Complex Cardiovascular Therapeutics 2011

CCT 2011

10th Anniversary

DATES | **November 3** thurs.- **5** sat., 2011

VENUE | Kobe International Exhibition Hall, Portopia Hotel

Takahiko Suzuki
CCT Supervisory Director
President of Toyohashi Heart Center

CCT News Publication

With the launch of this CCT News, as a representative of CCT directors, I would like to first of all thank everyone for their participation and I would also like to mention the chronology that led us to where we are today and explain our future goals and direction.

The Start of CCT Live Demonstrations

CCT began with the Osaka Live in the spring of 1992 followed by Toyohashi Live in the fall of the same year and Naka Nihon Live was held in Shiga the next year. After overcoming numerous obstacles, the name was changed to the Complex Coronary Intervention Conference (CCIC) and the name then became Complex Cardiovascular Therapeutics (CCT) in 2001. Since that beginning until today, we have held 21 live demonstration courses. At the time of our first live course in 1992, PTCA had become established with balloon angioplasty and as its limitations became clear, we longed for the emergence of new devices. And so, with limited information, we set our end goal as "complex angioplasty."

Contributing Valuable Technical Information to the Rest of the World

Through these live demonstrations we have not only contributed valuable technical information to within Japan but also to the rest of the world. Four major contributions are, 1) IVUS guided DCA, 2) LMT-PCI, 3) Cutting Balloon, and 4) CTO-PCI, all of which, I believe, are techniques that have received attention from around the world. DCA became available in Japan in 1992 and we were the first in the world to perform IVUS guided DCA and prove its efficacy. This was soon adapted for the treatment of LMT disease and continuously, we were able to lead the way to the PCI indication for the unprotected LMT with debulking stent. In addition, regarding the Cutting Balloon efficacy, we quickly used it in a live demonstration. The CCT group has proposed various techniques to the world, but from the very beginning in 1992, we have grappled with the theme that represents the final target of PCI and that is the treatment of CTO lesions. At that time, there were no high performance guidewires available and balloon profiles were very poor, and as a result, performing PCI for CTO lesions was like climbing up a rocky precipice. Afterwards, with improvements in CTO guidewires and microcatheters, excellent techniques such as the retrograde approach (CART Technique) were developed and the extent to which PCI of CTO lesions has grown and advanced, as all of you know. PCI's biggest weak point with regard to long term prognosis was restenosis against which the emergence of DES was a significant advancement. PCI naturally has limits as a local therapy in eliminating stenosis. However, we believe that we must advance toward the final goal of further improvement in long term prognosis by not only PCI but by the systemic management of overall coronary artery disease treatment, to begin with drug therapy. We at CCT believe we need to make progress in establishing this course of action and sincerely wish to continue to contribute our energy to this field.

CCT 2011 Next Fall

Based on the above course of action, CCT2011 will be held next fall. We look forward to creating a program with an emphasis on clinically useful education. And I think the most important characteristic of CCT is the demonstration of the best technique. A live demonstration should not be about only showing the results but should be organized in such a way as to show the progression of the case for better understanding. Of course, the scientific session consists of presentations of the latest knowledge, but I also look forward to striving to continue to provide live demos with technical explanations and commentary that cannot be seen at other live demonstrations. We look forward to seeing you next fall at CCT2011 for three days from November 3 to 5.

From Experience to Evidence

Furthermore, from now on CCT should lead the world which, of course, means putting our energies into development and advancement of new technology, but we will also propose excellent techniques and the fruits of that labor to the world in the form of our planned official publication, "Journal of CCT" with the catchphrase, "From Experience to Evidence." The Journal of CCT will include not only research results but we also plan to include discussion of the theory and implications of the nature of PCI technique. Also, from a practical and educational point of view, we plan to have case presentations on the web site and we look forward to everyone's contribution. We at CCT, with all of you, aspire to furthering the progress and deepening of PCI and concentrate all our efforts into contributing valuable information to the rest of the world. Thank you for your cooperation.

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CCT's Future Development

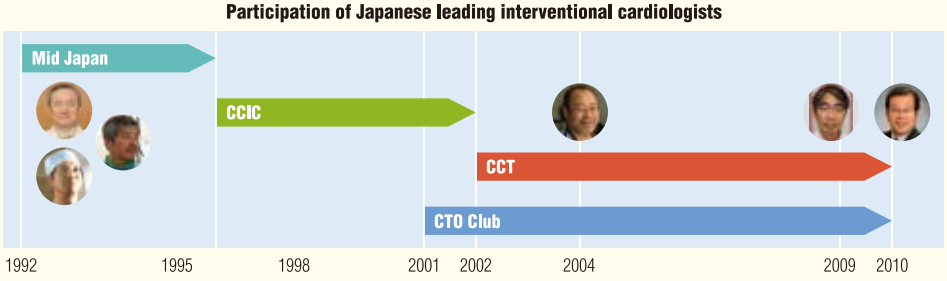
Fumiaki Ikeno
CCT Secretary-General

CCT was established for the purpose of spreading technology for the treatment of cardiovascular disease. The predecessors of CCT, Naka Nihon Live and CCIC began in 1991 and with CCT we began the 21st Century. (see Fig. 1)

The dawn of PCI was brought to the world by Andreas Gruentzig in 1977 and with it, the advent of live technical education became the format that spread this technique throughout the world making it the gold standard for the treatment of ischemic heart disease. Although it is hard to believe now, PCI met with harsh criticism at that time and did not hold a high place in the medical world. However, Andreas Gruentzig and his aspirations received endorsement from physicians around the world and with their incessant hard work towards improvement and revision, the technique of PCI has brought to the world very stable treatment results. Similarly, if we look back on the history of CCT, it is no exaggeration to say that we pushed the leading edge of medical technology at that time and helped spread it throughout the world. As we approach 20 years since 1991, we place importance on providing information with the purpose of spreading education of not only the treatment by coronary artery catheterization, but also that of cardiovascular surgery, catheter treatment of arrhythmia, peripheral intervention, co-medical education, and new medical devices and pharmaceuticals. Accordingly, the number of non-physician participants has increased and we are contributing to the dissemination of the treatment of general cardiovascular disease. (see Fig. 2) From now on, we will add and lay emphasis on the new catheter treatment of valvular disease. Also, we must strive toward our common goal of continuing to develop the treatment of heart disease by eliminating the device lag and drug lag of our country, engage in mutual education between ourselves and the authorities who govern the inspection of medical devices and pharmaceuticals, provide medical training and education for students, the future of Japanese medicine, provide opportunity to medical device industries to develop new devices and educate the public about the treatment of ischemic heart disease.

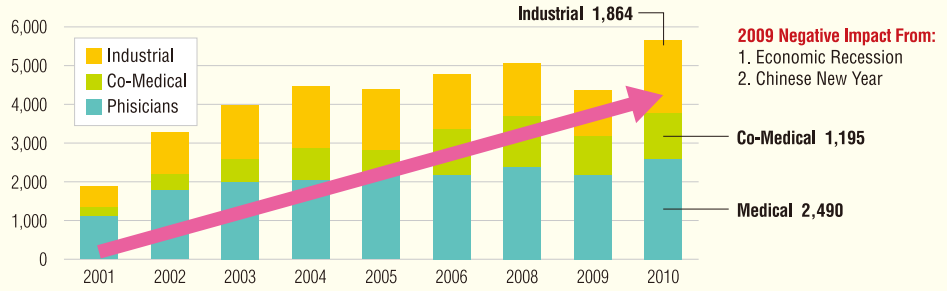
OUR HISTORY

(Fig. 1)



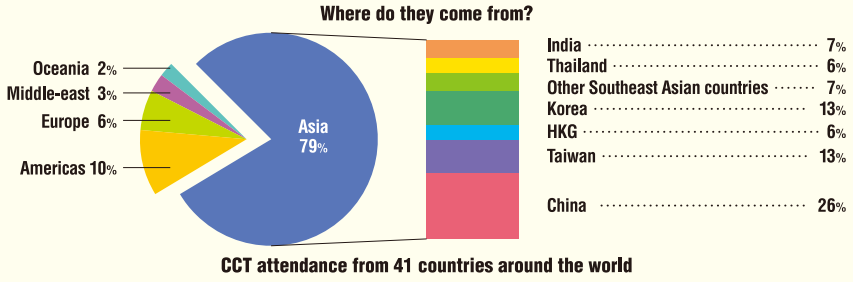
CCT Participants in 2010

(Fig. 2)



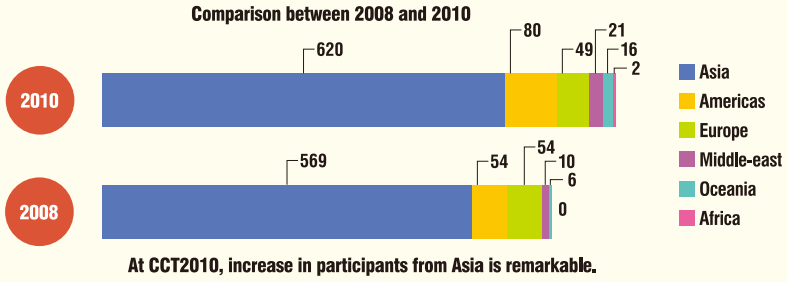
CCT2010 International Attendants

(Fig. 3)



CCT2010 International Attendants

(Fig. 4)



During the past 20 years, the surprising development of the media and transportation has made the world seem much smaller and we have become less aware of country borders regarding medical care. And at CCT, within this history, we have endeavored toward internationalization with "medical care" as our lingua franca. CCT was first in Japan to choose English as the official language and accordingly, we have had an increase in participation so that now, with Euro PCR and TCT, we are among the three largest live research societies and are recognized around the world. (see Figures 3, 4) Such efforts as these, especially in intervention, have resulted in Japan's clinical technology reaching world preeminence with international acknowledgment. Japanese physicians are working in countries all over the world and international cooperation in medical care has virtually moved beyond national borders and nationalities. It is CCT's intention to center on Asia and promote internationalization through medical care, and contribute to medical care development in the world.

CCT will endeavor to contribute nationally and internationally to the advancement of medical care.

Rx ONLY

The XIENCE™ V Everolimus Eluting Coronary Stent on the MULTI-LINK MINI-VISION® or MULTI-LINK VISION® Delivery System

INDICATIONS

The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

CONTRAINDICATIONS

The XIENCE V stent is contraindicated for use in patients:

- Who cannot receive antiplatelet and/or anti-coagulant therapy
- With lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- With hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers.

WARNINGS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Judicious patient selection is necessary because device use has been associated with stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

PRECAUTIONS

- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent is presently unknown.
- Risks and benefits should be considered in patients with severe contrast agent allergies.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Use fluoroscopy to avoid arterial damage.
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death.
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the XIENCE V SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number of and total length of implanted stents. See *Instructions for Use* for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE V stent have not been established for subject populations with the following clinical settings:
  - Patients with prior target lesion or in-stent restenosis related brachytherapy, patients in whom mechanical atherectomy devices or laser angioplasty devices are used simultaneously, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.5 mm or > 4.25 mm or lesion lengths > 28 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, chronic total occlusions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent acute myocardial infarction (AMI) or evidence of thrombus in target vessel, moderate or severe lesion calcification, multivessel disease, in-stent restenosis, and patients with longer than 24 months follow-up
- Everolimus has been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE V stent because of limited systemic exposure to everolimus eluted from XIENCE V.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients was associated with increased serum cholesterol and triglycerides that in some cases required treatment.
- Non-clinical testing has demonstrated that the XIENCE V stent, in single and in overlapped configurations up to 68 mm in length, is MR Conditional. It can be scanned safely under the conditions in the *Instructions for Use*.
- The XIENCE V stent should be handled, placed, implanted, and removed according to the *Instructions for Use*.

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with coronary stent use in native coronary arteries include but are not limited to:

- Abrupt closure, Access site pain, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic and fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Distal emboli (air, tissue or thrombotic), Emergent or non-emergent coronary artery bypass graft surgery, Fever, Hypotension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular injury), Pseudoaneurysm, Renal Failure, Restenosis of the stented segment of the artery, Shock/pulmonary edema, Stroke / cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular complications including at the entry site which may require vessel repair, Vessel dissection

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:

- Abdominal pain, Acne, Anemia, Coagulopathy, Diarrhea, Edema, Hemolysis, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypertriglyceridemia, Hypogonadism male, Infections: wound infection, urinary tract infection, pneumonia, pyelonephritis, sepsis and other viral, bacterial and fungal infections, Leukopenia, Liver function test abnormality, Lymphocele, Myalgia, Nausea, Pain, Rash, Renal tubular necrosis, Surgical wound complication, Thrombocytopenia, Venous thromboembolism, Vomiting

Prior to use, please reference the *Instructions for Use* at **www.abbottvascular.com/ifu** for more information on indications, contraindications, warnings, precautions, and adverse events.

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A Promise for Life

Contact your Abbott Vascular sales representative for more information.

Indications: The XIENCE V® Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

For Important Safety Information, see adjacent page.

1. Reference: SPIRIT III 2 year and SPIRIT II 2 year stent thrombosis rates from XIENCE V IFU.

For more information, visit our website at **www.XienceV.com**

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