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

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.

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.
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 (ASIAN 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 ASIAN-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 analysis.

The rates of TVR were also higher in the DES group than the CABG group. In the 5-year follow-up cohort of DES 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 analysis.

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The 2nd 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 2nd 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.

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) optimal medical treatment with Drug-eluting stent implantation (variety) or b) optimal medical treatment (variety). The primary endpoint is a composite outcomes of all cause death, myocardial infarction, stroke, and any revascularization for 3 years after randomization.

STABLE 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 STABLE trial is a double-blind, placebo-controlled, parallel group, multi-center, double-blind, placebo-controlled, parallel group, randomized clinical trial of 1,300 patients enrolled at 26 centers in Korea and 11 centers in Asian-pacific region. The primary endpoint is a composite outcomes of all cause death, myocardial infarction, stroke, and any revascularization for 3 years after randomization.
The 4th IMAGING & PHYSIOLOGY SUMMIT 2010

The 4th 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 5th IMAGING & PHYSIOLOGY Summit and 6th CHRONIC TOTAL OCCLUSION LIVE will be held on January 6 (Fri) – 7 (Sat), 2012 at Asan Medical Center, Seoul, Korea.

The 5th CTO (Chronic Total Occlusions) LIVE 2011

The 5th 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.

Q: What is your life in Korea as an international trainee?
Chaohui Jiang: As an international trainee, I have hardly any difficulty 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.

Interview with CVRF fellowship traineee, 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.

ACT Program

Asan Medical Center Interventional Cardiology Training Program

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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