation PCI

Andrejs Erglis, MD
Pauls Stradins Clinical University Hospital, Latvia

Upfront 2-Stent; New Concept in LM Bifurcation PCI

The popularity of percutaneous coronary intervention (PCI) for the treatment of unprotected left main (ULM) lesions has increased in the past few years due to the advances in stent technologies and adjunctive pharmacotherapies. However, PCI of complex bifurcation lesions is still challenging in the drug-eluting stent (DES) era, and the results are worse compared with the simple coronary lesions.

Although the provisional stent (PS) strategy is generally considered as the default strategy for bifurcation lesions, there are scenarios in which the two-stent strategy is initially necessary to improve the patency of both the main branch and the side branch. Unfortunately, the high occurrence of in-stent restenosis (ISR) of the left circumflex artery (LCx) ostium is a major limitation of the 2-stent strategy for ULM lesion, with a recent study reporting that an ISR rate of 25.4% with this strategy (majority in the LCx ostium) versus a rate of 6.3% with a PS strategy.

Bioresorbable vascular scaffolds (BVS) has the unique ability to restore vascular physiology and anatomical integrity, such as native tortuosity and angulation, with only a temporary scaffold necessary to maintain the patency of the vessel after the intervention. Studies have shown a complete resorption of scaffold struts at five-years. Therefore, it may provide a novel way to treat ULM distal bifurcation lesions, that would benefit from a two-stent strategy at the time of intervention but leave nothing behind to preclude later surgical revascularization or noninvasive imaging.

The study aimed to investigate the long-term outcomes of a two-stent strategy in patients with LM bifurcation lesions involving the ostium of the LCx artery, utilizing a DES in the LM extending into the left anterior descending artery (LAD) and a BVS in the LCx ostium (**Figure 1**). The primary outcome at four-years was the composite of deaths, myocardial infarction, stroke, and target lesion revascularization (TLR).

At four-years, the primary outcome was identified in nine patients (19.6%) (**Figure 2**). All events were TLRs except one myocardial infarction due to BVS thrombosis. Seven of the eight TLRs were a result of side branch BVS restenosis. Univariate predictors of the four-year outcome were higher LDL cholesterol and BVS size ≤2.5 mm. On multivariate analysis, LCx lesion preparation with a cutting balloon and post-procedure use of intravascular ultrasound for optimization was found to be independent protective factors of major adverse cardiovascular events (MACE).

In selected patients with LM distal bifurcation disease, an imaging-guided two-stent strategy with DES in the LM and BVS in the LCx ostium was technically successful in all patients and was reasonably safe and effective for four years.

Methods

- A single-center, prospective, single-arm study of 46 consecutively enrolled patients with stable coronary artery disease and significant unprotected LM distal bifurcation disease.
- The primary outcome at four years was the composite of death, myocardial infarction, stroke, and target lesion revascularization (TLR).
- Main inclusion criteria:
  - Patients age >18 years with stable coronary artery disease
  - True left main bifurcation lesions
  - Planned 2-stent strategy
- Main exclusion criteria:
  - Acute myocardial infarction
  - Anaemia (Hb<9 g/dl)
  - Suspected intolerance to 1 of the study drugs

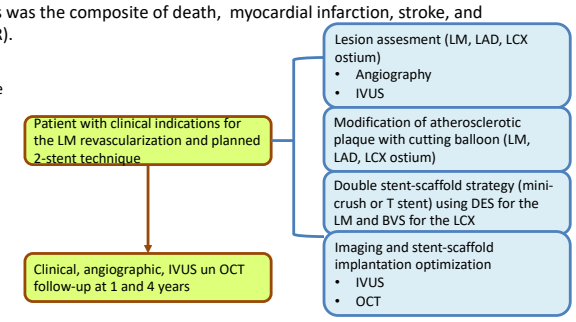


Figure 1. Methods of study

Major adverse cardiac events (4 year)

- Mean follow-up at 4 year: 4.1 years ± 4.2 months
- Angiographic 33 (71.7%), by phone 13 (28.3%)

Cumulative events at 4 years	All patients (n=46)
Death, n (%)	0 (0.0)
Cardiovascular death, n (%)	0 (0.0)
Myocardial infarction, n (%)	1 (2.2)
Stroke, n (%)	0 (0.0)
Target lesion revascularization, n (%)	9 (19.6)
LM-LAD DES restenosis	1 (2.2)
LCX BVS restenosis	7 (15.2)
LCX BVS stent thrombosis	1 (2.2)
Stent thrombosis	1 (2.2)
MACE (death, myocardial infarction, stroke, TLR)	9 (19.6)

Survival free from MACE

Figure 2. Four-year clinical outcomes of 2-stent strategy in LM bifurcation PCI

Meet the Experts over Breakfast
All Bifurcation PCI
›› Monday, May 08, 7:00 AM - 7:50 AM
›› Presentation Theater 1, Vista 3, B2

Clinical Science

Late-Breaking Clinical Trials 2023 in Asia-Pacific

Duk-Woo Park, MD
Asan Medical Center, Korea (Republic of)

Published in NEJM

Routine Functional Testing or Standard Care in High-Risk Patients after PCI

Lack of Evidence for Routine Functional Testing after PCI

The effectiveness of regular stress functional testing after percutaneous coronary intervention (PCI) in improving clinical outcomes is uncertain. The 2019 European guidelines recommend non-invasive stress testing 6 months after high-risk PCI and coronary angiography 3-12 months later, and non-invasive stress testing 1 year after general PCI. However, the recommendations are weak (Class IIB recommendation, Level of evidence C), relying on expert opinions, and the 2021 ACC/AHA guidelines do not mention them.

POST-PCI Trial: Routine Functional Testing vs. Standard Care after High-Risk PCI

From November 2017 to September 2019, the POST-PCI investigators randomly assigned 1,706 patients with high-risk anatomical or clinical characteristics who had undergone PCI to a follow-up strategy of routine functional testing (nuclear stress testing, exercise electrocardiography, or stress echocardiography) at 1 year after PCI (849 patients), or to standard care alone (857 patients).

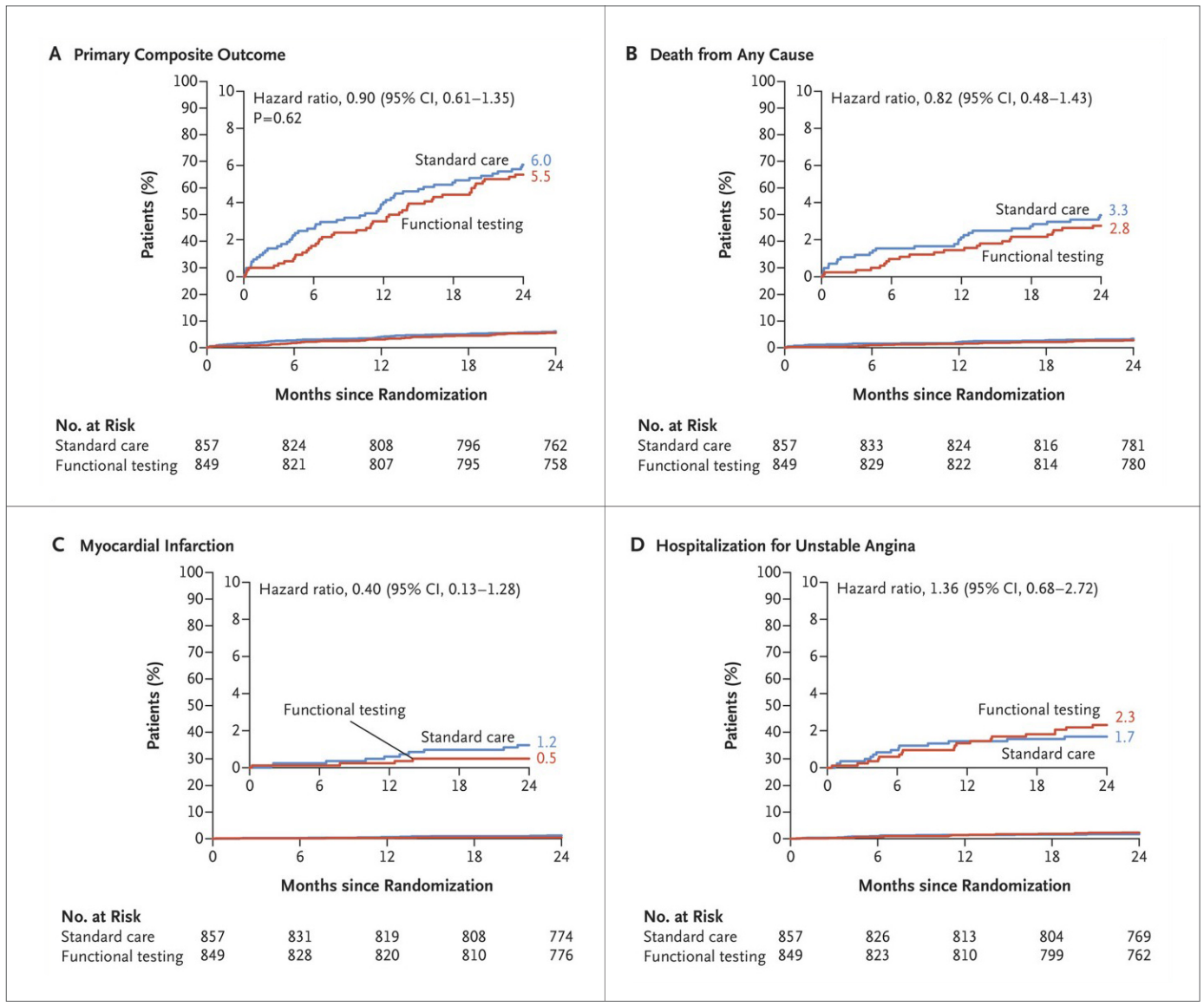


Figure 1. Time-to-event curves for the primary composite outcome and the components of the primary composite outcome

The primary outcome was a composite of death from any cause, myocardial infarction (MI), or hospitalization for unstable angina at 2 years.

The mean age of the patients was 64.7 years, 21.0% had left main disease, 43.5% had bifurcation disease, 69.8% had multivessel disease, 70.1% had diffuse long

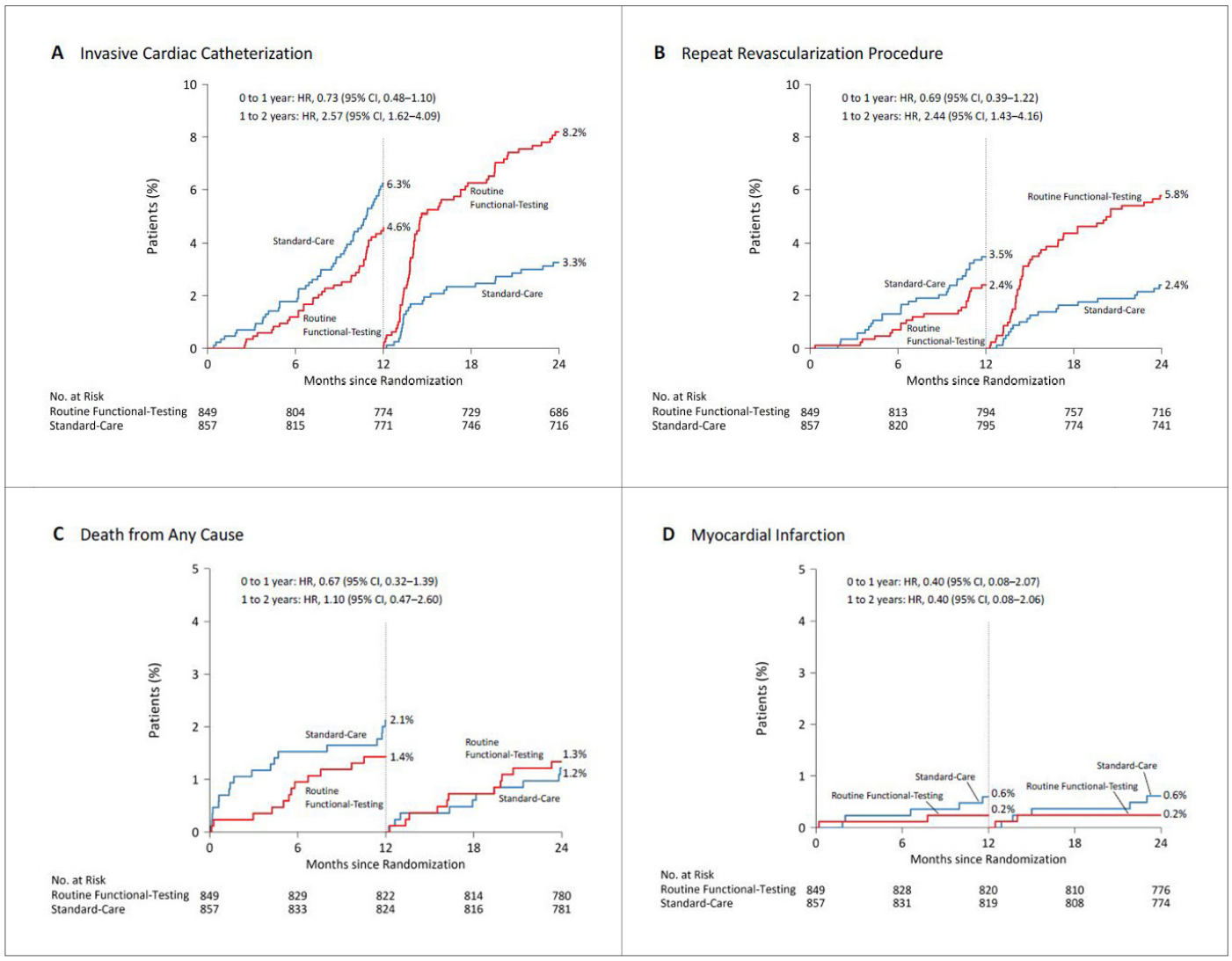


Figure 2. Landmark analysis for outcomes

lesions, 38.7% had diabetes, and 96.4% had been treated with drug-eluting stents. At 2 years, a primary outcome event had occurred in 46 of 849 patients (Kaplan–Meier estimate, 5.5%) in the functional-testing group and in 51 of 857 (Kaplan–Meier estimate, 6.0%) in the standard-care group (hazard ratio [HR], 0.90; 95% confidence interval [CI], 0.61-1.35; *P*=0.62) (**Figure 1**). There were no between-group differences with respect to the components of the primary outcome. At 2 years, 12.3% of the patients in the functional-testing group and 9.3% in the standard-care group had undergone invasive coronary angiography (difference, 2.99 percentage points; 95% CI, 0.0-5.99), and 8.1% and 5.8% of patients, respectively, had undergone repeat revascularization (difference, 2.23 percentage points; 95% CI, -0.22-4.68).

Further, a landmark analysis performed between 1 and 2 years showed a more than twofold higher incidence of coronary angiography (8.2% vs. 3.3%; HR, 2.57; 95% CI, 1.62-4.09) and revascularization (5.8% vs. 2.4%; HR, 2.44; 95% CI, 1.43-4.16) in the functional-testing group compared with the standard-care group. Yet, there were still no meaningful between group-differences in the rate of death or MI (**Figure 2**).

Despite more testing and repeat procedures based on the regular functional testing results, hard clinical endpoints such as death or MI were not reduced. The result was consistent with the recent ISCHEMIA study, which showed that an initial invasive strategy, as compared with an initial conservative strategy, did not reduce mortality or ischemic events among stable patients with myocardial ischemia. The POST-PCI trial results also showed that more aggressive and invasive testing and treatment did not provide additional clinical benefits over a conservative strategy based on guideline-directed medical therapy.

In this multicenter, pragmatic, randomized trial of high-risk patients who had undergone PCI, routine functional testing did not result in a lower risk of ischemic cardiovascular events or death from any cause at 2 years. Therefore, routine surveillance stress testing for post-PCI patients is not recommended unless they exhibit clinical signs or symptoms of stent failure.

Clinical Science
Late-Breaking Clinical Trials 2023 in Asia-Pacific
›› Monday, May 08, 9:30 AM - 10:50 AM
›› Presentation Theater 1, Vista 3, B2

26th Annual Conference for Cardiovascular Nurse & Technologist Joint Program with TCTAP 2023

This year, TCTAP KCTA Symposium celebrated its 26th year and was held on MAY 9th at Valve & Endovascular Theater, Vista 1, B2.

This year's TCTAP 2023 KCTA symposium is the first offline meeting held at TCTAP after COVID-19. In this KCTA session, we prepared sessions with various topics, such as STEMI, Valve & Clip, Image session, and Cardiology Nurse session, which have recently become issues in various academic meetings.

Part 1: In the Hot Topic & Hot Discussion session, we plan to listen to and discuss various opinions on hemodynamic support options for ST elevation and myocardial infarction (STEMI) patients, and diagnosis and treatment options for STEMI patients through imaging and physiology.

Part 2: What is Your One Pick for Guiding PCI? This is a session to discuss what is the best option for guiding percutaneous coronary intervention (PCI), and it will be a time to compare intravascular ultrasound (IVUS), optical coherence tomography (OCT), and angio-guided PCI through cases and learn the pros and cons of each. In particular, it seems to be of interest how the angio-analysis tool, that employs machine learning technology through AI, complements the shortcomings of the existing angio-guided procedure.

Part 3: In the Valve & Clip session, we will learn about the complications of the transcatheter aortic valve implantation (TAVI) procedure, which is rapidly increasing recently, and discuss various access roots of the TAVI procedure. There will also be an in-depth discussion on the transcatheter mitral valve repair option. In addition, you will be able to learn the procedure for each valve, such as the current status of the pulmonary valve and the difference between each valve, along with the case.

Part 4: In the KCTA Nursing session, we will directly share the latest knowledge of intervention cardiology nursing, especially the transcatheter aortic valve replacement (TAVAR) program of Icahn School of Medicine at Mount Sinai in the US.

Please participate in the offline TCTAP Allied Professionals session held three years after COVID-19, and hope to gain various experiences and knowledge through the sessions.

26th KCTA Symposium
›› Tuesday, May 9, 12:00 PM – 4:20 PM
›› Valve & Endovascular Theater, Vista 1, B2

Hot Topic

Game of Thrones, TAVR vs. SAVR

Alain Cribier, MD

Hospital Charles Nicolle,
University of Rouen, France

The 20th Anniversary of TAVR Ceremony – From Concept to Human Application

The history of interventional medicine is short with an explosion of innovative treatments emerging at the end of the 20th century and dramatically expanding in the 21st century. For the younger generation of interventional specialists, with the armamentarium of these strategies at their fingertips, it is intellectually impossible to imagine what it was like treating cardiovascular disease less than 50 years ago. For those of us who were witnesses to that period and the developments that followed, it was another world.

The treatment of aortic stenosis (AS) is the most prevalent acquired valvular disease, and the first successful implantation of an aortic stented valve in a human, performed on April 16th 2002, is celebrated the 20th anniversary. But before the development of transcatheter aortic valve implantation (TAVI), non-coronary heart diseases, along with their dedicated interventional techniques, saw rapid growth from the transcatheter treatment of congenital pulmonic stenosis in 1979 and aortic valvular stenosis (AVS) in 1983, mitral valvuloplasty in 1984, and balloon aortic valvuloplasty (BAV) in 1985. In September 1985, faced with a 72-year-old female patient with calcified AS, recurrent syncope, and imminent death, the team at Rouen University Hospital adapted an existing technology from the field of congenital valve disease. Under local anaesthesia, a pulmonary balloon was employed to dilate the patient's aortic valve using a percutaneous transcatheter femoral approach. This first-in-human BAV led to an immediate hemodynamic and clinical improvement, followed by relief of symptoms and a return to normal life for the patient. However, after several years it became evident that balloon dilatation was not a long-lasting solution due to early valvular restenosis in 80% of patients at one-year follow-up. The merciless criticism to the failure of BAV reinforced a resolution to find a viable solution to deal with the issue of aortic valve re-stenosis. Remarkably, this technique knew re-birth with the onset of TAVI since it is used in daily practice to predilate the native valve or post-dilate the prosthesis.

The concept of implanting a dedicated stented valve for calcified AS was born out of this challenge. All BAV balloons could fully expand the calcified aortic valve despite the calcification. The idea that emerged was to maintain the initial positive results of the expansion by implanting a stent with a valve inside using the diseased native calcified valve as an anchor. This concept posed other issues besides the nature of the diseased native valve itself. Critical questions arose concerning the immediate proximity of essential anatomical structures: above, the coronary ostia and below, the mitral valve insertion, and the His bundle at the upper part of the interventricular septum. In Rouen, a landmark intensive, in-depth research with autopsies validated the concept of valvular stenting in AS. With my colleague, Helene Eltchaninoff, we did validate the correct dimensions of the stented valve to ensure there would not be damage to the surrounding structure, a key step to guarantee the feasibility and safety of the concept. The stents were strongly anchored within the calcified valve structures, thus decreasing the risk of secondary device embolization.

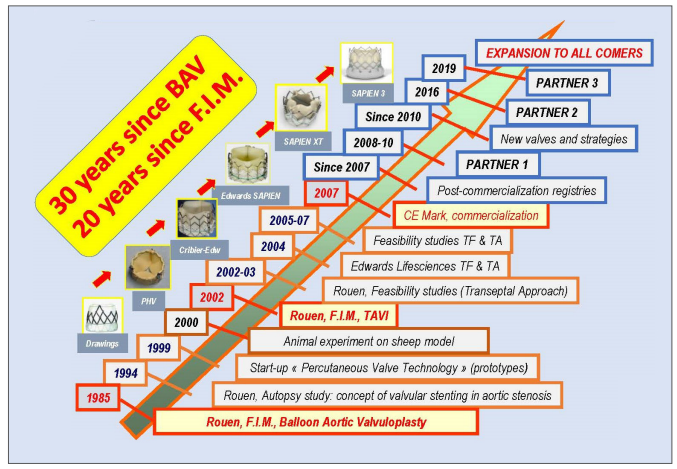


Figure 1. Developing TAVI, a long bulky road

In 2002, the first-in-man implantation of this revolutionary device could be performed as a last resort option in a 57-year-old male patient, with severe AS on a very calcified bicuspid valve. He was dying, in cardiogenic shock, with a 12% left ventricular ejection fraction. He had severe comorbidities, including lung cancer, acute ischemia of the leg by occlusion of an aortofemoral bypass, and a floating thrombus into the left ventricle. For these reasons, he had been turned down for surgical valve replacement despite his age. Against all odds, we could successfully perform this first TAVI case using an unplanned highly challenging transeptal approach since the femoral arteries were not usable. This was followed by a breath-taking clinical improvement. The case reported in Circulation hit the headlines. The technique then expanded first in our center with 38 patients treated on a compassionate basis, then in a few centers in Europe and the USA. In 2005, a total number of 100 patients had received TAVI. The turning point was the acquisition of our start-up by Edwards Lifesciences in 2004, leading to an evolution in the technology that continues to this day. A valve size of 26 mm was added, and a steerable delivery system was created to allow an easier and safer transfemoral approach. This approach was pioneered by John Webb in Canada. In 2005, there was the launch of a concurrent TAVI system, the self-expanding CoreValve later acquired by Medtronic, which played an incontestable role in the fabulous expansion of TAVI worldwide. Rapidly many technological improvements were made year after year, with the development of new TAVI systems, new approaches, lower profile devices, and preventive solutions against paravalvular leaks. Consequently, the simpler and safer transfemoral approach progressively turned into the standard strategy for TAVI, used in more than 90% of patients, leading to a 'democratisation' of the procedure and contributing to the burst of implantations worldwide (**Figure 1**).

In parallel with the advanced models of TAVI systems, a careful process of staged evidence-based medicine led to the proof that a treatment, originally limited to 'compassionate' use in high surgical risk patients, could be enlarged by the American and European guidelines to include patients at intermediate risk and finally, in 2019, to low surgical risk patients as well. The acute and long-lasting non-inferiority or superiority of TAVI over surgery was consistently demonstrated on many main or secondary endpoints, more particularly death and stroke rates. The number of patients who benefited from TAVI is now reaching two million, in over 80 countries. In numerous countries, the number of TAVI procedures now exceeds the number of surgical valve replacements (**Figure 2**). How can be seen the future of TAVI? A continuous expansion of the procedure can be predicted, in the range of 10% per year for several reasons: 1) The aging population,

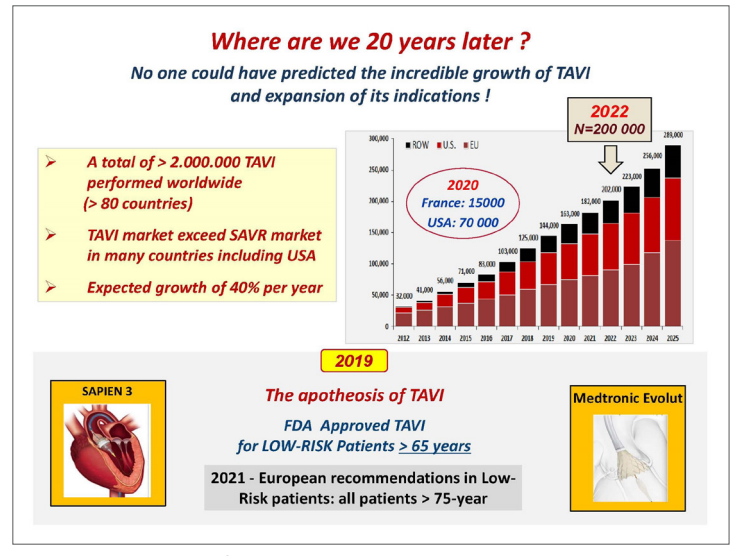


Figure 2. Current position of TAVI

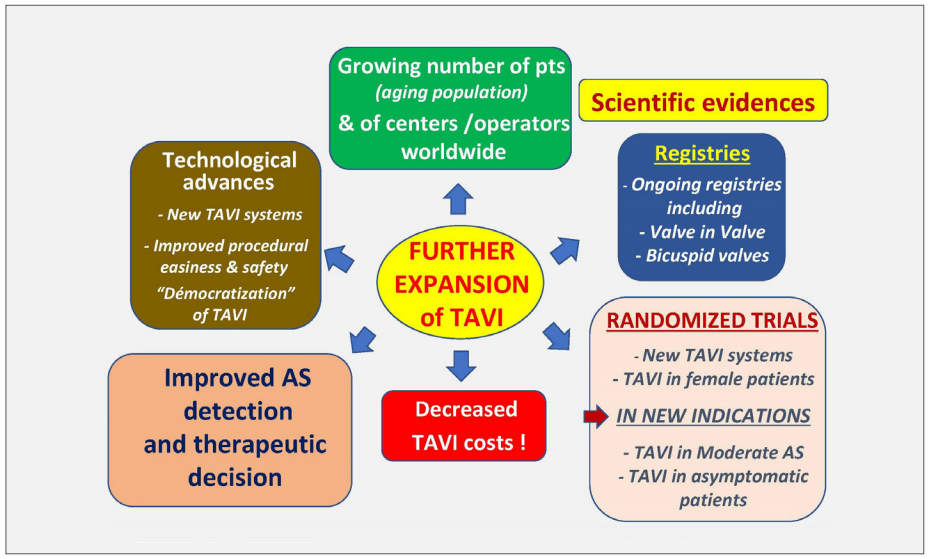


Figure 3. Predictable future of TAVI

whereas aortic stenosis is typically a disease of the elderly, earlier detection of the disease by regular practitioners. 2) The continuous improvement in technology which has notably increased the safety of the procedure. 3) A growing experience of the individual operators leading to an increase in the number of specialized centers practicing TAVI. When combined, experience and accessibility have made TAVI an easy procedural choice where in the past cardiac surgery would have been the only option. 4) The continued expansion of indications to low-risk younger patients provided that the long-term durability of the implanted valves will be fully demonstrated. This has encouraged research on other types of valves than those made of the pericardium, less prone to deterioration. 5) The continued and future expansion of TAVI to other indications, such as valve-in-valve procedures (such as treating future TAVI dysfunction) or the treatment of moderate AS in patients with heart failure or asymptomatic patients with severe AS. 6) Also, importantly, the increase in TAVI procedures and the vital competition between devices should lead to an overall decrease in the cost of TAVI which is of particular interest for lower-income and developing countries. 7) And of course, the outstanding combination of excellent clinical results and the simplicity of the procedure for the patients themselves: no sternotomy, the use of local anaesthesia, a short hospital stay, and, most importantly, a rapid return to normal life without the need for rehabilitation.

This steady expansion is an excellent example of successful translational research, and moving findings from concept to bench, bench to bedside, feasibility trials to larger clinical registries, and evidence-based trials to everyday practice. The constructive dialogue that continues between multidisciplinary physicians and engineers has been central to the evolution of TAVI. However, it is of interest that TAVI, unlike PCI, began with the most untreatable of patients and only now is being used in lower-risk groups (**Figure 3**). In the advances in the treatment for valve disease TAVI played – and continues to play – a seminal role. Looking back over the last 20 years since that first TAVI, we are astonished by the impact this procedure has had. TAVI crystallized the study of structural heart disease, inspiring a younger generation of interventionalists and scientists. It remains an innovative and disruptive technology influencing many of the ways that medicine is practiced today. In cardiology alone, it paved the way for percutaneous transcatheter treatment of the mitral and tricuspid valves, has led to far-reaching developments in cardiac imaging, and has been instrumental in bringing together specialists in the Heart Team concept. After 20 years, the future stories of TAVI are still being written.

Hot Topics
Game of Thrones, TAVR vs. SAVR
›› Sunday, May 7, 4:10 PM - 5:30 PM
›› Valve & Endovascular Theater, Vista 1, B2

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