



# THE PULSE OF CRF

The Newsletter of the Cardiovascular Research Foundation

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## TCT 2011 Offers Groundbreaking Research Presentations



The annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium is the world's preeminent forum for interventional cardiologists, cardiac surgeons, and vascular medicine specialists. Attendees gather to hear the latest data from key clinical trials and to observe live cases focusing on coronary artery disease, peripheral vascular disease, and structural heart disease. At the 23rd annual TCT conference, held in San Francisco, November 7-11, 2011,

numerous practice-changing results were presented across a broad range of cardiovascular topics.

### Catheter-Based Valve Therapy

#### PARTNER AT 2 YEARS

The groundbreaking results at one year from the PARTNER (Placement of Aortic Transcatheter Valves) trial were maintained at two years, continuing to support the superiority of catheter-based heart valve replacement over

standard therapy for patients with severe aortic disease who are not candidates for surgery.


PARTNER randomly assigned over 350 inoperable patients with severe aortic disease and heart-related symptoms to catheter-based valve replacement or standard therapy, which consisted of drug management, conservative care, and/or balloon angioplasty inside the aortic valve.

*(See TCT 2011 Research, page 3)*

## CARDIOVASCULAR RESEARCH FOUNDATION

### Upcoming Educational Activities


 **Complex PCI: Left Main and CTO Summit**  
February 23-25, 2012 · New York, NY

 **Optimizing PCI Outcomes: A Vision for 2012**  
March 23, 2012 · Chicago, IL

 **Interventional Cardiology Fellows Course**  
April 19-22, 2012 · Miami, FL

 **TCT Mediterranean 2012**  
May 4-5, 2012 · Limassol, Cyprus

 **TCT Russia - XIV Moscow International Course on Endovascular Therapies**  
May 28-30, 2012 · Moscow, Russia

 **Transcatheter Valve Therapies (TVT) 2012**  
June 2-5, 2012 · Seattle, WA

 **Transcatheter Cardiovascular Therapeutics (TCT) 2012**  
October 22-26, 2012 · Miami, FL



## TCT Attendees Take a Glimpse into the Future

Michio Kaku, PhD, describes a world, in the not too distant future, where the stuff of today's science fiction becomes reality.

The interventional cardiologists attending TCT 2011 were treated to a trip into the future during the meeting's keynote lecture, "The Future of Humankind," delivered by the noted quantum physicist and futurist. Dr. Kaku is currently the Henry Semat Professor of

Theoretical Physics at the Graduate Center of the City University of New York. Through descriptions and videos, Dr. Kaku provided TCT attendees with a glimpse into what he believes medicine will evolve into over the next several decades based on current trends in research, software and intelligence systems.

### A Very Different World

In his presentation, Dr. Kaku likened the diagnostic tools of the future to the "tricorder" device seen on "Star Trek," which is a representation of a multifunctional

*(See Glimpse into the Future, page 5)*

# Message from the Faculty

Welcome to the Cardiovascular Research Foundation's Winter Newsletter. The end of 2011 saw the culmination of a year's worth of planning as TCT 2011 took place in San Francisco, CA, November 7-11. The conference was a huge success, drawing close to 12,000 attendees.



A total of 1,555 abstracts were submitted from 60 countries and 39 US states. Reviewers narrowed that number down to 799—a 50% acceptance rate. After being graded by an average of 10 reviewers per abstract, the accepted submissions were divided into 140 oral presentations and 659 posters. In addition to abstracts, there were over 40 hours of live case transmissions from 21 sites around the world.

TCT featured the latest data from groundbreaking clinical trials, enabling physicians to incorporate the most advanced techniques for treating patients into their everyday

practices. This year's late breaking trials covered a wide range of areas from innovative stents to the latest medication strategies for heart attack patients (see story, page 1).

Two-year results from Cohort B of the PARTNER trial headlined the meeting and continue to support the superiority of catheter-based aortic valve replacement over standard therapy for patients with severe aortic disease who are not candidates for surgery.

Another highlight from the meeting was the keynote address by Michio Kaku, PhD, who enthralled attendees with his lecture, "The Future of Humankind" (see story, page 1). Dr. Kaku discussed the possibilities of what lies ahead in the realms of medicine, communication, and day-to-day life based on current and ongoing scientific and technological developments.

TCT 2011 was a huge endeavor, and we wish to thank all of the faculty, staff, and sponsors for their tireless efforts in making this year's meeting one of the most successful and educational TCT symposia ever. Planning for TCT 2012 is already in full swing and we look forward to seeing you October 22-27 in Miami, FL.

CRF's annual Pulse of the City Gala and the first Women's Heart Health Summit were held December 9, 2011, in New York City (see stories, pages 5 and 6). The Gala was held at the Mandarin Oriental, while the Summit took place earlier in the day. The Gala honored Mehmet C. Oz, MD, and Elizabeth G. Nabel, MD, for their contributions to the field of women's heart health. The Summit brought together both clinical experts on heart failure and peripheral disease as well as advocates in women's heart health to discuss the challenges in our current health care system.

Please mark your calendars for next year's Pulse of the City Gala, Friday, December 14, 2012, at the Mandarin Oriental in New York City.

We would also like to take this opportunity to recognize the appointment of Helen Parise, ScD, as Executive Director of the CRF

Clinical Trials Center (CTC). Helen will be responsible for the entire CTC activity at CRF, working directly with faculty leadership. We are pleased to recognize Helen's immense skills and talents in this important area and look forward to working with her in this new role.

From the educational experience of TCT to the Gala and Women's Heart Health Summit, CRF is grateful for your support in fulfilling our mission of improving the lives of patients with heart disease.

Sincerely,

**Martin B. Leon, MD**

*Founder and Chairman Emeritus  
Co-Director, Medical Research and  
Education Division  
Cardiovascular Research  
Foundation*

**Gregg W. Stone, MD**

*Co-Director, Medical Research and  
Education Division  
Cardiovascular Research  
Foundation*

## Helen Parise Appointed Executive Director of CRF Clinical Trials Center



Helen Parise, ScD, has been named the Executive Director of the CRF Clinical Trials Center. As Executive Director, Helen will be responsible for all CTC activities. Since 2008, she has served as Director of Biometrics, having joined CRF in 2007.

"We are pleased to welcome Helen in her new role at the CRF Clinical Trials Center," said Gregg W. Stone, MD. "Helen's professionalism as well as her skills and expertise in clinical trials have been instrumental in many of the trials conducted at CRF, including the landmark HORIZONS-AMI trial."

Helen earned her doctorate in biostatistics from Harvard and has a master's degree in mathematics from the University of Massachusetts. She has held a number of faculty positions in her career, including currently as an Associate in Medicine at the Columbia College of Physicians and Surgeons. She has also served as faculty for TCT.

## THE PULSE of CRF

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## TCT 2011 Research



At two years, overall rates of heart-related death, repeat hospitalization, and severe heart failure symptoms were all lower with catheter-based valve replacement, while stroke rates were higher. According to the researchers, these findings continue to support the role of catheter-based valve replacement as the standard-of-care for patients with severe aortic disease who are not surgical candidates.

### PARTNER QUALITY OF LIFE/COST-EFFECTIVENESS

Additional data from a portion of the PARTNER trial that looked at high-risk patients with severe aortic disease showed that catheter-based aortic valve replacement was less invasive and no worse than surgical valve replacement in this patient subgroup.

Specifically, when the catheter-based approach was used to perform the procedure via an artery in the thigh, there was a significant increase in quality of life at one month, although at six and 12 months the difference decreased and was the same as surgery. Both surgical and catheter-based aortic valve replacement resulted in substantial improvement in quality of life over one year of follow-up.

Another study performed in the same group of patients investigated 12-month cost-effectiveness of catheter-based valve replacement compared with the surgical method. In terms of resource use, the catheter-based method when performed via an artery in the thigh shortened hospital length of stay by about six days compared with surgery.

Meanwhile, major blood vessel-related complications were higher with the catheter-based method compared with surgery while major bleeding was lower. The costs of the first hospital admission and those that accumulated during the year after treatment were equivalent between the two techniques; however, the catheter-based method performed via an artery in the thigh showed slightly fewer complications at less cost over one year than surgical aortic valve replacement, and was thus declared “economically dominant.”

### STACCATO

In the STACCATO trial, researchers focused on a comparison between elderly surgical candidates with aortic disease who were randomly assigned to catheter-based valve replacement via an incision in the ribs or surgical replacement. Despite a planned enrollment of 200, the trial was stopped early after only 70 patients were signed up due to an excess number of complications in the group treated via catheter.

Questions were raised, however, about whether the results reflected poorly on the catheter approach. Because only a relatively small number of patients enrolled, for example, the excess complications in the catheter-based arm may have been due to chance. In addition, only one valve size was available during the trial enrollment period. The results with the catheter-based method performed via an incision in the ribs from this small trial also may not have been representative of those currently being achieved at experienced centers.

## Primary Angioplasty in Severe Heart Attack

### RIFLE STEACS

The RIFLE STEACS trial randomly assigned 1,001 patients with severe heart attack to stent implantation via an artery in the wrist or the groin.

When considered together, heart-related deaths, heart attacks, repeat procedures, strokes, and bleeding unrelated to bypass surgery were lower with the wrist-based stenting technique. Looking at outcomes individually, heart related death was less common with wrist-based stenting, but there was no difference between the two groups in heart attacks, repeat procedures, or strokes.

Based on the results, researchers concluded that the wrist-based approach should no longer be considered just an alternative to groin-based stenting but should be recommended for severe heart attack patients.

### MUSTELA

For the MUSTELA trial, investigators presented data on over 200 patients with severe heart attack and large clots randomly assigned to stenting with or without thrombus aspiration, a technique that sucks pieces of clot out of arteries.

At one hour, key electrical activity in the heart had normalized in over half of the aspiration patients, but only about a third of the patients who did not receive clot aspiration. However, three months after the heart attack, the amount of heart muscle damage was equal in both groups, and at one year, complications were equally low with or without the aspiration technique.

The data provided a mixed picture regarding the worth of clot aspiration in addition to stenting.

### DEB-AMI

Drug-coated angioplasty balloons, which reduce the amount of time patients are exposed to drugs compared with drug-releasing stents, have been touted as a way to lower the chances of a dangerous blood clot forming after treatment. But according to the DEB-AMI trial, emergency use of these balloons in people having heart attacks is not as effective at keeping treated vessels open at six months as standard

metal or drug-releasing stents. There is, however, no difference between the three therapies in major complications.

## Drug Therapy and Risk After Angioplasty

### ADAPT-DES

According to another study, the level of effectiveness of therapy that combines aspirin with the blood-thinning agent clopidogrel can predict dangerous and potentially fatal blood clots. The findings presented by CRF faculty member Gregg W. Stone, MD, of NewYork-Presbyterian Hospital/Columbia University Medical Center (New York, NY), provide little usefulness in individual patients now but will aid clinical trials, researchers said, especially those focusing on heart attacks or unstable chest pain.

ADAPT-DES included over 8,500 patients with stable heart disease or heart attacks/unstable chest pain who were treated with drug-releasing stents between 2008 and 2010. Patients were given aspirin and clopidogrel and tested to determine how well the combined drug therapy was working.

Clotting was observed in less than 1% of patients, but low levels of drug effectiveness were significantly associated with increased clotting.

### DESERT

Results of the DESERT study showed that even seven years after patients are implanted with drug-releasing stents, they are still at risk of developing dangerous and potentially fatal blood clots. The findings, which were collected from a registry of over 950 patients treated with drug-releasing stents, also revealed that patients with blood clotting more than 30 days after stent implantation had a lower risk of death than those who had blood clotting earlier.

### PARIS

After patients are implanted with a stent, it is crucial that they take drugs that suppress blood platelets in order to discourage dangerous clots from forming. This regimen can last from 30 days for bare-metal stents to a year or more for drug-releasing stents. Patients who

(See TCT 2011 Research, page 4)

## Glimpse into the Future



device used to scan body systems and record that information for patient treatment.

“When you first saw the tricorder on TV, you probably laughed and said ‘ha, impossible.’ But the tricorder does not violate the laws of physics,” Dr. Kaku said. He went on to add that the systematic miniaturization of imaging equipment could very well yield MRIs that are the size of the average cell phone today.

Dr. Kaku described a world, maybe 50 years in the future, where people

will reside in “intelligent houses” where sensors monitor body and mental functions to facilitate health.

In the future, Dr. Kaku said, “your bathroom will have more computer power than a modern university hospital.” He said the cost of computer chips will dramatically drop to about a penny, making them cheap and easily placed in areas like mirrors and toilets, to monitor for cancer or other health issues before they become problematic.

“It is possible that the sensors that will be located in your home could



change the way we deliver medical care,” Dr. Kaku said. The down side to that, he added, is that “you’ll have no secrets.” In a video, Dr. Kaku showed an example of a man who had too much to drink the night before, and the information about that alcohol use was downloaded directly to his insurance carrier. On the upside, he said, for those that do drink too much, tissue engineering will likely make it easier than ever to get new livers and other organs that people must wait years for today.

Dr. Kaku added that it is likely that nanoparticles will enable patients to take pills that will act like “smart bombs” in the body, systematically eradicating cancer cells and possibly viruses. He said he envisions a time when surgeons will not actually touch their patients, but rather conduct surgery virtually, while robotic equipment simultaneously carries out the actions, similar to the avatars used in today’s popular gaming systems. While the surgery is ongoing, Dr. Kaku said it is possible that the surgeon would be wearing glasses or contact lenses, which are continually being updated with the patient’s vitals and other relevant information. He said this type of “augmented reality” will have broad-reaching implications, from how people communicate with each other — such as having a translating microphone perched on your glasses during a foreign film — to how wars will be fought.

## CRF Summit Examines Gender Disparities in Heart Health



Dr. Grines delivers Keynote Address at the Women’s Heart Health Summit in New York City.

Last month’s CRF Women’s Heart Health Summit: In Pursuit of Excellence: Improving Cardiovascular Outcomes in Women brought together top national experts in research, academia, and health policy to examine the importance of gender in cardiovascular disease research. The program, led by Summit Chair Roxana Mehran, MD, took place on December 9, 2011, at the Princeton Club in New York City.

The Summit featured a keynote address on the current state of heart disease in women by Cindy L. Grines, MD, Vice President of Academic and Clinical Affairs of the Heart and Vascular Institute at the Detroit Medical Center. The panel also discussed the lack of awareness surrounding women’s heart health and the general belief among the public that other diseases, such as breast cancer, pose a greater threat to women’s health. Participants

noted that the stereotype of older men having high rates of heart disease has caused many women to delay treatment because they do not recognize their symptoms.

Summit faculty encouraged health care providers and cardiologists to work closer with primary care and Ob/Gyn physicians to educate their patients on the risk factors and signs of heart disease. Prominently displayed posters and reading material in physician offices may lead more women to consider screening for heart disease or prompt them to receive treatment when needed.

Clinicians and summit participants also discussed some of the reasons why women don’t receive cardiovascular procedures for which they are clinically indicated and the underrepresentation of women in clinical trials. Some of the suggested theories as to why women are

not receiving indicated treatments include male-focused device design, lack of time to seek care, and skepticism of treatment necessity. Panel members also discussed potential new ways to encourage women to participate in clinical trials, such as providing child care and conducting more remote check-ins with patients.



## TCT 2011 Research



don't comply with the protective drugs, or do so intermittently, are at increased risk of a potentially fatal heart attack.

In the PARIS study, investigators led by CRF faculty member Roxana Mehran, MD, of Mount Sinai Medical Center (New York, NY), found that after 30 days, a little over 2% of patients were no longer following the prescribed regimen. More than two-thirds simply stopped the therapy, in some cases due to episodes of bleeding, while others interrupted the drugs because they were scheduled for surgery or halted therapy on their doctor's recommendation. Although such patients had higher rates of complications such as heart attacks, the numbers were too small to draw any firm conclusions about how much risk they incurred.

#### RAPID GENE

Other researchers found that using a specialized device to analyze a patient's genetic likelihood of responding to blood thinner agents can help physicians to individually tailor treatment after angioplasty and make treatment more effective. Saving time and energy, the genetic analysis can be done easily through a cheek swab taken by a nurse.

#### TRIGGER-PCI

Although stopped early for failing to show a difference that would actually affect the risk of adverse events, the TRIGGER-PCI study still linked treatment with the new blood thinning agent prasugrel after angioplasty to a better response by blood platelets compared with the older agent clopidogrel. Over 400 patients were randomly assigned to prasugrel or clopidogrel and all patients received drug-releasing stents. The study primarily looked at

heart-related death and heart attack rates; overall, there was only one such occurrence—in the clopidogrel group.

#### BRIDGE

An additional trial looked at over 200 patients with heart attacks or unstable chest pain who had previously been implanted with a stent and had discontinued blood-thinning therapy prior to heart surgery. These patients were randomly assigned to therapy with the alternative blood-thinning agent cangrelor or placebo. Researchers found that cangrelor is safe to use in these patients, and rates of excessive bleeding were similar in both groups, with a total of 22 bleeding events observed.

### Drug-Releasing Stents and Drug-Coated Balloons

#### EVOLVE

The EVOLVE trial tested whether a drug-releasing stent with an absorbable polymer coating on one side was as effective as a standard stent with a permanent all-over coating. The latter is thought to contribute to the risk of a serious blood clot insofar as the coating provokes inflammation and slows healing from the trauma of stenting.

Australian researchers found that the new stent—at both full and half drug doses—was as good as the one with the conventional coating at keeping vessels open at six months. Moreover, there were no differences between the devices in terms of heart-related deaths or need for repeat procedures to open the artery.

#### REMEDEE

The REMEDEE trial tested the safety and effectiveness of a drug-releasing stent that incorporates two strategies: a standard drug (sirolimus) that helps keep vessels open and a molecule that enhances healing around the stent. It marked the first time the stent was investigated in humans. According to the German investigators, at nine months the dual-therapy stent matched a conventional drug-releasing stent both in maintaining blood flow and in rates of major complications such as death, heart attack, and need for a repeat procedure.

#### NEXT

Compared with an older stent that releases the drug paclitaxel, a new stent that releases the drug sirolimus and has no polymer coating on its metal frame is more effective, according to data from the multicenter NEXT trial. Researchers randomly assigned over 300 patients to one of the two devices. The newer product utilizes technology that controls and directs drug release to the blood vessel wall along with a drug formulation that enhances overall safety and effectiveness. In the study, it proved better at reducing artery narrowing compared with the older stent.

#### TWENTE

The TWENTE trial, involving over 1,300 patients with chronic stable or acute heart disease, found that a stent that releases the drug zotarolimus is no worse than an everolimus-releasing stent for both safety and effectiveness. It is only the second randomized study to compare these two stents head-to-head.

One year after patients underwent angioplasty, there was no difference between the stent groups in terms of heart attack, need for additional artery-opening heart procedures, or death due to heart disease.

#### PEPCAD-DES

Even coronary vessels treated in a timely fashion with drug-releasing stents can become reblocked by progressive atherosclerosis. The PEPCAD-DES trial compared treatment of these repeat offenders with a drug-releasing balloon vs. an uncoated angioplasty balloon. German researchers reported that at six months the drug-releasing balloon performed better on several measures of effectiveness. The incidence of major complications also was lower among patients who received the drug-releasing balloon, driven mainly by the reduced need for repeat procedures.

### Interventional Techniques and Adjunctive Procedures

#### PROFI

A balloon device appears to be more effective than a filter in preventing

patients from suffering a stroke during or after procedures to open blocked carotid arteries in the neck.

For the PROFIT trial, investigators randomly assigned 62 patients with internal blockage of the carotid artery undergoing angioplasty to either a filter or balloon occlusion device. At 30 days, the filter group had a higher incidence of new brain lesions, which can lead to stroke.

#### ROTAXUS

Rotablation, a process of drilling through plaque deposits in the arteries before implanting a drug-releasing stent, offers no advantage over stenting without drilling, according to findings from the ROTAXUS trial.

#### ADVISE

A new drug-free method for measuring the severity of blockages in coronary arteries compares favorably to the more conventional method, which involves injection of a drug.

For the ADVISE trial, investigators tested the drug-free measurement method, called instant wave-free ratio, and reported excellent efficiency and accuracy in diagnosing blockages.

#### COBRA

Cryoplasty, a process of dilating and cooling blood vessel walls, was found to result in better outcomes in patients with diabetes than standard balloon angioplasty.

In the COBRA trial, researchers studied 90 patients with diabetes as well as severe atherosclerosis of the femoral artery in the thigh due to plaque build-up.

Patients were randomly assigned to undergo cryoplasty or conventional balloon angioplasty without vessel cooling. The main difference between the techniques is that cryoplasty uses liquid nitrous oxide rather than saline to inflate the angioplasty balloon, cooling its surface temperature to approximately -10° C.

At 12 months, renarrowing of treated arteries was significantly less severe in patients who received cryoplasty compared with conventional angioplasty.

## CRF's Pulse of the City Gala Raises Funds for Medical Research and Education

The 2011 Pulse of the City Gala was held December 9 at the Mandarin Oriental in New York City. The evening honored Elizabeth G. Nabel, MD, and Mehmet C. Oz, MD, for championing women's heart health.

Nearly 400 guests gathered to pay tribute to these two distinguished heart health advocates. Their tireless efforts to raise awareness and encourage women to take positive action to reduce their risk factors have helped improve the survival and quality of life for millions of people living with heart disease.



Mehmet C. Oz, MD, is presented with his award for championing women's heart health by Martin B. Leon, MD.



Gregg W. Stone, MD, presents Elizabeth G. Nabel, MD, with her award for championing women's heart health.

SAVE THE DATE  
FOR 2012

### THE ANNUAL **PULSE** *of the city gala*

FRIDAY, DECEMBER 14, 2012

6:30 PM

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*Cocktails, Dinner,  
and Dancing*

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## Complex PCI: Left Main and CTO Summit *A Live Case Demonstration Course*

**February 23-25, 2012**  
New York Marriott Marquis  
New York, NY

[www.complexpci.com](http://www.complexpci.com)

The new, enhanced Complex PCI: Left Main and CTO Summit will emphasize advanced techniques and evidence-based medicine, with a heavy reliance on live case transmissions featuring the world's leading experts in CTO and left main stenting from Institut Cardiovasculaire Paris Sud (Massy, France) and NewYork-Presbyterian Hospital/Columbia University Medical Center (New York, NY).

  
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