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 The Newsletter of the CVRF

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## Randomized Trial of Stents vs. Bypass Surgery in Left Main Coronary Disease: The PRECOMBAT Trial Results Published in the New England Journal of Medicine



The NEW ENGLAND  
 JOURNAL of MEDICINE

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

### Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease

Seung-Jung Park, M.D., Young-Hak Kim, M.D., Duk-Woo Park, M.D., Sung-Cheol Yun, Ph.D., Jung-Min Ahn, M.D., Hae Geun Song, M.D., Jong-Young Lee, M.D., Won-Jang Kim, M.D., Soojin Kang, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Seong-Wook Park, M.D., Cheol-Hyun Chung, M.D., Jae-Won Lee, M.D., Do-Sun Lim, M.D., Seung-Woon Rha, M.D., Sang-Gon Lee, M.D., Hyeon-Cheol Gwon, M.D., Hyo-Soo Kim, M.D., In-Ho Chae, M.D., Yangsoo Jang, M.D., Myung-Ho Jeong, M.D., Seung-Jea Tahk, M.D., and Ki Bae Seung, M.D.

In April 2011, Seung-Jung Park, MD from Asan Medical Center, Seoul, Korea presented the results of left main-specific randomized trial (the PRECOMBAT study) in a Late-Breaking Clinical Trials session at ACC i2 summit in New Orleans and simultaneously published an article entitled "Randomized Trial of Stents vs. Bypass Surgery in Left Main Coronary Disease" in the New England Journal of Medicine.

Several registry data and a substudy from the SYNTAX trial have suggested that percutaneous coronary intervention (PCI) could be an acceptable alternative to standard coronary artery bypass grafting (CABG) in patients with unprotected left main coronary artery disease. However, registry results have an inherent limitation of selection bias, prohibiting a fair comparison of the two treatments and were limited by inadequate statistical power, and the sub-study in the SYNTAX trial is just hypothesis-generating. Therefore, the definite comparability of PCI with CABG in such patients remains uncertain due to the lack of large randomized clinical trials.

In the Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease (PRECOMBAT) trial, Dr. Park and his colleague analyzed patients with unprotected left main coronary stenosis who were randomly assigned to undergo CABG (N=300) or PCI with sirolimus-eluting stents (N=300). Primary end point was major adverse cardiac or cerebrovascular events (MACCE) including all-cause death, myocardial infarction, stroke, or ischemia-driven target vessel revascularization at 1 year and these event rates were also compared over 2 years. At 1 year, the primary outcome occurred in 26 (8.7%) of patients randomized to PCI versus 20 (6.7%) of patients randomized to CABG (absolute risk difference, 2.0%; 95% CI, -1.6 to 5.6, P=0.011 for noninferiority). At 2 years, the primary outcome occurred in 36 patients in the PCI group and 24 in the CABG group (12.2% vs. 8.1%; HR, 1.50; 95% CI, 0.90-2.52; P=0.12). The rate of hard safety end points (death, myocardial infarction or stroke) were similar between the PCI and the CABG group (4.4% vs. 4.7%; HR, 0.92; 95% CI, 0.43-1.96; P=0.83). However, the rate of target-vessel revascularization was significantly higher in the PCI group than in the CABG (9.0% vs. 4.2%; HR, 2.18; 95% CI, 1.10-4.32; P=0.02).

This result of the PRECOMBAT trial suggested that drug-eluting stents were found to be noninferior to CABG with respect to MACCE and could be an alternative option for selected patients with unprotected left main disease. This article was of paramount importance to provide more definite suggest for the optimal revascularization strategy for such patients in clinical practice.

With support from CVRF, a total of 80 research papers since 2004, have been published in such prestigious academic journals as SCI, NEJM. Notably, this is the highest number of domestic research these published under the support of a single organization.

 **Incidence, predictors, treatment, and long-term prognosis of patients with restenosis after drug-eluting stent implantation for unprotected left main coronary artery disease. J Am Coll Cardiol. 2011;57:1349-58.**

Few data on the clinical course and management of patients experiencing restenosis after DES treatment for unprotected LMCA disease have appeared. The ASAN-MAIN registry evaluated the incidence, predictors, and long-term outcomes of patients with in-stent restenosis (ISR) after percutaneous coronary intervention (PCI) with drug-eluting stents (DES) for unprotected left main coronary artery (LMCA) disease. Between February 2003 and November 2007, 509 consecutive patients with unprotected LMCA disease underwent DES implantation, with 402 (80.1%) undergoing routine surveillance or clinically driven angiographic follow-up. A major adverse cardiac event was defined as the composite of death, myocardial infarction (MI), or target-lesion

revascularization. The overall incidence of angiographic ISR in LMCA lesions was 17.6% (71 of 402 patients, 57 with focal-type and 14 with diffuse-type ISR. Forty patients (56.3%) underwent repeated PCI, 10 (14.1%) underwent bypass surgery, and 21 (29.6%) were treated medically. During long-term follow-up (a median of 31.7 months), the incidence of major adverse cardiac event was 14.4% in the medical group, 13.6% in the repeated PCI group, and 10.0% in CABG group. This study showed that the long-term clinical prognosis of patients with DES-ISR associated with LMCA stenting might be benign, given that these patients were optimally treated with the clinical judgment of the treating physician

## PAPER PUBLICATION

## Program Highlights: The 16<sup>th</sup> ANGIOPLASTY SUMMIT-TCTAP 2011

This year ANGIOPLASTY SUMMIT-TCTAP 2011 provides all the delegates with very latest, interesting information and technology throughout various practical sessions designed to improve their knowledge, skills and experience in interventional cardiology and endovascular medicine. Following topics will be covered during this course; Left Main and Bifurcation, IVUS and FFR, and Transcatheter Valve Therapies.

The 5th Left Main and Bifurcation Summit had been jointly organized by CVRF(Korea) and CRF(USA) since 2007, and this year two international societies which are APSIC and CIT newly join to this session.

Imaging Workshop delivers specialized messages about both invasive and non-invasive imaging from world's leading experts in Imaging and Physiology. With the first part of this session being held on 28<sup>th</sup>, Thursday, Decision making by IVUS and FFR, Vulnerable Plaque and OCT Focusing on DES Failure will be covered, and the rest will be composed by non-invasive imaging for interventional cardiologists. Besides those, below are the program highlights what TCTAP2011 makes especially useful for people in the field of cardiology.

### TCTAP Highlights 1: Meet the Experts over Breakfast 7:00 am to 8:10 am, 27 (Wed) through 29 (Fri)

Of the sessions be awaited, this session every year is extremely popular and well attended. Interesting cases on various subjects, including bifurcation intervention, FFR, DES technologies and left main intervention and much more are presented and also addressed in detail by expert

panels from around the world within an interactive environment. One of the main advantages of this session is a lively open communication on each topic between the experts and attendees, and it will enable them to get fresh perspectives and greater understanding of the most challenging issues every morning relating cardiovascular and endovascular intervention.

### TCTAP Highlights 2: Technology & Innovation 6:00 pm to 9:00 pm, 26 (Tue)

The session starts with introduction followed by numbers of interesting presentations about technology and innovation under the topic of "How to Innovate in Cardiovascular Technology." There are different fundamental analyses in terms of cardiovascular technology, and the audience experiences two different approaches to this issue. One is to speak about How to Teach and Train Innovation: US Approach, while the other is to expound Innovation in Medicine: Korean Approach. And for the next two hours, it provides with interactive analyses of global products of divergent point of views from clinical trial investigators and industry professionals that allow the audience to experience worldwide view of the products. Many of globally recognized companies and highly qualified professionals also present their research and clinical trials.

### TCTAP Highlights 3: Fellows Course 2:00 pm - 5:00 pm, 26 (Tue)

It is really exciting to see and listen to knowledge and technical know-how presented by the most experienced cardiologists. Especially it will provide step by step learning points covering two main interesting learning subjects which are Left Main and Bifurcation and Chronic Total Occlusion Intervention. During three hours long world's qualified leaders in these fields will share their own experiences and many tips and tricks by presenting lectures and addressing questions from the audience. This session is specially designed for fellows and young cardiologists just starting his career, and all the presentations seek to give the attending an understanding of the techniques they perform on a daily basis.

### TCTAP Highlights 4: Most Distinguished Studies 2010-2011 in the Interventional and Clinical Cardiology: Meet the Authors and Discuss with the Experts 8:30 am - 12:30 pm, 28 (Thu)

The best publications of 2010-2011 are presented during this opening session for second day of TCTAP2011. Don't miss this exclusively special opportunity to meet the most influential and significant publications in the interventional cardiology and talk with the authors. This session consists of four main topics presenting on which Anti-Platelets and Anti-Coagulants in ACS, ACS Treatment, STEMI Management, and Revascularization Strategy for CAD to gives the audience a summary of worldwide experience. This puts them in contact with the best innovations and the latest developments in the field.

## PAPER PUBLICATION

➔ Long-term outcomes after stenting versus coronary artery bypass grafting for unprotected left main coronary artery disease: 10-year results of bare-metal stents and 5-year results of drug-eluting stents from the ASAN-MAIN (ASAN Medical Center-Left MAIN Revascularization) Registry. *J Am Coll Cardiol.* 2010;56:1366-75.

Data on the long-term (beyond 5-year up to 10-year) comparative results of treatment of unprotected LMCA disease with stent implantation or CABG are limited. The ASAN-MAIN registry evaluated very long-term safety and effectiveness of PCI with stenting and CABG for unprotected left main coronary artery (LMCA) disease.

This study performed a 10-year clinical follow-up of 350 patients with unprotected LMCA disease who underwent PCI with bare-metal stents (BMS) (n=100) or CABG (n=250) from January 1995 to April 1999, and 5-year clinical follow-up of 395 patients with unprotected LMCA disease who underwent PCI with drug-eluting stents (DES) (n=176) or CABG (n=219) from January 2003 to May 2004.

In the 10-year follow-up cohort of BMS and concurrent CABG, the adjusted risks of death and the composite of death, Q-wave MI, or stroke were similar between the 2 groups. The rate of TVR was significantly higher in the group that received BMS. In the 5-year follow-up cohort of DES and concurrent CABG, there was no significant difference in the adjusted risk of death or the risk of the composite outcome.

The rates of TVR were also higher in the DES group than the CABG group. This longest follow-up study showed that PCI with stenting showed similar long-term mortality and rates of death, Q-wave MI, or stroke, but higher repeat revascularization compared with CABG up to 5 and 10 years.

## CVRF NEWS

➔ Seung-Jung Park, MD, won Medical Awards

Seung-Jung Park, M.D., Ph.D., FACC, Chairman of CardioVascular Research Foundation, was presented the Yullhan Prize in a ceremony held at Lotte hotel on February 14 (Mon), sponsored by Yuhan Foundation.

Nomination committee of Yullhan Prize revealed that Dr. Park has been recommended by Korean Academy of Medical Science and shown his great creativity and insight as a medical scientist, deserve to set an example for our society.

Dr. Park also won the Asan Medical Award in April recognizing his overall accomplishment not only treatment for patients but also innovative research, dedicated education and passionate conduct of international conference, ANGIOPLASTY SUMMIT-TCTAP.

One of the Scientific Committee members of ANGIOPLASTY SUMMIT-TCTAP, sponsored by CVRF,

Dr. Duk-Woo Park also won the Wunsch Medical Award last January, co-hosted by Boehringer Ingelheim Korea and Korean Academy of Medical Science. The award recognizes Dr. Park as a prominent young physician in interventional vascular medicine, achieving his publication results 'C-reactive protein and the risk of stent thrombosis and cardiovascular events after drug-eluting stent implantation' in *Circulation*.

## Upcoming CVRF Sponsored Conferences

2012

5<sup>th</sup> IMAGING & PHYSIOLOGY Summit and  
6<sup>th</sup> CHRONIC TOTAL OCCLUSION LIVE 2012

January 6 (Fri) - 7 (Sat), 2012  
Asan Medical Center, Seoul, Korea

### Call for Cases

May 30 (Mon) - October 7 (Fri), 2011  
[www.imaging-physiology.com](http://www.imaging-physiology.com)  
[www.cto-live.com](http://www.cto-live.com)

17<sup>th</sup> ANGIOPLASTY SUMMIT-TCTAP

April 25 (Wed) - 27 (Fri), 2012  
The Convention Center, Sheraton Grand Walkerhill Hotel,  
Seoul, Korea

### Call for Abstracts

August 1 (Mon) - November 11 (Fri), 2011

### Call for Cases

August 1 (Mon), 2011 - January 9 (Mon), 2012  
[www.summit-tctap.com](http://www.summit-tctap.com)

## 📍 The 2<sup>nd</sup> CVRF Night



"In close collaboration with global working groups, this meeting delivers an unparalleled program that appeals to over 3,000 attendees around the world with unsurpassed evidence-based contents. And this year, more than 3,500 participants from a wide range of disciplines will participate in this conference." said Dr. Seung-Jung Park, the Founder and Chairman of CVRF, at the 2<sup>nd</sup> CVRF Night, which was held on February 9 (Wed) at the W-Seoul Walkerhill Hotel.

CVRF hosted the dinner for the industry supporters to show the special thanks for their continued support on the growth of ANGIOPLASTY SUMMIT-TCTAP as well as to introduce the CVRF's activities and next meeting.

Over 35 guests including the physicians from Asan Medical Center, representatives of companies that have supported CVRF, and CVRF members gathered.

In this dinner, there was a presentation about CVRF's Marketing Activities, Report of ACT Program and CVRF's Fundraising. CVRF also plans to have this event next year.

## The Heart Beat of CVRF

The Heart Beat of CVRF is produced by the CardioVascular Research Foundation.

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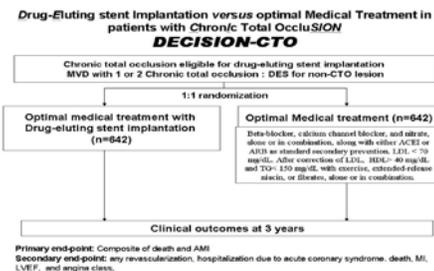
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## CLINICAL RESEARCH

### 📍 DECISION-CTO Trial

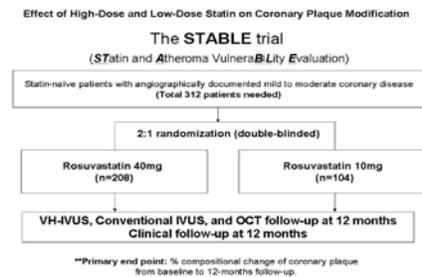


The purpose of this trial is to compare the safety and effectiveness of drug-eluting stent implantation compared to optimal medical treatment in patients with chronic total occlusion.

The DECISION-CTO trial is prospective, two arms, randomized multi-center trial of 1,300 patients enrolled at 26 centers in Korea and 11 centers in Asian-pacific region. Following angiography, patients with chronic total occlusion (more than 3 months) have documented myocardial ischemia or symptoms of angina, and eligible for stenting without any exclusion criteria will be randomized 1:1 to: a) drug-eluting stent vs. b) optimal medical treatment. All patients will be followed for at least 3 year.

Primary endpoint is a composite outcomes of all cause death, myocardial infarction, stroke, and any revascularization for 3 years after randomization.

### 📍 STABLE Trial



At present, there is no proven drug or modality to stabilize the vulnerable plaques. A number of drugs that are beneficial for patients with coronary disease may act in part by improving the stability of plaques that are vulnerable for future rupture. Especially, Lipid-lowering therapy, particularly with statins, can stabilize vulnerable plaques or those that have already ruptured by improving endothelial function and reducing thrombogenicity, platelet aggregation, and possibly inflammation. As the atherosclerotic disease has progressed, there is an increase of the atherosclerotic plaque amounts. However, the changes of specific plaque compositions within the atherosclerotic lesions have not been sufficiently evaluated. Previous pathologic findings reported that there was a significant relation between the plaque size and necrotic core size. Conventional grey-scale intravascular ultrasound (IVUS) has significant limitations in accurately assessing atheromatous plaque composition. These limitations have been partially addressed by radiofrequency signal processing with spectral analysis of the back-

scattered ultrasound signals. Using this technology, Virtual Histology (VH) IVUS is capable of characterizing plaque as calcified (white), fibrotic (dark-green), fibrofatty (yellow-green), and necrotic core (red). In addition, optical coherence tomography (OCT) is a light-based imaging modality that can be used in biological systems to study tissues in vivo with near-histologic, ultrahigh resolution. The rationale for intravascular application of OCT is its potential for in vivo visualizations of the coronary artery microstructure. This unique image resolution of OCT offers the potential to detect key features of vulnerable plaque in vivo. Beyond the inherent limitations of angiography and intravascular ultrasound, OCT might offer a much higher sensitivity in the detection of necrotic/lipid cores within coronary atheromas. Therefore, plaque characterization using VH-IVUS and OCT may provide detailed morphologic insights of plaque vulnerability.

We hypothesized that statin would provide benefits to stabilize coronary plaque composition by LDL-reduction and/or a pleiotropic effect. We also hypothesized that high-dose statin would be more beneficial in reducing the vulnerable plaque and stabilizing the vulnerable plaque composition than low-dose statin.

The purpose of the STABLE trial is to evaluate the effect of statin therapy on the modification of atherosclerotic plaque composition and vulnerability in non-intervened coronary arteries with mild to moderate stenosis using VH-IVUS and OCT.

## CardioVascular Research Foundation (CVRF)

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



## MEETINGS UPDATE

### The 4<sup>th</sup> IMAGING & PHYSIOLOGY SUMMIT 2010

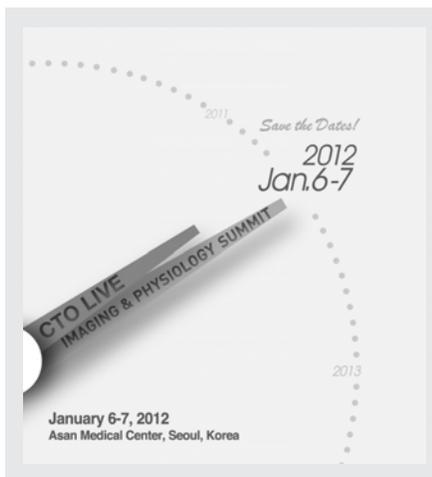


The 4<sup>th</sup> IMAGING & PHYSIOLOGY Summit 2010 was held on October 29 (Fri) ~ 30 (Sat), 2010 at Asan medical center in Seoul, Korea. It was designed to provide highly specialized noninvasive imaging and physiology through lectures and interesting cases, this very practical course has been successfully completed with 300 participants.

This symposium was made up of practical workshops and scientific program with live case demonstrations related imaging clinical state-of-the-art lectures, expanded "case-base imaging interpretation workshop: from basic to advanced" for IVUS & VH-IVUS, OCT, MDCT & MRI, FFR and challenging case competition with the experts.

It offered a unique opportunity for the audience to review advanced imaging modalities and the latest investigations regarding coronary imaging and physiology and to share practical information about the developed imaging modalities.

In 2012, 2-Day joint symposium of 5<sup>th</sup> IMAGING & PHYSIOLOGY Summit and 6<sup>th</sup> CHRONIC TOTAL OCCLUSION LIVE will be held on January 6 (Fri) ~ 7 (Sat), 2012 at Asan Medical Center, Seoul, Korea.



### The 5<sup>th</sup> CTO (Chronic Total Occlusions) LIVE 2011

The 5<sup>th</sup> CTO LIVE 2011, which was held on January 8 (Tue), 2011 at Asan Medical Center, Seoul, Korea, has ended successfully with over 300 attendees including the world-leading CTO masters, interventional cardiologists, and industry supporters from all over the world.

In close collaboration with the Toyohashi Heart Center and Shonan Kamakura General Hospital, CTO LIVE 2011 featured the intensive live case demonstrations guided by the invited operators from Japan and it provided practical lessons to interventional cardiologists on the advanced techniques and useful know-how in dealing with novel devices for their daily practices.

Especially, with the increased number of case submission compared to last year, total 27 challenging cases were actively presented at the 4 competition sessions and each session was run interactively by discussions and Q & A with the experts.

In addition, it added more practical academic value through the exhibition & learning center which offered the latest information on the novel CTO devices with hands on training.

## TRAINING PROGRAM

### Interview with CVRF fellowship trainee, Dr. Chaohui Jiang



Dr. Chaohui Jiang, 42, is a professor, department of cardiology, The First Hospital Affiliated to Xiamen University, Xiamen, China. He has been joining short term fellowship training program sponsored by CVRF (CardioVascular Research Foundation) from March, 2011 and experiencing interventional cardiology in Asan Medical Center. Recently CVRF interviewed Dr. Chaohui Jiang about his life to be served as a visiting fellow in Asan Medical Center.

Q: How did you know about this fellowship program?

Chaohui Jiang: First of all, I hope to express my gratitude to CVRF and the Board members. I admire Prof. Seung-Jung Park, who conducted the first-in-man study using the nonpolymer-coating paclitaxel-eluting stent and is a pioneer in the treatment for unprotected left main trunk disease with a percutaneous approach. So I hope to be trained in AMC and got contact with Prof. Park, he kindly introduced this fellowship program to me.

Q: What is your life in Korea as an international trainee?

Chaohui Jiang: As an international trainee, I have hardly any difficult to live in Seoul which is an international city. I live in the family town of AMC, which is only 5 minutes walk from AMC with convenience facilities.

Q: What was your first impression of heart institute, Asan Medical Center?

Chaohui Jiang: The first impression of heart institute is their strict and hard working. In the first day I came catheter Laboratory at 7 am ahead of 1 hour of schedules, to my surprise, all of the colleagues already work from 6:30am. I knew that their strict and hard works lead to the outstanding achievements.

Q: What did you learn and experience from this program?

Chaohui Jiang: First of all, I learned the serious attitude to work. Then, the complex PCI guided by IVUS and FFR will be

the future trends, I have fundamentally mastered the new skill and concept. I learned a lot from Prof. Park and colleagues here. For example, Prof. Seung-Jung Park always tell me the most important skills during procedures, Dr. Young-Hak Kim shows me the PCI strategy and Dr. Cheol Whan Lee always show me the interventional technical tips. My colleagues always show me the special cases. So, it is the most rewarding visit to me.

Q: What do you enjoy most about this fellowship program? And what is your plan after going back to China?

Chaohui Jiang: It is great to have the opportunity to work with the first-class professionals in interventional cardiology field; I enjoy most the functional PCI and complex cases. I hope I will keep in touch with CVRF and these first-class colleagues and I'd like to utilize the FFR guided PCI in my hospital.

## ACT Program

Asan Medical Center  
Interventional Cardiology  
Training Program



Organizing Director  
Seung-Jung Park, MD

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

Left Main Intensive Course FFR & IVUS Guided PCI

#### ■ Catheterization Laboratory Activities

- Live Case Demonstration
- Hands-on Experience in Cath Lab
- Free Discussion in the Training Center during the Procedure
- Visiting Professors' Activities-Case Presentation & Featured Lecture

#### ■ Evidence-Based Lectures

- Core Lab Analysis
- Complex Angioplasty
- Preventive Medicine
- DES Issues
- ACS Guideline

#### ■ Lunchtime Activities

- Asan Medical Center Tour
- Dynamic Round Table Discussion
- Case Presentation & Discussion

#### ■ Registration site & Contact

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